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SUPPLEMENT

Poster Abstracts

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AMCP POSTER ABSTRACT PROGRAM

The AMCP Poster Abstract Program provides a forum for authors to share their research with the managed care pharmacy community. Authors submit their abstracts to AMCP, and each abstract is reviewed by a team of peer reviewers and editors. All accepted abstracts are presented as posters at AMCP's Annual and Nexus meetings. These abstracts are also available through the AMCP meeting app. This JMCP supplement publishes all abstracts that were peer reviewed and accepted for presentation at AMCP 2026. Abstracts submitted in the Student and Encore categories did not undergo peer review; therefore, these abstracts are not included in the supplement.

ABSTRACT REVIEW PROCESS

Eighty-one reviewers and 4 JMCP editors completed the review process for AMCP 2026. Each abstract was reviewed and scored using a 1-5 scale with the following 5 criteria (15 rating scores per abstract), which are used by JMCP to evaluate manuscripts for publication:

• Relevance • Originality • Quality
• Bias • Clarity

Each of the reviewers also made an independent accept/reject recommendation.

The 15 rating scores and 3 accept/reject recommendations for each abstract were reviewed by a JMCP editor, who made an accept/reject decision. These decisions were reviewed and finalized by the JMCP editor-in-chief. The mean rating scores were used to award Platinum, Gold, and Silver medals for the best abstracts submitted. The abstract reviewers for AMCP 2026 were as follows:

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S2 Medal-Winning Abstracts
S4 Platinum Award-Winning Abstracts
S7 Professional Reviewed Abstracts
S7 Analgesics/Pain
S7 Benefit Design and Management
S10 Biosimilars
S13 Cardiovascular
S21 Central Nervous System
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S86 Precision Medicine
S87 Quality and Safety Programs
S88 Real-World Evidence
S106 Respiratory
S111 Specialty Pharmacy
S113 Student Abstract Titles
S125 Encore Abstract Titles

Medal-Winning Abstracts

Each abstract was assessed by reviewers using a 1-5 scale on the following 5 criteria: relevance, originality, quality, bias, and clarity. These are the same criteria used by JMCP to evaluate manuscripts. The abstract's mean score on the 5 criteria was used to award Platinum, Gold, or Silver medals.

Ulrich Neumann, MBA, MSc, MA [10] Out-of-pocket (OOP) cost burden for prescription drugs: Trends and disparities in commercial insurance design

Liang-Yuan Lin, MS [46] GLP-1RA vs. SGLT-2i: preventing kidney function deterioration among patients with type 2 diabetes and chronic kidney disease

Kyle Null, PharmD, PhD [174] Development of a systematic ulcerative colitis and Crohn's disease informatics clinical toolkit to identify characteristics of patients eligible for advanced therapies in inflammatory bowel disease (SUCCINCT)

Stella Ko, PharmD, MS [192] Impact of the Illinois biomarker testing law on utilization in advanced non-small cell lung cancer (aNSCLC) and metastatic colorectal cancer (mCRC) patients

James Chamberlain, PharmD, MS [362] Characteristics associated with nonadherence from data collected as part of an automated refill reminder program

Jerald Simmons, MD [78] Effectiveness and safety of greater than 9 gram dosage of low-sodium oxybate in participants with narcolepsy with or without concomitant use of alerting agents: A subgroup analysis from the DUET study

Feride Frech, PhD, MPH [83] Retrospective analysis of costs of amyloid diagnostic tests for Alzheimer's disease from a health-system perspective

Gehna Shah, PharmD [111] Enhancing Payer Engagement Through Digital Dossiers: An Interactive Formulary Decision-Making Asset Complementing Traditional PDF Formats

Miranda Murray, PharmD, CSP [170] Evaluating the Access Process for Patients Transitioning from Intravenous to Subcutaneous Biologic Administration for Inflammatory Bowel Disease

Hyllore Imeri, MrPh [181] Influence of social determinants of health on advanced therapy initiation in patients with inflammatory bowel diseases in the US

Alexjandro Daviano, DN, DO(MP), DrPH, MSDS, MPH [182] Identifying unmet health-related social needs (HRSNs) among Medicare Advantage (MA) enrollees with systemic lupus erythematosus (SLE) to optimize care

Mary Christoph, PhD, MPH [231] Healthcare resource utilization and costs among people with HIV (PWH) in the 3 years following diagnosis

Nicholas Liu, PharmD [285] Evaluation of healthcare resource utilization and costs among patients diagnosed with extra-pulmonary neuroendocrine carcinoma (epNEC): a non-interventional multimodal database analysis in the US

Paolo Tarantino, MD [291] A Cost-Effectiveness Comparison of Ribociclib and Palbociclib in Combination with Fulvestrant as First- or Second-Line Therapy for Postmenopausal Women with HR+/HER2- Advanced Breast Cancer: A Medicare Analysis

Medal-Winning Abstracts

Heather Houska, PharmD [344] Factors associated with persistence to glucagon-like peptide-1 (GLP-1) receptor agonists in obese and overweight patients without diabetes

Jacinda Tran, PhD, PharmD, MBA [355] Real-world Treatment-adherent Three-Year Cost Impact Assessment of Glucagon-Like Peptide-1 Agonists to Treat Obesity among Commercially Insured Members without Diabetes

Brianna Cartwright, MS [361] Impact of the CVS GLP-1 formulary change

Arun B. Jesudian, MD [366] Prediction of Overt Hepatic Encephalopathy using Machine Learning: a claims-based study of a prevalent cohort

Joseph Yang, PharmD, MS [399] Healthcare costs among Medicare Fee-for-Service beneficiaries with idiopathic pulmonary fibrosis during the last year of life

Stephanie Tran, PharmD, MPH, BCPS [6] The impact of expanded indications for glucagon-like peptide-1 receptor agonists-based anti-obesity medications in state Medicaid fee-for-service pharmacy programs

Jacinda Tran, PhD, PharmD, MBA [7] The Value of Pharmacy Benefit Integration: A Retrospective Comparison of Healthcare Costs and Utilization, 2022–2023

Evelyn Sarnes, PharmD, MPH [45] Real-world assessment of LDL-C response of patients initiating bempedoic acid and bempedoic acid plus ezetimibe in routine practice

W. Clay Jackson, MD, DipTh [75] Impact of routine screening for agitation with the AASC® in Alzheimer's dementia

Elmor Pineda, PharmD, RPh, MS [76] Real-World Impact of Discontinuing Ocrelizumab on Health Care Utilization and Cost Among Older Adult Patients With Multiple Sclerosis in the United States

Alyssa Cairns, PhD [77] Self-reported sleep quality and changes in functional status, work productivity, and daily activities in people with idiopathic hypersomnia or narcolepsy treated with low-sodium oxybate: Results from the phase 4 DUET study

Elizabeth Lubelczyk, PhD [142] Individuals with obesity or overweight who switched to tirzepatide from another GLP1-RA Obesity Management Medication demonstrated clinically meaningful weight reduction after persistent tirzepatide use: Results from 2 Real-World Studies

Anuj Gupta, MSc [176] Predictive Modeling for IBD Flares: AI-Driven Insights from Claims and EHR Data to Improve Early Detection and Optimize Disease Management

Jungyoon Moon, MS [180] The impact of social determinants of health on access barriers and health outcomes in sickle cell disease from the US payer perspective

Scott Bilder, PhD [195] Medicare Advantage vs. traditional fee-for-service Medicare: Different populations, different outcomes

Tami Sova, PharmD [250] Real-world effectiveness of zuranolone in postpartum depression: interim results of a prospective observational study

Benjamin Urick, PharmD, PhD [350] Real-world Three-Year Cost Impact Assessment of Glucagon-Like Peptide-1 Agonists to Treat Obesity among a Commercially Insured Members without Diabetes

Vanessa Perez Patel, PhD, MS [356] Willingness to Trade Effectiveness for Other Contraceptive Features: A Discrete Choice Experiment

Platinum Award-Winning Abstracts

10 Out-of-pocket (OOP) cost burden for prescription drugs: Trends and disparities in commercial insurance design

Neumann U[1], *Adjei K*[2], *Chang H*[3]; *uneuman1@its.jnj.com*; *KAdjei@ITS.JNJ.com*
[1]*J&J Center for Healthcare Policy Research*; [2]*J&J Scientific Affairs*; [3]*J&J Innovative Medicine*

BACKGROUND: Prescription drug affordability remains a persistent challenge for U.S. patients despite insurance coverage. Over the past decade, shifts in benefit design, such as the rise of high-deductible health plans, have reshaped cost exposure. Prior research emphasized aggregate trends, but few studies examine distributional impacts and subgroup disparities. A focus on the "average beneficiary" can mask disproportionate burdens among patients using branded drugs, those with chronic conditions, and lower-income households.

OBJECTIVE: To quantify trends in prescription out-of-pocket (OOP) costs among commercially insured U.S. adults, characterize cost distribution, and identify patient characteristics most associated with high reliance on insurance by examining disparities across income, health status, and benefit design.

METHODS: Repeated retrospective cross-sectional analyses of branded Marketscan claims and Optum Socioeconomic Status all-drug claims data (2014-2023) for adults aged 18-64 with continuous commercial coverage and ≥1 annual pharmacy claim. OOP costs (copay, coinsurance, deductible) were summed per capita and inflation-adjusted to 2023 USD (CPI-U). Analyses examined trends by year, cost component shifts, and stratification by income, education, race, and comorbidities. Sensitivity tests assessed stability.

RESULTS: Per capita OOP spending for branded Rx in Marketscan rose 194% from 2014 to 2023 ($290 vs $851), 160% after inflation ($372 vs $851). Among patients with ≥2 comorbidities, inflation-adjusted costs increased 70% ($592 vs $1,000). Patient burden was impacted by benefit design changes: deductible and coinsurance shares grew while fixed co-pays declined, especially among those with ≥2 comorbidities (co-pay spending ↓15%; coinsurance ↑60%; deductible ↑10%). Among the top 10% facing greatest cost, absolute all-drug OOP spending was similar across different income groups in Optum SES data; however, as a share income, households earning <$40k faced a relative burden eight times that of those earning ≥$100k—a gap that widened by 60% since 2014—underscoring the regressive nature of benefit designs.

CONCLUSIONS: In contrast to moderate per capita OOP cost growth averaged across the insurance pool, the OOP burden falls disproportionally on beneficiaries using branded medications, those with multiple chronic conditions, and lower-income households. Shifts in benefit design toward coinsurance and deductibles can exacerbate disparities. More research 'beyond the average' is needed to inform benefit structures that promote affordability and protect high-need populations.

SPONSORSHIP: Johnson & Johnson

46 GLP-1RA vs. SGLT-2i: preventing kidney function deterioration among patients with type 2 diabetes and chronic kidney disease

Liang-Yuan Lin, MS, PhD Student, 111 Taylor Meadows Dr., Oxford, Mississippi, 38655; llin3@go.olemiss.edu

BACKGROUND: Emerging evidence suggests that glucagon-like peptide-1 receptor agonists (GLP-1RA) may improve kidney outcomes in individuals with type 2 diabetes mellitus (T2DM). However, direct head-to-head comparisons of their renal effectiveness with sodium-glucose cotransporter 2 inhibitors (SGLT-2i), the recommended first-line therapy for older adults with T2DM and chronic kidney disease (CKD), remain limited.

OBJECTIVE: To compare the renal effectiveness of GLP-1RA and SGLT-2i among older adults with T2DM and CKD.

METHODS: A new-user, active comparator, matched cohort study was conducted using 5% Medicare data from 2012 to 2020. Older adults (≥65 years) with T2DM and CKD who initiated either a GLP-1RA or an SGLT-2i were identified; the first prescription date was defined as the index date. The 12-month period prior to index served as the baseline. Inclusion criteria required ≥2 outpatient or ≥1 inpatient diagnosis for both T2DM and CKD, continuous enrollment in Medicare Parts A, B, and D, and no prior use of GLP-1RA or SGLT-2i during baseline. Propensity score matching was used to balance baseline characteristics, with standardized differences reported pre- and post-matching. Both intention-to-treat and as-treated analyses were conducted. Risk of any CKD progression and end-stage renal disease (ESRD) was assessed using the Fine and Gray subdistribution hazard model and cumulative

incidence functions. As a sensitivity analysis, cohorts were directly matched on baseline CKD stage to assess the robustness of findings.

RESULTS: Between 2013 and 2020, Medicare beneficiaries aged 65 and older initiating GLP-1RA (n=3,967) or SGLT-2i (n=2,443) therapies were included. After 1:1 propensity score matching (n=2,418 per group), GLP-1RA initiators showed a significantly higher risk of CKD progression compared to SGLT-2i initiators in both intention-to-treat (subdistribution hazard ratio [sHR] 1.24, 95% CI 1.09–1.41, p<0.001) and as-treated analyses (sHR 1.21, 95% CI 1.02–1.43, p=0.028). For ESRD, GLP-1RA initiators showed a non-significant trend toward increased risk as compared to SGLT-2i initiators. Sensitivity analyses with exact matching on baseline CKD stage confirmed these results. No significant effect modification by sex was observed.

CONCLUSIONS: Initiation of SGLT-2i is associated with a lower risk of kidney disease progression compared to GLP-1RA, supporting preferential use of SGLT-2i for kidney protection among older adults with CKD and T2DM.

SPONSORSHIP: None

174 Development of a systematic ulcerative colitis and Crohn's disease informatics clinical toolkit to identify characteristics of patients eligible for advanced therapies in inflammatory bowel disease (SUCCINCT)

Kyle Null, PharmD, PhD, Senior Director, Takeda Pharmaceuticals U.S.A., Inc., Cambridge, Massachusetts, 02142; kyle.null@takeda.com

BACKGROUND: Determining which patients with moderate to severe Crohn's disease (CD) or ulcerative colitis (UC) may benefit from advanced therapies (ATs) can be challenging. Clinical tools that aid decision-making for the initiation of ATs may ensure timely, appropriate treatment to improve clinical outcomes.

OBJECTIVE: To train and test machine learning (ML) models to classify patients with CD or UC into AT-treated or AT-untreated cohorts based on clinical variables.

METHODS: This retrospective study used de-identified electronic health record (EHR) data from patients aged <89 years with CD or UC, treated in the Mayo Clinic system. The AT-treated and AT-untreated cohorts included patients with ≥1 administration of an AT or a non-AT medication, respectively, between November 1, 2015, and November 1, 2023. The feature space for characterization of AT-treated and AT-untreated cohorts included patient demographics, symptoms, endoscopic findings, disease location and activity, medication, healthcare encounters, surgeries, orders for and results of laboratory tests, and unstructured clinical notes. A self-supervised ML model using structured data (ConVIRT) and supervised ML models using structured and unstructured data (logistic regression, XGBoost, random forest) were trained and tested using a 60/20/20 training/validation/test split. Model performance was assessed by evaluation metrics including area under the curve (AUC), and the top predictive features for the AT-treated cohorts were extracted.

RESULTS: Supervised models outperformed the self-supervised ConVIRT model in distinguishing AT-treated from AT-untreated patients (AUC: logistic regression, CD = 0.839, UC = 0.807; random forest, CD = 0.832, UC = 0.838; ConVIRT, CD = 0.797, UC = 0.780). The supervised XGBoost model was the best performing model (CD, AUC = 0.903, specificity = 0.880, sensitivity = 0.926; UC, AUC = 0.869, specificity = 0.905, sensitivity = 0.833). The top predictive features contributing to the AT-treated label in the XGBoost CD model were prescriptions of immunomodulators and 5-aminosalicylic acid, number of unique medication classes, microbiology orders, and age. For the XGBoost UC model, these top predictive features were prescriptions of immunomodulators and prednisolone, number of orders, number of unique medication classes, and C-reactive protein levels.

CONCLUSIONS: ML models trained on clinical variables from EHR data can accurately classify AT-treated and AT-untreated patients. Such models have the potential to aid clinical decision-making for initiation of ATs in patients with CD or UC.

SPONSORSHIP: Takeda Pharmaceuticals U.S.A., Inc.

192 Impact of the Illinois biomarker testing law on utilization in advanced non-small cell lung cancer (aNSCLC) and metastatic colorectal cancer (mCRC) patients

Stella Ko, PharmD, MS, Associate Health Economist, 350 DNA Way, South San Francisco, California, 94080; koy3@gene.com

BACKGROUND: Recently, some states have enacted legislation to expand insurance coverage of biomarker testing. However, the impact of these laws on improving access to testing remains unknown. Illinois (IL), the first state to implement a law on Jan 1, 2022, may offer insights into how state policy can shape patient access.

OBJECTIVE: To determine whether the implementation of a new biomarker testing coverage law in IL had a significant impact on the utilization rates of testing in patients with advanced non-small cell lung cancer (aNSCLC) or metastatic colorectal cancer (mCRC).

METHODS: A retrospective analysis of medical and pharmacy claims was conducted using the IQVIA PharMetrics Plus closed health plan claims database to evaluate trends in upfront biomarker testing by health plan type in IL. Patients who had an initial diagnosis (defined as index date) of aNSCLC or mCRC between Jul 1, 2020, and Jun 30, 2023, with follow-up to assess quarterly testing through Sep 30, 2023, were included. Patients were categorized into those who had any upfront testing (+/- 90 days of index) and those who had no upfront testing. Interrupted time series analysis was used to compare the patients with state-regulated (fully insured (FI) or Medicaid) versus federally regulated self-funded plans (SF).

RESULTS: A total of 1,122 patients were included across three plan types: SF (N=515), FI (N=436), and Medicaid (N=171). 53.4% of patients were diagnosed with mCRC and 46.6% with aNSCLC. The overall use of any biomarker testing increased from 79.2% to 89.7%, and multi-gene panel testing (MGPT) from 16.4% to 28.1%. The effect of the legislation resulted in additional 1.6 times greater odds in any upfront testing for FI/Medicaid plans (vs SF plans, OR=1.59, [95% CI: 1.10, 2.33], p=0.015). The effect of the legislation also resulted in an additional 1.6 times greater odds in any MGPT for FI/Medicaid plans (vs SF plans, OR=1.61, [95% CI: 1.15, 2.26], p=0.006). However, a gap in MGPT use remained at the end of the study period, with SF plans having a 20.2 percentage point greater difference in MGPT use compared to FI/Medicaid plans.

CONCLUSIONS: The IL law significantly increased access to upfront biomarker testing for aNSCLC and mCRC patients, with the effect of the legislation having an additional 1.6 times greater odds of any testing for FI/Medicaid patients compared to SF. While the law also improved the use of upfront MGPT, the disparity in use between SF and FI/Medicaid was still present. Thus, further action is needed to ensure equal access to all biomarker tests.

SPONSORSHIP: Genentech, Inc

362 Characteristics associated with nonadherence from data collected as part of an automated refill reminder program

James Chamberlain, PharmD, MS, Health Economics & Outcomes Manager, 10181 Scripps Gateway Ct, San Diego, California, 92131; james.chamberlain@medimpact.com

BACKGROUND: Refill reminder programs are often used to address medication nonadherence and improve health outcomes. These programs collect member activity data that may help plans identify members at greater risk of nonadherence. Health plans may use this information to develop targeted outreach programs to improve adherence measures.

OBJECTIVE: To evaluate the association of selected plan member characteristics and the outcome of having a proportion of days covered (PDC) less than 80% (nonadherent) for each of three medication classes: diabetes (DM), hypertension (HTN), and statins in Part D plans participating in an automated refill reminder program.

METHODS: Members participating in the refill reminder program in both 2023 and 2024 were identified for the study, and those that were ineligible for CMS measure reporting for that year were excluded. Descriptive statistics and logistic regression using generalized estimating equations for a binary outcome was used to model the odds of nonadherence based on member characteristics (year, age group, preferred language, urban vs. rural home address, use of extended day supply [EDS] prescriptions (84 or greater days supply), continuing therapy vs. new start, number of drug classes late, late claim rate for each drug class, whether or not the index claim for the reporting year was late, whether or not any of the late claims were refilled within 7 days of a call, and whether or not the member reported a barrier to refill).

RESULTS: A total of 29,472 members were included in the study. Characteristics associated with increased odds of being nonadherent included late claim rate of 0.50 or greater (OR 6.88-7.65), not using EDS prescriptions (OR 3.50-4.48), late refilling the index claim (OR 3.51-3.89), reporting at least one refill barrier (OR 1.22-1.57), new start to therapy (OR 1.16-1.29), late refilling multiple drug classes (OR 1.12-1.24), and age <65 or age >84 (OR 1.04-1.2). Characteristics associated with decreased odds of nonadherence included refilling at least one late claim within 7 days of the automated call (OR 0.27-0.30) and preferred language not English (OR 0.75-0.88 for Spanish and OR 0.64-0.85 for 'Other').

CONCLUSIONS: This study demonstrates the value in the data collected through automated member outreach to identify members at risk for nonadherence. Implementing predictive modeling to develop additional targeted member outreach programs may support health plans' efforts to maintain operational efficiency while still improving outcomes.

SPONSORSHIP: MedImpact Healthcare Systems, Inc.

Professional Reviewed Abstracts

Analgesics/Pain

4 Where you live matters: Regional and racial disparities in opioid treatment for chronic noncancer pain

Arefin P, Oliorah P, Sansgiry S;
PAREFIN@COUGARNET.UH.EDU
UNIVERSITY OF HOUSTON

BACKGROUND: Chronic non-cancer pain remains a major U.S. public health issue. Despite declines in opioid prescribing, it is unclear whether racial, socioeconomic, and geographic factors still influence access to opioid versus non-opioid therapies.

OBJECTIVE: To evaluate racial and ethnic differences in opioid use among U.S. adults with chronic non-cancer pain and assess how regional, income, poverty, insurance, and employment factors contribute to receiving opioid treatment.

METHODS: We analyzed pooled 2017–2021 MEPS data for adults with chronic non-cancer pain identified by ICD-10 codes. Treatment was classified as opioid versus non-opioid. Survey-weighted descriptive statistics, group differences, and multivariable logistic regression (adjusted for demographics and socioeconomic factors) were conducted using SAS 9.4 with MEPS weights, strata, and PSUs. Only Non-Hispanic White (NHW), Non-Hispanic Black (NHB), and Hispanic adults were included.

RESULTS: The cohort included 7,004 adults (weighted N = 13,008,598), of whom 74.56% were NHW, 11.98% NHB, and 13.50% Hispanic. Regional context contributed substantially to treatment differences. Compared with the Northeast, opioid use likelihood was higher in the Midwest (160%; 95% CI: 142.0–180.4), South (150%; 95% CI: 133.7–168.6), and West (163%; 95% CI: 143.6–184.4). Because racial and socioeconomic groups are unevenly distributed across these regions, regional prescribing norms may influence the treatment differences observed. Socioeconomic gradients were also pronounced. Adults with low income (124%; 95% CI: 114.3–135.4), near-poor income (127%; 95% CI: 113.6–142.7), and poor/negative income (133%; 95% CI: 121.3–146.1) had higher opioid likelihood than high-income adults. Insurance coverage followed similar trends: private insurance (144%; 95% CI: 123.1–168.2) and public insurance (172%; 95% CI: 147.0–202.0) were associated with higher use than being uninsured. Employment was protective, with employed adults demonstrating a 79% likelihood of opioid use (95% CI: 73.2–84.9).

CONCLUSIONS: Marked racial, regional, and socioeconomic disparities in opioid therapy use were observed. NHW adults had the highest likelihood of opioid use, while NHB and Hispanic adults had lower use even after adjustment. Elevated use in the Midwest, South, and West highlights the role of regional prescribing environments. Region-based efforts to address racial differences in pain treatment should also consider income, insurance coverage, and employment, as these structural factors shape treatment patterns across U.S. regions.

SPONSORSHIP: None

Benefit Design and Management

6 The impact of expanded indications for glucagon-like peptide-1 receptor agonist–based anti-obesity medications in state Medicaid fee-for-service pharmacy programs

Tran S, Holderread B, Guest A; stran@ipdanalytics.com
IPD Analytics

BACKGROUND: Medicaid coverage of glucagon-like peptide-1 receptor agonist (GLP-1)–based anti-obesity medications (AOMs) has increased due to these products gaining additional medical indications (i.e., Wegovy [semaglutide] for reduction of major adverse cardiovascular events [MACE] or metabolic dysfunction–associated steatohepatitis [MASH]; Zepbound [tirzepatide] for obstructive sleep apnea [OSA]) beyond weight loss, which are required to be covered by Medicaid. Coverage dynamics in this category are evolving rapidly as expanded indications are approved.

OBJECTIVE: To evaluate how state Medicaid fee-for-service (FFS) coverage of GLP-1–based AOMs changed with the approval of additional medical indications.

METHODS: In August 2024 (baseline) and August 2025, we reviewed state Medicaid FFS websites to identify GLP-1–based AOMs preferred drug list (PDL) placement and prior authorization (PA) criteria. We compared changes in

Medicaid coverage and management trends to evaluate the impact of these drugs gaining additional medical indications.

RESULTS: From 2024 to 2025, there was a 76% (17 to 30) increase in states listing the GLP-1–based AOMs (semaglutide and/or tirzepatide) on PDLs. There was an 18% decrease (22 to 18) in states with existing PA criteria for chronic weight management (CWM). As of August 2025, semaglutide and tirzepatide are preferred in 6 and 10 states, respectively; both are preferred in 7 states. We analyzed 18 states with PA criteria and found 10 states manage AOMs beyond the specific labeled indication, including higher body mass index (BMI) requirements or more extensive lifestyle modifications, or had unique approval durations. Eight states require step therapy on a preferred AOM (semaglutide or tirzepatide) before access to a non-preferred GLP-1–based AOM. Thirty-five states have criteria for semaglutide (MACE risk reduction) and 28 states have criteria for OSA (tirzepatide). Four states had criteria for MASH prior to semaglutide's MASH label expansion.

CONCLUSIONS: States significantly expanded coverage of AOMs for additional indications as evidenced by increases in PDL placement and criteria. Conversely, there was a decrease in states with criteria for the CWM indication, likely signaling a decrease in coverage for weight loss alone. Due to federal Medicaid spending cuts, states may continue to narrow access to AOMs for CWM alone or adopt stricter management such as a single preferred product.

SPONSORSHIP: IPD Analytics

7 The value of pharmacy benefit integration: A retrospective comparison of healthcare costs and utilization, 2022-2023

Tran J[1], *Gill P*[2], *Healy M*[2], *Prestipino B*[2], *O'Shea T*[3], *Urick B*[1]; *jacinda.tran@primetherapeutics.com*
[1]*Prime Therapeutics*; [2]*Horizon BCBS of NJ*; [3]*Horizon BCBS*

BACKGROUND: Pharmacy benefits may be delivered as part of a total health plan ("integrated") or administered by an external pharmacy benefit manager ("nonintegrated"). Evidence has shown that members in plans with integrated benefits tend to have lower healthcare spending than members with non-integrated benefits.

OBJECTIVE: To evaluate differences in medical costs and healthcare resource utilization (HCRU) between commercially insured members with integrated pharmacy benefits compared to those with nonintegrated pharmacy benefits.

METHODS: Data for this project come from medical claims and enrollment information from public sector employers provided by a single large regional health insurer covering 2022 and 2023. Age <65 and continuous enrollment throughout the study period were required. Integration was defined as enrollment at any point during a given calendar year with pharmacy benefits from the insurer's integrated pharmacy benefit manager partner. Members were 1:1 matched on gender, age, care management program enrollment, benefit generosity, state of residence, fully insured vs. self-insured status, group size, and chronic disease indicators (asthma, congestive heart failure, coronary artery disease, chronic obstructive pulmonary disease, diabetes, rheumatoid arthritis, depression, multiple sclerosis). A generalized linear model with gamma log-link was used to assess the difference in per member per year (PMPY) total medical spending among the integrated cohort compared to nonintegrated. For HCRU, the odds of inpatient hospitalization and emergency department (ED) visit were estimated with logistic regression.

RESULTS: The final matched population included 49,748 members (24,874 in each cohort). 52.7% were female, and the mean age was 35.2 (standard deviation [SD] 18.0) years in the integrated population and 35.3 (SD 18.0) in the nonintegrated. Integrated members had 10.5% ($p<0.001$; 95% confidence interval [CI]: 5.8%-15.0%) lower PMPY spending compared to nonintegrated, equating to $801 (95% CI: $465-$1,137) PMPY less on average ($6,809 integrated vs $7,610 nonintegrated). Integrated members were found to have 10.6% ($p=0.03$; 95% CI: 0.8%-19.4%) lower odds of an inpatient hospitalization and 8.9% ($p<0.001$; 95% CI: 4.0%-13.4%) lower odds of an ED visit.

CONCLUSIONS: Health plan members enrolled in integrated pharmacy benefits had significantly lower medical costs and HCRU compared to nonintegrated members, suggesting potential advantages of integrating pharmacy and medical coverage such as improved care management and coordination.

SPONSORSHIP: Prime Therapeutics, LLC

8 Benefit type used by individuals initiating cabotegravir long-acting for human immunodeficiency virus pre-exposure prophylaxis in the United States: Findings from the PrEPFACTS study

Herman G[1], *Nguyen C*[2], *Metzner A*[1], *Alinezhad F*[3], *Martinez D*[1], *Walko S*[1], *Banatwala A*[2], *Shi S*[2], *Young-Xu L*[2], *DerSarkissian M*[2]; *gabrielle.f.herman@viivhealthcare.com*
[1]*ViiV Healthcare*; [2]*Analysis Group, Inc.*; [3]*Analysis Group*

BACKGROUND: APRETUDE (cabotegravir long-acting [CAB-LA]) was approved for human immunodeficiency virus 1 (HIV-1) pre-exposure prophylaxis (PrEP) in December 2021. Long-acting injectables (LAIs) offer distinct coverage opportunities compared to daily oral PrEP regimens due to differences in reimbursement pathways. While oral PrEP

medications are traditionally covered under the pharmacy benefit, LAIs may be reimbursed through the medical benefit, the pharmacy benefit, or both. Limited data are available regarding the real-world utilization of benefit types among individuals initiating CAB-LA.

OBJECTIVE: To describe benefit utilization by characterizing medical benefit or pharmacy benefit use by individuals (indv) initiating CAB-LA.

METHODS: A retrospective cohort study was conducted using data from the Komodo Research Database from 12/20/2021 to 09/30/2024. Indv were required to have >1 month of continuous enrollment eligibility for both medical and pharmacy coverage after 12/20/2021. Indv who received at least one injection of CAB-LA after its approval were included. CAB-LA use was identified using National Drug Codes (NDCs) appearing in either medical or pharmacy data, and claim dates were required to fall within indv continuous enrollment periods for both medical and pharmacy coverage. If a claim was submitted but did not adjudicate successfully, it was not analyzed.

RESULTS: Of 8,059 indv with ≥1 pharmacy or medical claim for CAB-LA, 6,420 (79.7%) had only a pharmacy claim, 771 (9.6%) had only a medical claim, and 868 (10.8%) had both a pharmacy and medical claim for CAB-LA.

CONCLUSIONS: These findings suggest pharmacy benefit pathways are the primary mechanism for CAB-LA reimbursement in real-world settings, likely reflecting payer policies and provider practices. The relatively small proportion of individuals utilizing medical benefits may reflect factors influencing the use of provider-administered injectables, such as logistical challenges or variations in coverage. Dual utilization of pharmacy and medical benefits by 10.8% of individuals underscores the complexity of benefit pathways, suggesting these mechanisms can overlap or complement each other. Utilization across both benefit types may reflect specific scenarios, such as patients navigating transitions between benefit types due to administrative factors, clinical considerations, or providers utilizing both pathways to ensure uninterrupted access to CAB-LA. Further research is warranted to explore factors driving benefit utilization patterns and their impact on adherence, access, and outcomes in the context of long-acting PrEP.

SPONSORSHIP: ViiV Healthcare

9 Breadth of Medicare Part D preferred pharmacy networks, 2019-2025

Feyman Y, Campbell J, Wagner T; yfeyman@npcnow.org
National Pharmaceutical Council

BACKGROUND: As pharmacy benefit managers (PBMs) have expanded utilization management strategies to control spending, they increasingly rely on preferred networks to steer patients towards select pharmacies. While steering to potentially lower-cost or more efficient pharmacies may reduce costs or improve medication adherence, these preferred networks create a two-tier system: preferred pharmacies within the network and non-preferred pharmacies outside it. Limited networks can restrict access and increase costs for patients who use non-preferred pharmacies. Preferred pharmacy networks are prevalent in Medicare Part D, where over 80% of enrollees fill prescriptions each year.

OBJECTIVE: We examined whether preferred pharmacy networks changed over time, and whether changes were associated with plan characteristics, including premiums, deductibles, and the type of plan being offered.

METHODS: Using Medicare Part D pharmacy network files from July 2019 to July 2025, we calculated the share of retail pharmacies (including all chain and independent pharmacies) reported in each Medicare Advantage (MA) and stand-alone Medicare Part D (PDP) plan's pharmacy network that were considered preferred. We assessed changes over time using enrollment-weighted Welch t-tests. We assessed association with plan-level factors (Part D deductibles, Part D premiums, plan type, and Part D summary star ratings) using enrollment-weighted linear regression with year-fixed effects and standard errors clustered by contract.

RESULTS: From 2019 to 2025, all plan types except stand-alone PDPs saw a decline in the share of preferred pharmacies: Local Preferred Provider Organizations (LPPOs) fell from 62.5% to 42.3%, Health Maintenance Organizations (HMOs) from 63.3% to 42.4%, and Regional PPOs (RPPOs) from 74.6% to 47.1%, while stand-alone PDPs grew from 36.3% to 44.6% (all $p<0.001$). Plan-level factors were not associated with network size, except that PDPs had a smaller share of preferred pharmacies (-0.11, $p=0.02$) compared to HMOs, although this trend reversed in recent years. All plan types converged to similar preferred pharmacy shares (42%-48%) by 2025, despite disparate 2019 starting points.

CONCLUSIONS: Preferred networks decreased over time, raising concerns about potential misalignment between Part D sponsor practices and beneficiary interests, as network restrictions appear to be occurring without observable cost savings for enrollees.

SPONSORSHIP: National Pharmaceutical Council

10 Out-of-pocket (OOP) cost burden for prescription drugs: Trends and disparities in commercial insurance design

Neumann U[1], *Adjei K*[2], *Chang H*[3]; *uneuman1@its.jnj.com*; *KAdjei@ITS.JNJ.com*
[1]*J&J Center for Healthcare Policy Research*; [2]*J&J Scientific Affairs*; [3]*J&J Innovative Medicine*

BACKGROUND: Prescription drug affordability remains a persistent challenge for U.S. patients despite insurance coverage. Over the past decade, shifts in benefit design, such as the rise of high-deductible health plans, have reshaped cost exposure. Prior research emphasized aggregate trends, but few studies examine distributional impacts and subgroup disparities. A focus on the "average beneficiary" can mask disproportionate burdens among patients using branded drugs, those with chronic conditions, and lower-income households.

OBJECTIVE: To quantify trends in prescription out-of-pocket (OOP) costs among commercially insured U.S. adults, characterize cost distribution, and identify patient characteristics most associated with high reliance on insurance by examining disparities across income, health status, and benefit design.

METHODS: Repeated retrospective cross-sectional analyses of branded MarketScan claims and Optum Socioeconomic Status all-drug claims data (2014–2023) for adults aged 18–64 with continuous commercial coverage and ≥1 annual pharmacy claim. OOP costs (copay, coinsurance, deductible) were summed per capita and inflation-adjusted to 2023 USD (CPI-U). Analyses examined trends by year, cost component shifts, and stratification by income, education, race, and comorbidities. Sensitivity tests assessed stability.

RESULTS: Per capita OOP spending for branded Rx in MarketScan rose 194% from 2014 to 2023 ($290 vs $851), 160% after inflation ($372 vs $851). Among patients with ≥2 comorbidities, inflation-adjusted costs increased 70% ($592 vs $1,000). Patient burden was impacted by benefit design changes: deductible and coinsurance shares grew while fixed co-pays declined, especially among those with ≥2 comorbidities (co-pay spending ↓15%; coinsurance ↑60%; deductible ↑10%). Among the top 10% facing greatest cost, absolute all-drug OOP spending was similar across different income groups in Optum SES data; however, as a share income, households earning <$40k faced a relative burden eight times that of those earning ≥$100k—a gap that widened by 60% since 2014—underscoring the regressive nature of benefit designs.

CONCLUSIONS: In contrast to moderate per capita OOP cost growth averaged across the insurance pool, the OOP burden falls disproportionally on beneficiaries using branded medications, those with multiple chronic conditions, and lower-income households. Shifts in benefit design toward coinsurance and deductibles can exacerbate disparities. More research 'beyond the average' is needed to inform benefit structures that promote affordability and protect high-need populations.

SPONSORSHIP: Johnson & Johnson

Biosimilars

18 Real-world adherence, persistence and switching patterns of an adalimumab biosimilar (ABP 501; adalimumab-atto) in patients with inflammatory bowel disease and other approved indications: A retrospective US claims database analysis

Zhou Z[1], *Vuvu F*[2], *Tuly R*[1], *Multani J*[1], *Khalid S*[1], *Chen C*[1], *Kricorian G*[3], *Melmed G*[4]; *fiston.vuvu@hotmail.com*; *chi-chang.chen@iqvia.com*
[1]IQVIA; [2]*Apellis Pharmaceuticals*; [3]*Amgen*; [4]*Cedars-Sinai*

BACKGROUND: Biosimilars may provide a cost-saving alternative to reference biologics, while offering similar treatment outcomes without clinically meaningful differences.

OBJECTIVE: To evaluate the treatment patterns of adalimumab-atto (ADA-atto) in patients with inflammatory bowel disease (IBD) and other approved indications.

METHODS: This retrospective cohort study used IQVIA open-source medical (Dx) and pharmacy (LRx) claims data to identify patients initiating ADA-atto between 1/31/2022 and 12/31/2024 (index date=first ADA-atto claim). All patients had ≥12 months of pre-index data availability. Treatment adherence (proportion of days covered [PDC]≥80%), persistence (no treatment gap of ≥90 days), and switching patterns were evaluated over 6 and 12 months of follow-up (f/u) in patients with ADA approved indications, including Crohn's disease (CD) and ulcerative colitis (UC). Results were also stratified by baseline ADA reference product (RP) exposure.

RESULTS: A total of 1,101 patients were included (mean age 47 years, 67% female, mean Charlson comorbidity index 0.9), among whom 728 (CD: n=125; UC: n=77) had ≥6 months and 429 (CD: n=71; UC: n=44) had ≥12 months of f/u. Among patients with ≥6 months of f/u, 55% were RP-naïve (RP-N). Adherence was 45% (CD: 50%; UC: 39%; RP-N: 40%; RP-experienced [RP-E]: 51%) and persistence was 82% (CD: 85%; UC: 83%; RP-N: 79%; RP-E: 86%). Seventy-three percent of non-persistent patients switched to another therapy (CD: 47%; UC: 54%; RP-N : 76%; RP-E: 68%), with only 6% to RP (CD: 11%; UC: 8%; RP-N: 5%; RP-E: 9%) and 5% to other ADA biosimilars (CD: 0; UC: 8%; RP-N: 4%; RP-E: 6%). Patients frequently

switched to biologics and Janus kinase inhibitors (JAKi; overall: 19%; CD: 21%; UC: 15%; RP-N: 19%; RP-E: 19%). Among patients with ≥12 months of f/u, 59% were RP-N. Adherence was 26% (CD: 31%; UC: 25%; RP-N: 22%; RP-E: 32%) and persistence was 47% (CD: 52%; UC: 45%; RP-N: 41%; RP-E: 56%). Eighty-nine percent of nonpersistent patients switched to another therapy (CD: 82%; UC: 83%; RP-N: 91%; RP-E: 84%), with only 8% to RP (CD: 9%, UC: 13%; RP-N: 6%; RP-E: 10%) and 7% to other biosimilars (CD: 3%; UC: 8%; RP-N: 5%; RP-E: 12%). Patients frequently switched to biologics and JAKis (overall: 27%; CD: 29%; UC: 25%; RP-N: 33%; RP-E: 17%).

CONCLUSIONS: This study provides real-world evidence that the adherence and persistence of ADA-atto corroborate those reported in literature for RP. Switching to RP and other biosimilars was uncommon among patients initiating ADA-atto. RP-naïve patients exhibited lower adherence and persistence compared to RP-experienced patients.

SPONSORSHIP: Amgen

19 Real-world adoption patterns for adalimumab biosimilars: A comparison of specialty and other channels

Viteri Y[1], *Mager D*[2], *Pitts S*[3], *Bridges G*[1], *Fairbrother E*[1]; *yvonne.viteri@evernorth.com*
[1]*Evernorth Health Services*; [2]*Evernorth*; [3]*Accredo*

BACKGROUND: Availability of biosimilars in the US is expected to drive lower costs and improved patient access. However, patient and prescriber uptake has been slow. Our specialty pharmacy implemented a program to help mitigate barriers through education on cost, efficacy, safety, interchangeability, and administration.

OBJECTIVE: To identify the adoption, discontinuation, and switching patterns of patients using an adalimumab biosimilar at a specialty pharmacy.

METHODS: Retrospective analysis of pharmacy claims from a large commercially insured database among those continuously eligible >6 months before and 12 months after initiation of the reference drug in 2023. Index date was the first fill of the reference drug with no prior history of its use in the preceding 6 months. Two cohorts were assessed in this study. One cohort consisted of patients initiating therapy at the specialty pharmacy (SP), and the other consisted of those initiating therapy by another channel (Other). Bivariate and multivariable analyses were conducted to measure the impact of channel on switching to either a biosimilar or another branded drug to treat inflammatory conditions (IC). Secondary outcomes included adherence using proportion of days covered (PDC) and utilization.

RESULTS: There were 8,129 patients in the SP cohort and 2,170 in the Other cohort. Patients in the SP and Other cohorts had average ages of 40.9 (SD 15.2) and 41.6 (SD 14.9), respectively ($p = 0.04$) and were 39.2% and 37.9% male, respectively ($p = 0.28$). Patients in the SP continued to fill only the referenced drug 74.5% of the time compared to 75.5% in the Other cohort, while 17.6% and 18.2% (OR 0.784, CI 0.646-0.950) filled other branded IC drugs, and 7.9% and 6.3% (respectively) filled a biosimilar (OR 1.008, CI 0.890-1.142). Average PDC for members that moved to another branded IC drug in SP was 84.1% (SD 17.4%) compared to 83.3% (SD 18.5%) in Other ($p = 0.40$). Average PDC among those switching to a biosimilar in SP was 89.8% (SD 13.2%) vs. 85.7% (SD 17.1%) in Other, $p < 0.01$.

CONCLUSIONS: Biosimilar-adopting patients in the SP channel were more adherent to biosimilar therapy than those utilizing Other channel. SP biosimilar patients were less likely to switch back to a branded IC drug. We attribute this to the proactive clinician support the SP cohort received regarding safety and efficacy of biosimilars, as well as the availability of clinicians to answer questions about administration of a new biosimilar drug. In addition to a robust IC clinical model, the SP included social, financial, and adherence support.

SPONSORSHIP: None

20 Real-world switching patterns after formulary changes related to adalimumab biosimilars

Lister M, Stapley M, Ham B, Wilson A, Dunn J, Oliveira-Nguyen J; tylerlister93@gmail.com
Cooperative Benefits Group

BACKGROUND: Following the market entry of multiple Humira (adalimumab) biosimilars in 2023, pharmacy benefit managers (PBMs) implemented strategies to adjust formularies and promote biosimilar adoption—all with the goal of achieving savings. Despite these strategies, members may have transitioned to other branded biologics, limiting the savings. Understanding these switching patterns is key to evaluating biosimilar program success.

OBJECTIVE: To evaluate Humira users' switching patterns after adalimumab biosimilars replaced it on the formulary by assessing conversion to biosimilars, switches to other branded biologics, therapy discontinuation, or reversion to Humira over a 16-month period.

METHODS: Retrospective analysis used pharmacy claims data from a PBM's multi-state, regional health plan to identify members who were stable on Humira. Stability was defined as having at least 90 days of paid claims between 8/1/2024 and 11/30/24. For each stable user, all paid claims for any biologic agents were extracted through 10/1/2025. Members who discontinued therapy or disenrolled were excluded.

Switching patterns were determined based on their most recent biologic fill and categorized as conversion to an adalimumab biosimilar, change to different branded biologic, or remaining on or returning to Humira. A subset analysis was conducted for members who switched to other branded biologics to assess whether they had previously tried an adalimumab biosimilar.

RESULTS: Of 175 identified Humira users, 112 remained after excluding 54 who disenrolled and 9 who discontinued therapy. Of these, 99 users (88%) successfully transitioned to and maintained on biosimilar therapy. Nine (8%) switched directly to another branded biologic without first trying a biosimilar, two (2%) remained on Humira, one (1%) reverted to Humira after an unsuccessful biosimilar trial, and one (1%) switched to a branded biologic following a biosimilar failure.

CONCLUSIONS: This real-world analysis shows strong biosimilar conversion, with 88% of members maintaining biosimilar therapy. Despite 8% switching to other branded biologics, PBM-led strategies, such as preloaded authorizations and education campaigns, facilitated high biosimilar uptake. This "leakage" likely reflects clinical decisions outside PBM control rather than systematic barriers. Well-designed transition programs can achieve high conversion rates while maintaining care continuity. Future research should focus on long-term adherence and outcomes to optimize biosimilar adoption and maximize savings.

SPONSORSHIP: None

21 Real-world treatment persistence and switching patterns among biologic therapies in psoriatic arthritis: A retrospective cohort study

Gupta A[1], *Verma* V[1], *Roy* A[1], *Nayyar* A[1], *Arora* A[1], *Khatavkar* V[1], *Parmar* C[1], *Amin* T[1], *Batra* K[1], *Kumar* K[1], *Arora* S[1], *Brooks* L[2], *Seligman* M[2], *Heath* K[3]; *anuj_gupta457@optum.com*; *vikash.verma@optum.com*; *abhimanyu.roy@optum.com*; *abhinav.nayyar@optum.com*; *ankitkumar_arora@optum.com*; *vishan_khatavkar@optum.com*
[1]*Optum Inc.*; [2]*OptumInsight*; [3]*Optum*

BACKGROUND: Biologic therapies have reshaped the treatment paradigm for psoriatic arthritis (PsA), offering targeted interventions for patients with moderate to severe disease. However, real-world treatment persistence remains inconsistent across biologic classes, influenced by patient characteristics, comorbidities, and drug tolerability. Understanding these patterns is essential for optimizing therapeutic sequencing, minimizing treatment disruptions, and informing value-based care strategies.

OBJECTIVE: To assess treatment persistence, switching behavior, and demographic characteristics among patients with PsA initiating biologic therapies, using real-world data from electronic health records and claims.

METHODS: This retrospective cohort study used the Optum® Market Clarity database to identify adults with an ICD-10 diagnosis of PsA who initiated biological therapy between July 2016 and June 2024. The index date was defined as the first initiation of biologics. Eligible patients were required to have ≥6 months of continuous enrollment prior to initiation and ≥12 months of post-index follow-up. Patients with prior non-biologic use for during months pre-index period were excluded to ensure true first-line biologic initiation. Key outcomes included treatment persistence (defined as continuous use without any discontinuation or switch), switching rates across biologic classes.

RESULTS: Among 165,585 adults initiating first-line biologic therapy, the mean age was 53.8 years with 61.9% female. Tumor Necrosis Factor-alpha (TNF-α) inhibitors were the most frequently initiated biologics (49.5%), followed by Interleukin (IL) inhibitors (27.8%), Phosphodiesterase-4 (PDE4) inhibitors (14.1%), Janus Kinase (JAK) inhibitors (3.2%), and T-cell modulators (1.1%). Persistence over 12 months was highest for T-cell modulators (51.7%) and lowest for PDE4 inhibitors (16.6%). IL inhibitors showed greater persistence (39.3%) compared to TNF-α (34.3%) and JAK inhibitors (38.1%). Switching was least common among PDE4 users (33%).

CONCLUSIONS: Real-world persistence and switching patterns in PsA biologic therapy vary substantially across drug classes. T-cell modulators demonstrated the highest durability, while PDE4 inhibitors showed poor persistence but low switching, indicating potential challenges in long-term management. These findings highlight the importance of individualized treatment strategies to optimize outcomes in PsA care.

SPONSORSHIP: None

Cardiovascular

39 Formulary barriers to accessing finerenone for the treatment of chronic kidney disease (CKD) and type 2 diabetes (T2D)

Katta A[1], *Hocum B*[1], *Betts K*[2], *Wu A*[3], *Earl J*[1], *Wang T*[3], *Beller Ferri M*[1], *Zheng Z*[1], *Wang Y*[1], *Mares J*[1], *Brixner D*[4]; *arvind.katta@bayer.com*
[1]*Bayer U.S. LLC*; [2]*Analysis Group Inc.*; [3]*Analysis Group*; [4]*University of Utah*

BACKGROUND: Formulary restrictions, such as prior authorization and formulary exclusion, may delay or prevent finerenone access (approved on July 9, 2021) for patients with CKD and T2D.

OBJECTIVE: To evaluate the real-world patterns of finerenone access and rejection reasons.

METHODS: Adult patients with ≥1 finerenone prescription were identified in the Komodo Research Data claims database (Jan 1, 2016, to Jun 30, 2024). Patients were classified into four cohorts based on the transaction results of the first finerenone prescription's lifecycle claims: (1) timely approval and dispensation (Cohort 1), (2) delayed approval and dispensation after initial rejection (Cohort 2), (3) abandonment of an approved prescription (Cohort 3), and (4) rejection with no subsequent approval (Cohort 4). The study was indexed on the written date of the first prescription claim. Patient characteristics were assessed during the 6 months before index date. Rejection status and rejection reasons were described overall and by calendar year. Time from prescription written to dispensation was summarized for Cohort 1 and 2.

RESULTS: The study included 9,579 patients prescribed finerenone, with a mean (SD) age at index of 65.5 (11.9) years; 55.9% were male. At index, 10.2%, 38.0%, and 10.2% of patients had stage 1/2, stage 3, and stage 4 CKD, respectively. Among all patients, 6,647 (69.4%) received timely approval and dispensation (Cohort 1), 644 (6.7%) experienced delayed approval and dispensation (Cohort 2), 678 (7.1%) abandoned the approved prescription (Cohort 3), and 1610 (16.8%) never received approval (Cohort 4). The mean (SD) time from prescription written to dispensation was 11.3 (33.2) days in Cohort 1 and 101.2 (126.1) days in Cohort 2. From 2021 to 2024, the proportion with timely approval increased from 62.0% to 67.4%, while the proportion never approved remained stable (17.7% to 18.8%). In Cohort 2 and 4, the leading rejection reasons were prior authorization (41.9% and 54.3%, respectively) and drug not on formulary (36.8% and 33.7%, respectively). Among rejected index prescriptions due to prior authorization, only 23.6% were subsequently approved. Over time, the dominant rejection reason changed from drug not on formulary (50.1%-71.4% in 2021-2022) to prior authorization (57.6%-69.6% in 2023-2024).

CONCLUSIONS: In this study, patients who received a prescription for finerenone experienced rejection reasons that changed over time. This research underscores the need for careful evaluation of coverage policies and their impact on patient outcomes.

SPONSORSHIP: Bayer U.S. LLC.

40 Clinical and financial impact of treating heart failure patients with finerenone in hospitals with Medicare alternative payment models

Sun L[1], *Hocum B*[2], *Katta A*[2], *Earl J*[2], *Sullivan S*[3]; *lucille.sun@curta.com*; *arvind.katta@bayer.com*
[1]*Curta*; [2]*Bayer U.S. LLC*; [3]*University of Washington CHOICE Institute*

BACKGROUND: Heart failure (HF) is associated with high hospitalization burden, especially among Medicare beneficiaries. Alternative payment models (APMs) administered by the CMS Innovation Center, including the Medicare Shared Savings Program (MSSP), Hospital Readmissions Reduction Program (HRRP), and the Bundled Payments for Care Initiative Advanced Program (BPCI-A), aim to improve outcomes and reduce readmissions through financial incentives. In addition to these programs, guideline-directed medical therapy for HF, including the non-steroidal MRA finerenone, has been shown to reduce hospitalizations and readmissions for HF.

OBJECTIVE: To estimate the financial impact to hospitals of adding finerenone (Kerendia) as a treatment for patients hospitalized for HF with left ventricular ejection fraction (LVEF) ≥40% under the three CMS APM strategies.

METHODS: We estimated the aggregate and relative change in hospital financial margin under the three APMs for Medicare patients with HF (LVEF ≥40%) with and without finerenone treatment. The probability of HF readmission and emergency department (ED) visits for HF was informed by event rates from the FINEARTS-HF study. Hospital margin was estimated using gross margin per encounter, incremental drug costs, and the specific CMS APM payment methodology. In the base case, hospitals had 75% capacity constraint and a historic 0.32% HRRP penalty. Based on CMS reporting, 29.4% of hospitals participated in MSSP, 58.3% in HRRP, and 1.1% in BPCI-A.

RESULTS: For an average hospital with 6,330 all-cause admissions per year (4.5% for HF), there were 123 Medicare patients with HF and LVEF ≥40% eligible for finerenone. Considering average CMS APM participation, the total annual margin would increase by $70,820 per hospital or $580 per treated

patient with the addition of finerenone. The change in total margin was most sensitive to variables affecting HRRP payment, including total admissions per year, cost of all-cause admissions, and HRRP baseline penalty.

CONCLUSIONS: The addition of finerenone as a treatment for patients hospitalized for HF with LVEF ≥40% would increase annual margin for the average US hospital participating in the various CMS alternative payment models.

SPONSORSHIP: Bayer

41 Managed care perspectives on hard-to-control hypertension: AMCP Market Insights program

Richardson T[1], *Wolff D*[2], *Rader F*[3], *Gandhi G*[4], *Reiter D*[5], *Pourarsalan H*[6]; *terry.richardson@impactedu.net*
[1]*Impact Education, LLC*; [2]*Denise & Co, LLC*; [3]*Cedars-Sinai*; [4]*PolarisRx, Prime Therapeutics*; [5]*Priority Health*; [6]*Mercy Care Advantage at Aetna, a CVS Health Company*

BACKGROUND: Despite the availability of multiple effective antihypertensive agents, blood pressure control rates in the United States remain suboptimal. Patients with resistant hypertension—defined as elevated blood pressure despite treatment with three or more antihypertensive agents of different classes—are at heightened risk for cardiovascular events, kidney disease, and mortality. Variability in payer management approaches, coupled with persistent gaps in care coordination, patient adherence, and real-world data utilization, contributes to ongoing challenges in optimizing outcomes for these patients.

OBJECTIVE: To characterize managed care organization (MCO) perspectives on unmet needs, payer decision-making, and opportunities to improve management strategies for patients with hard-to-control hypertension.

METHODS: An AMCP Market Insights roundtable was convened in Q4 2025 with participation from managed care leaders, clinical pharmacists, and hypertension experts. The program included presentations on guideline-based management and quality improvement measures, followed by moderated discussions and live polling to assess payer perspectives. Topics included coverage decision processes, barriers to care, use of real-world evidence, and opportunities to strengthen outcomes through policy and system-level interventions.

RESULTS: Roundtable participants had a high level of agreement that unmet needs remain in achieving blood pressure goals among patients with hard-to-control hypertension, underscoring the need for innovation in both treatment and care delivery. Polling identified how payers implement treatment guidelines, top payer priorities (e.g. HEDIS), and key health plan barriers to reaching hypertension goals. Discussion of addressing secondary causes of hypertension, social determinants of health, and emerging therapeutic approaches highlighted optimism for novel agents that may address safety concerns and achieve greater blood pressure control.

CONCLUSIONS: Findings from this Market Insights roundtable highlight ongoing unmet needs in the management of hard-to-control hypertension from the payer perspective. Greater alignment of health plan coverage policies with current clinical guidelines, coupled with focused quality improvement efforts and attention to social and system-level barriers, may help close performance gaps and improve outcomes for patients at highest cardiovascular risk.

SPONSORSHIP: AstraZeneca

42 Electronic patient-reported cardiovascular-related and clinically relevant symptoms in patients diagnosed with chronic lymphocytic leukemia/small lymphocytic lymphoma and treated with a second-generation Bruton tyrosine kinase inhibitor

Ascha M[1], *Copher R*[2], *Ding L*[3], *Knoth R*[4], *Essell J*[5]; *mustafa.ascha@canopycare.us*; *lee.ding@beonemed.com*
[1]*Canopy Care, Austin, TX, USA*; [2]*BeOne Medicines Ltd.*; [3]*BeOne Medicines Ltd*; [4]*Snell Medical Communication, Inc.*; [5]*OHC/Jewish Hospital Cincinnati OH*

BACKGROUND: Electronic patient-reported outcomes (ePROs) provide valuable insights into the patient experience during treatment and inform clinical decision-making.

OBJECTIVE: To characterize, using the Canopy ePRO-based Remote Therapeutic Monitoring Program (Canopy RTM), cardiovascular-related and other clinically relevant symptoms reported by patients diagnosed with chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) and treated with a second-generation Bruton tyrosine kinase inhibitor (BTKi; zanubrutinib or acalabrutinib) in the first 6 months of treatment. Canopy RTM is an electronic medical record-integrated cloud-based symptoms questionnaire delivered via smartphone apps, web app, or interactive voice response (Cherny 2022 DOI: 10.1200/OP.22.00180).

METHODS: This was a retrospective study of adult patients with CLL/SLL, who were BTKi-treatment-naïve and treated with a BTKi from 1/2024 to 9/2025 in a US community oncology setting. Patients were identified from electronic health records and invited to participate in the Canopy RTM. Patients were included if they submitted at least one symptom report in the first 6 months of treatment. Index was the date of BTKi treatment initiation. Patients were stratified into cohorts by BTKi. Symptoms of interest included chest pain, heart palpitations, difficulty breathing, weakness/fatigue, lightheadedness/dizziness, nausea/vomiting, headache, pain, and edema.

RESULTS: A total of 177 patients submitted at least one RTM ePRO report in the first 6 months of treatment. Of these, 89 (50.3%) were treated with zanubrutinib and 88 (49.7%) with acalabrutinib. Mean age at index was 72 years, and 66.1% were male. Patients treated with zanubrutinib vs acalabrutinib reported chest pain (2.2% vs 6.8%, respectively), heart palpitations (2.2% vs 8.0%), weakness/fatigue (41.6% vs 51.1%), difficulty breathing (12.4% vs 17.0%), lightheadedness/dizziness (11.2% vs 18.2%), nausea/vomiting (6.7% vs 10.2%), headache (14.6% vs 25.0%), pain (14.6% vs 17.0%), and edema (5.6% vs 3.4%).

CONCLUSIONS: In the absence of a head-to-head clinical trial, these results suggest patients diagnosed with CLL/SLL and newly treated with zanubrutinib generally report fewer cardiovascular-related and other clinically relevant symptoms than those treated with acalabrutinib. Understanding the patient experience, particularly in the first 6 months of cancer treatment, enables timely and targeted management of patient symptoms and may optimize outcomes and patient quality of life.

SPONSORSHIP: BeOne Medicines, Ltd.

43 Switching to zanubrutinib in patients diagnosed with chronic lymphocytic leukemia/small lymphocytic lymphoma and previously treated with another Bruton tyrosine kinase inhibitor in a US community oncology setting

Andorsky D[1], *Wentworth C*[2], *Wang Y*[2], *Copher R*[3], *Seymour E*[3], *Balk M*[4], *Maglinte G*[5], *Zackon I*[2]; *David.Andorsky@usoncology.com*; *ronda.copher@beonemed.com*
[1]*Rocky Mountain Cancer Center*; [2]*Ontada*; [3]*BeOne Medicines Ltd.*; [4]*BeOne Medicines*; [5]*BeOne Medicines Ltd*

BACKGROUND: Bruton tyrosine kinase inhibitors (BTKis) are a preferred treatment for patients with chronic lymphocytic lymphoma/small lymphocytic lymphoma (CLL/SLL). With the advent of second-generation BTKis, in-class switching has become more common.

OBJECTIVE: To describe the demographic and treatment characteristics of patients who initiated zanubrutinib following discontinuation of another covalent BTKi in a US community oncology setting.

METHODS: This was a retrospective study of patients in the US Oncology Network diagnosed with CLL/SLL who initiated treatment on zanubrutinib following discontinuation of another BTKi, with no intervening therapy, between 1/2022 and 9/2023. Data were captured from structured and unstructured fields in the iKnowMed electronic health record. Descriptive analyses evaluated patient demographics, clinical characteristics, treatment patterns, including time to discontinuation (TTD) and time to next treatment (TTNT) for prior BTKis and zanubrutinib, and reasons for discontinuation of prior BTKis. Reasons for discontinuation included physician-reported adverse events (AEs), patient/physician preference, or physician-reported disease progression.

RESULTS: A subset of 200 charts was randomly selected for review. Of these, 56 patients (28%) had switched to zanubrutinib from another BTKi; 33 (58.9%) previously treated with ibrutinib and 23 (41.1%) with acalabrutinib. Median time from diagnosis was 84.6 months and follow-up after zanubrutinib initiation was 15.7 months. Median age was 75.0 years and 71.4% were male. Median TTD for ibrutinib was 39.9 months and 4.6 months for acalabrutinib. Reasons for discontinuation from ibrutinib included 42.4% for physician-reported AEs, 30.3% for physician/patient preference, and 24.2% for physician-reported disease progression. For acalabrutinib, 91.3% of patients discontinued due to physician-reported AEs, and 8.7% due to physician-reported disease progression. Following the switch to zanubrutinib, 62.5% discontinued, with a median TTD of 11.4 months. Median TTNT was not reached.

CONCLUSIONS: In patients diagnosed with CLL/SLL and switched to zanubrutinib following another BTKi, the most common reason for discontinuation of the prior BTKi was physician-reported AEs. Once switched to zanubrutinib, many remained on treatment. This suggests an "in-class" switch to zanubrutinib can be an effective clinical option for physicians who prefer to treat CLL/SLL with a BTKi. Future work will continue to follow patients switched to zanubrutinib with a focus on time on treatment and reasons for discontinuation.

SPONSORSHIP: BeOne Medicines, Ltd.

44 Healthcare resource use and expenditures among adults with paroxysmal supraventricular tachycardia in the United States

Pokorney S[1], *Hooda N*[2], *Jiang X*[2], *Liu Y*[3], *Sacks N*[3], *Sheikh M*[4], *Bharucha D*[4], *Desai N*[5]; *sean.pokorney@duke.edu*
[1]*Duke Clinical Research Institute and the Division of Cardiology, Duke University School of Medicine*; [2]*Epidstrategies*; [3]*BlueRidge Life Sciences Pharmaceutical Commercialization*; [4]*Milestone Pharmaceuticals*; [5]*Yale University School of Medicine*

BACKGROUND: Paroxysmal supraventricular tachycardia (PSVT) is the second most common sustained arrhythmia with an estimated US prevalence of 2.1 million. Symptoms include palpitations, weakness or fatigue, dizziness, syncope, and chest pain. Prior studies report significantly higher healthcare resource use (HRU) and costs in newly diagnosed patients, including higher emergency department (ED) visit and

inpatient admission (IP) rates and expenditures. However, the HRU burden of PSVT among prevalent patients has not been previously assessed.

OBJECTIVE: To define patient characteristics, HRU, and expenditures among US adults with PSVT.

METHODS: Enrollment, demographic, and claims data for >300 million individuals were identified from IQVIA's PharMetrics database. Patients were 18-64 years old, were continuously enrolled with medical and prescription drug coverage from 6/1/2021 to 5/31/2024, and had 1 IP or ED claim or 2 outpatient (OP) claims with a PSVT diagnosis. Control patients with no evidence of PSVT were propensity-score matched on demographic and clinical characteristics. HRU and expenditures were measured from 6/1/2023 to 5/31/2024 and reported as mean [SD] per-patient-per-year (PPPY).

RESULTS: Among 17,112 PSVT and 17,112 matched non-PSVT patients, mean age was 51.0 years [11.1]; 64.2% were female; mean Charlson Comorbidity Index (CCI) was 0.7 [1.4]. Annual per patient expenditures were significantly higher for PSVT vs. matched non-PSVT ($26,799 [$83,110] vs. $15,613 [$52,987]; p<0.0001), reflecting higher inpatient ($7,415 [$59,487] vs. $3,546 [$33,241]; p<0.0001), outpatient ($14,182 [$39,646] vs. $7,948 [$28,559]; p<0.0001), and prescription drug ($5,202 [$20,918] vs. $4,119 [$18,245]; p<0.0001) expenditures. These higher expenditures reflected significantly higher IP admissions (0.16 [0.61] vs. 0.08 [0.41]; p<0.0001), including higher ICU stays (0.06 [3.0] vs 0.02 [0.19]; p<0.0001). A higher number of PSVT patients had at least one ED visit (31% vs non-PSVT: 18%; p<0.0001). ED visit rates were significantly higher for PSVT patients (0.61 [1.54] vs. 0.31 [0.99]; p<0.0001), as were office visit (10.82 [11.64] vs. 7.93 [9.73]; p<0.0001), OP hospital visit (3.74 [8.89] vs. 2.49 [9.11]; p<0.0001), and prescription drug fill rates (26.5 [28.7] vs. 21.1 [25.9]; p<0.0001).

CONCLUSIONS: Rates of ED visits and hospital admissions are higher among US adults with PSVT, contributing to significantly higher HRU and expenditures, compared with matched adults without PSVT. Thus, these data support the impact of PSVT on patients and health systems.

SPONSORSHIP: Milestone Pharmaceuticals, Inc.

45 Real-world assessment of LDL-C response of patients initiating bempedoic acid and bempedoic acid plus ezetimibe in routine practice

Nelson J[1], *Coleman C*[2], *Pagidipati N*[3], *Powell H*[4], *Lewandowski D*[1], *Ajose M*[1], *Bonafede M*[1], *Sarnes E*[5], *Shapiro M*[6]; *esarnes@esperion.com*
[1]*Veradigm*; [2]*University of Connecticut School of Pharmacy*; [3]*Duke Clinical Research Institute, Duke University School of Medicine*; [4]*Esperion Therapeutics, Inc.*; [5]*Esperion Therapeutics, Inc*; [6]*Wake Forest University School of Medicine*

BACKGROUND: Clinical guidelines recommend early initiation of lipid-lowering therapy (LLT) in order to achieve and maintain desirable low-density lipoprotein cholesterol (LDL-C) levels for patients with or at high risk for cardiovascular disease (CVD). Bempedoic acid (BA) alone or in a fixed dose combination with ezetimibe (BA+EZE) have been shown to significantly reduce LDL-C in clinical trials; however, their real-world effects when used in routine practice warrant investigation.

OBJECTIVE: To evaluate the LDL-C response at 3 months among patients starting BA or BA+EZE in routine practice.

METHODS: Adults newly initiating BA or BA+EZE between 01/01/2022 and 07/28/2025 were identified in the Veradigm Network EHR linked to Komodo Health claims. All patients were required to have ≥1 BA or BA+EZE claim (index), ≥1 LDL-C laboratory result 6 months before or on the index (baseline value) and an LDL-C result post-index, and continuous BA or BA+EZE use (<60-day gap) up to a valid LDL-C result in follow-up. Patients initiating BA+EZE who were on EZE within the prior 30 days were included in the BA cohort. LDL-C values closest to 3 and 12 months post-initiation were reported among those with continuous use.

RESULTS: A total of 2,431 BA and 1,511 BA+EZE new users were identified, of whom 1,021 and 638 were continuous users with a 3-month LDL-C result. The majority had CVD (86.4% of BA and 86.8% of BA+EZE) at any time in their patient history before initiating index therapy. More specifically, in the 12-month pre-index period, 30.0% and 26.0% of patients, respectively, had ≥1 ASCVD event, and nearly all had hyperlipidemia (92.7% and 91.1%) and hypertension (74.9% and 74.7%); 40.6% and 43.9% had diabetes. Among LLTs in the 12 months pre-index, statins were the most frequently used (61.7% and 64.8% of patients) followed by EZE (53.8% and 20.1%) and PCSK9 inhibitors (16.2% and 14.1%). Median baseline LDL-C was 124 mg/dL (IQR 92-156) and 126 mg/dL (93-160), respectively. From baseline to 3 months, the proportion of patients with LDL-C < 70 mg/dL increased for BA (8.8% to 22.2%) and BA+EZE (10.3% to 37.8%). By 12 months, 32.6% and 48.0% had LDL-C < 70 mg/dL, respectively. Roughly 31% in

each group had LDL-C < 100 mg/dL at baseline; by 3 months, 53.5% and 68.5% of BA and BA+EZE patients had LDL-C < 100 mg/dL. By the end of follow-up, this increased to 64.9% and 79.6% with LDL-C < 100 mg/dL ($p < 0.0001$ vs baseline at all timepoints).

CONCLUSIONS: BA or BA+EZE users experienced LDL-C improvements on top of background LLT use within 3 months of initiation.

SPONSORSHIP: Esperion Therapeutics, Inc.

46 GLP-1RA vs SGLT-2i: Preventing kidney function deterioration among patients with type 2 diabetes and chronic kidney disease

Lin L[1], *Bhattacharya K*[2], *Bentley J*[1], *Yang Y*[1]; *llin3@go.olemiss.edu*
[1]*University of Mississippi*; [2]*Department of Pharmacy Administration and Center for Pharmaceutical Marketing & Management, University of Mississippi School of Pharmacy*

BACKGROUND: Emerging evidence suggests that glucagon-like peptide-1 receptor agonists (GLP-1RA) may improve kidney outcomes in individuals with type 2 diabetes mellitus (T2DM). However, direct head-to-head comparisons of their renal effectiveness with sodium-glucose cotransporter 2 inhibitors (SGLT-2i), the recommended first-line therapy for older adults with T2DM and chronic kidney disease (CKD), remain limited.

OBJECTIVE: To compare the renal effectiveness of GLP-1RA and SGLT-2i among older adults with T2DM and CKD.

METHODS: A new-user, active comparator, matched cohort study was conducted using 5% Medicare data from 2012 to 2020. Older adults (≥65 years) with T2DM and CKD who initiated either a GLP-1RA or an SGLT-2i were identified; the first prescription date was defined as the index date. The 12-month period prior to index served as the baseline. Inclusion criteria required ≥2 outpatient or ≥1 inpatient diagnosis for both T2DM and CKD, continuous enrollment in Medicare Parts A, B, and D, and no prior use of GLP-1RA or SGLT-2i during baseline. Propensity score matching was used to balance baseline characteristics, with standardized differences reported pre- and post-matching. Both intention-to-treat and as-treated analyses were conducted. Risk of any CKD progression and end-stage renal disease (ESRD) was assessed using the Fine and Gray subdistribution hazard model and cumulative incidence functions. As a sensitivity analysis, cohorts were directly matched on baseline CKD stage to assess the robustness of findings.

RESULTS: Between 2013 and 2020, Medicare beneficiaries aged 65 and older initiating GLP-1RA (n=3,967) or SGLT-2i (n=2,443) therapies were included. After 1:1 propensity score matching (n=2,418 per group), GLP-1RA initiators showed a significantly higher risk of CKD progression compared to SGLT-2i initiators in both intention-to-treat (subdistribution hazard ratio [sHR] 1.24, 95% CI 1.09-1.41, $p < 0.001$) and as-treated analyses (sHR 1.21, 95% CI 1.02-1.43, $p = 0.028$). For ESRD, GLP-1RA initiators showed a non-significant trend toward increased risk as compared to SGLT-2i initiators. Sensitivity analyses with exact matching on baseline CKD stage confirmed these results. No significant effect modification by sex was observed.

CONCLUSIONS: Initiation of SGLT-2i is associated with a lower risk of kidney disease progression compared to GLP-1RA, supporting preferential use of SGLT-2i for kidney protection among older adults with CKD and T2DM.

SPONSORSHIP: None

47 Systemic inflammation is associated with chronic kidney disease progression among those with comorbid atherosclerotic cardiovascular disease: Insights from the Veterans Affairs Healthcare System

Sandhu A[1], *Furst A*[1], *Chang T*[1], *Din N*[2], *Khachatourian K*[3], *Skaar J*[4], *Tonnu-Mihara I*[3]; *ats114@stanford.edu*
[1]*Stanford University*; [2]*Palo Alto VA*; [3]*Novo Nordisk*; [4]*Novo Nordisk, Inc*

BACKGROUND: Systemic inflammation (SI) is common among individuals with chronic kidney disease (CKD) and atherosclerotic cardiovascular disease (ASCVD). The relationship between SI and CKD outcomes in a real-world population is unclear.

OBJECTIVE: To evaluate the association between SI and CKD progression among those with CKD and ASCVD.

METHODS: We identified veterans with CKD and ASCVD and outpatient high-sensitivity C-reactive protein (hsCRP) measurement from 2008 to 2022. CKD was identified based on estimated glomerular filtration rate (eGFR) >15 and <60 mL/min/1.73 m^2 or eGFR >60 with urinary albumin-creatinine ratio >200 mg/g. Baseline eGFR was calculated via the most recent serum creatinine prior to the hsCRP using the 2021 CKD-EPI equations. ASCVD was identified based on diagnosis codes or prior arterial revascularization. Veterans with prior dialysis or comorbidities known to increase SI and mortality (eg, active cancer) were excluded. We compared those with SI (hsCRP >2 mg/L and <10 mg/L) vs without SI (hsCRP <2 mg/L). The primary outcome was a CKD progression composite (eGFR stage progression or initiation of outpatient dialysis) following hsCRP measurement. Secondary outcomes included progression to kidney failure (KF: defined as eGFR <15 mL/min/1.73 m^2 or initiation of outpatient dialysis) and sustained eGFR reduction (eGFR reduction of >40% or initiation of outpatient dialysis). Cox regression was used to

compare patients with vs without SI, adjusting for demographics, comorbidities, and ASCVD and CKD-related medications. Analyses were censored at the time of death or end of follow-up.

RESULTS: We identified 94,166 veterans with CKD and ASCVD with an hsCRP measurement: 20,879 had hsCRP <2 mg/L, 48,224 had hsCRP >2 mg/L and <10 mg/L, and 25,063 had hsCRP >10 mg/L. Those with hsCRP >10 mg/L were excluded. Among 69,103 veterans with hsCRP <10 mg/L, the mean age was 73 years (SD: 9). There were 3,148 veterans with CKD stage 1/2 with albuminuria, 60,874 with CKD stage 3, and 5,081 with CKD stage 4. The median follow-up was 4.3 years prior to death or loss to follow-up. The incidence of CKD progression was 5.0 events/100 patient-years in those with SI vs 3.6/100 patient-years in those without SI ($p < 0.001$). After adjustment, SI remained associated with a higher risk of CKD progression (HR: 1.12; 95% CI: 1.08-1.17). SI was also associated with an increased risk of KF (HR: 1.09; 95% CI: 1.04-1.15) and sustained eGFR reduction (HR: 1.16; 95% CI: 1.11-1.21).

CONCLUSIONS: Among individuals with CKD and ASCVD, SI is associated with increased risk of CKD progression.

SPONSORSHIP: Novo Nordisk

48 Mortality, morbidity, and treatment costs associated with the use of lomitapide in the treatment of adult homozygous familial hypercholesterolemia in the US

Hovland S[1], *Ronquest N*[2], *Hao Q*[2], *Barnett C*[2], *Causse Safar P*[3]; *sara.hovland@chiesi.com*
[1]*Chiesi USA*; [2]*RTI Health Solutions*; [3]*Chiesi FRANCE S.A.S*

BACKGROUND: Homozygous familial hypercholesterolemia (HoFH) is a rare inherited genetic disorder characterized by markedly elevated levels of circulating low-density lipoprotein cholesterol (LDL-C) since birth. It affects 3 in 1M people and can lead to severe health consequences, particularly premature and accelerated atherosclerotic cardiovascular (CV) disease often resulting in early death. Treatments include lomitapide, a microsomal triglyceride transfer protein inhibitor that impedes the production of lipoproteins in the liver, evinacumab, and the current standard of care (SOC), which includes PCSK9 inhibitors, statins, ezetimibe, and apheresis.

OBJECTIVE: To compare lifetime clinical and economic outcomes associated with the use of lomitapide+SOC vs SOC alone, in adults with HoFH from the US payer perspective.

METHODS: The model employed a semi-Markov structure simulating adult patients with HoFH experiencing five types of non-fatal CV events and death. Based on baseline LDL-C and estimated LDL-C changes for patients treated with lomitapide+SOC vs SOC alone, the model predicted downstream CV events and mortality using established relationships between LDL-C reduction and CV risk reported in the literature. Age- and gender-specific risk of CV events were modeled on a survival analysis based on an international registry of patients with HoFH. Drug costs were obtained from Redbook. Procedure and monitoring costs were obtained from CMS reimbursement schedules using corresponding CPT and HCPCS codes. Costs of CV events were estimated using HCUP and published data.

RESULTS: Estimated changes from baseline LDL-C for patients treated with lomitapide+SOC vs SOC alone were −50.0% and +1.9%, respectively. If initiated at age 18, over a lifetime the model predicted a reduction in LDL-C with lomitapide+SOC vs SOC alone would result in a 48.91% decrease in risk of CV death, avoid 0.75 non-fatal CV events and 251 apheresis procedures, and result in an 8.01 life-year extension. Cost savings were $28,294 due to the reduction in CV deaths, $46,407 due to avoided non-fatal CV events, and $1.20M due to avoided apheresis procedures. In a 1M member health plan, with an estimated number of 2.2 adults with HoFH, the total per- member per-month cost to introduce lomitapide to the plan was $0.13.

CONCLUSIONS: The model demonstrated that lomitapide can reduce CV risk and morbidity, extend life-years, and reduce costs associated with fatal and non-fatal CV events when used to treat adult patients with HoFH.

SPONSORSHIP: Chiesi USA Inc.

49 Mortality, morbidity, and treatment costs associated with lomitapide in the treatment of pediatric homozygous familial hypercholesterolemia in the US

Hovland S[1], *Ronquest N*[2], *Hao Q*[2], *Barnett C*[2], *Causse Safar P*[3]; *sara.hovland@chiesi.com*
[1]*Chiesi USA*; [2]*RTI Health Solutions*; [3]*Chiesi FRANCE S.A.S*

BACKGROUND: Homozygous familial hypercholesterolemia (HoFH) is a rare inherited genetic disorder characterized by markedly elevated levels of circulating low-density lipoprotein cholesterol (LDL-C) since birth. It affects 3 in 1M people and can lead to severe health consequences, particularly premature and accelerated atherosclerotic cardiovascular (CV) disease often resulting in early death. Treatments include lomitapide, a microsomal triglyceride transfer protein inhibitor that impedes production of lipoproteins by the liver, evinacumab, and the current standard of care (SOC), which includes PCSK9 inhibitors, statins, ezetimibe, and apheresis.

OBJECTIVE: To compare lifetime clinical and economic outcomes associated with the use of lomitapide+SOC vs SOC alone, in pediatric patients with HoFH from the US payer perspective.

METHODS: The model employed a semi-Markov structure simulating pediatric patients with HoFH experiencing five types of non-fatal cardiac events and death. Based on baseline LDL-C and estimated LDL-C changes for patients treated with lomitapide+SOC vs SOC alone, the model predicted downstream CV events and mortality using previously reported established relationships between LDL-C reduction and CV risk. Age and gender-specific risk of CV events were modeled on a survival analysis based on an international registry of patients with HoFH. Drug costs were obtained from Redbook. Procedure and monitoring costs were obtained from CMS with corresponding CPT and HCPCS codes. Costs of CV events were estimated using HCUP and published data.

RESULTS: Estimated changes from baseline in LDL-C for patients treated with lomitapide+SOC vs SOC alone were −53.5% and +1.9%, respectively. If initiated at age 5, over a lifetime the model predicted a reduction in LDL-C with lomitapide+SOC vs SOC alone would result in a 56.59% decrease in the risk of CV death, avoid 1.16 non-fatal CV events and 218 apheresis procedures, and result in a 15.16 life-year extension. Cost savings were $42,210 due to the reduction in CV deaths, $72,565 due to avoided non-fatal CV events, and $1.04M due to avoided apheresis procedures. In a 1M member health plan, with an estimated number of 0.5 pediatric patients with HoFH, the total per-member per-month cost to introduce lomitapide to the plan was $0.03.

CONCLUSIONS: The model demonstrated that lomitapide can reduce CV risk and morbidity, extend life years, and reduce costs associated with fatal and non-fatal CV events when used to treat pediatric patients with HoFH.

SPONSORSHIP: Chiesi USA, Inc.

50 Impact of medication adherence on clinical and economic outcomes in cardiovascular disease: A scoping review of real-world evidence

Keast S[1], *Mendelsohn A*[2], *Lockhart C*[2];
shellie.keast@medimpact.com
[1]*MedImpact*; [2]AMCP

BACKGROUND: Adherence to chronic medications, especially those for chronic conditions such as cardiovascular conditions, is important for reducing risk of poor outcomes. While many studies have published research related to adherence to medications in this disease state, a scoping review of the association of adherence with reduced risk and costs was needed to establish both the primary measurement for adherence and the potential associations with outcome reduction.

OBJECTIVE: To evaluate the impact of adherence on outcomes and costs related to cardiovascular disease using real-world data through a scoping review.

METHODS: A scoping review of published research evaluating medication adherence or persistence was conducted. We examined full text articles identified from PubMed, EMBASE, and Web of Science using the terms compliance, adherence, administrative claims, real-world, and observational. Among 1,505 articles initially retrieved, 595 met the inclusion criteria. We identified 8 studies that reviewed the association of adherence with outcomes related to cardiovascular disease (CVD).

RESULTS: The studies examined a broad spectrum of outcomes, including serious cardiovascular events such as major adverse cardiovascular events (MACE), acute myocardial infarction (AMI), stroke, revascularization procedures, hospitalizations and emergency room (ER) visits, and cardiovascular-related mortality. The proportion of days covered (PDC) was the primary adherence calculation method followed by the medication possession ratio (MPR) or similar method. Across the various studies high adherence (e.g., PDC ≥ 80%) was associated with decreased risk of MACE, ER visits, hospitalizations, and all-cause mortality. In one study, improving pre-AMI PDC < 40% to PDC 40-80% or >80% post-AMI realized the same health benefits as those who were consistently adherent. Another study found hazard ratios for mortality ranging from 0.59 to 0.73 for MPR >80% across multiple drug classes. Across the various studies, overall, high adherence (e.g. PDC ≥ 80%) was associated with decreased risk of MACE, ER visits, hospitalizations, and all-cause mortality improved outcomes.

CONCLUSIONS: Having high levels of adherence was associated with reduced risk of adverse cardiovascular outcomes including MACE, hospitalizations, and mortality. These studies highlight the critical role that high adherence plays in reducing cardiovascular outcomes and healthcare costs.

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51 Statin adherence patterns among older adults on triple therapy: A real-world study using group-based trajectory model

Ofili S, Cheruvu S, Olumeko I, Abughosh S;
scofili@CougarNet.UH.EDU
University of Houston

BACKGROUND: Atherosclerotic cardiovascular disease, driven by elevated LDL-C, is a global health crisis. Statins are foundational for treatment, yet non-adherence is a major challenge, particularly among older adults managing multimorbidity with concurrent triple therapy (statin, RAS antagonists, and oral antidiabetics). Poor adherence worsens outcomes. Understanding statin-specific adherence patterns is critical

for targeted interventions and improving Medicare STAR quality measures.

OBJECTIVE: To evaluate distinct adherence patterns to statin monotherapy over 12 months among older adults in a Medicare Advantage population on concurrent triple therapy and to identify associated predictors using Group-Based Trajectory Modeling (GBTM).

METHODS: This retrospective cohort study utilized 2016–2017 Texas Medicare Advantage claims data. The cohort of 7,847 continuously enrolled older adults had confirmed diabetes, hypertension, and dyslipidemia, and were required to have used concurrent statins, RAS antagonists, and an oral anti-diabetic during a 6-month index period. Statin adherence was measured monthly using the Proportion of Days Covered ≥ 0.8 over a 12-month follow-up. GBTM was employed to empirically map dynamic adherence patterns. Predictors, guided by the Andersen Behavioral Model, were analyzed using multinomial logistic regression, referencing the adherent group.

RESULTS: The GBTM identified three distinct adherence trajectories: near-perfect adherence (47.3%), adherent (34.8%), and rapid decline (17.8%). Compared to the adherent group, multinomial regression showed females had significantly higher odds of being in the rapid decline group (OR 1.35, $p < 0.0001$). Patients with > 1 prior hospitalization also had 43% higher odds of rapid adherence decline (OR 1.43, 95% CI 1.02–2.01; $p = 0.0385$). Conversely, increasing age (≥65 years) was protective; patients aged 70–74 years were significantly less likely to experience a rapid decline compared to those ≤65 years (OR 0.66, 95% CI 0.53–0.82; $p = 0.0002$). Additionally, a greater total number of other medications was associated with lower odds of rapid decline (OR 0.98 per unit increase; $p = 0.016$).

CONCLUSIONS: This study identified three clear, longitudinal statin adherence patterns. A critical subgroup exhibited a rapid decline, predicted by female sex, prior hospitalization, and younger age. These findings highlight high-risk subgroups, supporting the need for proactive, tailored interventions post-hospitalization and specialized behavioral support for females and younger adults to improve adherence and optimize performance on healthcare quality metrics.

SPONSORSHIP: None

52 Pulmonary hypertension: Predictive model for early diagnosis

Gupta A[1], *Verma* V[1], ROY A[1], *Nayyar* A[1], *Arora* A[1], *Khatavkar* V[1], K K[1], V V[1], *Karayat* K[1], *Sachdev* A[1], *Bansal* V[1], *Dewan* R[1], S S[1], *Gandla* V[1], *Brooks* L[2], *Seligman* M[2], *Heath* K[3]; *anuj_gupta457@optum.com*; *vikash.verma@optum.com*; *abhimanyu.roy@optum.com*; *abhinav.nayyar@optum.com*; *ankitkumar_arora@optum.com*; *vishan_khatavkar@optum.com*
[1]*Optum Inc.*; [2]*OptumInsight*; [3]*Optum*

BACKGROUND: Despite affecting ~1% of the global population, the early diagnosis of Pulmonary Hypertension (PH), a progressive and life-threatening condition often leading to heart failure, remains challenging due to reliance on invasive procedures like right heart catheterization. Early identification could offer timely initiation of treatment preventing irreversible vascular modeling.

OBJECTIVE: To develop a machine learning-based algorithm that predicts PH utilizing critical signs, disease and symptoms (SDS) captured in electronic health records.

METHODS: Incident adult PH patients were identified using ICD-10-CM code I27.0 from Optum® Market Clarity database from January 2021 to March 2025. The index event was defined as the first recorded PH diagnosis. Eligibility criteria required at least 12 months of continuous activity prior to the index date to capture SDS, and no prior history of PH during this baseline period. A matched cohort was constructed using age, gender, race, and geographic region to compare PH-diagnosed patients with controls without PH. Key predictors (SDS) explored were fainting, edema, cyanosis, murmur and hemoptysis. The dataset was randomly split into training (75%) and testing (25%) subsets. Three machine learning (ML) models —Logistic Regression (LR), XGBoost, and Random Forest (RF)—were developed to predict PH occurrence based on SDS. Model performance was evaluated using accuracy, precision, recall, and F1 scores.

RESULTS: Among 55,170 patients with pulmonary hypertension, 70% were male, 41% identified as Hispanic, and the mean age was 71 years (±13). Among the three ML models evaluated, LR demonstrated the strongest association between explored SDS and the likelihood of PH diagnosis. It achieved 81% accuracy, 80% precision, 78% recall, and 79% F1 score. Among the SDS, pulmonary embolism, chest pain, dry cough, and shortness of breath were the most influential features, explaining a significant portion of the variability in PH diagnosis.

CONCLUSIONS: The predictive model developed using clinical SDS demonstrates promising potential for early identification of PH in resource-limited or pre-diagnostic settings. By leveraging non-invasive, symptom-based parameters, like SDS, the model facilitates timely risk stratification, which may

enhance early detection, reduce diagnostic delays, and support clinical decision-making, particularly in primary care and underserved populations. Further validation is required to enhance its clinical applicability.

SPONSORSHIP: None

53 Risk of chronic kidney disease in obese adults: A real-world perspective

Gupta A[1], *Verma V*[1], *Roy A*[1], *Nayyar A*[1], *Arora A*[1], *Khatavkar V*[1], *Misra A*[1], *Karayat K*[1], *Motila S*[1], *Sundaram S*[1], *Gandla V*[1], *Paul A*[1], *Brooks L*[2], *Seligman M*[2], *Heath K*[3]; *anuj_gupta457@optum.com*; *vikash.verma@optum.com*; *abhimanyu.roy@optum.com*; *abhinav.nayyar@optum.com*; *ankitkumar_arora@optum.com*; *vishan_khatavkar@optum.com*
[1]*Optum Inc.*; [2]*OptumInsight*; [3]*Optum*

BACKGROUND: Chronic Kidney Disease (CKD) is a progressive, often undetected condition linked to obesity, leading to high disease burden. Prior studies highlight the increased risk of CKD in obese patients. However, real world evidence on obesity and CKD and its risk factors is limited.

OBJECTIVE: To evaluate CKD incidence among obese adults using real-world data to identify early predictors of CKD to improve outcomes by preventing disease advancement.

METHODS: The retrospective Optum® Market Clarity database study utilized claims and electronic health records (EHR) data from 01 January 2017 to 31 December 2023. Patients aged 18-65 years with an obesity diagnosis (≥1 inpatient or ≥2 outpatient claims at least 30 days apart—defined as index event) were included. Continuous medical and pharmacy eligibility, and clinical activity for 12-month baseline and 72-month follow-up, and presence of baseline renal labs (≥1 eGFR and ≥1 creatinine) were required. Those with prior advanced CKD or end stage renal disease (ESRD)/dialysis in the baseline were excluded. CKD incidence rates per 100,000 persons and Kaplan-Meier analysis were performed. Cox proportional hazards models were conducted to identify baseline predictors of CKD.

RESULTS: Overall, 27,151 obese adults aged 18–65 with renal lab availability and no prior advanced CKD were identified, with mean ± SD age as 51.1 ± 9.8 years, 78.7% non-Hispanic White, 59.9% female, and 89.1% patients with Charlson comorbidity score of 0-2. The 6-year cumulative incidence of any-stage CKD was 2,300 cases per 100,000 individuals among obese patients. Cox proportional hazards revealed lower CKD risk among females and younger age groups, while Non-Hispanic Black race, elevated HbA1C, serum uric acid, and low total cholesterol were significant predictors ($p < 0.001$). Among baseline comorbid conditions, elevated blood urea nitrogen-BUN (HR = 1.3), HbA1C (HR = 1.4), serum uric acid-SUA (HR = 1.5), and total protein (HR = 2.5) were associated with increased CKD risk.

CONCLUSIONS: The real-world study reveals a significant CKD burden among obese adults. These findings highlight the need for proactive metabolic monitoring and targeted screening, especially in high-risk groups. Integrating predictive modeling into routine care may improve early detection and long-term outcomes.

SPONSORSHIP: None

Central Nervous System

72 Cost-effectiveness of Symbravo (MoSEIC meloxicam and rizatriptan) compared with gepants for the acute treatment of migraine in adults in the United States

Ailani J[1], *Graham C*[2], *Erbe A*[2], *Grinnell T*[3], *DePue R*[4], *Zhao Y*[5]; *jessica.ailani@gunet.georgetown.edu*; *rdepue@axsome.com*
[1]*MedStar Georgetown University Hospital*; [2]*RTI Health Solutions*; [3]*Axsome Therapeutics, Inc.*; [4]*Axsome Therapeutics Inc., New York, NY, USA*; [5]*Axsome Therapeutics, Inc., New York, NY, USA*

BACKGROUND: Migraine is a disabling neurologic condition requiring acute treatment. Existing treatments are often suboptimal in providing rapid and sustained relief or freedom from pain and associated symptoms, and can increase resource utilization and costs due to medication overuse headache, treatment discontinuation, and progression to chronic migraine. New acute treatments for migraine include oral CGRP inhibitors (gepants) and Symbravo® (MxRz), a novel, multimechanistic oral medication comprising MoSEIC(TM) meloxicam and rizatriptan.

OBJECTIVE: To assess the cost-effectiveness of treatment with MxRz for patients with acute migraine compared with rimegepant, ubrogepant, and zavegepant from a US payer perspective.

METHODS: A semi-Markov model was developed following the Institute for Clinical and Economic Review Acute Treatments for Migraine 2020 Report to capture the costs and utilities associated with the treatment of acute migraine over 1-2 years. The patient population reflects those enrolled in the phase 3 MOMENTUM clinical trial for Symbravo. Efficacy data were derived from a Bayesian network meta-analysis, and cost and utility data were extracted from the literature. Total costs, and effectiveness measured via quality-adjusted life-years (QALYs), total hours of pain, pain freedom at 2 h, sustained pain freedom from 2-24 h, and avoidance of rescue medications from 2-24 h were estimated. Incremental

costs were assessed for QALYs gained and hours of pain avoided, and cost per responder for pain freedom at 2 h and sustained pain freedom from 2-24 h and cost per rescue medication avoided from 2-24 h were evaluated.

RESULTS: Over a 2-year horizon, treatment with MxRz was associated with the lowest total cost ($20,766) compared with rimegepant ($22,114), ubrogepant ($22,186), and zavegepant ($28,072). MxRz also generated slightly more QALYs (1.860) and fewer hours of pain (1,219) than each of the gepants (rimegepant: 1.855 QALYs/1,436 hours, ubrogepant: 1.855 QALYs/1,451 hours, zavegepant: 1.853 QALYs/1,483 hours), making it the dominant intervention from a US payer perspective. Similar trends were observed in 1-year analyses. In addition, MxRz demonstrated the lowest costs per responder for pain freedom at 2 hours, sustained pain freedom from 2-24 h, and rescue medication avoided from 2-24 h, followed by rimegepant, ubrogepant, and zavegepant. Sensitivity analyses confirmed the model's robustness.

CONCLUSIONS: This analysis finds MxRz to be a cost-effective option compared with gepants for the acute treatment of migraine, a disease for which healthcare costs have been increasing.

SPONSORSHIP: Axsome Therapeutics, Inc.

73 Economic burden of multisystemic impacts (MSIs) in Medicare beneficiaries with myotonic dystrophy (DM)

Straubing R[1], *Persky M*[2], *Davis M*[3], *Cong Z*[4], *Johnson N*[5]; *rebecca.straubing@medicuseconomics.com*
[1]*Medicus Economics LLC*; [2]*Medicus Economics*; [3]*Medicus Economics, LLC*; [4]*Avidity Biosciences*; [5]*Virginia commonwealth university*

BACKGROUND: Myotonic dystrophy (DM) is a systemic disorder characterized by myotonia and progressive skeletal muscle weakness, with multisystem impacts including immobility as well as cardiac, respiratory, gastrointestinal (GI), ocular, speech and swallowing, and metabolic dysfunction.

OBJECTIVE: To quantify the economic burden of MSIs for Medicare beneficiaries with DM.

METHODS: A retrospective longitudinal study was conducted of beneficiaries in 100% Medicare fee-for-service claims (2016–2023) with an *International Classification of Diseases* diagnosis code for DM (G71.11) with ≥6 months of continuous enrollment before (baseline) and after the index date (first such DM diagnosis). Follow-up extended until study end, death, or disenrollment. Each 6-month follow-up interval was classified into MSI categories based on relevant diagnosis codes. Increase in spending was estimated from pair-wise generalized linear models of each MSI category relative to DM patients without MSIs, controlling for baseline characteristics (sex, age, race, region, year, dual Medicaid eligibility status, and Charlson Comorbidity Index) and within-person effects with a gamma distribution and log-link.

RESULTS: Among 7,752 patients with DM, the mean age was 58 and 51% were female. Over 77% of beneficiaries had MSIs at baseline, including metabolic dysfunction (51%), cardiac (31%), fatigue (26%), speech and swallowing (21%), moderate GI (21%), severe immobility (16%), respiratory/moderate immobility/ophthalmological (each 9%), and severe GI (3%). Annual spending on DM patients with MSIs was significantly higher than DM patients without MSIs. Adjusted total/medical cost ratios of DM with MSIs relative to DM without MSIs were 2.8×/4.2× for any MSI, and highest for respiratory (7.6×/13.6×), severe GI (6.2×/11.0×), severe immobility (4.8×/7.7×), fatigue (4.4×/7.1×), speech and swallowing (4.3×/7.2×), and cardiac (3.8×/6.1×) (all $p < 0.05$). The coexistence of severe immobility with cardiac, severe GI, or respiratory dysfunctions further increased total costs by 6.4×, 7.8×, and 9.6× and medical costs by 10.9×, 14.4×, and 17.6×, respectively (all $p < 0.05$).

CONCLUSIONS: DM imposes a high systemic disease burden, with multisystem involvement present in 77% of patients. While DM incurs elevated healthcare spending in general, the presence of MSIs further amplified costs, particularly among patients with more than one organ dysfunction. Novel disease modifying interventions that delay or prevent MSIs could yield substantial cost offsets for the healthcare system.

SPONSORSHIP: Avidity Biosciences, Inc.

74 Migraine medication trends among mid-size employer groups: Are newer brands taking over?

Sheen J, LaDuke R, Brown K, Carter J, Pucik K, Look K, Jain B; janelle.sheen@navitus.com; Ron.Laduke@navitus.com
Navitus

BACKGROUND: Migraine treatment has evolved more rapidly in recent years than in previous decades. In 2024, migraine therapies emerged as a top three non-specialty trend driver. While higher-cost therapies, including the calcitonin gene-related peptide (CGRP) medications, are marketed as breakthroughs, their use brings financial challenges. To understand these dynamics, and the impact of management strategies, we conducted an analysis to identify trends.

OBJECTIVE: To analyze utilization trends in prophylactic and acute-use migraine medications.

METHODS: Pharmacy claims data were retrospectively evaluated for 160 groups from January 1, 2022, to April 30, 2025.

Migraine medications for prophylactic and acute-use treatment were identified using guidance from the American Academy of Neurology. Claims were categorized by acute and prophylactic use, followed by triptan and non-triptans. Non-triptan acute-use treatments included the serotonin agonist, lasmiditan, and the CGRPs. Claims were aggregated by quarter for member age/gender, number of fills, and adherence. Non-adherence was defined as a medication possession ratio < 67%.

RESULTS: A total of 120,218 paid claims were identified for 6,638 members aged 3-81. Migraine medication use was more prevalent in females compared to males and most utilizers were aged 40-59. Forty-nine percent of utilizers had claims for both prophylactic and acute-use therapies, 46% had claims for acute-use medications only, and 5% were only utilizing prophylactic medications. Among members using acute-use medications and no prophylactic medication, 63 members filled acute-use medications 8 or more times per year. Within this group, 48 members filled triptan prescriptions and 15 filled prescriptions for a non-triptan. Eighty-six percent of members taking prophylactic medications were adherent to therapy. Utilization of CGRPs has increased in comparison with triptans.

CONCLUSIONS: There is opportunity to enhance migraine prevention in members using acute treatments without prophylactic therapy. Specifically, members overusing acute treatments may benefit from preventive therapy, potentially reducing reliance on acute medications. Furthermore, adherence with prophylactic therapy is impactful. Increased adherence in this group could lead to a reduced need for acute treatments. Lastly, among members overusing acute therapies, triptans remain the most commonly used therapies. This suggests that current strategies for newer migraine treatments are effective in promoting first-line use of lower-cost triptans.

SPONSORSHIP: None

75 Impact of routine screening for agitation with the AASC in Alzheimer's dementia

Jackson W[1], *Palma A*[2], *Chumki S*[2], *Bucior I*[2], *Laubmeier K*[2], *Zhang Z*[2], *Patel A*[3], *Montano C*[4]; *mydocjackson@live.com*
[1]*University of Tennessee College of Medicine*; [2]*Otsuka Pharmaceutical Development & Commercialization*; [3]*Dayton Psychiatric Associates*; [4]*Connecticut Clinical Research*

BACKGROUND: Agitation in patients with Alzheimer's dementia is frequently underrecognized, contributing to suboptimal care and a greater burden on patients, caregivers, and the healthcare system.

OBJECTIVE: The Agitation in Alzheimer's Screener for Caregivers (AASC®) has been quantitatively validated against the International Psychogeriatric Association criteria for agitation in cognitive disorders. This study examined its value in supporting screening of agitation in patients with Alzheimer's dementia.

METHODS: A microsimulation model of a hypothetical population (N=100,000) newly diagnosed with Alzheimer's was used to examine the impact of AASC® screening on the identification of agitation in Alzheimer's dementia and related healthcare outcomes. Model inputs included recently published data on prevalence, burden, and treatment of agitation, along with AASC® sensitivity/specificity metrics (0.77/0.70). All positive AASC® screens were assumed to lead to specialist assessment and correct diagnosis of agitation in Alzheimer's dementia, and that US Food and Drug Administration–approved pharmacological treatment for agitation associated with dementia due to Alzheimer's disease was assigned to diagnosed patients. Screening performance (changes in agitation diagnosis rates) was assessed; outcomes included healthcare resource utilization (HCRU) rates (hospitalizations, office visits, long-term care [LTC] placement), total healthcare costs, and caregiver burden defined using the Short-Form Zarit Burden Interview (ZBI-12).

RESULTS: Screening with AASC® resulted in 28.1%, 19.9%, 13.6%, 10.2%, and 8.0% additional diagnoses of agitation in patients with Alzheimer's dementia in years 1 through 5, respectively. Pharmacological treatment for agitation in diagnosed patients vs no treatment for agitation resulted in lower rates of hospitalization (11.5%-15.7% less hospitalizations over 5 years), fewer office visits (median 1.4 fewer visits per year), lower rates of LTC placements (11.1%-29.7% less placements over 5 years), and reduced total healthcare costs (median decrease of $18,420 over 5 years). Additionally, improvements were associated with a reduction in caregiver burden, corresponding to 0.62 fewer person-years on the ZBI-12.

CONCLUSIONS: Based on this model, routine screening with the AASC® led to earlier identification of agitation in patients with Alzheimer's dementia, and timely treatment of agitation was associated with lower HCRU and reduced caregiver burden.

SPONSORSHIP: Otsuka Pharmaceutical Development & Commercialization, Inc. (Princeton, New Jersey).

76 Real-world impact of discontinuing ocrelizumab on health care utilization and cost among older adult patients with multiple sclerosis in the United States

Pineda E, Patel A, Sheinson D, Xia Z, Abioye I;
pineda.elmor@gene.com
Genentech, Inc.

BACKGROUND: Older patients with MS (pwMS) face unique challenges such as comorbidities, reduced immune function and a transition from relapsing to progressive disease typically around age 50 y. Ocrelizumab (OCR), a high-efficacy disease-modifying therapy, has demonstrated benefit in reducing disease activity and progression. The real-world impact of discontinuing ocrelizumab on healthcare resource utilization (HRU) and costs among older pwMS remains unclear.

OBJECTIVE: To compare all-cause and MS-related HRU and costs among pwMS aged ≥50 y who continued vs de-escalated or discontinued OCR.

METHODS: This retrospective cohort study used IQVIA PharMetrics Plus claims (1/1/2018-6/30/2024). Patients aged ≥50 y had ≥1 MS claim, ≥1 OCR claim and ≥2 y of continuous enrollment post-initiation. Discontinuation was defined as a ≥90-day treatment gap with no OCR claims beyond the gap. For discontinuers, the index date was the discontinuation date (6 mo after last claim) and included patients who de-escalated to lower-efficacy therapies; they were 1:1 matched to continuers by follow-up duration. Continuers were assigned a pseudo-index date based on time to discontinuation of the matched case. Inverse probability treatment weights addressed residual confounding. Quasipoisson (counts) and Tweedie (costs, CPI-adjusted) regression models with cluster-robust standard errors generated adjusted effect estimates.

RESULTS: A total of 683 discontinuers were matched to 683 continuers. Mean (SD) age was 59 (7) vs 57 (6) y, respectively. All-cause HRU and costs were higher for discontinuers vs continuers, including hospitalizations (0.48 [1.67] vs 0.15 [0.49]; rate ratio [RR]=2.21 [1.48-3.30]), length of stay (5.1 [26.0] vs 0.9 [4.4] days; RR=3.56 [2.12-5.97]) and inpatient costs ($10,186 [$56,180] vs $4295 [$20,398]; cost ratio [CR]= 1.95 [1.18-3.23]). MS-related hospitalizations (0.46 [1.65] vs 0.13 [0.46]; RR=2.34 [1.54-3.57]), length of stay (4.5 [24.3] vs 0.8 [4.1] days; RR=3.44 [1.99-5.95]) and inpatient costs ($6682 [$25,768] vs $3099 [$15,986]); CR=1.90 [1.20-3.02]) were also higher.

CONCLUSIONS: PwMS aged ≥50 y who discontinued OCR had higher adjusted all-cause and MS-related hospitalizations, lengths of stay and associated costs than continuers, suggesting that discontinuation may be premature and linked to increased disease activity or disability progression following treatment withdrawal. Age-related immune decline and comorbidities may exacerbate disease reactivation, leading to higher HRU and suboptimal outcomes. Continued OCR therapy in appropriately selected older pwMS may help mitigate these risks.

SPONSORSHIP: Genentech, Inc.

77 Self-reported sleep quality and changes in functional status, work productivity, and daily activities in people with idiopathic hypersomnia or narcolepsy treated with low-sodium oxybate: Results from the phase 4 DUET study

Cairns A[1], Schneider L[2], Plante D[3], Nichols D[1], Steininger T[1], Dai J[1], Whalen M[1], Beaty S[1], Ruoff C[4];
alyssa.cairns@jazzpharma.com
[1]Jazz Pharmaceuticals; [2]Stanford University Center for Sleep Sciences and Medicine; [3]University of Wisconsin-Madison; [4]Mayo Clinic

BACKGROUND: DUET was a phase 4, prospective, open-label study assessing effectiveness of low-sodium oxybate (LXB) on nighttime sleep and daytime symptoms in participants with idiopathic hypersomnia (IH) or narcolepsy.

OBJECTIVE: To evaluate effectiveness of LXB on secondary and exploratory outcomes of self-reported sleep quality, functional status, and work/daily activities in DUET.

METHODS: DUET comprised screening (with washout for current oxybate users), 8-day baseline (BL), 2- to 8-week LXB titration, 2-week stable-dose, 8–day end-of-treatment (EOT), and 2-week safety follow-up periods. Participants completed an electronic sleep diary during BL and EOT, with newly developed daily questions on sleep quality (5-point scale) and how rested/refreshed they felt upon awakening (5-point scale). The Functional Outcomes of Sleep Questionnaire-10 (FOSQ-10; score range=5–20, higher scores are better; individuals without sleep disorders= 17.8]) and Work Productivity and Activity Impairment Questionnaire: Specific Health Problem (WPAI:SHP; score range=0%–100%, higher percentages are worse) were administered at BL and EOT. Results are descriptive.

RESULTS: Forty-six participants with IH and 55 with narcolepsy enrolled and took LXB (female, 80.4%/72.7%; White, 84.8%/80.0%; mean [SD] age, 38.1 [11.8]/33.4 [12.9] years); 40 and 34 completed the study, respectively. The percentage of participants rating sleep quality as "very good" or "good" increased (BL to EOT) from 19.4% to 56.7% (IH) and from 15.6% to 70.0% (narcolepsy). The percentage of participants with "very well" or "well" or "somewhat" rested sleep increased

from 22.2% to 73.3% (IH) and from 46.9% to 90.0% (narcolepsy). BL FOSQ-10 mean (SE) scores were 11.8 (0.4) (IH) and 11.4 (0.5) (narcolepsy); mean (SE) changes (BL to EOT) were 3.3 (0.4) and 2.9 (0.5). BL WPAI:SHP mean (SE) percent impairments for IH and narcolepsy, respectively, were 59.8% (3.3%) and 61.3% (4.4%) for overall work and 67.5% (3.1%) and 56.2% (3.6%) for non–work-related activity; mean (SE) changes in percent impairment (BL to EOT) were –32.4% (4.6%) and –36.1% (4.6%) for overall work and –37.3% (4.7%) and –23.7% (4.6%) for non–work-related activity. Treatment-emergent adverse events were consistent with the known safety profile of LXB.

CONCLUSIONS: Participants with IH or narcolepsy treated with open-label LXB reported improvements in sleep quality and feeling more rested upon awakening. LXB treatment was associated with improvements in functional status, overall work productivity, and non–work-related activities.

SPONSORSHIP: Jazz Pharmaceuticals

78 Effectiveness and safety of greater than 9 gram dosage of low-sodium oxybate in participants with narcolepsy with or without concomitant use of alerting agents: A subgroup analysis from the DUET study

Simmons J[1], *Schneider L*[2], *Ruoff C*[3], *Plante D*[4], *Nichols D*[5], *Steininger T*[5], *Whalen M*[5], *Dai J*[5], *Cairns A*[5], *Beaty S*[5], *Bogan R*[6]; *jsimmonsmd@csma.clinic*
[1]*Comprehensive Sleep Medicine Associates*; [2]*Stanford University Center for Sleep Sciences and Medicine*; [3]*Mayo Clinic*; [4]*University of Wisconsin-Madison*; [5]*Jazz Pharmaceuticals*; [6]*University of South Carolina School of Medicine*

BACKGROUND: Low-sodium oxybate (LXB; Xywav®) is FDA approved to treat cataplexy or excessive daytime sleepiness in patients ≥7 years of age with narcolepsy and may be used alone or with alerting agents (AAs; stimulants/wake-promoting agents).

OBJECTIVE: To evaluate LXB effectiveness/safety among participants with narcolepsy taking 9g/night at study entry and optimizing up to 12g/night with or without concomitant AA use in the phase 4, open-label DUET (Develop hypersomnia Understanding by Evaluating low-sodium oxybate Treatment) study (NCT05875974).

METHODS: Participants underwent screening, 8-day assessment on LXB 9g/night ("9g"), 2- to 8-week gradual titration, 2-week stable-dose, 8-day end-of-treatment (EOT) on optimized LXB >9g/night (up to 12g), and 2-week safety follow-up periods. Outcomes (analyzed by with or without AA use) included Epworth Sleepiness Scale (ESS), Patient Global Impression of Severity (PGI-S) and Change (PGI-C), and Narcolepsy Severity Scale (NSS). Least squares mean (LSM) changes (comparing assessments at 9g vs EOT) were adjusted for values at 9g; P values are nominal.

RESULTS: Of 48 participants who enrolled and took >9g LXB, 28 (58.3%) were taking AAs. Most with/without AAs were female (60.7%/65.0%) and White (71.4%/85.0%), with a mean±SD age of 40.5±10.7/37.3±11.2 years. Mean±SD optimized total LXB dosage was 11.2±1.1 (with AAs, n=26) and 10.9±1.0 (without AAs, n=19) g/night. ESS scores improved from 9g to EOT—LSM changes (95% CI): with AAs −3.1 (−4.6, −1.6; P=0.0002; n=25), without AAs −3.0 (−4.7, −1.2; P=0.0014; n=19). In participants with and without AAs, 80.0% and 36.8%, respectively, endorsed moderately severe/severe/extremely severe overall disease on PGI-S on 9g, which decreased to 36.0% and 21.1% at EOT. On PGI-C, 95.8% with AAs and 86.7% without AAs reported minimally/much/very much improvement at EOT. NSS scores improved—LSM changes (95% CI): NSS-NT1, with AAs −5.4 (−8.6, −2.3; P=0.0015; n=15), without AAs −11.2 (−14.9, −7.6; P<0.0001; n=11); NSS-NT2, with AAs −6.0 (−8.7, −3.3; P=0.0004; n=10), without AAs −4.4 (−8.2, −0.5; P=0.0289; n=5). Treatment-emergent adverse events (TEAEs) were reported in 75.0% of participants in each group; most were mild or moderate and 1 (without AAs) was serious.

CONCLUSIONS: Participants with narcolepsy who optimized to LXB >9g/night reported improvements in overall disease and across multiple effectiveness outcomes relative to 9g/night, regardless of AA use. TEAEs across subgroups taking LXB >9g/night align with the safety profile at lower dosages.

SPONSORSHIP: Jazz Pharmaceuticals

79 Effectiveness and safety of low-sodium oxybate in participants with narcolepsy with or without concomitant use of alerting agents: A subgroup analysis of the DUET study

Meskill G[1], *Ruoff C*[2], *Nichols D*[3], *Steininger T*[3], *Dai J*[3], *Cairns A*[3], *Whalen M*[3], *Beaty S*[3], *Foldvary-Schaefer N*[4]; *gmeskillmd@tricoastalsleep.com*
[1]*Tricoastal Narcolepsy and Sleep Disorders Center*; [2]*Mayo Clinic*; [3]*Jazz Pharmaceuticals*; [4]*Cleveland Clinic Neurological Institute*

BACKGROUND: Low-sodium oxybate (LXB; Xywav®) is FDA approved to treat cataplexy or excessive daytime sleepiness (EDS) in patients aged ≥7 years with narcolepsy. LXB may be taken alone or with alerting agents (AAs; ie, stimulants/wake-promoting agents) to treat EDS.

OBJECTIVE: To evaluate LXB effectiveness/safety by concomitant AA use among participants with narcolepsy in the phase 4, open-label DUET (Develop hypersomnia Understanding

by Evaluating low-sodium oxybate Treatment) study (NCT05875974).

METHODS: DUET had screening, 8-day baseline (BL), 2–8-week LXB dose titration/optimization, 2-week stable-dose, 8-day end-of-treatment (EOT), and 2-week safety follow-up periods. Outcomes (analyzed by with or without AA use) included Epworth Sleepiness Scale (ESS), Patient Global Impression of Severity (PGI-S) and Change (PGI-C), and Narcolepsy Severity Scale (NSS). Least squares mean (LSM) changes from BL to EOT were BL adjusted; P values are nominal. Treatment-emergent adverse events (TEAEs) were assessed throughout.

RESULTS: Of 55 participants who enrolled and took LXB, 31 (56.4%) were taking AAs at BL. Most with/without AAs were female (64.5%/83.3%), White (80.6%/79.2%), with a mean±SD age of 34.1±11.9/32.6±14.2 years. Mean±SD optimized total LXB dosage was 6.9±1.8 (with AAs; n=21) and 7.3±1.3 (without AAs; n=15) g/night. ESS scores improved—LSM changes (95% CI): with AAs −6.3 (−8.7, −3.9; P< 0.0001; n=20), without AAs −9.6 (−12.5, −6.7; P<0.0001; n=14). Proportions reporting moderately severe/severe/extremely severe ratings on PGI-S decreased (BL to EOT) from 80.0% to 30.0% (with AAs; n=20) and 78.6% to 14.3% (without AAs, n=14) for overall disease, from 60.0% to 10.0% (with AAs) and 71.4% to 7.1% (without AAs) for sleep inertia, and from 65.0% to 30.0% (with AAs) and 78.6% to 14.3% (without AAs) for fatigue. On PGI-C, most participants with AAs (n=18)/without AAs (n=12) endorsed improved overall disease (88.9%/100.0%), sleep inertia (66.7%/83.3%), and fatigue (72.2%/83.3%). NSS scores improved—LSM changes (95% CI): NSS-NT1, with AAs −18.5 (−24.2, −12.7; P<0.0001; n=9), without AAs −21.6 (−28.7, −14.6; P<0.0001; n=6); NSS-NT2, with AAs −8.6 (−12.6, −4.5; P=0.0005; n=9), without AAs −14.7 (−19.3, −10.1; P<0.0001; n=7). TEAEs were reported in 54.8% (with AAs) and 70.8% (without AAs); most (with/without AAs) were mild (35.5%/25.0%) or moderate (19.4%/45.8%) and none were serious.

CONCLUSIONS: Participants with narcolepsy taking LXB had improved overall disease and symptom burden, with consistent benefit regardless of AA use.

SPONSORSHIP: Jazz Pharmaceuticals

80 Effectiveness and safety of low-sodium oxybate in participants with idiopathic hypersomnia with or without concomitant use of alerting agents: A subgroup analysis of the DUET study

Schneider L[1], *Nichols D*[2], *Steininger T*[2], *Dai J*[2], *Cairns A*[2], *Whalen M*[2], *Beaty S*[2], *Plante D*[3]; *logands@gmail.com*
[1]*Stanford University Center for Sleep Sciences and Medicine*; [2]*Jazz Pharmaceuticals*; [3]*University of Wisconsin-Madison*

BACKGROUND: Alerting agents (AAs; ie, stimulants/wake-promoting agents) are used off-label to manage excessive daytime sleepiness in idiopathic hypersomnia; however, residual symptoms may be experienced. Low-sodium oxybate (LXB; Xywav®) is the only FDA-approved medication for treatment of idiopathic hypersomnia in adults.

OBJECTIVE: To evaluate LXB effectiveness/safety by concomitant AA use in participants with idiopathic hypersomnia in the phase 4, open-label DUET (Develop hypersomnia Understanding by Evaluating low-sodium oxybate Treatment) study (NCT05875974).

METHODS: DUET included a screening, 8-day baseline (BL), 2–8-week LXB dose titration/optimization, 2-week stable-dose, 8-day end-of-treatment (EOT), and 2-week safety follow-up period. Outcomes (analyzed by with or without AA use) were Epworth Sleepiness Scale (ESS), Idiopathic Hypersomnia Severity Scale (IHSS), and Patient Global Impression of Severity (PGI-S) and Change (PGI-C). Least squares mean (LSM) changes (BL to EOT) were BL adjusted; P values are nominal. Treatment-emergent adverse events (TEAEs) were assessed.

RESULTS: Of 46 participants who enrolled and took LXB, 19 (41.3%) were taking AAs at BL. Most with/without AAs were female (84.2%/77.8%) and White (89.5%/81.5%), with a mean±SD age of 39.3±9.8/37.3±13.1 years. Mean±SD optimized total LXB dosage with/without AAs at stable dose was 4.0±1.4 g (n=4)/5.0±0.9 g (n=11) once nightly and 7.9±1.3 g (n=12)/7.5±1.2 g (n=14) twice nightly. ESS and IHSS scores improved from BL to EOT (all P< 0.0001)—LSM changes (95% CI) with/without AAs: ESS, −6.5 (−8.7, −4.3; n=15)/−9.5 (−11.2, −7.8; n=25); IHSS, −13.9 (−19.1, −8.8; n=13)/−16.4 (−20.3, −12.6; n=23). Proportions reporting moderately severe/severe/extremely severe on PGI-S decreased (BL to EOT) from 86.7% to 26.7% (with AAs; n=15) and 84.0% to 20.0% (without AAs; n=25) for overall disease, 73.3% to 13.3% (with AAs) and 52.0% to 20.0% (without AAs) for sleep inertia, and 86.7% to 13.3% (with AAs) and 88.0% to 20.0% (without AAs) for fatigue. On PGI-C, those with (n=14)/without (n=23) AAs endorsed improved overall disease (100.0%/91.3%), sleep inertia (85.7%/78.3%) and fatigue (92.9%/91.3%). TEAEs were reported in 57.9% (with AAs) and 85.2% (without AAs); most

(with/without AAs) were mild (36.8%/48.1%) or moderate (21.1%/37.0%) and 1 (without AA) was serious.

CONCLUSIONS: LXB was effective across all symptoms assessed, with or without AA use. All those taking AAs reported improved overall disease with LXB; thus, LXB had additional benefit for those taking AAs.

SPONSORSHIP: Jazz Pharmaceuticals

81 Real-world clinical, safety and patient-reported outcomes of treatment with lecanemab in a New England Alzheimer's disease center

Napoli S, O'Donnell R, Nassr L, Maize E;
snapoli@myneurodr.com
Alzheimer's Neurology and Infusion Centers of New England

BACKGROUND: Lecanemab has been shown to reduce a complex group of protein interactions associated with early Alzheimer's disease (AD) and slow decline on clinical endpoints of cognition and function for up to 48 months to date. Lecanemab was well tolerated in clinical trials, with common adverse events including amyloid-related imaging abnormalities (ARIA) and infusion reactions.

OBJECTIVE: To provide real-world experience with individuals with early AD who were treated with lecanemab in a retrospective study at our infusion center.

METHODS: Data collection included patient demographic characteristics, clinical history, lecanemab treatment exposure, and time from diagnosis to treatment. Assessments included Mini-Mental State Examination (MMSE), Montreal Cognitive Assessment (MoCA) Test for Dementia, and safety measures. Clinician perspectives from our real-world experience with lecanemab and patient survey feedback on subcutaneous lecanemab were collected.

RESULTS: Overall, 47 patients with early AD were included in the data analysis. Most of the patients were Caucasian (85%) and female (63%), with a mean age of 74 years. The most common diagnosis was mild AD (68%), and 66% of patients were ApoE4 carriers (51% heterozygotes; 15% homozygotes). Eight patients were initially on aducanumab and successfully transitioned to lecanemab. At 6 and 12 months, mean MMSE (baseline:23.8; 6-months:23.5; 12-months:23.4) and mean MoCA scores (baseline:18.7; 6-months:19.0; 12-months:18.2) were generally maintained or improved. The overall safety profile for lecanemab was similar to that observed in published clinical trials. One asymptomatic ARIA-E (2.2%) case, 2 asymptomatic ARIA-H (4.4%) cases, one symptomatic ARIA-E case (resolved), and 14 infusion-site reactions (31.1%) were observed. Of the survey responders, 93.5% (n=31, mean follow-up 298 days) reported feeling 'very satisfied' (20/31) or 'satisfied' (9/31) with lecanemab treatment and experiencing stabilization or slowing of disease progression on lecanemab.

CONCLUSIONS: Real-world evidence of lecanemab were consistent with published clinical trials, with no new safety signals and consistently positive patient-reported outcomes.

SPONSORSHIP: Eisai and Biogen

82 Lecanemab use in the real world: a multicenter case series review in patients with early Alzheimer's disease

Weisman D[1], *Rosenbloom M*[2], *Soria J*[3], *Cooper G*[4], *Giles S*[5], *Leahy C*[6], *Sadowski M*[7], *Schreiber C*[8], *Schulz P*[9], *Camargo C*[10], *Allen B*[11], *Frech F*[12], *Adams C*[13], *Jones D*[12], *Sabbagh M*[14];
greg.cooper@nortonhealthcare.org;
marwan.sabbagh@commonspirit.org
[1]*Abington Neurological Associates*; [2]*University of Washington*; [3]*The Neuron Clinic*; [4]*Norton Neuroscience Institute*; [5]*Memory Treatment Centers*; [6]*Memorial Healthcare Institute for Neuroscience*; [7]*Department of Neurology, NYU Langone Health, New York, NY, USA; Department of Psychiatry, NYU Langone Health, New York, NY, USA; Department of Biochemistry and Molecular Pharmacology, NYU Langone Health*; [8]*Missouri Memory Center, Citizens Memorial Hospital*; [9]*Neurocognitive Disorders Center, Department of Neurology, The McGovern Medical School of UTHealth-Houston*; [10]*Department of Neurology and Evelyn F. McKnight Brain Institute, University of Miami Miller School of Medicine*; [11]*Roaring Fork Neurology*; [12]*Eisai Inc.*; [13]*Eisai Inc*; [14]*Barrow Neurological Institute*

BACKGROUND: Lecanemab is indicated for the treatment of patients with early Alzheimer's disease (AD). While efficacy and safety were proven in clinical trials, real-world lecanemab data are important to understand its clinical outcomes beyond controlled trial settings.

OBJECTIVE: To assess lecanemab real-world utilization patterns and associated clinical outcomes in the United States.

METHODS: This ongoing multicenter, retrospective cohort and patient pathway study is being conducted in 15 geographically diverse neurology clinics, each abstracting deidentified medical chart data for up to 25 patients receiving lecanemab (≥7 infusions) and 1 neurologist per site completing an electronic survey plus an interview. Clinical characteristics, safety, and treatment outcomes of patients treated with lecanemab, including disease progression from baseline to last follow-up visit, were collected from medical charts. The surveys/interviews gathered perceived effectiveness and safety of lecanemab and pathway implementation learnings. Descriptive statistics were run for the overall study population collected through July 1, 2025 (interim cutoff, 9 sites).

RESULTS: A total of 178 patients were included. Mean age was 74 years, 55% female, 90% White, 5% Black and 15% Hispanic/Latino. A total of 81 (46%) patients were from urban areas, 46 (26%) rural, and 35 (20%) suburban. Approximately 58% and 42% had mild cognitive impairment and mild dementia due to AD, respectively. Most patients were APOE ϵ4 carriers (68%); 18% were homozygotes; 93% had no baseline microhemorrhages; 53% had baseline white matter hyperintensities. Blood-based biomarkers supported diagnosis in 28% of cases. After an average of 20 lecanemab doses, an estimated 77% of patients remained in the baseline AD stage and 7% improved. Overall, 23 (13%) patients had an ARIA event (14 [8%] ARIA-E; 11 [6%] ARIA-H [2 patients had concurrent ARIA-E/ARIA-H]). Eight patients discontinued due to adverse events; of these, 5 were related to ARIA. Survey data indicates favorable views of lecanemab, a growing trend in BBM use and consistent application of diagnostic and treatment protocols across the patient pathway.

CONCLUSIONS: These findings underscore the benefits and safety profile of lecanemab in real-world clinical settings. Most patients did not progress to the next disease stage during the one-year follow-up period (interim data). ARIA rates in this multicenter real-world study were consistent with approved labelling, occurring with numerically lower frequency than that observed in Clarity AD.

SPONSORSHIP: Eisai and Biogen

83 Retrospective analysis of costs of amyloid diagnostic tests for Alzheimer's disease from a health-system perspective

Nair K[1], *Frech F*[2], *Adams C*[3], *Schott L*[4], *Sunday I*[5], *Jones D*[2], *Mattke S*[6]; *kavita.nair@cuanschutz.edu*; *feride_frech@eisai.com*
[1]*Department of Neurology, University of Colorado Anschutz Medical Campus, Department of Clinical Pharmacy, Skaggs School of Pharmacy & Pharmaceutical Sciences, University of Colorado, Aurora, CO*; [2]*Eisai Inc.*; [3]*Eisai Inc*; [4]*Premier Applied Sciences, Premier Inc*; [5]*Premier Applied Sciences, Premier Inc.*; [6]*The USC Brain Health Observatory, University of Southern California, Los Angeles*

BACKGROUND: Alzheimer's disease (AD) is characterized by beta-amyloid and tau build-up in the brain (outside and inside neurons, respectively), causing neurodegeneration. Beta-amyloid testing can be done via cerebrospinal fluid (CSF), amyloid positron emission tomography (PET) brain scans, and, more recently, via highly sensitive blood-based biomarker (BBM) tests. As diagnostic testing becomes more widespread, understanding cost implications is critical for optimizing resource allocation and access.

OBJECTIVE: To estimate direct costs of conducting such tests from the perspective of US hospitals/health systems.

METHODS: This retrospective cohort study used the Premier Healthcare Database containing standard hospital discharge files for >1.4 billion patient encounters from across >1,400 U.S. facilities. Patients who received care from 1 Jan 2023 to 31 Mar 2025, were aged ≥55 years, and had an inpatient/outpatient encounter for a diagnostic (PET, CSF or BBM) for AD were considered. Procedure costs included hospital billed services, such as lab tests, supplies, and diagnostic services, and were stratified by site of care (inpatient/outpatient). PET and CSF costs were compared to 2025 Medicare rates (not currently available for BBMs). Descriptive statistics were conducted.

RESULTS: A total of 4823 unique patients (2514 PET, 1233 CSF and 1182 BBM) received amyloid diagnostic procedures. Mean age was 73 (standard deviation, SD=7.6), 53.7% female, 84.5% White, and 6.7% Hispanic. Most procedures were in patients ≥65 years old (85.3%), outpatient (92.6%), in teaching facilities (65.0%), and in urban areas (90.9%). The overall median cost (mean±SD) for CSF was $439 ($429± 309); BBMs $140 ($179±122); PET $2637 ($2344±1,299); inpatient and outpatient costs were similar. Medicare reimbursement for PET ($4880) was significantly higher than cost and similar for CSF ($433). PET utilization increased by >400% post-Medicare policy changes (330 in 2023, 1571 in 2024); BBM utilization tripled (313 in 2023, 949 in 2024). CSF utilization remained stable during the study period.

CONCLUSIONS: Amyloid BBMs are increasingly used at a fraction of the cost of PET and CSF and are also a less invasive, more scalable option. Guidelines for minimum acceptable performance of BBM tests for AD diagnosis should be considered in selecting appropriate options. Further research should assess clinical utility and cost-effectiveness to inform payer and provider decisions.

SPONSORSHIP: Eisai Inc and Biogen

84 AXS-12 for the treatment of narcolepsy: Topline results from the phase 3 SYMPHONY trial

Thorpy M[1], *Krahn L*[2], *Bogan R*[3], *Corser B*[4], *Shapiro C*[5], *Chhabra A*[6], *Leary E*[7], *DePue R*[8], *Tabuteau H*[8]; *michael.thorpy@einsteinmed.edu*; *rdepue@axsome.com*
[1]*Albert Einstein College of Medicine*; [2]*Mayo Clinic College of Medicine and Science*; [3]*University of South Carolina School of Medicine*; [4]*Intrepid Research*; [5]*University of Toronto*; [6]*Axsome Therapeutics, Inc*; [7]*Formerly of Axsome Therapeutics, Inc*; [8]*Axsome Therapeutics Inc., New York*, NY, USA

BACKGROUND: Narcolepsy is characterized by excessive daytime sleepiness (EDS), cataplexy (narcolepsy type 1 [NT1]), and accompanied by cognitive impairment. AXS-12 (reboxetine), a potent, highly-selective norepinephrine reuptake inhibitor and cortical dopamine modulator, is under development for narcolepsy.

OBJECTIVE: To evaluate the safety and efficacy of AXS-12 in patients with NT1 in SYMPHONY, a Phase 3, randomized, double-blind, placebo-controlled trial.

METHODS: Patients (15-75 years) with NT1 were randomized 1:1 to AXS-12 or placebo for 5 weeks. Stable concurrent modafinil/armodafinil use was allowed. The primary endpoint was the ratio of weekly cataplexy attacks (Week 5/Baseline). Secondary endpoints included EDS (Clinical Global Impression-Severity [CGI-S]), inadvertent naps (Narcolepsy Symptom Assessment Questionnaire [NSAQ]), and Cognitive Function items of the Functional Outcomes of Sleep Questionnaire-10.

RESULTS: Ninety patients were randomized; 32.6% (AXS-12) and 29.5% (placebo) took concurrent modafinil/armodafinil. Baseline mean weekly cataplexy attacks were 27.7 (AXS-12) and 35.4 (placebo). AXS-12 reduced attacks by 83% vs 66% with placebo at Week 5 (rate ratio=0.49; p=0.018). At Week 1, reductions were 56% (AXS-12) vs 31% (rate ratio=0.65; nominal p=0.007). Cataplexy remission occurred in 33% (AXS-12) vs 9.5% (placebo) (nominal p=0.008) at Week 5. Mean percentages of cataplexy-free days at Week 5 were 84.5% (AXS-12) vs 22.6% (placebo) (nominal p=0.014). Changes in CGI-S for EDS at Week 5 were -1.8 (AXS-12) vs -0.9 (placebo) (nominal p=0.027). Patients reporting fewer inadvertent naps (NSAQ) were 54% (AXS-12) vs 28% (placebo) (nominal p=0.016). AXS-12 led to greater improvements in concentration and memory (1.6 vs 0.7 points, nominal p=0.004). AXS-12 was well-tolerated with no new safety signals or serious adverse events; common TEAEs included dry mouth (n=6), nausea (n=6), and constipation (n=4), all mild/moderate.

CONCLUSIONS: AXS-12 met its primary endpoint, leading to a substantial, statistically significant reduction in weekly cataplexy attacks. Improvements in EDS and cognition were also observed, suggesting AXS-12 may offer effective treatment for multiple narcolepsy symptoms with a favorable safety profile.

SPONSORSHIP: Axsome Therapeutics, Inc.

Clinical Programs

89 Zeleciment basivarsen targets the underlying cause of myotonic dystrophy type 1 (DM1) to enable functional improvement in the phase 1/2 ACHIEVE trial

Danese D[1], *Bassez G*[2], *Diaz-Manera J*[3], *Lilleker J*[4], *Mul K*[5], *Pane M*[6], *Roxburgh R*[7], *Schoser B*[8], *Turner C*[9], *Andersson S*[1], *Ray S*[1], *Chen H*[10], *Kerr D*[1], *Sansone V*[11]; *Dave.Danese@dyne-tx.com*; *valeria.sansone@centrocliniconemo.it*
[1]*Dyne Therapeutics*; [2]*Institute of Myology*; [3]*Newcastle University*; [4]*Northern Care Alliance NHS Foundation Trust*; [5]*Radboud University Medical Center*; [6]*Agostino Gemelli University Policlinic*; [7]*University of Auckland*; [8]*Friedrich-Baur-Institut LMU München*; [9]*UCLH*; [10]*Dyne*; [11]*Neurorehabilitation Unit, The NeMO Clinical Center*

BACKGROUND: DM1 is a rare genetic neuromuscular disorder caused by mutations in the DMPK gene, leading to disruption of normal RNA splicing, or spliceopathy. Spliceopathy results in a wide range of symptoms, including myotonia (delayed muscle relaxation after contraction), muscle weakness, fatigue, cardiac and respiratory issues, excessive daytime sleepiness, and cognitive symptoms, which drive functional impairment. Individuals with DM1 have 137% higher annual healthcare costs and a 53% higher hospitalization rate than those without DM1, and 46% are unable to work. There is currently no approved disease-modifying treatment for DM1. Zeleciment basivarsen (z-basivarsen, also known as DYNE-101) is an investigational therapeutic designed to target mutant nuclear DMPK RNA in both muscle and CNS to correct splicing with the goal of enabling functional improvement in DM1.

OBJECTIVE: Determine the safety and efficacy of z-basivarsen in adults with DM1 in the Phase 1/2 ACHIEVE trial (NCT05481879).

METHODS: In the completed 24-week placebo-controlled Multiple Ascending Dose (MAD) portion of ACHIEVE, 56 participants received one of 5 intravenous dose regimens of z-basivarsen or placebo. Thereafter, eligible participants subsequently entered the long-term extension, in which all received z-basivarsen 6.8 mg/kg Q8W (dose selected for registrational cohort).

RESULTS: In six participants who received 6.8 mg/kg Q8W z-basivarsen in the MAD portion, substantial knockdown of

DMPK RNA levels and improvement in splicing were noted as early as 3 months. Improvement from baseline in myotonia and in multiple measures of muscle strength and function was sustained through 12 months and these data were accompanied by improvement in patient-reported outcomes (PROs), including in the Myotonic Dystrophy Health Index (MDHI) total score and individual MDHI subscales assessing the impact of DM1 on physical movement, daily functioning, and CNS symptoms. Improvement from baseline on clinician-reported global impression of change scales was reported by 83% of patients at 12 months. As of April 23, 2025, z-basivarsen has demonstrated a favorable safety profile, with no serious related TEAEs.

CONCLUSIONS: These data suggest that z-basivarsen has a favorable safety profile and showed functional improvement across several clinical measures, including myotonia, muscle strength and function, further contextualized by improvement in PROs. These functional improvements, if confirmed, may lessen the considerable clinical impact and economic burden of DM1.

SPONSORSHIP: Dyne Therapeutics

90 Impact of a pharmacist-led academic detailing program: Results from clinician and detailer surveys

Caballes N, Dave S, Purathur S, Hudak B; ncabal2@uic.edu; sashah2@uic.edu; spurat2@uic.edu
University of Illinois Chicago Retzky College of Pharmacy

BACKGROUND: Academic detailing (AD) entails 1:1 interactive education to clinicians. Utilizing evidence-based information, clinicians learn about the latest recommendations to guide clinical decision-making, improve prescribing behaviors, and enhance patient care. Providing clinician education to improve medication outcomes is a core tenant for managed care pharmacy. Illinois ADVANCE (ILA) is a pharmacist-led AD program that provides clinical education throughout the state of Illinois. ILA had several educational campaigns in 2024, including opioid use disorder, asthma, and diabetes. For quality improvement purposes and to determine the effectiveness of AD, ILA utilized two validated survey instruments, the Provider Satisfaction with AD (PSAD) and the Detailer Assessment of Visit Effectiveness (DAVE).

OBJECTIVE: To assess the impact of ILA AD services on detailer effectiveness and clinician learner satisfaction.

METHODS: Survey data was collected Jan to Dec 2024 in the Qualtrics platform. After each AD visit, in which several topics could be discussed, detailers completed the DAVE as part of their post-visit duties and shared the PSAD with clinician learners as an optional questionnaire to provide feedback for program improvement. PSAD and DAVE items are scored on a Likert-type scale from 1 (not at all) to 5 (extremely).

RESULTS: In 2024, ILA completed 4489 visits on 19 topics. A total of 350 PSAD questionnaires (7.8% response rate) were completed by 233 unique clinician learners. The average rating for overall satisfaction was 4.64 and likelihood to change practice 4.25. For the DAVE, a total of 1659 questionnaires were completed for 936 unique learners. The average rating for likelihood to change practice was 4.24, feasibility was 4.27, and communication was 4.53.

CONCLUSIONS: This poster evaluates the impact of AD with ILA using the PSAD and DAVE. Clinicians rated high satisfaction and likelihood to change practice based on visits. Detailer ratings were in alignment. The results highlight AD's role in providing impactful, evidence-based education.

SPONSORSHIP: None

91 Evaluating case management referral patterns: Insights from an enhanced utilization management program

Ventura E, Divona E, MacDonald B, Watson A, Calvet M, Makanji H; erin.ventura@primetherapeutics.com; emily.divona@primetherapeutics.com
Prime Therapeutics

BACKGROUND: Drug spend surpassed $435B in 2023, with specialty drug spend accounting for over half. On the medical benefit alone, there are over 150 therapies on the market with annual costs over $300,000. These high-cost therapies (HCTs) are often used for complex or rare conditions and require specialized management. Case management (CM) services have demonstrated the ability to significantly impact quality of life and health outcomes for patients, as well. Prime Therapeutics implemented an enhanced utilization management (UM) program for HCTs that incorporates a CM referral process that is initiated after determination when certain patient needs are noted to ensure the best outcomes for patients.

OBJECTIVE: To evaluate CM referral patterns for HCTs to identify patient populations and disease states that may benefit from increased CM support.

METHODS: A retrospective review of an HCT program across nine health plans (~9.2M total lives) was conducted. Data was collected from prospective prior authorization reviews completed for 97 drugs across both Commercial and Medicaid lines of business from 1/1/25 to 6/30/25. CM referrals were based on pharmacist reviews of clinical notes provided during the UM process, identifying triggers such as recent hospitalization, medication-related issues or other clinical concerns.

RESULTS: Of 933 reviews from 1/1/2025 to 6/30/2025, 6.65% (n=62) were referred to CM, with a median of 6.98% (range 0% to 20%). At a drug level, Gamifant (n=4/6, 67%), Haegarda (n=2/5, 40%), Tecartus (n=1/3, 33%), Vimizim (n=1/3, 33%), Kymriah (n=1/4, 25%) and Tivdak (n=2/9, 22%) were the drugs with the highest percentages of CM referrals relative to requests received for each drug. A higher percentage of denied requests were referred for CM compared to approvals, 9.8% (n=13/133) vs. 6.5% (n=49/749), respectively. Referrals due to inpatient admissions or emergency department (ED) visits were the most frequent CM trigger identified (n=47/62, 76%).

CONCLUSIONS: Implementation of an enhanced UM program led to varying rates of CM referrals across drug categories. Therapies with the highest CM referral rates were linked to complex conditions with frequent hospitalizations and clinical concerns, highlighting the need for targeted CM. These patient populations experienced hospitalizations and ED visits, medication-related complications and clinical concerns, suggesting they may achieve the greatest benefit from CM intervention. While these findings offer important insights, further research is warranted to better understand evolving referral patterns and long-term impact of CM interventions.

SPONSORSHIP: Prime Therapeutics

92 Reducing pharmacy costs associated with the proton pump inhibitor (PPI) and belumosudil (BEL) drug interaction through a managed care pharmacist (MCP)-to-prescriber telephonic outreach program

Friedlander N[1], *Gleason P*[1], *O'Shea T*[2];
nicholas.friedlander@primetherapeutics.com
[1]*Prime Therapeutics*; [2]*Horizon BCBS*

BACKGROUND: To address costly drug interactions, we developed targeted interaction identification logic and integrated this into an MCP-to-prescriber clinical intervention program. The interaction between PPIs and BEL, which requires doubling of dose when used with a PPI, was used as a case example to demonstrate financial value. For identified cases, MCPs outreached to providers recommending PPI discontinuation/therapeutic substitution with simultaneous halving of the BEL dose.

OBJECTIVE: To describe the BEL-PPI drug interaction opportunity identification logic. Quantify number of interventions, outcomes, and drug cost savings from BEL-PPI interaction MCP-to-provider interventions.

METHODS: Pharmacy claims from 13.7 million commercially insured members enrolled in the MCP outreach program, from Feb 2025 to Oct 2025 (9 months), were analyzed weekly using targeted drug interaction identification logic. Logic assessed claims at a member level over the preceding 6 months for the presence of paid claims for high dose BEL based on billed quantity and days supply, identifying cases whose most recent claim is consistent with PPI interaction dosing. Cases were provided to MCPs via an integrated web tool; case details provided to MCPs included enrollment and claims data and estimated intervention drug cost savings. Case savings were calculated by subtracting annualized post-intervention therapy drug cost from pre-intervention annualized therapy drug cost.

RESULTS: 58 cases (4 per million members) of recent high-dose BEL and PPI utilization were identified across the enrolled commercial population during the study period. MCP-to-prescriber interventions were attempted for 36 cases, 9 (25%) resulted in successful conversion to standard-dose BEL, resulting in total annualized BEL drug cost savings of $1,899,617 ($211,069 per case); 4 (11%) of these cases are in progress at the time of abstract submission with $873,840 in estimated annualized savings. Interventions were unsuccessful for 23 (64%) cases, mainly due to provider rejection of MCP recommendation (19 of 23, 83%). 20 cases were closed by MCPs without outreach for a variety of reasons (e.g., BEL discontinuation, clear clinical need for PPI). 2 cases are pending MCP review at time of submission.

CONCLUSIONS: MCP-to-provider outreach is an effective means of addressing the rare but costly interaction between PPIs and BEL. Over a 9 month period, MCPs successfully addressed 9 of 58 identified (16%) drug interaction cases, discontinuing PPI and halving the dose of BEL, generating total annualized savings of $1.90 million ($0.015 per member per month).

SPONSORSHIP: Prime Therapeutics

Dermatology

107 The budget impact of introducing a new aryl hydrocarbon receptor agonist, tapinarof, for treatment of atopic dermatitis in adults and pediatric patients from the US commercial plan perspective

Goto D[1], *Dupclay L*[1], *Tangirala K*[1], *Proudman D*[2], *Samandur A*[2], *Seal B*[1], *Chima K*[3]; *daisuke.goto1@organon.com*
[1]*Organon*; [2]*Analysis Group, Inc.*; [3]*Schweiger Dermatology Group*

BACKGROUND: Tapinarof is an aryl hydrocarbon receptor agonist indicated for the topical treatment of atopic dermatitis (AD) in adults and pediatric patients 2 years of age and older. This first-in-class treatment provides a new option for patients with all severity levels of AD.

OBJECTIVE: To estimate the budget impact of introducing tapinarof to a US commercial plan for the treatment of AD for pediatric and adult patients, and the financial value of treatment-free periods that tapinarof offers to certain patients.

METHODS: A budget impact model with a 2-year time horizon was developed to compare formulary budgets with and without tapinarof. Pediatric (<18 years old) and adult AD patients were both categorized into new or chronic patients. Published annual incidence and prevalence of AD, and age-based population estimates from the US Census were used to calculate the size of each demographic group. For each group, annual AD treatment utilization per patient was estimated from Merative MarketScan data. Comparator treatments included topical therapies such as corticosteroids, macrolide immunosuppressants, and JAK and PDE4 inhibitors, as well as oral and subcutaneously administered systemic therapies, such as IL-13 inhibitors. 2025 drug prices came from Merative Micromedex RED BOOK. Year 2 tapinarof market share was assumed to be 1.0%, taken from all comparator treatments, with a gradual uptake over 2 years. Cost savings for tapinarof patients were separately estimated based on avoided use of existing treatments during treatment-free periods, as observed in the ADORING-3 clinical trial, where 51.9% of tapinarof patients experienced an average treatment-free period of 80 days.

RESULTS: In a hypothetical 1-million-member commercial plan, the model estimated that 14,331 chronic adult, 9,780 chronic pediatric, 5,309 new adult, and 3,623 new pediatric patients would receive AD treatment in a typical year, totaling 33,042 patients, with 331 receiving tapinarof in year 2. The introduction of tapinarof was associated with a net budget impact of $0.021 in year 1 and $0.036 in year 2 per member per month (PMPM). Deterministic sensitivity analysis varying key inputs confirmed the robustness of these results. The financial value of the 80-day treatment-free period was $0.012 PMPM in year 1 and $0.021 PMPM in year 2.

CONCLUSIONS: Introducing tapinarof for AD treatment is associated with a minimal budget impact. Treatment-free periods provide measurable value by reducing the treatment cost to zero for an extended period of time for more than half of patients.

SPONSORSHIP: Organon

108 Real-world insights into first-line use of topical roflumilast cream for psoriasis

Chovatiya R[1], *Soung J*[2], *Jaworski J*[3], *Seal M*[3], *Hanna D*[3], *Stephenson B*[3]; *raj.chovatiya@gmail.com*; *bstephenson@arcutis.com*
[1]*Chicago Medical School, Rosalind Franklin University of Medicine and Science, North Chicago, IL, and Center for Medical Dermatology + Immunology Research, Chicago, IL*; [2]*Southern California Dermatology, Santa Ana, CA*; [3]*Arcutis Biotherapeutics, Inc. Westlake Village, CA*

BACKGROUND: Roflumilast cream 0.3% was approved for the treatment of plaque psoriasis in patients aged ≥12 years in July 2022 and for patients aged 6-11 years in October 2023.

OBJECTIVE: To understand treatment patterns among patients who filled a roflumilast cream prescription for plaque psoriasis.

METHODS: A retrospective administrative claims analysis of the IQVIA PharMetrics Plus database (2021–2024) was conducted to evaluate treatment patterns among patients initiating roflumilast cream 0.3% for plaque psoriasis. The index date was defined as the first claim for roflumilast cream 0.3%, with 6-month pre- and post-index periods to assess prior, subsequent, and/or concomitant therapies.

RESULTS: 1213 patients had a claim for roflumilast cream 0.3%, most (69%) treated with roflumilast monotherapy; 2 (<1%) initiated roflumilast cream in combination with a biologic agent. 303 patients (25%) had no psoriasis treatment in the 6-month pre-index period. Of these treatment-naive patients, 259 (83%) initiated topical roflumilast monotherapy. Among 44 patients who initiated roflumilast cream in a combination regimen, 39 (89.6%) used another topical agent, 2 (4.5%) an oral phosphodiesterase 4 inhibitor (PDE4), and 2 (4.5%) a biologic agent. Within the 6-month post-index period, 14/303 (4.6%) treatment-naive patients initiated a biologic agent.

CONCLUSIONS: In this real-world analysis, a substantial portion of patients used roflumilast cream 0.3% as first-line therapy for plaque psoriasis, the majority as monotherapy.

Most treatment-naive patients who initiated topical roflumilast as monotherapy did not initiate a subsequent treatment during the 6-month follow-up period, and only a small portion escalated to biologic therapy or an oral PDE4 inhibitor. Among patients who initiated roflumilast cream, <1% (2/303) did so in combination with a biologic agent. These findings suggest that roflumilast cream 0.3% is frequently utilized as a monotherapy and an initial treatment option, suggesting topical roflumilast may help delay or reduce the need for oral and biologic therapy in routine clinical practice.

SPONSORSHIP: Arcutis Biotherapeutics, Inc.

Digital Health and Technology

111 Enhancing payer engagement through digital dossiers: An interactive formulary decision-making asset complementing traditional PDF formats

Shah G, Kazeem T, Steinzaig B, Rai R, Hu A; Gshah12@its.jnj.com
Johnson & Johnson Innovative Medicine Scientific Affairs

BACKGROUND: AMCP dossiers are evidence documents used by healthcare decision makers (HCDMs) to evaluate the clinical, economic, and real-world value of therapies. Traditionally delivered as static PDFs, these documents—often exceeding hundreds of pages—can be time-intensive to navigate. There is a growing demand for interactive, user-centric digital content that improves accessibility and speed of information retrieval. In response to this, the Johnson & Johnson (J&J) Innovative Medicine Scientific Affairs Medical Information (MI) team developed digital, interactive, modular dossiers that maintain AMCP Format 5.0 standards while improving content clarity and engagement.

OBJECTIVE: To assess the impact of complementing static PDF AMCP dossiers with digital dossier format by (1) comparing usage/engagement metrics, (2) evaluating payer preferences and feedback, and (3) identifying opportunities to inform future digital dossier creation and updates.

METHODS: A retrospective analysis compared dossier engagement metrics between static PDF and digital AMCP dossiers from January to September 2025. Key metrics examined were the number of sessions, user counts, and highest areas of interest for digital dossiers. Findings were analyzed by the MI team to identify optimization opportunities while maintaining adherence to AMCP Format 5.0 standards.

RESULTS: Digital dossiers demonstrated higher engagement than static PDFs, with increases in session and user counts. Digital dossiers received higher session counts than static PDF dossiers across three therapeutic areas, with mean increases of 118% in Oncology (range: 42%–409%), 135% in Immunology (range: 73%–154%), and Neuroscience by 115%. The highest areas of interest within the digital dossier were the interactive evidence tables, clinical presentation, and epidemiology sections across therapeutic areas. Incorporating these insights during digital dossier creation allows for enhanced comprehension of the product value proposition.

CONCLUSIONS: Digital dossiers are visual, interactive, and dynamic assets that complement static PDF AMCP dossiers which allow customers to quickly and easily find the information most relevant to them. Supplementing static PDF AMCP dossiers with digital dossiers accessible 24/7 via J&J Medical Connect modernizes evidence delivery and improves payer engagement. These findings underscore the value of stakeholder-driven innovation in advancing digital, interactive scientific content to support formulary decision-making.

SPONSORSHIP: Johnson & Johnson Innovative Medicine Scientific Affairs

Drug Pricing, Payment, and Reimbursement

119 A 5-year actuarial impact of employer coverage of semaglutide for patients with obesity

Luo R[1], Olivares Martínez A[2], Faurby M[1], Leier J[3], Stokes N[3], Warren G[3]; RGVL@novonordisk.com; greg.warren@axenehp.com
[1]*Novo Nordisk, Inc.*; [2]*Novo Nordisk Inc.*; [3]*Axene Health Partners, LLC*

BACKGROUND: Obesity is associated with multiple comorbidities (eg, type 2 diabetes, cardiovascular disease, and metabolic dysfunction–associated steatohepatitis) that increase healthcare costs and reduce productivity. These burdens translate into higher employer expenditures through absenteeism and reduced performance. Semaglutide 2.4 mg (SEMA) is a glucagon-like peptide-1 receptor agonist approved for treatment of overweight and obesity. The actuarial impact of SEMA treatment coverage on payer, employer, and societal costs remains underexplored.

OBJECTIVE: To estimate the 5-year actuarial impact of SEMA coverage for obesity treatment on employer, health plans, and patient costs.

METHODS: An Excel-based actuarial model simulated 1 million covered lives to project 5-year actuarial impact of covering SEMA for people with obesity from the perspective of multiple stakeholders. Data from the MarketScan database were

analyzed to quantify the association between comorbidities and healthcare costs. Relationships between body mass index (BMI) and healthcare cost savings, productivity, and societal-costs were informed by published literature. Efficacy inputs were obtained from clinical trials, and real-world utilization data from Komodo Health informed prescription estimates. The base case assumed a 10% treatment rate for eligible members, drug cost of $1,349 per fill with a 63% rebate and 7 annual prescription fills. Eligibility was defined as BMI ≥30 or BMI ≥25, with at least one weight-related comorbidity. Outputs were incremental per-member-per-month (PMPM) costs and return on investment (ROI) by stakeholder.

RESULTS: Among 1 million simulated lives (38% commercial self-funded, 22% commercial fully insured, 16% Medicare, and 24% Medicaid), 49% were eligible for obesity treatment. Employer coverage of SEMA resulted in net savings of $2.35 PMPM and a 1.4:1.0 ROI. Health plans realized net savings of $2.95 PMPM, pharmacy benefit managers $0.67 PMPM, society $0.51 PMPM, and government payers $0.41 PMPM. Providers and patients experienced cost increases of $1.04 and $8.58 PMPM, respectively. Total system costs decreased 2.73$ PMPM, corresponding to an ROI of 0.9:1.0. Reduction in obesity-related comorbidity costs were the primary driver of savings. Key sensitivity factors were rebate level, adherence, and annual prescription rate.

CONCLUSIONS: Coverage of semaglutide 2.4 mg for obesity generated employer and payer savings while improving overall system efficiency through lower comorbidity-related costs, thereby supporting the value of obesity pharmacotherapy within managed-care populations.

SPONSORSHIP: Novo Nordisk Inc., Plainsboro, NJ

120 Budget impact of belumosudil for third-line or later treatment of chronic graft-versus-host disease in the United States

Berenson K[1], *Revel A*[2], *Desai K*[2], *Lebovics G*[1], *Preblick R*[2]; *karinaberenson@emaxhealth.net*; *garylebovics@emaxhealth.net*
[1]*eMAX Health*; [2]*Sanofi*

BACKGROUND: Chronic graft-versus-host disease (cGVHD) is a common and potentially life-threatening complication following allogeneic hematopoietic stem cell transplantation.

OBJECTIVE: To assess the 3-year budget impact of adding belumosudil to formulary for treating cGVHD patients who have failed two prior lines of systemic therapies, from a US commercial payer perspective.

METHODS: An Excel-based model was constructed using a hypothetical cohort of 10 million US commercial health plan enrollees. Estimates for cGVHD prevalence were derived from published literature in those aged 12 years and older. Comparators included standard of care (SOC) treatments such as steroids and extracorporeal photopheresis (ECP) in addition to FDA-approved agents, including ruxolitinib and ibrutinib. Products introduced since 2024 were not included in this analysis. Based on literature review and publicly available databases, the model inputs included grade 3–4 adverse event (AE) rates and associated costs, cost offsets from steroid discontinuation and avoided complication costs, and drug acquisition costs. AE costs were weighted averages of inpatient and outpatient costs by assumed proportions. Belumosudil twice daily dosing regimen was modeled as 30%. Budget impact was calculated as cost per member per month (PMPM) and total cost. One-way sensitivity analysis identified key cost drivers across input parameter ranges.

RESULTS: Over the 3-year time horizon, there were 438 patients with cGVHD and of these, 236 patients (166 3L, 70 4L+) were eligible for third-line or later treatment in the hypothetical 10-million-member health plan. Adding belumosudil to formulary resulted in a total budget increase of $1,492,488 (0.8% higher cost). The PMPM cost with belumosudil was $1.46 compared to $1.45 without belumosudil, resulting in a PMPM cost increase of $0.01. Sensitivity analysis revealed that belumosudil and ruxolitinib acquisition costs, ECP costs, market share of belumosudil, and belumosudil twice-daily dosing frequency had the greatest impact on results.

CONCLUSIONS: Adoption of belumosudil as a third-line or later treatment for cGVHD demonstrates negligible budget impact from a US commercial health plan perspective.

SPONSORSHIP: Sanofi

121 Changes in patient out-of-pocket (OOP) costs and medication use following West Virginia's rebate pass through legislation

Doherty B[1], *Chang H*[2], *Neumann U*[3]; *bdohert1@its.jnj.com*; *hchang25@its.jnj.com*
[1]*Johnson & Johnson*; [2]*J&J Innovative Medicine*; [3]*J&J Center for Healthcare Policy Research*

BACKGROUND: West Virginia House Bill 2263, passed in 2021, required Pharmacy Benefit Managers (PBMs) to pass through rebates and discounts received from manufacturers directly to patients at the pharmacy point of sale, rather than be retained by the PBMs.

OBJECTIVE: Research is needed to evaluate the extent of the law's implementation and its potential impact on patients. The study aims to examine the short-term changes following the legislation with respect to patient OOP costs and medication use.

METHODS: This retrospective cohort study employs a difference-in-differences design using the Merative™ MarketScan® Commercial Database. Because of implementation guidance, 2021 pre and 2023 post data were used to assess annual outcomes, including OOP expenses and medication use. Baseline characteristics were constructed from 2020 data for propensity score weighting. The study included adult patients aged 18 to 64 with continuous residency and enrollment and used generalized estimating equations model (GEE) to control for patient-level correlated observations. 13,565 West Virginia (WV) residents were the exposure group, with 84,343 Kentucky (KY) residents serving as the control group given similar policy environments, population characteristics, and geographic proximity.

RESULTS: WV residents in this study experienced a statistically significant average per-person reduction of $33 in annual pharmacy OOP relative to KY residents. WV residents also saw a statistically significant increase in the average number of prescriptions filled (.45) and average days of medication supply relative (39) to KY residents. Among high baseline utilizers in WV and KY (defined as 15+ prescriptions in 2020), WV residents experienced $95 less in average annual pharmacy OOP and 85 days more in average days of supply versus Kentucky residents. When comparing 2021-2023 changes descriptively across all states, WV also had a lower increase in OOP and the biggest increase in days of supply in the US.

CONCLUSIONS: Preliminary findings in this study suggest that the first-of-its-kind legislation was linked to relatively lower OOP costs and increased prescriptions and days of supply for WV residents, particularly among high utilizers who may face greater challenges with OOP costs. Results should be interpreted descriptively, recognizing that strict causal inference assumptions could not be fully satisfied in real-world policy settings comparing the two states. Future analysis may explore using additional approaches and continued evaluation of patient impact and implementation effectiveness.

SPONSORSHIP: Johnson & Johnson Innovative Medicine

122 Costs of first-line treatment of chronic lymphocytic leukemia/small lymphocytic lymphoma with Bruton tyrosine kinase inhibitors and simulation of the impact of the Inflation Reduction Act

Srivastava B[1], *Emond B*[2], *Bacchus S*[1], *Davis A*[1], *Maitland J*[3], *Franceschini E*[1], *Hore E*[2], *Wong G*[2], *Zhu S*[2], *Sail K*[1]; *bhavini.srivastava@abbvie.com*
[1]*AbbVie, Inc.*; [2]*Analysis Group, Inc.*; [3]*Analysis Group, Toronto, ON, Canada*

BACKGROUND: Bruton tyrosine kinase inhibitors (BTKis) are standard of care for first-line (1L) treatment of chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL). Per the Inflation Reduction Act (IRA) Drug Price Negotiations (DPN), ibrutinib (Ibr) became the first BTKi with a negotiated maximum fair price (MFP) in Initial Price Applicability Year (IPAY) 2026. Estimating the potential IRA pricing impact on total cost of care for patients (pts) treated with BTKis is critical to inform payer decision making.

OBJECTIVE: To compare total healthcare costs for pts with CLL/SLL receiving 1L Ibr vs other covalent BTKis (acalabrutinib or zanubrutinib) post IRA price reduction and MFP effectuation for Ibr.

METHODS: This retrospective cohort study used Optum Clinformatics™ Data Mart (01/01/12–12/31/24) to identify adults with CLL/SLL initiating 1L monotherapy with Ibr or other BTKis. Costs (2024 USD) were assessed from index (start of 1L after acalabrutinib approval [11/21/19]) until end of 1L, death, or data cutoff. Outcomes were analyzed overall and in cohorts by insurance type (commercial or Medicare). Overlap-weighted adjusted regression models were used to estimate mean per-patient-per-month (PPPM) cost differences with bootstrapped 95% CIs. Based on Wholesale Acquisition Cost mirroring of the published 38% price reduction per the IRA MFP, a 41% Ibr price reduction was applied to simulate costs post-MFP effectuation, holding all other parameters constant.

RESULTS: A total of 2097 pts were included (commercial, n=228 [Ibr, n=99; other BTKis, n=129]; Medicare, n=1869 [Ibr, n=668; other BTKis, n=1201]). Cohorts were well balanced after weighting. Post-MFP effectuation, 41% price reduction for Ibr is expected to result in cost savings with Ibr vs other BTKis, with a mean (95% CI) cost difference of −$3448 (−$6386 to $488; P=0.09) in commercial pts, −$3594 (−$4635 to −$2412; P<0.001) in Medicare pts, and −$3456 (−$4412 to −$2492; P<0.001) in the overall sample.

CONCLUSIONS: Post-IRA DPN modeling projected meaningful total cost savings with Ibr vs other covalent BTKis, suggesting reductions in overall plan-level expenditures with use of Ibr for 1L treatment of CLL/SLL.

SPONSORSHIP: AbbVie

123 Payer perspectives on manufacturer-led direct-to-consumer (DTC) offerings for anti-obesity medications (AOMs)

Yoshida S, Sequeira A, Friedman M;
arvin.sequeira@cencora.com;
michelle.friedman@cencora.com
Cencora

BACKGROUND: Direct-to-consumer (DTC) offerings for anti-obesity medications (AOMs) represent a rapidly evolving payment model, with manufacturers like Eli Lilly and Novo Nordisk providing GLP-1 AOMs directly to patients. Despite positive clinical outcomes, GLP-1 AOMs face coverage challenges due to high budget impacts on payer organizations. As a result, AOM manufacturers are pursuing DTC models to overcome insurance barriers and enhance patient access. The emergence of DTC channels for AOMs introduces potential implications for payers, though the extent of this impact remains uncertain.

OBJECTIVE: To understand payer perceptions of DTC models for AOMs and assess their impact on US payer coverage and management of AOMs.

METHODS: An online survey of US payers was conducted through Cencora's Managed Care Network research panel in September 2025.

RESULTS: A total of 10 payers, including health plans (n=5) and pharmacy benefit managers (n=5) completed the survey, representing 268 million commercial covered lives. Overall, payers demonstrate an educated awareness of leading DTC offerings including LillyDirect® (80%), and NovoCare® (70%). Fifty percent estimate that AOM DTC models are not currently impactful in rebate negotiations, while 60% believe they will make it easier to control drug spend for AOMs. Regarding the rise of AOM DTC models, payers are most concerned with pressures to adjust formulary designs as well as the visibility of health outcomes data. Majority of payers anticipate operational challenges such as increased patient confusion about coverage and DTC/prescriber care coordination issues. Payers agree AOM DTC models remain a niche segment; however, they are also concerned with competing coverage pathways. In response, payers are considering strategies such as formulary adjustments, pharmacy partnerships, member/provider education, and innovative contracting strategies. Half of payers expect DTC to play a larger role over the next 3 years, especially in obesity, diabetes, and migraine therapeutics.

CONCLUSIONS: DTC models for AOMs offer a novel approach to increasing patient access, though payers remain cautious, citing key operational challenges. Nonetheless, payers expect DTC models to grow over the next 3 years, particularly in the obesity space. Future research should monitor the impact of DTC offerings on AOM access after 1 year of market presence. With the administration's focus on innovative drug pricing strategies (eg, MFN Executive Order), an AOM DTC portal could significantly influence access pathways.

SPONSORSHIP: Cencora

Endocrine and Metabolic

135 A US real-world study of burden of illness among patients with acquired hypothalamic obesity

Chan J[1], Liu J[2], Gallienne S[3], Ionescu-Ittu R[3], Mallya U[4], Haber R[3], Machineni S[5]; jliu@rhythmtx.com
[1]Pediatric Endocrinology, University of Utah; [2]Rhythm Pharmaceuticals; [3]STATLOG Inc.; [4]Rhythm Pharmaceuticals, Inc. Boston, MA; [5]Division of Endocrinology and Metabolism, Albert Einstein College of Medicine

BACKGROUND: Acquired hypothalamic obesity (aHO) is a rare form of obesity characterized by accelerated and sustained weight gain in the setting of broad hypothalamic impairment following an injury to the hypothalamus, such as from suprasellar brain tumors or surgical resection of those tumors and traumatic brain injury. It is associated with elevated risk of negative long-term health consequences.

OBJECTIVE: To assess the real-world burden of disease for US adult aHO patients.

METHODS: A large US claims/electronic medical records database (2010-2023) was used to select adult aHO patients, ascertained as having clinical evidence of hypothalamic insult due to brain tumor and/or trauma (potentially resulting in hypothalamic damage), subsequently accelerated weight gain and neuroendocrine aHO indicators (e.g., pan-hypopituitarism, diabetes insipidus). Clinical burden was evaluated for the 12-month period prior to (i.e., baseline) and 12-month period following (i.e., follow-up) hypothalamic insult among aHO patients. Disease burden from hypothalamic insult to end of observation was compared between aHO cohort and a propensity score matched non-aHO cohort (i.e., those with no clinical evidence of aHO following comparable hypothalamic insult).

RESULTS: Of the 112 adult aHO patients identified, 61 and 51 were tumor- and trauma-related cases, respectively (mean age 48.5 years; 53% female, 63% white, 33% with commercial insurance and 32% with Medicaid). During follow-up, an average 17.7% increase in body mass index (4.7 kg/m2) was observed, and 60% of the patients experienced gain of ≥1 obesity class. Large increases in obesity-related sequelae were observed from baseline to follow-up, including diabetes mellitus (17% to 32%), hypertension (30% to 49%), metabolic-related fatty liver disease (3% to 8%), depression (29% to 40%) and various sleep disorders (14% to 26%). Additionally, increased uses of anti-depressants (11% to 20%), anti-diabetic agents (15% to 25%), steroids (20% to 26%) and stimulants (22% to 37%) were also observed. Of the 94 matched aHO and non-aHO pairs, aHO patients had significantly higher clinical burden and numerically higher annual per-patient per-year incident rates of all-cause inpatients stays (0.68 vs. 0.55) and all-cause outpatient visits (30.3 vs. 25.9) following hypothalamic insult.

CONCLUSIONS: This is the first US real-world study highlighting the significant burden of disease among adult aHO patients, suggesting the urgency in the timely diagnosis and treatment of aHO.

SPONSORSHIP: Rhythm Pharmaceuticals, Inc.

136 A real-world study of adherence and persistence to resmetirom in patients with MASH

Debenham J[1], *Kumar R*[1], *Fernandes J*[1], *Thomas S*[1], *Thomas B*[2], *Atreja N*[2], *Lobo F*[2]; *jennidebenham@gmail.com*; *flobo@madrigalpharma.com*
[1]*CVS Health*; [2]*Madrigal Pharmaceuticals*

BACKGROUND: Metabolic dysfunction-associated steatohepatitis (MASH), formerly known as NASH/NAFLD, is a progressive liver disease with limited approved treatments. Resmetirom, a thyroid hormone receptor beta (THR-β) agonist, was approved in March 2024 as the first liver directed therapy for MASH. Given the recent approval, understanding real-world treatment patterns, specifically adherence and persistence, with resmetirom is critical to optimizing its clinical impact.

OBJECTIVE: To evaluate real-world adherence and persistence in MASH patients initiating resmetirom, using a large prescription fill database.

METHODS: This retrospective cohort study utilized large specialty and retail pharmacies fill data for resmetirom between March 2024 and August 2025. Inclusion criteria were patients (aged ≥18 years) with at least 2 prescription fills for resmetirom consistent with standard medication measures used to assess treatment compliance. Patients were considered persistent if they were actively filling resmetirom scripts at 6- and 12-months post initiation with a permissible 60/90-day fill grace period. Adherence was measured using a proportion of days covered (PDC), calculated from the first dispensation for 6 and 12 months.

RESULTS: At 6 months, 5,389 patients were evaluated (mean age = 56.4 years, female = 56.8%). Using 60/90-day fill grace periods persistency was 89.1%/94.3% with a mean PDC of 85.3%, At 12 months, 1,869 patients were assessed (mean age = 55.9 years, female = 57.3%), persistency was 71.2%/73.8% at 60/90-day fill grace periods with a mean PDC of 75.1%.

CONCLUSIONS: These results suggest high initial adherence and persistence to resmetirom among patients with MASH, supporting its potential for sustained real-world use. The consistency of results at 6 and 12 months reinforces the robustness of adherence patterns. Future research should explore factors influencing long-term persistence and assess clinical outcomes associated with high adherence to resmetirom.

SPONSORSHIP: Madrigal Pharmaceuticals

138 Assessing the impact of continuous glucose monitors (CGMs) on clinical and economic outcomes in patients with diabetes

Verma V[1], *Roy A*[1], *Nayyar A*[1], *Arora A*[1], *Gupta A*[1], *Khatavkar V*[1], *Parmar C*[1], *Brooks L*[2], *Seligman M*[2], *Heath K*[3]; *vikash.verma@optum.com*; *abhimanyu.roy@optum.com*; *abhinav.nayyar@optum.com*; *ankitkumar_arora@optum.com*; *vishan_khatavkar@optum.com*
[1]*Optum Inc.*; [2]*OptumInsight*; [3]*Optum*

BACKGROUND: Continuous glucose monitors (CGMs) are increasingly integrated into diabetes care, offering real-time glucose tracking and the potential to enhance disease management. Despite growing adoption, real-world evidence on their clinical and economic impact in type 2 diabetes (T2DM) remains limited, particularly from a managed care perspective.

OBJECTIVE: To evaluate the association of CGM use with clinical outcomes, healthcare resource utilization (HCRU), and costs among adults with T2DM using real-world data.

METHODS: A retrospective cohort study was conducted using the Optum® Market Clarity database. Adults (≥18 years) with T2DM (index event) and ≥1 CGM claim between Jan 1, 2022, and Mar 31, 2024, with continuous enrollment for 24 months, were included. Patients with gestational diabetes or clinical trial participation were excluded. CGM users were propensity score-matched 1:1 to non-users based on demographics and clinical characteristics. Outcomes assessed over 12-month

follow-up period included HbA1c, hypoglycemia, diabetes-related complications, hospitalizations, ER visits, and total healthcare costs. Statistical comparisons used t-tests and chi-square tests.

RESULTS: Matched cohorts included 42,423 patients each (mean age 60 years, 51% female). CGM users had higher baseline HbA1c but maintained stable levels over time, indicating effective glycemic monitoring. Rates of hypoglycemia and complications were higher among CGM users, likely reflecting greater disease complexity and closer clinical oversight. CGM users exhibited increased HCRU and costs, consistent with more intensive disease management. Notably, higher ambulatory and outpatient care utilization among CGM users may help offset future acute care needs.

CONCLUSIONS: In this large real-world study, CGM users demonstrated distinct clinical profiles and higher engagement with healthcare services, suggesting CGMs are preferentially adopted by patients with complex needs. Elevated costs and utilization appear to reflect proactive care rather than inefficiency. These findings support the role of CGMs in value-based diabetes management. Future longitudinal studies and advanced modeling are warranted to isolate causal effects and guide payer strategies.

SPONSORSHIP: None

139 Cost per responder analysis of tirzepatide versus semaglutide in GLP-1 RA-naive patients with T2D

Terrell K[1], *Vallarino C*[2], *Maldonado J*[3], *Grabner M*[4], *Teng C*[4], *Hoog M*[2], *Richard E*[4]; *kendra_terrell@lilly.com*
[1]*Eli Lilly and Company*; [2]*Eli Lilly and Company*; [3]*Eli Lilly*; [4]*Carelon Research*

BACKGROUND: Guidelines from the American Diabetes Association highlight the importance of achieving HbA1c ≤6.5% and weight reduction ≥10% to improve long-term outcomes in patients with type 2 diabetes (T2D).

OBJECTIVE: To compare the costs per responder among glucagon-like peptide-1 receptor agonist (GLP-1 RA)–naive patients with T2D starting tirzepatide or injectable semaglutide.

METHODS: This retrospective, observational cohort study utilized claims and clinical data from the Healthcare Integrated Research Database (HIRD®) to identify patients with T2D starting any dose of tirzepatide or injectable semaglutide indicated for T2D (i.e., index medication) between May 13, 2022, and May 29, 2023. Patients had at least 6 months of continuous enrollment before and 12 months after initiation (index date) and no GLP-1 RA use during the 6-month pre-index period. Propensity score matching (1:1) was used to improve baseline balance across the two cohorts. The cost per responder, calculated as mean T2D-related pharmacy cost divided by proportion of patients achieving select outcomes (HbA1c ≤6.5%, weight reduction ≥10%, and a composite endpoint of both), was compared between tirzepatide and semaglutide initiators. HbA1c was assessed at follow-up (45 days before or after index + 12 months), and weight reduction was assessed from baseline (90 days before to 14 days after index) to follow-up.

RESULTS: Each matched cohort had 10,702 patients (tirzepatide: mean age 53.2 years, 56% males; semaglutide: mean age 53.2 years, 55% males). Among the matched patients, 2,125 tirzepatide and 1,909 semaglutide initiators had follow-up HbA1c data; 454 tirzepatide and 432 semaglutide initiators had both baseline and follow-up weight data; and 213 tirzepatide and 197 semaglutide initiators had follow-up HbA1c data, as well as baseline and follow-up weight data. Tirzepatide initiators had a numerically lower cost per responder for HbA1c ≤6.5% compared to semaglutide initiators (point estimate [SE]: $20,639 [381] and $21,392 [522] respectively, p=0.244). A similar trend was observed for the exploratory endpoints: cost per responder for weight reduction ≥10% (point estimate [SE]: $37,241 [2,634] tirzepatide; $55,703 [5,250] semaglutide), and the composite outcome (point estimate [SE]: $38,290 [3,683] tirzepatide; $59,399 [8,810] semaglutide).

CONCLUSIONS: In this real-world study, GLP-1 RA-naive patients with T2D who initiated tirzepatide had lower costs per responder than patients who initiated injectable semaglutide over the 12-month post-index period.

SPONSORSHIP: Eli Lilly and Company

140 Cost per responder analysis of tirzepatide versus semaglutide in GLP-1 RA-experienced patients with T2D

Terrell K[1], *Vallarino C*[2], *Maldonado J*[3], *Grabner M*[4], *Teng C*[4], *Hoog M*[2], *Richard E*[4]; *kendra_terrell@lilly.com*
[1]*Eli Lilly and Company*; [2]*Eli Lilly and Company*; [3]*Eli Lilly*; [4]*Carelon Research*

BACKGROUND: The American Diabetes Association guidelines emphasize the importance of achieving HbA1c ≤6.5% and weight reduction ≥10% to improve long-term outcomes in patients with type 2 diabetes (T2D).

OBJECTIVE: To compare costs per responder among glucagon-like peptide-1 receptor agonist (GLP-1 RA)–experienced patients with T2D starting tirzepatide or injectable semaglutide.

METHODS: This retrospective, observational cohort study utilized claims and clinical data from Healthcare Integrated

Research Database (HIRD®) to identify patients with T2D starting any dose of tirzepatide or injectable semaglutide indicated for T2D (i.e., index medication) from May 13, 2022, to May 29, 2023. Patients had at least 6 months of continuous enrollment before and 12 months after initiation (index date) and ≥1 pharmacy claim for a non-index GLP-1 RA during the 6-month pre-index period. Propensity score matching was used to reduce bias across the two cohorts. The cost per responder, calculated as mean T2D-related pharmacy cost divided by proportion of patients achieving select outcomes (HbA1c ≤6.5%, weight reduction ≥10%, and a composite endpoint of both), was compared between tirzepatide and semaglutide initiators. HbA1c was assessed at follow-up (45 days before or after index + 12 months) and weight reduction was assessed from baseline (90 days before to 14 days after index) to follow-up.

RESULTS: Each matched cohort had 5,577 patients (tirzepatide: mean age 54.9 years, 55% males; semaglutide: mean age 55.0 years, 54% males). Among the matched patients, 1,173 tirzepatide and 1,130 semaglutide initiators had follow-up HbA1c data; 296 tirzepatide and 224 semaglutide initiators had both baseline and follow-up weight data; and 156 tirzepatide and 107 semaglutide initiators had follow-up HbA1c data, as well as baseline and follow-up weight data. Tirzepatide initiators had a significantly lower cost per responder for HbA1c ≤6.5% compared to semaglutide initiators (point estimate [SE]: $36,855 [1,244] and $50,689 [2,374] respectively, p<0.001). A similar trend was observed for the exploratory endpoints: cost per responder for weight reduction ≥10% (point estimate [SE]: $55,116 [4,758] tirzepatide; $128,404 [23,042] semaglutide), and the composite outcome (point estimate [SE]: $65,823 [8,854] tirzepatide; $294,538 [119,547] semaglutide).

CONCLUSIONS: In this real-world study, GLP-1 RA–experienced patients with T2D who initiated tirzepatide had lower costs per responder than patients who initiated injectable semaglutide over the 12-month post-index period.

SPONSORSHIP: Eli Lilly and Company

141 Evaluating healthcare cost changes following glucagon-like peptide-1 receptor agonist anti-obesity medication initiation: Evidence from Mississippi Medicaid

Bazzazzadehgan S[1], Ly-Ha A[2], Smith D[2], Kirby T[2], Pittman E[3], Bhattacharya K[3]; sbazzazz@go.olemiss.edu
[1]Department of Pharmacy Administration, University of Mississippi School of Pharmacy, University, Mississippi, USA; [2]Mississippi Division of Medicaid; [3]Department of Pharmacy Administration and Center for Pharmaceutical Marketing & Management, University of Mississippi School of Pharmacy

BACKGROUND: Mississippi Medicaid's inclusion of semaglutide (Wegovy®) and liraglutide (Saxenda®) as preferred anti-obesity medications (AOMs) in July 2023 marked a significant step toward expanding access to glucagon-like peptide-1 receptor agonist (GLP-1 RA) therapies. From a payer's perspective, it is critical to understand how adherence and comorbid conditions impact the economic value of GLP-1 RA AOMs.

OBJECTIVE: To estimate the real-world impact of GLP-1 RA AOMs initiation on healthcare costs among Mississippi Medicaid members, and to examine the role adherence plays in cost differences observed across comorbid conditions.

METHODS: This cohort study used Mississippi Medicaid claims data (2022–2025). Members aged ≥18 years who initiated GLP-1 RA AOMs between July 2023 and June 2024 and were continuously enrolled between 12-month pre-initiation (baseline) and post-initiation (follow-up) periods were included. Total, medical, and pharmacy costs (excluding GLP-1 RA AOMs costs) were compared between the baseline and follow-up periods. Adherence was measured using the proportion of days covered (PDC) during the follow-up period, with members classified as having low (PDC < 50%), moderate (50% ≤ PDC ≤ 79%), or high adherence (PDC ≥ 80%). Costs were stratified by adherence level and baseline comorbid conditions. Median costs with interquartile ranges (IQRs) were reported.

RESULTS: Total of 1,095 members initiated GLP-1 RA AOMs; most were women (91.51%) and Black (47.40%). Overall, median total costs showed modest pre-post changes; however, pre-post cost differences varied substantially by comorbidity profile and adherence. Members with high adherence demonstrated greater cost savings, ranging from -$4,502.56 (IQR: -$12,350.22 to $1,020.09) among those with kidney-related conditions to -$11.79 (IQR: -$5,024.43 to $2,926.02) among those with baseline hypertension. In contrast, members with low adherence showed smaller or negative cost savings, with estimates ranging from -$2,196.83 (IQR: -$10,497.30 to $973.93) for metabolic dysfunction–associated

steatohepatitis and increased costs up to $2,648.68 (IQR: -$3,468.26 to $8,104.61) for kidney-related conditions.

CONCLUSIONS: This early cost evaluation suggests that higher adherence to GLP-1 RA AOMs is associated with moderate cost savings, though the magnitude varies by comorbidity profile. Future longitudinal analyses comparing initiators and non-initiators are warranted to better understand the long-term economic impact of GLP-1 RA AOMs in Medicaid populations.

SPONSORSHIP: This study was supported by funding from the Mississippi Division of Medicaid.

142 Individuals with obesity or overweight who switched to tirzepatide from another GLP1-RA obesity management medication demonstrated clinically meaningful weight reduction after persistent tirzepatide use: Results from 2 real-world studies

Chinthammit C[1], *Gibble T*[1], *Mojdami D*[1], *Crocker K*[2], *Vallarino C*[1], *Huang A*[3], *Dehghan M*[1], *Bays H*[4], *Lubelczyk E*[1]; *hunter_theresa_marie@lilly.com*; *elizabeth.lubelczyk@lilly.com*
[1]*Eli Lilly and Company*; [2]*Carelon Research*; [3]*Tigermed-BDM*; [4]*Louisville Metabolic and Atherosclerosis Research Center*

BACKGROUND: Tirzepatide is approved for the treatment of obesity.

OBJECTIVE: To understand weight reduction of individuals with obesity or overweight who switch to tirzepatide from another GLP 1-RA obesity medication (OM).

METHODS: These retrospective, observational, descriptive analyses used data from Optum's de-identified Market Clarity (Market Clarity [MC]) database and the Healthcare Integrated Research Database (HIRD®). Individuals were included in these analyses if they met the following criteria: adults (age ≥18 years); had no diagnosis for T2D; met eligibility criteria for OM [body mass index [BMI] ≥30 kg/m^2 or ≥27 kg/m^2 with ≥1 obesity-related complication (ORC)]; had ≥1 prescription claim for tirzepatide (Zepbound®); had continuous medical/pharmacy enrollment for ≥12 months pre-index; and were persistent (no gap in medication ≥45 days) on tirzepatide for ≥12 months. The date of the first observed tirzepatide claim was identified as the index date. Individuals were included in these analyses if they switched to tirzepatide from another GLP-1 RA OM (GLP-1 RA-switchers). The analyses included a pre-index period for assessing the demographics and clinical characteristics, and post-index period for evaluating change in weight and proportion of individuals meeting ≥5%, ≥10%, ≥15%, and ≥20% weight reduction thresholds. Individuals were included in these analyses if they had weight records at baseline (from 90 days prior to 3 days after index date) and 365 (±30 [HIRD] or ±45[MC]) days after tirzepatide initiation.

RESULTS: Overall, 123 OM-eligible adults were identified in MC and 179 in the HIRD; mean age was 48.9 years and 49.9 years, respectively, and in both databases, >80% were female. A total of 85.4% (MC) and 94.4% (HIRD) of individuals had at least one ORC, with the most prevalent being hypertension and dyslipidemia. 71.5% (MC) and 72.1% (HIRD) of individuals were started on 2.5 mg; and 81.3% (MC) and 75.4% (HIRD) were on a ≥10 mg dose closest to weight capture at 12 months. Individuals achieved weight reduction of 13.1% (MC) and 12.9% (HIRD) after 12 months of persistent use. During the 12-month follow-up, 78.9% (MC) and 83.8% (HIRD) of tirzepatide initiators achieved ≥5% weight reduction; and 21.1% (MC) and 19.6% (HIRD) of tirzepatide initiators achieved ≥20% weight reduction with 12 months of persistent use.

CONCLUSIONS: In both databases used in these analyses, individuals with obesity or overweight who switched to tirzepatide from another GLP-1 RA OM demonstrated clinically meaningful weight reduction after 12 months of persistent tirzepatide use.

SPONSORSHIP: Eli Lilly and Company

143 Tirzepatide use resulted in clinically meaningful weight reduction among GLP-1 RA naive individuals with obesity or overweight: Results from 2 real-world studies

Gibble T[1], *Chinthammit C*[1], *Mojdami D*[1], *Desai K*[2], *Vallarino C*[1], *Huang A*[3], *Dehghan M*[1], *Bays H*[4], *Kern S*[1]; *hunter_theresa_marie@lilly.com*; *kern_scott_a@lilly.com*
[1]*Eli Lilly and Company*; [2]*Carelon Research*; [3]*Tigermed-BDM*; [4]*Louisville Metabolic and Atherosclerosis Research Center*

BACKGROUND: Tirzepatide is approved for the treatment of obesity.

OBJECTIVE: To understand weight reduction of individuals with obesity or overweight who were persistent on tirzepatide for 12 months.

METHODS: These retrospective, observational, descriptive analyses used data from Optum's de-identified Market Clarity Data (Market Clarity [MC]) database and the Healthcare Integrated Research Database (HIRD®). Individuals were included in these analyses if they met the following criteria: adults (age ≥18 years) who were GLP-1 RA naive; had no evidence for Type 2 diabetes; met eligibility criteria for obesity medication (OM) [body mass index [BMI] ≥30 kg/m^2 or ≥27 kg/m^2 with ≥1 obesity-related complication (ORC)]; had ≥1 prescription claim for tirzepatide (Zepbound®); had continuous medical/pharmacy enrollment for ≥12 months pre-index; and were persistent (no gap in medication ≥45 days)

on tirzepatide for ≥12 months. The date of the first observed tirzepatide claim was identified as the index date. The analyses used the pre-index period for assessing the demographics and clinical characteristics, and post-index period for evaluating change in weight and proportion of individuals meeting ≥5%, ≥10%, ≥15%, and ≥20% weight reduction thresholds. Individuals were included in these analyses if they had weight records at baseline (from 90 days prior to 3 days after index date) and 365 (±30 [HIRD] or ±45 [MC]) days after tirzepatide initiation.

RESULTS: Overall, 230 OM-eligible adults were identified in the MC database and 437 in the HIRD database; mean age was 49.5 yrs and 49.0 yrs, respectively, and in both databases, >70% were female. A total of 86.1% (MC) and 93.6% (HIRD) of individuals had at least one ORC, with the most prevalent being hypertension and dyslipidemia. 91.3% (MC) and 92.7% (HIRD) of GLP-1 RA–naive users were started on 2.5 mg; and 70.5% (MC) and 68.2% (HIRD) were on ≥10 mg dose closest to weight capture at 12 months. Individuals achieved weight reductions of 19.3% (MC) and 18.8% (HIRD) after 12 months of persistent use. During the 12-month follow-up, 93.5% (MC) and 95.7% (HIRD) of tirzepatide initiators achieved ≥5% weight reduction; and 44.8% (MC) and 40.7% (HIRD) of tirzepatide initiators achieved ≥20% weight reduction with 12 months of persistent use.

CONCLUSIONS: Commercially insured individuals with obesity or overweight exhibited consistent, clinically meaningful weight reductions (~19%) following ≥12 months of persistent tirzepatide use. These findings from 2 US real-world databases are consistent with results from the SURMOUNT clinical trials.

SPONSORSHIP: Eli Lilly and Company

144 12-Month utilization patterns of tirzepatide in adults with obesity or overweight: US commercial claims database analysis

Gibble T[1], *Crocker K*[2], *Mojdami D*[1], *Vallarino C*[1], *Grabner M*[2], *Upadhyay N*[1], *Desai K*[2], *Marrone C*[1]; *hunter_theresa_marie@lilly.com*; *marrone_chris@lilly.com*
[1]*Eli Lilly and Company*; [2]*Carelon Research*

BACKGROUND: Tirzepatide is approved for the treatment of obesity.

OBJECTIVE: To assess the 12-month utilization of tirzepatide among individuals with obesity or overweight.

METHODS: This retrospective, observational study used administrative claims and electronic health records from the Healthcare Integrated Research Database. Obesity medication (OM)–eligible (body mass index [BMI] ≥30 kg/m^2 OR ≥27 kg/m^2 with ≥1 obesity-related complication [ORC] adults (age ≥18 yrs) without T2D with ≥1 prescription claim for tirzepatide between Nov 2023 and June 2024 and continuous medical/pharmacy enrollment for ≥12 months pre-index and ≥12 months post-index were included. The date of the first tirzepatide (Zepbound®) claim in the index period was identified as the index date. The study included a 12-month pre-index period for assessing the demographics and clinical characteristics, and a 12-month post-index period for evaluating utilization (adherence, persistence/discontinuation, switching and reinitiation). Individuals were considered adherent if the PDC was ≥80% (sum of days of supply on all tirzepatide prescriptions filled during the 12-month post-index period). Persistence was defined as no gap in days' supply of more than 60 days over 12 months. Stockpiling (overlap of days' supply are added on to total days' supply) was allowed for persistence analyses. Proportions of individuals switching to non-index GLP-1 RA and non-GLP-1 RA medications and those reinitiating tirzepatide during the 12-month post-index period were also reported.

RESULTS: During the study period, 21,167 individuals initiated tirzepatide and had continuous enrollment for 12 months post-index. The majority were female (73.0%), White (77.3%), with a mean age of 46.4 yrs, mean BMI of 37.7 kg/m^2. 91.4% had ≥1 ORC at baseline, with dyslipidemia, hypertension, and anxiety being the most frequent. During the 12-month follow-up, 57.0% (n=12,066) of tirzepatide initiators were persistent. Among those who discontinued tirzepatide (n=9,101), the mean time to discontinuation was 115.3 days. Overall, 71.0% (n=15,036) of individuals either remained persistent on tirzepatide or, after discontinuation, restarted tirzepatide; and 75.6% (n=15,995) of individuals either remained persistent on tirzepatide or, after discontinuation, restarted tirzepatide or switched to an OM GLP-1 RA. During the 12-month follow-up period, 49.4% (n=10,447) were adherent.

CONCLUSIONS: Among US adults with obesity or overweight and with commercial health insurance, the majority of tirzepatide initiators were persistent for 12 months.

SPONSORSHIP: Eli Lilly and Company

145 Leveraging artificial intelligence for early identification of Fabry disease from claims, EHRs, and physician notes

Gupta A[1], *Verma* V[1], *Roy* A[1], *Nayyar* A[1], *Arora* A[1], *Khatavkar* V[1], *Acharjee* N[1], *Khan* S[1], *Khan* S[1], K K[1], *Kumar* S[1], *Mahashay* G[1], *Somani* M[1], *Brooks* L[2], *Seligman* M[2], *Heath* K[3]; *anuj_gupta457@optum.com*; *vikash.verma@optum.com*; *abhimanyu.roy@optum.com*; *abhinav.nayyar@optum.com*; *ankitkumar_arora@optum.com*; *vishan_khatavkar@optum.com*
[1]*Optum Inc.*; [2]*OptumInsight*; [3]*Optum*

BACKGROUND: Fabry disease is a rare X-linked lysosomal storage disorder caused by mutations in the GLA gene, leading to globotriaosylceramide (Gb3) accumulation in organs such as the kidneys, heart, and nervous system. Its heterogeneous symptoms often mimic more common conditions, resulting in frequent diagnostic delays and suboptimal outcomes. Early identification is critical, as timely intervention can prevent irreversible organ damage and reduce healthcare burden.

OBJECTIVE: To develop an artificial intelligence (AI)/machine learning (ML)–based risk prediction model for early identification of Fabry disease in adults using integrated claims, EHR, and physician notes.

METHODS: A retrospective analysis was conducted using Optum® de-identified Market Clarity Data, integrating structured claims and EHRs from July 1, 2023, to June 30, 2025. Adults (≥18 years) with at least one claim or EHR records for Fabry disease (ICD-10: E75.2, E75.21) were included. After applying inclusion criteria, 1,191 Fabry disease cases were matched 1:2 with controls (patients without Fabry disease) on age, sex, race and ethnicity. Sixteen clinical features, including hallmark symptoms and comorbidities, were extracted from structured data and clinical notes using natural language processing. Logistic Regression, XGBoost, and Random Forest models were trained and evaluated using an 80:20 split. Model performance was assessed using AUROC, Precision, Recall, and Odds Ratios (OR) for key predictors.

RESULTS: The XGBoost model achieved the highest performance (AUROC: 0.873), with 77% Precision and 72% Recall for Fabry disease identification. Key predictors included neuropathic pain (OR: 1.2), angiokeratomas (OR: 1.1), chronic kidney disease (OR: 1.5) and left ventricular hypertrophy (OR: 1.1). The model outperformed Logistic Regression and Random Forest in discrimination and calibration. Sensitivity analyses confirmed robustness across subgroups.

CONCLUSIONS: This AI/ML-based model may facilitate early identification of Fabry disease in real-world settings, enabling timely intervention to prevent irreversible complications and improve patient outcomes. Further research is warranted to refine the model and assess its impact on clinical practice.

SPONSORSHIP: None

146 Impact of naltrexone-bupropion therapy on weight and metabolic outcomes in obese adults: A real-world perspective

Gupta A[1], *Verma* V[1], *Roy* A[1], *Nayyar* A[1], *Arora* A[1], *Khatavkar* V[1], *Markan* R[2], *Mishra* R[1], *Kumar* S[1], *Misra* A[1], *Karayat* K[1], S S[1], *Singh* A[1], *Motila* S[1], *Brooks* L[3], *Seligman* M[3], *Heath* K[4], K K[1]; *anuj_gupta457@optum.com*; *vikash.verma@optum.com*; *abhimanyu.roy@optum.com*; *abhinav.nayyar@optum.com*; *ankitkumar_arora@optum.com*; *vishan_khatavkar@optum.com*
[1]*Optum Inc.*; [2]*Optum Inc*; [3]*OptumInsight*; [4]*Optum*

BACKGROUND: Obesity is a chronic and progressive condition that affects millions of individuals worldwide. Along with lifestyle modifications, several anti-obesity medications, such as combination of naltrexone (opioid receptor antagonist) and bupropion (dopamine/norepinephrine reuptake inhibitor), aid in weight loss by modulating appetite and reward pathways. Despite its clinical potential, real-world evidence on its effectiveness across diverse populations remains limited.

OBJECTIVE: To evaluate real-world effectiveness of naltrexone-bupropion (NB) therapy in adults with obesity by assessing changes in clinical parameters, like body mass index (BMI) and glycated hemoglobin (HbA1c), over a 12-month follow-up period among diverse ethnic/gender subgroups.

METHODS: This retrospective cohort study utilized the Optum® Market Clarity database, integrating claims and electronic health records (EHRs), to identify adults with a prescription for NB between January 1, 2016, and June 30, 2024. Eligible patients had a diagnosis of obesity within 6 months prior to NB initiation (index date), continuous health plan enrollment, and active EHR data for ≥6 months pre-index and ≥12 months post-index. Patients with prior NB use, weight reduction interventions, cancer, amputation, or unintentional weight changes during baseline or follow-up were excluded. Clinical outcomes—BMI and HbA1c—were assessed at baseline, 6 months, and 12 months.

RESULTS: Of 8,706 adults initiating NB therapy, 2,595 met inclusion criteria. BMI reductions were observed across all gender and ethnic subgroups. Caucasian females (n = 1,342) achieved a mean BMI reduction of 3.8% at 12 months, followed by African American females (n = 464) with a 3.6% decrease. During the same time, Caucasian males and African American males showed 3.1% and 1.1% reduction, respectively, during the same time. HbA1c improvements were most

notable in African American females (10.8%) followed by Caucasian males (7.7%) at 6 months.

CONCLUSIONS: NB therapy demonstrated clinically meaningful improvements in weight and glycemic control among obese adults, with most subgroups achieving 2–4% reductions in BMI and up to 10% improvement in HbA1c. Despite data attrition and limited glycemic measurements, NB remains a viable option for personalized obesity management, particularly for patients who may not be candidates for newer agents such as glucagon-like peptide-1 (GLP-1) receptor agonists. Future studies should explore long-term outcomes and broader metabolic markers to guide comprehensive obesity care.

SPONSORSHIP: None

147 Predicting CKD stage transitions in diabetic patients: A real-world approach

Arora A[1], *Verma V*[1], *Roy A*[1], *Nayyar A*[1], *Gupta A*[1], *Khatavkar V*[1], *Mishra R*[1], *Gaonkar A*[1], *Amin T*[1], *Shukla G*[1], *Sundaram S*[1], *Brooks L*[2], *Seligman M*[2], *Heath K*[3]; *ankitkumar_arora@optum.com*; *vikash.verma@optum.com*; *abhimanyu.roy@optum.com*; *abhinav.nayyar@optum.com*; *anuj_gupta457@optum.com*; *vishan_khatavkar@optum.com*
[1]*Optum Inc.*; [2]*OptumInsight*; [3]*Optum*

BACKGROUND: Chronic kidney disease (CKD) is a common and serious diabetes complication, often progressing silently across stages. Predicting CKD stage transitions enables timely interventions and personalized care.

OBJECTIVE: To develop and validate a predictive model using real-world data to identify high-risk patients with CKD progression amongst a diabetic population.

METHODS: A retrospective study was conducted using Optum® Market Clarity data (July 2018 to June 2025) to identify adults aged 18–84 with diabetes and no baseline CKD, who were diagnosed with CKD stages 1–4 (index event) during index period (July 2019 to June 2020). Continuous medical and pharmacy enrollment of 1-year pre- and 5-year post-index was ensured. Patients with CKD stage 5, ESRD, renal transplant, acute kidney injury, or incomplete claims were excluded. CKD stage transitions and healthcare utilization were assessed during the follow-up period. Predictors included demographics, comorbidities, medication use, healthcare engagement, and eGFR trends. BMI, blood pressure, HbA1C, diabetes duration, smoking status, albuminuria, and hyperlipidemia were covariates. Primary outcome was CKD stage transitions; secondary outcomes included time-to-disease progression and healthcare utilization.

RESULTS: After applying inclusion/exclusion criteria, 936,851 patients with newly diagnosed CKD stages 1–4 with diabetes were identified, with a mean age of 69.9 years; and 51.3% were male. At index, CKD stage 3 was most common (12.7%), followed by stages 2 and 4 (3% each). Baseline HbA1c elevations were observed in 1.8% (mild), 1.2% (moderate) and 0.6% (severe) of patients. Mild elevations in blood pressure (78.7%) and slightly elevated BMI (15.0%) were also prevalent. CKD staging revealed a predominance of stage 3a (70.6%), followed by stage 2 (18.1%) and stage 3b (17.0%). Among the models tested were Random Forest, XGBoost, and Logistic Regression (LR); the LR model demonstrated superior predictive accuracy. Significant predictors of CKD stage transition included female gender and high healthcare utilization across inpatient, outpatient, and emergency visits ($p<0.0001$). Medications, particularly RAAS inhibitors, SGLT2 inhibitors, and NSAIDs, also showed strong associations with progression ($p<0.0001$). The LR model exhibited good discriminative performance with ROC=0.8032.

CONCLUSIONS: Predictive modeling of CKD progression in diabetic patients enables the payer to optimize a risk-based contract, guides providers in early intervention, and helps pharma identify populations for renal-protective therapies, thereby fostering proactive, value-based care.

SPONSORSHIP: None

Ophthalmic

159 Real-world pegcetacoplan and anti-VEGF treatment patterns among patients with geographic atrophy

Tobitt J[1], *Leng T*[2], *Schneider E*[3], *Rahimy E*[4], *Toth J*[5], *Gu C*[5], *Sylman J*[5], *Maro G*[5], *Schwartz R*[1], *Enlow N*[1], *Kim A*[1], *Broderick k*[1], *Baumal C*[1], *Borkar D*[6]; *jamie.tobitt@apellis.com*; *ted.leng@veranahealth.com*
[1]*Apellis Pharmaceuticals*; [2]*Byers Eye Institute at Stanford*; [3]*Tennessee Retina*; [4]*Sutter Health*; [5]*Verana Health*; [6]*Duke Eye Center*

BACKGROUND: Age-related macular degeneration (AMD) can progress to neovascular AMD (nAMD) and/or geographic atrophy (GA). There is a lack of data around treatment patterns and effectiveness in patients with coexisting GA and nAMD.

OBJECTIVE: We describe the largest real-world evaluation of patients treated with pegcetacoplan, the first therapy approved for GA in the US. Some patients received concomitant anti-VEGF therapy for coexisting nAMD, providing an opportunity to assess the potential impact of GA treatment on anti-VEGF treatment patterns.

METHODS: This study used the American Academy of Ophthalmology IRIS® Registry (Intelligent Research in Sight).

Patients with GA who received their first pegcetacoplan injection (index) between March 2023 and December 2024 were included if they had at least 12 months of pre-index data, 6 months of potential follow-up, and a visual acuity (VA) measurement at baseline. Eyes were divided into cohorts based on whether they had received anti-VEGF injections pre- and/or post-index. Treatment patterns with pegcetacoplan and anti-VEGF were evaluated.

RESULTS: A total of 49,313 eyes from 34,908 patients were included: 15,510 eyes (31%) had received anti-VEGF prior to pegcetacoplan ("anti-VEGF first" cohort), 3,527 eyes (7%) only received anti-VEGF on or after index ("pegcetacoplan first" cohort), and 30,276 eyes (61%) did not receive anti-VEGF pre- or post-index ("pegcetacoplan only" cohort). Across all cohorts, the population was 77% white, 67% female, and had a median age of 82-84 years. Additionally, 53% of patients received pegcetacoplan bilaterally during the study. Eyes received a median of 5 pegcetacoplan injections per year, and the average interval between pegcetacoplan injections was about 56 days for eyes across cohorts. The "anti-VEGF first" and "pegcetacoplan first" cohorts received a median of 5 and 3 anti-VEGF injections per year post-index, respectively. Among the "anti-VEGF first" cohort, 11,590 eyes (75%) also received anti-VEGF injections post-index. The median interval between anti-VEGF injections was 59 days, and the median change in anti-VEGF intervals between pre- and post-index was +8 days.

CONCLUSIONS: In this real-world study, about a third of eyes treated with pegcetacoplan had previously received anti-VEGF. The majority (75%) of eyes previously treated with anti-VEGF were also on anti-VEGF post-index while receiving concomitant pegcetacoplan. Prior or current anti-VEGF treatment did not appear to impact pegcetacoplan treatment patterns.

SPONSORSHIP: Study funded by Apellis Pharmaceuticals

161 Retrospective comparative analysis of demographic and clinical profiles in pegcetacoplan-treated and untreated patients with geographic atrophy

Tobitt J[1], *Patel N*[2], *Sambhara D*[3], *Boucher N*[4], *Ishii F*[4], *Schwartz R*[1], *Enlow N*[1], *Kim A*[1], *Broderick k*[1], *Baumal C*[1], *Weng C*[5]; *jamie.tobitt@apellis.com*; *nimeshpatel300@gmail.com*
[1]*Apellis Pharmaceuticals*; [2]*Mass. Eye and Ear, Boston Children's Hospital*; [3]*Eye Clinic of Wisconsin*; [4]*Vestrum Health*; [5]*Baylor College of Medicine, Cullen Eye Institute*

BACKGROUND: Progression of age-related macular degeneration (AMD) can lead to either neovascular AMD (nAMD) and/or geographic atrophy (GA). Pegcetacoplan, the first approved treatment for GA, has limited real-world data on the patients receiving this therapy.

OBJECTIVE: To describe demographic and clinical characteristics of patients diagnosed with GA secondary to AMD who received pegcetacoplan in routine clinical practice.

METHODS: This retrospective observational study used the Vestrum Health Retinal Database, an electronic health record database from US-based retinal specialists, from January 2015 to July 2025. Demographic, clinical, and treatment characteristics were assessed among eyes diagnosed with GA that received ≥1 pegcetacoplan injections during the index period (02/17/2023–01/31/2025; treated cohort) and those that did not receive treatment (untreated cohort). The index date was date of first pegcetacoplan treatment or first visit during index period.

RESULTS: There were 11,152 eyes (8,178 patients) in the treated cohort and 79,105 eyes (53,953 patients) in the untreated cohort, and 12.4% of eyes received pegcetacoplan during the study period. Time between diagnosis and index date was similar between cohorts (median [IQR]: 278 [864] and 183 [1093] days, respectively). In the treated cohort, mean (SD) age was 82.0 (7.74) years, 67.2% were female, and 38.3% were current/former smokers—similar to the untreated cohort. Bilateral GA was less common in the treated cohort (36.4%) vs untreated (46.6%), and fewer treated eyes had neovascular AMD (31.1% vs 51.1%) at baseline. Common comorbidities included hypertension, cataracts, diabetes, and glaucoma. More treated eyes had GA involving the central retina (subfoveal region) (53.2% vs 33.8%); visual acuity (VA) was generally better at baseline among treated. In the treated cohort, the median (IQR) number of pegcetacoplan injections was 7 (2) over 12 months, with a median interval between pegcetacoplan injections of 57 (11) days. The median number of anti-VEGF injections remained consistent over time in the treated and untreated populations, including before and after

initiating pegcetacoplan for those who were previously on an anti-VEGF agent.

CONCLUSIONS: In this real-world comparison of treated and untreated patients with GA, those who received intravitreal pegcetacoplan had a lower rate of concurrent nAMD at baseline. However, receiving pegcetacoplan did not impact the number anti-VEGF injections received over time. These findings underscore the need for ongoing assessment of treatment patterns and clinical decision-making in managing GA.

SPONSORSHIP: Apellis

Gastrointestinal

169 Improving care in eosinophilic esophagitis: Managed care insights from a multistakeholder forum

Richardson T[1], *Dellon E*[2], *Bauer M*[3], *Gandolfi R*[4], *Kobernick M*[5], *Kheloussi S*[6], *Buechel B*[7], *Chang J*[8], *Strobel M*[9]; *terry.richardson@impactedu.net*
[1]*Impact Education, LLC*; [2]*Center for Esophageal Diseases and Swallowing, Division of Gastroenterology and Hepatology, Department of Medicine, University of North Carolina at Chapel Hill, Chapel Hill, NC, USA*; [3]*University of Colorado School of Medicine*; [4]*Select Health*; [5]*Blue Cross Blue Shield of Michigan*; [6]*Kheloussi Consulting, LLC*; [7]*Mayo Clinic*; *Alluma, LLC*; [8]*University of Michigan*; [9]*American Partnership for Eosinophilic Disorders (APFED)*

BACKGROUND: Eosinophilic esophagitis (EoE) is a chronic, immune-mediated disease. Despite two available FDA-approved therapies and updated clinical guidelines, variations in payer policies, diagnostic delays, and limited access to specialists continue to hinder optimal disease management. Managed care professionals are central to aligning coverage and care coordination strategies to improve timely diagnosis, equitable access to treatment, and adherence to evidence-based care.

OBJECTIVE: To identify payer-relevant challenges, knowledge gaps, and opportunities to improve access and quality of care for patients with EoE through structured discussions, real-time polling, and post-meeting survey findings.

METHODS: A national managed care forum brought together payers, gastroenterologists, allergists, and patient advocates to examine the evolving EoE treatment landscape and its implications for managed care. Topics included real-world diagnostic barriers, clinical application of 2025 treatment guidelines, and strategies to improve coordination among providers and payers. Quantitative polling explored payer intervention priorities, and a post-meeting survey measured intent to implement organizational change.

RESULTS: Polling revealed that top payer opportunities to improve care included initiating guideline-based therapy (88%), simplifying prior authorization and step-therapy requirements (72%), and enhancing the timeliness of referrals to specialists (63%) and the time to endoscopy and diagnosis (63%). Most anticipated that emerging clinical trial data and updated guidelines would increase preferred formulary status for FDA-approved agents (75%) and expand biologic coverage (25%). In the post-forum survey, respondents reported intent to implement or advocate for at least one policy or operational change, such as revising biologic coverage criteria, exploring reimbursement for nutrition services, and improving internal collaboration around EoE policy development.

CONCLUSIONS: Insights from this multistakeholder forum highlight the role of managed care in improving outcomes for patients with EoE. Aligning payer policies with current clinical evidence, simplifying utilization management processes, and strengthening multidisciplinary collaboration can meaningfully advance patient access, adherence, and long-term disease control.

SPONSORSHIP: Regeneron Pharmaceuticals, Inc, Sanofi, and Takeda Pharmaceuticals U.S.A., Inc.

170 Evaluating the access process for patients transitioning from intravenous to subcutaneous biologic administration for inflammatory bowel disease

Murray M[1], *Kissel T*[2], *DeClercq J*[3], *Zuckerman A*[1]; *miranda.z.kozlicki@vumc.org*
[1]*Vanderbilt Specialty Pharmacy*; [2]*Deaconess Specialty Pharmacy*; [3]*Vanderbilt University Medical Center*

BACKGROUND: Vedolizumab and infliximab were recently approved for subcutaneous (SC) administration for patients with inflammatory bowel disease (IBD), including Crohn's disease (CD) and Ulcerative Colitis (UC), providing a convenient option to administer medication at home instead of clinic-administered intravenous (IV) infusions. Research is needed to evaluate challenges associated with payers' and patients' uptake of vedolizumab and infliximab SC formulations.

OBJECTIVE: To evaluate the medication access process and outcomes for patients with IBD initiating SC vedolizumab or infliximab.

METHODS: A single-center, ambispective study evaluated patients with IBD with a referral to start or transition to SC vedolizumab or infliximab between September 1, 2023, and December 31, 2024. The primary outcome was time to SC

formulation access. Secondary outcomes included whether patients were approved for SC therapy, method of approval for SC formulation, and number of patients not starting SC maintenance therapy after referral. Multivariable regression analyses evaluated whether patients were approved to start SC (logistic regression) and time to approval for SC formulation (proportional odds [PO] logistic regression).

RESULTS: For the 262 included patients, median age was 44 years (Interquartile range [IQR] 34-56). Most patients were White (89%), female (55%) and had commercial prescription insurance (84%). Diagnoses included CD (53%) and UC (47%) with a median disease duration of 14 years (IQR 7-23). Most referrals were for vedolizumab (81%), and were established on IV therapy (87%). Of the 248 patients included in the regression analyses, most patients (n = 179, 72%) referred to SC were approved; over half of those approvals occurring via prior authorization (56%). Of the 179 patients approved for SC, 21% of patients did not start (n=38/179), largely due to patient decision (45%, n =17/38). Median time to access was 11 days (IQR 1-43) with a range of 0 to 457 days. Patients with commercial pharmacy insurance were 3 times more likely to have a longer time to medication access (odds ratio [OR]: 3.0, 95% confidence interval [CI]: 1.5-6.1, p=0.003). Patients not in remission at baseline were 90% more likely to have a longer time to medication access than patients in remission (OR: 1.9, 95% CI 0.8-4.2, p=0.127).

CONCLUSIONS: Many patients prescribed SC vedolizumab or infliximab do not start due to payer restrictions or patient preference. Patients with commercial insurance may be less likely to access SC therapy.

SPONSORSHIP: None

171 Factors associated with the highest costs among US adults with primary biliary cholangitis

Wong R[1], *Gish R*[2], *Fadli E*[3], *Gomez Rey G*[4], *Rock M*[5], *Leung G*[5], *Agapova M*[5], *Kim C*[5]; *rwong123@stanford.edu*; *maria.agapova@gilead.com*; *Chong.Kim9@gilead.com*
[1]*Division of Gastroenterology and Hepatology, Stanford University School of Medicine*; [2]*Hepatitis B Foundation, Doylestown, PA University of Nevada, Kirk Kerkorian School of Medicine at UNLV, Las Vegas, USA*; [3]*Gilead*; [4]*Gilead Sciences*; [5]*Gilead Sciences, Inc., Foster City, CA, USA*

BACKGROUND: Primary biliary cholangitis (PBC) is a cholestatic liver disease characterised by progressive destruction of intrahepatic bile ducts.

OBJECTIVE: To evaluate factors associated with the highest costs in PBC.

METHODS: This observational, retrospective cohort study used data from the US HealthVerity database between 01/01/2016 and 30/06/2024 to identify adults diagnosed with PBC (≥1 inpatient or ≥2 outpatient claims [≥30 days apart] with an ICD-10-CM code of K74.3) and continuous health plan enrolment for ≥12 months pre- and post-index (defined as date of first claim with PBC diagnosis). All-cause costs (in 2024 US dollars) were calculated using total allowable charges from medical and pharmacy claims. Multivariable logistic regression was used to evaluate demographic and clinical factors associated with patients in the upper quartile (UQ; top 25th percentile of costs) cohort vs those in the non-UQ (NUQ) cohort.

RESULTS: In total, 9134 patients were identified, with mean (SD) age of 55 (14) years; most were female (82%) and commercially insured (50%), with median (IQR) 1-year, all-cause costs of $15,523 ($6,165–$41,882). In the UQ cohort (n=2283), fewer were female (74%) or commercially insured (40%), with median (IQR) 1-year, all-cause costs 8 times higher than in the NUQ: $82,799 ($57,275–$137,614) vs $9,908 ($4,731–$19,618), respectively. Presence of anaemia (UQ = 71%; NUQ = 26%), cardiovascular disease (CVD; UQ=62%; NUQ = 25%), rheumatoid arthritis (RA; UQ = 13%; NUQ = 6%), and inflammatory bowel disease (IBD; UQ = 12%; NUQ = 4%) were more common among patients in the UQ cohort than among those in the NUQ cohort. Hepatocellular carcinoma, RA, CVD, IBD, liver transplantation, anaemia, and decompensated cirrhosis increased the odds of being in the UQ cohort by 194%, 158%, 119%, 119%, 117%, 106%, and 102%, respectively.

CONCLUSIONS: Among the demographic and clinical characteristics evaluated, comorbidities were most strongly associated with the highest costs in PBC, suggesting that opportunities to contain costs in PBC may include concurrent optimization of PBC treatment with treatment of RA, IBD, CVD, and anaemia. Decompensated cirrhosis and liver transplantation emerged as costly consequences of PBC, highlighting the value of slowing disease progression.

SPONSORSHIP: Gilead Sciences, Inc.

172 Treatment persistence of first- and second-line advanced therapies in adults with ulcerative colitis using US claims data

Brown J[1], *Si Z*[2], *Zhao W*[2], *Chen Y*[2], *Friderici J*[2], *Munshi K*[3], *Gravlee E*[4], *Muller B*[1], *Wojtowicz A*[1], *Afzali A*[5]; *joshua.brown@takeda.com*; *ben.muller@takeda.com*
[1]*Takeda Pharmaceuticals U.S.A., Inc., Cambridge, MA, USA*; [2]*KMK Consulting Inc., Morristown, NJ, USA*; [3]*Takeda Pharmaceuticals U.S.A., Inc., Cambridge, MA, USA.* *Affiliation at the time of the study.*; [4]*Alfred E. Mann School of Pharmacy and Pharmaceutical Sciences, University of Southern California, Los Angeles, CA, USA*; [5]*University of Cincinnati College of Medicine, Cincinnati, OH, USA*

BACKGROUND: Several advanced therapies (ATs) are approved for the treatment of moderate-to-severe ulcerative colitis (UC) but clinical uncertainty remains around optimal treatment sequencing.

OBJECTIVE: To evaluate the distribution and treatment persistence of first-line (1L) and second-line (2L) ATs in patients with moderate-to-severe UC.

METHODS: This retrospective cohort study of adults with UC initiating 1L AT used claims data from the Optum's de-identified Clinformatics® Data Mart Database. The index date was the first claim for an AT during the identification period (Jan 1, 2020, to Mar 31, 2024). Baseline and follow-up were variable periods of continuous enrollment in medical and pharmacy benefits of ≥730 days before and ≥180 days after the index date, respectively. Baseline characteristics and the distribution of 1L and 2L ATs were summarized with descriptive statistics. Median time to discontinuation (time from AT initiation to therapy end date, switching, end of continuous enrollment, or study end date) was estimated by Kaplan–Meier analysis with 95% confidence intervals (CIs).

RESULTS: Of 2,719 included patients, 50.7% were male and the mean (standard deviation [SD]) age was 52.5 (19.0) years. Most (65.2%) had commercial insurance. Mean (SD) Charlson Comorbidity Index and UC severity scores were 1.9 (2.5) and 10.9 (6.7), respectively. The most prescribed 1L AT was vedolizumab (39.5%, n = 1,073), followed by adalimumab (23.8%, n = 646), infliximab (22.3%, n = 605), ustekinumab (10.8%, n = 293), upadacitinib (1.1%, n = 31), tofacitinib (1.1%, n = 30), ozanimod (1.1%, n = 30), and golimumab (0.4%, n = 11). 2L AT was not observed for most patients (76.4%, n = 2,078). For patients who received 2L AT, vedolizumab was most commonly prescribed (25.0%, n = 160), followed by infliximab (22.2%, n = 142), ustekinumab (21.4%, n = 137), upadacitinib (14.7%, n = 94), adalimumab (6.1%, n = 39), combination AT (4.2%, n = 27), tofacitinib (3.4%, n = 22), ozanimod (1.9%, n = 12), golimumab (0.9%, n = 6), and mirikizumab (n < 5). Median time to discontinuation of 1L AT was longest for vedolizumab (902 days [95% CI, 793–1,013]), followed by ustekinumab (692 days [95% CI, 520–not reached]). As a 2L AT, median time to discontinuation was longest for golimumab (1,150 days [95% CI, 506–not reached]) and shortest for adalimumab (312 days [95% CI, 185–451]).

CONCLUSIONS: As a 1L AT, treatment persistence was higher for vedolizumab than other ATs. As therapeutic options for UC evolve, real-world data may help determine optimal sequencing to improve patient outcomes.

SPONSORSHIP: Takeda Pharmaceuticals U.S.A., Inc.

173 Comparison of budesonide oral suspension and off-label corticosteroids for eosinophilic esophagitis: A structured literature review

Gonsalves N[1], *Khankhel Z*[2], *Wada K*[2], *Goodwin B*[3], *Liu Y*[3], *Schaeffer-Koziol C*[3], *Terreri B*[3], *Wechsler J*[4]; *n-gonsalves@northwestern.edu*; *bridgett.goodwin@takeda.com*
[1]*Kenneth C. Griffin Esophageal Center, Division of Gastroenterology and Hepatology, Department of Medicine, Northwestern University Feinberg School of Medicine, Chicago, IL, USA*; [2]*Genesis Research Group, Hoboken, NJ, USA*; [3]*Takeda Pharmaceuticals USA, Inc., Lexington, MA, USA*; [4]*Division of Gastroenterology, Hepatology, and Nutrition, Department of Pediatrics, Ann & Robert H. Lurie Children's Hospital of Chicago, Chicago, IL, USA*

BACKGROUND: Off-label corticosteroids are used to treat eosinophilic esophagitis (EoE), but they are not intended for esophageal delivery and may result in suboptimal outcomes. Eohilia (budesonide oral suspension [BOS]) 2.0 mg twice daily (b.i.d.) is the first US Food and Drug Administration (FDA)-approved swallowed corticosteroid for EoE and is indicated for the 12-week treatment of patients aged ≥11 years.

OBJECTIVE: To evaluate the quality of clinical evidence from randomized clinical trials (RCTs) of BOS compared with off-label corticosteroids for the treatment of EoE in the USA, and to assess the feasibility of an indirect treatment comparison (ITC).

METHODS: A structured literature search of the Cochrane Library and ClinicalTrials.gov was conducted to identify RCTs assessing the efficacy and safety of BOS or off-label corticosteroids versus other off-label corticosteroids or placebo in patients with EoE. The feasibility of ITC (e.g., matching-adjusted, network meta-analysis, or population-adjusted methods) was assessed by comparing each RCT with a reference RCT (SHP621-301/NCT02605837); this multicenter, double blind, placebo controlled, phase 3 RCT examined the efficacy and safety of BOS in 318 patients with EoE

(aged 11–55 years) who received BOS 2.0 mg b.i.d. or placebo for 12 weeks.

RESULTS: In total, eight RCTs reporting data for off-label corticosteroids for EoE were identified; two were multicenter, three had a treatment duration of ≥12 weeks, and only one enrolled ≥50 patients. Most RCTs were double blind and placebo controlled (six studies); three enrolled both pediatric (aged <11 years) and adolescent/adult patients (aged ≥11 years). The off-label corticosteroids investigated were beclomethasone dipropionate, fluticasone/fluticasone propionate, and oral viscous budesonide. The FDA-recommended stringent histologic response (≤6 eosinophils per high-power field) used in SHP621-301 was used in five RCTs. Symptom tools were validated in three studies, and only one RCT reported a minimal clinically important difference (MCID) for symptom response. Relevant safety outcomes (i.e., adrenal monitoring and reporting of candidiasis) were assessed in only two RCTs.

CONCLUSIONS: These findings suggest evidence for the use of off-label corticosteroids in EoE is of low quality (e.g., small sample size, short duration, single-center) and would be insufficient for an ITC with BOS. Data supporting the efficacy and safety of BOS are of higher quality than that for off-label corticosteroids.

SPONSORSHIP: Takeda Pharmaceuticals USA, Inc.

174 Development of a systematic ulcerative colitis and Crohn's disease informatics clinical toolkit to identify characteristics of patients eligible for advanced therapies in inflammatory bowel disease (SUCCINCT)

Faubion W[1], *Rangarajan N*[2], *Manoharan M*[2], *Aman A*[2], *Carlson K*[3], *Wagner T*[3], *Maron J*[2], *Barman H*[3], *Young L*[4], *Sanchirico M*[4], *Null K*[4]; *faubion.william@mayo.edu*; *kyle.null@takeda.com*

[1]*Division of Gastroenterology and Hepatology, Mayo Clinic, Rochester, MN, USA;* [2]*nference Inc., Cambridge, MA, USA;* [3]*nference Inc., Cambridge, MA, USA.* *Affiliation at the time of the study.;* [4]*Takeda Pharmaceuticals U.S.A., Inc., Cambridge, MA, USA*

BACKGROUND: Determining which patients with moderate to severe Crohn's disease (CD) or ulcerative colitis (UC) may benefit from advanced therapies (ATs) can be challenging. Clinical tools that aid decision-making for the initiation of ATs may ensure timely, appropriate treatment to improve clinical outcomes.

OBJECTIVE: To train and test machine learning (ML) models to classify patients with CD or UC into AT-treated or AT-untreated cohorts based on clinical variables.

METHODS: This retrospective study used de-identified electronic health record (EHR) data from patients aged <89 years with CD or UC, treated in the Mayo Clinic system. The AT-treated and AT-untreated cohorts included patients with ≥1 administration of an AT or a non-AT medication, respectively, between November 1, 2015, and November 1, 2023. The feature space for characterization of AT-treated and AT-untreated cohorts included patient demographics, symptoms, endoscopic findings, disease location and activity, medication, healthcare encounters, surgeries, orders for, and results of, laboratory tests, and unstructured clinical notes. A self-supervised ML model using structured data (ConVIRT) and supervised ML models using structured and unstructured data (logistic regression, XGBoost, random forest) were trained and tested using a 60/20/20 training/validation/test split. Model performance was assessed by evaluation metrics including area under the curve (AUC), and the top predictive features for the AT-treated cohorts were extracted.

RESULTS: Supervised models outperformed the self-supervised ConVIRT model in distinguishing AT-treated from AT-untreated patients (AUC: logistic regression, CD = 0.839, UC = 0.807; random forest, CD = 0.832, UC = 0.838; ConVIRT, CD = 0.797, UC = 0.780). The supervised XGBoost model was the best performing model (CD, AUC = 0.903, specificity = 0.880, sensitivity = 0.926; UC, AUC = 0.869, specificity = 0.905, sensitivity = 0.833). The top predictive features contributing to the AT-treated label in the XGBoost CD model were prescriptions of immunomodulators and 5-aminosalicylic acid, number of unique medication class es, microbiology orders, and age. For the XGBoost UC model, these top predictive features were prescriptions of immunomodulators and prednisolone, number of orders, number of unique medication classes, and C-reactive protein levels.

CONCLUSIONS: ML models trained on clinical variables from EHR data can accurately classify AT-treated and AT-untreated patients. Such models have the potential to aid clinical decision-making for initiation of ATs in patients with CD or UC.

SPONSORSHIP: Takeda Pharmaceuticals U.S.A., Inc.

175 Clinical landscape in human epidermal growth factor receptor 2-positive (HER2+) gastroesophageal adenocarcinoma (GEA): A targeted review

Bridgewater J[1], *Su W*[2], *Sabater J*[2], *Bowditch S*[2], *Smith M*[3], *Lin J*[2], *Ku G*[4], *Ko A*[5]; *j.bridgewater@ucl.ac.uk*; *wayne.su@jazzpharma.com*
[1]*UCL Cancer Institute*; [2]*Jazz Pharmaceuticals*; [3]*Lumanity*; [4]*Memorial Sloan Kettering Cancer Center*; [5]*University of California*

BACKGROUND: GEA includes adenocarcinomas of the stomach (gastric; GC), esophagus (EC), and esophagogastric junction (GEJ).

OBJECTIVE: A targeted review was conducted in the first-line (1L) HER2+ GEA setting to identify treatments and genomic testing recommended by clinical guidelines, the clinical trial landscape, and patient management considerations.

METHODS: MEDLINE®, Trip, WHO, GIN, and NCCN® databases were searched between 2018 and 2023. Pre-specified selection criteria included quality of research, priority countries (EU4, Japan, UK, US), and extent of focus on research questions. Supplementary hand-searches and a review of clinicaltrials.gov supported findings.

RESULTS: Seven clinical guidelines were included from ESMO, NCCN, NICE and the Japanese GC Association and Esophageal Society, for GC and EC/GEJ separately except for NICE. All guidelines recommended genomic testing for HER2, PD-L1 and MSI/MMR. ESMO, NCCN and NICE specify HER2 testing to guide 1L GEA treatment decisions. For 1L HER2+ GEA, trastuzumab with platinum/fluoropyrimidine chemotherapy is recommended as standard care (with pembrolizumab add-on for PD-L1 subgroup in NCCN guidelines). There are no other recommended 1L HER2-targeted therapies; trastuzumab deruxtecan (T-DXd) is recommended in 2L+. Six HER2-targeted therapies are currently being evaluated in ≥3 trials, either as monotherapy or combination: trastuzumab, T-DXd, disitamab vedotin, zanidatamab, pertuzumab, and tucatinib. Patient management considerations include variation in concordance rates for HER2 status between next-generation sequencing and circulating tumour DNA or tumour tissue (60-90%). Temporal and spatial variations of HER2 expression should also be considered in relation to resistance to HER2-targeted therapies.

CONCLUSIONS: Despite an active clinical trial development landscape, there are limited recommended treatment options for HER2+ GEA. Trastuzumab and T-DXd are the only HER2-targeted therapies recommended in 1L and 2L+, respectively. There is a lack of consistency across guidelines and regions for the PD-L1 subgroup treatment. This review summarizes a few key considerations to help oncologists refine treatment planning in clinical practice.

SPONSORSHIP: Jazz Pharmaceuticals, Lumanity Inc

176 Predictive modeling for IBD flares: AI-driven insights from claims and EHR data to improve early detection and optimize disease management

Gupta A[1], *Verma V*[1], *Roy A*[1], *Nayyar A*[1], *Arora A*[1], *Khatavkar V*[1], *Bhatia U*[1], *Mishra R*[1], *Markan R*[2], *Wajih S*[1], *Bhardwaj P*[1], *Brooks L*[3], *Seligman M*[3], *Heath K*[4]; *anuj_gupta457@optum.com*; *vikash.verma@optum.com*; *abhimanyu.roy@optum.com*; *abhinav.nayyar@optum.com*; *ankitkumar_arora@optum.com*; *vishan_khatavkar@optum.com*
[1]*Optum Inc.*; [2]*Optum Inc*; [3]*OptumInsight*; [4]*Optum*

BACKGROUND: Inflammatory Bowel Disease (IBD) is a chronic, relapsing condition characterized by unpredictable flares that impair quality of life and drive healthcare utilization. Due to disease heterogeneity, predicting flare onset remains a clinical challenge. Early identification of patients at risk for flares can enable timely intervention and improve outcomes.

OBJECTIVE: This study leverages artificial intelligence (AI) applied to claims and electronic health record (EHR) data to identify early indicators of IBD flares, enabling proactive, data-informed disease management.

METHODS: Adults aged ≥18 years with a diagnosis of IBD were identified from the Optum® Market Clarity database between January 1, 2022, and June 30, 2024. Index event was defined as the first diagnosis of IBD. Inclusion required continuous eligibility for 12 months pre- and 6 months post-index. Flares were defined as (a) inpatient or emergency department visits with initiation of intravenous corticosteroids or biologics, or (b) outpatient visits with a new oral corticosteroid prescription within ±7 days. Patients with other chronic gastrointestinal conditions, malignancy, organ transplant, or baseline flares were excluded. These patients were matched with control cohort having no IBD diagnosis via propensity score matching (1:1) using age, gender, ethnicity, and Charlson Comorbidity Index. Three ML models, Random Forest, XGBoost, and Logistic Regression (LR), were trained and evaluated

RESULTS: Of 10,985 initial patients, 2,097 (19.1%) met inclusion criteria, and after 1:1 propensity score matching, the final cohort comprised 4,180 patients (2,090 IBD cases; 2,090 controls). Among three evaluated ML models, the LR model demonstrated the highest predictive performance and interpretability. It achieved good discriminative ability with an area under the receiver operating characteristic curve (ROC AUC) of 0.7244 (95% CI: 0.7091–0.7397). Among

healthcare utilization variables, inpatient visits, IBD-related clinic visits, and outpatient visit ($p<0.0001$) emerged as strong predictors, indicating that higher healthcare engagement correlates with increasing likelihood of IBD. Among demographic predictors, female gender was significantly associated with higher odds of IBD diagnosis ($p=0.0445$).

CONCLUSIONS: The model showed strong performance and supports AI-driven approaches for early flare detection. Future enhancements will incorporate symptom-level data (e.g., abdominal pain, tenesmus, fatigue) to improve predictive precision and clinical utility.

SPONSORSHIP: None

Health Disparities/Equity

180 The impact of social determinants of health on access barriers and health outcomes in sickle cell disease from the US payer perspective

Moon J[1], *Chamberlain C*[1], *Shih V*[1], *Yates A*[1], *Davis J*[1], *Harris A*[2], *Jarvis J*[3], *Steward C*[3], *Stone M*[3], *Akkas B*[3]; *jungyoon.moon@agios.com*
[1]*Agios Pharmaceuticals, Inc.*; [2]*Sickle Cell Association of Houston*; [3]*Medicus Economics LLC*

BACKGROUND: Recent initiatives from the Centers for Medicare & Medicaid Services (CMS), including the 2023 CMS SCD (sickle cell disease) Action Plan, seek to combat the impacts of social determinants of health (SDoH) in SCD, a disease affecting primarily Black or African American and Hispanic or Latino individuals. However, significant challenges remain in overcoming SDoH in SCD and alleviating health disparities experienced by individuals with SCD.

OBJECTIVE: To understand US payer perspectives on SDoH and their impacts on SCD.

METHODS: In-depth interviews were conducted with 10 US Commercial or Medicaid payer decision-makers, focusing on managed and traditional Medicaid lives. Payers rated the level of priority and/or impact (scale 1–7; 7 indicated highest priority/impact) attributed to specific SDoH in SCD, issues with access to care/treatment, and patient outcomes.

RESULTS: Payers showed high awareness of the links between SDoH in SCD, suboptimal access to SCD-specific healthcare, and worse health outcomes. Multiple SDoH were perceived as having a high impact on care/treatment access and overall health outcomes in SCD, most notably healthcare system (average: 6.2), neighborhood or physical environment (5.9), and community, safety, and social context (5.9). Most care and treatment access barriers were viewed as highly impactful to SCD health outcomes, especially access to specialists (6.1), pain management medications (5.8), and disease-modifying treatments (DMTs; 5.7). Patient outcomes prioritized by payers were the reduction of emergency room visits (6.0) and hospitalizations (5.5), along with the need for improved daily chronic pain management (5.6), which mitigates avoidable healthcare resource use. More specifically, payers acknowledged that reducing high-cost vaso-occlusive crises requires comprehensive disease management supported by therapies that not only are more effective than the standard of care but also minimize barriers to adherence and offer broader accessibility compared to gene therapies. Payers identified opportunities to address SDoH and their downstream impacts: SCD-specific education for providers, patients, and payers; innovative DMTs to resolve significant gaps in the SCD treatment landscape; and use of SDoH data to proactively inform access initiatives/policies.

CONCLUSIONS: US payer perspectives on SDoH and their impacts on SCD highlighted treatment access barriers and suboptimal care and health outcomes. Opportunities to combat SDoH in SCD include expanded treatment options, disease education, and access programs driven by analyses of SDoH data.

SPONSORSHIP: Agios Pharmaceuticals, Inc.

181 Influence of social determinants of health on advanced therapy initiation in patients with inflammatory bowel diseases in the US

Brown J[1], *Sindaco M*[2], *Munshi K*[3], *Imeri H*[4], *Gravlee E*[5], *Barfield E*[4], *Siegel C*[6]; *joshua.brown@takeda.com*; *hyllore.imeri@takeda.com*
[1]*Takeda Pharmaceuticals U.S.A., Inc., Cambridge, MA, USA*; [2]*Cobbs Creek Healthcare, Newtown Square, PA 19073, USA*; [3]*Takeda Pharmaceuticals U.S.A., Inc., Cambridge, MA 02142, USA.* *Affiliation at the time of the study.*; [4]*Takeda Pharmaceuticals U.S.A., Inc., Cambridge, MA 02142, USA*; [5]*Alfred E. Mann School of Pharmacy and Pharmaceutical Sciences, University of Southern California, Los Angeles, CA, USA*; [6]*Walter and Carole Young Center for Digestive Health, Dartmouth Hitchcock Medical Center, The Dartmouth Institute for Health Policy and Clinical Practice, Geisel School of Medicine at Dartmouth, Lebanon, NH 03755-1404, USA*

BACKGROUND: Advanced therapies (AT) are effective for the treatment of Crohn's disease (CD) and ulcerative colitis (UC) but there are limited data on how health inequities and social determinants of health (SDOH) may influence AT initiation in patients in the US.

OBJECTIVE: This retrospective, observational study evaluated differences in AT initiation between patients living in rural or urban settings and the association between AT initiation and

SDOH over 5 key domains defined by the Healthy People 2030 SDOH framework.

METHODS: Real-world healthcare data were used from the Inovalon payer closed claims database, including medical and pharmacy data for >80 million people in the US, and individual-level health data from the LexisNexis Socioeconomic Health Attributes database, including >400 data elements on SDOH. Patients identified between January 1, 2019, and March 31, 2023, who were aged ≥18 years, were newly diagnosed with CD or UC (≥1 medical claim with a CD/UC ICD-10 code), and had ≥12 months of continuous health insurance before the index date for diagnosis were eligible. Kaplan–Meier analyses were used to determine time to AT initiation among patients with CD or UC who lived in rural or urban areas. Cox proportional hazard models were used to analyze SDOH associated with AT initiation.

RESULTS: Baseline disease characteristics were similar for patients in rural and urban areas; a greater proportion of rural patients with CD or UC were white. For CD, 13.2% of rural patients initiated an AT with a mean (standard deviation) time to initiation of 6.4 (8.1) months; 14.3% of urban patients initiated an AT with a time to initiation of 6.9 (8.7) months. For UC, 4.5% of rural patients and 4.7% of urban patients initiated an AT with time to initiation of 8.7 (9.8) months and 9.3 (10.3) months, respectively. There was a significant difference in time to AT initiation between rural and urban patients for CD ($p = 0.0108$) but not UC ($p = 0.4842$). Being female, Hispanic/Latino, and not having commercial insurance were associated with lower AT initiation in patients with CD. Being a property owner was associated with higher AT initiation. Similar findings were observed for patients with UC.

CONCLUSIONS: After 4.2 years of follow-up, we found low combined AT initiation rates of 14.1% and 4.7% for patients with CD or UC, respectively. Only small differences in AT initiation were observed between rural and urban settings, but some SDOH were associated with differences in AT initiation.

SPONSORSHIP: Takeda Pharmaceuticals U.S.A., Inc.

182 Identifying unmet health-related social needs (HRSNs) among Medicare Advantage (MA) enrollees with systemic lupus erythematosus (SLE) to optimize care

Haq S[1], *Daviano A*[1], *Nadipelli V*[2], *Xu Y*[1], *Worley K*[2], *Ohioma J*[3], *Ellis J*[2], *Suehs B*[1], *Lim S*[4]; *shaq4@humana.com*; *adaviano@humana.com*
[1]*Humana Healthcare Research, Inc.*; [2]*Global Real-World Evidence & Health Outcomes Research, GSK*; [3]*US Medical Affairs, GSK*; [4]*Emory University School of Medicine*

BACKGROUND: SLE is a complex condition associated with high disease and economic burden; economic insecurities and social vulnerability may impact health outcomes. Previously we described real-world social determinants of health for MA enrollees with SLE using community-level data; however, self-reported HRSN data (social/economic factors that impact patient health) are lacking for this population.

OBJECTIVE: To evaluate self-reported HRSNs and their relationship with health outcomes in an MA population.

METHODS: Humana MA enrollees aged 18–89 years with SLE and continuous enrollment during 2023 were included (GSK Study 222168; retrospective analysis). Medical claims with SLE diagnoses (≥1 in 2023 and ≥1 in 2016–2022) were used to identify eligible enrollees and to assess disease burden. HRSN burden from 5 domains (scored 0–5) was captured from a large, national survey of MA enrollees to identify the presence of HRSN. Dual eligibility, low-income status, and disability status from enrollment files established CMS Excellent Health Outcomes for All (EHO4All) eligibility. Analyses were descriptive.

RESULTS: Patients who completed the HRSN survey (n=615) were older (mean age: 67.3 vs 63.7 years), more likely to identify as Black (37% vs 31%), and had longer continuous enrollment (mean: 55.6 vs 48.4 months) and time since first observed SLE diagnosis (mean: 44.5 vs 38.7 months) than non-completers (n=19,573). Self-reported HRSN burden (unadjusted for demographic differences) was high (73% with ≥1 need; 20% with ≥3 needs). Prevalence of need was highest for financial strain (65%) and food insecurity (50%), then transportation (16%), loneliness (13%), and housing insecurity (8%). Most patients (71%) met EHO4All eligibility, increasing with rising HRSN burden (0 HRSN: 44%; ≥3 HRSNs: 91%). A higher HRSN burden correlated with increased prevalence of comorbidities based on ≥1 inpatient or ≥2 outpatient claims ≥30 days apart, i.e., depression (34% vs 19%), pulmonary disease (34% vs 25%), and myalgia (34% vs 16%) (HRSN score: ≥3 vs 0, respectively).

CONCLUSIONS: Our findings offer a patient perspective of the significant intersection between social risk factors and

disease burden among MA enrollees with SLE based on their lived experience. EHO4All criteria was confirmed as a practical signal for identifying those who may benefit from deeper assessments and targeted interventions. Innovative care programs that address the challenges faced by vulnerable patients, and encourage integrated clinical, social, and behavioral healthcare, could improve outcomes.

SPONSORSHIP: GSK

183 Trends in distance to the nearest community pharmacy among PACE beneficiaries in Pennsylvania, 2022-2025

Khan S[1], *Rubertone J*[2], *Heller D*[1], *Latty L*[1], *Brown T*[3]; *shivani.khan@primetherapeutics.com*
[1]*Prime Therapeutics*; [2]*Pennsylvania Department of Aging | Bureau of Pharmaceutical Assistance*; [3]*Pennsylvania Department of Aging, Bureau of Pharmaceutical Assistance*

BACKGROUND: Access to community pharmacies plays a critical role in medication adherence and health outcomes, particularly among older adults. Recent pharmacy closures may have increased travel distances for patients.

OBJECTIVE: To examine trends in the average distance to the nearest community pharmacy among beneficiaries of Pennsylvania's Pharmaceutical Assistance Contract for the Elderly (PACE) program from 2022 to 2025 and evaluate urban-rural differences over time.

METHODS: Using annual PACE enrollment and pharmacy datasets from 2022-2025, we geocoded addresses for cardholders and community pharmacies. For each enrollee (2022: n=181,940; 2023: n=203,722; 2024: n=183,880; 2025: n=161,046), the straight-line distance to the nearest community pharmacy was calculated. Adjusted mean distances were estimated using PROC GLM including main effects of year and county group (urban vs rural) and their interaction, controlling for age group, sex, race, and marital status. Type III tests of fixed effects evaluated the significance of predictors, and least squares means (LS-means) provided adjusted mean distances with 95% confidence intervals (CIs).

RESULTS: Year ($p<.001$), county group ($p<.001$), and the year and county group interaction ($p<.001$) were all significant, indicating that both average distance and its change over time differed by urban-rural status. The adjusted mean distance to the nearest community pharmacy increased modestly from 1.66 miles (95% CI: 1.65, 1.68) in 2022 to 1.77 miles (95% CI: 1.76, 1.79) in 2025. Rural residents consistently lived farther from pharmacies than urban residents, with rural distances averaging 1.6 miles greater across all years. From 2022 to 2025, rural distances increased from 2.46 to 2.64 miles, while the urban distances rose slightly from 0.86 to 0.92 miles. The urban-rural gap widened from 1.60 to 1.72 miles by 2025.

CONCLUSIONS: From 2022 to 2025, PACE beneficiaries faced a gradual increase in distance to the nearest community pharmacy, with more evident effects in rural areas. The widening of urban-rural disparity highlights growing challenges in pharmacy access for rural older adults and underscores the need for strategies to maintain equal access to pharmacy services across Pennsylvania.

SPONSORSHIP: None

184 Evaluating the state-level economic and clinical returns of increased oral pre-exposure prophylaxis uptake in the general population and among MSM

Copeland C[1], *Coaquira Castro J*[2], *Connolly M*[3], *Hsiao A*[2], *Class J*[2], *Sullivan P*[4]; *cillian@gmasoln.com*; *JeanPierre.Coaquira@gilead.com*
[1]*Global Market Access Solutions Sàrl, Chardonne, Switzerland*; [2]*Gilead Sciences, Inc., Foster City, California, United States*; [3]*Global Market Access Solutions, Mooresville, North Carolina, United States*; [4]*Emory University, Atlanta, Georgia, United States*

BACKGROUND: Pre-exposure prophylaxis (PrEP) is a key strategy in ending the HIV epidemic (EHE), yet uptake remains suboptimal and disproportionate across US states. The EHE plan centers on local support to 50 priority areas where more than half of new HIV diagnoses occur. This study explores the potential state level impact of different patterns of oral PrEP uptake on HIV diagnosis rates and healthcare costs. These data are essential to inform state level allocation and policy decisions.

OBJECTIVE: To assess the impact of changes in oral PrEP uptake on cumulative HIV infections and the subsequent economic implications at the national and state level in the US over 10 years.

METHODS: A Markov model, previously published by Massey et al. (2023), was adapted to explore the impact of augmenting oral PrEP uptake. Cumulative HIV infections over a 10-year horizon were compared between two scenarios: one where current rates of PrEP uptake were kept constant and a counterfactual scenario where relative PrEP uptake was increased by 1% annually. The efficacy of PrEP was assumed constant, and costs were calculated based on a weighted average of oral PrEP products. Each averted HIV case was valued based on the lifetime excess healthcare costs of a person with HIV. The analysis considered two populations: the general US population and the subgroup of men who have sex with men (MSM).

RESULTS: Results were generated for the general US population both nationally and by state, with a particular focus on the seven states prioritized by the EHE initiative. At a national level, 2,667 HIV cases were averted and for every additional $1 spent on PrEP, $1.89 was returned. The savings from avoided lifetime costs of HIV infections was estimated to be $1.37 billion and $825 million among the general population and the MSM subgroup, respectively. Among the seven EHE priority states, positive trends were observed, with benefit cost ratios (BCRs) between 1.80 and 6.19. Among the MSM subgroup, similar results were found, with 1,448 HIV cases averted and a BCR of 1.87 calculated at a national level.

CONCLUSIONS: This analysis demonstrated significant state-level reductions in new cases of HIV and subsequent long-term health-related cost savings with even a minimal increased uptake of oral PrEP. While not limited to EHE areas, states with higher HIV incidence and burden realize the greatest returns, demonstrating that targeted investment in PrEP can yield substantial fiscal and public health gains in underserved geographies.

SPONSORSHIP: Gilead Sciences, Inc.

Health Policy

192 Impact of the Illinois biomarker testing law on utilization in advanced non-small cell lung cancer (aNSCLC) and metastatic colorectal cancer (mCRC) patients

Ko S, To T, Wong W; koy3@gene.com
Genentech

BACKGROUND: Recently, some states have enacted legislation to expand insurance coverage of biomarker testing. However, the impact of these laws on improving access to testing remains unknown. Illinois (IL), the first state to implement a law on Jan 1, 2022, may offer insights into how state policy can shape patient access.

OBJECTIVE: To determine whether the implementation of a new biomarker testing coverage law in IL had a significant impact on the utilization rates of testing in patients with advanced non–small cell lung cancer (aNSCLC) or metastatic colorectal cancer (mCRC).

METHODS: A retrospective analysis of medical and pharmacy claims was conducted using the IQVIA PharMetrics Plus closed health plan claims database to evaluate trends in upfront biomarker testing by health plan type in IL. Patients who had an initial diagnosis (defined as index date) of aNSCLC or mCRC from Jul 1, 2020, to Jun 30, 2023, with follow-up to assess quarterly testing through Sep 30, 2023, were included. Patients were categorized into those who had any upfront testing (+/- 90 days of index) and those who had no upfront testing. Interrupted time series analysis was used to compare the patients with state-regulated (fully insured [FI] or Medicaid) versus federally regulated self-funded plans (SF).

RESULTS: A total of 1,122 patients were included across three plan types: SF (N=515), FI (N=436), and Medicaid (N=171). 53.4% of patients were diagnosed with mCRC and 46.6% with aNSCLC. The overall use of any biomarker testing increased from 79.2% to 89.7%, and multi-gene panel testing (MGPT) from 16.4% to 28.1%. The effect of the legislation resulted in additional 1.6 times greater odds in any upfront testing for FI/Medicaid plans (vs SF plans, OR=1.59, [95% CI: 1.10, 2.33], p=0.015). The effect of the legislation also resulted in an additional 1.6 times greater odds in any MGPT for FI/Medicaid plans (vs SF plans, OR=1.61, [95% CI: 1.15, 2.26], p=0.006). However, a gap in MGPT use remained at the end of the study period, with SF plans having a 20.2 percentage point greater difference in MGPT use compared to FI/Medicaid plans.

CONCLUSIONS: The IL law significantly increased access to upfront biomarker testing for aNSCLC and mCRC patients, with the effect of the legislation having an additional 1.6 times greater odds of any testing for FI/Medicaid patients compared to SF. While the law also improved the use of upfront MGPT, the disparity in use between SF and FI/Medicaid was still present. Thus, further action is needed to ensure equal access to all biomarker tests.

SPONSORSHIP: Genentech, Inc

193 Return on investment of reducing out-of-pocket costs for oral PrEP in high-incidence US populations

Ayer T[1], Coaquira Castro J[2], Gursel E[3], Hsiao A[2], Zachry W[2], Kocak I[3], Sullivan P[4]; tayer@valueanalyticslabs.com; JeanPierre.Coaquira@gilead.com
[1]*Value Analytics Labs, Boston, Massachusetts, United States; and Georgia Institute of Technology, Atlanta, Georgia, United States;* [2]*Gilead Sciences, Inc., Foster City, California, United States;* [3]*Value Analytics Labs, Boston, Massachusetts, United States;* [4]*Emory University, Atlanta, Georgia, United States*

BACKGROUND: HIV-1 incidence in the US is disproportionately high in Black and Hispanic men who have sex with men (MSM), transgender women (TGW), and cisgender women (CGW) with PrEP indications. Despite US Preventative Services Task Force (USPSTF) recommendations for zero cost sharing under the Affordable Care Act (ACA), many people still face the barrier of out-of-pocket (OOP) costs, which limits PrEP access, PrEP uptake, and HIV prevention efforts. In 2018, approximately 11.4% of PrEP prescriptions in the US required

OOP payments over $100. These OOP costs were associated with higher rates of PrEP abandonment and up to a 3-fold increase in HIV-1 acquisition.

OBJECTIVE: To estimate the clinical and economic returns of removing OOP costs for PrEP in the US for MSM, TGW, and CGW with PrEP indications.

METHODS: We developed an HIV-1 microsimulation model to assess the clinical and economic impact of removing OOP costs in US underserved populations over a lifetime horizon from the payer, healthcare ecosystem, and societal perspectives. We evaluated two scenarios per population: current status quo with OOP cost barriers (comparator) and OOP costs fully removed (intervention). Model inputs (HIV-1 progression, treatment costs, PrEP use behavior, and PrEP OOP costs) were estimated based on real-world data and published sources. The primary outcome was return on investment (ROI), calculated as downstream HIV-related treatment costs averted per additional dollar spent on PrEP; ROI >1 implied net economic savings.

RESULTS: The intervention increased PrEP uptake and costs but reduced new HIV-1 cases, lowering treatment costs and increasing productivity. For the combined populations, an estimated 79.6 new cases were averted per 10,000 people over 5 years, ranging from 54.3 to 105.2 cases across populations. Over the lifetime horizon, each additional dollar spent on PrEP after removing OOP costs returned $2.1 to payers (range across populations: $1.5–$2.7), $3.9 to the healthcare ecosystem ($2.8–$5.0), and $4.2 to society ($3.0–$5.5).

CONCLUSIONS: Improving PrEP access by removing OOP costs for underserved populations has the potential for long-term net economic savings. Our results reinforce the importance of following USPSTF recommendations for zero cost sharing to prevent new HIV-1 cases and produce long-term overall savings. Conversely, if these recommendations are not followed, OOP barriers to PrEP could undermine progress toward the Ending the HIV Epidemic goals and increase the economic burden to healthcare stakeholders.

SPONSORSHIP: Gilead Sciences, Inc.

194 Differential responses to a medication therapy management star rating measure by Medicare Part D plan type

Raver E[1], *Jung J*[2], *Donneyong M*[1], *Gure T*[1], *Wing J*[1], *Xu W*[1]; *raver.61@buckeyemail.osu.edu*
[1]*The Ohio State University*; [2]*George Mason University*

BACKGROUND: Medicare Part D prescription drug plans are required to establish medication therapy management (MTM) programs intended to optimize therapeutic outcomes and reduce the risk of adverse drug events. Stand-alone Part D prescription drug plans (PDP) and Medicare Advantage plans offering prescription drug benefits (MA-PD) set their own eligibility criteria for MTM programs, based on the number of prescription drugs and health conditions. In 2016, Medicare introduced a Part D star rating measuring the proportion of enrollees eligible for MTM services who complete a comprehensive medication review (CMR). Unlike PDPs, MA-PD plans that achieve high overall star ratings are eligible for quality bonus payments, which may create an incentive to increase the CMR completion rate. However, improving this star rating may be partly achieved by limiting eligibility for MTM services.

OBJECTIVE: To examine the effects of implementing a CMR star rating measure on MTM program participation and CMR completion, among enrollees in stand-alone PDPs and MA-PD plans.

METHODS: This observational study used 2013-2019 Medicare Part D MTM files and prescription drug claims linked with the 2014-2020 survey waves of the Health and Retirement Study. We included survey respondents age 65 or older with linked Medicare data who were continuously enrolled in a stand-alone PDP or MA-PD plan for a given calendar year. Among Part D enrollees, we measured the proportion enrolled in an MTM program for at least 60 days. Among MTM enrollees, we measured the proportion who completed a CMR. We estimated a repeated cross-sections difference-in-differences model to assess the impact of implementing the 2016 CMR star rating in PDP vs MA-PD.

RESULTS: Among 18,665 person-years in stand-alone PDPs, 1682 (9.0%) were enrolled in MTM programs, and among 20,305 person-years in MA-PD, 2176 (10.7%) were enrolled in MTM programs. Implementation of the 2016 CMR star rating was associated with decreased MTM enrollment for both PDP and MA-PD plans. While MTM enrollment was higher in MA-PD overall, the CMR star rating implementation was associated with a 3.1-percentage-point (p=0.006) greater decrease in MTM enrollment for MA-PD plans, compared with PDPs. CMR completion rates increased overall, with a 17.3-percentage-point (p=0.005) greater increase for MA-PD plans, associated with the star rating implementation.

CONCLUSIONS: Implementing the 2016 CMR star rating was associated with higher CMR completion rate but lower MTM enrollment for MA-PD plans, compared with PDPs.

SPONSORSHIP: National Institute on Aging

195 Medicare Advantage vs traditional fee-for-service Medicare: Different populations, different outcomes

Bilder S, Teigland C, Sunkari K, Pulungan Z;
scott.bilder@inovalon.com
Inovalon

BACKGROUND: The rapid growth of Medicare Advantage (MA) makes it increasingly important for relevant stakeholders—policymakers, health plans, and patients—to understand how it differs from traditional fee-for-service (FFS) Medicare.

OBJECTIVE: We conducted a retrospective, real-world, cohort study that followed new Medicare enrollees as they transitioned from commercial and Medicaid plans into MA or FFS and measured their healthcare utilization, costs, and quality outcomes.

METHODS: This analysis captured beneficiaries' data before they enrolled in Medicare and matched MA and FFS members on important social, clinical, and cost variables to ensure that the two cohorts were similar but for their choice of insurance type. Outcome variables included use of acute and routine care, associated costs, and quality measures reflecting avoidance of rehospitalization and of potentially preventable hospitalizations.

RESULTS: We found that new MA members differed substantially from those choosing FFS: in the year before Medicare enrollment they were more likely to have been insured in Medicaid rather than commercial plans, had more chronic conditions such as diabetes and cardiovascular diseases, and had received more costly care. Moreover, they lived in more socially disadvantaged neighborhoods characterized by lower income, educational attainment, English-language proficiency, and home and vehicle ownership. After matching on pre-Medicare characteristics, we found that those in MA plans had fewer hospital admissions (6.5 vs. 9.1 per-1000-members-per-month; P1000MPM) and emergency department visits (23.5 vs. 35.7 P1000PMP) in the first two years in Medicare but were more likely to use prescription medications. Inpatient costs were 35% lower while pharmacy costs were 13% higher. Additionally, our analysis using published quality measures demonstrated lower rates of 30-day hospital readmissions (9.1% vs. 20.6%) and 41% lower hospitalizations for potentially preventable complications in MA. Additional analysis of unmatched cohorts demonstrated that failing to identify and control for pre-Medicare differences would have greatly distorted these findings.

CONCLUSIONS: This study showed that Medicare beneficiaries choosing an MA plan use less high-intensity inpatient and emergency care than those in FFS Medicare and avoid those types of hospitalizations that are often a result of ineffective or non-existent care coordination. Higher levels of prescription drug use in MA suggests that plans are successfully substituting routine treatment in place of more disruptive and costly acute care.

SPONSORSHIP: None

196 Perception of shared clinical decision-making recommendations and impacts to clinical practice among vaccines in the United States

Timmel E[1], Rines-MacEachern A[1], Byrnes M[2];
emma.timmel@thermofisher.com
[1]Thermo Fisher Scientific; [2]ThermoFisher

BACKGROUND: The Advisory Committee on Immunization Practices (ACIP) defines shared clinical decision-making (SCDM) as an individually based decision process informed by discussion between a healthcare provider (HCP) and the patient/caregiver. In 2025, ACIP updated the recommendation for COVID-19 vaccination in individuals aged ≥6 months from routine to SCDM.

OBJECTIVE: To understand implications of the SCDM recommendation for COVID-19 vaccination by assessing evidence on HCP/patient perceptions and potential impacts to clinical practice as it relates to earlier vaccines given an SCDM designation, i.e., human papilloma virus (HPV) vaccine for adults aged 27-45 years, meningococcal serogroup B bacteria (MenB) vaccine for patients aged 16-23 years, and pneumococcal conjugate vaccine 13-valent (PCV13) for adults aged ≥65 years.

METHODS: A targeted review was conducted using PubMed® and web searches to identify literature from 2015 on discussing HPV, MenB, and PCV13 vaccines in relation to their SCDM recommendations. Included studies focused on HCP/patient perceptions related to SCDM and impacts to clinical practice in the US.

RESULTS: Across indications, the proportion of HCPs aware of SCDM recommendations varied from 38% to 81%. Patient/caregiver awareness of SCDM designation was low (45% of vaccinated patients and 35% of caregivers for MenB). Routine discussions about SCDM were reported by 42%-80% of HCPs, although one analysis of MenB reported that most conversations did not truly reflect SCDM. A survey assessing SCDM for PCV13 reported that 52% of HCPs were less likely to recommend PCV13 due to the switch from routine recommendation to SCDM. SCDM may contribute to low vaccine uptake, with one study reporting substantially higher uptake of the meningococcal serogroup A, C, W, and Y vaccine (MenACWY; routine recommendation) compared to MenB (SCDM recommendation) and another reporting decreased PCV13 uptake following the switch from routine recommendation to SCDM. Barriers and limitations associated with

SCDM included HCP time commitment, limited guidance on SCDM implementation, lack of patient/caregiver and HCP awareness, and uncertainty about insurance coverage.

CONCLUSIONS: HCP/patient awareness of SCDM recommendations varies, leading to inconsistent implementation in clinical practice impacting vaccine uptake. As similar impacts may be anticipated for COVID-19 vaccination, barriers and limitations associated with SCDM should be addressed to improve clinical practice associated with this recommendation type.

SPONSORSHIP: Thermo Fisher Scientific

197 Characterizing subsequent indications following accelerated approval of non-oncology medicines in the US

Zheng H, Campbell J, Wagner T; hzheng@npcnow.org
National Pharmaceutical Council

BACKGROUND: The accelerated approval (AA) program facilitates earlier access to therapies for serious conditions with unmet medical needs, yet little is known about the post-approval landscape of AA medicines.

OBJECTIVE: To characterize subsequent indications following initial AA, focusing on non-oncology medicines.

METHODS: Using the Food and Drug Administration's (FDA) Center for Drug Evaluation and Research Accelerated Approval, Drugs@FDA, and Orphan Drug Product Designation databases, we analyzed non-oncology medicines with indications approved through the AA program from 1992 to 2024. We excluded drugs that were not initially approved through the AA program. For each drug, we collected molecule size and therapeutic class of the initial AA indication. We documented all indication approvals, approval dates, regulatory pathways, and orphan designation status. We categorized drugs by their total number of subsequent indications and whether those were for rare diseases. Descriptive statistics were applied.

RESULTS: We identified 66 non-oncology medicines that received AA during the study period and then excluded two drugs that received traditional approvals before AA. Among the 64 drugs initially approved by the AA program, 89.1% were small molecules, and 53.1% received their initial AA indication in hematology or neurology. More than three-quarters (78.1%) of the drugs have only a single AA indication and did not expand to other indications. Six drugs (9.4%) were followed by indication approvals for rare diseases exclusively, and eight drugs (12.5%) had at least one non-rare subsequent indication approval. More than half (56.3%) of the initial AA indications were approved with an orphan designation status. There were 26 subsequent approvals in total, following the initial AA approval, and nearly half of those indications (46.2%) still focus on rare diseases.

CONCLUSIONS: Since the launch of the FDA's AA program, most non-oncology AA medicines have received only a single AA indication, primarily for rare diseases where unmet needs remain high. Fewer than one-quarter of these drugs gained subsequent indication approvals, with many continuing to focus on rare conditions.

SPONSORSHIP: National Pharmaceutical Council

198 Navigating Medicare advantage coverage policies for complementary diagnostics required to initiate Alzheimer's disease drug therapies

Rajput Y[1], DeNave M[2], Roth S[3]; yamina.rajput@roche.com
[1]Roche Diagnostics Corp; [2]Roche Diagnostics Corporation; [3]Roche Diagnostics International Ltd

BACKGROUND: Medicare Advantage (MA) plans follow National or Local Coverage Determinations (NCD/LCD) issued by CMS. They can exercise discretion in the absence of NCD/LCD-behaving similar to commercial plans, which have autonomy. For Alzheimer's disease (AD), treatment with FDA-approved anti–amyloid disease–modifying therapies (DMTs) requires confirmation of amyloid pathology using FDA-approved biomarker tests (amyloid PET, cerebrospinal fluid [CSF] biomarkers, emerging blood-based biomarkers [BBBMs]). These tests are classified as complementary diagnostics. Unlike companion diagnostics, their coverage is not linked to the drug's NCD/LCD.

OBJECTIVE: To understand the impact on MA and commercial coverage policies for AD, given the NCD for AD treatments and the lack of a Medicare determination for diagnostics, allowing payers the discretion to establish their own medical policies for MA plans.

METHODS: We retrieved publicly available AD coverage policies (1/1/2024–12/31/2025) for DMTs (lecanemab, donanemab) and in vitro diagnostic tests (CSF and BBBM) from 15 major US health payers. Policies were categorized based on coverage determination: covered, noncovered, or silent. We compared coverage for the same technology across MA and commercial plans to assess the impact of discretionary payer decisions.

RESULTS: All MA DMT policies were assumed to be consistent with the AD DMT NCD due to statutory requirements. For commercial plans, which maintain autonomy on DMT coverage decisions, lecanemab and donanemab were covered by 71% and 64% of health plans, respectively. For the AD in vitro diagnostic policies, the absence of an NCD or LCD resulted in MA plans using their discretion to restrict coverage, with CSF only having 40% coverage and BBBM having 0% coverage.

Commercial plans had similar coverage with 36% coverage for CSF and 0% for BBBM.

CONCLUSIONS: This analysis shows that the lack of Medicare determination for AD biomarkers has created access barriers. Despite evidence of diagnostic tests' critical role in timely access to DMTs, payers are applying restrictive policies, at their own discretion, to both MA and commercial plans. This underscores the need for policymakers to establish positive Medicare coverage determinations for AD diagnostics to ensure consistent and timely access to AD care for all beneficiaries.

SPONSORSHIP: Roche Diagnostics

Hematologic

205 Healthcare resource utilization and costs among patients with paroxysmal nocturnal hemoglobinuria in the United States

Tomassetti S[1], *Kuypers N*[2], *Paulose J*[2], *Marvel J*[2], *Bilano V*[3], *Buchan T*[4], *Buchan C*[4], *Baraka E*[4], *Bollu V*[2]; *sarah.tomassetti@lundquist.org*
[1]*Harbor-UCLA Medical Center*; [2]*Novartis Pharmaceuticals Corporation*; [3]*Novartis Pharmaceuticals UK Ltd*; [4]*Asclepius Analytics*

BACKGROUND: Paroxysmal nocturnal hemoglobinuria (PNH) is a rare, life-threatening blood disorder. Despite newer complement inhibitors (CIs), patients continue to require acute medical care, incurring additional costs.

OBJECTIVE: To describe healthcare resource utilization (HCRU) and costs among US patients with PNH.

METHODS: This retrospective, observational cohort study used US claims data from Komodo's Healthcare Map® and included adults with ≥2 PNH-related claims from January 1, 2018, to April 4, 2025. Index was defined as the date of the first claim for the most recent PNH treatment (index therapy) within the identification period (June 14, 2023, to April 4, 2025) for the CI-treated cohort and the date of the earliest claim associated with a PNH diagnosis within the identification period for the CI-untreated cohort. Patients were stratified based on index therapy, were required to have continuous enrollment for ≥90 days prior to index, and had ≥6 months' follow-up. All-cause and PNH-specific HCRU (inpatient [IP] hospitalizations, emergency room [ER] visits, and outpatient [OP] visits) and cost endpoints were measured over 12 months of follow-up post index or until data cutoff, whichever occurred first.

RESULTS: Overall, 2398 patients (1149 CI-treated and 1249 CI-untreated) were included. The distribution of claims for the most recent CI therapy was ravulizumab (n=755 [66%]), eculizumab (n=165 [14%]), pegcetacoplan (n=84 [7%]), and iptacopan (n=130 [11%]). Among CI-treated patients, fewer receiving iptacopan had all-cause OP, ER, and IP visits (91%, 18%, and 6%, respectively) than those receiving pegcetacoplan (97%, 39%, 17%), ravulizumab (98%, 24%, 10%), and eculizumab (99%, 36%, 9%). Iptacopan incurred the lowest total all-cause healthcare costs compared with the other CI therapies ($22,927 vs $32,515-$49,299 PPPM), with the lowest OP, ER, and IP visit costs. Fewer patients receiving iptacopan had PNH-specific OP, ER, and IP visits (69%, 3%, and 3%, respectively) than those receiving pegcetacoplan (82%, 17%, 14%), ravulizumab (94%, 6%, 6%), and eculizumab (95%, 7%, 6%). Iptacopan also had the lowest PNH-specific total healthcare costs compared with other CI therapies ($19,227 vs $24,472-$61,844 PPPM), with the lowest OP and ER costs.

CONCLUSIONS: Real-world data among US patients with PNH show fewer all-cause and PNH-specific OP, ER, and IP visits and lower associated costs with iptacopan vs other CI therapies. Results may help clinicians tailor PNH management strategies to patients to improve outcomes and reduce HCRU burden.

SPONSORSHIP: Novartis

206 Practice efficiency and institutional costs associated with epcoritamab + rituximab + lenalidomide in patients with relapsed or refractory follicular lymphoma

Li Q[1], *Bains Chawla S*[2], *Meyer K*[1], *Jun M*[3], *Marques Goncalves F*[3], *Lei M*[4]; *qianyi.li@cencora.com*; *sbs@genmab.com*
[1]*Cencora Global Consulting Services US Corporation*; [2]*Genmab, US Inc.*; [3]*Genmab US, Inc.*; [4]*Massachusetts General Hospital*

BACKGROUND: Follicular lymphoma (FL) accounts for up to 30% of all lymphomas, ranking the first among indolent non-Hodgkin lymphomas (NHL). For patients with relapsed/refractory (R/R) FL with 1+ prior line of systemic therapy, tafasitamab + rituximab and lenalidomide (R2) is the first approved CD19- and CD20-targeted immunotherapy combination. Subcutaneous (SC) epcoritamab in combination with R2 has recently demonstrated statistically significant improvement in patient outcomes versus R2 alone in the phase 3 EPCORE® FL-1 trial.

OBJECTIVE: To understand practice efficiencies and the total costs of care associated with epcoritamab + R2 versus tafasitamab + R2.

METHODS: A micro-costing analysis was developed to compare the practice efficiencies and total costs of epcoritamab

+ R2 versus tafasitamab + R2 over a time horizon of up to 1 year. Dosing schedules, treatment duration, and adverse event (AE) rates followed the pivotal trials and drug labels. Practice efficiency was based on clinical personnel (technician, pharmacist, and nurse) time and chair time across treatment stages. Total costs (2025 USD) included cost of blood work, drug costs, personnel costs, and AE costs. Unit costs were sourced from published studies and publicly available databases.

RESULTS: Over a 1-year time horizon with trial-reported median treatment duration, epcoritamab + R2 was associated with lower personnel time (36 versus 87 hours) and chair time (41 versus 105 hours) per patient, translating to $3,551 savings in institutional personnel cost per patient and an increase in institutional capacity to treat at least one more patient over a year. With fewer doses (18 versus 30), epcoritamab + R2 was also expected to alleviate time burden on patients due to commuting to infusion centers (71 versus 155 hours). When looking at the total costs, the average costs per month with epcoritamab + R2 were $2,152 higher than tafasitamab + R2. For cases where inpatient monitoring with epcoritamab is required after the first full dose, personnel time would increase by 7 hours.

CONCLUSIONS: Epcoritamab SC + R2 is associated with 58% reduction in personnel time and 61% reduction in chair time, which improves institutional capacity and infusion center throughput. Adoption of epcoritamab + R2 for this patient population helps alleviate patient and institutional burden.

SPONSORSHIP: Genmab and AbbVie

Immunology

213 Reductions in healthcare resource utilization among patients with hereditary angioedema after initiating berotralstat, lanadelumab, or subcutaneous plasma-derived C1-inhibitor

Christiansen S[1], *Yee T*[2], *Winer I*[3], *Dean A*[3], *Manjelievskaia J*[3], *Nestler-Parr S*[2], *Gillard P*[4], *Zuraw B*[5]; *tyee@biocryst.com*; *bzuraw@health.ucsd.edu*
[1]*UCSD Division of Allergy & Immunology*; [2]*BioCryst Pharmaceuticals*; [3]*Veradigm*; [4]*BioCryst*; [5]*UCSD*

BACKGROUND: There are limited studies comparing first-line long-term prophylaxis (LTP) options for hereditary angioedema (HAE): berotralstat, lanadelumab, and subcutaneous plasma-derived C1-inhibitor (SC-pdC1-INH).

OBJECTIVE: To assess changes in healthcare resource utilization (HRU) following initiation of berotralstat, lanadelumab, or SC-pdC1-INH among patients with HAE.

METHODS: Patients at least 12 years of age initiating 1 of the 3 LTPs between 06/22/2017-10/24/2024 were identified using Veradigm Network EHR linked to claims data (first claim = index date). Patients were required to have evidence of HAE, no evidence of prior LTP, and at least 6 months of continuous enrollment pre-index. The variable-length baseline period began at either the first evidence of HAE or 6 months pre-index and ended the day before the index date. The variable-length follow-up period began on the index date and continued until the end of continuous enrollment. Outcomes included changes in annualized all-cause and angioedema-related HRU between baseline and follow-up reported as rate ratios with 95% confidence intervals (95% CI), and p-values from general estimating equations Poisson regression models with robust standard errors.

RESULTS: 128 patients indexed on berotralstat, 236 indexed on lanadelumab, and 95 indexed on SC-pdC1-INH met study inclusion criteria. In all cohorts, patients were on average 39-40 years of age and majority female (73%–81%). Mean observation periods ranged from 4.2 to 5.2 months for the baseline period and from 20.9 to 31.4 months for the follow-up period. All cohorts saw a significant reduction in all-cause and angioedema-related inpatient admissions, emergency department visits, and outpatient office visits after index LTP initiation. Rate ratios (95% CI) of all-cause inpatient admissions were 0.35 (0.21–0.58) for berotralstat ($p<0.001$), 0.50 (0.37–0.69) for lanadelumab ($p<0.001$), and 0.54 (0.36–0.79) for SC-pdC1-INH ($p=0.002$). Rate ratios (95% CI) of all-cause emergency department visits were 0.42 (0.34–0.52) for berotralstat ($p<0.001$), 0.54 (0.46–0.62) for lanadelumab ($p<0.001$), and 0.56 (0.46–0.69) for SC-pdC1-INH ($p<0.001$). Rate ratios (95% CI) of all-cause outpatient office visits were 0.79 (0.74–0.84) for berotralstat ($p<0.001$), 0.83 (0.79–0.86) for lanadelumab ($p<0.001$), and 0.87 (0.82–0.92) for SC-pdC1-INH ($p<0.001$). The lower the rate ratio, the higher the reduction in HRU. Similar reductions observed for angioedema-related HRU.

CONCLUSIONS: Berotralstat, lanadelumab, and SC-pdC1-INH were associated with significant decreases in HRU in patients with HAE.

SPONSORSHIP: BioCryst Pharmaceuticals, Inc.

214 Cost-effectiveness analysis of obinutuzumab for the treatment of lupus nephritis in the United States

Patel A[1], Rosettie K[2], El Moustaid F[1], Sussell J[1], Heuser C[3], Pendergraft W[1], Saxena A[4]; patel.anisha@gene.com; sussellj@gene.com
[1]Genentech, Inc.; [2]Genentech, Inc., South San Francisco, CA 94080, USA; [3]F. Hoffmann-La Roche Ltd; [4]Division of Rheumatology, Department of Medicine, NYU Grossman School of Medicine

BACKGROUND: Lupus nephritis (LN) is a serious manifestation of systemic lupus erythematosus, with 10-30% of patients progressing to end-stage kidney disease requiring dialysis or kidney transplant. The REGENCY trial (NCT04221477) evaluated obinutuzumab (OBI) plus standard therapy (ST), demonstrating superior complete renal response with OBI + ST at Week 76 versus placebo + ST, leading to its approval in the US in 2025 for active LN.

OBJECTIVE: To assess the cost-effectiveness of OBI + ST in LN compared with ST (mycophenolate mofetil, methylprednisolone and prednisone) alone, belimumab (BEL; intravenous [IV] or subcutaneous [SC]) + ST, and voclosporin (VOC) + ST.

METHODS: We developed an Excel-based Markov model with health states reflecting chronic kidney disease stages 1–3b (complete response [CR], partial response [PR], active disease [AD]); stage 4 (CR, PR, AD); stage 5 (dialysis, transplant); and death. A network meta-analysis was conducted to compare OBI with BEL and VOC. We applied a 3% annual discount to costs and outcomes over a lifetime horizon. Patients received active treatment for 3 years, with treatment effects maintained thereafter. Transition probabilities were derived from REGENCY and a US real-world analysis. Adverse event (AE) rates were sourced from the REGENCY, BLISS-LN and AURORA-1 trials. Health state utilities were obtained from health technology assessment submissions. The base case was the US healthcare payer perspective and included the following costs (2025 USD): drug wholesale acquisition cost, administration, AE management, and supportive and end-of-life care. Model outcomes included total costs, life-years (LYs), quality-adjusted life-years (QALYs) and the incremental cost-effectiveness ratio.

RESULTS: In the base case, OBI was dominant (more effective and less costly) compared with ST alone and BEL (IV or SC). Compared with ST, OBI resulted in a mean gain of 1.21 LYs and 1.37 QALYs with estimated cost savings of $32,406. Compared with BEL, OBI yielded a mean gain of 0.11 LYs and 0.12 QALYs with estimated cost savings ranging from $80,171 to $116,153 versus BEL IV and SC, respectively. Compared with VOC, OBI led to a marginal LY loss of 0.24 and QALY loss of 0.30, but substantial cost savings of $403,127, making it cost-effective at the $150,000/QALY willingness-to-pay threshold.

CONCLUSIONS: OBI delivers meaningful QALY gains versus ST alone and is cost-effective or cost saving versus all included comparators, supporting the clinical and economic value of OBI for LN in the US.

SPONSORSHIP: Genentech, Inc.

215 Two-year real-world switching patterns for patients with psoriatic arthritis on first-line advanced therapies

Walsh J[1], Ye X[2], Li C[3], Patel M[3], Saffore C[3], Vora J[3], Bergman M[4]; jessica.walsh2@va.gov; abbvrheumpubs-ienvision@avalerehealth.com
[1]Salt Lake City Veterans Affairs and University of Utah Health; [2]AbbVie, Inc.; [3]AbbVie Inc.; [4]College of Medicine, Drexel University

BACKGROUND: First-line advanced therapies (1LAT) approved for active psoriatic arthritis (PsA) include interleukin (IL)-23, IL-12/23 and IL-17 inhibitors (i); phosphodiesterase-4 inhibitors (PDE-4i); and tumor necrosis factor inhibitors (TNFi). Treatment goals for PsA include achieving lowest possible disease activity, optimizing functional status and avoiding treatment complications; if these goals are not met, treatment switch may be recommended. Previously, the IL-23i, risankizumab (RZB), was shown to have the lowest switch rates over 12 months; however, long-term data are lacking.

OBJECTIVE: To evaluate real-world switching patterns among patients with PsA initiating 1LAT over 24 months.

METHODS: Data were drawn from the Merative (TM) Marketscan® databases between 1/1/2016 and 1/31/2025. Biologic-naive patients aged ≥18 years with ≥1 PsA diagnosis at baseline who initiated a new 1LAT on or after 1/21/2022 (index date) were included. Patients had continuous enrollment for ≥6 months pre- (baseline) and ≥24 months post-index date. Switch rates (the proportion of patients who switched to a new advanced therapy in the 24-month follow-up after index date) were evaluated for the overall population, stratified by the mechanism of action (MOA; reference IL-23i) and individual drugs (reference RZB). Multivariate logistic regression was used to compare switch rates accounting for differences in baseline characteristics.

RESULTS: A total of 1019 patients were included in the analysis. Baseline characteristics were similar between MOAs. Over 24 months, 38.0% of patients switched therapies. Switch rates were lower in patients initiating IL-23i (15.7%) compared to TNFi (49.4%), PDE-4i (40.0%) and IL-17i (32.6%). Compared to IL-23i, the odds of switching were significantly (P<0.001)

higher for TNFi (Adjusted odds ratio 5.61 [95% confidence interval]: 3.57-8.80), PDE-4i (3.78 [2.37-6.04]) and IL-17i (2.57 [1.52-4.35]). Switch rates over 24 months were lower in patients initiating RZB (10.6%), compared to guselkumab (GUS) (21.5%), ixekizumab (IXE) (26.8%), apremilast (APR) (40.0%), secukinumab (SEC) (40.3%), adalimumab (ADA) (49.8%) and etanercept (ETN) (50.0%) (all P<0.05). Compared to RZB, the adjusted odds ratios of treatment switch were 9.00 (3.99-20.3), 8.92 (4.49-17.75), 5.90 (2.97-11.71), 5.60 (2.48-12.64), 3.17 (1.42-7.09) and 2.45 (1.09-5.48) for ETN, ADA, APR, SEC, IXE and GUS, respectively (all P<0.05).

CONCLUSIONS: Patients with PsA initiating IL-23i had the lowest switch rates over 24 months. At the individual drug level, RZB was associated with the lowest switch rates compared to other 1LATs.

SPONSORSHIP: AbbVie Inc.

216 Cost comparison of intravenous immunoglobulin and subcutaneous efgartigimod in patients with chronic inflammatory demyelinating polyneuropathy

Muley S[1], *Gucciardi I*[2], *Kaisare V*[3], *Wissmann C*[2], *Bandy S*[4], *Yeh D*[4], *Myers L*[5]; *surajmuley@gmail.com*; *christoph.wissmann@octapharma.com*
[1]*Bob Bove Neuroscience Institute at Honorhealth; University of Arizona;* [2]*Octapharma AG;* [3]*Octapharma USA;* [4]*AESARA Inc.;* [5]*CSI Pharmacy*

BACKGROUND: Chronic inflammatory demyelinating polyneuropathy (CIDP) is a rare immune-mediated disorder of the peripheral nerves, causing weakness, numbness, and balance issues. Standard of care for patients with CIDP include intravenous or subcutaneous immunoglobulin (IVIG or SCIG), corticosteroids or plasma exchange. Efgartigimod alfa and hyaluronidase-qvfc (EFG), a human IgG1 antibody fragment, was recently approved for the treatment of CIDP.

OBJECTIVE: Given that IVIG has demonstrated efficacy and safety in CIDP, we aimed to compare the economic value of EFG and Panzyga® IVIG from a US commercial payer's perspective.

METHODS: Due to lack of a head-to-head clinical trial, a cost-per-responder analysis was performed to evaluate total cost and cost per responder of CIDP patients receiving either EFG or Panzyga® (IVIG) over 6- and 12-month time horizons. Efficacy and safety data were sourced from pivotal clinical trials: ADHERE (NCT04281472) for EFG and ProCID (NCT02638207) for IVIG. The model compared EFG with IVIG at both the standard (1 g/kg) and a higher (2 g/kg) maintenance dose regimens. Total treatment cost includes drug cost, administration fees, and non-responder costs in US dollars. Number of doses were derived based on the US package inserts for IVIG and EFG. Responders were defined as patients demonstrating improvement or no deterioration in adjusted inflammatory neuropathy cause and treatment disability score, or confirmed evidence of clinical improvement from the clinical trials considering trial design differences. For the 12-month analysis, IVIG response was modeled using clinical guidelines and published evidence to differentiate between responders and non-responders (requiring dose escalation or corticosteroids).

RESULTS: Total treatment cost of IVIG 1 g/kg, 2 g/kg, and EFG are $121,275, $211,049, and $450,800 at 6 months, and are $218,010, $389,838, and $680,853 at 12 months, respectively. Responder rates for IVIG 1 g/kg, 2 g/kg, and EFG were 80%, 92%, and 53% respectively at 6 months. At 12 months, responder rates for IVIG 1 g/kg, 2 g/kg, and EFG were 74%, 85%, and 48% respectively. Both IVIG 1 g/kg and 2 g/kg had a lower cost per responder compared to EFG at both 6 and 12 months. For IVIG 1g/kg, the cost per responder was $151,594 at 6 months and $296,209 at 12-months. For IVIG 2 g/kg, it was $229,401 and $460,584, respectively. In comparison, EFG costs were $853,789 at 6 months and $1,430,784 at 12 months.

CONCLUSIONS: In US adults with CIDP, both 1 g/kg and 2 g/kg IVIG provide better value than EFG, with lower total cost and lower cost per responder.

SPONSORSHIP: Octapharma

217 Incidence, prevalence, and mortality of Sjögren's disease: A comprehensive systematic literature review

Grader-Beck T[1], *Egana A*[2], *Lalla A*[2], *Takyar S*[3], *Pandey V*[3], *DiRenzo D*[4]; *tgrader1@jhmi.edu*
[1]*Johns Hopkins School of Medicine Faculty, Division of Rheumatology;* [2]*Novartis Pharmaceuticals Corporation;* [3]*Novartis Private Healthcare Ltd.;* [4]*Division of Rheumatology, Department of Medicine, University of Pennsylvania*

BACKGROUND: Sjögren's disease (SjD) is a systemic autoimmune disorder affecting the exocrine glands alongside other organs. SjD can occur alone (primary SjD) or with other autoimmune conditions (associated SjD). Prior systematic literature reviews (SLRs) have either focused on primary SjD or limited outcomes.

OBJECTIVE: To synthesize current evidence on global prevalence and incidence of, and mortality with, primary and associated SjD and identify demographic, geographical variation, and temporal trends.

METHODS: We searched electronic databases from January 2012 to 2025 and conference records from the last 3 years.

Publications were systematically screened for English articles reporting epidemiologic metrics of adult patients with SjD.

RESULTS: Of 3468 records identified, our SLR summarized 43 studies reporting prevalence (n=30), incidence (n=18), or mortality (n=11). Most studies sourced data from national databases/registries or claims data and used ICD diagnosis codes to identify SjD. Globally, the mean age at diagnosis ranged from 40 to 64 years. Global diagnosed prevalence of primary SjD ranged from 0.0033 to 0.6% (US: 0.0033-0.21% across all ages), with a 2-fold increase in temporal trends from 2007 to 2015. Diagnosed prevalence rates differed by age (higher in >55 years), sex (women had 2-19 times higher prevalence than men), diagnostic criteria (higher with physician diagnosis vs AECG 2002), and race (highest in White individuals). Globally, incidence rates of primary SjD ranged from 0.0007 to 0.026% (US: 0.0035-0.005%), with an increase in temporal trends from 1976 to 2015. Incidence increased with age, peaking between 65 and 75 years (US: 1.9 in 18-44 years to 12.3 in ≥75 years per 100,000), with women showing 4-16 times higher rates than men (US: 9.5 vs 1.6 per 100,000). Rates differed by diagnostic criteria: lower incidence with ACR/EULAR 2016 criteria vs physician diagnosis (0.0011% vs 0.0035%) in North America, while ICD-9/10 and AECG 2002 did not significantly affect incidence in Europe but varied in Asia. Globally, mortality rates from 11 studies ranged from 1.3 to 30%. Elevated ESSDAI scores, age, and serum cryoglobulins significantly increased mortality risk (P<.05).

CONCLUSIONS: Global SjD incidence and prevalence varied by diagnostic criteria, geography, and year. Our SLR quantified epidemiological data, highlighting female predominance, age-related increases, study methods, and SjD types. These insights stress the need for standardized frameworks to reduce heterogeneity and improve future study interpretation.

SPONSORSHIP: Novartis Pharmaceuticals Corporation

218 Real-world patterns of on-demand utilization following initiation of long-term prophylaxis in hereditary angioedema

Heuring T, Liang A, Wilson A, Eckwright D, MacDonald B, Makanji H; tim.heuring@primetherapeutics.com
Prime Therapeutics

BACKGROUND: Hereditary angioedema (HAE) is a rare genetic disorder associated with recurrent severe edema attacks involving the skin and mucosa. Guidelines recommend treating HAE attacks with on-demand (OD) therapy and individualizing long-term prophylaxis (LTP) initiation based on disease activity, burden, and patient preference. HAE can result in annual total care costs exceeding $1M per member, with roughly 97% attributable to drug costs. However, real-world evidence on how initiation patterns and LTP influences OD drug use and costs remain limited.

OBJECTIVE: To evaluate real-world OD treatment patterns in HAE patients initiating LTP and assess the impact on OD medication use and costs among members with prior OD experience.

METHODS: This was a retrospective analysis of medical and pharmacy claims from a Commercial database of 17M lives. Claims were queried to identify members' first HAE index LTP (C1-esterase agents, berotralstat, lanadelumab) between 1/2023 and 9/2024. Member requirements included continuous enrollment 12 months prior to (pre-LTP period) and after (post-LTP period) their index date, no pre-index LTP claims and at least one OD claim in the pre-LTP period. Drug costs were calculated using OD drug (non-LTP C1-esterase agents, icatibant, ecallantide) and LTP allowed amounts. OD drug utilization was estimated by dividing clinical units by the minimum OD dose per product labeling.

RESULTS: Among 61 members initiated on LTP for HAE, 52.5% (n = 32) started LTP without prior OD therapy, while 47.5% (n = 29) had previously received OD treatment. In the OD-experienced subgroup, 65.5% (n = 19) experienced a reduction in OD utilization after LTP initiation, 10.3% (n = 3) had no change, and 24.1% (n = 7) showed an increase. Members with reduced OD use had an average cost decrease of $114K, while those with increased OD use had an average cost increase of $112K; both groups averaged four OD claims per member. Overall, OD spend in this subgroup declined by $1.37M, averaging a $47,358 reduction per member. After starting LTP, the average number of OD claims per member decreased from 3.8 to 2.1, a 46% reduction.

CONCLUSIONS: Over half of the members initiated LTP without prior OD therapy, indicating variability in treatment patterns among HAE patients. For most members with prior OD use, LTP initiation reduced OD utilization and costs, though over one-third saw no improvement or even an increase. Given the high costs of LTP and OD therapies, these findings highlight opportunities for targeted drug management strategies and case management interventions to optimize cost-effective HAE care.

SPONSORSHIP: Prime Therapeutics

219 Impact of anxiety on healthcare utilization among hereditary angioedema patients receiving long-term prophylaxis: Results of a claims database analysis

Tachdjian R[1], *Soteres D*[2], *O'Connor M*[3], *Sehgal A*[4], *Wang A*[5], *Audhya P*[5], *Craig T*[6]; *ucladoc@gmail.com*; *awang@kalvista.com*
[1]*University of California at Los Angeles, Division of Allergy, Immunology, and Rheumatology, Los Angeles, California, United States of America*; [2]*Asthma & Allergy Associates and Research Center, P.C., Colorado Springs, Colorado*; *UCHealth Anschutz, Aurora, Colorado, United States of America*; [3]*Integrative Immunology Care and Consortium of Independent Immunology Clinics*; [4]*Pharmsight*; [5]*KalVista Pharmaceuticals*; [6]*Allergy, Asthma and Immunology, Departments of Medicine, Pediatrics, and Biomedical Sciences, Director ACARE International Hereditary Angioedema Resource Center, Penn State University, Hershey, Pennsylvania, United States of America*; *Vinmec-VinUni Institute of Immunology, Vinmec Hospital, Times City and Vin University, Hanoi, Vietnam*

BACKGROUND: While several non-androgen long-term prophylaxis (LTP) therapies are approved for hereditary angioedema (HAE) in the US, patients still experience attacks, leading to significant healthcare resource utilization. Beyond the physical burden of HAE attacks, anxiety is a frequently reported comorbidity in HAE. Limited real-world data related to anxiety exists among patients receiving LTP.

OBJECTIVE: This study leveraged a national administrative claims database to assess the impact of anxiety on healthcare utilization in patients with HAE receiving LTP.

METHODS: Based on the IQVIA PharMetrics® Plus Closed Health Plan Database (Jan 2019 to Dec 2024) patients with ≥1 claims of LTP. Anxiety diagnosis: ICD-10 F41.x. Claims of on-demand therapy use, inpatient, outpatient, emergency room (ER) and home health (HH) visits were evaluated 12 months following index date (first LTP claim). P-values were calculated using a Chi-square test.

RESULTS: Among 874 non-androgen LTP users (mean age 39 years; 73% female), 21% (n=180) had a diagnosis of anxiety one year pre-index and 25% (n=221) post-index. Overall, 61.3% of LTP users had ≥1 post-index on-demand therapy claim. A higher proportion of patients with anxiety utilized more healthcare services compared to those without anxiety: outpatient, 86% vs 78% (OR: 1.82); ER, 28% vs 15% (OR: 2.29); inpatient, 18% vs 5% (OR: 4.30); HH, 22% vs 14% (OR: 1.67). Patients with anxiety also had higher mean annual number of healthcare visits across all types of services compared to those without anxiety (outpatient, 5.5 vs 4.0, p<0.05; ER, 2.9 vs 2.1, p=0.078; inpatient, 3.7 vs 1.8, p<0.001; and HH, 15.4 vs 11.2, p=0.361). Annual on-demand treatment doses were higher among patients with anxiety compared to those without (mean 26.0 vs 18.7, p<0.05). Among those with higher on-demand doses, the proportion with anxiety was higher (39% vs 22%, OR: 2.28).

CONCLUSIONS: Anxiety is a common comorbidity among HAE patients receiving non-androgen LTP. Anxiety was associated with a greater burden on the healthcare system, increasing the odds of utilizing healthcare services with the strongest association observed for inpatient and ER visits. LTP patients with anxiety utilized significantly more on-demand therapy than those without. Conversely, LTP users who had greater on-demand use were more likely to have anxiety. These real-world findings underscore that anxiety is a driver of increased healthcare resource utilization including on-demand treatments among HAE patients receiving LTP.

SPONSORSHIP: KalVista Pharmaceuticals

220 Real-world treatment patterns and healthcare utilization in newly diagnosed lupus nephritis: A claims and EHR-based analysis

Gupta A[1], *Verma V*[1], *Roy A*[1], *Nayyar A*[1], *Arora A*[1], *Khatavkar V*[1], *Sharma T*[1], *Rahman S*[1], *Zaheer M*[1], *Raj U*[1], *Chauhan S*[1], *Paul K*[1], *Brooks L*[2], *Seligman M*[2], *Heath K*[3]; *anuj_gupta457@optum.com*; *vikash.verma@optum.com*; *abhimanyu.roy@optum.com*; *abhinav.nayyar@optum.com*; *ankitkumar_arora@optum.com*; *vishan_khatavkar@optum.com*
[1]*Optum Inc.*; [2]*OptumInsight*; [3]*Optum*

BACKGROUND: Lupus nephritis (LN), a severe manifestation of Systemic Lupus Erythematosus (SLE), affects up to 70% of patients and contributes significantly to morbidity and healthcare burden. Despite established guidelines, real-world management remains variable, with limited data on early treatment patterns and healthcare resource utilization (HCRU) in incident cases.

OBJECTIVE: To assess treatment patterns, adherence, HCRU, and comorbidity profiles in incident LN patients using claims and EHR data.

METHODS: Incident LN patients were identified between January 1, 2021, and June 30, 2024, using ICD-10 codes from the Optum® de-identified Market Clarity database. The index event was defined as the first observed LN diagnosis within the study period. Continuous medical and pharmacy eligibility was ensured for ≥12 months pre and post index period. Patients with history of renal transplant, dialysis, or ESRD were excluded. Treatment patterns were assessed based on the use of immunosuppressants (mycophenolate mofetil) and glucocorticoids (prednisone). Medication adherence was evaluated using the proportion of days covered

(PDC ≥80%). HCRU was categorized by the site of care. We will also be evaluating the comorbidity profile and treatment persistence using Kaplan-Meier.

RESULTS: Among 7,994 incident LN patients, 84.0% were female; 45.0% were Caucasian and 26.0% African American. Adherence to mycophenolate mofetil was suboptimal, with a mean PDC of 0.628 (SD = 0.264). Only patients in the 75th percentile met the commonly accepted adherence threshold. Prednisone adherence was lower, with a mean PDC of 0.403 (SD = 0.308), indicating widespread non-adherence. HCRU analysis revealed office/clinic visits were most frequent (n = 3,119; mean = 4.25; SD = 4.47), followed by outpatient (n = 2,836; mean = 3.59; SD = 4.15) and inpatient services (n = 1,283; mean = 7.29; SD = 10.71). Home health services, though less common (n = 208), had the highest mean utilization (mean = 10.82; SD = 14.94), suggesting intensive care needs for a subset of patients. Laboratory services (n = 1,349; mean = 2.83; SD = 2.81) and emergency room visits (n = 225; mean = 1.36; SD = 0.87) were also common, while skilled nursing facility and urgent care visits were infrequent.

CONCLUSIONS: Adherence to immunosuppressants and corticosteroids was generally poor, and HCRU showed high variability, especially in inpatient and home health settings. These findings highlight the need for payer-driven adherence initiatives, provider-led care coordination, and pharma-supported patient engagement to improve outcomes and reduce avoidable costs.

SPONSORSHIP: None

221 Real-world comparative analysis of FcRn antagonists vs C5 inhibitors in generalized myasthenia gravis: Insights from claims data on economic burden

Gupta A[1], *Verma* V[1], *Roy* A[1], *Nayyar* A[1], *Arora* A[1], *Khatavkar* V[1], *Singh* S[1], *Sundaram* S[1], *Malhotra* J[1], *Roy* T[1], *Sharma* N[1], *Kaur* D[1], *Khandelwal* H[1], *Batra* K[1], *Brooks* L[2], *Seligman* M[2], *Heath* K[3]; *anuj_gupta457@optum.com*; *vikash.verma@optum.com*; *abhimanyu.roy@optum.com*; *abhinav.nayyar@optum.com*; *ankitkumar_arora@optum.com*; *vishan_khatavkar@optum.com*
[1]*Optum Inc.*; [2]*OptumInsight*; [3]*Optum*

BACKGROUND: Generalized myasthenia gravis (gMG) is a chronic autoimmune disorder causing muscle weakness due to immune-mediated acetylcholine receptor impairment. Current targeted approved therapies include FcRn antagonists and C5 inhibitors, for gMG patients unresponsive to standard treatments. As the therapeutic landscape evolves, understanding the economic implications of these agents is critical for informed clinical and payer decision-making.

OBJECTIVE: To compare the economic burden associated with FcRn antagonists versus C5 inhibitors in adults with gMG using real-world claims data.

METHODS: This retrospective cohort study utilized Optum® Market Clarity claims data from Jul 2021 to Mar 2025. The study included adults (≥18 years) with a new diagnosis of gMG (ICD-10: G70.0, G70.00, G70.01) during the index period (Jan 2022 to Sep 2024). Two cohorts were defined by receipt of FcRn antagonists or C5 inhibitors. Continuous enrollment for 6 months pre- and post-index were ensured and patients with prior gMG diagnosis or drug use during baseline were excluded. Medical and pharmacy costs were assessed during follow-up period. Descriptive statistics summarized outcomes, and unpaired t-tests compared mean costs between cohorts.

RESULTS: Of 58,242 gMG patients identified, 14,113 met all inclusion criteria. Mean time to treatment initiation was longer for FcRn antagonists (87.6 days, SD±52.8) than C5 inhibitors (72.4 days, SD±57.3). For all-cause total costs, FcRn antagonist users (n=172) had higher mean total costs than C5 inhibitor users (n=555): $131,022 (SD±172,043) vs. $94,234 (SD±133,980; p=0.0107). Pharmacy costs were greater for FcRn antagonists ($91,653 vs. $40,344; p< 0.0001), while medical costs were lower ($39,370 vs. $53,889; p=0.0098). For gMG-specific costs, FcRn antagonist users incurred higher mean total expenses ($51,378 vs. $31,912; p=0.0029), with both medical ($33,084 vs. $20,833; p=0.0166) and pharmacy ($18,294 vs. $11,079; p=0.0411) costs elevated compared to C5 inhibitors.

CONCLUSIONS: FcRn antagonists are associated with higher overall and pharmacy-related costs compared to C5 inhibitors, despite lower medical expenses. These findings underscore the importance of economic considerations in gMG treatment selection and may inform payer and provider strategies to balance clinical efficacy with affordability.

SPONSORSHIP: None

Infectious Disease

230 Characterizing the epidemiology of patients with refractory and resistant herpes simplex virus (HSV) infections: Findings from an electronic health record (EHR)-linked claims analysis

Chemaly R[1], *Edwards L*[2], *Lawrence K*[3], *Wat C*[2], *Birkmann A*[4], *Ouellette T*[5], *Herath D*[2], *Spurrier M*[6], *Schossler A*[6], *Ali A*[6], *Leavitt E*[7], *Hadker N*[7], *Bhatnagar V*[7]; *rfchemaly@mdanderson.org*; *Thomas.Ouellette@aicuris.com*
[1]*University of Texas MD Anderson Cancer Center, Houston, TX (USA)*; [2]*Aicuris Anti-infective Cures AG (DEU)*; [3]*Aicuris*; [4]*AiCuris Anti-Infective Cures AG*; [5]*Aicuris Inc. – Waltham, MA (USA)*; [6]*Trinity Life Sciences*; [7]*Trinity Partners LLC*

BACKGROUND: As per WHO, in 2020, 64.2% of people aged 0-49 were infected with HSV-1, and 13.4% of people aged 15-49 were infected with HSV-2. Available antiviral agents are less effective against refractory and resistant HSV (R/R HSV) infections in immunocompromised (IC) hosts, including recipients of hematopoietic cell transplantation (HCT) or solid organ transplantation (SOT), people living with human immunodeficiency virus (PLWH), and those receiving immunosuppressive therapy (Rx IC). Foscarnet is IV-only and poorly tolerated. Epidemiological data on these patients remain limited.

OBJECTIVE: To determine the epidemiology and current antiviral treatment of R/R HSV infections in the US.

METHODS: This retrospective analysis used de-identified 2022-2024 EHR and claims data from HealthVerity, Inovalon (claims), and Arcadia (EHR), linked at the patient level. HSV cases were identified by diagnostic and treatment codes. Prevalence in the US was estimated using age and sex rates applied to Census data. Overlapping claims and EHR records were used to identify R/R HSV. This was defined by changes in medication regimen (second-line therapy), such as adjustments in dosing, escalation or switching of therapy (including IV acyclovir, foscarnet, cidofovir, imiquimod). AE rates were evaluated during the 30-day period following antiviral therapy.

RESULTS: In 2024, there were 3,912,607 diagnosed HSV cases in the US; 6.8% (266,652) of patients were IC. Among 152,835 patients with both claims and EHR data, IC prevalence rates were 0.19% (HCT), 0.35% (SOT), 2.12% (PLWH), and 4.15% (Rx IC). These IC patients were disproportionately affected by R/R HSV; use of second-line therapy, indicative of R/R HSV infection, was identified in 7.4% of HCT patients, 4.3% of SOT patients, 4.3% of PLWH, and 2.1% of Rx IC patients. Of the patients receiving second-line therapy, 14% experienced AEs such as electrolyte disturbances and renal toxicity, typically associated with second-line therapy, compared to 7% of patients receiving first-line therapy. The risk was more pronounced among those receiving IV therapy, where 40% experienced AEs.

CONCLUSIONS: HSV is highly prevalent in the US and poses a public health risk. About 1 in 15 people with HSV are immunocompromised. There is an urgent need for safe oral treatments to reduce patient burden for ACV-R/R HSV infections, especially for immunocompromised patients who often experience adverse events from second-line or IV therapies.

SPONSORSHIP: Aicuris

231 Healthcare resource utilization and costs among people with HIV (PWH) in the 3 years following diagnosis

Cohen J[1], *Christoph M*[2], *Anupindi V*[3], *Coaquira Castro J*[4], *Mordi U*[2], *Haloski K*[2], *Hsiao A*[4], *Shaikh N*[3], *Zhou X*[3], *Near A*[3]; *joshua.parsons.cohen@gmail.com*; *mary.christophschubel1@gilead.com*
[1]*Formerly Tufts University*; [2]*Gilead Sciences*; [3]IQVIA *Inc*; [4]*Gilead Sciences, Inc., Foster City, California, United States*

BACKGROUND: While it is well established that the economic burden of HIV is substantial, there is limited data on how healthcare resource utilization (HCRU) and costs evolve in the years immediately following an HIV diagnosis (dx).

OBJECTIVE: To quantify and compare HCRU and costs among people with HIV (PWH) in the US during the three years following HIV dx versus 1 year before dx.

METHODS: Using IQVIA PharMetrics® Plus claims data, adults (≥18 years) with an initial HIV dx (index date) from 01/2014 to 09/2023 were identified. HIV dx was defined as (1) ≥1 inpatient claim for HIV-1 dx, or (2) ≥2 outpatient claims for HIV-1 dx ≥30 days apart, with ≥1 claim not coinciding with an HIV screening test date, or (3) ≥1 outpatient claim with HIV dx and ≥1 prescription claim for antiretroviral therapy (ART) on or after the dx claim. Selection criteria included continuous enrollment ≥12 months before and ≥3 years after index, and no record of HIV-1/HIV-2 infection or ART use (excluding pre-exposure prophylaxis [PrEP]) any time before index. Annual all-cause HCRU and costs per person were described and compared during the 12-month baseline and annually during 3 years of follow-up.

RESULTS: Among PWH (N=2,370; 73.7% male; mean±standard deviation (SD) age, 45.4±14.6 years), 52.9% had commercial insurance, 36.8% had Medicaid managed care plans and 6.7% had Medicare Advantage. Annual mean±SD all-cause total healthcare costs were $40,937±49,583, $29,957±31,595, and $30,217±31,563 during follow-up years 1 to 3, respectively,

significantly higher than the 12-month baseline cost of $12,095 ±27,771 (p<0.001; all 3 comparisons). Medical costs (including inpatient, emergency room [ER] and outpatient medical) were $10,146±25,978 at baseline, $20,986±41,302 at year 1, $10,497± 23,071 at year 2, and $10,539±22,419 at year 3 (p<0.001; all 3 comparisons). Mean pharmacy costs were $1,949±6,175 at baseline, $19,951±23,159 at year 1, $19,460±21,582 at year 2, and $19,678±21,651 at year 3 (p<0.001; all 3 comparisons). PWH with ≥1 hospitalization increased from 13.4% at baseline to 27.0% at year 1, then declined to 12.2% by year 3, whereas ER visits were relatively stable and all other categories of HCRU (outpatient visits and surgery, radiology, laboratory tests, ancillary services) increased during follow-up (p<0.05).

CONCLUSIONS: HCRU increased in the year following HIV Dx with hospitalization rates doubling and healthcare costs more than tripling. In addition to ongoing support in the care of PWH, prevention of HIV is critical through policies and clinical programs that align stakeholders and create broad access to PrEP.

SPONSORSHIP: Gilead Sciences

232 Fiscal impact of antiretroviral therapy for the management of HIV in Southern United States (1987-2023)

Mordi U[1], *Sullivan P*[2], *Paquete A*[3], *Yeh A*[4], *Thaliffdeen R*[5], *Rush J*[1], *Connolly M*[6], *Kotsopoulos N*[3], *Zachry W*[7], *Jarrett J*[8]; *uche.mordi@gilead.com*; *pssulli@emory.edu*
[1]*Gilead Sciences*; [2]*Emory University, Atlanta, Georgia, United States*; [3]*Global Market Access Solutions*; [4]*Gilead Sciences, Inc.*; [5]*Gilead*; [6]*Global Market Access Solutions, Mooresville, North Carolina, United States*; [7]*Gilead Sciences, Inc., Foster City, California, United States*; [8]*Gilead Sciences, Inc., Foster City, California, USA*

BACKGROUND: Antiretroviral therapy (ART) has resulted in improved health outcomes for people with human immunodeficiency virus (HIV) and reduced onward transmission. Clinical benefits of ART are expected to result in wider economic implications, with a positive impact on productivity and tax revenue.

OBJECTIVE: To estimate the economic impact of ART on employment, tax revenue, and healthcare costs in select Southern states (Florida [FL], Georgia, Mississippi [MS], South Carolina, and Texas) since its introduction in 1987.

METHODS: Historical state-specific epidemiological data (1987-2023) was compared to a counterfactual scenario without ART. The scenario without ART was constructed using time series analysis alongside a transmission equation based on the effectiveness of ART. ART coverage and healthcare costs financed by the public sector were assumed to be similar across states, and those on ART were assumed to achieve viral suppression. Pre-exposure prophylaxis was not included. Clinical outcomes assessed were the number of HIV transmissions, acquired immunodeficiency syndrome (AIDS) diagnoses, and HIV-related deaths. These estimates were translated to workforce participation and to HIV- and AIDS-related healthcare costs, sourced from the literature. Employment status was used to estimate tax revenue and expenditure on social transfers to determine the fiscal gains for governmental accounts by state. A secondary analysis was conducted to explore the longevity effects (i.e., differential public outlays for disability benefits, retirement pensions) given the increased life expectancy of those treated with ART.

RESULTS: Investments in ART in the Southern states from 1987 through 2023 were estimated to have prevented over 310,000 HIV cases and 400,000 HIV-related deaths. Improved life expectancy and labor market outcomes were estimated to provide savings ranging from $20 (MS) to $387 (FL) billion across individual states. States with historically high HIV incidence showed greater total savings (e.g., FL). In each Southern state considered, savings exceeded costs, generating a return on ART investment range of $3.4 (MS) to $6.0 (FL) to the public sector per $1 invested. Results remained favorable when longevity effects were added.

CONCLUSIONS: Our analysis of ART funding by the public sector found positive fiscal returns across key Southern states, despite variations in epidemiological patterns and public health programs. Insurance coverage, formulary protections, and provider availability to support ART engagement for PWH may further maximize individual health and magnitude of fiscal return.

SPONSORSHIP: Gilead Sciences, Inc.

233 Adherence to pharmacological interventions in hepatitis delta virus (HDV) infection: A systematic literature review

Buti M[1], Papadakis Sali A[2], Sharma S[3], Der-Torossian C[4], Kim C[4], Singh B[3], Rock M[4], Lampertico P[5]; mariabutiferret@gmail.com; marvin.rock@gilead.com
[1]Liver Unit, Hospital Universitario Vall d'Hebron, Barcelona, Spain; [2]Gilead Sciences, Stockley Park, United Kingdom; [3]Pharmacoevidence, Mohali, India; [4]Gilead Sciences, Inc., Foster City, CA, USA; [5]Division of Gastroenterology and Hepatology, Foundation IRCCS Ca' Granda Ospedale Maggiore Policlinico, Milan, Italy; CRC A. M. and A. Migliavacca Center for Liver Disease, Department of Pathophysiology and Transplantation, University of Milan, Milan, Italy

BACKGROUND: Hepatitis delta virus (HDV) infection is the most severe form of viral hepatitis with a poor prognosis. Suboptimal adherence to therapy due to administration challenges and inadequate patient support can reduce clinical effectiveness and worsen long-term outcomes. Given limited treatment options, understanding adherence patterns and barriers is critical for improving outcomes and guiding clinical decisions.

OBJECTIVE: This systematic literature review (SLR) aimed to identify existing evidence on treatment adherence among patients with HDV infection.

METHODS: Embase®, Medline®, Cochrane, and relevant conferences were searched from database inception to August 2025 to identify studies reporting adherence to HDV treatments. The SLR followed the standard methodology as outlined in the Cochrane Handbook and PRISMA guidelines.

RESULTS: Of the 624 publications screened, 12 studies (9 observational; 3 clinical trials) were identified (sample size: 2 to 498). Most studies reported adherence with bulevirtide (BLV, n=8; sample size: 3 to 498), pegylated interferon/ interferon (PEG-IFN/IFN, n=5; sample size: 2 to 60), and nucleos(t)ide analogs for Hepatitis B virus infection (n=3; sample size: 3 to 118). Adherence was assessed using physician/author reporting (n=6), self-reporting (n=3), proportion of days covered ≥90% (PDC, n=1), medication proportion ratio (MPR, n=1), and dispensing medication rate (DMR, n=1). Overall, adherence was high (PDC ≥90%: 90.3%, MPR: 89%). Longitudinal data (2 studies) showed a slight decline in adherence from Week 24 to 96 (BLV 2 mg: 99.9 to 98.1% and 91 to 87%; BLV 10 mg: 96.5 to 94.6%). Patient-reported adherence ranged from 76.9 to 100% and physician-reported adherence 80 to 81% (completely or mostly adherent). A study showed a higher proportion of patients being completely adherent to BLV than IFN (54% vs 43%). Difficulties integrating medication into daily routine and forgetfulness were the most common adherence barriers.

CONCLUSIONS: Adherence to HDV treatments was generally high, despite the varying measurement definitions. Sustained adherence is critical for achieving optimal long-term outcomes. Standardized adherence metrics, patient education, improved access, and less frequent dosing may improve treatment success.

SPONSORSHIP: Gilead Sciences, Inc.

234 Real-world treatment patterns among adults with hepatitis delta virus (HDV) infection in the United States: A systematic literature review

Wong R[1], Papadakis Sali A[2], Rai P[3], Der-Torossian C[4], Agapova M[4], Park S[4], Singh B[3], Kim C[4], Rock M[4], Gish R[5]; rwong123@stanford.edu; marvin.rock@gilead.com
[1]Division of Gastroenterology and Hepatology, Stanford University School of Medicine; [2]Gilead Sciences, Stockley Park, United Kingdom; [3]Pharmacoevidence, Mohali, India; [4]Gilead Sciences, Inc., Foster City, CA, USA; [5]Hepatitis B Foundation, Doylestown, PA University of Nevada, Kirk Kerkorian School of Medicine at UNLV, Las Vegas, USA

BACKGROUND: Major gaps in the hepatitis delta virus (HDV) care cascade exist, including delays in timely diagnosis as well as HDV treatment. Understanding current real-world treatment patterns (TP) and their alignment with existing clinical practice guidelines (CPG) will help identify HDV treatment gaps towards which targeted interventions can be implemented to improve outcomes among HDV patients.

OBJECTIVE: To perform a systematic literature review (SLR) to evaluate real-world HDV TP in the United States (US) and analyze how these HDV practice patterns align with existing US CPG.

METHODS: Embase®, Medline®, and relevant congresses were searched for published studies from database inception to August 2025, reporting HDV TPs. A separate comprehensive literature review was performed to identify CPGs providing recommendations on HDV management. The SLR followed the standard methodology for conducting reviews as per Cochrane Handbook and PRISMA guidelines.

RESULTS: Of 1,134 publications screened, four HDV TP studies were identified (sample size: 96-6,719 patients; study period: 2006–2021). Two studies utilized IQVIA PharMetrics Plus, 1 evaluated US HealthVerity, and 1 evaluated US All-Payer Claims. Overall, HDV treatment rates with pegylated interferon (PEG-IFN/IFN) were low, ranging from 0.1% to 11.5%. HBV treatment with nucleos(t)ide analogues (NAs) including entecavir, tenofovir disoproxil fumarate (TDF), or tenofovir alafenamide (TAF) ranged from 8.8% to 55.2%, with TDF being

the most frequently prescribed (5.3%–35.4%), followed by entecavir (2.9%–14.8%) and TAF (1%–20.8%). Our study identified three CPGs in the US providing recommendations on HDV management: Chronic Liver Disease Foundation 2022, AASLD 2018, and Asian Americans physician's expert consensus 2016. All three CPGs recommended PEG-IFN-α treatment for at least 12-18 months, with concurrent NAs to treat coexisting HBV infection for patients with elevated HBV DNA (>2000 IU/mL).

CONCLUSIONS: Our assessment of HDV TP in the US reveals low utilization of CPG-recommended PEG-IFN (<10%), highlighting a disconnect between CPGs and real-world practice patterns. Equally concerning are the parallel gaps in HBV therapy, among HDV patients. Current AASLD 2018 HBV/HDV guidelines are outdated and do not reflect emerging therapies. Updating guidelines, strengthening HDV awareness, and promoting timely, guideline-aligned therapy for both HDV and underlying HBV are critical to improving outcomes and advancing equitable access to HDV-specific care.

SPONSORSHIP: Gilead Sciences, Inc

235 Budget impact model of new oral treatments for uncomplicated urogenital gonorrhea

Keast S[1], *Chamberlain J*[2], *Hendricks J*[3]; *shellie.keast@medimpact.com*
[1]*MedImpact*; [2]*MedImpact Healthcare Systems, Inc.*; [3]*MedImpact Healthcare Systems*

BACKGROUND: The Centers for Disease Control and Prevention (CDC) estimates 1.6 million new cases of gonococcal infections occur in the US each year. Of those, approximately 34% are diagnosed with only 70% of identified cases being treated as gonococcal infections may remain asymptomatic until complications occur. Current standard of care for uncomplicated urogenital gonorrhea is intramuscular injection with ceftriaxone 500 mg as a single dose. However, studies have shown that azithromycin either alone or with ceftriaxone is used in approximately 75% of cases, despite wide-spread antimicrobial resistance. Two new treatment options await approval by the Food and Drug Administration (FDA) in December 2025, gepotidacin, a triazaacenaphthylene, and zoliflodacin, a spiropyrimidinetrione.

OBJECTIVE: To investigate future financial impact using a budget impact model (BIM) for the treatment of uncomplicated urogenital gonorrhea in a hypothetical 1-million-member commercial health plan.

METHODS: A BIM analysis was conducted comparing two scenarios with and without the new antimicrobial products. In the base case scenario, the percentage of members utilizing ceftriaxone injection and oral azithromycin was estimated using information from published research. In the future scenario, the percentages of members utilizing the new oral antimicrobial agents were estimated based on low uptake scenarios (between 2.5% and 5%). Costs were estimated using current AWP, HCPCS, and CPT code pricing for ceftriaxone and azithromycin. Projected costs for gepotidacin and zoliflodacin were estimated based on the current unit AWP for gepotidacin's non-gonorrheal indication. A one-year time horizon was modeled. One-way sensitivity analyses varying the costs of treatments and the uptake of the new products were performed.

RESULTS: In the commercial plan an estimated 1,300 patients were treated each year. The projected budget impact was a $151,472 increase in pharmacy plan spend ($0.008 PMPM). Sensitivity analysis indicated the results were most sensitive to changes in price and uptake for new products, with zoliflodacin changes causing the largest fluctuations in PMPM.

CONCLUSIONS: While early uptake of new oral antibiotic therapies may be limited, the price per treatment difference between ceftriaxone and/or azithromycin and the new therapies along with the shift to the pharmacy benefit will result in an increase in the pharmacy PMPM. Plans will experience the impact as physicians begin to adopt these newer therapies in place of injectable ceftriaxone or resistance-associated azithromycin-only prescribing.

SPONSORSHIP: MedImpact Healthcare Systems, Inc.

Mental Health

249 Acute care events and treatment patterns 12 months after initiating olanzapine/samidorphan: Subgroup analyses of patients with schizophrenia or bipolar I disorder

Panchmatia H[1], *Cutler A*[2], *Webb N*[3], *Hughes A*[3], *Doane M*[1], *Oyedeji H*[4], *Jain R*[5]; *hemangi.panchmatia@alkermes.com*; *acutler@ajcmd.com*
[1]*Alkermes, Inc.*; [2]*SUNY Upstate Medical University*; [3]*Optum, Inc.*; [4]*Fortitude Behavioral Health*; [5]*Department of Psychiatry, Texas Tech University School of Medicine-Permian Basin*

BACKGROUND: In prior real-world studies, initiating combination olanzapine and samidorphan (OLZ/SAM) significantly reduced disease-related acute care events, which are a proxy for relapse, in patients with schizophrenia or bipolar I disorder (BD-I).

OBJECTIVE: To examine 12-month acute care events and treatment patterns by subgroups of patients with schizophrenia or BD-I before and after initiating OLZ/SAM.

METHODS: This retrospective claims analysis used data from Komodo Healthcare Map (10/18/2020–12/31/2023). Adults with schizophrenia or BD-I, ≥1 claim for OLZ/SAM, and ≥12 months' continuous enrollment in medical/pharmacy benefits before (baseline) and after (follow-up) OLZ/SAM initiation were eligible. Inpatient (IP) admissions and emergency department (ED) visits were compared between 12-month baseline and follow-up periods by age (18–34/35–54/≥55 years), sex (male/female), antipsychotic treatment prior to initiating OLZ/SAM (olanzapine/non-olanzapine), and insurance type (commercial/Medicaid/Medicare Advantage). Treatment patterns (adherence, persistence, discontinuation) were assessed during the follow-up period.

RESULTS: Overall, 1287 patients with schizophrenia and 1004 with BD-I were included. Initiating OLZ/SAM was associated with significant (P≤0.05) reductions in proportions of patients with ≥1 all-cause, mental health–related, or disease-related IP admission across most subgroups (absolute change ranges, schizophrenia: −3% to −22%; BD-I: −6% to −23%). Significant (P≤0.05) reductions in proportions of patients with ≥1 all-cause, mental health–related, or disease-related ED visit were observed across most subgroups (ranges, schizophrenia: 5% to −21%; BD-I: −3% to −18%). Adherence, persistence, and discontinuation were generally similar across subgroups in both cohorts.

CONCLUSIONS: Regardless of subgroup, initiating OLZ/SAM was generally associated with meaningful reductions in IP admissions and ED visits (suggesting reduced relapse risk) and with generally similar treatment patterns.

SPONSORSHIP: Alkermes, Inc.

250 Real-world effectiveness of zuranolone in postpartum depression: Interim results of a prospective observational study

Baker L[1], *Nagle-Yang S*[2], *Bian B*[3], *Lupton L*[4], *Patel K*[4], *Sova T*[3], *Belviso N*[3], *Mendoza J*[3], *Nguyen V*[3]; *ljoybakermd@gmail.com*; *kazumi014@gmail.com*; *tami.sova@biogen.com*
[1]*Wellstar West GA Medical Center, GA, USA*; [2]*University of Colorado School of Medicine, CO, USA*; [3]*Biogen*; [4]*CVS Health*

BACKGROUND: Postpartum depression (PPD) symptoms affect ~13.2% of women with a recent live birth in the US, with a global prevalence of 10-20%. Zuranolone was approved in the US (2023) as an oral, once-daily, 14-day treatment for adults with PPD.

OBJECTIVE: To assess the real-world effectiveness of zuranolone for treatment of PPD at 15 and 45 days following its initiation.

METHODS: This ongoing decentralized, patient-reported outcomes study uses live-agent calls and email to recruit patients filling zuranolone prescriptions through a national specialty pharmacy from 26 June 2025 until a 200-participant sample size is reached. Adults (≥18 years) who were pregnant within the last 12 months, have a diagnosis of PPD, are filling an initial prescription for zuranolone, and have no history of schizophrenia, schizoaffective or bipolar disorder are invited to enroll. Treatment effectiveness is assessed by changes in participant-reported Edinburgh Postnatal Depression Scale (EPDS) scores from Day 0 (treatment initiation) to Day 15 (immediately post-treatment) and Day 45 (30 days post-treatment).

RESULTS: Mean ± standard deviation (SD) age for the 122 participants enrolled as of 25 September 2025 was 30.5±5.3 years, and the majority (83.6%) were White. History of depression/major depressive disorder was reported by 54.1% of participants, and anxiety disorders (68.0%) were the most common psychiatric comorbidities. For the majority of participants (51.6%), zuranolone was the first medication used to treat PPD. Overall, 38.5% of participants were using zuranolone only (monotherapy) for PPD treatment; the remaining 61.5% of participants received other treatments concomitantly with zuranolone, most commonly antidepressants (46.7%) and/or psychotherapy (27.9%). At baseline (Day 0), mean ± SD EPDS scores were 18.8±6.0, with significant improvement observed among participants completing follow-up surveys: -8.9±5.4 points (95% CI: 7.8-9.9; p<0.001, n=95) at Day 15, and -10.3±5.6 points (95% CI: 8.9-11.7; p<0.001, n=65) at Day 45. Those with moderate PPD symptoms (EPDS 14-19) at baseline reported improvement of -9.0±3.8 points by Day 15 (95% CI: 7.7-10.2; n=37) with continued improvement that totaled -10.2±3.7 points (95% CI: 8.7-11.8; n=25) at Day 45.

CONCLUSIONS: In this interim analysis of an ongoing study, participants across a range of PPD symptom severity who received zuranolone reported significant improvement in depressive symptoms, with clinically meaningful EPDS score improvement by Day 15 that was maintained at Day 45

SPONSORSHIP: Biogen

251 Zuranolone and antidepressant real-world treatment pattern among adults with postpartum depression

Patel K[1], *Nguyen V*[2], *Bian B*[2], *Earnest J*[3], *Formella A*[4], *Nahm K*[2], *Belviso N*[2], *Parsons T*[1], *Unverferth K*[5], *Maximos B*[6], *Simon M*[7], *Lupton L*[1]; *kazumi014@gmail.com*
[1]*CVS Health*; [2]*Biogen*; [3]*Supernus*; [4]*Supernus Pharmaceuticals*; [5]*4 Department of Psychiatry and Biobehavioral Sciences, David Geffen School of Medicine at UCLA*; [6]*University of Houston*; [7]*Department of Obstetrics and Gynecology, Northwestern University Feinberg School of Medicine*

BACKGROUND: Postpartum depression (PPD) symptoms affect ~13.2% of women with a recent live birth in the US. Zuranolone (ZRN) was approved in the US (2023) as an oral, once-daily, 14-day treatment for adults with PPD.

OBJECTIVE: To describe real-world patient characteristics and treatment patterns in adults with PPD initiating ZRN or antidepressants (ADTs) using retrospective claims data (2023-2024).

METHODS: This study included adults aged ≥18 years with ≥1 pregnancy claim and ≥1 PPD or major depressive disorder (MDD) ICD-10–coded claim during or within 12 months after the end of pregnancy, and prior to initiating ZRN or ADT. Patient characteristics and treatment patterns were analyzed among individuals continuously enrolled in the claims database ≥12 months prior to pregnancy through 3 months following index treatment. Patients were categorized into 3 groups: ZRN first-line (ZRN-1L; n=233), ZRN following first-line ADTs (ADT-ZRN; n=332), and first-line ADTs only (ADT-1L; 15,779). Patients taking ZRN were identified from a national specialty pharmacy; linked medical and ADT claims were obtained from a third-party database.

RESULTS: Among the ZRN-1L group, 63.1% (n=147) were prescribed ZRN as monotherapy while 36.9% were co-prescribed an ADT. Of those on monotherapy, 82.3% (n=121) did not fill a subsequent ADT prescription within 3 months, whereas 17.7% (n=26) did. Among the ADT-ZRN group, 69.6% (n=231) discontinued first-line ADTs upon initiating ZRN, suggesting a switch to ZRN, while 30.4% (n=101) did not immediately (≤3 months) discontinue first-line ADTs. Among the ZRN-1L group, 83.3% (n=194) did not fill new prescriptions for additional treatment (ZRN or new ADT) within 3 months of their index ZRN prescription, whereas 16.7% did. Similarly, in the ADT-ZRN group, 88.3% (n= 293) did not fill additional ZRN or new ADT prescriptions within 3 months, whereas 11.7% did. Among the ADT-1L (only) group (n=15,779), 55.3% persisted on treatment, 34.0% discontinued, and 11.4% were prescribed a new ADT or antipsychotic within 3 months of the index ADT prescription.

CONCLUSIONS: This real-world study assessed PPD treatment patterns in adults receiving ZRN and/or ADTs. Most (83%-88%) patients treated with 14-days of ZRN first-line or following initial ADT did not appear to require additional pharmacologic intervention, suggesting ZRN was sufficient for initial management of PPD in many cases.

SPONSORSHIP: Sage Therapeutics, LLC; Supernus Pharmaceuticals, Inc.; Biogen.

252 Healthcare resource utilization and costs for diagnosed generalized anxiety disorder (GAD): Insights from real-world evidence

Louie D[1], *Ferries E*[1], *Suponcic S*[2], *Robinson K*[3], *Gallivan M*[3], *Lam F*[3], *Silber A*[3], *O'Hara M*[3], *Duong P*[1], *Strawn J*[4], *McIntyre R*[5]; *dlouie@mindmed.co*
[1]*Mind Medicine, Inc.*; [2]*Value and Access Advisors*; [3]*Trinity Life Sciences*; [4]*University of Cincinnati*; [5]*University of Toronto*

BACKGROUND: Generalized anxiety disorder (GAD) is a chronic and debilitating condition marked by excessive worry. Despite the extensive burden of GAD and impact on patients' lives, knowledge gaps remain in understanding the patient journey and healthcare resource utilization (HCRU).

OBJECTIVE: To assess HCRU between patients with GAD and matched non-GAD patients to quantify the healthcare burden and associated costs.

METHODS: A retrospective analysis was performed utilizing closed claims data from the Komodo Healthcare Map™, a longitudinal, deidentified, US pharmacy and medical claims database. Patients were ≥18 years old with continuous enrollment of 36 months from 2021 to 2023. Included GAD patients were required to have two or more medical claims at least 30 days apart for F41.1 or one medical claim and at least one GAD-related treatment claim. The GAD cohort's HCRU was compared against an exact matched non-GAD general population cohort, balanced by age, gender, US Census region, and payer type to control for confounding variables. HCRU was measured across inpatient, outpatient, office, emergency room (ER), and home visits in calendar year 2023 using the primary diagnosis code on a claim. Costs were calculated using estimates for services by setting of care and age to evaluate potential cost variations beyond visit frequency.

RESULTS: HCRU patterns were assessed in a GAD cohort (n=184,663) versus a non-GAD matched cohort (n=184,663). GAD patients incurred over twice the mean all-cause costs of non-GAD patients (~$34,000 vs ~$14,000). GAD patients incurred double the number of total medical visits. Inpatient care accounted for the largest differences in cost between cohorts, in part due to longer median inpatient stays (7 days vs 4 days, $p < 0.05$). Outpatient visits were more

frequent for GAD patients (84% vs 70%; median 5 vs 3 visits) and office visits were notably higher (median 12 vs 5 visits). ER (median, 1) and home visits (median, 2) were similar across cohorts.

CONCLUSIONS: These findings underscore the frequency of healthcare visits among GAD patients, highlighting the substantial clinical and economic burden associated with GAD. Expenditures related to symptom management or comorbidities within the GAD cohort were four times greater than the costs for managing their mental health. Over the past decade, limited studies have evaluated the patient journey for individuals with GAD using large claims databases. These findings reinforce and emphasize the need for innovation in GAD care and targeted strategies to improve disorder management and reduce avoidable healthcare costs.

SPONSORSHIP: Mind Medicine, Inc.

253 Real-world comparison of olanzapine/samidorphan versus olanzapine: An assessment of treatment patterns and acute care events among patients with schizophrenia or bipolar I disorder

Panchmatia H[1], *Jain R*[2], *Hughes A*[3], *Doane M*[1], *Chepke C*[4], *Cutler A*[5]; *hemangi.panchmatia@alkermes.com*; *michael.doane@alkermes.com*
[1]*Alkermes, Inc.*; [2]*Department of Psychiatry, Texas Tech University School of Medicine-Permian Basin*; [3]*Optum, Inc.*; [4]*Excel Psychiatric Associates, P.A.*; [5]*SUNY Upstate Medical University*

BACKGROUND: Combined olanzapine and samidorphan (OLZ/SAM) provides the antipsychotic efficacy of olanzapine while mitigating olanzapine-associated weight gain. In a 4-year open-label study, OLZ/SAM maintained symptom control, with small changes in body weight and minimal changes in lipid/glycemic parameters..

OBJECTIVE: To compare treatment patterns and acute care events in patients with schizophrenia or bipolar I disorder (BD-I) initiating OLZ/SAM versus olanzapine.

METHODS: This claims analysis used Komodo Healthcare Map data (10/18/2020-12/31/2023). Medicaid-insured adults with schizophrenia or BD-I with ≥1 OLZ/SAM or olanzapine claim were eligible; OLZ/SAM claims were prioritized over olanzapine claims to set the index date. Patients were propensity score matched 1:1 on baseline demographic/clinical variables between the OLZ/SAM and olanzapine cohorts. Treatment patterns (adherence, persistence, discontinuation), acute care events including inpatient (IP) admissions and emergency department (ED) visits (all cause, mental health related, or disease related [often used as a proxy for relapse]), and numbers of days hospitalized per patient were compared between cohorts during the 12-month follow-up period.

RESULTS: After matching, 1614 patients with schizophrenia (OLZ/SAM, n=807; olanzapine, n=807) and 1008 with BD-I (OLZ/SAM, n=504; olanzapine, n=504) were included across both treatment cohorts. In both cohorts, OLZ/SAM was associated with significantly higher adherence, longer persistence, and lower discontinuation rates versus olanzapine. OLZ/SAM was associated with significantly lower likelihood of ≥1 all-cause, mental health–related, or disease-related IP admission (odds ratio [OR] range, schizophrenia: 0.52-0.59; BD-I: 0.52-0.58) or ED visit (OR range, schizophrenia: 0.47-0.54; BD-I: 0.62-0.74). Across all-cause, mental health–related, and disease-related events, mean numbers of days hospitalized per patient were significantly lower (range, schizophrenia: −4.7 to −5.7 days; BD-I: −3.2 to −4.5 days) for OLZ/SAM versus olanzapine

CONCLUSIONS: OLZ/SAM treatment offers meaningful real-world effectiveness benefits over olanzapine, as observed by favorable treatment patterns and significantly lower likelihood of acute care events. Significantly lower likelihood of disease-related acute care events suggests a lower likelihood of relapse with OLZ/SAM treatment vs olanzapine.

SPONSORSHIP: Alkermes, Inc.

254 Using NLP and agentic AI to uncover care gaps in pediatric ADHD: A real-world data approach

Verma V[1], *Roy A*[1], *Nayyar A*[1], *Arora A*[1], *Gupta A*[1], *Khatavkar V*[1], *V V*[1], *Brooks L*[2], *Seligman M*[2], *Heath K*[3]; *vikash.verma@optum.com*; *abhimanyu.roy@optum.com*; *abhinav.nayyar@optum.com*; *ankitkumar_arora@optum.com*; *anuj_gupta457@optum.com*; *vishan_khatavkar@optum.com*
[1]*Optum Inc.*; [2]*OptumInsight*; [3]*Optum*

BACKGROUND: Attention-deficit/hyperactivity disorder (ADHD) is a common pediatric neurodevelopmental condition. Despite established clinical guidelines, care gaps in ADHD management persist, affecting outcomes. Advances in natural language processing (NLP) and agentic AI offer scalable methods to identify and address these gaps using real-world healthcare data.

OBJECTIVE: To apply NLP and agentic AI to identify care gaps in pediatric ADHD management by analyzing large-scale claims data, enabling targeted interventions.

METHODS: A retrospective cohort study was conducted using the Optum® Market Clarity database. Pediatric patients diagnosed with ADHD (index event) between 1 Jan 2022 and 31 Mar 2023 were included. Patients required continuous enrollment and healthcare activity for 12-month look-back, 24-month

follow-up from index event. Exclusions included prior ADHD diagnosis during the look-back period and clinical trial participation. NLP algorithms extracted care gap indicators from structured claims and unstructured activity records. Agentic AI models stratified patients by risk of non-adherence and predicted likelihood of care gaps based on demographic, behavioral, and clinical features.

RESULTS: Of ~2.5M pediatric patients identified with ADHD, ~1.2M (51.46%) had no prior diagnosis in the look-back period. After applying enrollment and activity 38,921 patients were included in the study. NLP analysis revealed several key care gaps; less than half (42%) of patients received a follow-up visit within 30 days of initiating ADHD medication, falling short of HEDIS benchmarks. Medication adherence was low, with only 27.5% maintaining ≥80% adherence over 12 months; average adherence was 56%. Behavioral therapy documentation was limited—only 35% had evidence of therapy recommendations in clinical notes. Disparities were observed, with lower adherence and follow-up rates among racial and ethnic minority groups and patients with coexisting depressive symptoms. Agentic AI models effectively identified high-risk subgroups, enabling proactive targeting of interventions.

CONCLUSIONS: NLP and agentic AI can uncover actionable care gaps in pediatric ADHD management using real-world data. Despite guideline availability, gaps in follow-up care, adherence, and behavioral therapy utilization remain prevalent. These findings highlight the need for targeted, data-driven interventions, especially for vulnerable populations. Agentic AI offers a scalable solution for monitoring care quality and guiding personalized strategies to improve outcomes.

SPONSORSHIP: None

Musculoskeletal

263 Zeleciment rostudirsen targets the underlying cause of duchenne muscular dystrophy (DMD) to enable sustained functional improvement in males with DMD mutations amenable to exon 51 skipping enrolled in the phase 1/2 DELIVER trial

Henderson C[1], *Guglieri M*[2], *Campbell C*[3], *Deconinck N*[4], *De Waele L*[5], *Flanigan K*[6], *Lorentzos M*[7], *Phan H*[8], *Shieh P*[9], *Danese D*[1], *Ray S*[1], *Naylor M*[1], *Wang D*[1], *Kerr D*[1]; *crystal.henderson@dyne-tx.com*; *kevin.flanigan@nationwidechildrens.org*
[1]*Dyne Therapeutics*; [2]*Newcastle University*; [3]*Western University*; [4]*Neuromuscular Reference Center UZ Gent*; [5]*University Hospitals Leuven*; [6]*Nationwide Children's Hospital*; [7]*Children's Hospital at Westmead*; [8]*Rare Disease Research, LLC*; [9]*Westwood Neurology*

BACKGROUND: DMD is a progressive, X-linked neuromuscular disorder caused by deficiency of functional dystrophin protein, leading to loss of ambulation, cardiopulmonary complications, and premature mortality. This severe clinical burden is accompanied by substantial increases in healthcare resource use (HCRU). Patients with DMD show a ~10-fold increase in hospitalizations and 2–3 times higher direct medical costs versus age-matched peers, with expenditures rising sharply as function declines.

OBJECTIVE: The safety and efficacy of zeleciment rostudirsen (z-rostudirsen, or DYNE-251, an investigational therapeutic) is studied in the phase 1/2 DELIVER trial (NCT05524883) in 4–16-year-old males with DMD mutations amenable to exon 51 skipping.

METHODS: In the completed multiple ascending dose (MAD) portion of DELIVER, participants were randomized to receive z-rostudirsen or placebo every 4 to 8 weeks (Q4W or Q8W) for 6 months across 7 dose levels up to 40 mg/kg. Participants are currently receiving 20 mg/kg z-rostudirsen Q4W in the open-label /long-term extension (OLE/LTE). Based on MAD results, 20 mg/kg Q4W was selected as the dose regimen for the DELIVER registrational expansion cohort, which is fully enrolled. Outcomes included safety and tolerability, change from baseline in dystrophin levels by Western blot, and multiple assessments of muscle function such as North Star Ambulatory Assessment (NSAA), Stride Velocity 95th Centile (SV95C) and certain timed functional tests.

RESULTS: In participants who received 20 mg/kg Q4W in the MAD portion of DELIVER, z-rostudirsen led to robust expression at Month 6 of near full-length dystrophin protein, at mean levels of 8.72% (muscle content-adjusted) of normal.

Functional improvement vs. baseline in SV95C was evident by Month 6 and sustained through Month 12 (latest data cut) in participants treated with 20 mg/kg Q4W z-rostudirsen (n=6) and through Month 18 (latest data cut) in participants who enrolled at 10 mg/kg Q4W and moved to 20 mg/kg Q4W DYNE-251 in the OLE/LTE (n=6). Early and sustained functional improvement vs. baseline was also seen in both cohorts for other motor function endpoints, including NSAA, Time to Rise from floor (TTR), and 10-meter walk/run (10MWR). As of February 7, 2025, z-rostudirsen has shown a favorable safety profile, with up to ~2.5 years of follow-up in some participants.

CONCLUSIONS: Z-rostudirsen has a favorable safety profile and has shown early and sustained functional improvement vs. baseline across multiple assessments. These improvements may lessen the considerable burden of DMD.

SPONSORSHIP: Dyne Therapeutics

264 Diagnostic journey and care in myotonic dystrophy type 1 (DM1)

Kreuzer A[1], *Novack* A[1], *Kerr* D[1], *Stevenson* T[2], *Rohrwasser* A[2], *Skinner* N[2], *Dugar* A[3], *Beaverson* K[3], *Melchior* A[4], *Jackson* S[4]; *allison.kreuzer@dyne-tx.com*
[1]*Dyne Therapeutics*; [2]*Myotonic Dystrophy Foundation*; [3]*Formerly of Dyne Therapeutics*; [4]*Engage Health Inc.*

BACKGROUND: DM1 is a rare, progressive, genetic, neuromuscular disease with high morbidity and early mortality. Caused by expansions in CTG repeats in the DMPK gene, this spliceopathy presents with multi-system manifestations and significant quality of life (QoL) impacts.

OBJECTIVE: To understand the lived experience of individuals diagnosed with DM1.

METHODS: Qualitative PRO study using the Myotonic Dystrophy Health Index (MDHI) to assess disease impact among 100 participants (92 individuals with DM1 and 8 caregivers), followed by telephone interviews.

RESULTS: DM1 participants (mean age 48.8 years) had on average experienced symptoms for 19.3 years prior to study completion. DM1 participants reported first recognized symptom, at mean age 29.5 years, was most often hand myotonia (25.6%), hand/arm weakness (12%), or tongue myotonia (6%). Many DM1 participants (84%) had family members diagnosed with DM1, most often a sibling/cousin (31.9%). Despite strong family history, only 9% were diagnosed before symptom onset (mean 8.4 years prior). For 91% diagnosed after symptom onset, diagnosis occurred 7.2 years after first symptom. Neurologists (77%) located at an academic center most often made the diagnosis. When looking across 17 disease domains (MDHI), fatigue and sleep scored as the most burdensome disease aspects (mean 60.1 and 48.5, respectively). Most DM1 participants (60%) received ongoing care from a neurologist/neuromuscular specialist (74%) at a multidisciplinary clinic. Only 3% had been refused care due to DM1. Eighty-six (86%) used at least one medication, medication categories were consistent with the multi-system nature of DM1: cardiac, GI, antidepressant/antianxiety, wakefulness, and pain, among others. Modafinil was the single medication most used. Most participants (58%) used caregiver assistance, most often for activities of daily living (40.2%), assisting with medical paperwork/appointments/medications (28.7%), physical help (20.7%), and personal care (10.3%). Significant work impacts due to DM1 were identified; many did not work (26%) or worked part time (13%) due to DM1. 29% worked without limits, 14% were retired/in college, 14% did not answer the question, and 4% did not work for unspecified reasons.

CONCLUSIONS: DM1 is a complex disease leading to significant multi-systemic impacts, occasional refusal of care, polypharmacy, assistance needs, and work impacts. Disease-modifying therapies are needed to improve QoL, and family history should be used to shorten time to diagnosis and potentially reduce time to treatment initiation.

SPONSORSHIP: Dyne Therapeutics, Myotonic Dystrophy Foundation

265 Health insurance profile and literacy in myotonic dystrophy type 1 (DM1)

Novack A[1], *Kerr* D[1], *Kreuzer* A[1], *Stevenson* T[2], *Rohrwasser* A[2], *Skinner* N[2], *Dugar* A[3], *Melchior* A[4], *Jackson* S[4], *Beaverson* K[3]; *anovack@dyne-tx.com*
[1]*Dyne Therapeutics*; [2]*Myotonic Dystrophy Foundation*; [3]*Formerly of Dyne Therapeutics*; [4]*Engage Health Inc.*

BACKGROUND: Health insurance literacy (HIL) is the extent to which individuals have the knowledge, ability, and confidence to find and evaluate health plan information, choose a plan suited to their financial and health needs, and use it effectively. HIL is critical in complex diseases such as myotonic dystrophy type 1 (DM1), where patients need optimal access to new therapies as they emerge.

OBJECTIVE: To understand the health insurance profile and literacy of individuals with DM1, compared with the general population.

METHODS: Mixed-methods PRO study, including a survey with 10 Kaiser Family Foundation health insurance knowledge questions that allowed reference to the general population, followed by a telephone interview.

RESULTS: The study included 100 participants aged 18+ with a confirmed diagnosis of juvenile (onset 11–20 years), adult (21–40), or late-onset (40+) DM1, or the parent/legal guardian of

such an individual. Of 100 participants, 92 were individuals diagnosed with DM1 —82 managed their own insurance and 10 did not—and 8 were caregivers who managed insurance. Most (99%) were insured: private (51%), government [Medicare, Medicaid, or both] (41%), both private and government (7%), and uninsured (1%). Private insurance was mostly employer-based and HMO (62.1%) vs. PPO (37.9%). Among government-insured participants, Medicare was most common (61%) followed by Medicaid (14.6%). For Medicare recipients, Advantage plans were more common than traditional (57.7% vs. 42.3%). Most were not on a Medicaid waiver (79%), citing ineligibility (19.4%), were not interested or believed they were insufficiently disabled (15.1% each), or unawareness of the waiver (7.5%). Few used co-pay support (4%), reduced co-pay (7%), or free drug programs (5%) or received non-profit financial support (4%), despite many reporting difficulties paying medical bills. Regarding HIL, participants scored better than the general population. Caregivers who managed insurance scored better than patients, and patients managing their own insurance scored better than those who did not. For practical concepts, only 8% correctly defined a patient assistance program, 33% off-label use, and 54% correctly prior authorization. When identifying their plan type, 23% misidentified it—most often related to managed Medicare.

CONCLUSIONS: While most participants were covered by health insurance and scored well on terminology, they had difficulty understanding their own plan types and concepts related to new therapies. These findings are helpful to address educational and programming needs.

SPONSORSHIP: Dyne Therapeutics

Oncology

273 Real-world treatment patterns and clinical outcomes of sacituzumab govitecan among patients with HR+/HER2- metastatic breast cancer: A retrospective administrative claims database cohort study in the US

Rugo H[1], *Dasgupta A*[2], *Kaushik A*[2], *Verret W*[3], *Gary D*[4], *Rehnquist M*[5], *Beal J*[6], *Sjekloca N*[7], *Yakkala V*[8], *Rajagopalan K*[8], *Tolaney S*[9]; *Hrugo@coh.org*; *anandaroop.dasgupta1@gilead.com*

[1]*Women's Cancer Program, Division Chief, Breast Medical Oncology, City of Hope Cancer Center*; [2]*Health Economics Outcomes Research (HEOR), Global Value and Access, Oncology, Gilead Sciences, Inc.*; [3]*Global Development Leader, Gilead Sciences, Inc.*; [4]*Patient Safety, Gilead Sciences, Inc.*; [5]*Real world evidence, Gilead Sciences, Inc.*; [6]*Oncology Strategy, Patient Access & Quality of Care, U.S. Medical Affairs, Gilead Sciences, Inc.*; [7]*Global Medical Affairs, Oncology, Gilead Sciences, Inc.*; [8]*Health Economics Outcomes Research, Anlitiks*; [9]*Department Of Medical Oncology, Dana-Farber Cancer Institute*

BACKGROUND: Patients with hormone receptor-positive/human epidermal growth factor 2-negative (HR+/HER2-; [IHC0, IHC1+, and IHC2+ and in situ hybridization negative]) metastatic breast cancer (mBC) who are resistant to endocrine therapy (ET) were limited to only chemotherapy (CT) treatments till the approval of antibody drug conjugates (ADCs). Sacituzumab govitecan (SG) is an approved ADC for HR+/HER2– mBC after ET and ≥2 prior systemic therapies in the metastatic setting, supported by efficacy and manageable safety in TROPiCS-02 and EVER-132-002 trials.

OBJECTIVE: To evaluate SG treatment patterns and associated clinical outcomes (i.e., real-world time on treatment [rwToT] and real-world time to treatment discontinuation [rwTTD]).

METHODS: A retrospective cohort study of adults with ≥2 diagnostic claims for mBC (ICD-10-CM codes: C50x, D05x, C77x, C78x, C79x) ≥30 days apart using the Anlitiks All Payor Claims (AAPC) database from 01/01/16 to 06/30/24 (i.e., study period) was conducted. Eligible patients had (1) evidence of estrogen receptor-positive (ER+) diagnosis (ICD-10: Z17.0) or ≥1 claim for approved treatments for HR+ BC, and not have any claims for anti-HER2 medications anytime during the study period, (2) initiated SG (index date) between 02/01/23 and 03/31/24, and (3) had continuous enrollment for ≥12-months and ≥3-months in the pre- and post-index periods, respectively. Patient characteristics (e.g., age, baseline comorbidities) and prior treatment history (e.g., ET, CT, ADC) for advanced disease were examined. Kaplan Meier analysis was used to estimate rwTOT (i.e., time

from index to last recorded SG date) and rwTTD (i.e., time from index to date of discontinuation or death).

RESULTS: Of the 914 SG patients, median age was 60 years. Pre-index comorbidities included chronic obstructive pulmonary disease (36%), congestive heart failure (19%) and myocardial infarction (6%). Prior treatment history included ≥1 line of treatment with CT (78%), ET (70%), CDK4/6i (36%), targeted therapy (19%), immunotherapy (13%) or ADC (famtrastuzumab deruxtecan-nxki (T-DXd), 33%) in the advanced setting. Among previously treated T-DXd patients, 78% initiated SG immediately after T-DXd. Median SG rwToT and rwTTD was approximately 4.9 months (95% CI: 4.5–5.4) and 6.4 months (95% CI: 6.1–7.0), respectively.

CONCLUSIONS: In this analysis, real-world clinical outcomes confirm treatment effectiveness of SG in a heavily pretreated population.

SPONSORSHIP: Gilead Sciences, Inc.

274 Real-world (RW) evaluation of health care resource utilization (HCRU) and costs for Medicare fee-for-service (FFS) patients with R/R large B-cell lymphoma (LBCL) treated with lisocabtagene maraleucel (liso-cel) versus bispecific antibodies (BsAbs)

Lei M[1], *Sorial M*[2], *Liu F*[3], *Toron F*[3], *Ditlevson J*[3], *Castro-Dickson C*[3], *Charafi L*[3], *Priyadarshini M*[3], *Kardel P*[4], *Maynard J*[4], *Humphreys S*[5], *Soefje S*[6]; *mlei1@mgh.harvard.edu*
[1]*Massachusetts General Hospital*; [2]*Dana-Farber Cancer Institute*; [3]*Bristol Myers Squibb*; [4]*ADVI Health LLC*; [5]*Providence Health*; [6]*Mayo Clinic*

BACKGROUND: Novel treatments for R/R LBCL, including chimeric antigen receptor (CAR) T-cell therapies and BsAbs, differ in mechanism of action, administration logistics, schedules, and costs. Liso-cel is recommended earlier than BsAbs in several LBCL subtype NCCN algorithms, but RW HCRU and costs are limited.

OBJECTIVE: To compare HCRU and cost of liso-cel and BsAbs in CAR T cell–naive patients (pts) with R/R LBCL.

METHODS: This retrospective study assessed HCRU using Medicare FFS claims data (inpatient [IP], outpatient [OP], and physician office [OFF]) and associated costs of liso-cel, glofitamab (GLO), and epcoritamab (EPC) in pts with R/R LBCL with ≥6 mo of follow-up (identification period: 02/2021–05/2024) irrespective of therapy line. Pts were followed after a 30-day index period (starting at first drug infusion) or through death. Results are reported with descriptive statistics.

RESULTS: Of pts included, 604, 171, and 97 received liso-cel, EPC, and GLO, respectively; median age was 75 y, 78 y, and 77 y, median Charleson Comorbidity Index was 3.0, 3.0, and 4.0, and median follow-up was 12 mo, 8 mo, and 7 mo, respectively. During the index period, numerically more pts received liso-cel (91%) as IPs compared with GLO (66%) and EPC (68%). Over 3 mo post-index, fewer liso-cel–treated pts were admitted as IPs (7%–9% per mo) versus EPC (14%–21%) and GLO (11%–30%). OP visits during index were similar, but numerically more common with liso-cel 3 mo post-index (77%–89%) compared with EPC (66%–70%) and GLO (70%–74%). OFF-based visits during index were 30%, 63%, and 54% for liso-cel, EPC, and GLO, respectively, but similar thereafter. Liso-cel had the highest 30-day index cost. Mean all-cause cost during index, including drug costs, was as follows: liso cel, $406,167; EPC, $58,702; GLO, $71,731. Post-index monthly costs for liso-cel were numerically lowest (range, $5814–$8196; GLO, $23,375–$59,736; EPC, $20,293–$44,535). In post-index Months 1–3, pts receiving liso-cel versus GLO and EPC incurred numerically lower IP costs ($6820 vs $16,755 and $12,316), Part B drug costs ($3607 vs $6344 and $5675), and OP costs ($4781 vs $6985 and $12,061). Projected from the index mo + 6 mo of costs, liso-cel may offer cost-savings over BsAbs at 14–17 mo after infusion.

CONCLUSIONS: Despite higher upfront costs of CAR T cell therapy, pts receiving liso-cel incurred numerically lower all-cause spending over the 3-mo post-index period, indicating a shift towards less intensive care settings. Liso-cel may offer long-term cost savings compared with BsAbs in R/R LBCL.

SPONSORSHIP: BMS

275 Budget impact analysis of revumenib for the treatment of relapsed or refractory (R/R) NPM1-mutated acute myeloid leukemia (AML) in the United States

Abraham I[1], *Xie Y*[2], *Gu Q*[2], *Chen H*[2], *Vaghela S*[3], *Lopez-Gonzalez L*[4], *Zhou Z*[2], *Huang H*[4]; *iabraham@arizona.edu*
[1]*The University of Arizona, Center for Health Outcomes & PharmacoEconomic Research and Department of Pharmacy Practice & Science, R. Ken Coit College of Pharmacy, The University of Arizona, and The University of Arizona Cancer Center*; [2]*Analysis Group, Inc.*; [3]*HealthEcon Consulting, Inc.*; [4]*Syndax Pharmaceuticals, Inc.*

BACKGROUND: NPM1 mutations are the most common genetic aberration in adults with AML, present in ~30% of newly diagnosed cases. Revumenib, a first-in-class, oral, potent, and selective menin inhibitor, is approved in the United States for adult and pediatric patients (≥1 year) with R/R acute leukemia harboring a KMT2A translocation or R/R AML with a

NPM1 mutation and is recommended by the National Comprehensive Cancer Network (NCCN) Guidelines for these populations.

OBJECTIVE: To evaluate the budget impact of adding revumenib to the formulary for adults with R/R NPM1-mutated (NPM1m) AML from the perspective of a hypothetical US commercial health plan with 1,000,000 (1M) members. The analysis included 6 alternative therapies representing key NCCN–recommended classes for R/R AML (not specific to NPM1m): gilteritinib, ivosidenib, enasidenib, FLAG-IDA (fludarabine, cytarabine, G-CSF, idarubicin), venetoclax+azacitidine, and azacitidine.

METHODS: Budget impact was calculated as the difference in total costs between formulary scenarios with and without revumenib over 3 years. The eligible population was based on AML incidence from SEER (2017-2021) and literature-based eligibility estimates. Cost components (USD 2025) included drug acquisition and administration (accounting for treatment duration), hospitalization for FLAG-IDA (for infusion and recovery), grade ≥3 adverse events (AEs), outpatient services (lab tests, physician visits, blood transfusions, and others), and post-progression and end-of-life care. AE costs were applied as a one-time cost in the first year of treatment initiation. Clinical data were obtained from pivotal trials and drug labels, and costs from published literature and databases. Revumenib market share was assumed to increase linearly from 10% in Year 1 to 20% in Year 3.

RESULTS: In a hypothetical 1M-member health plan, 6.4 adults with R/R NPM1m AML were estimated to be treatment eligible annually. In a formulary without vs with revumenib, total costs were $3,106,431 vs $3,104,026 in Year 1, and $9,684,072 vs $9,666,137 over 3 years. Adding revumenib yielded savings of $2,405 in Year 1 ($0.0002 PMPM) and cumulative savings of $17,935 over 3 years ($0.0005 PMPM on average). Sensitivity analyses confirmed the robustness of the results.

CONCLUSIONS: Formulary inclusion of revumenib for adults with R/R NPM1m AML was approximately cost neutral. Revumenib is a novel, oral, targeted therapy that addresses a significant unmet need and may reduce the overall burden for patients through treatment convenience.

SPONSORSHIP: Syndax Pharmaceuticals, Inc.

276 Managed care provider perceptions and experiences with chimeric antigen receptor T-cell and bispecific antibody therapies for relapsed/refractory multiple myeloma

Hashmi H[1], *Stinchon M*[2], *Gurska L*[3], *Zyborowicz E*[3], *Heggen C*[3], *Carter J*[3], *Anderson Chadha C*[3], *Sullivan S*[3]; *hashmih1@mskcc.org*; *michaelstinchon@gmail.com*; *s.sullivan@primeinc.org*
[1]*Memorial Sloan Kettering Cancer Center*; [2]*OptumRx*; [3]*PRIME Education*

BACKGROUND: Chimeric antigen receptor (CAR) T-cell and bispecific antibody (BsAb) therapies are transformative treatment options for relapsed/refractory multiple myeloma (R/R MM), addressing a setting with limited alternatives. Managed care decision-makers have an important role in guiding evidence-based integration of these novel therapies into clinical care.

OBJECTIVE: To assess managed care decision-makers' perspectives on key barriers and potential solutions related to the clinical integration of BsAb and CAR T-cell therapies for R/R MM.

METHODS: From January 15 to February 14, 2025, 110 managed care decision-makers completed surveys distributed in partnership with the AMCP Foundation. Descriptive statistics, including means and ranges, were used for quantitative analysis.

RESULTS: Of the 110 respondents, most were employed by pharmacy benefit manager (27%), health plan (22%), and health system (19%). Key responsibilities included formulary decision-making (21%), medication counseling (15%), and reviewing treatment guidelines or new therapies (13%). While managed care decision-makers reported varying levels of knowledge on new and emerging therapies for MM, with only 35% reporting feeling knowledgeable/very knowledgeable (4/5 on a 5-point Likert scale), two-thirds (66%) agreed/strongly agreed (4/5 on a 5-point Likert scale) that CAR T-cell and BsAb therapies have greatly improved survival and quality-of-life outcomes for patients with R/R MM. However, respondents recognized barriers to evidence-based integration (in addition to cost) and reported determining the optimal place in formulary (20% CAR T-cell; 9% BsAb), appropriate sequencing (13%; 23%), development of appropriate eligibility criteria (11%; 11%), and lack of documentation supporting patient eligibility (11%; 5%) as top challenges. Proposed strategies to support evidence-based integration of novel MM therapies included enhanced analysis of prior therapies attempted, utilization of pharmacist support in the prior authorization (PA) process, establishing streamlined PA processes for patients meeting NCCN Category 1 or FDA-approved

criteria to minimize unnecessary delays, or preapproved patient eligibility criteria pathways integrated in medical records to reduce repetitive documentation.

CONCLUSIONS: These findings revealed real-world barriers and potential managed care–driven solutions to support appropriate evidence-based integration of CAR T-cell and BsAb therapies for eligible patients with R/R MM.

SPONSORSHIP: Janssen Biotech, Inc., administered by Janssen Scientific Affairs, LLC and Legend Biotech

277 The economic impact of venetoclax plus acalabrutinib treatment sequences for chronic lymphocytic leukemia (CLL) in the United States (US): A cost of care and budget impact model

Fakhri B[1], *Shadman M*[2], *Manzoor B*[3], *Hazra N*[4], *Fang H*[5], *Budlong H*[3], *Guérin A*[6], *Li S*[7], *Chen W*[5], *Davids M*[8]; *bfakhri@stanford.edu; beenish.manzoor@abbvie.com*
[1]*Stanford Cancer Institute, Stanford University*; [2]*Fred Hutchinson Cancer Research Center*; [3]*AbbVie Inc.*; [4]*Analysis Group, Inc.*; [5]*Analysis Group Inc.*; [6]*Analysis Group, Montreal, QC, Canada*; [7]*Genentech, Inc.*; [8]*Dana Farber Cancer Institute*

BACKGROUND: Venetoclax + obinutuzumab (V+O) is a fixed-duration treatment (FDT) regimen approved for previously untreated CLL. Prior analyses have shown initiating treatment with V+O leads to cost savings compared to continuous therapies. V + acalabrutinib (V+A), another FDT regimen with guideline placement (AMPLIFY trial), is more recently being used. Evaluating the economic value of V+A considering current prices is increasingly important as treatment options expand.

OBJECTIVE: To estimate 10-year cumulative costs of CLL sequences and the 5-year budget impact of introducing first-line (1L) V+A in the US.

METHODS: Cumulative costs of sequences with up to 3 lines of treatment were estimated based on a partitioned survival model, from a US payer perspective (80%/20% commercial/Medicare). A total of 52 sequences for patients without high-risk del 17p and/or TP53 aberrations and 60 for patients with high-risk aberrations were modeled: starting with V-based FDT (V+A, V+O) or covalent BTKi-based continuous (A, A+O, ibrutinib [I], zanubrutinib [Z]) regimens. Costs included drug acquisition, administration, monitoring, tumor lysis syndrome prophylaxis (for V-based regimens), adverse events, and terminal care. Market shares of 1L V+A were assumed to increase from 3.0% (year 1) to 16.8% (year 5) and remain steady.

RESULTS: Sequences starting with FDT V-based regimens had lower 10-year costs in the model compared to continuous cBTKi-based regimens. For patients without high-risk aberrations, V-based sequences had 49% lower costs (average: $1.2 million [M] overall; $1.3M V+A, $1.1M V+O) than cBTKi-based sequences ($2.3M overall; $2.2M A, $2.3M A+O, $2.4M I, $2.2M Z). For patients with aberrations, V-based sequences were 37% lower ($1.4M overall; $1.5M V+O) than BTKi-based sequences ($2.2M overall; $2.0M A, $2.3M A+O, $2.2M I, $2.3M Z). Under a Medicare discount scenario (38% for I) (Inflation Reduction Act [IRA]), cost savings with 1L FDT V+A and V+O remained. For a health plan of 1M members, introducing 1L V+A led to $4.1M savings over 5 years, increasing to $4.3M when assuming a reduced price for sequences including I.

CONCLUSIONS: Treatment sequences in CLL that begin with FDT regimens, whether V+A or V+O, demonstrate potentially significantly lower costs compared to cBTKi-based continuous regimens. If widely utilized, V+A as an additional FDT option in 1L CLL could yield further cost savings for US health plans. Notably, these savings remain robust even when accounting for future price reductions under the IRA, underscoring the relevance of FDT strategies in formulary planning.

SPONSORSHIP: AbbVie, Inc., and Genentech Inc.

278 Treatment patterns and healthcare resource utilization (HRU) in advanced esophageal cancer (EC) across racial and ethnic groups in the immunotherapy era: A retrospective claims data analysis in the United States

El-Rayes B[1], *Lockhart A*[2], *Tang W*[3], *Delinger R*[4], *Yuan D*[3], *Esselman K*[4], *Furnback W*[4], *Fu Q*[3], *Zhan L*[3]; *belrayes@uabmc.edu*
[1]*UAB*; [2]*Medical University of South Carolina*; [3]*BeOne Medicines*; [4]*Real Chemistry*

BACKGROUND: Anti–programmed cell death protein 1 (PD-1) based systemic therapy has emerged as a standard of care for advanced EC.

OBJECTIVE: To assess treatment patterns and HRU across racial/ethnic groups among advanced/metastatic EC patients receiving first-line (1L) treatment using claims data.

METHODS: Adult EC patients initiating 1L treatment between 7/1/2019 and 3/31/2025 were selected from Symphony Integrated Dataverse (IDV®). Continuous enrollment for ≥12 months pre- and 3 months post-treatment initiation was required. Baseline characteristics, treatment distribution, duration of therapy (DoT), and HRU were reported among non-Hispanic White (NHW), non-Hispanic Black (NHB), and Hispanic cohorts. DoT was estimated by the Kaplan-Meier method.

RESULTS: A total of 4,371 1L patients were included. Most patients were male (80%). NHB (n=304) and Hispanic (n=163) patients were younger than NHW (n=2850) patients (median

age: 67 and 67 vs 70) and had higher Charlson Comorbidity Index score (mean: 6.5 and 5.9 vs 5.6). Chemotherapy only was utilized by 62% of 1L-treated patients. The utilization rate of 1L anti-PD-1 increased during the study period (8% of treated patients in 2019; 48% in 2024) and was highest among Hispanic patients (44.2%), followed by NHB (38.5%) and NHW (36.4%) patients. The median DoT was longer among patients who utilized PD-1 monotherapy or PD-1 combination regimens (7.9 and 7.4 months, respectively) compared to chemotherapy only regimens (2.3 months) and was similar across racial groups (NHB: 3.5 months, Hispanic: 3.5, NHW: 3.8). During 1L, 27% of NHB patients had ≥1 EC-related inpatient admission, compared to 26% of Hispanic and 22% of NHW patients.

CONCLUSIONS: Overall uptake of PD-1 inhibitors remains limited among advanced EC patients, highlighting an opportunity to improve adoption of novel immunotherapy treatments. Equitable access was observed across racial groups; however, higher HRU among minority patients suggests potential disparities and unmet needs.

SPONSORSHIP: BeOne Medicines, Ltd.

279 Clinical and economic value of MET immunohistochemistry testing for patients with EGFR wild-type locally advanced/metastatic, non-squamous non-small cell lung cancer

Kakehi S[1], *Hejazi A*[1], *Woll K*[1], *Martin P*[2], *Klein T*[3], *Prashar A*[1], *Illei P*[4]; *sumie.kakehi@abbvie.com*
[1]*AbbVie*; [2]*Medical Decision Modeling, Inc.*; [3]*Medical Decision Modeling Inc.*; [4]*Johns Hopkins University School of Medicine*

BACKGROUND: Telisotuzumab vedotin (Teliso-V) is a targeted antibody-drug conjugate therapy for patients (pts) with locally advanced/metastatic, non-squamous non–small cell lung cancer (mNSCLC) with high c-Met (MET) protein overexpression. Teliso-V eligibility is determined by MET immunohistochemistry (IHC), though the value of MET IHC testing is still being understood. Preliminary evidence supports clinical value for pts with mNSCLC requiring second-line (2L) therapy.

OBJECTIVE: To assess the clinical and economic value of adopting MET IHC testing in EGFR wild-type (wt) mNSCLC from the payor perspective.

METHODS: A decision-analytic model assessed the clinical and economic value of simulated MET IHC testing among 36 068 pts with EGFRwt mNSCLC requiring 2L therapy. Model inputs included data from real-world studies, published literature, outcomes from the LUMINOSITY trial, and insights from a pathologist and pt advocacy group. Clinical and economic inputs were derived from a partitioned survival analysis comparing Teliso-V versus standard of care. The base case (BC) scenario assumed a MET IHC testing rate of 49.3% before 2L with archival tissue availability (ATA) for 80% of pts and rebiopsy for 20%. Analyzed scenarios included (1) 10% testing rate increase before 2L (59.3%) and (2) testing before first-line (1L) (ATA: 100%). Outcomes included life years (LYs), quality-adjusted life years (QALYs), and costs.

RESULTS: In the simulated BC, 17 782 and 2929 pts received MET IHC testing and Teliso-V, respectively, yielding an additional 1933 LYs and 1380 QALYs compared to no testing. The 10% testing rate increase resulted in 3606 and 594 additional pts being tested and treated with Teliso-V, respectively, yielding an additional 393 LYs and 280 QALYs compared to BC. Testing-related costs increased by $9.08M, primarily due to rebiopsies, and treatment-related adverse event (TRAE) costs were reduced by $2.25M. When testing was performed before 1L, compared with BC, an additional 20 270 pts were tested and no additional pts received Teliso-V per simulation assumption. There was no change in LYs, 19 QALYs were added, and test-related costs were reduced by $40.30M by avoiding rebiopsies.

CONCLUSIONS: Increased MET IHC testing improved clinical outcomes, increased testing costs, and reduced TRAE costs. Testing before 1L slightly improved QALYs and reduced testing costs. These findings highlight the clinical and economic value of implementing MET IHC testing for pts with EGFRwt mNSCLC, adhering to NCCN guidelines, and the importance of tissue stewardship.

SPONSORSHIP: AbbVie

280 Continuity of Part D Plan enrollment among Medicare beneficiaries initiating fixed duration venetoclax treatment for chronic lymphocytic leukemia in the frontline setting: A real-world analysis

Huntington S[1], *Puckett J*[2], *Manzoor B*[3], *Li S*[4], *Kamal-Bahl S*[2], *Emechebe N*[3], *Reyes C*[4], *Budlong H*[3], *Doshi J*[5]; *scott.huntington@yale.edu; beenish.manzoor@abbvie.com*
[1]*Yale University*; [2]*COVIA Health Solutions*; [3]*AbbVie Inc.*; [4]*Genentech, Inc.*; [5]*University of Pennsylvania*

BACKGROUND: The BCL-2 inhibitor venetoclax (VEN) is a fixed-duration therapy (FDT) for chronic lymphocytic leukemia (CLL), administered for twelve 28-day cycles (~11 months) in the frontline setting, after which patients typically stop treatment per label. This can lead to substantial cost savings for payers during the off-treatment period, when patients remain in remission but no longer require active CLL therapy. However, because Medicare beneficiaries reselect their Part D plans annually, there is limited real-world evidence examining plan enrollment stability and whether payers will ultimately realize the downstream savings

associated with the off-treatment period for patients treated with FDT VEN.

OBJECTIVE: To examine the continuity of enrollment in the same Part D plan or parent organization among fee-for-service Medicare beneficiaries initiating VEN for CLL in the frontline setting.

METHODS: This retrospective cohort study used 100% Medicare claims. Older patients newly initiating VEN in the frontline setting between 6/1/2019 and 12/31/2023 (index date = first VEN claim) were followed from their index date until plan switching, death, or end of study period (i.e., 12/31/2024), whichever occurred earliest. Continuous enrollment in the same Part D plan or parent organization following VEN initiation was assessed using a Kaplan-Meier curve. Patients were deemed to have switched if they changed to another Part D plan outside the parent organization (e.g., switching from any Part D plan offered by UnitedHealthcare to one offered by Humana); patients were censored if they died.

RESULTS: We identified 1,419 patients receiving frontline VEN during our study period; the sample had a mean (SD) age of 76.3 (5.8) years and was largely White (92.0%), male (63.4%), and resident in the South (37.1%). Nearly 90% of VEN patients remained enrolled in the same Part D plan or parent organization 1 year after initiating treatment. A substantial proportion of patients remained enrolled in the same Part D plan or organization even 2 years (79.4%), 3 years (72.5%), and 4 years (65.1%) after the VEN initiation date.

CONCLUSIONS: The vast majority of Medicare beneficiaries receiving FDT VEN for frontline CLL remain continuously enrolled in their Part D plan for several years following treatment initiation. These findings suggest that any possible concerns about plan-switching may be overstated and that Part D plans are likely to capture both the costs of treatment and the benefits of the off-treatment period offered by VEN FDT.

SPONSORSHIP: AbbVie Inc., Genentech Inc

281 Fixed-duration subcutaneous mosunetuzumab has the lowest total cost of care compared with alternative novel treatment options in third-line or later follicular lymphoma in the United States

Ghosh N[1], *Rosettie K*[2], *Wu M*[2], *Ma E*[2]; *Nilanjan.Ghosh@advocatehealth.org*; *ma.esprit.em1@gene.com*
[1]*Atrium Health Levine Cancer Institute Wake Forest University School of Medicine, Charlotte, NC 28204, USA;* [2]*Genentech, Inc., South San Francisco, CA 94080, USA*

BACKGROUND: Fixed-duration mosunetuzumab (Mosun), a CD20xCD3 T-cell-engaging bispecific antibody, has been approved in the United States (US) as an intravenous infusion formulation in third-line or later (3L+) follicular lymphoma (FL); subcutaneous (SC) Mosun is being evaluated in a pivotal Phase 2 study (Bartlett et al. ASH 2024). Several other novel treatments (Tx) have been approved since 2020, including tazemetostat (Taz), axicabtagene ciloleucel (Axi-cel), lisocabtagene maraleucel (Liso-cel), tisagenlecleucel (Tisa-cel), epcoritamab (Epcor), and zanubrutinib-obinutuzumab (Zanu+G).

OBJECTIVE: To quantify the total cost of care (TCC) of Mosun SC vs alternative novel Tx options from a US population–based decision-maker's perspective.

METHODS: TCC per patient (including drug, wastage, administration, routine care, Grade ≥3 adverse event [AE] management, and any grade cytokine release syndrome [CRS] management costs) was evaluated annually and cumulatively for up to 3 years. Drug costs were estimated from Wholesale Acquisition Costs at the mean duration of Tx (DOT) reported (or extrapolated mean DOT from median DOT by fitting exponential distribution) from each regimen's pivotal trial (Taz: NCT01897571; Axi-cel: NCT03105336; Liso-cel: NCT04245839; Tisa-cel: NCT03568461; Mosun SC: NCT02500407; Epcor: NCT03625037; Zanu+G: NCT03332017). Drug wastage was estimated from differences between vial size and actual dosage. Administration costs were based on the schedule from each regimen's pivotal trial and estimated per the Centers for Medicare and Medicaid Services (CMS) physician fee schedule. Routine care utilization was based on clinical expert opinion and costs were obtained from CMS physician and laboratory fee schedules. AE and CRS management costs were estimated from AE rates from each regimen's pivotal trial at costs set out in the Healthcare Cost and Utilization Project, and CRS hospitalization costs from Liu et al. J Med Econ (2021). All costs were adjusted to 2025 US dollars.

RESULTS: The cumulative 3-year TCC was $269,288 for Mosun SC, $275,881 for Taz, $411,346 for Zanu+G, $432,960 for Epcor, $540,085 for Tisa-cel, $579,445 for Liso-cel, and $589,750 for Axi-cel. Mosun SC had the lowest TCC with savings of $6,593

vs Taz, $142,058 vs Zanu+G, $163,672 vs Epcor, $270,797 vs Tisa-cel, $310,157 vs Liso-cel, and $320,462 vs Axi-cel.

CONCLUSIONS: Fixed-duration Mosun SC had the lowest cumulative 3-year TCC per patient vs alternative novel Tx in 3L+ FL. Alongside efficacy and safety, the varied economic impact of Tx should also be considered when selecting Tx for 3L+ FL.

SPONSORSHIP: Genentech, Inc.

282 Fixed-duration subcutaneous mosunetuzumab is cost-effective compared with alternative novel treatment options in third-line or later follicular lymphoma in the United States

Ghosh N[1], *Rosettie K*[2], *Elsea D*[2], *Wu M*[2], *Ma E*[2]; *Nilanjan.Ghosh@advocatehealth.org*; *elsead@gene.com*
[1]*Atrium Health Levine Cancer Institute Wake Forest University School of Medicine, Charlotte, NC 28204, USA*; [2]*Genentech, Inc., South San Francisco, CA 94080, USA*

BACKGROUND: Fixed-duration (FD) intravenous mosunetuzumab (Mosun), a CD20xCD3 T-cell-engaging bispecific antibody, has been approved by the United States (US) Food and Drug Administration (FDA) for third-line or later (3L+) follicular lymphoma (FL), while FD subcutaneous (SC) Mosun is being evaluated in a pivotal Phase 2 study (Bartlett et al. ASH 2024). Several other novel treatments (Tx) have also been FDA approved and are common Tx options in US community practices, including epcoritamab (Epcor), zanubrutinib-obinutuzumab (Zanu+G), and tazemetostat (Taz).

OBJECTIVE: To quantify the long-term cost-effectiveness of Mosun SC vs other novel Tx options commonly used in the US community setting, from a US population–based decision-maker's perspective.

METHODS: A partitioned survival model was developed using three health states: progression-free survival (PFS), post-progression survival and death. Individual patient-level 3-year follow-up data of Mosun SC (GO29781 [NCT02500407]) was used to conduct matching-adjusted indirect Tx comparisons to quantify the relative efficacy of Mosun SC vs other Tx options (Epcor: EPCORE NHL-1 [NCT03625037]; Zanu +G: ROSEWOOD [NCT03332017]; Taz: E7438-G000-101 [NCT01897571]). Based on goodness-of-fit statistics and visual inspection, PFS and overall survival were extrapolated using a log-normal model and an exponential model, respectively. Costs (2025 US dollars) comprised drug acquisition, administration, routine care, adverse event management, subsequent Tx and terminal care. Over a lifetime horizon, cost and outcomes were discounted at 3% annually. Cost-effectiveness was evaluated using the incremental cost-effectiveness ratio (ICER; ratio of incremental costs to incremental quality-adjusted life-years [QALYs]), and the net monetary benefit (NMB; overall value of the Tx at a willingness to pay [WTP] threshold of $150,000 per QALY).

RESULTS: Over a lifetime horizon, per the ICER Mosun SC was dominant with a lower cost and higher QALYs vs Epcor (incremental cost: -$502,896; incremental QALY: 3.47), vs Zanu+G (incremental cost: -$721,280; incremental QALY: 0.85), and vs Taz (incremental cost -$138,221; incremental QALY: 1.33). At a WTP of $150,000 per QALY, positive NMBs showed that Mosun SC was cost-effective vs Epcor at $1,022,806, vs Zanu+G at $849,509, and vs Taz at $338,470.

CONCLUSIONS: FD Mosun SC is cost-effective vs other Tx options commonly utilized by US community practices for patients with 3L+ FL. This study showed the long-term value of Mosun SC vs other Tx options, offering an additional aspect to consider when selecting Tx for 3L+ FL.

SPONSORSHIP: Genentech, Inc.

283 Comparative economic analysis of B-cell maturation antigen (BCMA)-targeted bispecific antibodies (BsAbs) in triple-class exposed relapsed/refractory multiple myeloma (RRMM): Linvoseltamab versus teclistamab and elranatamab

Portuguese A[1], *Inocencio T*[2], *Quon P*[2], *Harnett J*[2], *Zhou Z*[3], *Hazra N*[3], *Xu M*[3], *Eales J*[3], *Chen H*[3], *Little M*[2], *Ma Q*[2]; *aportugu@fredhutch.org*; *timothy.inocencio@regeneron.com*
[1]*Fred Hutchinson Cancer Center, Seattle*; [2]*Regeneron Pharmaceuticals, Inc.*; [3]*Analysis Group, Inc.*

BACKGROUND: Linvoseltamab is a BCMA×CD3 BsAb approved in the US for adults with RRMM after ≥4 prior lines of therapy, including a proteasome inhibitor, immunomodulatory drug, and anti-CD38 antibody. In two matching-adjusted indirect comparisons (MAICs), linvoseltamab demonstrated favorable response rates and survival vs teclistamab and elranatamab. Economic evaluation of these outcomes is critical to inform healthcare decision-making.

OBJECTIVE: To estimate total cost of care and cost per outcome of linvoseltamab vs teclistamab and elranatamab in adults with RRMM, from a US commercial payer perspective.

METHODS: A model was developed to estimate total cost per patient and per outcome over 1- and 2-year time horizons. Costs included drug acquisition, administration, monitoring, adverse events (AEs), progression, and death. Treatment administration and dosing schedules followed prescribing information; patients switched to less frequent dosing at the earliest eligible time point. Efficacy data, duration of treatment (DOT), and AE rates were drawn from pivotal trials; linvoseltamab efficacy and DOT were adjusted using MAICs. Cost inputs were sourced from public sources

(e.g., REDBOOK, CMS). Key outcomes were cost per progression-free (PF) month, cost per overall response achieved, and cost per month on treatment.

RESULTS: The total estimated cost for linvoseltamab was lower than teclistamab at 1 year ($387,773 vs $488,762) and 2 years ($488,088 vs $623,707). Linvoseltamab also had lower 2-year cost per PF month ($29,036 vs $49,658), per overall response achieved ($677,901 vs $990,011), and per month on treatment ($30,452 vs $50,283) than teclistamab. Compared with elranatamab, total 1-year cost was slightly lower ($383,368 vs $404,951) and 2-year cost was slightly higher ($472,907 vs $463,365) despite the DOT of linvoseltamab being double that of elranatamab (11.3 vs 5.6 months). Linvoseltamab had a lower 2-year cost per PF month ($29,912 vs $32,426), per overall response achieved ($666,066 vs $759,614), and per month on treatment ($31,997 vs $50,039). Similar trends were observed for cost per month alive and cost per complete response vs both BsAbs in favor of linvoseltamab.

CONCLUSIONS: Linvoseltamab was associated with lower 1- and 2-year total cost, cost per month on treatment, and cost per outcome vs teclistamab and lower 1-year total cost vs elranatamab. Linvoseltamab 2-year costs per outcome were lower than elranatamab, despite linvoseltamab DOT being longer. These findings suggest that linvoseltamab provides favorable economic value in heavily pretreated patients with RRMM.

SPONSORSHIP: Regeneron Pharmaceuticals, Inc.

284 Budget impact analysis of linvoseltamab for the treatment of relapsed/refractory multiple myeloma (RRMM) in the United States

Inocencio T[1], *Zhou Z*[2], *Hazra N*[2], *Xu M*[2], *Eales J*[2], *Chen H*[2], *Quon P*[1], *Ma Q*[1]; *timothy.inocencio@regeneron.com*
[1]*Regeneron Pharmaceuticals, Inc.*; [2]*Analysis Group, Inc.*

BACKGROUND: Linvoseltamab, a BCMA×CD3 bispecific antibody, was approved in the US in July 2025 for adult patients with RRMM who have received at least 4 prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 antibody, based on the Phase 1/2 LINKER-MM1 study.

OBJECTIVE: To estimate the budget impact of linvoseltamab market entry for RRMM from a US commercial payer perspective.

METHODS: A budget impact model was developed to compare total costs associated with two hypothetical scenarios without and with linvoseltamab over a three-year time horizon. The size of the eligible target population was estimated using incidence data from literature and the US Census Bureau. Treatment options based on NCCN Clinical Practice Guidelines in Oncology (NCCN guidelines®) included bispecific antibodies, CAR T-cell therapies, as well as other new or conventional therapies. Cost components included costs associated with drug acquisition and administration, monitoring, management of adverse events, progression, subsequent treatments, and death. Unit costs were obtained from public sources (e.g., RedBook, CMS) or literature, and clinical data from LINKER-MM1 and comparator trials. The market uptake of linvoseltamab was assumed to increase from 11.8% in Year 1 to 23.7% in Year 3, taken proportionally from teclistamab and elranatamab. Results were presented as 3-year cumulative plan total and per member per month (PMPM) costs for the two scenarios and the budget impact.

RESULTS: In a hypothetical 1-million-member health plan, 11 patients were eligible to receive linvoseltamab each year. The estimated plan total budget impact of linvoseltamab market entry was –$219,775 (–$63,032, –$90,373, –$66,370 for Year 1, 2, 3 respectively), or a cost saving of 1.19% over 3 years. The 3-year average PMPM was –$0.0061 (–$0.0053, –$0.0075, –$0.0055). Overall savings (–$281,553) were mostly attributed to reduced costs due to higher progression-free survival (PFS) and overall survival (OS) with linvoseltamab compared to teclistamab and elranatamab, which completely offset higher drug acquisition and regular monitoring costs of linvoseltamab ($61,778). Key drivers of budget impact were treatment duration, relative dose intensity, and the proportion of patients receiving less frequent dosing of linvoseltamab.

CONCLUSIONS: The introduction of linvoseltamab for patients with RRMM is expected to be cost saving to a US commercial payer over 3 years due to reductions in costs associated with PFS and OS.

SPONSORSHIP: Regeneron Pharmaceuticals, Inc.

285 Evaluation of healthcare resource utilization and costs among patients diagnosed with extra-pulmonary neuroendocrine carcinoma (epNEC): A non-interventional multimodal database analysis in the US

Gay C[1], *Liu N*[2], *Liu E*[3], *Curran A*[3], *DelGobbo L*[4], *Scherrer E*[5], *Vrieze K*[2], *Christensen A*[2], *Ijioma S*[2], *Vijayvergia N*[6]; *cgay@mdanderson.org*; *nicholas.liu@boehringer-ingelheim.com*
[1]*Department of Thoracic/Head and Neck Medical Oncology at MD Anderson Canc*; [2]*Boehringer Ingelheim Pharmaceuticals, Inc.*; [3]*Tempus AI*; [4]*Epidemiologist & Clinical Affairs, Tempus AI*; [5]*HEOR, Tempus AI*; [6]*Fox Chase Cancer Center*

BACKGROUND: Extra-pulmonary neuroendocrine carcinomas (epNECs) are a rare and aggressive subset of neuroendocrine neoplasms, with an incidence rate of approximately 1 per 100,000 individuals. They are associated with high morbidity

and poor prognosis. Platinum-based chemotherapy is generally accepted as the preferred first-line (1L) therapy, based on practices from small cell lung cancer; however, there is no evidence-based recommendation or standard for second-line (2L) therapy. Furthermore, the healthcare resource utilization (HCRU) and economic impact of patients with epNEC has not been characterized.

OBJECTIVE: To evaluate HCRU and costs among patients diagnosed with epNEC in the US.

METHODS: A retrospective study of patients diagnosed with epNEC from August 2012 to March 2025 was conducted using the Tempus multimodal dataset, linked to claims data from the Komodo Healthcare Map. The Tempus data model includes de-identified, longitudinal data across multiple cancer types, supporting a comprehensive analysis of this rare tumor. HCRU and cost outcomes were assessed as a per-patient per-month (PPPM) rate by line of therapy. All-cause costs were determined by applying standardized reference costs from the 2025 Medicare Fee Schedule.

RESULTS: Of 146 epNEC patients identified, claims data were available for 112 patients treated with 1L therapy. During 1L therapy, mean number of hospitalizations was 0.47 PPPM ($924 PPPM), with a mean hospital stay of 2.28 days. The mean number of outpatient visits, emergency room visits, and pharmacy claims was 4.75 PPPM ($4,185 PPPM), 0.10 PPPM ($57 PPPM), and 4.74 PPPM ($2,636 PPPM), respectively. All other costs during 1L therapy averaged $296 PPPM resulting in mean total all-cause costs of $8,099 PPPM in 1L. During 2L therapy (N=44), mean number of hospitalizations was 0.47 PPPM ($1,001 PPPM), with a mean hospital stay of 3.37 days. The mean number of outpatient visits, emergency room visits, and pharmacy claims was 3.30 PPPM ($4,351 PPPM), 0.14 PPPM ($132 PPPM), and 3.60 PPPM ($11,401 PPPM), respectively. All other costs during 2L therapy averaged $116 PPPM resulting in mean total all-cause costs of $17,001 PPPM in 2L.

CONCLUSIONS: Patients with epNEC face high HCRU and cost burden across 1L and 2L therapy, mainly driven by outpatient visits and pharmacy claims. Furthermore, despite lower pharmacy utilization and lack of standard therapy in 2L, total all-cause costs more than doubled in 2L versus 1L due to pharmacy claims.

SPONSORSHIP: Boehringer Ingelheim Pharmaceuticals, Inc.

286 Estimating the real-world US prevalence of platinum-resistant ovarian cancer stratified by insurance type

He J[1], *Wang T*[1], *Iyer N*[1], *Liu E*[1], *Darbha S*[2], *Joish V*[1]; *jihe@genmab.com*; *vijo@genmab.com*
[1]*Genmab*; [2]*Datawave Solutions Corp*

BACKGROUND: Platinum-resistant ovarian cancer (PROC) represents a high-burden subset of ovarian cancer (OC), defined by disease progression within 6 months of completing platinum-based therapy. Estimating prevalence across commercial insurance, Medicare, and Medicaid populations provides a foundation for payer-specific burden assessments and informs resource allocation and access planning for patients with advanced disease.

OBJECTIVE: To estimate the prevalence of PROC in the United States, stratified by age and insurance type (commercial, Medicare, Medicaid), using real-world data sources.

METHODS: A multistep analysis integrated multiple data sources to estimate PROC prevalence using the latest data available for calendar year 2023. Claims from the MarketScan Commercial and Medicare Fee-for-Service databases were used to identify patients with OC and PROC via a validated line-of-therapy algorithm. The Surveillance, Epidemiology, and End Results (SEER) program provided age-specific (≤18, 19–64, ≥65 years) OC prevalence rates among women. US Census data were used to obtain corresponding female population counts, including Medicaid enrollees. PROC prevalence was calculated as Female population × OC prevalence rate × PROC/OC proportion, stratified by age group and distributed by insurance type.

RESULTS: In 2023, out of approximately 170 million US women, 205,000 living with OC were identified. Further, an estimated 11,776 women were living with PROC, representing ~6% of the total OC population. Most were aged ≥65 years (6164; 52%) or 19–64 years (5589; 47%). By payer, patients with PROC fit into these coverage categories: Medicare, 44% (5226), commercial insurance, 39% (4571), and Medicaid, 17% (1979). The concentration among Medicare beneficiaries highlights the age-related and payer-specific burden of disease.

CONCLUSIONS: Approximately 12,000 women in the US were living with PROC in 2023, with the greatest prevalence among Medicare beneficiaries. These findings provide payers with critical insight into the distribution of disease burden across insurance segments, supporting evidence-based policy decisions, resource planning, and the development of value-based strategies to improve access and outcomes for patients with advanced OC.

SPONSORSHIP: Genmab

287 Real-world utilization and outcomes of idecabtagene vicleucel (ide-cel) in inpatient vs outpatient settings in the US

Ailawadhi S[1], *Mukherjee D*[2], *J S S*[2], *Goyal A*[2], *Lee K*[3], *Dhanda D*[4]; *ailawadhi.sikander@mayo.edu*
[1]*Mayo Clinic*; [2]*ZS Associates*; [3]*Bristol Myers Squibb*; [4]*BMS*

BACKGROUND: Relapsed/refractory multiple myeloma (RRMM) is a plasma cell malignancy for which CAR T-cell therapies, including idecabtagene vicleucel (ide-cel), are available as treatment options. Evidence on real-world outcomes and healthcare resource utilization (HCRU) for ide-cel by care setting remains limited. Outpatient administration may offer a more convenient and cost-efficient alternative to inpatient administration and care.

OBJECTIVE: To evaluate and compare post-infusion outcomes and HCRU patterns for ide-cel across inpatient (IP) and outpatient (OP) settings

METHODS: We conducted a retrospective analysis of Komodo Health claims (Jan 2016–Jun 2025). Adults with ≥2 multiple myeloma diagnoses and ≥1 ide-cel infusion (Mar 2021–Mar 2025) were included. Healthcare resource utilization and outcomes were compared based on the setting of ide-cel administration (inpatient [IP] vs outpatient [OP]). Outcomes included time to next treatment (TTNT), grade ≥3 adverse events (cytokine release syndrome [CRS], neurotoxicity [ICANS]), and HCRU (ER visits, ICU visits, office visits, and inpatient length of stay [LOS] within 30 days post-infusion).

RESULTS: Among 934 ide-cel patients meeting inclusion criteria, 842 (90%) received their ide-cel infusion in IP and 92 (10%) in OP settings. Median age was 66.8 (IP) vs 64.5 (OP) years; 58% vs 61% were male; 71% vs 61% had Medicare. Median TTNT was similar (19 vs 17 months). Grade ≥3 CRS/ICANS occurred infrequently (6.5% IP vs 4.4% OP) in both cohorts. Mean 30-day LOS was longer for IP vs OP (13.6 vs 6.6 days including index admission; 10.1 vs 6.6 days excluding index admission). All-cause per patient per month (PPPM) visits: inpatient 2.45 vs 3.32, ER 0.13 vs 0.25, ICU 0.72 vs 0.34 for IP and OP, respectively. Trends for MM-related HCRU were similar.

CONCLUSIONS: These findings suggest that outpatient administration of ide-cel is feasible and associated with outcomes comparable to inpatient treatment. Ide-cel outpatient administration is practical with favorable HCRU. Limitations include potential patient selection bias and institutional feasibility for outpatient administration.

SPONSORSHIP: Bristol Myers Squibb

288 Real-world patient (pt) characteristics, treatment patterns, and overall survival (OS) in metastatic hormone-sensitive prostate cancer (mHSPC): Insights by PTEN status

Rathkopf D[1], *Zhao D*[2], *Kovacevic L*[2], *Collins J*[2], *Hankinson E*[2], *Marshall H*[3], *Springford A*[4], *Shokar S*[5], *Von Bandemer H*[4], *Li W*[4]; *rathkopd@mskcc.org*; *simran.shokar@astrazeneca.com*
[1]*Memorial Sloan Kettering Cancer Center*; [2]*Flatiron Health*; [3]*AstraZeneca contracted through Phastar*; [4]*AstraZeneca*; [5]*AstraZeneca, Toronto, Ontario*

BACKGROUND: The loss of function of the tumor suppressor gene PTEN is associated with an increased risk of recurrence and poor clinical outcomes in advanced prostate cancer.

OBJECTIVE: To provide insights into pt characteristics, treatment patterns, and OS outcomes by PTEN status among pts with mHSPC in real-world settings, which are currently limited.

METHODS: This cohort study utilized retrospective longitudinal data from the US-based deidentified Flatiron Health-Foundation Medicine mPC clinicogenomic database. Male pts diagnosed with mHSPC between January 1, 2018, and March 31, 2024, who underwent comprehensive genomic profiling of a solid tumor specimen were included. Pts with PTEN alterations were classified as PTEN-altered (homozygous deletion, defined as a copy number variant=0 or mutation, known or likely pathologic short variant alterations or rearrangements). All other patients were included in the PTEN-non-altered group. Pt characteristics and treatment patterns were descriptively analyzed. Kaplan-Meier survival probabilities for real-world OS (rwOS; unadjusted) were estimated by PTEN status (PTEN-altered or PTEN-non-altered).

RESULTS: Of 1508 included pts, 34.2% had PTEN-altered tumors. Overall, pts were predominantly White (62.4%) with a mean (SD) age of 68.8 (9.1) years at mHSPC diagnosis (dx). At initial dx, 67.2% had a Gleason score of 8–10 and 69.6% had de novo metastatic disease. The PTEN-altered group included a lower proportion of Black or African American pts (6.2% vs 13.6%) and had lower prostate-specific antigen (PSA) levels at metastatic dx (median [IQR] PSA: 46 [10–200] vs 69 [15–331] ng/mL), relative to pts with PTEN-non-altered mHSPC. BRCA and non-BRCA HRR mutations were less frequent in pts with PTEN-altered relative to PTEN-non-altered tumors (8.9% vs 12.4% and 13.2% vs 22.0%, respectively); TP53 and RB1 mutations were more frequent (48.3% vs 33.1% and 9.9% vs 4.4%). The most common first line treatments in both PTEN groups were ADT alone and ARPI ± ADT. Median (95% CI) rwOS was 33.4 (29.3–38.2) and 43.5 (39.7–47.9) months in pts with PTEN-altered and PTEN-non-altered mHSPC, respectively. Pts with PTEN alterations tended to have lower

landmark survival probabilities (% [95% CI]) than pts without PTEN alterations (12 months: 83.8 [79.5–88.3] vs 89.9 [87.3–92.6]; 24 months: 62.8 [57.7–68.2] vs 74.2 [70.8–77.7], respectively).

CONCLUSIONS: Among pts with mHSPC, worse survival was observed in pts with tumors harboring PTEN alterations relative to pts without PTEN tumor alterations, despite similar treatment patterns.

SPONSORSHIP: AstraZeneca

291 A cost-effectiveness comparison of ribociclib and palbociclib in combination with fulvestrant as first- or second-line therapy for postmenopausal women with HR+/HER2- advanced breast cancer: A Medicare analysis

Tarantino P[1], *Gadi V*[2], *Pathak P*[3], *Sopher G*[3], *Delea T*[4], *Stellato D*[4], *Lloyd J*[5]; *paolo_tarantino@dfci.harvard.edu*
[1]*Dana-Farber Cancer Institute*; [2]*University of Illinois Cancer Center*; [3]*Novartis Pharmaceuticals Corporation*; [4]*Avalere Health*; [5]*Avalere Health, Washington, DC 20005, USA*

BACKGROUND: CDK4/6 inhibitors like ribociclib (RIB) and palbociclib (PAL), combined with fulvestrant (FUL), are commonly used as first- or second-line treatments for postmenopausal women with HR+/HER2– advanced breast cancer in US practice.

OBJECTIVE: With PAL selected for negotiation under the Medicare Drug Price Negotiation Program and other CDK4/6 inhibitors likely to follow, this study compares the cost-effectiveness of RIB+FUL versus PAL+FUL as 1L or 2L therapy from the Medicare perspective

METHODS: A partitioned survival model was created in Excel, using progression-free survival (PFS) and overall survival (OS) data from the MONALEESA-3 and PALOMA-3 Phase 3 trials. The analysis used a lifetime horizon with 28-day cycles. Survival curves for PFS and OS were calculated by applying hazard ratios (HRs) for RIB+FUL vs. FUL and PAL+FUL vs. FUL to estimated survival distributions for FUL using individual patient data from MONALEESA-3. Incremental cost-effectiveness ratios (ICERs) were calculated from a Medicare perspective, measuring effectiveness as life-years (LYs), equal value life-years (evLYs), and health years in total (HYT), with all outcomes and costs discounted at 3% per year. Cost-effectiveness was determined using a willingness-to-pay threshold of $150,000 per evLY.

RESULTS: The combination of RIB+FUL demonstrated superior outcomes compared to PAL+FUL, showing incremental gains of 0.210 LYs, 0.156 evLYs, and 0.171 HYT. Additionally, RIB+FUL resulted in cost savings of $19,760 relative to PAL +FUL ($522,807 vs. $542,567), indicating dominance and cost-effectiveness across all measures at any willingness-to-pay threshold. Probabilistic analyses using Monte Carlo simulation revealed an 81% likelihood that RIB+FUL would be cost-effective when compared with PAL+FUL.

CONCLUSIONS: From a Medicare perspective, RIB+FUL leads to better health outcomes and lower costs, making it likely more cost-effective than PAL+FUL for PMW receiving first or second-line HR+/HER2- aBC treatment.

SPONSORSHIP: Novartis Pharmaceuticals Corporation

292 Real-world treatment patterns, healthcare resource utilization, and costs among patients with unresectable/metastatic GEP-NETs after progression on somatostatin analogs-based therapy

Guérin A[1], *Maitland J*[2], *Sasane M*[3], *Krishna A*[4], *Tsai J*[5], *Sawant R*[4]; *Annie.Guerin@analysisgroup.com*; *Ruta.Sawant@sanofi.com*
[1]*Analysis Group, Montreal, QC, Canada*; [2]*Analysis Group, Toronto, ON, Canada*; [3]*Sanofi, Morristown, NJ, USA*; [4]*Sanofi, Cambridge, MA, USA*; [5]*Sanofi, Stockholm, Sweden*

BACKGROUND: Patients with unresectable/metastatic (advanced) gastroenteropancreatic neuroendocrine tumors (GEP-NETs) experience considerable disease burden and suboptimal long-term outcomes despite advances in therapeutic options including chemotherapy, molecular targeted therapies (MTT), and more recently, peptide receptor radionuclide therapy (PRRT). Long acting somatostatin analogs (SSA) remain the standard frontline therapy; however, most patients experience disease progression within 2–3 years and require subsequent treatments. Real-world evidence characterizing the burden following progression after SSA-based therapy among these patients remains limited.

OBJECTIVE: To evaluate the healthcare resource use (HCRU) and costs following progression after SSA-based therapy among patients with GEP-NETs.

METHODS: A retrospective cohort study using Komodo Research Data (KRD+ insurance claims; Jan 2016 to Oct 2024) was conducted. Patients with ≥2 diagnoses of GEP-NET ≥30 days apart who had ≥1 line of therapy (LOT) with SSA followed by a subsequent LOT were included. HCRU and costs were assessed during the index LOT, spanning from initiation of the first LOT after SSA-based therapy (i.e., index date) to the earliest of the day before initiation of a next LOT or end of follow up, reported per-patient-per-year (PPPY) and per month (PPPM).

RESULTS: A total of 530 patients were included. Mean (standard deviation [SD]) age was 62.1 (11.9) years, and a majority were male (53.2%), white (61.1%), and commercially insured (60.9%). Following the progression on SSA-based therapy,

patients received PRRT ± SSA (43.0%), chemotherapy ± SSA (27.7%), MTT ± SSA (26.6%), or other regimens (2.6%). Over the average duration of the index LOT of 14.3 months, 32.5% of patients had ≥1 inpatient (IP) stay and 12.6% had ≥2 IP stays; average length of stay was 8.7 days and average cost per stay was $32,422. Overall, 48.3% of patients had ≥1 emergency department (ED) visit and 26.0% had ≥2; average number of outpatient (OP) visits PPPY was 42.5. Mean total healthcare costs during the index LOT were $34,269 PPPM. Costs were higher during the first 6 months of the index treatment period ($47,421 PPPM).

CONCLUSIONS: In this real-world analysis of patients with advanced GEP-NETs progressing after SSA-based therapy, substantial HCRU and costs were observed during the subsequent LOT. These findings highlight the significant economic impact and unmet need among GEP-NET patients with prior SSA-exposure.

SPONSORSHIP: Sanofi

293 Bispecific antibodies in real-world care of multiple myeloma: Patient characteristics, healthcare resource utilization, and costs

Ailawadhi S[1], *Boytsov N*[2], *Multani J*[3], *Zhou Z*[3], *Niehoff N*[4], *Purser M*[4], *Hartman J*[4], *Palumbo T*[4], *Chen C*[3]; *ailawadhi.sikander@mayo.edu*; *natalie.n.boytsov@gsk.com*
[1]*Mayo Clinic*; [2]*GSk*; [3]IQVIA; [4]GSK

BACKGROUND: Real-world data on characteristics, healthcare resource utilization (HCRU), and costs of bispecific T-cell engager (BiTE) treatment for patients (pts) with multiple myeloma (MM) may help guide payer formulary decision making.

OBJECTIVE: To evaluate administration-related/all-cause/diagnoses-specific HCRU and costs per pt per month (PPPM) 1/6/12 months (mos) after the 7-day step-up dosing period (index).

METHODS: This retrospective cohort study used the IQVIA PharMetrics Plus® Enhanced Closed Claims database. A cohort of adults with MM treated with BiTEs was identified that included patients with a first observed claim for teclistamab (tec), talquetamab (tal), and elranatamab (elra) during the period aligned with the FDA approval of tal and elra (Aug 1, 2023–Aug 31, 2024). Continuous medical/pharmacy benefit enrollment for ≥6 mos before and ≥1 mo post-index was required. All study periods ended on Sep 30, 2024.

RESULTS: The cohort included 478 pts (tec n=374; tal n=78; elra n=26). Median age was 65 years (interquartile range 58–74); most pts were male (59%). Overall, 17% of pts had ≥1 all-cause inpatient admission in the 1 mo post index, 7% had an ICU stay, and 14% had an ER visit; inpatient and ICU stays were each a mean (standard deviation) of 8 (5) days. During 6 and 12 mos post index, 46% of pts had ≥1 all-cause inpatient admission. Mean costs PPPM (including inpatient/ER/outpatient visits and outpatient pharmacy) were $42,938/$34,036/$29,827 in the 1/6/12 mos post index. In the 1 mo post index, infections and hypogammaglobulinemia were reported in 17% and 32% of pts, with both reported together in 5% of pts. In the 1 mo post index, mean associated costs for infections/hypergammaglobulinemia were $64,532/$17,806 PPPM. Intravenous immunoglobulin (IVIG) was administered in 46% of pts from 6 mos before index to 1 mo post index, costing a mean of $817 PPPM in the 1 mo post index. Hematologic complications/hypertension were also frequent (34%/32% of pts) with mean costs of $65,600/$9,250 in the 1 mo post-index period; 43%/42% of these pts had inpatient care.

CONCLUSIONS: Inpatient visits/ICU stays were required for almost half of pts during the follow-up period. Total costs were mainly driven by outpatient visits and medication administration. Almost half of pts had IVIG during the reporting period; however, noticeable rates of costly infections/hypogammaglobulinemia were still observed shortly after initiating the treatment. Part of this data was previously presented at ASH December 6–9, 2025.

SPONSORSHIP: GSK

294 Chimeric antigen receptor T cells in real-world care of multiple myeloma: Patient characteristics, healthcare resource utilization, and costs

Ailawadhi S[1], *Boytsov N*[2], *Multani J*[3], *Zhou Z*[3], *Niehoff N*[4], *Purser M*[4], *Hartman J*[4], *Palumbo T*[4], *Chen C*[3]; *ailawadhi.sikander@mayo.edu*; *natalie.n.boytsov@gsk.com*
[1]*Mayo Clinic*; [2]*GSk*; [3]IQVIA; [4]GSK

BACKGROUND: Healthcare resource utilization (HCRU) and costs data with chimeric antigen receptor T-cell (CAR-T) therapies including idecabtagene vicleucel (ide-cel) and ciltacabtagene autoleucel (cilta-cel) may inform payer formulary decisions for these multiple myeloma (MM) treatments.

OBJECTIVE: To evaluate all-cause and diagnosis-specific HCRU/costs per patient per month (PPPM) for CAR-Ts at first administration (admin; index date) and during 1/6/12 months (mos) post-index.

METHODS: This retrospective cohort study used the IQVIA PharMetrics Plus® Enhanced Closed Claims database, and included adults with MM not participating in clinical trials. Patients must have had the first claim for CAR-T therapy within the relevant FDA-approved period (from Mar 1, 2021, for ide-cel, Feb 1, 2022, for cilta-cel) and continuous enrollment in medical/pharmacy benefits for ≥6 mos before and

≥1 mo after the first administration of CAR-T. Study period ended on Sep 30, 2024. Results are reported for the combined CAR-T cohort.

RESULTS: The cohort included 190 patients (cilta-cel n=101; ide-cel n=89). Median (interquartile range) age was 63 (57–69) years; most patients were male (66%). Inpatient admission at index occurred in 77%, lasting a mean (standard deviation) of 16 (8) days. Mean costs (including inpatient/ER/outpatient visits and outpatient pharmacy) were $369,334 per patient at index and $15,311/$11,300/$9,875 PPPM at 1/6/12 mos post-index. Costs were driven by all-cause inpatient and outpatient visits. Hematologic complications (58%), cytokine release syndrome (CRS; 55%), pyrexia (40%), and hypertension (38%) were among the most common diagnoses 1 mo post-index. Mean diagnosis-related costs per patient 1 mo post-index were $93,076 for hematologic complications, $109,168 for CRS, $66,612 for pyrexia, and $99,561 for hypertension. Intravenous immunoglobulin (IVIG) was administered in 31% of patients from 6 mos pre-index to 1 mo post-index, costing $129 PPPM during 1 mo post-index. During 6 mos and 12 mos post-index, 58% and 71% of patients received IVIG, costing $760 and $737 PPPM, respectively.

CONCLUSIONS: Patients treated with CAR-T therapy required inpatient and outpatient care after admin. Diagnosis-related costs added substantial financial burden to patients who were affected. The majority of patients received IVIG following CAR-T admin. Altogether, this led to high costs during the follow-up period. These findings inform patient care planning and resource allocation. Part of this data was previously presented at ASH, December 6–9, 2025.

SPONSORSHIP: GSK

295 Total cost of care for third-line or later treatment among patients with relapsed/refractory multiple myeloma: Comparison of standard-of-care triplets and B-cell maturation antigen-targeting therapies

Boytsov N[1], *Purser M*[2], *Zur R*[3], *Samyshkin Y*[2], *Palumbo T*[2], *Batts T*[2], *Kamdar M*[2], *Osborne J*[2], *Ferrufino C*[3]; *natalie.n.boytsov@gsk.com*
[1]GSk; [2]GSK; [3]IQVIA

BACKGROUND: In the fragmented relapsed/refractory multiple myeloma (RRMM) landscape, cost of care plays a key role in payer decision making.

OBJECTIVE: This US analysis compared total cost of care (TCoC) for belantamab mafodotin (belamaf) plus bortezomib and dexamethasone (BVd) with standard of care (SoC) triplets and other B-cell maturation antigen (BCMA)-targeted agents (chimeric antigen receptor T-cells [CAR-Ts]; bispecific T-cell engager therapies [BiTEs]).

METHODS: TCoC was assessed in patients (pts) with RRMM and ≥2 prior lines of therapy who received BVd, SoC triplets (daratumumab plus pomalidomide/lenalidomide/bortezomib/carfilzomib and dexamethasone [D+P/R/V/K +d], isatuximab [Isa] + P/Kd, PVd, elotuzumab + Pd), CAR-Ts (ciltacabtagene autoleucel [cilta-cel], idecabtagene vicleucel [ide-cel]), or BiTEs (teclistamab [tec], elranatamab [elra]). Drug costs were sourced from Medi-Span Price Rx. BVd dosing was from DREAMM-7 (mean infusions/pt of 7/6/5 in Years 1/2/3). Dosing from prescribing information and median relative dose intensity was applied for SoC. Administration (admin)/monitoring costs were from the CMS Medicare Physician/Clinical Laboratory Fee Schedule. Adverse event (AE)–related costs (Grade ≥3, clinical trial incidence ≥10%) were applied from the Healthcare Cost and Utilization Project; BVd Grade ≥2 ocular AEs were from DREAMM-7. Year 1 costs/pt from commercial plan perspective are reported.

RESULTS: TCoC for BVd ($540,517) was lower than K-based triplets (DKd, K once/week [QW] $671,779 and K twice/week [BIW] $810,873; IsaKd, K QW $636,072 and K BIW $775,175), anti–CD38-based triplets (IsaPd $544,289/DPd $594,831), CAR-Ts (cilta-cel $775,336/ide-cel $775,355), and BiTEs (tec $587,657/elra $686,696). BVd admin costs ($1427) were similar to SoC triplets and substantially lower than CAR-Ts and BiTEs (cilta-cel and ide-cel $107,729; tec $69,610/elra $46,185). Monitoring costs were $4067 for BVd, $12,497/$11,535 for cilta-cel/ide-cel, and $2331/$2535 for tec/elra. Overall BVd AE-related costs were $21,151, including ocular-related management costs of $985, and the costs were substantially lower than AE-related costs for other anti-BCMA agents (range $66,524 [elra] to $125,924 [ide-cel]).

CONCLUSIONS: The TCoC analysis indicated BVd is a lower cost option than CAR-Ts, BiTEs, and most SoC triplets. Belamaf admin costs are low, with monitoring costs similar to other treatments. The safety profile of belamaf and low AE-related costs contribute to the low cost of care relative to other therapies.

SPONSORSHIP: GSK

296 Clinical and economic burden among patients with unresectable/metastatic GEP-NETs in second line or later following prior treatment with somatostatin analogs

Guérin A[1], *Maitland J*[2], *Sasane M*[3], *Krishna A*[4], *Tsai J*[5], *Sawant R*[4], *Halperin D*[6]; *Annie.Guerin@analysisgroup.com*; *Ruta.Sawant@sanofi.com*
[1]*Analysis Group, Montreal, QC, Canada*; [2]*Analysis Group, Toronto, ON, Canada*; [3]*Sanofi, Morristown, NJ, USA*; [4]*Sanofi, Cambridge, MA, USA*; [5]*Sanofi, Stockholm, Sweden*; [6]*Winship Cancer Institute of Emory University, Atlanta, Georgia, USA*

BACKGROUND: Long-acting somatostatin analogs (SSA) are commonly used as first-line therapy in treating patients with unresectable/metastatic (advanced) gastroenteropancreatic neuroendocrine tumors (GEP-NETs). However, many patients progress and subsequently receive additional lines of therapy, such as molecular targeted therapies (MTTs), chemotherapy, or peptide receptor radionuclide therapy (PRRT), which may impose additional clinical and economic burden, with each subsequent line of therapy.

OBJECTIVE: To characterize treatment patterns, time to next treatment (TTNT), and healthcare costs by line of treatment among patients with unresectable/metastatic GEP-NETs in 2L+ with previous SSA exposure.

METHODS: A retrospective cohort study using Komodo Research Data (KRD+ insurance claims; Jan 2016 to Oct 2024) was conducted. Patients with ≥2 diagnoses of GEP-NET ≥30 days apart with ≥1 line of therapy (LOT) with SSA followed by ≥1 subsequent line of therapy were included. Real-world TTNT was assessed from initiation of the first line of therapy after SSA-based therapy to initiation of next LOT, death, or end of follow-up (censored). Healthcare costs were assessed by line of therapy (1L – 3L) and was reported as per-patient-per-month (PPPM).

RESULTS: A total of 530 patients were included. Mean (SD) age was 62.1 (11.9) years, and a majority were male (53.2%), white (61.1%), and commercially insured (60.9%). After SSA-based therapy, patients received PRRT ± SSA (43.0%), chemotherapy ± SSA (27.7%), MTT ± SSA (26.6%), or other regimens (2.6%). After progression on SSA-based therapy, overall median TTNT was 23.9 months. By LOT, median TTNT was 24.3 months for 2L and 11.5 months for 3L, indicating that patients may be progressing faster with later lines of therapy. In addition, the mean total healthcare costs increased from $14,857 PPPM in 1L to $33,065 PPPM in 2L and $35,469 in 3L.

CONCLUSIONS: Real-world data indicate that patients with advanced GEP-NET experience shorter TTNT despite higher healthcare costs as they progress past 1L. The worsening of clinical outcomes with disease advancement along with the higher economic burden highlights the need for effective therapies that can delay disease progression and provide valuable improvements to patients.

SPONSORSHIP: Sanofi

Precision Medicine

306 The economic case for next-generation sequencing (NGS) in early-stage lung cancer: A forward-looking analysis

Malin J[1], *Ma Q*[2], *Ye W*[3], *White J*[4], *Sheffield K*[4], *Aminnejad N*[3], *Zou D*[3], *Brechtelsbauer E*[4]; *drjmalin@gmail.com*
[1]*Health&Care Insights and Innovation Consulting*; [2]*Eli Lilly & Company*; [3]*PPD™ Evidera™ Health Economics & Market Access, Thermo Fisher Scientific*; [4]*Eli Lilly and Company*

BACKGROUND: In early-stage non–small cell lung cancer (NSCLC, stage IB-IIIA), emerging genomic biomarker therapeutic targets create a need to consider the optimal biomarker testing strategy. While NGS is well established in advanced disease, its economic value in early-stage settings remains unclear.

OBJECTIVE: This study takes a forward-looking approach, evaluating how the economic outcome of NGS evolves as new biomarkers become clinically actionable.

METHODS: We developed a decision-tree model from a US Medicare payer perspective comparing NGS with single-gene testing (SGT). Five scenarios were evaluated for SGT strategies to simulate the sequential addition of biomarkers. NGS, represented as small gene panels (5-50 genes), remained constant. Actionable biomarkers included ALK (prevalence: 2.0%), EGFR (17.9%), KRAS G12C (12.4%), RET (1.1%), BRAF (0.9%), and ROS1 (0.4%), prioritized by clinical prevalence, product/trial pipelines and guideline relevance. Biomarker prevalence and test performance were informed by published sources, supplemented with conservative assumptions for NGS. Testing costs were obtained from the 2025 CMS Clinical Diagnostic Laboratory Fee Schedule; treatment costs were not considered. Primary outcomes included cost per correctly identified patient (CCIP)—derived by monetizing the number needed to predict (NNP), a function of positive and negative predictive values—to measure cost in achieving an accurate diagnosis of a patient's genomic alterations, and cost per member per month (PMPM).

RESULTS: Across all scenarios, NGS showed better diagnostic performance versus SGT, requiring fewer patients for accurate diagnosis (i.e., lower NNP). NGS achieved an accurate diagnosis with a lower cost (CCIP) beginning at the scenario with 3 actionable biomarkers (EGFR&ALK, + KRAS G12C)

(CCIP difference =-$459), the "tipping point" beyond which NGS becomes cost-saving. The potential saving associated with NGS increased as additional biomarkers were added (+RET, +BRAF, +ROS1). For a hypothetical 1-million-life Medicare plan with full testing of eligible patients, NGS resulted in PMPM savings of $0.05 for three biomarkers, $0.08 for four, and $0.14 for six.

CONCLUSIONS: Our analysis suggests that, in addition to its potential to improve diagnostic accuracy, broad-panel NGS will become cost-saving relative to SGT in early-stage NSCLC as the number of actionable biomarkers increases. These findings support a forward-looking strategy in which broader biomarker availability strengthens the clinical and economic rationale for NGS testing in early-stage cancer patients.

SPONSORSHIP: Eli Lilly and Company

Quality and Safety Programs

310 Anticholinergic drug utilization in Medicare Part D: Insights for the POLY-ACH quality measure to guide deprescribing opportunities in older adults

Rizk R[1], *Bahroos A*[2], *Pike S*[2], *Kim P*[2], *Kogut S*[1]; *ramezrizkelkosary@gmail.com*
[1]*University of Rhode Island*; [2]*University of Rhode Island College of Pharmacy*

BACKGROUND: The Centers for Medicare & Medicaid Services (CMS) will begin reporting the Use of Multiple Anticholinergic Medications in Older Adults (POLY-ACH) measure in the 2027 Medicare Part D Star Ratings, using 2025 as the first measurement year. Given the various anticholinergic drug classes included in this measure, understanding the relative utilization of each class is essential to identify key drivers of anticholinergic burden and guide deprescribing efforts. To current knowledge, no US studies have examined which anticholinergic drug classes and medications included in the POLY-ACH specification are most frequently prescribed to older adults in Medicare Part D.

OBJECTIVE: To quantify the utilization of anticholinergic drug classes among older Medicare Part D beneficiaries and inform targeted strategies to reduce poly-anticholinergic use.

METHODS: A cross-sectional analysis was conducted using the 2023 CMS Medicare Part D Prescribers – by Provider and Drug database. The anticholinergic medications included in the POLY-ACH measure were identified according to each therapeutic class. Annual prescribing rates for each medication were estimated using standardized 30-day fills and approximate beneficiary counts were calculated at both the drug-class and individual-drug levels.

RESULTS: Among anticholinergic medications included in the POLY-ACH measure, antidepressants and antimuscarinics for urinary incontinence each accounted for 28% of claims, followed by skeletal muscle relaxants (13%), antihistamines (12%), and antipsychotics (8%). Antispasmodics (6%), antiemetics (2%), and antiparkinsonian agents (2%) were prescribed less frequently. At the individual-drug level, oxybutynin accounted for the largest share of total anticholinergic claims (20%) and beneficiaries (15%), followed by paroxetine (13%/8%), cyclobenzaprine (12%/18%), and amitriptyline (10%/7%). Other commonly prescribed agents included hydroxyzine (8%/9%), olanzapine (7%/6%), dicyclomine (5%/6%), and meclizine (5%/7%). All remaining medications each represented ≤4% of claims.

CONCLUSIONS: A limited number of anticholinergic drugs (primarily from the urinary, antidepressant, and muscle relaxant classes) appear to drive the majority of anticholinergic exposure among older Medicare Part D beneficiaries. Many of these anticholinergic drugs have safer alternatives, underscoring opportunities for targeted deprescribing and quality improvement to enhance performance on the POLY-ACH measure.

SPONSORSHIP: None

311 Therapy optimization and waste reduction through deprescribing

Lee S[1], *Corder A*[1], *Leach T*[2], *Ziu R*[1]; *sharlee@healthfirst.org*; *acorder@Healthfirst.org*
[1]*Healthfirst*; [2]*Healthfirst, New York*

BACKGROUND: Polypharmacy remains a longstanding concern in healthcare, as older adults are often subject to use of numerous medications across different providers, specialists, and care settings. Use of unnecessary or duplicative medications leads to increased risk of adverse effects, emergency department visits, and hospitalizations. Polypharmacy also contributes to increased drug costs and healthcare expenditures

OBJECTIVE: To identify potential deprescribing opportunities within Medicare Advantage Prescription Drug (MAPD) plans, Essential Plans (EP), and Qualified Health Plans (QHP) through retrospective review of prescription claims data, and to evaluate outcomes from a managed care organization (MCO) perspective.

METHODS: A retrospective program evaluation was conducted at Healthfirst across EP, QHP, and Medicare plans from January to August 2025. Two deprescribing initiatives were assessed: (A) EP/QHP duplicate therapy with GLP-1 receptor agonists (GLP-1 RA) and DPP-4 inhibitors (DPP4i);

and (B) Medicare Medication Therapy Management (MTM) outreach for targeted drugs. Data sources included pharmacy claims, plan enrollment, and outreach records as of August 2025. For Initiative A, members with concurrent GLP-1 RA and DPP4i use were identified and contacted; the outreach date is used as the index date. For Initiative B, MTM patients with documented pharmacist interventions were evaluated. Outcomes included medication discontinuation and adjusted cost savings, calculated as typical cost per fill multiplied by preventable fills, and summarized by plan, drug, prescriber, and month.

RESULTS: Within MAPD plans, 390 members were outreached from April to October 2025, resulting in 469 deprescribing opportunities. Total cost savings from medication discontinuations are $1.2 million. Within EP/QHP plans, 445 members had GLP-1 RA and DPP4i duplication; 385 were successfully outreached. Four months after outreach, 98 members discontinued the DPP4i, 69 discontinued the GLP-1 RA, and 120 discontinued both. 98 members remain under observation for potential discontinuation. Discontinued fills produced $585,513 in savings, with $119,329 in remaining opportunity.

CONCLUSIONS: Pharmacist-led outreach and interventions by MCOs can effectively reduce polypharmacy and unnecessary drug costs. Improving care coordination helps to decrease duplicate therapy. Future efforts should address evaluating medical cost outcomes following deprescribing.

SPONSORSHIP: None

Real-World Evidence

339 Association of FreeStyle Libre use with HbA1c change in adults with type 2 diabetes on non-insulin therapy: A real-world cohort study using electronic health record data

Mehta S[1], *Wright E*[2], *Virdi N*[1]; *shivani.mehta@abbott.com*; *eewright51@gmail.com*
[1]*Abbott Diabetes Care*; [2]*South Piedmont Area Health Education Center*

BACKGROUND: FreeStyle Libre (FSL) is a continuous glucose monitor that has been shown to improve glycemic outcomes such as A1C and hypoglycemia in people living with diabetes and treated with insulin. Evidence supporting use in non-insulin treated type 2 diabetes (T2D) populations is growing, but questions remain on longer-term, real-world clinical value.

OBJECTIVE: To evaluate the association between FSL use and changes in HbA1c among adults with T2D managed with non-insulin therapies.

METHODS: This retrospective cohort study used electronic health record data from Truveta, a network of 30 United States health systems, to identify adults (≥18 years) with T2D on non-insulin therapy, baseline HbA1c between 8.0 and 12.0%, and follow-up HbA1c 3–6 months. Exclusion criteria included insulin use, dialysis, or with prior continuous glucose monitoring (CGM). FSL users were identified by first acquisition after January 1, 2020; non-CGM users were assigned index dates using stratified sampling. Propensity score matching (1:4) balanced covariates including demographics, payer type, comorbidities, baseline HbA1c, and medication use. Doubly robust regression estimated HbA1c changes at 3, 6, 9, and 12 months. Subgroup analyses by age (<65 and ≥65 years) were conducted.

RESULTS: After matching, 2,143 FSL users were compared with 5,499 non-CGM users. FSL users had greater HbA1c reductions at 3 months (−0.57%, 95% CI: −0.65 to −0.50), 6 months (−0.57%, 95% CI: −0.66 to −0.49), 9 months (−0.49%, 95% CI: −0.62 to −0.37), and 12 months (−0.37%, 95% CI: −0.47 to −0.26). Among adults <65 years, reductions were −0.59%, −0.60%, −0.52%, and −0.38% at 3, 6, 9, and 12 months, respectively. Similar patterns were observed in adults ≥65 years (−0.54%, −0.48%, −0.41%, and −0.32%). All differences were statistically and clinically significant, consistently linking FSL use to improved glycemic outcomes across short-term (3, 6 months) and long-term (9, 12 months) follow-up and age groups.

CONCLUSIONS: FSL use was associated with significantly greater HbA1c reductions over 12 months in non–insulin-treated adults with T2D across age groups compared with CGM nonusers. The degree of A1C improvement is similar to findings in a recent meta-analysis of RCTs in this population. Taken together, these findings support expansion of CGM access in non-insulin T2D to improve glycemic control. The findings may inform value-based formulary decisions and population health strategies aimed at improving outcomes and lowering long-term costs.

SPONSORSHIP: This work was supported by Abbott Diabetes Care.

340 Healthcare resource utilization among patients with immune thrombocytopenia who switched to avatrombopag from a prior thrombopoietin receptor agonist

Oladapo A[1], *Piatek C*[2], *Kolodny S*[1], *Lucht S*[3], *Bland E*[3], *Pathak P*[3], *Feinberg B*[3], *Maitland H*[4], *Vredenburg M*[1]; *abiola.oladapo@sobi.com*
[1]*Sobi Inc*; [2]*University of Southern California*; [3]*Cardinal Health*; [4]*University of Virginia*

BACKGROUND: Current evidence supports the effectiveness of avatrombopag (AVA) in patients with immune thrombocytopenia (ITP) who switched from a prior thrombopoietin receptor agonist (TPO-RA) due to inadequate response or other reasons. However, limited real-world (RW) data exist on healthcare resource utilization (HCRU) among patients with ITP who switched to AVA from eltrombopag (ELT) or romiplostim (ROMI).

OBJECTIVE: To describe HCRU in patients with primary ITP who switched treatment to AVA from ELT or ROMI.

METHODS: This retrospective chart-review study included adults with primary ITP who initiated ELT or ROMI on or after July 1, 2019, initiated AVA within 30 days of discontinuing ELT or ROMI, and had ≥6 months of follow-up after AVA initiation. Patients were followed from AVA initiation until date of last contact, death, or study end (March 21, 2025), whichever occurred first. Data on ITP-related emergency room (ER) visits, inpatient (IP) hospitalizations, and unplanned outpatient (OP) visits were collected for the 3-month period prior to AVA initiation (pre-AVA period) and while on AVA. Mean HCRU visits during the pre-AVA period and while on AVA were calculated by estimating the mean number of visits per patient per month (PPPM) and averaging individual month means across the corresponding quarter. Patients were included in monthly analyses if treated with AVA during that month.

RESULTS: Among 201 patients, median (IQR) duration of AVA was 8.4 months (6.7-10.8). Frequency of ITP-related ER visits decreased from 15.4% of patients pre-AVA to 1.5%, 1.6%, 0.0%, and 0.0% of patients during quarters 1 (Q1), 2 (Q2), 3 (Q3), and 4 (Q4) post-AVA initiation, respectively. Frequency of unplanned OP visits decreased from 17.9% of patients pre-AVA to 1.0% (Q1), 3.1% (Q2), 1.5% (Q3), and 0.0% (Q4) post-AVA initiation. Frequency of ITP-related IP hospitalizations decreased from 2.0% of patients pre-AVA to 1.5% (Q1), 1.1% (Q2), 0.0% (Q3), and 0.0% (Q4) post-AVA initiation. Between the pre-AVA period and Q1 post-AVA initiation, mean ITP-related ER visits decreased by 80.0% (0.05 to 0.01 visits PPPM); mean unplanned ITP-related OP visits declined by 85.7% (0.07 to 0.01 visits PPPM), and mean ITP-related IP hospitalizations remained stable at 0.01 visits PPPM. Similar decreases in mean PPPM were seen for all HCRU parameters in Q2-Q4 post- vs pre-AVA period.

CONCLUSIONS: In this RW study, ITP-related HCRU declined across all visit types after AVA initiation, supporting AVA's effectiveness among patients with ITP who switched from a prior TPO-RA.

SPONSORSHIP: Sobi Inc

341 Real-world persistence in patients with tardive dyskinesia: a comparative study of valbenazine and deutetrabenazine XR

Doshi R[1], *Pandya S*[1], *Zhou X*[2], *Nedzesky J*[3], *Tapp P*[3], *Serbin M*[3], *Borrelli E*[3]; *riddhi.doshi@iqvia.com*; *eborrelli@neurocrine.com*
[1]IQVIA; [2]IQVIA *Inc*; [3]*Neurocrine Biosciences, Inc.*

BACKGROUND: Vesicular monoamine transporter 2 inhibitors (VMAT2is), valbenazine and deutetrabenazine-XR, are the only once-daily, FDA-approved, guideline-recommended treatments for tardive dyskinesia (TD). To date, no published studies have evaluated persistence outcomes among matched deutetrabenazine-XR and valbenazine cohorts.

OBJECTIVE: To evaluate persistence outcomes among matched deutetrabenazine-extended-release (XR) and valbenazine cohorts.

METHODS: A retrospective claims analysis using IQVIA's longitudinal prescription and professional fee claims US databases evaluated persistence outcomes between valbenazine and deutetrabenazine-XR. Adults with TD were indexed at VMAT2i initiation (March 1, 2023, to September 30, 2024). Patients with Huntington's disease were excluded. Propensity score matching (1:1) was used to create balanced valbenazine and deutetrabenazine-XR cohorts, accounting for potential confounders (e.g., baseline demographics, comorbidities, psychiatric condition(s), antipsychotic use). Patient characteristics were assessed during a 6-month baseline period. Outcomes assessed during 6-month follow-up period included persistence, discontinuation (>45-day gap), and switching. Outcomes were assessed descriptively with statistical comparisons conducted using chi-square tests (categorical) and Wilcoxon rank-sum tests (continuous; medians). Kaplan Meier analyses with log-rank test were used to compare persistence over time.

RESULTS: Each matched cohort included 1,494 patients. Persistence at each month and overall was significantly higher with valbenazine vs deutetrabenazine-XR (overall 55.6% vs 48.1%; all comparisons P<0.001). A lower proportion of valbenazine cohort switched to a different VMAT2i than matched deutetrabenazine-XR cohort (7.7% vs 11.2%; P<0.01). Median time to discontinuation or switch from VMAT2i therapy was

129 days for the deutetrabenazine-XR cohort, while the median was not reached for the valbenazine cohort, indicating longer persistence (log-rank P<0.0001).

CONCLUSIONS: To our knowledge, this is the first study comparing persistence between valbenazine and deutetrabenazine-XR in a real-world setting. Results showed valbenazine had greater persistence and less switching vs deutetrabenazine-XR. Higher persistence rates with valbenazine were seen after the first month and were sustained through the 6-month follow-up. Future studies may investigate potential reasons for differences in persistence, such as titration difficulty, clinical effectiveness, and tolerability.

SPONSORSHIP: Neurocrine Biosciences, Inc.

342 Real world assessment of cost and utilization trends of chimeric antigen receptor T-cell (CAR-T) therapy and bispecific T-cell engager (BiTE) antibody therapy among different sites of care (SOC)

Decker S, Eckwright D, Wilson A, Parikh P;
samantha.decker@primetherapeutics.com
Prime Therapeutics

BACKGROUND: CAR-T and BiTE therapies are increasingly becoming standard of care for treating malignancies. Due to risks of cytokine release syndrome (CRS) and immune effector cell–associated neurotoxicity syndrome (ICANS), these therapies have traditionally been administered in hospitals—CAR-T inpatient and BiTE outpatient and inpatient. There is market interest in safely using these therapies in lower-acuity SOC. This study aims to inform payers of the utilization trends and treatment day costs among these various SOC.

OBJECTIVE: To evaluate utilization trend and treatment day costs of CAR-T and BiTE by SOC.

METHODS: Medical claims from 17 million commercial lives were queried to identify CAR-T and BiTE claims between 03/31/2022 and 06/30/2025. All associated claim lines were aggregated and allowed amount summed to calculate the treatment day cost. SOC for these claims were assigned based on place of service code and facility bill type codes. SOC included inpatient, outpatient hospital, provider office, and home infusion. The number of claims and percent of total claims for each quarter (Q) was calculated for each SOC to report utilization trend.

RESULTS: A total of 541 CAR-T and 8,061 BiTE claims were identified during the study period. Between 2Q2022 and 2Q2025, the number of CAR-T claims increased 108% (25 to 52) and the percentage of inpatient CAR-T claims decreased from 81% to 61%. Commensurately, hospital outpatient CAR-T claims rose from 19% to 39%, reflecting a consistent upward trend across years—16% in 2022, 20% in 2023, 27% in 2024, and 35% in 2025. The total number of BiTE claims grew more than five-fold, rising from 238 in 2Q2022 to 1,279 in 2Q2025. During this period, the percentage of hospital claims declined 63% to 60%, while office-based claims increased from 8% to 27%. The average treatment day cost was $707,577 and $499,831 for CAR-T in the inpatient and outpatient settings, respectively, and $45,155, $31,532, $20,334, and $21,848 for BiTE in inpatient, outpatient, office, and home infusion, respectively. Inpatient SOC had the highest variation in treatment day costs.

CONCLUSIONS: This study confirms a significant increase in utilization of CAR-T and BiTE therapies, accompanied by a consistent shift toward lower-acuity, lower-cost sites of care. While cost differences between SOC are substantial, they may be influenced in part by differences in patient health status and the intensity of services delivered on the treatment day. Payers should continue to monitor SOC trends to support safe, clinically appropriate, and cost-effective CAR-T and BiTE therapy administration.

SPONSORSHIP: None

343 Real-world adherence and MRI monitoring patterns among patients treated with lecanemab in the United States

Cartwright B[1], Feisst D[1], Liang J[2], Geogy N[2], Masters N[1], Farrar K[1]; briannac@truveta.com
[1]Truveta; [2]Truveta, Inc

BACKGROUND: Lecanemab (Leqembi) received accelerated FDA approval in January 2023 and full approval in July 2023 for treatment of mild cognitive impairment. Given its cost, biweekly infusion schedule, and risk of amyloid-related imaging abnormalities (ARIA), understanding real-world adherence and monitoring patterns is essential to inform clinical implementation.

OBJECTIVE: To quantify six-month adherence to lecanemab in routine practice and examine factors associated with adherence. We also characterized MRI monitoring patterns after treatment initiation.

METHODS: Using Truveta electronic health record data, we identified patients treated with lecanemab between January 2023 and March 2025. The Montreal Cognitive Assessment (MoCA) and Mini-Mental State Examination (MMSE) results prior to treatment initiation were extracted from clinical notes to characterize the population. Adherence was defined as receiving ≥90% of recommended doses within six months (≥12 of 13). Logistic regression quantified demographic and clinical predictors of adherence. Among patients with MRI

data, we evaluated MRI receipt and timing within six months of initiation.

RESULTS: The study included 327 patients (56.3% female, 91.4% White, 91.4% not Hispanic or Latino, and mean [SD] 73.5 [7.0] years). Nearly half of patients (46.5%) had a documented MoCA (20.8 [4.1]) or MMSE (24.6 [6.2]) score. Overall, 62.7% of the population was considered adherent. Controlling for race, sex, and age, those who initiated in 2024 (64.0%) or 2025 (70.1%) were more likely to be adherent ($p \leq 0.001$) than those in 2023 (16.7%). A small percentage of patients received only one or two doses (7.0%). The majority of patients who were non-adherent received four or five doses (12.8%). Nearly all with prior MRI had repeat imaging within six months (91.3%), typically after the third dose.

CONCLUSIONS: In this real-world analysis of patients treated with lecanemab, nearly two-thirds were adherent within the first six months. Adherence increased among those initiating treatment in later years, suggesting growing familiarity with the therapy and evolving clinical management practices. Most patients received follow-up MRI imaging consistent with monitoring recommendations. All patients began treatment before the FDA advised adjusting MRI monitoring to between the second and third infusion. Analyses will be updated before the meeting to include additional patients and assess adherence and monitoring under the new guidance. These findings highlight improvements in adherence to lecanemab over time and underscore the need for continued study.

SPONSORSHIP: All authors are employed by Truveta.

344 Factors associated with persistence to glucagon-like peptide-1 (GLP-1) receptor agonists in obese and overweight patients without diabetes

Houska H[1], *Qiu Y*[1], *Reidt S*[2]; *heather@evio.com*
[1]*Evio Pharmacy Solutions*; [2]*Evio*

BACKGROUND: GLP-1 receptor agonists (GLP-1s) are effective treatments for weight management, but real-world persistence remains suboptimal. Poor persistence can reduce clinical benefits and increase overall costs. Predictive modeling using administrative claims data may help identify patients at risk for early discontinuation and guide intervention strategies.

OBJECTIVE: To develop a claim-based model identifying factors associated with GLP-1 discontinuation at 120 and 365 days among patients initiating treatment for weight management.

METHODS: The study used medical and pharmacy claims data from July 1, 2019, through March 31, 2024, to identify patients initiating Saxenda, Wegovy, or Zepbound for weight management, excluding patients with diabetes. Persistence was defined as the proportion of patients without a ≥60-day gap in GLP-1 supply and was assessed at 120 and 365 days. Logistic regression models were developed to identify factors associated with persistence, including demographics, comorbidities, out-of-pocket (OOP) costs, prescriber visit frequency, BMI changes, and dose titration.

RESULTS: Among the 53,183 patients initiating a GLP-1, persistence declined from 65% at 120 days to 34% at 365 days. Compared to patients with low OOP costs (<$42), those with OOP ≥$150 had higher discontinuation rates. Regular visits with the prescribing clinician strongly predicted persistence. Patients with ≥5 visits were 49 times more likely to remain on therapy at 120 days, and patients with ≥11 visits were 8 times more likely at 365 days. Other predictors of persistence included older age (38–53), early BMI reduction (≥2-point drop), and a history of bariatric surgery. Use of low-dose Wegovy or Zepbound beyond 28 days was associated with discontinuation. Adverse events were not strongly associated with discontinuation except for biliary disease in the early period.

CONCLUSIONS: Among patients initiating a GLP-1 for weight management, persistence dropped substantially within the first year. A prediction model using routine claims data identified patients at risk for early discontinuation. Frequent clinician follow-up, dose titration, and minimizing OOP costs were key modifiable factors associated with improved persistence. These findings may inform targeted interventions and payer strategies to optimize long-term treatment success with GLP-1 therapy.

SPONSORSHIP: Evio Pharmacy Solutions

345 Real-world effectiveness of cannabidiol on antiseizure medication cycling, polypharmacy, and healthcare resource utilization (HCRU): A US retrospective claims analysis

Burn L[1], *Faller R*[2], *Bennett K*[2], *Faithe M*[1], *Harrison M*[3], *Osborne V*[3], *Pritchard D*[2], *Rajasekaran K*[1], *Sillah A*[1]; *Leah.Burn@jazzpharma.com*; *Michael.faithe@jazzpharma.com*; *Arthur.Sillah@jazzpharma.com*
[1]*Jazz Pharmaceuticals, Inc.*; [2]*Target RWE*; [3]*Jazz Pharmaceuticals, UK Ltd.*

BACKGROUND: Randomized clinical trials established the efficacy of cannabidiol (CBD, Epidiolex®, 100 mg/mL oral solution) for treating seizures associated with Dravet syndrome (DS), Lennox-Gastaut syndrome (LGS), and tuberous sclerosis complex (TSC). In patients with refractory epilepsy, inadequate seizure control or undesirable side effects may cause antiseizure medication (ASM) cycling, polypharmacy, and

increased HCRU. Data on the real-world impact of CBD on these outcomes are limited.

OBJECTIVE: This retrospective cohort study used the US Optum® Market Clarity Database to assess the effectiveness of CBD on these outcomes in CBD-naive adult and pediatric patients with DS, LGS, or TSC.

METHODS: Adult (≥18 years old) and pediatric (<18 years old) patients who initiated CBD between 6/25/2018 and 9/30/2023 were included. Baseline was defined as the 12 months before CBD initiation (index event); follow-up was ≤12 months post-initiation and varied across patients. An interrupted time series analysis assessed observed changes in ASM cycling (number of new maintenance ASMs per patient per year), polypharmacy burden (number of concomitant maintenance ASMs, anxiolytics, antidepressants or antipsychotics per patient per month [PPPM]), and HCRU (seizure-related hospitalization, emergency department [ED] or physician office visits PPPM) before and after CBD initiation relative to pre-CBD initiation trends. Results were stratified by epilepsy type and age group.

RESULTS: A total of 2937 pediatric (DS, n=1362; LGS, n=1406; TSC, n=169) and 1624 adult (DS, n=468; LGS, n=1044; TSC, n=112) patients were included. Most were male (56% pediatric; 55% adult), were non-Hispanic White (50%; 60%), and had intellectual disability or developmental delay (63%; 54%). At 12 months after CBD initiation, reductions relative to pre-initiation trends in ASM cycling were seen in both groups in the overall cohort (34% pediatric; 28% adult) and within each indication-specific subgroup. Reductions were also seen in polypharmacy (32%; 16%) and HCRU (hospitalizations [62%; 40%], ED visits [69%; 65%], and physician visits [28%; 8%]) in pediatric and adult groups, respectively, in the overall cohort and within the indication-specific subgroups (no change seen in physician visits among adults with LGS).

CONCLUSIONS: These real-world data reveal overall reductions in ASM cycling, polypharmacy burden, and HCRU at 12 months after CBD initiation in pediatric and adult patients with DS, LGS, or TSC. Results suggest CBD may reduce clinical and economic burden of disease in pediatric and adult patients living with these rare epilepsies.

SPONSORSHIP: Jazz Pharmaceuticals, Inc.

346 Prevalence of diagnosed fragile X syndrome among males in the United States in 2023: A claims-based study

Ganguli S[1], *Schepart A*[2], *Fakih I*[3], *Ionescu-Ittu R*[4], *Wilkins V*[5]; *sohini.ganguli@shionogi.com*
[1]*Shionogi Inc*; [2]*Shionogi*; [3]STATLOG; [4]STATLOG *Inc.*; [5]*University of Utah*

BACKGROUND: Fragile X syndrome (FXS) is the most common inherited cause of intellectual disability and leading single-gene cause of autism. Because males have a single X chromosome, their FXS symptoms are often more severe. A 2014 meta-analysis of molecular screening–based FXS prevalence in males at 1.4 per 10,000 (corresponding to ~1:7,000), but prior chart reviews suggested FXS may be underdiagnosed in clinical practice. Accurate estimates of diagnosed FXS prevalence are vital for improving diagnosis and guiding health resource allocation in the US, especially for males.

OBJECTIVE: (1) To estimate the claims-based 2019-2023 period prevalence of diagnosed FXS in males in the US and (2) to estimate the 2023 prevalent male population with diagnosed FXS in the US.

METHODS: This cross-sectional study used the Symphony Health Solutions IDV open claims database (2019-2023). Diagnosed FXS prevalence in males was calculated as the proportion of males with ≥1 FXS diagnosis (ICD-10: Q99.2) among all males with ≥1 medical or pharmacy claim during the 5-year period. Prevalence was stratified by age group and geography, and was applied to 2023 US census data to estimate the national burden.

RESULTS: The overall claims-based 2019-2023 period prevalence of diagnosed FXS among males was 0.78 per 10,000 (~1:13,000). Male prevalence peaked at ages 5-9 y, 10-19 y, and 20-29 y (1.45, 1.50, and 1.47 per 10,000, respectively; ~1:6,500-7,000) and was lower in ages <5 y (0.40 per 10,000; ~1:25,000) and 30+ y (0.34-1.08 per 10,000; 1:9,000-29,000 depending on age). The male prevalence also varied across states, with Delaware, Iowa, Maine, Nebraska, and Wyoming at the higher end (>1.00 per 10,000) and North Dakota, Mississippi, Louisiana, Hawaii, and Arkansas at the lower end (<0.5 per 10,000). Extrapolating the age-stratified rates to the 2023 US male population, the estimated number of males with diagnosed FXS was 14,148.

CONCLUSIONS: The US claims-based prevalence of diagnosed FXS in males estimated in the current study was lower than global screening estimates overall, yet comparable among ages 5-29 years. Age-related variations indicate diagnostic delays and/or underdiagnosis in younger children and older adults, potentially due to misattribution to conditions such as autism. Geographic variations may reflect underlying genetic

clustering or unequal access to FXS-expert care. Elucidating these factors is key to enhancing timely FXS identification and access to FXS specialized care.

SPONSORSHIP: Shionogi Inc.

347 Clinical and economic burden in patients with fibromyalgia (FM): A retrospective claims analysis

Gould E; errol.gould@tonixpharma.com
Tonix Medicines

BACKGROUND: Fibromyalgia (FM) is a chronic pain disorder that presents significant diagnostic and therapeutic challenges, compounded by multiple comorbidities. No new therapies have been approved for FM since 2009. Prior research indicates, despite existing therapies, patients experience high clinical and economic burden.

OBJECTIVE: To quantify FM comorbidities, healthcare resource utilization (HCRU), and costs associated with the current approach to FM treatment.

METHODS: This retrospective database analysis was conducted using closed claims from the Symphony database (04/2021 to 04/2024). The cohort comprised patients aged ≥18 years with FM identified in claims using the M79.7 FM ICD-10-CM code. Patients were assessed for FM-specific comorbidities by corresponding ICD-10-CM codes. Subsequently, average healthcare services and costs were calculated on a per-patient basis. Analysis captured the third study year (2023-2024; Y3 cohort).

RESULTS: A total of 261,776 patients were included in the Y3 cohort; mean (SD) age of 52.3 (13.02) years; 92.1% were female, and 49.6% patients were white, non-Hispanic. Among these patients, 90.3% (n=236,303) experienced at least one comorbidity, and 93.2% (n=244,166) experienced FM-related comorbidities. The most frequently reported comorbidities included depression/anxiety (63.9%), back pain (56.5%), and hypertensive diseases (51.4%). Other comorbid conditions included falls/fractures (21.2%) and gait abnormalities (13.4%). In terms of insurance coverage, 35.2% (n=92,258) of patients had commercial insurance, and 13% (n=34,133) had Medicare Advantage. Overall, 73% (n=92,157) had at least one non-zero HCRU claim. Annually, patients had an average of 2.58 inpatient admissions, 13.35 outpatient visits, 17.81 office visits, 2.12 ER visits, and 2.95 ambulatory services per patient (corresponding to 29.8%, 79%, 93.6%, 32.5%, and 19.5% of patients, respectively). The mean per-patient costs were $29,896 for inpatient, $6,196 for outpatient, $4,669 for office, $2,275 for ER, and $2,917 for ambulatory services. Most patients (61.3%) also had pharmacy claims, with an associated mean annual cost of $9,453 per patient. The average total annual cost across all patients was $27,941.

CONCLUSIONS: These findings suggest that many patients with FM experience significant burden of illness due to comorbidities. Despite FDA-approved therapies being available, annual HCRU and costs are elevated, highlighting the need for new, more effective treatments to address the substantial unmet needs in this population.

SPONSORSHIP: Tonix Medicines, Inc.

348 Characteristics of individuals initiating cabotegravir long-acting for human immunodeficiency virus pre-exposure prophylaxis in the United States: Updated results from the PrEPFACTS study

Herman G[1], Nguyen C[2], Metzner A[1], Alinezhad F[3], Martinez D[1], Walko S[1], Banatwala A[2], Young-Xu L[2], DerSarkissian M[2]; gabrielle.f.herman@viivhealthcare.com; aimee.a.metzner@viivhealthcare.com
[1]ViiV Healthcare; [2]Analysis Group, Inc.; [3]Analysis Group

BACKGROUND: APRETUDE (cabotegravir long-acting [CAB-LA]) was approved for human immunodeficiency virus 1 (HIV-1) pre-exposure prophylaxis (PrEP) in December 2021. Limited data exists regarding characteristics of individuals (indv) initiating CAB-LA in the real world.

OBJECTIVE: To describe updated demographic and clinical characteristics of indv initiating CAB-LA, overall, and stratified by payer type (Commercial, Medicare, Medicaid).

METHODS: A retrospective analysis was previously conducted using data from the Komodo Research Database from 12/01/2020 to 09/30/2023. This analysis extended the study period to 09/30/2024. Indv 12 years of age and older who received at least 1 injection of CAB-LA after its approval (first injection defined as index), having at least 12 months of continuous insurance eligibility before the index (i.e., baseline) and at least 6 months after, were included. Indv with HIV-1 or HIV-2 diagnosis and those receiving 60+ days of non-PrEP antiretroviral therapy during baseline were excluded.

RESULTS: The updated results included 2,913 indv (Commercial [n=1,754; 60%]; Medicare [n=111; 4%]; Medicaid [n=1,046; 36%]) with a median age of 34 years (Commercial, 35; Medicare, 53; Medicaid, 32). Overall, 82% of indv were male (sex recorded by payer). Among those with recorded race (78% of sample), 40% were White, 28% Black, and 23% Hispanic/Latino. A larger proportion of Medicaid enrollees with known race were Black (39%). Most indv were located in the Northeast (45%). The most common comorbidities were anxiety disorders (30%), sexually transmitted infections (STIs) (21%), and hypertension (19%) (Commercial); hypertension

(50%), anxiety disorders (41%), and sleep-wake disorders (34%) (Medicare); anxiety disorders (34%), substance-related and addictive disorders (28%), and STIs (28%) (Medicaid). The most frequently dispensed medications were systemic corticosteroids (16%), hormone replacement therapy (12%), and phosphodiesterase-5 inhibitors (7%). Overall, 32% of indv were new PrEP starters, while the remaining 68% received oral PrEP at some point during baseline. Thirty-six percent switched directly from oral PrEP to CAB-LA.

CONCLUSIONS: Consistent with US PrEP use statistics, CAB-LA users were most often male or White but more likely to be female or Black than PrEP users overall. The data demonstrate a steady increase in the proportion of new PrEP initiators using CAB-LA over time. These findings can inform care of indv receiving CAB-LA, including possible comorbidities and concomitant medications.

SPONSORSHIP: ViiV Healthcare

349 Payer churn in a real-world cohort of hemophilia B patients receiving prophylaxis with factor IX

Alizadeh E[1], *Hinchcliffe D*[2], *Everson K*[3], *Crecelius E*[3], *Sullivan J*[4], *Incerti D*[5], *Drelich D*[6], *Yan S*[6]; *elmar.alizadeh@entityrisk.com*
[1]*EntityRisk Inc.*; [2]*CSL*; [3]*EntityRisk*; [4]*EntityRisk, Inc*; [5]*EntityRisk, Inc.*; [6]*CSL Behring*

BACKGROUND: Hemophilia B is a bleeding disorder caused by a deficiency of factor IX (FIX). Traditionally, the recommended treatment for severe patients is prophylaxis with FIX. Evidence in hemophilia A suggests that patients remain with the same insurer for 4+ years, but hemophilia B data are lacking.

OBJECTIVE: To estimate the rate of payer churn (i.e., switching from one payer to another) in hemophilia B patients on FIX prophylaxis.

METHODS: The open claims IQVIA Longitudinal Access and Adjudication Data was utilized to identify a cohort of hemophilia B patients on prophylaxis aged 18-64 with claims between January 2019 and February 2025. Patients had to be observed for at least 30 days with at least 2 Rx claims on separate days for BeneFIX, Alprolix, Idelvion, Rebinyn, or Rixubis. Prophylaxis status was assigned if at least one criterion from a publication was satisfied: (1) 6 or more dispenses of 15 or more days supply on 6 separate days; (2) maximum gap in days supply of ≤60 days; (3) combined days supply of ≥273. The primary endpoint was time until a prophylaxis therapy payer switch (i.e., a churn event). The payer listed on the first Rx claim for one of the prophylaxis therapies was the initial payer. All subsequent prophylaxis claims were assessed for a change in payer name; the first claim with a payer name differing from the initial payer was a churn event. The difference between the date of the first prophylaxis claim and the churn event was recorded as the churn event time. Baseline characteristics stratified by churn status were reported and tested for statistical significance. Parametric survival models were fit with a churn event as the outcome. Model fit was assessed using Akaike Information Criterion, and the fitted models were used to estimate time until first payer switch for the average patient. Survival curves were produced and time until first payer churn was predicted.

RESULTS: 666 patients were included in the final analysis cohort. On average, patients were observed for 4.3 years, had 1.6 payers, and 24.6 prophylaxis dispenses. 235 (35.3%) of the patients experienced a payer churn. Under the best fitting parametric model, mean time to payer churn was estimated to be 5.21 years, with the 25%/50%/75% quantiles being 1.54, 4.60, and 10.9 years, respectively.

CONCLUSIONS: The average Hemophilia B prophylactic patient in a real-world cohort remains with the same insurer for ~5 years. This is likely a lower bound since open claims lack enrollment data, and patients likely had prophylaxis claims prior to their first observation.

SPONSORSHIP: CSL Behring

350 Real-world three-year cost impact assessment of glucagon-like peptide-1 agonists to treat obesity among commercially insured members without diabetes

Tran J[1], *Urick B*[1], *Marshall L*[2], *Farley J*[3], *McCann M*[1], *Gleason P*[1]; *jacinda.tran@primetherapeutics.com*; *ben.urick@primetherapeutics.com*
[1]*Prime Therapeutics*; [2]*Prime Therapeutics, LLC*; [3]*University of Minnesota College of Pharmacy*

BACKGROUND: GLP1 products to treat obesity remain a major driver of prescription drug spending. While some of this increase may be offset by medical spending reductions, evidence is mixed and data on use longer than 2 years is lacking.

OBJECTIVE: To describe changes in annual medical spending and total cost of care (TCC) one year before and three years after GLP1 obesity treatment initiation among commercially insured members without diabetes compared to a matched control group, regardless of treatment persistence.

METHODS: Prime Therapeutics' integrated pharmacy and medical claims data from 2020 to 2025 were used in this study. The study population consisted of new initiators of a GLP1 ("treatment") or a chronic medication ("control") between 1/1/2021 and 3/31/2022. Inclusion criteria were continuous enrollment in the 12 months prior to index ("pre-period"), an obesity diagnosis on ≥1 medical claim during the

pre-period, aged 19+ years at index, and no GLP1 use or evidence of diabetes during the pre-period. Members were matched 3:1 on a range of demographic and clinical characteristics. Spending was assessed using rolling 91-day periods relative to index. All members had 4 pre-period and up to 12 post-period measurements, depending on eligibility. Controls who initiated a GLP1 were censored beginning with the period of initiation. Difference-in-differences (DID) regression was used to compare medical spending and TCC trends.

RESULTS: 29,570 controls were matched to 10,094 treatment members. 80.6% were female, with mean age of 45.6 years old. Treatment members had 1.7% (95% CI: -0.5% to 3.9%) greater medical spending trend compared to controls for the 3-year post-period compared to pre. Medical spending for treatment members averaged $8,224, $8,906, $9,810, and $10,705 for the pre-period and years 1-3, respectively, and TCC averaged $11,072, $19,316, $17,621, and $18,396. For controls over the same periods, medical spending averaged $8,028, $8,872, $8,942, and $9,597, and TCC averaged $10,794, $12,429, $12,775, and $13,742. DID in year 3 vs. the pre-period for treatment vs. controls was significantly higher for both medical spending ($912 [95% CI: $415 to $1,409]) and TCC ($4,377 [95% CI: $3,752 to $5,002]).

CONCLUSIONS: For members without diabetes using GLP1 products to treat obesity, this real-world intent to treat study found TCC remained $4,377 higher in year 3 compared to controls with no indication of a trend towards medical spending reductions. These findings indicate substantial ongoing investment over the first 3 years of therapy for the general GLP1 obesity treatment population.

SPONSORSHIP: Prime Therapeutics

351 Glucagon-like peptide-1 agonist use and outcomes in heart failure with preserved ejection fraction

Maass E[1], *Reidt S*[1], *Patrick A*[2]; *eric.maass@evio.com*; *mandy@evio.com*
[1]*Evio*; [2]*Evio Pharmacy Solutions, LLC*

BACKGROUND: A growing body of evidence suggests GLP-1 agonists are cardioprotective in patients with heart failure with preserved ejection fraction (HFpEF) who have type 2 diabetes (T2DM) or obesity, with benefits attributed to weight loss and decreased inflammation. However, it is uncertain whether the cardiovascular-related benefits outweigh the cost of the medication. Few real-world studies have examined the clinical outcomes and healthcare resource utilization (HCRU) associated with GLP-1 agonist use in patients with HFpEF, and none have assessed the economic impact.

OBJECTIVE: To assess the effect of adding a GLP-1 agonist to HF standard of care (SOC) medications among patients with HFpEF who have T2DM and/or obesity on clinical, cost, and HCRU outcomes.

METHODS: In this retrospective cohort study, patients with HFpEF who have T2DM and/or obesity were identified within the Evio 2019–2025 medical and prescription claims database. Patients initiating a GLP-1 agonist in addition to HF SOC medications were propensity score matched 1:1 with patients who continued HF SOC medications alone. Regression models were used to compare the incidence of hospitalization for heart failure, hospitalization for a cardiovascular diagnosis, major cardiac adverse events (MACE), and 365-day costs and HCRU in the matched population.

RESULTS: Among 2,363 patients initiating a GLP-1 agonist matched to patients continuing HF SOC medications, the mean age was 63, 45% were male, and 67% were commercially insured. The majority of patients had T2DM (81%) and obesity (95%). Patients initiating a GLP-1 agonist had a 27% lower incidence of hospitalization for cardiovascular disease, a 62% lower incidence of hospitalization for heart failure, and no difference in the incidence of MACE. There was no significant difference in one-year total cost of care between the GLP-1 agonist and HF SOC groups ($54,349 vs. $53,741; $p = 0.866$). Decreased inpatient costs offset increased pharmacy costs. Patients initiating a GLP-1 agonist had lower HF and cardiovascular disease-related costs and fewer inpatient hospitalizations.

CONCLUSIONS: Addition of a GLP-1 agonist to HF SOC medications was associated with a reduction in the incidence of hospitalization for cardiovascular disease and no difference in total cost among patients with HFpEF who have T2DM and/or obesity.

SPONSORSHIP: Evio

352 Atypical antipsychotics and adults with autism spectrum disorder: A retrospective real-world comparison of risperidone and aripiprazole

Myers S; *scottmyers@pearldiverinc.com*
PearlDiver Technologies

BACKGROUND: Atypical antipsychotics such as aripiprazole (AZ) and risperidone (RD) are used to treat distressing symptoms such as irritability and repetitive behaviors in patients with autism spectrum disorder (ASD). While having fewer side effects than conventional antipsychotics, AZ and RD still carry side effects that need to be considered when utilized.

OBJECTIVE: Using the PearlDiver Mariner170 national, all-payer database, we compared adverse effects arising from the administration of AZ and RD when prescribed to adults

with ASD. Eleven common adverse effects, and the risks of developing these effects depending on course of treatment, were assessed.

METHODS: All patients who had ≥1 inpatient or ≥2 outpatient claims for ASD were identified. Patients had to have ≥1 claim at least 2 years following the initial ASD diagnosis. Patients were also required to have ≥1 claim at least 1 year following initial prescription administration. Patients had to be aged ≥18 at ASD diagnosis. Propensity score matching was performed using the Charleson Comorbidity Index, age range, gender, region, and year on two cohorts: ASD patients prescribed RD with no history of AZ claims, and ASD patients prescribed AZ claims with no history of RD claims. This resulted in two cohorts of 65,288 patients each. Chi-square analysis was then performed to compare the two drugs across 11 complications. To be considered, patients had to have no incidents of adverse events in the year preceding index date with ≥1 instance of adverse events in the year following the index date.

RESULTS: With AZ as the reference, statistically significant differences in risk ratios for RD were seen in self-harm (.61, p≤.05), depression (.75, p≤.05), headache/migraine (.87, p≤.05), mood disorders (.79, p≤.05), alcohol use disorder (.81, p≤.05), and chest pain (.78, p≤.05). In all cases, RD produced lower risk than AZ. No significant difference was seen in tardive dyskinesia, neuroleptic malignant syndrome, high cholesterol, diabetes, or akathisia.

CONCLUSIONS: Results show either similar or reduced risk across the 11 adverse events for patients prescribed RD as opposed to those prescribed AZ. Patient history and existing comorbidities should be carefully considered when selecting an atypical antipsychotic for adults with ASD.

SPONSORSHIP: PearlDiver Technologies

353 Dose escalation and therapeutic drug monitoring in biologics indicated for Crohn's disease

Alvord T[1], *Seguin S*[2], *Reidt S*[1]; *trevormalvord@gmail.com*
[1]*Evio*; [2]*Evio Pharmacy Solutions*

BACKGROUND: Biologics are effective treatments for moderate to severe Crohn's disease (CD) but can lead to increased risk of infection due to immunosuppression. Over time, loss of response to biologics often necessitates an increase in dose (dose escalation) that may exceed FDA-approved labeling. Therapeutic drug monitoring (TDM) measures biologic levels and anti-drug antibodies to guide the decision to increase dose or switch biologics. Real-world evidence describing the incidence and impact of dose escalation and use of TDM is limited.

OBJECTIVE: To assess the incidence of biologic dose escalation, serious infection, and TDM use among patients with CD initiating a biologic.

METHODS: This retrospective descriptive cohort study utilized US medical and pharmacy claims data. Patients with CD who initiated adalimumab, infliximab, ustekinumab, vedolizumab, or their biosimilars from June 30, 2019, to June 01, 2023, were included. Dose escalation was defined as a ≥10% increase in dose from first maintenance dose or increase in dose above FDA labeling. The proportion of patients experiencing dose escalation was calculated for each biologic. Baseline demographic characteristics, incidence of serious infection, and TDM utilization patterns were summarized descriptively.

RESULTS: A total of 5,610 patients met inclusion criteria. Dose escalation occurred in 33.9% to 59.6% of patients, lowest with adalimumab and highest with infliximab biosimilars; rates for vedolizumab, ustekinumab, and brand infliximab were 43.3%, 48.2%, and 57.1%, respectively. Patients experiencing dose escalation had higher incidence of infection during follow-up (27.7% vs. 20.3%). Among patients experiencing dose escalation, TDM only occurred in 30.8% to 39.7% of cases depending on biologic. Overall, 1,439 (25.7%) patients had a claim for TDM during follow-up, and patients who experienced dose escalation were more likely to have a claim for TDM during follow-up than patients who did not (35.2% vs. 17.0%). Among patients who experienced dose escalation, the lowest incidence of TDM occurred in the adalimumab population (30.8%) and the highest incidence in the infliximab biosimilar patients (39.7%), while infliximab (32.4%), vedolizumab (33%), and ustekinumab (34.2%) fell in between.

CONCLUSIONS: Dose escalation was common among patients with CD treated with biologics in a real-world setting, with patients experiencing dose escalation having a higher incidence of serious infection during follow-up. Despite this, TDM use to guide the decision was low, suggesting opportunities to expand TDM adoption to support personalized biologic management in CD.

SPONSORSHIP: Evio

354 Contraception preferences of women and healthcare providers: A discrete choice experiment

Perez Patel V[1], *Holub A*[2], *Betts K*[3], *Mattera M*[2], *Collins K*[4], *Rood K*[5], *Teal S*[6]; *vanessa.patel@organon.com*
[1]*Organon and Co.*; [2]*Analysis Group*; [3]*Analysis Group Inc.*; [4]*Organon*; [5]*The Ohio State University*; [6]*University Hospitals*

BACKGROUND: Preferences of women and healthcare providers (HCPs) for contraception, a cornerstone of women's health, are critical to decision-making when faced with competing options.

OBJECTIVE: This discrete choice experiment (DCE) quantified how attributes of contraceptive methods in the United States impact preferences informing choice.

METHODS: DCEs were conducted separately for women and HCPs. Seven attributes were assessed: effectiveness, mode of administration, return to fertility, cardiovascular (CV) risk, immediate postpartum use, breastfeeding, and amenorrhea. Participants completed 12 choice cards per DCE; each choice card displayed hypothetical yet realistic contraceptive methods with varying levels. HCPs completed a DCE for distinct patient profiles: (1) a young, nulliparous woman; (2) an older woman, family planning complete; and (3) a woman with higher body weight. Preference weight coefficients and relative importance (RI) were estimated using conditional logistic regression. Subgroup analyses were conducted. Guidelines for good research practices were followed.

RESULTS: A total of 612 participants were recruited. Women (n=307) were 29.9 years, on average; 52.4% had higher body weight (body mass index ≥25 kg/m^2). HCPs (n=305) practiced for 16.3 years, on average; 65.6% specialized in obstetrics/gynecology. Women most preferred a highly effective method (RI=30.7%) with low CV risk (RI=24.0%), a daily mode of administration (RI=18.1%), and a rapid return to fertility (RI=10.5%). Methods that can be used immediately postpartum were preferred over those requiring a delay. When considering long-acting reversible methods, women had a slight preference for the etonogestrel implant compared to intrauterine devices. HCPs most valued highly effective methods (RI: 37.0-40.1%). HCPs consistently preferred long-acting reversible methods as opposed to oral pills and injections.

CONCLUSIONS: Women and HCPs strongly prefer highly effective contraception. These findings, showing similarities and differences in stated preferences between women and HCPs, are central to informing educational efforts, contraceptive counseling, benefit-risk, and resource allocation.

SPONSORSHIP: Organon and Co.

355 Real-world treatment-adherent three-year cost impact assessment of glucagon-like peptide-1 agonists to treat obesity among commercially insured members without diabetes

Urick B[1], *Tran J*[1], *Marshall L*[2], *Farley J*[3], *McCann M*[1], *Gleason P*[1]; *ben.urick@primetherapeutics.com*; *jacinda.tran@primetherapeutics.com*
[1]*Prime Therapeutics*; [2]*Prime Therapeutics, LLC*; [3]*University of Minnesota College of Pharmacy*

BACKGROUND: GLP1 products to treat obesity continue to drive prescription drug spending. While some drug spending may be offset by medical spending reductions, low adherence may reduce medical savings.

OBJECTIVE: To describe changes in medical spending and total cost of care (TCC) one year before and three years after GLP1 obesity treatment initiation among treatment-adherent commercially insured members without diabetes compared to matched controls.

METHODS: Prime Therapeutics' integrated pharmacy and medical claims data from 2020 to 2025 were used in this study. The study population consisted of new initiators of a GLP1 ("treatment") or a chronic medication ("control") between 1/1/2021 and 3/31/2022. We required continuous enrollment 1 year before ("pre-period") and 3 years after ("post-period") index, a pre-period obesity diagnosis, age 19+, and no prior evidence of GLP1 use or diabetes pre-index. Adherence was defined as >80% proportion of days covered over the entire post-period. Members were matched 3:1 on a range of demographic and clinical characteristics. Spending was assessed using rolling 91-day periods relative to index. All members had 4 pre-periods and 12 post-periods. Controls who initiated a GLP1 were censored. Difference-in-differences (DID) regression was used to compare medical spending and TCC trends.

RESULTS: 1,906 controls were matched to 644 treatment members. 79.2% were female, with mean age of 48.2 years old. Treatment members had non-significant lower medical spending trend (-2.4% [95% CI: -10.0% to 5.8%]) compared to controls. Medical spending for treatment members averaged $8,645, $9,389, $9,799, and $11,220 across study periods and TCC averaged $12,176, $26,466, $26,807, $28,218. For controls over the same periods, medical spending was $8,504, $8,937, $9,463, and $9,676, and TCC was $11,706, $12,895, $13,626, and $14,069. DID in year 3 vs. the pre-period for treatment vs. controls was significantly higher for both medical spending ($1,402 [95% CI: $193 to $2,998]) and TCC ($13,679 [95% CI: $11,631 to $15,727]).

CONCLUSIONS: For adherent members without diabetes initiating GLP1 products to treat obesity, we found TCC

remained $13,679 higher in year 3 compared to controls. No medical spending offsets were observed, with statistically nonsignificant lower medical spending trends in the post period but higher spending in year 3 due to outliers in the last evaluation period. These findings suggest that adherence to GLP1s alone may not be enough to drive substantial medical spending reductions in patients with obesity.

SPONSORSHIP: Prime Therapeutics

356 Willingness to trade effectiveness for other contraceptive features: A discrete choice experiment

Perez Patel V[1], *Holub A*[2], *Betts K*[3], *Liu L*[2], *Collins K*[4], *Rood K*[5], *Teal S*[6]; *vanessa.patel@organon.com*
[1]*Organon and Co.*; [2]*Analysis Group*; [3]*Analysis Group Inc.*; [4]*Organon*; [5]*The Ohio State University*; [6]*University Hospitals*

BACKGROUND: Understanding tradeoffs when choosing contraception is fundamental to understanding the values of women and healthcare providers (HCPs).

OBJECTIVE: This discrete choice experiment (DCE) quantified the tradeoffs willing to be made between contraceptive attributes.

METHODS: DCEs were conducted separately for women and HCPs. Seven attributes were assessed: effectiveness, mode of administration, return to fertility, cardiovascular risk, immediate postpartum use, breastfeeding, and amenorrhea. Participants completed 12 choice cards per DCE; each choice card displayed hypothetical yet realistic contraceptive methods with varying levels. HCPs completed DCEs for distinct patient profiles: (1) a young, nulliparous woman; (2) an older woman, family planning complete; and (3) a woman with higher body weight. Tradeoffs were estimated using marginal utilities (continuous) or preference weights (categorical) for an attribute divided by the marginal utility for effectiveness; utilities derived from conditional logistic regression models. A negative (positive) beta coefficient for willingness to tradeoff (WTT) indicated that a method would need to be more (less) effective to accept a given attribute. Good research practice guidelines were followed.

RESULTS: A total of 612 participants were included. Women (n=307) were 29.9 years, on average. HCPs (n=305) practiced for 16.3 years, on average; 65.6% specialized in obstetrics/gynecology. Women required more effectiveness for a given method if it delayed fertility once stopping (WTT= -2.05) and would accept a less effective method if it had a daily mode of administration (WTT=3.04). When considering long-acting reversible methods, women required more effectiveness to accept intrauterine devices over the etonogestrel implant (WTT=-0.51). Across profiles, HCPs consistently indicated a dislike for oral pills and injections and required greater effectiveness to use these methods over their preferred contraceptive methods (i.e., etonogestrel implant, intrauterine devices).

CONCLUSIONS: Notable tradeoffs are willing to be made when considering various contraceptive attributes. These findings are central to educational efforts, contraceptive counseling, benefit-risk, and resource allocation.

SPONSORSHIP: Organon and Co.

357 Real-world efficacy of a digital therapeutic in older children with amblyopia: A population with reduced response to standard of care

Hancock S[1], *Bohnsack B*[2], *Koc I*[3], *Madsen C*[4]; *bbohnsack@luriechildrens.org*
[1]*Luminopia*; [2]*Ann & Robert H. Lurie Children's Hospital of Chicago*; [3]*Vanderbilt University Medical Center*; [4]*University of Utah College of Pharmacy*

BACKGROUND: Amblyopia, neurological suppression of visual stimuli from an eye during childhood, affects 2-4% of children and is typically treated via monocular part-time occlusion (PTO) of the stronger eye. This treatment often does not fully resolve amblyopia and has reduced efficacy in older children, as supported in clinical trials and real-world evidence. Luminopia, an FDA-cleared digital binocular treatment for amblyopia, has demonstrated efficacy in randomized trials and modeled cost-effectiveness, with a cost per quality-adjusted life year (QALY) of $618—supporting its relevance in payer evaluations. Real-world outcomes are being assessed through the PUPiL Registry (NCT06429280).

OBJECTIVE: To utilize real-world data to study the effect of Luminopia in patient subgroups outside the original trial, focusing on patient age, prior treatment, usage patterns, and associated costs.

METHODS: The PUPiL Registry was queried for children aged 8-12 years with clinically defined anisometropic and/or strabismic amblyopia and follow-up after treatment initiation. Demographics and change in best-corrected visual acuity (BCVA) from baseline (start of Luminopia) to most recent follow-up were analyzed. Subgroups based on severity of amblyopia and exposure to prior amblyopia treatment were evaluated. Prior treatment costs, usage, and duration were assessed.

RESULTS: Eighty-three pediatric patients qualified, of which 92% had been previously treated for amblyopia before Luminopia, with a mean of 34 months for an estimated average cost of $2,030.43 ± $1,501.06 in cumulative treatment and visit-related expenditures. Patients completed an average of 3.3 hours of treatment per week. Among those who

completed treatment (73%), the average treatment duration was 9.2 months (95% CI: 7.6, 10.8) costing $4,409.68 ± $2,449.34. Patients with moderate amblyopia (BCVA 20/40 to >20/100, 77%) gained 1.0 lines BCVA (95% CI: 0.7, 1.3) and severe patients (BCVA 20/100 and worse, 22%) gained 2.3 lines (95% CI: 0.4, 4.1). BCVA in the amblyopic eye was the strongest predictor of visual acuity improvement (p<.0001, r2=0.29). Patients with and without prior amblyopia treatment showed similar improvement in BCVA (p=0.919).

CONCLUSIONS: Patients aged 8-12 with extensive prior amblyopia treatment experienced meaningful improvement in visual acuity after using Luminopia. These real-world findings supported the expanded indication up to 12 years old and reinforce the clinical utility and economic value in a previously undertreated population.

SPONSORSHIP: Luminopia, Inc.

358 Real-world one-year persistence to glucagon-like peptide-1 receptor agonists by indication among commercially insured members without diabetes

Marshall L[1], *Gleason P*[2], *McCann M*[2], *Tran J*[2], *Farley J*[3], *Urick B*[2]; *landon.marshall@primetherapeutics.com*
[1]*Prime Therapeutics, LLC*; [2]*Prime Therapeutics*; [3]*University of Minnesota College of Pharmacy*

BACKGROUND: The list of FDA–approved indications for GLP1 receptor agonists continues to expand beyond diabetes and obesity. Tirzepatide (Zepbound) received approval for obstructive sleep apnea (oSA) in Dec 2024, and semaglutide (Wegovy) received accelerated approval in Aug 2025 for metabolic dysfunction–associated steatohepatitis (MASH) with fibrosis. Given their high cost and proven efficacy in clinical trials, it is imperative to understand the extent to which real-world persistence may vary by indication.

OBJECTIVE: To evaluate one-year persistence to semaglutide (Wegovy) or tirzepatide (Zepbound) by indication in a real-world cohort of commercially insured members without diabetes.

METHODS: Prime Therapeutics' integrated pharmacy and medical claims data were used to identify members newly initiating semaglutide (Wegovy) or tirzepatide (Zepbound) between 1/1/2024 and 6/30/2024 (index date period). Inclusion was limited to members with continuous enrollment in each 12-month study period and no GLP1 drug claim in the 12 months prior to index. Members were excluded if they had a pre-period diabetes diagnosis or diabetes drug claim and were <19 years of age at index. Indications were categorized exclusively and assigned hierarchically using pre-period medical claims in the order of MASH, sleep apnea, and obesity. Persistence was measured as no ≥60-day gap between the end of a claim's days' supply and the subsequent claim fill date in the 12-months following index. GLP1 product switching was allowed. Pairwise odds of persistence across indications were compared using a generalized linear model with logit link, with Bonferroni-adjusted p-values and 95% confidence intervals (CI) reported on the odds ratio (OR) scale.

RESULTS: Among the 11,286 members meeting full study criteria, 73% (8,251) had obesity, 21% (2,374) had oSA, and 6% (661) had MASH. The mean age was 46 years and 71% were female. One-year persistence rates were 65%, 61%, and 58% across oSA, obesity, and MASH, respectively. Pairwise comparisons found significantly higher odds of one-year persistence for oSA compared to obesity (OR= 1.16, 95% CI: 1.06-1.27) and MASH (OR= 1.33, 95% CI: 1.12-1.58).

CONCLUSIONS: Persistence to GLP1 remains challenging, with approximately 3 in 5 members remaining on therapy at end of 1 year, and varied by indication, with an additional 1 in 14 members persistent to therapy for oSA compared to MASH. These findings highlight significant investment risk due to waste and the need for indication specific management programs to maximize GLP1 therapy benefits and value-based contracts to mitigate financial risk.

SPONSORSHIP: Prime Therapeutics, LLC

359 Treatment patterns and outcomes among patients treated with next-generation covalent Bruton tyrosine kinase inhibitors (cBTKi) in chronic lymphocytic leukemia (CLL) at the University of California San Francisco Health (UCSF) system

Ayati A[1], *Wang X*[2], *Chandra K*[3], *Fu Q*[4], *Massoudi M*[4], *Maglinte G*[2], *Seshadri M*[1], *Rudrapatna V*[1]; *Aryan.Ayati@ucsf.edu*; *Marjan.massoudi@beonemed.com*
[1]*University of California San Francisco*; [2]*BeOne Medicines Ltd*; [3]*University of California Office of the President*; [4]*BeOne Medicines*

BACKGROUND: Next-generation cBTKis zanubrutinib (ZANU) and acalabrutinib (ACA) are established therapies for CLL. However, there is limited real-world evidence on clinical outcomes between treatments.

OBJECTIVE: To describe treatment patterns and outcomes for patients (pts) treated ZANU and ACA in a real-world setting.

METHODS: This retrospective observational study included adult pts receiving ZANU or ACA between 1/1/2020 and 1/6/2025 at the UCSF Health system. Pts were followed from first prescription until death, last encounter, or study end (1/6/2025). Demographic and clinical characteristics were summarized using structured data. Mutation status and adverse events (AEs) were extracted from clinical notes using a large language model. Time to next treatment or death

(TTNT) and overall survival (OS) were assessed using Kaplan-Meier methods and Cox proportional hazard models with inverse probability of treatment weighting (IPTW) between treatments.

RESULTS: 175 pts (126 ZANU and 49 ACA) were included, with average age of 72 years, 60% male, 67% White, 11% Asian, and 5% Hispanic. Most pts were treatment-naive (74%). More ZANU pts (n=126) had prior medications for hypertension (19% vs 12% ACA) and anticoagulants (28% ZANU vs 10% ACA). Among 145 pts with extractable notes (109 ZANU vs 35 ACA), 12% pts had TP53 mutation (14% ZANU vs 6% ACA), 13% with 17p deletion (15% ZANU vs 8% ACA), and 12% with 11q deletion (9% ZANU vs 19% ACA). The median TTNT was 59 (95% CI: 20-not reached [NR]) months for ACA and NR for ZANU. The median OS was 59 (95% CI: 59-NR) months for ACA and NR for ZANU. The 12-month event-free probabilities were 78% (95% CI: 64-88%) for ACA and 83% (95% CI: 74-89%) for ZANU. The 12-month survival probabilities were 89% (95% CI: 76-95%) for ACA and 91% (95% CI: 84-95%) for ZANU. After IPTW, pts with ZANU were 47% less likely to receive the next treatment or death than those with ACA (HR: 0.53; 95% CI: 0.32-0.89; P=0.015). Pts with ZANU also had better survival than those with ACA, although this was not statistically significant (HR: 0.55; 95% CI: 0.29-1.01; P=0.054). In addition, 97% pts had at least one documented AE (grade unspecified), with the most common AEs being bleeding/bruising (33%), fatigue (31%), and gastrointestinal symptoms (28%).

CONCLUSIONS: In this real-world study from a diverse patient population, we found that pts treated with ZANU had a lower risk of starting next treatment and a trend of better survival than ACA, despite having higher risk features or comorbidities.

SPONSORSHIP: BeOne Medicines, Ltd.

360 Demographic and clinical characteristics of individuals initiating low-sodium oxybate (LXB) by payer type

Markt S[1], *Drachenberg C*[1], *Alexander J*[1], *Whalen M*[1], *Dai J*[1], *Gibbs L*[2], *Irwin D*[2], *Dave U*[2], *Beaty S*[1], *Black J*[1]; *sarah.markt@jazzpharma.com*
[1]*Jazz Pharmaceuticals*; [2]*Aetion, a Datavant Company*

BACKGROUND: Individuals with narcolepsy have a higher prevalence and risk of developing cardiovascular (CV) and cardiometabolic (CM) comorbidities compared with those without narcolepsy. Literature on this burden among Medicaid enrollees is scant.

OBJECTIVE: To assess demographic characteristics and comorbidities among individuals with narcolepsy at low-sodium oxybate (LXB) initiation, overall and stratified by payer type (commercial vs Medicaid).

METHODS: Individuals with narcolepsy (defined as ≥2 medical claims with diagnosis ≥1 day apart) who had initiated LXB from 11/01/2020 to 12/31/2023 were identified from the Merative® MarketScan® Research Database. Additional inclusion criteria included aged 7–64 years, no history of idiopathic hypersomnia, and continuous enrollment in the 540 days prior to LXB initiation (index date). Demographic characteristics, medication use defined by pharmacy claims, and comorbidities defined by diagnosis claims codes (diabetes: diagnosis or diabetes medication use) were assessed in the 360-day pre-index period. Descriptive analyses were conducted.

RESULTS: A total of 478 individuals with narcolepsy initiated LXB. The mean (standard deviation) age was 38.4 (12.7) years among those commercially insured (n=408) and 31.2 (11.0) years among Medicaid enrollees (n=70). Most were female (71.1%), with a higher proportion of female individuals in the Medicaid population (81.4% vs 69.4%). Among Medicaid enrollees, 65.7% were White and 25.7% were Black. Overall, prior use of sodium oxybate (SXB) and alerting agents (AAs; defined as stimulants or wake-promoting agents) was high (70.3% and 85.8%, respectively). For Medicaid vs commercial enrollees, prior AA use was similar (87.1% vs 85.5%) and prior SXB use was numerically lower (60.0% vs 72.1%). Medicaid vs commercial enrollees had numerically higher prevalences of CV disease (18.6% vs 10.8%), obesity (30.0% vs 17.6%), diabetes (22.9% vs 17.6%), mood disorders (40.0% vs 31.6%), and sleep apnea (45.7% vs 33.6%). Among commercially insured enrollees, 73.5% had ≥1 CV/CM comorbidity; among Medicaid enrollees, 77.1% had ≥1 CV/CM comorbidity.

CONCLUSIONS: Among commercially insured and Medicaid-enrolled individuals with narcolepsy initiating LXB, more than 70% had ≥1 CV/CM comorbidity. The comorbidity burden was substantial and higher among Medicaid enrollees. Comprehensive management strategies that address overall health are warranted, including consideration of comorbidities and factors that may influence access to care and health outcomes.

SPONSORSHIP: Jazz Pharmaceuticals

361 Impact of the CVS GLP-1 formulary change

Farrar K, Feisst D, Masters N, Cartwright B;
kareng@truveta.com; briannac@truveta.com
Truveta

BACKGROUND: Glucagon-like peptide-1 receptor agonists (GLP-1 RAs) are revolutionary therapies for type 2 diabetes and obesity, demonstrating substantial benefits for glycemic control, weight loss, and cardiovascular outcomes. However, access to these medications can be influenced by formulary and payer decisions. On May 1, 2025, CVS Caremark announced that, effective July 1, the anti-obesity medication (AOM) tirzepatide (Zepbound) would be removed from its preferred formulary, designating semaglutide (Wegovy) as the preferred AOM.

OBJECTIVE: To assess the impact of the July 2025 CVS Caremark formulary change on (1) switching among active AOM tirzepatide users and (2) prescribing trends for AOM tirzepatide and AOM semaglutide.

METHODS: Using Truveta Data, we analyzed two complementary cohorts. Adults (≥18 years, BMI ≥27) with two-consecutive GLP-1 RA prescription fills between January and September 2025 were evaluated for switching, defined as an active supply of a different GLP-1 RA in sequential months. GLP-1 RA prescribing trends (January 2024–September 2025) were calculated as proportions of all prescriptions.

RESULTS: This analysis identified 700,907 patients with consecutive GLP-1 RA fills. Before May 2025, switching from AOM tirzepatide was uncommon, averaging 0.6% per month (baseline). Between June and July 2025, 10.2% of AOM tirzepatide users switched, representing a 17-fold increase. Of those, 82.4% transitioned to AOM semaglutide. After July, switching rates declined sharply but remained above baseline, averaging 1.8% from July to September 2025. Across all GLP-1 RA prescriptions (1.84 million patients; 7.1 million prescriptions), AOM tirzepatide had been increasing by +0.06 percentage points monthly between January and June 2025. Growth then slowed, rising only +0.03 points from June to July, declining by 0.02 points from July to August, and rebounding by 0.06 points in September. AOM semaglutide rose by 0.11 points between June and July, the largest one-month gain during the study period but remained stable thereafter (a change of −0.01 points through September).

CONCLUSIONS: The July 2025 CVS Caremark formulary change led to an immediate rise in switching from AOM tirzepatide to AOM semaglutide and a brief slowdown in tirzepatide prescribing growth. By September, AOM tirzepatide switching and prescribing stabilized, suggesting a rapid but transient formulary-driven shift. Continued tracking is important, as the impact of 90-day supplies before July 1, 2025, is still unfolding. Data will be refreshed prior to the meeting.

SPONSORSHIP: Truveta

362 Characteristics associated with nonadherence from data collected as part of an automated refill reminder program

Keast S[1], *Chamberlain J*[2], *Hendricks J*[3];
james.chamberlain@medimpact.com
[1]*MedImpact*; [2]*MedImpact Healthcare Systems, Inc.*;
[3]*MedImpact Healthcare Systems*

BACKGROUND: Refill reminder programs are often used to address medication nonadherence and improve health outcomes. These programs collect member activity data that may help plans identify members at greater risk of nonadherence. Health plans may use this information to develop targeted outreach programs to improve adherence measures.

OBJECTIVE: To evaluate the association of selected plan member characteristics and the outcome of having a proportion of days covered (PDC) less than 80% (nonadherent) for each of three medication classes: diabetes (DM), hypertension (HTN), and statins in Part D plans participating in an automated refill reminder program.

METHODS: Members participating in the refill reminder program in both 2023 and 2024 were identified for the study, and those that were ineligible for CMS measure reporting for that year were excluded. Descriptive statistics and logistic regression using generalized estimating equations for a binary outcome was used to model the odds of nonadherence based on member characteristics (year, age group, preferred language, urban vs. rural home address, use of extended day supply [EDS] prescriptions (84 or greater days supply), continuing therapy vs. new start, number of drug classes late, late claim rate for each drug class, whether or not the index claim for the reporting year was late, whether or not any of the late claims were refilled within 7 days of a call, and whether or not the member reported a barrier to refill).

RESULTS: A total of 29,472 members were included in the study. Characteristics associated with increased odds of being nonadherent included late claim rate of 0.50 or greater (OR 6.88-7.65), not using EDS prescriptions (OR 3.50-4.48), late refilling the index claim (OR 3.51-3.89), reporting at least one refill barrier (OR 1.22-1.57), new start to therapy (OR 1.16-1.29), late refilling multiple drug classes (OR 1.12-1.24), and aged <65 or aged >84 (OR 1.04-1.2). Characteristics associated with decreased odds of nonadherence included refilling at least one late claim within 7 days of the automated call (OR 0.27-0.30) and preferred language not English (OR 0.75-0.88 for Spanish and OR 0.64-0.85 for 'Other').

CONCLUSIONS: This study demonstrates the value in the data collected through automated member outreach to identify members at risk for nonadherence. Implementing predictive modeling to develop additional targeted member outreach programs may support health plans' efforts to maintain operational efficiency while still improving outcomes.

SPONSORSHIP: MedImpact Healthcare Systems, Inc.

363 Real-world assessment of healthcare expenditures and opioid intake following total hip arthroplasty in Medicare Advantage beneficiaries

Li H[1], *Asche C*[2], *Wong G*[3], *Priyanka P*[3]; *Haiyan.Li@pacira.com*
[1]*Pacira BioSciences, Inc*; [2]*University of Utah*; [3]*Pacira BioSciences, Inc.*

BACKGROUND: Although migration of hip surgeries to outpatient settings has increased, real-world data are limited on the impact of postsurgical analgesia on outcomes and patient recovery after hip surgery.

OBJECTIVE: To assess the impact of liposomal bupivacaine (LB), a long-acting local anesthetic, on outcomes of total healthcare cost and opioid intake (morphine milligram equivalents [MMEs]) over 6 months after total hip arthroplasty (THA) in hospital outpatient department settings.

METHODS: This retrospective cohort study included patients from Optum Clinformatics® (2019-2024) who underwent outpatient THA (CPT code: 27130). Patients treated with LB or standard of care options (non-LB) were included if they had no prior opioid exposure with Medicare Advantage plan, had ≥6 months of continuous enrollment before/after THA, and received THA in hospitals with moderate-to-high LB use (top 50%). Propensity scoring was used to match LB with non-LB patients (1:1) by 12 covariates. Outcome comparison was performed using generalized linear regression modeling with Gamma (cost) and Tweedie (MME) distribution.

RESULTS: In total, 2940 matched, well-balanced patients (1,470 per cohort; standardized mean difference, <0.1) had a mean age of 73 years and a mean Quan-Charlson comorbidity index of 1.4; 36% had a history of low back pain. Overall, compared with non-LB, LB was associated with lower total healthcare costs at 3 ($7,332 vs $8,153; P=0.007) and 6 months ($13,022 vs $15,081; P<0.001) after surgery. Such cost reduction was due to lower outpatient costs ($2,161 vs $2,472 at 3 months [P=0.015]; $4,421 vs $5,897 at 6 months [P<0.001]). A more pronounced cost reduction was observed with LB versus non-LB among patients with a history of low back pain. Specifically, LB was associated with $1,253 cost savings at 1 month ($3,997 vs $5,250; P<0.001), $2,092 at 3 months ($7,604 vs $9,696; P=0.004), and $5,038 at 6 months ($13,614 vs $18,652; P<0.001). Opioid intake was not significantly different between cohorts. Among patients with low back pain, LB was associated with numerically lower opioid intake (26 fewer MMEs; P=0.171) at 3 months and significantly fewer MMEs (51; P=0.027) at 6 months after surgery.

CONCLUSIONS: LB use for outpatient THA was associated with lower total healthcare costs over 6 months after surgery than non-LB use. The more pronounced cost savings and somewhat lower opioid intake with LB in patients with low back pain underscore the importance of LB use in pain management among these vulnerable patients.

SPONSORSHIP: Pacira BioSciences, Inc.

364 Budget impact of liposomal bupivacaine in the commercial and Medicare Advantage hospital outpatient department setting for total knee arthroplasty

Wong G[1], *Tremblay G*[2], *Lin J*[1]; *Gabriel.Wong@pacira.com*
[1]*Pacira BioSciences, Inc.*; [2]*Invincible Fund*

BACKGROUND: Total knee arthroplasty (TKA) is a surgical procedure aimed at relieving pain and restoring function in patients with knee arthritis. Effective postoperative pain management is essential for recovery and outcomes. Liposomal bupivacaine (LB) is a long-acting analgesic that may offer extended pain relief compared with traditional agents.

OBJECTIVE: To assess the budget impact of LB versus ropivacaine for TKA in the hospital outpatient department (HOPD) from a Commercial and Medicare Advantage payer perspective.

METHODS: A budget impact analysis was conducted projecting an environment with and without LB with increasing market share in a hypothetical 1-million-person health plan. Comparisons between LB and ropivacaine for healthcare resource utilization and costs were derived from NorstellaLinQ, a nationwide US closed claims database of Commercial and Medicare Advantage patients who received TKA (2020-2025). Sensitivity analysis was conducted varying the standard error of the means, as well as varying all model parameters by ±30%. Internal IQVIA claims and sales data were used for market share and projected increases. Drug cost was derived from Red Book wholesale acquisition costs. Epidemiology was sourced from published materials. A scenario analysis modeled the budget impact of opioid addiction reduction on the basis of published literature. The time horizon was set at 3 years.

RESULTS: In total, 1,819 patients were expected to have TKA in the baseline year, with 1,065 in Commercial and 754 in Medicare Advantage. Cumulative budget impact at year 3 with

LB resulted in savings of –$117,868 to the health plan. Cumulative per-member-per-month (PMPM) savings with LB over ropivacaine were –$0.003. In the sensitivity analyses using standard errors, the model was robust, showing a range of –$124,745 to –$111,018 annual budget impact and –$0.003 to –$0.003 PMPM over the time horizon. In sensitivity analyses using a ±30% variation, the model showcased a range of –$154,846 to –$81,644 annual budget impact and a –$0.004 to –$0.002 PMPM. The most sensitive variables were market share, market size, TKA incidence, and outpatient costs. In the scenario analysis incorporating opioid addiction, LB had projected cost savings of –$189 per patient per year compared with ropivacaine, which did not largely change the PMPM.

CONCLUSIONS: LB represents a cost-neutral treatment option for TKA over ropivacaine in the HOPD Commercial and Medicare Advantage setting.

SPONSORSHIP: Pacira BioSciences, Inc.

365 Postoperative pain management in association with total cost of care among patients undergoing total knee arthroplasty in the hospital outpatient department: A real-world retrospective cohort assessment

Wong G[1], *Scuderi G*[2], *Cui C*[3], *Lin J*[1], *Priyanka P*[1], *Rosenthal N*[3], *Curry L*[3]; *Gabriel.Wong@pacira.com*
[1]*Pacira BioSciences, Inc.*; [2]*Northwell Health*; [3]*Premier Applied Sciences, Premier Inc.*

BACKGROUND: Postoperative pain management is essential for recovery after total knee arthroplasty (TKA). Liposomal bupivacaine (LB), a long-acting local anesthetic, may reduce opioid use and improve outcomes.

OBJECTIVE: To evaluate the impact of LB use on total healthcare costs among patients undergoing TKA in hospital outpatient department (HOPD) settings, with a focus on cost differences between LB and non-LB cohorts and subgroup analysis in teaching hospitals.

METHODS: This retrospective cohort study used the Premier Healthcare Database to analyze adult patients who underwent TKA in HOPDs with most recent available data at time of study initiation (between January 1 and September 30, 2023) at facilities with high LB utilization. Exclusion criteria included bilateral TKA, trauma-related procedures, prior TKA within 180 days, and certain comorbidities. LB and non-LB cohorts were 1:1 exact matched on the basis of payer type, hospital, Charlson Comorbidity Index, and age (±2 years), with further adjustment for diabetes and chronic pulmonary disease. Generalized linear regression models with gamma distribution and log-link were used to estimate adjusted mean costs for the total cost of care at the surgical visit, 7 days, and 30 days. Differences between cohorts and their 95% confidence intervals (CIs) were derived through bootstrapping with 1,000 resamples. Subgroup analysis was performed for teaching hospitals.

RESULTS: Among 7,840 matched patients (3,920 per cohort), LB use was associated with numerically lower costs across all time points. At the surgical visit, adjusted mean cost was $15,600 for LB vs $15,719 for non-LB, with an adjusted difference (AD) of –$119 (95% CI, –$477 to $221). The LB cohort averaged $15,692 vs $15,805 (AD: –$113 [95% CI, –$460 to $218]) at 7 days and $15,949 vs $16,056 (AD: –$108 [95% CI, –$489 to $262]) at 30 days. In teaching hospitals, LB use was significantly associated with lower costs at the surgical visit (AD: –$1,527 [95% CI, –$2,292 to –$725]), 7 days (AD: –$1,511 [95% CI, –$2,314 to –$656]), and 30 days (AD: –$1,511 [95% CI, –$2,323 to –$753). Notably, pharmacy costs on day of surgery were at least $1,841 lower in the LB cohort ($1,031) compared with the non-LB cohort ($2,872).

CONCLUSIONS: LB use in HOPD TKA was associated with comparable or lower healthcare costs, particularly in teaching hospitals where implementation may be optimized. These findings support LB as a cost-effective opioid-sparing strategy for postoperative pain management, with potential for broad adoption through structured integration and care standardization.

SPONSORSHIP: Pacira BioSciences, Inc.

366 Prediction of overt hepatic encephalopathy using machine learning: A claims-based study of a prevalent cohort

Jesudian A[1], *Gagnon-Sanschagrin P*[2], *Cornwall T*[2], *Yokoji K*[2], *Gobeil N*[2], *Passos Chaves L*[3], *Olujohungbe O*[3], *Guérin A*[4]; *abj9004@med.cornell.edu*
[1]*Weill Cornell Medicine*; [2]*Analysis Group, Inc.*; [3]*Bausch Health*; [4]*Analysis Group, Montreal, QC, Canada*

BACKGROUND: Overt hepatic encephalopathy (OHE), a cirrhosis complication, is a major cause of hospitalization and mortality and may lead to long-term cognitive impairment, reduced quality of life, and increased healthcare resource utilization. Despite growing recognition of clinical predictors of OHE, relative contributions of these factors remain poorly characterized.

OBJECTIVE: To develop a machine learning (ML) algorithm using administrative claims data to predict OHE risk of patients with cirrhosis, assess relative importance of prognostic factors, and describe patient characteristics by predicted OHE risk.

METHODS: A Survival Random Forest model was developed to predict time from cirrhosis diagnosis to first OHE event using

Komodo Research Data (01/2016–09/2023; KRD+). Potential predictor selection was informed by literature and a Delphi panel of 12 US gastroenterologists and hepatologists and included 71 variables across demographics, diagnoses, medications, and laboratory results. For each patient, variables were measured at a randomly selected prediction point from cirrhosis diagnosis to first OHE event or censoring (liver transplant, secondary liver malignancy, end of continuous health plan enrollment, data end, or death) to mimic real-world clinical forecasting. Patients were stratified into quartiles of predicted OHE risk for descriptive analyses of demographic and clinical characteristics.

RESULTS: In total, 291,557 patients with cirrhosis were included (mean age: 61.5 years; 55.5% male; training vs validation split: 80%-20%). In the validation set, 23.2% of patients developed OHE within 1 year of prediction point (c-index= 0.79). The model selected literature- and Delphi-derived predictors including timing of most recent non-OHE decompensation event (e.g., ascites, variceal bleeding), cirrhosis diagnosis, ascites management (e.g., paracentesis, diuretic use), related comorbidities (e.g., coagulopathy), and biomarkers of liver function (e.g., bilirubin) as most influential. When stratified into predicted risk quartiles, 1-year incidence of OHE among patients at highest risk was 53.3% vs 12.2% in the lower risk groups (risk ratio=4.4), demonstrating model discrimination.

CONCLUSIONS: ML methods can effectively stratify patients with cirrhosis by OHE risk using routine administrative data. This proof-of-concept model demonstrates strong predictive performance and clinical interpretability. Future validation efforts are needed to incorporate more complete clinical data and refine OHE risk prediction in clinical practice.

SPONSORSHIP: Bausch Health

367 Real-world persistence, switching, and reinitiation in patients who are on faricimab in US

Ko S[1], Schuldt R[1], Bonine N[1], Brodie F[2]; koy3@gene.com
[1]Genentech; [2]University of California San Francisco

BACKGROUND: Faricimab is the only bispecific antibody targeting both angiopoietin-2 and vascular endothelial growth factor-A for intraocular use, offering a novel therapeutic approach for diabetic macular edema (DME) and neovascular age-related macular degeneration (nAMD). However, real-world evidence on treatment persistence with faricimab remains limited, creating a gap in understanding its long-term utilization in clinical practice.

OBJECTIVE: To evaluate real-world persistence, switching, and reinitiation among patients who are on faricimab with DME or nAMD in the US.

METHODS: Data for this study were obtained from the Vestrum EHR Database. The study period was Jan 1, 2021, to May 31, 2025. Patients were included if they had ≥2 faricimab injections with a minimum of 24 months of follow-up. The index date was defined as the first faricimab injection between Jan 1, 2022, and May 31, 2023, and a diagnosis of DME or nAMD. Persistence rate defined as remaining on faricimab without a gap in therapy was evaluated at eye-level (OS: left eye; OD: right eye) for all patients with injection data. Additionally, switching and reinitiation of therapy for the index treatment were evaluated for patients who had a gap in treatment (i.e., gap of ≥180 days with no injection).

RESULTS: A total of 2,207 patients (3,063 eyes) with DME and 8,358 patients (10,125 eyes) with nAMD were included. Among these, 178 patients (244 eyes) with DME and 821 patients (902 eyes) with nAMD were treatment-naive (tx-naive). By the end of 24 months, the persistence rate was 71% on average among previously treated (prev tx) eyes and 69% among tx-naive eyes. Prev tx eyes received a mean of 11.8 (OS) and 11.8 (OD) injections during the 24 months of follow-up (standard deviation [SD]: 5.0, 5.0) compared with 11.1 (OS) 11.4 (OD) injections (SD: 4.5, 4.4) among tx-naive eyes. At 24 months, among prev tx eyes, 2,392 (18.2%) switched to another anti–vascular endothelial growth factor (aVEGF), 875 (6.6%) experienced a gap in therapy but restarted faricimab, and 574 (4.3%) discontinued without initiating another aVEGF. Among tx-naive eyes, 151 (13.2%) switched to another aVEGF, 117 (10.2%) experienced a gap in therapy but restarted faricimab, and 85 (7.5%) discontinued without initiating another aVEGF. Additional results will be presented at the presentation.

CONCLUSIONS: Real-world persistence with faricimab was high at 24 months, with the majority of patients remaining on treatment without switching to other aVEGF therapies.

SPONSORSHIP: Genentech, Inc

368 Equivalent effectiveness of a prescription binocular treatment for amblyopia in real-world practice

Gaier E[1], *Bohnsack B*[2], *Bodack M*[3], *Hancock S*[4], *Koo E*[5], *Repka M*[6]; *eric.gaier@childrens.harvard.edu*
[1]*Picower Institute for Learning and Memory*; [2]*Ann & Robert H. Lurie Children's Hospital of Chicago*; [3]*Southern College of Optometry*; [4]*Luminopia, Inc.*; [5]*Stanford University*; [6]*Johns Hopkins University Wilmer Eye Institute*

BACKGROUND: The efficacy-effectiveness gap, where efficacy outcomes in clinical trials are not fully realized in clinical practice, is a critical challenge for new therapies. Luminopia, a prescription binocular treatment for amblyopia ("lazy eye"), a neuro-developmental disorder suppressing visual signals from an eye, received FDA approval (via de novo) after demonstrating efficacy in Phase 1, 2, and 3 clinical trials. A real-world patient registry has been established to characterize outcomes in clinical practice (PUPiL, NCT06429280), which collects outcomes for children undergoing 12+ weeks of treatment.

OBJECTIVE: To evaluate the efficacy-effectiveness gap for Luminopia treatment by directly comparing the efficacy outcomes from children randomized to receive treatment in the Phase 3 Randomized-controlled trial (RCT) to effectiveness outcomes of a comparable cohort of children from the PUPiL Registry.

METHODS: The PUPiL Registry was queried for patients who met key eligibility criteria of the pivotal trial with respect to age (4-7 years), amblyopia characteristics (type and severity of disease), and amount of prior treatment with a 12±6-week follow-up from start of treatment to create a cohort of pivotal-like patients. The primary outcome was the change in amblyopic eye best-corrected visual acuity (BCVA) at 12 weeks. This outcome was benchmarked against the intent-to-treat cohort (n=45) from the pivotal trial (Xiao et al 2021). Statistical equivalence was defined as a difference within a 0.75-line margin between the two groups. Outcomes of patients not included in the pivotal-like cohort were evaluated with respect to severity of disease and amount of prior treatment.

RESULTS: Within the Registry, 40 out of 215 children satisfied key criteria of the pivotal trial. The visual acuity improvement in the real-world cohort was statistically equivalent to the improvement seen in the RCT ($p>0.62$). The registry cohort showed a mean BCVA improvement of 1.7 lines (95% CI: 1.2, 2.2), compared to 1.8 lines (95% CI: 1.4, 2.3) in the RCT. Among those registry patients not included in the pivotal-like cohort, significant vision gains were also observed at 12 weeks. Greatest gains were observed in patients without prior amblyopia treatment (+1.1 lines, n=28), and in those with severe amblyopia (20/100 and worse, +1.8 lines, n=24).

CONCLUSIONS: Registry patients prescribed Luminopia in clinical practice had equivalent visual acuity outcomes to the gains noted in the RCT, indicating that the effectiveness of Luminopia generalizes to the real-world.

SPONSORSHIP: Luminopia, Inc.

369 Group-based trajectory modeling and predictors of adherence to oral antidiabetic therapy among older adults with diabetes on concomitant triple therapy in US Medicare Advantage plans

Olumeko I, Cheruvu S, Ofili S, Abughosh S; *iolumeko@cougarnet.uh.edu*
University of Houston

BACKGROUND: Diabetes is a leading chronic disease and a major cause of morbidity and mortality worldwide. In 2025, an estimated 17% of the US population is affected, with annual treatment costs exceeding $400 billion. Older adults with diabetes often have coexisting hypertension and dyslipidemia, increasing medication burden and the risk of poor adherence. Understanding real-world adherence patterns and predictors of oral antidiabetic therapy among patients with comorbid hypertension and hypercholesterolemia is essential for improving disease management and outcomes.

OBJECTIVE: To identify longitudinal adherence trajectories to oral antidiabetic medications and assess demographic and clinical predictors among older adults with diabetes and comorbid hypertension and hypercholesterolemia on concomitant triple therapy enrolled in Medicare Advantage plans.

METHODS: This retrospective cohort study used 2016–2017 Texas Medicare Advantage claims data. The study cohort comprised adults aged ≥65 years with diabetes, hypertension, and dyslipidemia who maintained continuous medical and pharmacy coverage throughout the study period. Eligible patients had ≥1 oral antidiabetic prescription during the index period and concurrent statin and RAS antagonist use. The monthly PDC was calculated over 12 months post-index, and group-based trajectory modeling (GBTM) was used to identify patterns of adherence. Sociodemographic and clinical patient characteristics (Predictors) based on the Andersen Behavioral Model were examined using multinomial logistic regression, with the adherent trajectory as reference. Analyses were performed in SAS 9.4.

RESULTS: The cohort included 7,847 older adults with diabetes, hypertension, and dyslipidemia. Three adherence trajectories emerged: perfect (59.2%), near perfect (29.2%), and rapid decline (11.6%). In univariate analyses, sex and health plan

subsidy were significant ($p < 0.05$). In adjusted models, female sex (OR 1.38; 95% CI 1.19–1.60) and no low-income subsidy (OR 0.79; 95% CI 0.68–0.92) were associated with rapid decline, while female sex (OR 1.13; 95% CI 1.02–1.25) and age ≥75 years (OR 1.20; 95% CI 1.00–1.43) were associated with near-perfect adherence.

CONCLUSIONS: Sex, health plan subsidy, and age were significant predictors of adherence to oral antidiabetic medications among older adults with diabetes, hypertension, and dyslipidemia. Understanding these factors can inform targeted strategies to improve medication adherence and quality outcomes in Medicare populations.

SPONSORSHIP: None

370 Real-world utilization of GIP/GLP-1 receptor agonists by sleep medicine providers in nondiabetic patients with obstructive sleep apnea

Reynolds T, Chen L; tim.reynolds@bswhealth.org
Baylor Scott & White Health

BACKGROUND: Obstructive sleep apnea (OSA) is the most common sleep disorder in US adults, with an estimated overall prevalence of 32.4% in 2024. Until recently, the mainstay of therapy for patients with moderate to severe OSA has been use of a continuous positive airway pressure (CPAP) device during sleep, along with weight loss in patients with comorbid obesity. On December 20, 2024, tirzepatide, a GIP/GLP-1 RA, was approved by the FDA for patients with OSA and comorbid obesity. While clinical trial evidence is promising for patients with obesity, real-world utilization patterns of tirzepatide or other GIP/GLP-1 RA agents by sleep medicine providers have yet to be reported in the literature.

OBJECTIVE: To evaluate factors associated with the initiation of GIP/GLP-1 RA agents by sleep medicine providers in nondiabetic patients with OSA after the approval of tirzepatide.

METHODS: This retrospective observational study utilized electronic health records in a large integrated delivery network in Texas to describe prescribing patterns of GIP/GLP-1 RA agents prescribed by sleep medicine providers between 12/20/24 and 9/30/25. Subjects included were aged ≥18, had a diagnosis of OSA, and had no history of type 2 diabetes. The index date was the first GIP/GLP-1 RA prescribing visit with a sleep medicine provider; if no GIP/GLP-1 RA was prescribed, then the first visit in the study period was used. Subject characteristics were described, and a multiple logistic regression model was used to determine the association between key factors and GIP/GLP-1 RA initiation.

RESULTS: A total of 307 subjects were initiated on a GIP/GLP-1 RA (100% tirzepatide) and 18,074 were not. Initiators were younger (55.2 vs. 59.9 years), female (55.4 vs 46.5%), had commercial insurance (64.8 vs 52.5%), and had a higher mean BMI (40.6 vs. 33.7 kg/m^2). Multiple logistic regression modeling suggested the following factors to be significantly associated with initiation: a very high BMI (≥50 kg/m^2), comorbid obesity hypoventilation syndrome, CPAP use, recent sleep study, prior use of GIP/GLP-1 RA, urban residence, Tricare coverage, being seen by a sleep medicine specialist, and being seen by a physician.

CONCLUSIONS: Only a small proportion of nondiabetic OSA patients (1.7%) were initiated on any GIP/GLP-1 RA after tirzepatide approval on December 20, 2024. Early use appears to be skewed towards patients with very high BMI, those with strong evidence for coverage (such as Tricare), or by providers with specialized sleep medicine training.

SPONSORSHIP: None.

Respiratory

396 Medication access barriers for patients with idiopathic pulmonary fibrosis: A retrospective claims analysis

Kharat A[1], Yang J[2], Kinkead F[3], Wang Y[3], Rossi C[3], Pilon D[3], Antao V[4], Mathai S[5]; akshay.kharat@boehringer-ingelheim.com
[1]Boehringer Ingelheim; [2]Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, Connecticut, USA; [3]Analysis Group, Inc.; [4]Boehringer Ingelheim Pharmaceuticals, Inc.; [5]Center for Advanced Heart & Lung Disease, Baylor University Medical Center/Texas A&M University College of Medicine

BACKGROUND: Oral antifibrotic (AF) medications, nintedanib and pirfenidone, are commonly used to treat idiopathic pulmonary fibrosis (IPF), a chronic respiratory condition with poor prognosis. Reduction in disease progression for patients with IPF is dependent on timely access to AF medications. There is limited real-world data on AF medication access patterns among this patient population, overall, and for those who have an initial rejected pharmacy claim in the United States (US).

OBJECTIVE: To describe medication access patterns for patients with IPF treated with nintedanib or pirfenidone in the US.

METHODS: A retrospective, longitudinal cohort study using the Komodo Research Database (1/1/2016–12/31/2024). Patients were included for analyses if they had ≥1 diagnosis code for IPF, had ≥1 pharmacy claim for pirfenidone or nintedanib (i.e., index date), had ≥12 months of claims activity prior to index date, were ≥18 years old on the index date, and had no medical claims for other interstitial lung disease any time prior to or up to 6 months post-index. Reasons, timing, and

number of rejected pharmacy claims before receiving an approved claim were described.

RESULTS: Overall, 3,986 of 13,030 patients (30.6%) had their initial pharmacy claim for nintedanib or pirfenidone rejected. The 3,986 patients with IPF whose initial claim was rejected had the following characteristics: median age 72 years, 64.7% male, 70.4% white, 10.3% Hispanic/Latino, 6.1% Black/African American, 67.5% initially prescribed nintedanib, and 45.9% Quan-CCI ≥2. The most frequent non-missing reasons for the initial rejected pharmacy claim were treatment not covered (25.8%) or prior authorization required (23.3%). Among 3,986 patients whose initial claim was rejected, 2,705 (67.9%) filled a claim for nintedanib or pirfenidone within 12 months of an initial rejection, with a mean time of 29.0 days to approval. Among patients with a filled claim within 12 months, 40.4% had ≥3 rejected claims before receiving an approval (mean 3.6 rejections prior to approval).

CONCLUSIONS: Important barriers to treatment continue to exist, potentially limiting care management of patients with IPF. Although most patients with IPF overcame an initial rejected claim within 12 months, approximately 1 in 3 patients did not receive timely access of prescribed AF medications and most patients had multiple rejections. Strict utilization management is a barrier to timely medication access and can potentially limit optimal outcomes in the treatment of patients with IPF.

SPONSORSHIP: Boehringer Ingelheim

397 Exploring perceived gaps in diagnosis and care for patients with refractory chronic cough: A survey of healthcare professionals' knowledge, attitudes, and practices in the United States

Bunniran S[1], *Henning C*[1], *Parikh B*[1], *Davenport E*[2], *Sweeney C*[2], *Calhoun S*[2], *Lim K*[3]; *Su.x.bunniran@gsk.com*
[1]*GSK*; [2]*RTI Health Solutions*; [3]*Mayo Clinic Rochester*

BACKGROUND: Refractory chronic cough (RCC) is a disease identified in a subset of people who experience chronic cough (defined in adults as a cough lasting >8 weeks), despite adequate treatment for known cough-related etiologies. RCC is considered a diagnosis of exclusion, and patients may endure persistent coughing for several years before a diagnosis. Without a coordinated approach across multidisciplinary care, patients can often be re-tested, be re-trialed, and require frequent follow-up. These gaps in care contribute to patient frustration and may lead to increased healthcare utilization and costs.

OBJECTIVE: To assess real-world diagnosis and management of RCC, we surveyed US healthcare professionals (HCPs) to understand their knowledge, attitudes, and practices.

METHODS: A cross-sectional, web-based survey was conducted in December 2024 among HCPs who had treated ≥1 adult patients with chronic cough in the past six months. Participants included allergists/immunologists (A/Is), otolaryngologists (ENTs), pulmonologists, primary care physicians (PCPs), pharmacists, nurse practitioners (NPs), and physician assistants (PAs). Survey questions explored perceptions of diagnostic pathways and delays, as well as treatment practices for RCC.

RESULTS: Responses from 717 HCPs were analyzed: A/Is, ENTs, pulmonologists (n=100 each), PCPs (n=212), pharmacists (n=104), NPs (n=51), and PAs (n=50). Nearly half of HCPs (46%) reported an average RCC diagnosis of 6–12 months, while a quarter (25%) indicated 1–2 years. HCPs (n=401, except PCPs and pharmacists) estimated that they would conduct their own diagnostic tests for 65% of patients with suspected RCC, regardless of previous testing. Of HCPs who provided reasons for repeated testing (n=397), these included perceptions of outdated prior testing (63%), preference for specific diagnostic facilities/personnel (47%), the need to establish a baseline for future evaluations (47%), and lack of access to prior test results (46%). Of HCPs (n=613, except pharmacists), around half (47%) reported that patients with RCC typically require ≥4 follow-up visits annually to manage treatment.

CONCLUSIONS: The findings suggest gaps in RCC diagnosis and management are driven by fragmented care, redundant testing, and frequent follow-up. A coordinated, cross-specialty cough management pathway is needed to streamline evaluations, enable faster escalation to definitive therapies, and improve patient outcomes while reducing cost of care.

SPONSORSHIP: GSK (study 300158)

398 Using a claims-based algorithm to identify patients with refractory and unexplained chronic cough: navigating real-world claims database research without an *International Classification of Diseases* code

Bunniran S[1], *Parikh B*[1], *Henning C*[1], *Joshi K*[1], *Chang R*[2], *Nguyen C*[2], *Zhang A*[2], *Young-Xu L*[2], *Duh M*[2], *Sundar K*[3]; *Su.x.bunniran@gsk.com*
[1]*GSK*; [2]*Analysis Group, Inc.*; [3]*University of California Davis*

BACKGROUND: Refractory chronic cough (RCC) is a disease identified in a subset of patients (pts) who experience chronic cough (CC, defined in adults as a cough lasting >8 weeks) despite adequate treatment for known cough-related etiologies. Unexplained chronic cough (UCC) describes CC for which an underlying condition has not been determined despite investigation. The *International Classification of Diseases* (ICD)-10 code R05.3 was introduced for CC in 2021 and includes persistent cough, RCC, and UCC. The lack of a

specific ICD-10 code hinders accurate identification of pts with RCC/UCC in claims-based data. As new treatments emerge, leveraging real-world data to accurately identify RCC/UCC pts is essential to understand pt outcomes and optimize their care.

OBJECTIVE: To identify pts with RCC/UCC via a published claims-based algorithm (CleaR-CC), developed with a targeted literature review and global cough experts.

METHODS: The Optum Clinformatics Data Mart claims database was analyzed (1/1/2016–12/31/2023). Pts were required to meet the criteria of one of two Pathways (1: Cough Event or 2: Specialist Event) for two consecutive calendar years. In Pathway 1, pts had ≥3 cough-related events within a 180-day period, identified through ICD-10 codes for cough (R05) or prescriptions for cough suppressants or neuromodulators/pain medications (excluding prescriptions for conditions not related to cough). The index date was the third cough event in the second year. In Pathway 2, pts had ≥1 medical claim with CC diagnosis (ICD-10: R05.3) associated with a specialist visit (Allergist, ENT, Pulmonologist) per year. The index date was the specialist event in the second year. Patients with ACE inhibitor-induced cough, lung conditions, respiratory tract infections, or uncontrolled asthma were excluded. After applying CleaR-CC, only pts aged ≥65 years with Medicare Advantage at the index date were included.

RESULTS: Upon applying CleaR-CC, 406,504 pts with RCC/UCC were identified (Pathway 1: N=391,643, Pathway 2: N=15,953). After exclusions, N=67,114 pts were identified, of whom N=38,995 were Medicare Advantage pts aged ≥65 years. Pts had a mean (standard deviation) age of 75.6 (6.6) years and were mostly female (69.1%) and White (68.5%).

CONCLUSIONS: The CleaR-CC algorithm offers a novel approach, in the absence of a specific ICD code, to identify RCC/UCC pts; future research is planned to validate its accuracy. Establishing an ICD code specific to RCC/UCC would further enhance pt identification, address data gaps, and support disease management.

SPONSORSHIP: GSK (study 223232)

399 Healthcare costs among Medicare fee-for-service beneficiaries with idiopathic pulmonary fibrosis during the last year of life

Yang J[1], *Marcum Z*[2], *Zuk E*[2], *Crowell M*[2], *Shetty S*[3], *Antao V*[3], *Brown K*[4]; *joseph.yang@boehringer-ingelheim.com*
[1]*Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, Connecticut, USA;* [2]*Medicus Economics;* [3]*Boehringer Ingelheim Pharmaceuticals, Inc.;* [4]*National Jewish Health*

BACKGROUND: Idiopathic pulmonary fibrosis (IPF) is the most common of the progressive fibrosing interstitial lung diseases and is associated with substantial economic burden in addition to its adverse impact on quality of life, functional status, and early mortality. Limited evidence exists on healthcare costs among individuals with IPF during their last year of life.

OBJECTIVE: To describe the distribution of total healthcare costs in the 12 months before death among Medicare Fee-for-Service (FFS) beneficiaries with IPF.

METHODS: Medicare FFS beneficiaries who had ≥2 inpatient or outpatient claims with ICD-10-CM diagnosis codes for IPF on different dates but ≤365 days apart and who died during the study period (01/2016–12/2023) were identified. Beneficiaries meeting cohort entry criteria followed by having ≥720 days of continuous medical/pharmacy enrollment before death were included; this period was divided in half, with the 360 days preceding death labeled as the "outcome year" and the earlier 360 days as the "baseline year." Total healthcare costs were calculated for the baseline and outcome years and for calendar quarters during the outcome year. Total healthcare costs during the outcome year were further characterized as quartiles. Costs were adjusted for inflation to 2023 real dollars.

RESULTS: A total of 22,256 Medicare FFS beneficiaries with IPF were identified (mean [SD] age at day –361 relative to death): 79.7 [8.4] years; female: 44.7%). Mean all-cause total healthcare costs were 55% greater in the outcome year than the baseline year ($101,830 vs. $65,527, respectively), with the inpatient share of total costs higher in the outcome year than in the baseline year (34.4% vs. 19.2%). Mean all-cause total healthcare costs increased substantially in the last quarter (Q) year of life (Q1 [day –360 to –271], $17,990; Q2 [–270 to –181], $19,688; Q3 [–180 to –91], $23,416; Q4 [–90 to death], $40,736). Mean all-cause total health costs during the outcome year showed 8-fold variation across quartiles of cost (Quartile 1 [lowest 25%], $26,137; Quartile 2, $60,018; Quartile 3, $104,047; Quartile 4 [highest 25%], $221,347).

CONCLUSIONS: Medicare FFS beneficiaries with IPF experience escalating health care needs and costs at the end of life. This study provides evidence on the magnitude and trajectory of the economic burden of IPF in the last year of life, revealing

significant variation in healthcare resource utilization among beneficiaries and highlighting opportunities to optimize care for those at risk of disproportional use of health care resources.

SPONSORSHIP: Boehringer Ingelheim Pharmaceuticals, Inc.

400 Healthcare costs among Medicare fee-for-service beneficiaries with progressive pulmonary fibrosis during the last year of life

Yang J[1], *Marcum Z*[2], *Zuk E*[2], *Crowell M*[2], *Shetty S*[3], *Antao V*[3], *Brown K*[4]; *joseph.yang@boehringer-ingelheim.com*
[1]*Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, Connecticut, USA;* [2]*Medicus Economics;* [3]*Boehringer Ingelheim Pharmaceuticals, Inc.;* [4]*National Jewish Health*

BACKGROUND: Progressive pulmonary fibrosis (PPF), the phenotype of fibrosing interstitial lung disease (ILD) other than idiopathic pulmonary fibrosis (IPF), is associated with substantial economic burden in addition to its adverse impact on quality of life, functional status, and early mortality. Limited evidence exists on healthcare costs among individuals with PPF during their last year of life.

OBJECTIVE: To describe the distribution of total healthcare costs in the 12 months before death among Medicare Fee-for-Service (FFS) beneficiaries with PPF.

METHODS: Medicare FFS beneficiaries who had ≥2 inpatient or outpatient claims with ICD-10-CM diagnosis codes for non-IPF ILD on different dates but ≤365 days apart, with evidence of progression, and who died during the study period (01/2016–12/2023) were identified. Beneficiaries meeting cohort entry criteria followed by having ≥720 days of continuous medical/pharmacy enrollment before death were included; this period was divided in half, with the 360 days preceding death labeled as the "outcome year" and the earlier 360 days as the "baseline year." Total healthcare costs were calculated for the baseline and outcome years and for calendar quarters during the outcome year. Total healthcare costs during the outcome year were further characterized as quartiles. Costs were adjusted for inflation to 2023 real dollars.

RESULTS: A total of 95,876 Medicare FFS beneficiaries with PPF were identified (mean [SD] age at day -361 relative to death): 78.8 [10.4] years; female: 57.8%). Mean all-cause total healthcare costs were 62% greater in the outcome year compared to the baseline year ($105,332 vs. $65,127, respectively), with the inpatient share of total costs higher in the outcome year than in the baseline year (40.3% vs. 27.7%). Mean all-cause total healthcare costs increased substantially in the last quarter (Q) year of life (Q1 [day −360 to −271], $17,893; Q2 [−270 to −181], $19,735; Q3 [−180 to −91], $23,782; Q4 [−90 to death], $43,923). Mean all-cause total health costs during the outcome year showed sizable variation across quartiles of cost (Quartile 1 [lowest 25%], $27,044; Quartile 2, $60,685; Quartile 3, $103,112; Quartile 4 [highest 25%], $229,620).

CONCLUSIONS: Medicare FFS beneficiaries with PPF experience escalating health care needs and costs at the end of life. The study findings reveal significant variation in healthcare resource utilization among beneficiaries and highlight opportunities to optimize care for those at risk of disproportional use of health care resources.

SPONSORSHIP: Boehringer Ingelheim Pharmaceuticals, Inc.

401 Cost offset calculator for budesonide/glycopyrrolate/formoterol (BUD/GLY/FORM) compared to fluticasone furoate/umeclidinium/vilanterol (FF/UMEC/VI) in uncontrolled asthma from US perspective

Parsekar K[1], *Edmonds C*[1], *Germack H*[1], *Walpole K*[1], *Bentley A*[2]; *krishnali.parsekar@astrazeneca.com*
[1]*AstraZeneca;* [2]*Petauri Evidence*

BACKGROUND: Asthma remains a substantial public health burden in the US, affecting 26.8 million people (8.2% of overall US population) and projected to cost $48 billion in 2038. Treatment with ICS/LABA therapy is the mainstay for patients with moderate-to-severe asthma; however, this is suboptimal as more than 50% patients continue to experience symptoms and/or exacerbations leading to increased costs. Single inhaler triple therapies have been evaluated in Phase III programs [Budesonide/Glycopyrrolate/Formoterol (BUD/GLY/FORM) in KALOS/LOGOS; Fluticasone Furoate/Umeclidinium/Vilanterol (FF/UMEC/VI) in CAPTAIN]. However, comparative budget impact and potential cost offsets between single inhaler triple therapies remain unexplored.

OBJECTIVE: To estimate the potential cost offset of using BUD/GLY/FORM compared with FF/UMEC/VI among patients with uncontrolled asthma on medium- or high-dose ICS/LABA from US perspective.

METHODS: A cost offset analysis from a payer perspective using a 1-year time horizon in a hypothetical cohort of 1,000,000 patients uncontrolled on medium/high dose ICS/LABA therapy was conducted. Two scenarios were compared: (1) FF/UMEC/VI with 43% of patients receiving 100/62.5/25 µg and 57% receiving 200/62.5/25 µg based on 2025 market shares; (2) 100% of patients were treated with BUD/GLY/FORM 320/36/9.6 µg. Annualized severe exacerbation rates for FF/UMEC/VI were sourced from CAPTAIN trial; rates for BUD/GLY/FORM were informed by a network meta-analysis (NMA) comparing BUD/GLY/FORM with single inhaler triple therapies. Exacerbation distributions

through emergency room visits, hospitalizations, and corticosteroid use were included with health care resource utilization, treatment, and exacerbation costs being derived from published literature.

RESULTS: The model estimated that treating 1,000,000 patients with BUD/GLY/FORM instead of FF/UMEC/VI could avoid 15,000 severe exacerbations, leading to 1020 fewer ER visits, 1035 fewer hospitalizations, and 4347 fewer inpatient days. The analysis suggests that compared to FF/UMEC/VI, BUD/GLY/FORM could reduce total healthcare costs by $176 million, equating to $155 million savings in drug costs and $21 million savings in exacerbation related costs per year.

CONCLUSIONS: In patients with uncontrolled asthma, treatment with BUD/GLY/FORM can reduce severe exacerbations and healthcare resource utilization (HCRU) compared to FF/UMEC/VI resulting in substantial cost savings.

SPONSORSHIP: AstraZeneca

402 Prevalence of refractory chronic cough and unexplained chronic cough in older adults (≥65 years) based on a claims algorithm using Optum Medicare Advantage prescription drug data

Bunniran S[1], *Parikh B*[1], *Henning C*[1], *Joshi K*[1], *Chang R*[2], *Nguyen C*[2], *Zhang A*[2], *Long T*[2], *Duh M*[2], *Sundar K*[3]; *Su.x.bunniran@gsk.com*
[1]*GSK*; [2]*Analysis Group, Inc.*; [3]*University of California Davis*

BACKGROUND: Chronic cough (CC) affects ~5.0% of the US population. Refractory chronic cough (RCC) is a disease identified in a subset of people with CC that persists >8 weeks despite treatment for cough-related etiologies. When no underlying condition is determined despite diagnostic testing, this is defined as unexplained chronic cough (UCC). Patients diagnosed with RCC/UCC have an average age of 56.9 years, but no data exist on the prevalence of RCC/UCC in the US. It can be challenging to accurately identify patients with RCC/UCC in real-world claims data due to lack of a specific ICD-10 code for RCC/UCC. Since 2021, the ICD-10 code R05.3 has been used, which encompasses persistent CC, RCC, and UCC. In the absence of a specific ICD-10 code, the CleaR-CC algorithm was developed, through targeted literature review and input from a global panel of cough experts, to identify patients with RCC/UCC in administrative claims data.

OBJECTIVE: To estimate the prevalence of RCC/UCC among older adults by applying the CleaR-CC algorithm to real-world claims data.

METHODS: The CleaR-CC algorithm was applied to Optum Medicare Advantage prescription drug (MAPD) claims data (2016–2023). Patients aged ≥65 years with ≥2 years of continuous enrollment in MAPD plans at the time of RCC/UCC identification were included. Patients with pre-existing lung conditions, recent uncontrolled asthma, respiratory tract infections, or ACE inhibitor use were excluded. Descriptive analyses on patient characteristics were performed, and RCC/UCC prevalence was calculated annually.

RESULTS: A total of 38,995 patients with RCC/UCC aged ≥65 years were identified using the CleaR-CC algorithm from 2018 to 2023. The majority were female (69.1%) and White (68.5%), with a mean (SD) age of 75.6 (6.6) years. The overall prevalence of RCC/UCC was 0.41% in 2023. Prevalence varied by age: 65–69 years, 0.21%; 70–74 years, 0.44%; 75–79 years, 0.50%; 80–84 years, 0.53%; 85–89 years, 0.58%.

CONCLUSIONS: In the absence of a specific ICD-10 code for RCC/UCC, the CleaR-CC algorithm enabled estimation of RCC/UCC prevalence in older adults in the Optum MAPD database, which has not been determined in the US previously. The RCC/UCC patient demographics identified by CleaR-CC are consistent with the literature, supporting the algorithmic pathway. Because the condition is diagnosed by exclusion and the recent use of the ICD-10 code R05.3, the low prevalence of RCC/UCC was expected. Future studies will validate the claims-based algorithm to accurately identify cases of RCC/UCC.

SPONSORSHIP: GSK (study 223232)

403 Preferences for biologic therapy according to disease severity in patients with chronic rhinosinusitis with nasal polyps

Wu S[1], *Gelhorn H*[2], *Collacott H*[2], *Webb E*[2], *Bond J*[1], *Zuluaga Sanchez S*[3], *Lindsley A*[3], *Damask C*[4], *Franzese C*[5], *Ambrose C*[1]; *sandrasze-jung.wu@astrazeneca.com*
[1]*AstraZeneca*; [2]*Evidera*; [3]*Amgen*; [4]*Orlando ENT & Allergy*; [5]*University of Missouri-Columbia*

BACKGROUND: Biologics have shown efficacy in managing chronic rhinosinusitis with nasal polyps (CRSwNP), particularly in patients with severe symptoms, but dosing regimens vary.

OBJECTIVE: To understand patient preferences for biologic therapy attributes, including administration frequency and location, and whether these preferences differ by CRSwNP severity.

METHODS: This cross-sectional, noninterventional online survey asked US adults with self-reported CRSwNP to indicate their preferences for the frequency and location of CRSwNP biologic administration and explain their rationale. Eligibility required prior or recommended biologic use, nasal polyp (NP) removal surgery and/or oral corticosteroid (OCS)

use within the past 2 years. CRSwNP severity was self-reported via a clinical questionnaire.

RESULTS: Of the 101 patients who completed the survey (mean [SD] age, 44.8 [8.9] years; 54.5% male; 62.4% White; mean [SD] time since CRSwNP diagnosis, 6.8 [8.4] years), 61 (60.4%) reported mild-to-moderate CRSwNP symptoms and 40 (39.6%) reported moderate-to-severe CRSwNP symptoms. Prior or recommended biologic use was higher in the moderate-to-severe group than in the mild-to-moderate group (77.5% vs 57.4%), as was OCS use (85.0% vs 57.4%) and prior NP surgery (40.0% vs 8.2%). Both the mild-to-moderate (62.3%) and moderate-to-severe (62.5%) patient groups more frequently preferred treatment every 4 weeks to every 2 weeks. The most cited reason for this preference in the mild-to-moderate group was convenience (n=23/38, 60.5%); in the moderate-to-severe group it was fewer side effects from fewer administrations (n=17/25, 68.0%). Preference for at-home vs in-clinic administration was 47.5% overall (42.6% mild-to-moderate; 55.0% moderate-to-severe). Reassurance of expert administration was the most cited reason for in-clinic preference in both CRSwNP severity groups (mild-to-moderate: n=19/35, 54.3%; moderate-to-severe: n=16/18, 88.9%). The most cited reason for preferring at-home administration was convenience in the mild-to-moderate group (n=20/26, 76.9%) and flexibility in the moderate-to-severe group (n=17/22, 77.3%).

CONCLUSIONS: Across CRSwNP severity groups, patients preferred biologics with dosing every 4 weeks versus every 2 weeks. Preference for at-home or in-clinic administration was similar in the overall patient cohort and in both CRSwNP severity groups, underscoring the importance of providing both options. These findings may help inform provider decisions to support treatment uptake and adherence.

SPONSORSHIP: AstraZeneca/Amgen

Specialty Pharmacy

411 Health-system specialty pharmacy support for weight loss medication management in patients without type 2 diabetes: Outcomes from a single health system

Fitzpatrick C[1], *Wash A*[1], *Tomaino C*[1], *Waters E*[1], *Daley J*[2], *Lopez-Medina A*[3], *Sypniewski A*[1], *Castilla N*[4]; *casey.fitzpatrick@cps.com*; *andrew.wash@cps.com*
[1]*CPS Solutions, LLC*; [2]*CPS Solutions LLC*; [3]*Comprehensive Pharmacy Solution*; [4]*CPS*

BACKGROUND: Nearly three-quarters of US adults are overweight or obese, creating a critical need for effective weight management strategies. Pharmacologic therapies, including GLP-1 and GIP/GLP-1 receptor agonists, are valuable tools, though access challenges persist. Health-system specialty pharmacy (HSSP) teams are well positioned to support patients through medication management and clinical monitoring.

OBJECTIVE: To evaluate medication access and clinical outcomes among patients enrolled in an HSSP-led chronic disease management (CDM) program for weight loss.

METHODS: This retrospective observational study included adults without type 2 diabetes who initiated a GLP-1 or GIP/GLP-1 receptor agonist for weight loss between December 2023 and September 2024. Patients who filled prescriptions through the HSSP received support with insurance navigation, financial assistance (FA), and clinical monitoring via standardized protocols. Weight was assessed at two or three check-ins, depending on therapy duration and whether the patient achieved a goal of >5% weight loss. HSSP teams documented baseline comorbidities, relevant clinical measures, and pain scores from recent provider visits. Descriptive statistics were used for all measures.

RESULTS: A total of 123 patients were included. At baseline, 50% had hypertension, 66% hyperlipidemia, and 34% prediabetes. Patients initiated tirzepatide (61%) or semaglutide (39%), 4% switched therapies, and 11% discontinued therapy. Of the 107 patients whose insurance required a prior authorization (PA), 92% had at least one approval, and 90% of appeals (n=10) were successful. FA was obtained for 99 of 101 patients (98%) who requested it. At the first check-in (84.0±26.5 days, n=123), mean weight loss was 6.9±4.1%, with 71% meeting the goal. At the second (96.5±32.1 days after first, n=117) and third check-ins (92.6±35.2 days after second, n=71), weight loss increased to 12.4±5.6% and 15.5±6.4%, respectively, with 94% meeting the goal at both. For those with adherence data (n=118), the median proportion of days covered was 0.99

(IQR=0.02). Among patients with comorbidities, improvements were observed in systolic (-5.8±12.9 mm Hg) and diastolic (-2.7±9.8 mm Hg) blood pressure (n=50), LDL cholesterol (-7.2±29.1 mg/dL, n=53), A1c (-0.4±0.2%, n=26), and pain scores (-0.5±2.9, n=33) at the final check-in.

CONCLUSIONS: Most patients remained on therapy and achieved meaningful weight loss. High rates of PA approvals, successful appeals, FA support, and strong adherence highlight the value of HSSP-led CDM programs.

SPONSORSHIP: None

421 Projecting potential annual event and cost savings with omalizumab from the reduction in food allergy reactions in the United States population

El Moustaid F[1], *Seetasith A*[1], *Raimundo K*[1], *Dawod F*[2], *Mooney O*[2], *Lukanova R*[2], *Sibanda D*[1]; *el_moustaid.fadoua@gene.com*
[1]*Genentech, Inc.*; [2]*Adelphi Real World*

BACKGROUND: Omalizumab is the first biologic approved for immunoglobulin E (IgE)–mediated food allergy (FA), offering a new approach to reduce the frequency and severity of allergic reactions following accidental exposure. This is particularly important given the substantial clinical and economic burden of FA, which often necessitates costly emergency care following allergic reactions.

OBJECTIVE: To estimate the potential annual reduction in allergic reactions and associated healthcare cost savings from the use of omalizumab in the United States (US) population.

METHODS: A US population model was developed to estimate the number of allergic reactions prevented and associated costs savings in patients with IgE-mediated FA. Real-world data on omalizumab effectiveness were derived from the Adelphi Real World FA Disease Specific Programme™, a cross-sectional survey of US physicians (Jan-Apr 2025). Annual rates of allergic reactions of the omalizumab-treated cohort were compared with an entropy-balanced non-omalizumab cohort. US 2024 population data, FA prevalence estimates, and cost inputs were sourced from published literature and available databases; costs were inflated to 2025 USD. Projected resource use was based on published risks associated with moderate-to-severe allergic reactions (52% of all reactions): epinephrine use (1 pack, 100%), ambulance (0.5%), emergency department visit (2.7%), hospitalization (0.18%), and outpatient visit (20.4%).

RESULTS: The Adelphi Real World analysis showed a mean reduction of 3.6 allergic reactions per patient per year (0.2 reactions in the omalizumab-treated cohort versus 3.8 reactions in the non-omalizumab cohort). Scaled to the estimated 17.1 million patients with IgE-mediated FA in the US, omalizumab is projected to prevent 62,044,997 allergic reactions annually, including 32,263,399 moderate-to-severe reactions. Reductions in allergic reactions and associated healthcare resource utilization could translate into a potential annual cost saving of over US$7.8 billion (US$7,774,803,826).

CONCLUSIONS: Omalizumab offers significant clinical benefits by reducing the frequency and severity of allergic reactions. These clinical benefits can potentially translate into substantial economic value, projecting over $7.8 billion for the entire US population in annual potential savings by reducing medical services associated with food allergy.

SPONSORSHIP: Genentech, Inc.

Student Abstract Titles

Analgesics/Pain

5 Outcomes of colectomy with liposomal bupivacaine

Shimko T[1]; *timofey.a.shimko@kp.org*
[1]*Kaiser Permanente*

Benefit Design and Management

11 Medicare Part D benefit design changes before and after the Inflation Reduction Act

Mundy Z[1], *Mangerie M*[1], *Relich T*[1]; *zane.mundy2@cvshealth.com*
[1]*CVS Health*

12 Characteristics of Medicare beneficiaries reaching the Part D out-of-pocket spending cap in 2025

Beachy T[1], *Hames A*[2], *Poonawalla I*[3], *Rosen J*[4], *Wind H*[5]; *tbeachy@humana.com*
[1]*Humana*; [2]*Humana Healthcare Research*; [3]*Humana Healthcare Research, Inc.*; [4]*Humana Inc*; [5]N/A

13 Evaluating the financial and clinical impacts of obesity GLP-1 formulary exclusions for self-insured employers in a group purchasing organization

Malloy E[1]; *emalloy@employershealthco.com*
[1]*Employers Health*

14 Investigating the impact of removing Xolair (omalizumab) cross-benefit management on total cost of care and member outcomes

Orcutt V[1]; *vanessa.orcutt@gmail.com*
[1]*UnitedHealthcare*

15 Healthcare cost savings from an adaptive medication management program: A retrospective cohort study

Duru E[1], *Kissi-Twum K*[2], *Baker P*[3], *Hohmeier K*[4], *Zulu M*[3], *Mattingly T*[2]; *elvis.duru@utah.edu*
[1]*The University of Utah*; [2]*The University of Utah*; [3]*HaloScrips*; [4]*The University of Tennessee Health Science Center Department of Clinical Pharmacy & Translational Science*

16 Evaluating the impact of medication policy restrictiveness on net per member per month (PMPM) spending for GLP-1 anti-obesity agents

Dang A[1], *Fou A*[1], *He J*[1], *Shinmoto M*[2]; *an.dang@ventegra.org*
[1]*Ventegra*; [2]*Ventegra Foundation*

Biosimilars

23 Average sales price erosion of oncology biologic agents following biosimilar entry into the US market

Beddor A[1], *Erstad B*[2], *MacDonald K*[3], *Alkhatib N*[4], *Abraham I*[2]; *ansambeddor@arizona.edu*; *Abraham@pharmacy.arizona.edu*
[1]*The University of Arizona*; [2]*University of Arizona R. Ken Coit College of Pharmacy*; [3]*Matrix45*; [4]*Path Economics, LLC*

24 Real-world uptake of Stelara biosimilars at parity among commercial insured new starts: A claims-based analysis

Ho T[1], *Needham C*[2], *Otroba T*[1], *Hoyceanyls R*[2]; *Theresa.Ho2@CVSHealth.com*
[1]*CVS Health*; [2]*CVS*

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Torres H[1], *Lott S*[1], *Phalen M*[1], *Bensami A*[1]; *hayleyjt@med.umich.edu*
[1]*University of Michigan Prescription Drug Plan*

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Arzt J[1], *McCollum K*[1], *Nelson T*[1], *Siwak A*[2], *Miller K*[1]; *justin.arzt@lumicera.com*
[1]*Lumicera Health Services, LLC*; [2]*Navitus Health Solutions*

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Brooks E[1], *Nguyen K*[1], *Xie Y*[2]; *elizabeth.brooks@carelon.com*
[1]*CarelonRx*; [2]N/A

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Ahmed S[1], *Shafiq I*[1]; *summayya.a01@gmail.com*
[1]*Centene*

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Huynh J[1], *Chan V*[1], *Tsiao E*[1], *Johnson A*[1], *Wilson Norton J*[1]; *jenn.huynh@premera.com*
[1]*Premera Blue Cross*

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Garimella N[1], *Johnson A*[1], *Tsiao E*[1], *Wilson Norton J*[1], *Chan V*[1]; *navya.garimella@premera.com*
[1]*Premera Blue Cross*

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Diep E[1], *Thomas T*[2], *Yang Y*[3]; *emily.diep@cdphp.com*
[1]*Capital District Physicians' Health Plan*; [2]*n/a*; [3]*CDPHP*

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Mann L[1], *Sandhu G*[1], *Wilcox K*[1]; *lmann1@chsbuffalo.org*
[1]*Catholic Health*

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Fuerte B[1], *Chen L*[1], *Reynolds T*[1]; *Beverly.Fuerte@BSWHealth.org*
[1]*Baylor Scott & White Health*

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Phung M[1], *Sislyan S*[2], *Niu F*[2], *Lester S*[2], *Lo C*[2], *Hui R*[2]; *mlphung100@gmail.com*
[1]*Kaiser Permanente Greater Southern Alameda Area*; [2]*Kaiser Permanente*

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Kalimian C[1], *Jang H*[1], *Patrikios A*[1], *Jan S*[1], *Prestipino B*[2]; *chloe_kalimian@horizonblue.com*
[1]*Horizon Blue Cross Blue Shield of New Jersey*; [2]*Horizon BCBS of NJ*

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Shafi S[1], *Dyer A*[1], *Watson T*[1]; *shafisd@vcu.edu*
[1]*HCA Healthcare*

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Sislyan S[1], *Niu F*[1], *Phung M*[1], *Lester S*[1], *Lo C*[1], *Hui R*[1]; *sarkis.s.sislyan@kp.org*
[1]*Kaiser Permanente*

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Fuerte B[1], *Kim D*[1], *Park C*[2]; *Beverly.Fuerte@BSWHealth.org*
[1]*Baylor Scott & White Health*; [2]*The University of Texas at Austin, College of Pharmacy, Health Outcomes Division*

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Braganza J[1], *Bowe A*[2], *Diaz M*[1], *Hayes M*[1], *John I*[1], *Wind H*[3], *Poonawalla I*[2], *Hames A*[4]; *jbraganza@humana.com*
[1]*Humana*; [2]*Humana Healthcare Research, Inc.*; [3]*N/A*; [4]*Humana Healthcare Research*

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Mouawad K[1], *Tayah T*[2]; *km42531@uga.edu*
[1]*University of Georgia College of Pharmacy*; [2]*n/a*

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Chea S[1], *He J*[1], *Kang S*[1]; *sara.chea@ventegra.org*
[1]*Ventegra*

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Castillo S[1], *Siwak A*[1], *Wickizer M*[1]; *smcastillo3@wisc.edu*
[1]*Navitus Health Solutions*

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Annor D[1]; *dannor@employershealthco.com*
[1]*Employers Health*

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Rajeev S[1], *Partosh D*[2], *Lazaridis D*[2], *Lopez C*[2], *Tawadrous M*[2], *Varughese M*[2], *Vinluan K*[2]; *srrajeev@mhs.net*
[1]*Memorial*; [2]*Memorial Healthcare System Pharmacy Population Health Services*

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Csurgo L[1], *Ceresa S*[1], *Pallisco A*[1], *Ramon R*[1]; *LCsurgo1@bcbsm.com*
[1]*Blue Cross Blue Shield of Michigan- Senior Health Services*

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Milch C[1], *Ziu R*[1], *Corder A*[1]; *cmilch@healthfirst.org*
[1]*Healthfirst*

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Mooney K[1], *Munro, PharmD, BCPS C*[1], *Venkatesan A*[2], *Voelker L*[2]; *kaley.wolff@yahoo.com*
[1]*Judi Health - Capital Rx*; [2]*Vida Health*

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Weber S[1], *Siwak A*[1], *Wickizer M*[1], *Kapitz C*[1], *Deschaine M*[1], *Stuhl A*[1]; *scott.weber@navitus.com*
[1]*Navitus Health Solutions*

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Bassett R[1], *Abbasi M*[2], *McNassar G*[1]; *rlbassett24@gmail.com*; *ma1762@scarletmail.rutgers.edu*; *gjm139@scarletmail.rutgers.edu*
[1]*Rutgers University Ernest Mario School of Pharmacy*; [2]*Rutgers University*

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Decano J[1], *Vuong M*[1], *Witty S*[2]; *jakob_decano@optum.com*
[1]*Optum Rx*; [2]*Optum*

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Rapp H[1], *Lynch K*[2], *Merrell A*[1]; *rapphe@upmc.edu*; *kevin.lynch@pfizer.com*
[1]*UPMC Health Plan*; [2]*Pfizer*

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Gooden A[1], *Teng E*[1], *He J*[2], *Shinmoto M*[1]; *ayanna.gooden@ventegra.org*
[1]*Ventegra Foundation*; [2]*Ventegra*

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Gaglio L[1], *Dorris J*[2]; *lgaglio@mail.lipscomb.edu*
[1]*Lipscomb University College of Pharmacy and Health Sciences*; [2]*Lipscomb University*

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Abbasi M[1], *Moustafa M*[1], *Gohar Q*[1]; *ma1762@scarletmail.rutgers.edu*; *mm3564@scarletmail.rutgers.edu*; *qg84@scarletmail.rutgers.edu*
[1]*Rutgers University*

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Gupta Y[1], *Shepherd M*[2], *Harris-Shapiro J*[3], *Hines D*[4], *Steele-Adjognon M*[5], *Lee A*[6], *Poon Y*[7]; *yanagupt@usc.edu*; *abraham.lee@abbott.com*
[1]*University of Southern California*; [2]*Vanderbilt Health at Metro Nashville Public Schools*; [3]*Benegration*; [4]*Me*; [5]*FTI Consulting*; [6]*Abbott Diabetes Care*; [7]*Abbott*

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Phan V[1], *McVay M*[2], *Prior M*[2], *Jeminiwa R*[2]; *vietbaophan99@gmail.com*
[1]*Thomas Jefferson University, Jefferson College of Population Health/Novartis*; [2]*Jefferson College of Pharmacy, Thomas Jefferson University*

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Giang J[1], *Duong J*[2], *Yoo Y*[2]; *jng112@scarletmail.rutgers.edu*; *jnd106@scarletmail.rutgers.edu*; *gy148@scarletmail.rutgers.edu*
[1]*Rutgers State University New Brunswick*; [2]*Rutgers University*

Drug Pricing, Payment, and Reimbursement

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Millheim E[1]; *millheet@mail.uc.edu*
[1]*University of Cincinnati*

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Langham B[1], *Loehr A*[1], *Ngorsuraches S*[2]; *bel0045@auburn.edu*; *arl0069@auburn.edu*
[1]*Auburn University Harrison College of Pharmacy*; [2]*Auburn University*

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Jeranek K[1]; *kpj21@scarletmail.rutgers.edu*
[1]*Ernest Mario School of Pharmacy*

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Chi A[1]; *annachi@usc.edu*
[1]*USC Mann School of Pharmacy and Pharmaceutical Sciences*

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Persaud V[1], *Wertheimer A*[2]; *vpersaud6@student.touro.edu*
[1]*Touro College of Pharmacy*; [2]*Touro College of Pharmacy, Department of Social, Behavioral and Administrative Sciences*

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Ho C[1], *Kyniston R*[2], *Dowell K*[1]; *courtney.ho@pacificsource.com*
[1]*PacificSource Health Plans*; [2]*PacificSource*

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Boland C[1], *Bain A*[1], *Motiwala T*[2]; *bola18@osumc.edu*
[1]*The Ohio State University Health Plan, Inc.*; [2]*The Ohio State University Health Plan, Inc. and The Ohio State University College of Medicine Department of Family and Community Medicine*

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Heidt K[1], *Kim S*[1], *Jeon K*[1]; *kah453@scarletmail.rutgers.edu*; *sk3107@scarletmail.rutgers.edu*; *kj554@scarletmail.rutgers.edu*
[1]*Ernest Mario School of Pharmacy at Rutgers University*

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Seella N[1], *Siwak A*[1], *Wickizer M*[1], *Stuhl A*[1]; *neha.seella@navitus.com*
[1]*Navitus Health Solutions*

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Dube S[1], *Mandal S*[1], *Boss K*[1], *Pomfret T*[1], *Alper C*[1], *Tesell M*[1], *Semmel K*[2], *Bacon R*[1], *Clements K*[3], *Lenz K*[4]; *sarah.dube@umassmed.edu*
[1]*ForHealth Consulting at UMass Chan Medical School*; [2]*MassHealth, Executive Office of Health and Human Services*; [3]*UMass Chan Medical School*; [4]*MassHealth*

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Goswami A[1], *Yahi M*[1], *Shah P*[1]; *aishee.goswami21@gmail.com*; *meriamayahi@gmail.com*; *pearl.shah108@gmail.com*
[1]*AMCP Chapter at Ernest Mario School of Pharmacy Rutgers University New Brunswick*

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Song J[1], *Mittal S*[2]; *jds455@scarletmail.rutgers.edu*; *sm2961@scarletmail.rutgers.edu*
[1]*Ernest Mario School of Pharmacy, Rutgers*; [2]*Ernest Mario School of Pharmacy at Rutgers University*

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Jones S[1], *Woodward C*[1], *Ronen R*[1], *Segura B*[2], *Kim J*[1], *Smith S*[1]; *sophia.jones@bcbsnc.com*
[1]*Blue Cross Blue Shield of North Carolina*; [2]*Blue Cross and Blue Shield of North Carolina*

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Kim D[1], *Reynolds T*[1], *Chen L*[1], *Godley P*[1]; *dak1878@BSWHealth.org*
[1]*Baylor Scott & White Health*

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Mahan M[1], *Bowe A*[2], *Diaz M*[1], *Hayes M*[1], *John I*[1], *Wind H*[3], *Poonawalla I*[2], *Hames A*[4]; *mmahan1@humana.com*
[1]*Humana*; [2]*Humana Healthcare Research, Inc.*; [3]*N/A*; [4]*Humana Healthcare Research*

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Calvet M[1], *Kracht K*[1], *Friedlander N*[1], *Brown-Gentry K*[1], *Hunter B*[1], *Scripture J*[1]; *marianna.calvet@primetherapeutics.com*
[1]*Prime Therapeutics*

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Talbot B[1], *Okasha A*[1], *Abbasi M*[1], *Hu J*[1]; *bdt48@scarletmail.rutgers.edu*; *ao687@scarletmail.rutgers.edu*; *jch301@scarletmail.rutgers.edu*
[1]*Rutgers University*

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Das N[1], *Badlani N*[1], *Kubiak J*[1]; *nd906@scarletmail.rutgers.edu*; *jmk590@scarletmail.rutgers.edu*
[1]*Rutgers University - Ernest Mario School of Pharmacy*

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Sconiers J[1]; *justicesconiers@gmail.com*
[1]*PCOM*

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Biswa S[1], *Haack S*[1], *Bryant G*[1]; *samana.biswa@drake.edu*
[1]*Drake University*

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Persaud V[1], *Elayan I*[1], *Selkow L*[2]; *vpersaud6@student.touro.edu*; *ielayan@student.touro.edu*
[1]*Touro College of Pharmacy*; [2]*Inland Society of Health-System Pharmacists*

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Loehr A[1], *Helms S*[1], *Andrus M*[1], *Hohmann N*[1], *Yang H*[1]; *arl0069@auburn.edu*
[1]*Auburn University Harrison College of Pharmacy*

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Watson A[1], *Hunter B*[1], *Wilson A*[1], *Eckwright D*[1], *Kracht K*[1], *Scripture J*[1], *Brown-Gentry K*[1]; *ailsa.watson@primetherapeutics.com*
[1]*Prime Therapeutics*

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Abdallah M[1], *Westergaard R*[1]; *mabdalanki@gmail.com*
[1]*Express Scripts*

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Lee W[1], *Liu I*[1], *Wang O*[1]; *wl618@scarletmail.rutgers.edu*; *il292@scarletmail.rutgers.edu*; *ow53@scarletmail.rutgers.edu*
[1]*AMCP Chapter at the Ernest Mario School of Pharmacy at Rutgers University*

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Alaeddin S[1], *Abdelhamid N*[1], *Aly Y*[1]; *SaifAlaeddin100@gmail.com*
[1]*Ernest Mario School of Pharmacy*

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Dokur M[1], *Aguirre E*[1], *Modrack J*[1], *Hasan M*[1]; *manueldokur@ufl.edu*
[1]*University of Florida College of Pharmacy*

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Shah G[1], *Devnani B*[1], *Sharma H*[1], *Salih R*[1], *York J*[1]; *gks39@scarletmail.rutgers.edu*; *salihrayanpharmd@gmail.com*
[1]*Rutgers Institute for Pharmaceutical Industry Fellowships*

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Asabere D[1], *Verma S*[2], *Parasuraman S*[2], *Dang A*[3], *Nagendra V*[3]; *DAsabere@incyte.com*
[1]*Incyte Corporation*; [2]*Incyte*; [3]*MarksMan Healthcare Communications*

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Keylon J[1], *Ivanova O*[2]; *jaycie.keylon@centene.com*
[1]*Centene*; [2]*Centene Management Company*

Hematologic

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Tae J[1], *Kim N*[1]; *jt1338@scarletmail.rutgers.edu*; *njk79@scarletmail.rutgers.edu*
[1]*Rutgers University*

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Soon L[1], *Musial L*[1], *Patel B*[1], *Bent K*[1]; *lsoon6@performrx.com*
[1]*PerformRx*

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Chan C[1], *Rajadhyaksha P*[1], *Suh K*[1]; *cmc392@pitt.edu*
[1]*University of Pittsburgh School of Pharmacy*

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Siwak A[1], Wickizer M[2], Schmidt R[2], Stuhl A[1], Mesia M[2]; marium.mesia@navitus.com
[1]Navitus Health Solutions; [2]Navitus

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Xie J[1], Jang H[1], O'Shea T[2], Jan S[1], Prestipino B[3]; joseph_xie@horizonblue.com
[1]Horizon Blue Cross Blue Shield of New Jersey; [2]Horizon BCBS; [3]Horizon BCBS of NJ

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Nguyen J[1], Henry C[1], Bowman D[2], Beeler B[2], Hammoud H[1], Evans B[1]; julia.nguyen@priorityhealth.com
[1]Priority Health; [2]Priority Health - Grand Rapids, MI

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Bodnar N[1], Modany A[1], Marr D[1], Good C[2], Huang Y[3], Peasah S[1]; bodnarna@upmc.edu
[1]UPMC Health Plan; [2]UPMC Health Plan, Insurance Services Division; [3]University of Pittsburgh Medical Center

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Giang J[1], Ha D[2], Lee K[1]; jng109@scarletmail.rutgers.edu; dh849@scarletmail.rutgers.edu; pl566@scarletmail.rutgers.edu
[1]Rutgers Ernest Mario School of Pharmacy; [2]Ernest Mario School of Pharmacy

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Phan V[1], Sottung E[2], Frasso R[3], Pogorzelska-Mariarz M[4], Maio V[3], Aryal Khanal S[5], Schmidt T[6], Mukhija J[5], de Cordova P[5]; vietbaophan99@gmail.com
[1]Thomas Jefferson University, Jefferson College of Population Health/Novartis; [2]Thomas Jefferson University, Jefferson College of Population Health/Otsuka; [3]College of Population Health, Thomas Jefferson University; [4]M. Louise Fitzpatrick College of Nursing, Villanova University; [5]Rutgers School of Nursing; [6]M. Louise Fitzpatrick College of Nursing

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Welter E[1], Mann A[1], Kim Y[2], Park C[2]; elizwelter4@gmail.com
[1]Curative; [2]The University of Texas at Austin, College of Pharmacy, Health Outcomes Division

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Franklin J[1], Pudim E[1], Pomfret T[1], McVeigh M[2], Anderson E[2], Jerard C[1], Stevens K[1], Alper C[1], Clements K[3], Lenz K[2]; jordan.franklin2@umassmed.edu
[1]ForHealth Consulting at UMass Chan Medical School; [2]MassHealth; [3]UMass Chan Medical School

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Nelson E[1], Hynicka L[1], Morgan J[1], Di Polito C[1], Reeves G[2], Ehret M[1]; emma.nelson@rx.umaryland.edu
[1]University of Maryland School of Pharmacy; [2]University of Maryland School of Medicine

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Olmsted A[1], Mo, PharmD M[2], Rogers B[3]; brogers3@bcbsm.com
[1]BCBSM; [2]Blue Cross Blue Shield of Michigan; [3]Blue Cross Blue Shield Of Michigan

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Gebremichael S[1], *Mathur S*[1]; *s.gebremichael3940@student.tsu.edu*
[1]*Southwest*

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Gilbert B[1], *McCluskey M*[1], *Vire S*[1], *Murphy E*[1]; *bgilbert@mjhlifesciences.com*
[1]*MJH Life Sciences*

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Lucas G[1], *Steele S*[1], *Dickey K*[1], *Medina E*[1], *Cope S*[1], *Enghauser A*[1]; *garriona.lucas@caresource.com*
[1]*CareSource*

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Saavedra J[1]; *j.oshssaavedra@gmail.com*
[1]*Rutgers University - Ernest Mario School of Pharmacy*

Musculoskeletal

266 Comparative efficacy and safety of methotrexate monotherapy versus biologic DMARDs in rheumatoid arthritis: A systematic review of randomized controlled trials

Wong T[1], *Duong K*[1], *Kim G*[1]; *timothy.s.wong@rutgers.edu*; *kad430@scarletmail.rutgers.edu*; *gk586@scarletmail.rutgers.edu*
[1]*Rutgers University*

Oncology

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Bassett R[1], *Gill P*[1], *Gallo G*[1], *Mychalko S*[1]; *rlbassett24@gmail.com*; *gg702@scarletmail.rutgers.edu*
[1]*Rutgers University Ernest Mario School of Pharmacy*

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Luaces A[1], *Gangoo-Dookhan T*[2], *Roebuck L*[1], *Butler J*[1], *Wu J*[3]; *annaluaces@gmail.com*
[1]*Community Care Plan*; [2]*Nova Southeastern University*; [3]*Nova Southeastern University, Barry and Judy Silverman College of Pharmacy*

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Patel J[1], *Nadiger A*[1]; *janvipatel07@gmail.com*; *adhyanadiger@gmail.com*
[1]*Rutgers University*

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Horvat D[1], *Chan S*[2], *Lockhart C*[3], *Pawloski P*[4]; *horvatd@duq.edu*
[1]*Duquesne University*; [2]*Elevance Health*; [3]AMCP; [4]*Academy of Managed Care Pharmacy Research Institute*

301 Favorable responses to BTKi-based regimens in relapsed or refractory mantle cell lymphoma: A prospective analysis from the MER and LION cohorts

Baird K[1], *McCook-Veal A*[2], *Switchenko J*[3], *Epperla N*[4], *Shah H*[5], *Pinilla-Ibarz J*[6], *Kirkpatrick G*[7], *Mou E*[8], *Farooq U*[8], *Kives M*[2], *Sawalha Y*[9], *Portell C*[10], *Rhodes J*[11], *Bock A*[4], *Larson M*[12], *Wang Y*[12], *Cohen J*[13], *Bond D*[14]; *kbaird1@mail.lipscomb.edu*
[1]*Lipscomb University College of Pharmacy and Emory University Winship Cancer Institute*; [2]*Emory University*; [3]*Emory University Department of Biostatistics & Bioinformatics*; [4]*Huntsman Cancer Institute, University of Utah*; [5]*Huntsman Cancer Center, University of Utah*; [6]*Moffitt cancer center*; [7]*University of Iowa Health Care*; [8]*University of Iowa*; [9]*Ohio State University The James Cancer Hospital and Solove Research Institute*; [10]*University of Virginia Emily Couric Clinical Cancer Center*; [11]*Rutgers Robert Wood Johnson Medical School*; [12]*Mayo Clinic*; [13]*Emory University, Winship Cancer Institute*; [14]*The James Cancer Hospital at The Ohio State University*

302 Systematic literature review of associations between concomitant glucagon-like peptide-1 receptor agonists and immune checkpoint inhibitors in non-small cell lung cancer

Shin J[1], *Len C*[2], *Sirimarapu S*[3]; *jjs519@scarletmail.rutgers.edu*; *cl1627@scarletmail.rutgers.edu*; *ss4630@scarletmail.rutgers.edu*
[1]*Rutgers University Ernest Mario School of Pharmacy*; [2]*Rutgers EMSOP*; [3]*Ernest Mario School of Pharmacy*

303 Real-world chronic lymphocytic leukemia (CLL)-specific biomarker testing patterns and frontline treatment patterns in community oncology patients with CLL/small lymphocytic lymphoma (SLL): An electronic health record study

McGovern M[1], *Kim D*[1], *Fuerte B*[1], *Reynolds T*[1], *Chen L*[1], *Sagar A*[1], *Eskandari M*[1], *Wang X*[2], *Ding L*[2], *Maglinte G*[2], *Godley P*[1]; *michael.mcgovern@bswhealth.org*
[1]*Baylor Scott & White Health*; [2]*BeOne Medicines Ltd*

304 Therapeutic implications of adagrasib in KRAS G12C-mutant NSCLC in overcoming four decades of resistance

Vijayakumar V[1], *Talati S*[1], *Manjooran E*[1]; *vv355@scarletmail.rutgers.edu*
[1]*Rutgers University*

305 A comparative evaluation of selective estrogen receptor modulators and degraders in the treatment of estrogen-positive breast cancer: A systematic literature review

Sze H[1], *Lee Y*[1], *Soldevilla K*[1]; *hs1278@scarletmail.rutgers.edu*; *yl2171@scarletmail.rutgers.edu*; *ks2108@scarletmail.rutgers.edu*
[1]*AMCP Chapter at Ernest Mario School of Pharmacy at Rutgers University*

Precision Medicine

307 Precision at the frontline: Developing a community pharmacy toolkit to support pharmacogenomics implementation and advance access to precision medicine

Umeadi O[1], *Agyemang E*[1]; *onyeka.umeadi@bruins.belmont.edu*
[1]*Belmont University College of Pharmacy and Health Sciences*

308 Analyzing the clinical relevance of CYP2D6 pharmacogenomic testing in tamoxifen therapy for hormone receptor-positive breast cancer

Chang Y[1], *Hwang I*[1]; *yena.chang.vtx@gmail.com*
[1]*Rutgers Ernest Mario School of Pharmacy*

Quality and Safety Programs

312 Insulin delivery optimization in adult inpatients across an integrated health system using process improvement methodology

Christopher C[1], *Casale J*[2], *Brophy A*[2], *Sternbach J*[2], *Abazia D*[3]; *caraochristopher@gmail.com*
[1]*Rutgers Health & RWJBarnabas Health*; [2]*RWJBarnabas Health*; [3]*Rutgers Health - Ernest Mario School of Pharmacy*

313 Impact of medication burden on the risk of concurrent anticholinergic use in Medicare Part D beneficiaries aged 65 and older

Uwaelue J[1], *Rangoonwala R*[1], *Englert S*[1], *Schmidt M*[1], *Gorgiz N*[1]; *Josephine.Uwaelue@csshealth.com*; *Riddhi.Rangoonwala@csshealth.com*
[1]*Clarest Health*

314 Evaluation of alignment between updated AGS Beers Criteria alternatives and FDA-approved labeling for cardiometabolic disorders in geriatric patients

Patel S[1], *Patel K*[1], *Joby L*[1], *Sheth M*[1]; *sap393@scarletmail.rutgers.edu*
[1]*Rutgers University*

315 Vancomycin continuous vs intermittent infusion and the risk of acute kidney injury: An umbrella review

Kim Y[1], *Krausz A*[1], *Alvarez Z*[1], *Duchi S*[1], *Kane-Gill S*[1]; *yuk55@pitt.edu*
[1]*University of Pittsburgh School of Pharmacy*

316 Impact of a provider letter on statin initiation and adherence among adults with diabetes enrolled in a managed care organization and a mixed population of commercial, Medicare, and Medicaid plans

Garcia M[1], *Williams T*[2]; *michelle.garcia@modahealth.com*
[1]*Moda Health*; [2]*Moda Health - Portland, OR*

317 Pharmacist-driven innovation in HEOR: AQUA-VIVE's impact on patient outcomes and healthcare resource utilization

Bell B[1], *White A*[2]; *Bobbybell@my.unthsc.edu*
[1]*UNT Health*; [2]*UNT Health College of Pharmacy*

318 Evaluating comprehensive medication reviews beyond ROI: A multi-domain framework for outcomes assessment in managed care

Duan H[1], *Dickey K*[1], *Enghauser A*[1], *Medina E*[1], *Steele S*[1], *Chen A*[2]; *huanyun.duan@caresource.com*
[1]*CareSource*; [2]*School of Pharmacy, Cedarville University*

319 Impact of a newly implemented enterprise-wide formulary strategy in outpatient physician clinics

Price I[1], *Dyer A*[1], *Watson T*[1], *Robinson P*[1]; *isabelle.c.price@gmail.com*
[1]*HCA Healthcare*

320 Impact of an anticoagulation stewardship program on reducing weight-based unfractionated heparin use across a multi-hospital health system

Muscarella V[1], *Abazia D*[2], *Brophy A*[3], *Casale J*[3], *Sternbach J*[3]; *vinbmuscarella5@gmail.com*
[1]*Rutgers University - Robert Wood Johnson Barnabas Health*; [2]*Rutgers Health - Ernest Mario School of Pharmacy*; [3]*RWJBarnabas Health*

322 Belimumab and voclosporin use in lupus nephritis from a US payer's perspective: A comparative study of monotherapies and concurrent treatment strategies

Hersi R[1]; *hersirathea@gmail.com*
[1]*Centene Management Company*

Real-World Evidence

371 Impact of polypharmacy on deutetrabenazine/deutetrabenazine XR utilization

Lang C[1], *Iruru E*[1], *Relich T*[1], *Mangerie M*[1]; *chase.lang@cvshealth.com*
[1]*CVS Health*

372 Healthcare resource utilization and costs associated with depression among people with Alzheimer's disease: A retrospective cohort study

Yip O[1], *Lee K*[1]; *oliviayipwc@gmail.com*
[1]*UW-CHOICE*

373 Treatment patterns for dry eye disease among Medicare Advantage beneficiaries

Fronizer L[1], *Kim K*[2], *Bloomfield A*[1], *Rastegar J*[3], *Wind H*[4], *Saundankar V*[5]; *lfronizer@humana.com*
[1]*Humana*; [2]*Humana Healthcare Research*; [3]*Humana Healthcare Research*; [4]*N/A*; [5]*Humana Healthcare Research, Inc.*

374 Integrating the patient voice into managed care evidence: Insights from Food and Drug Administration Patient-Focused Drug Development sessions and real world evidence use in oncology

Nguyen A[1], *Nguyen M*[1]; *abn40@scarletmail.rutgers.edu*
[1]*Rutgers University*

375 Budget impact/cost-offset model comparing once-daily extended-release vs twice-daily immediate-release ruxolitinib in myelofibrosis: A US payer perspective

Fortunato J[1], *Verma S*[2], *Parasuraman S*[2], *Sun Y*[3], *Nchekwube P*[3], *He J*[3], *Wagner S*[3]; *jfortunato@incyte.com*
[1]*Incyte Corporation*; [2]*Incyte*; [3]*Columbia Data Analytics*

376 GLP-1 medication utilization and costs among Medicaid users in the tri-state area in 2024

Lobo E[1]; *esha.lobo888@gmail.com*
[1]*Montgomery High School*

377 Association of COVID-19 vaccination status with nirmatrelvir/ritonavir utilization in Medicare beneficiaries: A retrospective cohort analysis

Albrecht A[1], *Siwak A*[1], *Wickizer M*[1], *Johnson R*[1]; *alan.albrecht@navitus.com*
[1]*Navitus Health Solutions*

378 AI integration in managed care pharmacy APPEs: Enhancing student learning

Pittman S[1], *Shaibany L*[2], *Lugo A*[3]; *savannaskye6@gmail.com*
[1]*University of the Incarnate Word Feik School of Pharmacy*; [2]*University of Texas at Austin College of Pharmacy*; [3]*LoneStar Health Solutions*

379 Real-world utilization patterns and economic burden of prophylactic plus on-demand therapy versus on-demand only therapy for hereditary angioedema

Norman N[1], *Megargell L*[1], *Fernandes H*[1], *Brooks J*[1]; *nikolasdnorman@gmail.com*
[1]*PerformRx*

380 Evaluation of Zoryve foam efficacy and use patterns through pharmacy benefit claims

Castro N[1]; *nina.castro@truerx.com*
[1]*True Rx Health Strategists*

381 Using real-world evidence from Rybelsus to inform payer value expectations for orforglipron versus injectable GLP-1 receptor agonists in type 2 diabetes

Ki N[1], *Kim M*[2], *Lee Y*[1]; *nathan.ki@rutgers.edu*; *mk1986@scarletmail.rutgers.edu*; *yl1754@scarletmail.rutgers.edu*
[1]*Rutgers University*; [2]*Rutgers School of Pharmacy*

382 Adherence to oral contraceptive pills and associated factors among women with MarketScan commercial insurance

Cheruvu S[1], *Abughosh S*[1]; *sscheruv@CougarNet.UH.EDU*
[1]*University of Houston*

383 Comparing healthcare utilization between healthcare employees and other industries: A claims-based analysis

Cupp C[1], *Collins K*[2], *Dugan B*[2]; *chandlercupprx@gmail.com*
[1]*Samford University McWhorter School of Pharmacy*; [2]*Samford University*

Respiratory

404 Cost-benefit analysis of dupilumab for patients with chronic obstructive pulmonary disease exacerbations

Cheng D[1], *Thomas T*[2], *Pfrommer A*[1], *Hwaszcz D*[1]; *daphncheng517@gmail.com*
[1]*Capital District Physicians' Health Plan*; [2]*n/a*

405 Asthma outcomes: An analysis of medication adherence and health care utilization by sociodemographics

Mortera B[1], *Bain A*[2], *Motiwala T*[3]; *bryce.mortera@osumc.edu*
[1]*The Ohio State University Health Plan*; [2]*The Ohio State University Health Plan, Inc.*; [3]*The Ohio State University Health Plan, Inc. and The Ohio State University College of Medicine Department of Family and Community Medicine*

406 Persistence with maintenance therapy in commercial patients with chronic obstructive pulmonary disease and asthma

Bactad M[1], *Bactad M*[1], *Mann A*[1], *Park C*[2], *Le A*[2]; *moniquebactad@curative.com*; *moniqueb131@gmail.com*
[1]*Curative*; [2]*The University of Texas at Austin, College of Pharmacy, Health Outcomes Division*

407 Prescribing patterns and switch rates of biologics used to treat asthma and chronic obstructive pulmonary disease: An analysis of pharmacy claims data within a group purchasing organization of self-insured employers

Dickens J[1]; *jdickens@employershealthco.com*
[1]*Employers Health*

408 Impact of value-based care pharmacy reviews on healthcare utilization in pediatric asthma patients

McLean A[1], *Murphy S*[1], *Adkins M*[1], *Lynch A*[1], *Packard M*[1]; *ana.mclean@advocatehealth.org*
[1]*Atrium Health Wake Forest Baptist Medical Center*

Specialty Pharmacy

412 Improving patient continuity of care: Investigating adherence barriers in PAP services

Greenwald D[1]; *dgreenwald@raremed.com*
[1]*RareMed Solutions*

413 Pharmacoeconomic and clinical analysis of the Conversio nebulizer program at Fidelis Care in the New York market

Von Cyga K[1], *Patel A*[2], *Papia A*[2]; *Kordian.VonCyga@fideliscare.org*
[1]*Centene Pharmacy Services*; [2]*Fidelis Care*

414 Evaluating the impact of dedicated clinicians on prior authorization outcomes and access to therapy in rare diseases

DiPaolo H[1], *Wolfe S*[2], *Lepro K*[2], *Nitkiewicz C*[2], *Jastrab A*[2], *Koerner P*[2], *Faris R*[2]; *hdipaolo@pantherxrare.com*
[1]PANTERx *Rare Pharmacy*; [2]PANTHERx *Rare Pharmacy*

415 Impact of Quick Start and Bridge programs on rare disease therapy initiation and preventing gaps in therapy

Owens K[1], *Hebble S*[1], *Dixon E*[1], *Jastrab A*[1], *Koerner P*[1], *Faris R*[1]; *kowens@pantherxrare.com*
[1]*PANTHERx Rare Pharmacy*

416 Assessing the role of texting and text-based refill support in improving adherence and access in a specialty pharmacy hub

Wilhelm H[1]; *hwilhelm@raremed.com*
[1]*RareMed Solutions*

417 The impact of team member engagement on quality metrics, process improvements, and patient safety

Pelejo K[1], *Millward J*[1], *Caspero G*[1], *Koerner P*[1], *Jastrab A*[1], *Jones L*[1], *Faris R*[1]; *kpelejo@pantherxrare.com*
[1]*PANTHERx Rare Pharmacy*

418 Comparative Analysis of Success Rate and Cost Outcomes in Mandatory and Voluntary Site-of-Care Programs for Medical Specialty Drugs in a Commercial Population

Chan S[1], *Nguyen K*[2], *Wang Y*[2]; *lkchn2000@gmail.com*
[1]*Elevance Health*; [2]*CarelonRx*

419 IRA Impact on Brand Medication Adherence: A Focus on Diabetes

Girgis M[1], *Dickey J*[1]; *Michael.Girgis@hf.org*
[1]*Health First Health Plans*

420 Three-Year Trends in Pharmacy Benefits Following Implementation of the Inflation Reduction Act

Girgis M[1], *Dickey J*[1]; *Michael.Girgis@hf.org*
[1]*Health First Health Plans*

Encore Abstract Titles

Analgesics/Pain

1 Efficacy and safety of two rimegepant dosing regimens for the prevention of episodic migraine: A double-blind, placebo-controlled study

Goadsby P[1], *Tassorelli C*[2], *Fountaine R*[3], *Antinew J*[3], *De Besi P*[3], *Dubrovin S*[3], *Kopf S*[3], *Loprinzo V*[3], *Fullerton T*[3]; *peter.goadsby@kcl.ac.uk*; *robert.j.fountaine@pfizer.com*
[1]*NIHR King's Clinical Research Facility, Wolfson Sensory, Pain and Regeneration Centre, King's College London*; [2]*University of Pavia*; [3]*Pfizer Inc.*

2 Rimegepant for the prevention of episodic migraine in adults with prior inadequate response to oral preventatives

Pozo-Rosich P[1], *Gien López J*[2], *Lisewski P*[3], *Aslan A*[4], *Seehra H*[5], *Thiry A*[4], *Abraham L*[5], *Ramirez L*[4], *Fountaine R*[4], *Fullerton T*[4]; *patricia.pozo@vhir.org*; *robert.j.fountaine@pfizer.com*
[1]*Vall d'Hebron Research Institute, Universitat Autònoma de Barcelona*; [2]*Star Médica*; [3]*Tricals*; [4]*Pfizer Inc.*; [5]*Pfizer R&D UK Ltd.*

3 A phase 4 randomized double-blind placebo-controlled study of rimegepant for acute treatment of migraine in adults unsuitable for triptan use

Ashina M[1], *McAllister P*[2], *Ramirez L*[3], *Nalpas C*[4], *Thiry A*[3], *Abraham L*[5], *Fountaine R*[3], *Fullerton T*[3]; *ashina@dadlnet.dk*; *robert.j.fountaine@pfizer.com*
[1]*Danish Headache Center, Department of Neurology, Rigshospitalet*; [2]*New England Institute for Neurology and Headache*; [3]*Pfizer Inc.*; [4]*Pfizer Inc*; [5]*Pfizer R&D UK Ltd.*

Biosimilars

17 The economic benefit of biosimilars in North America: A targeted literature review

Shastri K[1], *Ren S*[2], *Clarke K*[3], *Ainslie-Garcia M*[3]; *kunal.shastri@fresenius-kabi.com*; *steven.ren@fresenius-kabi.com*
[1]*Fresenius Kabi, SwissBioSim GmbH*; [2]*Fresenius Kabi USA, LLC*; [3]EVERSANA

Cardiovascular

31 Systemic inflammation and its association with major adverse cardiovascular events in patients with acute myocardial infarction

Nguyen C[1], *Ackermann A*[2], *Marieb E*[2], *Skaar J*[2], *Chow W*[1], *Ryali R*[1], *Popadic L*[3], *Wu X*[3], *Ma X*[3], *Blaha M*[4]; *cvne@novonordisk.com*
[1]*Novo Nordisk, Inc.*; [2]*Novo Nordisk, Inc*; [3]*Komodo Health*; [4]*Johns Hopkins Ciccarone Center for the Prevention of Cardiovascular Disease*

32 Risk of major atherosclerotic cardiovascular disease events in the United States among individuals with and without prior events

Desai N[1], *Ke X*[2], *Holub A*[3], *Done N*[3], *Song Y*[4], *Galvain T*[5], *Rajpathak S*[6], *McQueen R*[7]; *nihar.desai@yale.edu*; *swapnil.rajpathak@merck.com*
[1]*Yale University School of Medicine*; [2]*Merck & Co., Inc.*; [3]*Analysis Group*; [4]*Analysis Group, Inc*; [5]*Merck Sharp & Dohme AG*; [6]*Merck & Co, Inc.*; [7]*University of Colorado Skaggs School of Pharmacy and Pharmaceutical Sciences*

33 Clinical and economic burden of adding ezetimibe or PCSK9i therapy in patients with atherosclerotic cardiovascular disease

Galvain T[1], *Desai N*[2], *Bash L*[3], *Watanabe A*[3], *Eutsler J*[3], *McQueen R*[4]; *thibaut.galvain@msd.com*; *jeremy.eutsler@merck.com*
[1]*Merck Sharp & Dohme AG*; [2]*Yale University School of Medicine*; [3]*Merck & Co., Inc.*; [4]*University of Colorado Skaggs School of Pharmacy and Pharmaceutical Sciences*

34 Lipid-lowering therapy patterns of high-risk cardiovascular patients without prior myocardial infarction or stroke: VESALIUS-REAL—Results from patients with high-risk diabetes in the US

Chan Q[1], *Sakhuja S*[2], *Ochs A*[1], *Dhalwani N*[2], *Brooks C*[2], *Shannon E*[2], *Paiva Da Silva Lima G*[2], *Avcil S*[2], *Budoff M*[3], *Wong I*[4]; *qchan@amgen.com*
[1]*Amgen Ltd.*; [2]*Amgen Inc.*; [3]*Interventional and Preventive Cardiology, Lundquist Institute, Torrance, CA, USA*; [4]*Department of Pharmacology and Pharmacy, University of Hong Kong, Hong Kong and Aston Pharmacy School, Aston University, Birmingham, UK*

35 Excess cardiovascular events and healthcare resource utilization with lack of lipid lowering therapy in US adults with or at risk of atherosclerotic cardiovascular disease

Muntner P[1], *Ke X*[2], *Bash L*[2], *Wilson M*[3], *Yang X*[4], *Coderch Lanau R*[3], *Were J*[4], *Molnar N*[2], *Kohli P*[5]; *pmuntner@perisphere-rwe.com*; *lori_bash@merck.com*
[1]*Perisphere Real World Evidence, LLC.*; [2]*Merck & Co., Inc.*; [3]*Parexel International, Ltd., Durham, North Carolina, United States*; [4]*Parexel International, Ltd., London, United Kingdom*; [5]*Department of Medicine, Johns Hopkins University*

36 Healthcare resource use and costs among US patients are higher after a second ASCVD event than after a first

Marsolo K[1], *Thomas L*[2], *Solomon N*[3], *Victores A*[4], *Bash L*[4], *Galvain T*[5], *Pagidipati N*[1]; *keith.marsolo@duke.edu*; *lori_bash@merck.com*
[1]*Duke Clinical Research Institute, Duke University School of Medicine*; [2]*Duke University School of Medicine*; [3]*Duke Clinical Research Institute*; [4]*Merck & Co., Inc.*; [5]*Merck Sharp & Dohme AG*

37 Dose titration among patients receiving vericiguat in real-world clinical practice and association with clinical outcomes and health care resource use

Obi E[1], *Ambrosy A*[2], *Done N*[3], *Bali V*[1], *Song Y*[4], *Nason I*[4], *Stevenson A*[1], *Pfefferkorn J*[4], *Sears E*[4], *Signorovitch J*[4], *Lala A*[5]; *engels.obi@merck.com*; *Andrew.P.Ambrosy@kp.org*
[1]*Merck & Co., Inc.*; [2]*Kaiser Permanente Northern California*; [3]*Analysis Group*; [4]*Analysis Group, Inc*; [5]*The Mount Sinai Fuster Heart Hospital, Icahn School of Medicine*

38 Rilonacept reduces pericarditis recurrence risk: clinical outcomes from the RESONANCE patient registry

Khan A[1], *Cremer P*[2], *Garshick M*[3], *Luis S*[4], *Raisinghani A*[5], *Weber B*[6], *Rahme S*[4], *Salik J*[7], *Ryan J*[8], *Parameswaran V*[1], *Clair J*[1], *Curtis A*[1], *Klein A*[9], *Paolini J*[1]; *akhan@kiniksa.com*; *paul.cremer@nm.org*
[1]*Kiniksa Pharmaceuticals*; [2]*Northwestern University*; [3]*NYU Langone Health*; [4]*Mayo Clinic*; [5]*UC San Diego*; [6]*Brigham and Women's Hospital*; [7]*Massachusetts General Hospital*; [8]*University of Utah Health*; [9]*Cleveland Clinic*

Central Nervous System

63 Efficacy and safety of AXS-05 in Alzheimer's disease agitation: Results from ACCORD-2, a phase 3 randomized withdrawal double-blind placebo-controlled study

Cummings J[1], *Grossberg G*[2], *Streicher C*[3], *DePue R*[3], *Tabuteau H*[3]; *jcummings@cnsinnovations.com*; *rdepue@axsome.com*
[1]*University of Nevada, Las Vegas, Las Vegas, NV, USA*; [2]*Saint Louis University School of Medicine, St Louis, MO, USA*; [3]*Axsome Therapeutics Inc., New York, NY, USA*

64 Outcomes following initiation of amantadine DR/ER (Gocovri) in patients with Parkinson disease: Evaluation of the American Academy of Neurology Axon Registry database

Grall M[1], *Crouse N*[1], *Formella A*[2], *Zwick E*[3], *Moss H*[3]; *mgrall@supernus.com*
[1]*Supernus Pharmaceuticals Inc.*; [2]*Supernus Pharmaceuticals*; [3]*Verana Health*

65 High rates of discontinuation of D2 receptor antagonists as treatment of Tourette syndrome in children: A retrospective database analysis

Tomczak K[1], *Swindle J*[2], *Dabbous F*[3], *Karkanias G*[4], *Atkinson S*[4], *Munschauer F*[4], *Mazhar F*[3], *Pettersson C*[3], *Wanaski S*[5], *Cunniff T*[5], *Isaacs D*[6]; *Kinga.Tomczak@childrens.harvard.edu*; *gkarkanias@emalexbiosciences.com*
[1]*Tic Disorders and Tourette Syndrome Program, Department of Neurology, Boston Children's Hospital*; [2]*Thermo Fisher Scientific (at time study was conducted)*; [3]*Thermo Fisher Scientific*; [4]*Emalex Biosciences, Inc.*; [5]*Paragon Biosciences, LLC*; [6]*Department of Neurology, Vanderbilt University Medical Center*

66 Valbenazine improves physical, social, and emotional impacts on the Tardive Dyskinesia Impact Scale (TDIS): Post hoc analyses of KINECT-PRO data

Dunayevich E[1], *Perez-Rodriguez M*[2], *Aldrich K*[1], *Farber R*[1], *Parameswaran A*[1], *Turner M*[1], *Bron M*[1], *Franey E*[1], *Sparta D*[1], *Gao S*[1], *Cyriac R*[1], *Mathias S*[3], *Correll C*[4]; *eduardo.dunayevich@gmail.com*; *rcyriac@neurocrine.com*
[1]*Neurocrine Biosciences, Inc.*; [2]*Icahn School of Medicine at Mount Sinai*; [3]*Health Outcomes Solutions*; [4]*The Zucker Hillside Hospital; The Donald and Barbara Zucker School of Medicine at Hofstra/Northwell; Charité Universitätsmedizin*

67 Comparison of amyloid-related imaging abnormalities risk for lecanemab versus donanemab and the potential implications

Sabbagh M[1], *Cohen S*[2], *Chao A*[3], *Betts K*[3], *Holub A*[4], *Burke A*[1], *van Dyck C*[5]; *marwan.sabbagh@commonspirit.org*
[1]*Barrow Neurological Institute*; [2]*Toronto Memory Program*; [3]*Analysis Group Inc.*; [4]*Analysis Group*; [5]*Yale School of Medicine*

68 Effect of selumetinib treatment on long-term pain medication utilization in pediatric patients: A retrospective study of a US claims database

Meade J[1], *Lyons G*[2], *Anand A*[3], *Sicilia M*[3], *van der Pluijm W*[3], *Bowling A*[2], *Guikema B*[4], *Dettling T*[2]; *julia.meade@chp.edu*
[1]*UPMC Children's Hospital of Pittsburgh*; [2]*Alexion Pharmaceuticals Inc*; [3]*Forian Inc*; [4]*KalVista Pharmaceuticals, Inc*

69 Drug-drug interactions with vesicular monoamine transporter 2 inhibitors: Population estimate of patients with tardive dyskinesia at risk in real-world clinical practice

Mychaskiw M[1], *Ghibellini G*[2], *Dotiwala Z*[3], *Konings M*[4], *Gandhi P*[5], *Casciano J*[3]; *Marko.Mychaskiw@tevapharm.com*; *Pooja.Gandhi02@tevapharm.com*
[1]*Teva Branded Pharmaceutical Products R&D LLC., Global Health Economics and Outcomes Research, West Chester, PA, United States*; [2]*Teva Branded Pharmaceutical Products R&D LLC., Clinical Pharmacology, West Chester, PA, United States*; [3]*eMAX Health Systems, LLC, Delray Beach, FL, United States*; [4]*Teva Branded Pharmaceutical Products R&D LLC, Global Medical Affairs, Parsippany, NJ, United States*; [5]*Teva Branded Pharmaceutical Products R&D LLC, North America Medical Affairs, Parsippany, NJ, United States*

70 Changes in motor states throughout the waking day with Tavapadon in people with Parkinson's disease

Hauser R[1], *Pahwa R*[2], *Harmer L*[3], *Lind A*[3]; *rhauser@usf.edu*
[1]*USF Parkinson's Disease and Movement Disorders Center*; [2]*University of Kansas Medical Center*; [3]*AbbVie*

71 Long-term persistence and patient characteristics for lecanemab in real-world use in the United States

Brixner D[1], *Zhao C*[2], *Toyosaki H*[2], *Frech F*[2], *Rosenbloom M*[3]; *diana.brixner@utah.edu*
[1]*University of Utah*; [2]*Eisai Inc.*; [3]*University of Washington*

Dermatology

100 The economic impact of ustekinumab in the treatment of psoriasis: A targeted literature review

Shastri K[1], *Ren S*[2], *Clarke K*[3], *Ainslie-Garcia M*[3], *Ferko N*[3]; *kunal.shastri@fresenius-kabi.com*; *steven.ren@fresenius-kabi.com*
[1]*Fresenius Kabi, SwissBioSim GmbH*; [2]*Fresenius Kabi USA, LLC*; [3]EVERSANA

101 Generalized pustular psoriasis: A systematic literature review of mortality and comorbidity data

Lebwohl M[1], *Strober B*[2], *Choon S*[3], *Puig L*[4], *Warren R*[5], *Morita A*[6], *Pillai N*[7], *Lakshminarasimhan B*[7], *Khan S*[7], *Sani Simoes R*[7], *Zheng M*[8]; *Lebwohl@aol.com*
[1]*Icahn School of Medicine at Mount Sinai, New York, NY, USA*; [2]*Yale University School of Medicine, New Haven, CT, and Central Connecticut Dermatology, Cromwell, CT, USA*; [3]*Hospital Sultanah Aminah Johor Bahru, Clinical School Johor Bahru, Monash University, Subang Jaya, Malaysia*; [4]*Hospital de la Santa Creu i Sant Pau, Barcelona, Spain*; [5]*Dermatology Centre, Northern Care Alliance NHS Foundation Trust, Salford Royal, Salford, UK, and NIHR Manchester Biomedical Research Centre, Manchester University Hospitals NHS Foundation Trust, Manchester Academic Health Science Centre, Manchester, UK*; [6]*Department of Geriatric and Environmental Dermatology, Nagoya City University Graduate School of Medical Sciences, Nagoya, Japan*; [7]*Boehringer Ingelheim International GmbH, Ingelheim am Rhein, Germany*; [8]*The Second Affiliated Hospital, Zhejiang University, School of Medicine, Hangzhou, Zhejiang, China*

102 Better improvement for omalizumab versus dupilumab/remibrutinib for patients with chronic spontaneous urticaria: Week 12 disease activity matching adjusted indirect comparison

Raimundo K[1], *Mosnaim G*[2], *Holden M*[1], *Trzaskoma B*[1], *Raut P*[1], *Seetasith A*[1], *Bernstein J*[3]; *raimundo.karina@gene.com*
[1]*Genentech, Inc.*; [2]*Endeavor Health*; [3]*University of Cincinnati*

103 Impact of apremilast on work productivity in patients with early oligoarticular psoriatic arthritis

Kavanaugh A[1], *Ogdie A*[2], *Colgan S*[3], *Teng L*[3], *Wang R*[3], *Deignan C*[3], *Mease P*[4], *Lyons A*[3]; *akavanaugh@health.ucsd.edu*; *lyonsa@amgen.com*
[1]*UC San Diego*; [2]*University of Pennsylvania*; [3]*Amgen Inc*; [4]*Swedish Medical Center*

104 Real-world effect of ruxolitinib cream: decreased use of additional topical therapies and limited escalation to systemic treatments

Liu J[1], *Desai K*[2], *Teng C*[2], *Stockbower G*[2], *Chen P*[2], *Willey V*[2], *Sturm D*[1]; *JinLiu@incyte.com*
[1]*Incyte Corporation*; [2]*Carelon Research*

105 Prevalence and advanced systemic treatment prescription patterns for scalp psoriasis in the real-world dermatology setting in the United States

Chovatiya R[1], *Stephenson B*[2], *Rasouliyan L*[3], *Strober B*[4]; *raj.chovatiya@gmail.com*; *bstephenson@arcutis.com*
[1]*Chicago Medical School, Rosalind Franklin University of Medicine and Science, North Chicago, IL and Center for Medical Dermatology + Immunology Research, Chicago, IL*; [2]*Arcutis Biotherapeutics, Inc. Westlake Village, CA*; [3]*OMNY Health, Atlanta, GA*; [4]*Yale University School of Medicine, New Haven, CT, and Central Connecticut Dermatology, Cromwell, CT, USA*

106 Once-daily roflumilast cream 0.15% and 0.05% improve atopic dermatitis signs and symptoms that can be maintained with proactive twice-weekly treatment: 52-week phase 3 INTEGUMENT-OLE trial results in patients aged ≥2 years

Hebert A[1], *Eichenfield L*[2], *Paller A*[3], *Simpson E*[4], *Golant A*[5], *DiRuggiero D*[6], *Krupa D*[7], *Seal M*[7], *Hanna D*[7], *Stephenson B*[7]; *adelaide.a.hebert@uth.tmc.edu*; *bstephenson@arcutis.com*
[1]*UTHealth McGovern Medical School, Houston, TX*; [2]*Rady Children's Hospital–San Diego and University of California San Diego School of Medicine, San Diego, CA*; [3]*Northwestern University Feinberg School of Medicine, Chicago, IL*; [4]*Oregon Health & Science University, Portland, OR*; [5]*Icahn School of Medicine at Mount Sinai, New York, NY*; [6]*Skin Cancer and Cosmetic Dermatology Center, Rome, GA*; [7]*Arcutis Biotherapeutics, Inc. Westlake Village, CA*

Drug Princing, Payment, and Reimbursement

118 Estimating incident and prevalent essential thrombocythemia patients eligible for cytoreductive therapies in the US and Canada

Downey K[1], *Zimmerman C*[1], *Lavu A*[2], *Hummel N*[3]; *Kyle_Downey@pharmaessentia.com*
[1]*PharmaEssentia USA Corporation*; [2]*Certara*; [3]*Certara GmbH*

Endocrine and Metabolic

130 Patient- and caregiver-reported experience with acquired hypothalamic obesity in the TRANSCEND trial

Roth C[1], *Phillips S*[2], *McCormack S*[3], *Larson Ode K*[4], *Kelsey M*[5], *Liu J*[6], *Miller E*[7], *Mallya U*[8], *Norcross L*[7], *Miller J*[9]; *christian.roth@seattlechildrens.org*; *jliu@rhythmtx.com*
[1]*Seattle Children's Research Institute; Seattle Children's Hospital*; [2]*Rady Children's Hospital, University of California at San Diego, San Diego, CA, United States*; [3]*Division of Endocrinology and Diabetes, Children's Hospital of Philadelphia, Philadelphia, PA, United States; Department of Pediatrics, Perelman School of Medicine at the University of Pennsylvania, Philadelphia, PA, United States*; [4]*Department of Pediatrics, University of Iowa–Stead Family Children's Hospital, Fraternal Order of Eagles Diabetes Research Center, University of Iowa, Iowa City, IA, United States*; [5]*Department of Pediatrics, University of Colorado School of Medicine and Children's Hospital Colorado, Aurora, CO, United States*; [6]*Rhythm Pharmaceuticals*; [7]*RTI Health Solutions, Durham, NC, United States*; [8]*Rhythm Pharmaceuticals, Inc. Boston, MA*; [9]*Pediatric Endocrinology, Department of Pediatrics, University of Florida College of Medicine, Gainesville, FL, USA*

131 Clinical characteristics of patients with obesity secondary to different MC4R pathway diseases and 1-year response to setmelanotide

Collins J[1], *Roth C*[2], *Clément K*[3], *Abuzzahab J*[4], *Farooqi S*[5], *Okorie U*[6], *Argente J*[7], *Forsythe E*[8], *van den Akker E*[9], *Miller J*[10], *Malhotra S*[11], *Garrison J*[11], *Dubern B*[12], *Dollfus H*[13]; *jcollins@rhythmtx.com*; *christian.roth@seattlechildrens.org*
[1]*Rhythm Pharmaceuticals*; [2]*Seattle Children's Research Institute; Seattle Children's Hospital*; [3]*Sorbonne Université, Paris, France; Pitié-Salpêtrière Hospital, Paris, France*; [4]*Pediatric Endocrinology and Diabetes, Children's Minnesota, Saint Paul, MN, USA*; [5]*University of Cambridge, Cambridge, UK*; [6]*Department of Pediatrics, Marshfield Clinic, Marshfield, WI, USA*; [7]*Hospital Infantil Universitario Niño Jesús, Madrid, Spain; Universidad Autónoma de Madrid, Madrid, Spain*; [8]*UCL Great Ormond Street Institute of Child Health, London, UK*; [9]*Erasmus University Medical Center, Rotterdam, The Netherlands*; [10]*Pediatric Endocrinology, Department of Pediatrics, University of Florida College of Medicine, Gainesville, FL, USA*; [11]*Rhythm Pharmaceuticals, Inc. Boston, MA*; [12]*Hopital Trousseau, Paris, France*; [13]*Hôpitaux Universitaires de Strasbourg and Université de Strasbourg, Strasbourg, France*

132 Impact of obesity on employee retention in self-insured employer health plans

Bentz B[1], Naber J[2], Kuester M[2], Chmura L[2], Vallarino C[1], Hankosky E[1], Ward J[1], Tian H[1], Dell S[1], Xue J[1]; bobbi.bentz@lilly.com; JIAYIN.XUE@LILLY.COM
[1]*Eli Lilly and Company*; [2]*Milliman, Inc.*

133 Real-world trends in sodium-glucose co-transporter 2 inhibitor (SGLT2I) use in Medicaid: Expanding use beyond diabetes to cardio-renal populations

Atanda A[1], Rasu R[2], Lenear A[3], Zhang Y[4], Zhou B[1], Sambamoorthi U[5]; Adenike.atanda@unthsc.edu; rafia.rasu@unthsc.edu
[1]*UNT System College of Pharmacy*; [2]*University of North Texas Health Sciences Center*; [3]*Methodist Charlton Medical Center*; [4]*UNT Health Fort Worth*; [5]*UNT Health*

134 Obesity-related work impairment in people with obesity treated with tirzepatide and those not currently prescribed obesity management medications

Raikar S[1], Gibble T[1], Leith A[2], Harrison L[2], Gerber C[1], Artime E[1]; sonya.raikar@lilly.com; hunter_theresa_marie@lilly.com
[1]*Eli Lilly and Company*; [2]*Adelphi Real World*

Eye (or Ophthalmic)

158 Short- and long-term adherence and patient characteristics of adopters of perfluorohexyloctane in dry eye disease

Nair A[1], Manjelievskaia J[2], Cheng J[2], Nelson J[2], Coenen N[2], Bonafede M[2], Alexander A[1]; abhisheknairxi@gmail.com
[1]*Bausch and Lomb Americas Inc.*; [2]*Veradigm*

160 Real-world adherence patterns of latanoprostene bunod ophthalmic solution 0.024% in Medicare patients with comorbid dry eye disease

Sawhney G[1], Talwar A[2], Donckels E[3], Huang Y[3], Davis T[4], Brevetti T[2], Nair A[2]; gsawhney@gmail.com; ashna.talwar@bausch.com
[1]*Georgia Eye Partners*; [2]*Bausch+Lomb*; [3]*Inovalon*; [4]*Inovalon Inc.*

Gastrointestinal

163 Accessing escalated risankizumab in Crohn's disease: How long does it take?

Zuckerman A[1], Nichols P[2], Dalal R[3], Gargurevich N[4]; patrick.j.nichols@vumc.org
[1]*Vanderbilt Specialty Pharmacy*; [2]*Vanderbilt Health, Vanderbilt Specialty Pharmacy*; [3]*Vanderbilt University Medical Center*; [4]*VUMC Biostatistics*

164 Characteristics of older adults in the United States enrolled in Medicare fee-for-service with Crohn's disease and factors associated with advanced therapy selection

Kochar B[1], Abramovitz L[2], Lloyd J[2], Banks J[2], Garduno A[2], Gravlee E[3], Brown J[4], Null K[4], Young L[4], Sanchirico M[4], Faye A[5]; bkochar@mgh.harvard.edu; lisa.young@takeda.com
[1]*Division of Gastroenterology, Massachusetts General Hospital, Boston, MA 02114, USA; The Mongan Institute, Boston, MA 02114, USA; and Harvard Medical School, Boston, MA 02115, USA*; [2]*Avalere Health, Washington, DC 20005, USA*; [3]*Alfred E. Mann School of Pharmacy and Pharmaceutical Sciences, University of Southern California, Los Angeles, CA, USA*; [4]*Takeda Pharmaceuticals U.S.A., Inc., Cambridge, MA, USA*; [5]*NYU Langone Health, New York, NY 10016, USA*

165 Characteristics of older adults in the United States enrolled in Medicare fee-for-service with ulcerative colitis and factors associated with advanced therapy selection

Faye A[1], Abramovitz L[2], Lloyd J[2], Banks J[2], Garduno A[2], Gravlee E[3], Brown J[4], Null K[4], Young L[4], Sanchirico M[4], Kochar B[5]; Adam.Faye@nyulangone.org; joshua.brown@takeda.com
[1]*NYU Langone Health, New York, NY 10016, USA*; [2]*Avalere Health, Washington, DC 20005, USA*; [3]*Alfred E. Mann School of Pharmacy and Pharmaceutical Sciences, University of Southern California, Los Angeles, CA, USA*; [4]*Takeda Pharmaceuticals U.S.A., Inc., Cambridge, MA, USA*; [5]*Division of Gastroenterology, Massachusetts General Hospital, Boston, MA 02114, USA; The Mongan Institute, Boston, MA 02114, USA; and Harvard Medical School, Boston, MA 02115, USA*

166 Patient characteristics and treatment patterns among patients using resmetirom in the real-world setting

Atreja N[1], Bansal M[2], Rava A[3], Gutierrez C[3], Sun H[3], Van Voorhis D[3], Bruce L[3], MacEwan J[3], Thomas B[1], Lobo F[1], O'Donnell J[1]; natreja@madrigalpharma.com; meena.bansal@mssm.edu
[1]*Madrigal Pharmaceuticals*; [2]*Icahn School of Medicine at Mount Sinai*; [3]*Genesis Research Group*

167 Comparative persistence of advanced therapies for inflammatory bowel disease among older adults in the United States enrolled in Medicare fee-for-service

Faye A[1], Abramovitz L[2], Lloyd J[2], Banks J[2], Garduno A[2], Gravlee E[3], Brown J[4], Null K[4], Young L[4], Sanchirico M[4], Kochar B[5]; Adam.Faye@nyulangone.org; marie.sanchirico@takeda.com
[1]*NYU Langone Health, New York, NY 10016, USA;* [2]*Avalere Health, Washington, DC 20005, USA;* [3]*Alfred E. Mann School of Pharmacy and Pharmaceutical Sciences, University of Southern California, Los Angeles, CA, USA;* [4]*Takeda Pharmaceuticals U.S.A., Inc., Cambridge, MA, USA;* [5]*Division of Gastroenterology, Massachusetts General Hospital, Boston, MA 02114, USA; The Mongan Institute, Boston, MA 02114, USA; and Harvard Medical School, Boston, MA 02115, USA*

168 Effect of disease severity on histologic, dysphagia, and endoscopic outcomes in patients with eosinophilic esophagitis: Post hoc analysis from a phase 3 trial of budesonide oral suspension

Dellon E[1], Collins M[2], Falk G[3], Gonsalves N[4], Mukkada V[5], Goodman E[6], Gugiu C[7], Schaeffer-Koziol C[8], Terreri B[8], Katzka D[9]; evan_dellon@med.unc.edu; carolyn.schaeffer-koziol@takeda.com
[1]*Center for Esophageal Diseases and Swallowing, Division of Gastroenterology and Hepatology, Department of Medicine, University of North Carolina at Chapel Hill, Chapel Hill, NC, USA;* [2]*Division of Pathology and Laboratory Medicine, Department of Pediatrics, Cincinnati Children's Hospital Medical Center, Department of Pathology and Laboratory Medicine, University of Cincinnati College of Medicine, Cincinnati, OH, USA;* [3]*Division of Gastroenterology and Hepatology, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA, USA;* [4]*Kenneth C. Griffin Esophageal Center, Division of Gastroenterology and Hepatology, Department of Medicine, Northwestern University Feinberg School of Medicine, Chicago, IL, USA;* [5]*Division of Gastroenterology, Hepatology and Nutrition, Cincinnati Children's Hospital Medical Center, University of Cincinnati College of Medicine, Cincinnati, OH, USA;* [6]*Takeda Development Center Americas, Inc.;* [7]*Takeda Pharmaceuticals USA, Inc.;* [8]*Takeda Pharmaceuticals USA, Inc., Lexington, MA, USA;* [9]*Division of Digestive and Liver Diseases, New York-Presbyterian/Columbia University Irving Medical Center, New York, NY, USA*

Health Disparities/Equity

179 Efficacy of elinzanetant on menopause-related vasomotor symptoms/sleep disturbance in US African American women: Pooled analysis from 2 phase 3 trials

Neal-Perry G[1], Dunsmoor-Su R[2], Trigg A[3], Lee A[4], Zitko K[4], Al-Hendy A[5], Maki P[6]; genevieve_nealperry@med.unc.edu; kimberly.zitko@bayer.com
[1]*UNC-Chapel Hill;* [2]*Seattle Clinical Research;* [3]*Bayer plc;* [4]*Bayer;* [5]*University of Chicago;* [6]*UIC*

Health Policy

191 Removing insurance barriers to oral PrEP reduces HIV cases and costs in underserved US populations

Gursel E[1], Coaquira Castro J[2], Ayer T[3], Hsiao A[2], Zachry W[2], Edali M[4], Sullivan P[5]; egursel@valueanalyticslabs.com; JeanPierre.Coaquira@gilead.com
[1]*Value Analytics Labs, Boston, Massachusetts, United States;* [2]*Gilead Sciences, Inc., Foster City, California, United States;* [3]*Value Analytics Labs, Boston, Massachusetts, United States; AND Georgia Institute of Technology, Atlanta, Georgia, United States;* [4]*Value Analytics Labs, Boston, Massachusetts, United States; AND Yildiz Technical University, Istanbul, Turkey;* [5]*Emory University, Atlanta, Georgia, United States*

Immunology

209 Improvement in ulcerative colitis outcomes after mirikizumab induction therapy in real-world settings

Berggreen P[1], Vadhariya A[2], Fisher D[2], Bires N[2], Lazarou N[3], Smith N[3], Himes A[3], O'Donnell L[3], Balanean A[3], Grisik J[4], Chapman C[4], Lin A[2]; paul.berggreen@gialliance.com; alexandra.lin@lilly.com
[1]*GI Alliance, Arizona Digestive Health;* [2]*Eli Lilly and Company;* [3]*Cardinal Health;* [4]*GI Alliance, Gastroenterology Associates*

210 Matching-adjusted indirect comparison between garadacimab and donidalorsen for long-term prophylaxis in hereditary angioedema

Samjoo I[1], Gavata-Steiger S[2], Walsh S[1], Haltner A[1], Sears J[2], Li Y[2], Alvarez-Reyes M[3], Van Beurden-Tan C[4], Campioni M[4], Donohue C[2]; Imtiaz.Samjoo@Eversana.com; christine.donohue@cslbehring.com
[1]*Eversana;* [2]*CSL;* [3]*MARCP Ltd, UK;* [4]*Vifor*

211 Dupilumab effectiveness through two years in patients with CRSwNP treated in real-world practice: Results from the global AROMA registry

Hudspeth L[1], *Peters A*[2], *Pinto J*[2], *De Corso E*[3], *Wagenmann M*[4], *Fujieda S*[5], *Xia C*[6], *McGraw M*[7], *Corbett M*[8], *Nara J*[8], *Radwan A*[7]; *Louis.Hudspeth@sanofi.com*; *anjupeters@northwestern.edu*
[1]*Genzyme Corporation*; [2]*Professor, Northwestern University Feinberg School of Medicine, Chicago, IL, USA*; [3]*Gemelli Hospital Foundation IRCCS Rome*; [4]*Dept. of Otorhinolaryngology*; [5]*Department of Otorhinolaryngology*; [6]*Regeneron Pharmaceuticals Inc., Tarrytown, NY, USA*; [7]*Regeneron*; [8]*Sanofi*

212 Improved outcomes, emergency visits, and quality of life for patients with food allergy on omalizumab monotherapy

Seetasith A[1], *Kim E*[2], *Sindher S*[3], *Dawod F*[4], *Mooney O*[4], *Lukanova R*[4], *Sibanda D*[1], *Greenhawt M*[5]; *seetasith.arpamas@gene.com*
[1]*Genentech, Inc.*; [2]*University of North Carolina*; [3]*Stanford University*; [4]*Adelphi Real World*; [5]*Children's Hospital Colorado*

Infectious Disease

226 Perspectives on treatment with long-acting cabotegravir + rilpivirine injectable therapy from people with human immunodeficiency virus in the United States with prior adherence challenges to oral antiretroviral therapy: Long-acting therapy preference

Henry Z[1], *Kirk S*[2], *Brownlee M*[3], *Herrmann M*[4], *Zayas S*[5], *Mycock K*[6], *Reynolds N*[6], *Wallis H*[6], *Amet M*[6], *Linskey A*[7], *Patarroyo J*[7], *Merrill D*[7], *Overton E*[7], *Garris C*[7], *Brogan A*[7]; *cindy.p.garris@viivhealthcare.com*
[1]*AIDS Healthcare Foundation – Northpoint, Fort Lauderdale*; [2]*Division of Infectious Diseases, Department of Medicine, Medical University of South Carolina*; [3]*Wellness Homes of Chicago*; [4]*AIDS Healthcare Foundation – Westside*; [5]*Care Resource*; [6]*Adelphi Real World*; [7]*ViiV Healthcare*

227 Real-world effectiveness and tolerability of cabotegravir + rilpivirine long-acting in people living with human immunodeficiency virus type 1: A meta-analysis of real-world evidence

Orkin C[1], *Short W*[2], *Kolobova I*[3], *Danchenko N*[3], *Augusto I*[3], *Brown K*[3], *Sieverding M*[4], *Turner M*[5], *Hill S*[5], *Jacob I*[3], *Oglesby A*[3]; *alan.k.oglesby@viivhealthcare.com*
[1]*Queen Mary University of London*; [2]*Department of Infectious Diseases, University of Pennsylvania Perelman School of Medicine*; [3]*ViiV Healthcare*; [4]*GSK*; [5]*HEOR Ltd*

228 Real-world utilization and adherence of cabotegravir long-acting for human immunodeficiency virus pre-exposure prophylaxis in the United States: Results from the PrEPFACTS study using healthcare administrative claims data

Metzner A[1], *Herman G*[1], *Walko S*[1], *Martinez D*[1], *Nguyen C*[2], *Desai R*[3], *Shi S*[2], *Young-Xu L*[2], *DerSarkissian M*[2]; *shana.l.walko@viivhealthcare.com*
[1]*ViiV Healthcare*; [2]*Analysis Group, Inc.*; [3]*Groupe d'analyse, Ltée*

229 Improved adherence and viral control in real-world study of people with human immunodeficiency virus in the United States with adherence challenges on oral antiretroviral therapy switching to cabotegravir + rilpivirine long-acting

Short W[1], *Glassman R*[2], *Harbison C*[3], *Whitehead M*[4], *Mycock K*[5], *Reynolds N*[5], *Wallis H*[5], *Amet M*[5], *Linskey A*[6], *Patarroyo J*[6], *Merrill D*[6], *Overton E*[6], *Garris C*[6], *Brogan A*[6]; *andrew.p.brogan@viivhealthcare.com*
[1]*Department of Infectious Diseases, University of Pennsylvania Perelman School of Medicine*; [2]*Westchester Medical Center Health Network*; [3]*Prism Health North Texas*; [4]*AIDS Healthcare Foundation – Pensacola*; [5]*Adelphi Real World*; [6]*ViiV Healthcare*

Mental Health

242 Longitudinal trends in antipsychotic polypharmacy and associated outcomes in schizophrenia

Patel R[1], *Zhong Y*[2], *Gao W*[2], *Kim D*[3], *Appio J*[2], *Albright B*[4]; *doctor@rpatel.co.uk*
[1]*University of Cambridge*; [2]*Bristol Myers Squibb*; [3]*Bristol Myers Squibb; Gillings School of Global Public Health, University of North Carolina at Chapel Hill*; [4]*Sweetgrass Psychiatry; Medical University of South Carolina*

243 Healthcare resource utilization among adults with schizophrenia and negative symptoms: A real-world data study

Lipunova N[1], *Yeow J*[1], *Hadaya L*[1], *Palmer E*[1], *Surendran S*[1], *Sidovar M*[2], *Gillard K*[2]; *nadia.lipunova@holmusk.com*
[1]*Holmusk Technologies Inc.*; [2]*Bristol Myers Squibb*

244 Multivariable models reporting increased economic and humanistic burden among patients with epilepsy reporting focal seizures (FS) experiencing moderate to severe depression symptoms

Ong A[1], *Wagner J*[1], *Oak B*[2], *Smith B*[2], *Athavale A*[2], *Thornton D*[1]; *aong@xenon-pharma.com*
[1]*Xenon Pharmaceuticals Inc.*; [2]*Trinity Life Sciences*

245 Efficacy and safety of CTx-1301 in pediatric subjects with ADHD: Results from a phase 3, randomized, double-blind, placebo-controlled trial

Cattaneo M[1], Childress A[2], Brams M[3], Silva R[3], Koehn K[3]; mcattaneo@cingulate.com; drann87@aol.com
[1]Cingulate; [2]Center for Psychiatry and Behavioral Medicine, Inc; [3]Cingulate Therapeutics

246 Real-world use of xanomeline-trospium in schizophrenia: Patient characteristics and antipsychotic treatment patterns

Cutler A[1], Zhong Y[2], Gillard K[2], Appio J[2], Gao C[3], Laliberté F[4], Rubio J[5]; acutler@ajcmd.com
[1]SUNY Upstate Medical University; [2]Bristol Myers Squibb; [3]Analysis Group; [4]Groupe d'analyse; [5]Northwell Health

247 Healthcare resource utilization and cost burden in patients with schizophrenia with and without evidence of tardive dyskinesia

Patel R[1], Kim D[2], Gao W[3], Scott T[3], Cajigal A[3], Sidovar M[3]; doctor@rpatel.co.uk
[1]University of Cambridge; [2]Bristol Myers Squibb; Gillings School of Global Public Health, University of North Carolina at Chapel Hill; [3]Bristol Myers Squibb

248 Anxiolytic effects of dextromethorphan-bupropion (45 mg/105 mg): Post hoc analyses across trials in major depressive disorder

Strawn J[1], Alter S[2], Zeni C[2], Streicher C[3], Eglit G[4]; strawnjr@ucmail.uc.edu; salter@axsome.com
[1]University of Cincinnati; [2]Axsome Therapeutics, Inc., New York, NY, USA; [3]Axsome Therapeutics Inc., New York, NY, USA; [4]Axsome Therapeutics, Inc.

Musculoskeletal

261 Analyzing the economic impact of denosumab in the treatment of osteoporosis

Ren S[1], Shastri K[2], Jayawardena N[3], Griffin A[3], Ainslie-Garcia M[3]; steven.ren@fresenius-kabi.com
[1]Fresenius Kabi USA, LLC; [2]Fresenius Kabi, SwissBioSim GmbH; [3]EVERSANA

Oncology

267 A phase 2 study of participant-reported preference for pembrolizumab administered subcutaneously or intravenously

Casarini I[1], Kowalski D[2], Caglevic C[3], Yayla B[4], Sumbul A[5], Weber P[6], Castilla A[7], Bylicki O[8], Takagi T[9], McQuarrie K[10], Saraf S[10], Arunachalam A[10], Bhagwati N[10], Cohen G[11]; ignaciocasarini@gmail.com
[1]Hospital Houssay, Mar del Plata, Buenos Aires, B7600, Argentina; [2]Department of Lung Cancer and Thoracic Tumours, Maria Skłodowska-Curie National Research Institute of Oncology, Warsaw, 00-001, Poland; [3]Fundación Arturo López Pérez-Unidad de Investigación de Drogas Oncológicas, Santiago, 7500921, Chile; [4]Ege Üniversitesi Hastanesi, Bornova, 35100, Türkiye; [5]Adana Medical Park Seyhan Hastanesi-Medikal Onkoloji, Adana, 01140, Türkiye; [6]James Lind Centro de Investigación del Cáncer, Temuco, 4780000, Chile; [7]Fundación Respirar, Bueno Aires, C1426, Argentina; [8]Hôpital National d'Instruction des Armées Sainte Anne-Pneumology, Toulon, France and École du Val de Grace, Paris, 83000, France; [9]Tokyo Women's Medical University, Tokyo 164-8666, Japan; [10]Merck & Co., Inc., Rahway, NJ 07065, USA; [11]Life Groenkloof-Mary Potter Cancer Centre, Pretoria, 0181 South Africa

268 Estimating incidence and prevalence of polycythemia vera and associated eligibility for cytoreductive therapies in major US health plans

Downey K[1], Zimmerman C[1], Hummel N[2], Lavu A[3]; Kyle_Downey@pharmaessentia.com
[1]PharmaEssentia USA Corporation; [2]Certara GmbH; [3]Certara

269 Zongertinib in patients with pretreated HER2-mutant advanced NSCLC: Beamion LUNG-1

Heymach J[1], *Ruiter G*[2], *Ahn M*[3], *Girard N*[4], *Smit E*[5], *Planchard D*[6], *Wu Y*[7], *Cho B*[8], *Yamamoto N*[9], *Sabari J*[10], *Zhao Y*[11], *Tu H*[7], *Yoh K*[12], *Nadal E*[13], *Sadrolhefazi B*[14], *Rohrbacher M*[15], *von Wangenheim U*[16], *Eigenbrod-Giese S*[15], *Zugazagoitia J*[17]; *jheymach@mdanderson.org*
[1]*Department of Thoracic/Head and Neck Medical Oncology, Division of Cancer Medicine, University of Texas MD Anderson Cancer Center, Houston, TX, USA;* [2]*Department of Clinical Pharmacology; Department of Thoracic Oncology, Netherlands Cancer Institute, Amsterdam, The Netherlands;* [3]*Department of Hematology and Oncology, Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, Republic of Korea;* [4]*Institut Curie, Institut du Thorax Curie-Montsouris, Paris, France; Paris Saclay University, UVSQ, Versailles, France;* [5]*Department of Thoracic Oncology, Netherlands Cancer Institute, Amsterdam, the Netherlands; Department of Pulmonary Diseases, Leiden University Medical Center, Leiden, The Netherlands;* [6]*Department of Medical Oncology, Institut Gustave Roussy, Thoracic Group and International Centre for Thoracic Cancers, Villejuif, France; Faculty of Medicine, Paris-Saclay University, Paris, France;* [7]*Guangdong Lung Cancer Institute, Guangdong Provincial People's Hospital (Guangdong Academy of Medical Sciences), Southern Medical University, Guangzhou, China;* [8]*Division of Medical Oncology, Yonsei Cancer Center, Yonsei University College of Medicine, Seoul, Republic of Korea;* [9]*Department of Experimental Therapeutics, National Cancer Center Hospital, Tokyo, Japan;* [10]*Division of Medical Oncology, Perlmutter Cancer Center, New York University Langone Health, New York, NY, USA;* [11]*Department of Medical Oncology, The Affiliated Cancer Hospital of Zhengzhou University and Henan Cancer Hospital, Zhengzhou, China;* [12]*Department of Thoracic Oncology, National Cancer Center Hospital East, Kashiwa, Japan;* [13]*Thoracic Tumors Unit, Medical Oncology, Catalan Institute of Oncology (ICO), Bellvitge Biomedical Research institute (IDIBELL), L'Hospitalet, Barcelona, Spain;* [14]*Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT, USA;* [15]*Boehringer Ingelheim International GmbH, Ingelheim am Rhein, Germany;* [16]*Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach an der Riss, Germany;* [17]*Department of Medical Oncology, 12 de Octubre Hospital, Madrid, Spain*

270 Real-world treatment duration of ruxolitinib and use of transfusion among 2268 patients with myelofibrosis: An analysis of the Medicare fee-for-service claims database

Bose P[1], *Schwartz T*[2], *Repp J*[3], *Garduno A*[4], *Adams S*[2], *Naim A*[3], *Bhatt V*[3], *Yu J*[3]; *PBose@mdanderson.org*
[1]*The University of Texas MD Anderson Cancer Center;* [2]*Avalere Health;* [3]*Incyte Corporation;* [4]*Avalere Health, Washington, DC 20005, USA*

271 Ruxolitinib duration of treatment and effect on phlebotomy use among 2369 patients with polycythemia vera: A real-world analysis of the Medicare fee-for-service claims database

Pemmaraju N[1], *Garduno A*[2], *Repp J*[3], *Adams S*[4], *Schwartz T*[4], *Naim A*[3], *Bhatt V*[3], *Yu J*[3]; *NPemmaraju@mdanderson.org*
[1]*The University of Texas MD Anderson Cancer Center;* [2]*Avalere Health, Washington, DC 20005, USA;* [3]*Incyte Corporation;* [4]*Avalere Health*

272 Zongertinib in patients with previously treated HER2-mutant NSCLC and brain metastases at baseline: Beamion LUNG-1

Ruiter G[1], *Smit E*[2], *Soo R*[3], *Girard N*[4], *Planchard D*[5], *Ahn M*[6], *Nadal E*[7], *Wu Y*[8], *Zugazagoitia J*[9], *Yamamoto N*[10], *Cho B*[11], *Kim C*[6], *Park J*[12], *Yoh K*[13], *Sadrolhefazi B*[14], *Fernamberg K*[14], *Schroeter L*[15], *Heymach J*[16]; *g.ruiter@nki.nl*
[1]*Department of Clinical Pharmacology; Department of Thoracic Oncology, Netherlands Cancer Institute, Amsterdam, The Netherlands;* [2]*Department of Thoracic Oncology, Netherlands Cancer Institute, Amsterdam, the Netherlands; Department of Pulmonary Diseases, Leiden University Medical Center, Leiden, The Netherlands;* [3]*Department of Hematology-Oncology, National University Cancer Institute, Singapore;* [4]*Institut Curie, Institut du Thorax Curie-Montsouris, Paris, France; Paris Saclay University, UVSQ, Versailles, France;* [5]*Department of Medical Oncology, Institut Gustave Roussy, Thoracic Group and International Centre for Thoracic Cancers, Villejuif, France; Faculty of Medicine, Paris-Saclay University, Paris, France;* [6]*Department of Oncology, Lombardi Comprehensive Cancer Center, Georgetown University, Washington, DC, USA;* [7]*Thoracic Tumors Unit, Medical Oncology, Catalan Institute of Oncology (ICO), Bellvitge Biomedical Research institute (IDIBELL), L'Hospitalet, Barcelona, Spain;* [8]*Guangdong Lung Cancer Institute, Guangdong Provincial People's Hospital (Guangdong Academy of Medical Sciences), Southern Medical University, Guangzhou, China;* [9]*Department of Medical Oncology, 12 de Octubre Hospital, Madrid, Spain;* [10]*Department of Experimental Therapeutics, National Cancer Center Hospital, Tokyo, Japan;* [11]*Division of Medical Oncology, Yonsei Cancer Center, Yonsei*

University College of Medicine, Seoul, Republic of Korea; [12]*Macquarie Medical School, Macquarie University, Sydney, NSW, Australia*; [13]*Department of Thoracic Oncology, National Cancer Center Hospital East, Kashiwa, Japan*; [14]*Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT, USA*; [15]*Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach an der Riss, Germany*; [16]*Department of Thoracic/Head and Neck Medical Oncology, Division of Cancer Medicine, University of Texas MD Anderson Cancer Center, Houston, TX, USA*

289 Cost-effectiveness analysis of ribociclib vs abemaciclib as first-line treatments for postmenopausal women with HR+/HER2− advanced breast cancer: A Medicare perspective

Tarantino P[1], *Gadi V*[2], *Pathak P*[3], *Sopher G*[3], *Delea T*[4], *Stellato D*[4]; *paolo_tarantino@dfci.harvard.edu*
[1]*Dana-Farber Cancer Institute*; [2]*University of Illinois Cancer Center*; [3]*Novartis Pharmaceuticals Corporation*; [4]*Avalere Health*

290 Comparative cost-effectiveness of ribociclib vs palbociclib as first-line treatment for HR+/HER2− advanced breast cancer in postmenopausal women: Analysis from a Medicare perspective

Tarantino P[1], *Gadi V*[2], *Pathak P*[3], *Sopher G*[3], *Delea T*[4], *Stellato D*[4]; *paolo_tarantino@dfci.harvard.edu*
[1]*Dana-Farber Cancer Institute*; [2]*University of Illinois Cancer Center*; [3]*Novartis Pharmaceuticals Corporation*; [4]*Avalere Health*

Quality and Safety Programs

309 Evaluation of a quality of improvement program for the optimization of subcutaneous immune globulin therapy in primary immunodeficiency patients within a home infusion setting

Myers L[1], *Pratt E*[2], *Geoffroy C*[3], *O'Bryan E*[1], *Sheets J*[1]; *leslie.myers@csipharmacy.com*
[1]*CSI Pharmacy*; [2]*Acadiana Allergy*; [3]*CSI*

Real-World Evidence

323 Healthcare resource utilization with cariprazine versus lumateperone among patients with bipolar I depression

Ta J[1], *Hambrick A*[1], *Zanardo E*[2], *Laliberté F*[3], *Ripley S*[3], *Ma S*[4], *Parikh M*[1]; *jamie.ta@abbvie.com*; *aaron.hambrick@abbvie.com*
[1]*AbbVie*; [2]*Analysis Group, Inc.*; [3]*Groupe d'analyse*; [4]*Groupe d'analyse Ltée*

324 Real-world disability outcomes among patients treated with cariprazine versus quetiapine as adjunctive treatment for major depressive disorder

Nabulsi N[1], *Ripley S*[2], *Zanardo E*[3], *Spencer C*[4], *Laliberté F*[2], *Parikh M*[1]; *nadia.nabulsi@abbvie.com*
[1]*AbbVie*; [2]*Groupe d'analyse*; [3]*Analysis Group, Inc.*; [4]*Groupe d'analyse, Ltée*

325 Burden of illness and hematocrit (HCT) control among patients with high- and low-risk polycythemia vera receiving current standard of care treatment in the United States

Gerds A[1], *Fan Q*[2], *Jerry M*[3], *Cerretani A*[2], *Tran A*[3], *Hernandez L*[2]; *gerdsa@ccf.org*; *luis.hernandez3@takeda.com*
[1]*Cleveland Clinic Taussig Cancer Institute, Cleveland, OH, USA*; [2]*Takeda Pharmaceuticals America, Inc., Cambridge, MA, USA*; [3]*Merative, Ann Arbor, MI, USA*

326 Real-world observations on the use of immunoglobulin therapy in patients with multifocal motor neuropathy in a home infusion setting

Walton T[1], *Neal E*[1], *Sauerbrun C*[1], *Duruz E*[1], *Bruns J*[1], *Sheets J*[1], *Broyles R*[1], *Myers L*[1], *Way M*[1], *O'Bryan E*[1]; *timothy.walton@csipharmacy.com*; *jordan.bruns@csipharmacy.com*
[1]*CSI Pharmacy*

327 Prescribing patterns of subcutaneous immunoglobulin within a home infusion and specialty infusion pharmacy

Walton T[1], *Sauerbrun C*[1], *Duruz E*[1], *Way M*[1], *Sheets J*[1], *Broyles R*[1], *Myers L*[1], *O'Bryan E*[1]; *timothy.walton@csipharmacy.com*; *carol.sauerbrun@csipharmacy.com*
[1]*CSI Pharmacy*

328 Real-world characteristics and treatment patterns of patients with major depressive disorder initiating dextromethorphan-bupropion extended-release tablets, cariprazine, brexpiprazole, or esketamine

Muzyk A[1], *Syed F*[2], *Zeni C*[3], *Princic N*[4], *Richards M*[4], *Alter S*[3], *Zhao Y*[3]; *yzhao@axsome.com*
[1]*Campbell University College of Pharmacy and Health Sciences, Buies Creek, NC, USA and Duke University School of Medicine, Durham, NC, USA;* [2]*Division of General Internal Medicine, Duke University, Durham, NC, USA;* [3]*Axsome Therapeutics, Inc., New York, NY, USA;* [4]*Merative, Ann Arbor, MI, USA*

329 Clinical burden and unmet need in erythropoietic protoporphyria (EPP) and X-linked protoporphyria (XLP): A systematic literature review of symptoms, comorbidities, and treatments

Oak B[1], *Maher C*[1], *Silber A*[1], *Chin M*[2], *Hall M*[3], *Herod E*[2], *Amaefule A*[2], *Norregaard C*[2]; *boak@trinitylifesciences.com; aamaefule@discmedicine.com*
[1]*Trinity Life Sciences;* [2]*Disc Medicine;* [3]*Maria Hall Consulting*

330 Persistence to cariprazine versus other atypical antipsychotics in real-world treatment of bipolar I disorder and adjunctive treatment of major depressive disorder

Nabulsi N[1], *Ta J*[1], *Haile F*[1], *Zanardo E*[2], *Ripley S*[3], *Ma S*[4], *Laliberté F*[3], *Parikh M*[1]; *nadia.nabulsi@abbvie.com*
[1]*AbbVie;* [2]*Analysis Group, Inc.;* [3]*Groupe d'analyse;* [4]*Groupe d'analyse Ltée*

331 Comorbidities are a risk predictor of kidney disease progression among patients diagnosed with chronic kidney disease

Du C[1], *Erickson K*[2], *Modley B*[3], *Winkelmayer W*[2], *Fotheringham J*[4], *Zhang L*[1], *Steubl D*[5], *Wittrup-Jensen V*[6], *Akehurst R*[7]; *chengan.du@boehringer-ingelheim.com; villum.wittrup-jensen@boehringer-ingelheim.com*
[1]*Boehringer Ingelheim Pharmaceuticals, Inc.;* [2]*Baylor College of Medicine;* [3]*Leads Healthcare;* [4]*University of Sheffield;* [5]*Boehringer Ingelheim Pharma GmbH & Co. KG; Hospital Rechts der Isar, Technical University Munich;* [6]*Boehringer Ingelheim International GmbH;* [7]*Lumanity*

332 The utility of routinely collected non-invasive tests to assess mortality risk in a large real-world cohort of patients with metabolic dysfunction-associated steatohepatitis from the United States

Schattenberg J[1], *Aponte Torres Z*[2], *Raluy M*[3], *Yates M*[3], *Younes R*[4], *Sartini C*[4]; *joern.schattenberg@uks.eu*
[1]*Saarland University Medical Center;* [2]*Boehringer Ingelheim Pharmaceuticals, Inc.;* [3]*Thermo Fisher Scientific;* [4]*Boehringer Ingelheim International GmbH*

333 Real-world healthcare utilization and costs associated with using dextromethorphan-bupropion extended-release tablets versus branded comparators for the treatment of major depressive disorder

Citrome L[1], *Zhao Y*[2], *Zeni C*[2], *Princic N*[3], *Richards M*[3], *Alter S*[2], *Cutler A*[4]; *nntman@gmail.com; yzhao@axsome.com*
[1]*Psychiatry and Behavioral Sciences, School of Medicine, New York Medical College;* [2]*Axsome Therapeutics, Inc., New York, NY, USA;* [3]*Merative, Ann Arbor, MI, USA;* [4]*SUNY Upstate Medical University*

334 Retrospective review of the utilization and clinical monitoring of immunoglobulin therapy in patients with stiff-person syndrome in a home infusion and specialty pharmacy setting

Walton T[1], *Duruz E*[1], *Neal E*[1], *Sauerbrun C*[1], *Sheets J*[1], *Broyles R*[1], *Myers L*[1], *Way M*[1], *O'Bryan E*[1]; *timothy.walton@csipharmacy.com; elizabeth.duruz@csipharmacy.com*
[1]*CSI Pharmacy*

335 Healthcare costs for patients with major depressive disorder initiating dextromethorphan-bupropion extended-release tablets as a first or subsequent line of treatment

Cutler A[1], *Zhao Y*[2], *Zeni C*[2], *Princic N*[3], *Richards M*[3], *Alter S*[2], *Citrome L*[4]; *acutler@ajcmd.com; yzhao@axsome.com*
[1]*SUNY Upstate Medical University;* [2]*Axsome Therapeutics, Inc., New York, NY, USA;* [3]*Merative, Ann Arbor, MI, USA;* [4]*Psychiatry and Behavioral Sciences, School of Medicine, New York Medical College*

336 Real-world polypharmacy and healthcare resource utilization after early-line treatment with cannabidiol for Dravet syndrome, Lennox-Gastaut syndrome, and tuberous sclerosis complex

Sillah A[1], *Burn L*[1], *Faller R*[2], *Saurer T*[1], *Greco T*[1], *Shah S*[1], *Bennett K*[2], *Rathnayaka N*[2], *Navetta M*[1]; *Arthur.Sillah@jazzpharma.com*
[1]*Jazz Pharmaceuticals, Inc.;* [2]*Target RWE*

337 Persistence of cariprazine vs lumateperone among patients with bipolar I depression: A real-world claims-based study

Ta J[1], Zanardo E[2], Laliberté F[3], Ripley S[3], Ma S[4], Parikh M[1]; jamie.ta@abbvie.com; mousam.parikh@abbvie.com
[1]*AbbVie*; [2]*Analysis Group, Inc.*; [3]*Groupe d'analyse*; [4]*Groupe d'analyse Ltée*

338 Associations of eGFR decline with clinical outcomes in real world US patients with CKD

Erickson K[1], Modley B[2], Winkelmayer W[1], Fotheringham J[3], Zhang L[4], Du C[4], Steubl D[5], Wittrup-Jensen V[6], Akehurst R[7], Boersma C[8], Postma M[8]; kevin.erickson@bcm.edu; villum.wittrup-jensen@boehringer-ingelheim.com
[1]*Baylor College of Medicine*; [2]*Leads Healthcare*; [3]*University of Sheffield*; [4]*Boehringer Ingelheim Pharmaceuticals, Inc.*; [5]*Boehringer Ingelheim Pharma GmbH & Co. KG; Hospital Rechts der Isar, Technical University Munich*; [6]*Boehringer Ingelheim International GmbH*; [7]*Lumanity*; [8]*University of Groningen; Health-Ecore B.V.*

Respiratory

384 Effect of brensocatib on health-related quality of life in patients with non-cystic fibrosis bronchiectasis: Data from the ASPEN phase 3 trial

Flume P[1], Tolle J[2], Solomon G[3], Aliberti S[4], Wei X[5], Fastenau J[5], Fernandez C[5], Chalmers J[6]; flumepa@musc.edu; Carlos.Fernandez@Insmed.com
[1]*Medical University of South Carolina, Charleston, SC, United States of America*; [2]*Vanderbilt University Medical Center*; [3]*Division of Pulmonary, Allergy, and Critical Care Medicine, University of Alabama at Birmingham*; [4]*Department of Biomedical Sciences, Humanitas University*; [5]*Insmed Incorporated*; [6]*Division of Respiratory Medicine and Gastroenterology, University of Dundee, Dundee, United Kingdom*

385 Effects of nerandomilast in US patients with progressive pulmonary fibrosis (PPF) in the FIBRONEER-ILD trial

Nathan S[1], Maher T[2], Assassi S[3], Lievens D[4], Stowasser S[5], Gu H[4], Scholand M[6]; Steven.Nathan@inova.org
[1]*Inova Advanced Lung Disease and Transplant Program, Falls Church, Virginia, USA*; [2]*Keck School of Medicine, University of Southern California, Los Angeles, California, USA*; [3]*Division of Rheumatology, McGovern Medical School, UTHealth Houston, Houston, Texas, USA*; [4]*Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, Connecticut, USA*; [5]*Boehringer Ingelheim International GmbH, Ingelheim am Rhein, Germany*; [6]*Division of Respiratory, Critical Care, and Occupational Pulmonary Medicine, University of Utah Health, Salt Lake City, Utah, USA*

386 Effect of nerandomilast in US patients with idiopathic pulmonary fibrosis (IPF): Subgroup analysis of the FIBRONEER-IPF trial

Oldham J[1], Maher T[2], Liu Y[3], Olson A[3], Zoz D[3], Raghu G[4], Martinez F[5]; oldhamj@med.umich.edu; donald.zoz@boehringer-ingelheim.com
[1]*Pulmonary and Critical Care Medicine, University of Michigan, Ann Arbor, Michigan, USA*; [2]*Keck School of Medicine, University of Southern California, Los Angeles, California, USA*; [3]*Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, Connecticut, USA*; [4]*Center for Interstitial Lung Diseases, University of Washington, Seattle, Washington, USA*; [5]*University of Massachusetts (UMass) Chan Medical School/UMass Memorial Health System, Worcester, Massachusetts, USA*

387 A phase II study (CLAIRAFLY) to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of the dipeptidyl peptidase 1 (cathepsin C) inhibitor verducatib in adults with bronchiectasis due to cystic fibrosis

Mall M[1], *Davies J*[2], *Donaldson S*[3], *Fajac I*[4], *Glien M*[5], *Jain R*[6], *Li L*[7], *Rauch J*[8], *Rubin B*[9], *Shukla S*[8], *Sauter W*[10], *Schlange T*[11], *Chalmers J*[12]; *marcus.mall@charite.de*
[1]*Department of Pediatric Respiratory Medicine, Immunology and Critical Care Medicine, Charité – Universitätsmedizin Berlin, Berlin, Germany; German Center for Lung Research (DZL), associated partner site Berlin, Berlin, Germany; German Center for Child and Adolescent Health (DZKJ), partner site Berlin, Berlin, Germany; Cluster of Excellence ImmunoPreCept, Charité – Universitätsmedizin Berlin, Berlin, Germany;* [2]*National Heart and Lung Institute, Imperial College London, London, UK; Royal Brompton Hospital, part of Guy's & St Thomas' NHS Foundation Trust, London, United Kingdom;* [3]*Department of Medicine, Division of Pulmonary Diseases and Critical Care Medicine, The University of North Carolina at Chapel Hill, Chapel Hill, NC, United States of America;* [4]*Assistance Publique-Hôpitaux de Paris, Université Paris Cité, Paris, France;* [5]*Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach an der Riss, Germany;* [6]*Department of Internal Medicine, University of Texas Southwestern Medical Center, Dallas, TX, United States of America;* [7]*Boehringer Ingelheim (China) Investment Corporation Limited, Shanghai, People's Republic of China;* [8]*Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT, United States of America;* [9]*Virginia Commonwealth University School of Medicine, Richmond, VA, United States of America;* [10]*Boehringer Ingelheim International GmbH, Ingelheim am Rhein, Germany;* [11]*Boehringer Ingelheim Pharma GmbH & Co. KG, Ingelheim am Rhein, Germany;* [12]*Division of Respiratory Medicine and Gastroenterology, University of Dundee, Dundee, United Kingdom*

388 Efficacy and safety of brensocatib in patients with non-cystic fibrosis bronchiectasis and comorbid chronic obstructive pulmonary disease: A subgroup analysis of the ASPEN trial

Swenson C[1], *Chalmers J*[2], *De Soyza A*[3], *Haworth C*[4], *Fucile S*[5], *Wei X*[5], *Zhang X*[5], *Katz I*[5], *Teper A*[5]; *colin.swenson@emory.edu; Sebastian.Fucile@insmed.com*
[1]*Department of Medicine, Emory University School of Medicine;* [2]*Division of Respiratory Medicine and Gastroenterology, University of Dundee, Dundee, United Kingdom;* [3]*Population Health Sciences Institute Faculty of Medical Sciences Newcastle University;* [4]*Cambridge Centre for Lung Infection at Royal Papworth Hospital;* [5]*Insmed Incorporated*

389 Mepolizumab significantly reduces and delays chronic obstructive pulmonary disease exacerbations in a wide spectrum of patients: Pooled phase III trial results

Anzueto A[1], *Burrows E*[2], *Biswas A*[2], *Kraft M*[3], *Rabe A*[4], *Martinez F*[5]; *anzueto@uthscsa.edu*
[1]*University of Texas Health;* [2]*GSK;* [3]*Icahn School of Medicine at Mount Sinai;* [4]*GSK; Imperial College London;* [5]*University of Massachusetts (UMass) Chan Medical School/UMass Memorial Health System, Worcester, Massachusetts, USA*

390 Improved quality of life over 1 year in patients with asthma who initiate dupilumab in a real-world clinical setting: The RAPID registry

Gall R[1], *Peters A*[2], *Hilberg O*[3], *Ramsey A*[4], *Xia C*[1], *Awad H*[5], *Côté A*[6], *Gibson A*[7]; *rebecca.gall@regeneron.com; Alaina.Gibson@sanofi.com*
[1]*Regeneron Pharmaceuticals Inc., Tarrytown, NY, USA;* [2]*Professor, Northwestern University Feinberg School of Medicine, Chicago, IL, USA;* [3]*Lillebaelt Hospital, Vejle, Denmark and University of Southern Denmark, Odense, Denmark;* [4]*Rochester Regional Health, Rochester, NY, USA, and University of Rochester Medical Center, Rochester, NY, USA,;* [5]*Sanofi, Cambridge, MA, USA;* [6]*Quebec Heart and Lung Institute – Laval University, Québec City, QC, Canada;* [7]*Associate Director, Medical Value & Outcomes, Specialty Care at Sanofi, NJ, USA*

391 Efficacy and safety of brensocatib in patients with non-cystic fibrosis bronchiectasis by exacerbation history: Analysis of the ASPEN trial

Loebinger M[1], *Haworth C*[2], *Mauger D*[3], *Metersky M*[4], *Chalmers J*[5], *Lauterio M*[6], *Zhang X*[6], *Wei X*[6], *Teper A*[6], *Fernandez C*[6]; *michael.loebinger@nhs.net; Melanie.Lauterio@insmed.com*
[1]*Royal Brompton Hospital;* [2]*Cambridge Centre for Lung Infection at Royal Papworth Hospital;* [3]*Pennsylvania State University;* [4]*University of Connecticut School of Medicine;* [5]*Division of Respiratory Medicine and Gastroenterology, University of Dundee, Dundee, United Kingdom;* [6]*Insmed Incorporated*

392 Efficacy and safety of nerandomilast in the FIBRONEER trials in patients with idiopathic pulmonary fibrosis (IPF) and progressive pulmonary fibrosis (PPF)

Oldham J[1], *Assassi S*[2], *Azuma A*[3], *Cottin V*[4], *Hoffmann-Vold A*[5], *Kreuter M*[6], *Maher T*[7], *Richeldi L*[8], *Valenzuela C*[9], *Wijsenbeek M*[10], *Wachtlin D*[11], *Weimann G*[12], *Ritter I*[12], *Zoz D*[13], *Martinez F*[14]; *oldhamj@med.umich.edu*
[1]*Pulmonary and Critical Care Medicine, University of Michigan, Ann Arbor, Michigan, USA;* [2]*Division of Rheumatology, McGovern Medical School, UTHealth Houston, Houston, Texas, USA;* [3]*Clinical Research Center, Mihara General Hospital, Saitama, Japan, and Nippon Medical School, Tokyo, Japan;* [4]*National Reference Center for Rare Pulmonary Diseases, Louis Pradel Hospital, Hospices Civils de Lyon, Claude Bernard University Lyon 1, UMR 754, ERN-LUNG, Lyon, France;* [5]*Department of Rheumatology, Oslo University Hospital, Oslo, Norway, and Department of Rheumatology, University Hospital Zurich, University of Zurich, Zurich, Switzerland;* [6]*Center for Pulmonary Medicine, Department of Pneumology, Mainz University Medical Center and Pulmonary, Critical Care & Sleep Medicine, Marienhaus Clinic Mainz, Mainz, Germany;* [7]*Keck School of Medicine, University of Southern California, Los Angeles, California, USA;* [8]*Unità Operativa Complessa di Pneumologia, Fondazione Policlinico Universitario A. Gemelli IRCCS, Università Cattolica del Sacro Cuore, Rome, Italy;* [9]*Pulmonology Department, Hospital Universitario de la Princesa, Universidad Autónoma de Madrid, Madrid, Spain;* [10]*Center of Expertise for Interstitial Lung Diseases, Department of Respiratory Medicine, Erasmus MC, University Medical Centre, Rotterdam, The Netherlands;* [11]*Boehringer Ingelheim Pharma GmbH & Co. KG, Ingelheim am Rhein, Germany;* [12]*Boehringer Ingelheim International GmbH, Ingelheim am Rhein, Germany;* [13]*Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, Connecticut, USA;* [14]*University of Massachusetts (UMass) Chan Medical School/UMass Memorial Health System, Worcester, Massachusetts, USA*

393 Real-world outcomes after 2 years of dupilumab therapy for severe asthma: The ProVENT study

Patel N[1], *Lommatzsch M*[2], *Korn S*[3], *Schmidt O*[4], *Timmermann H*[5], *Gappa M*[6], *Watz H*[7], *Kwah J*[8], *Ledanois O*[1], *Nischan N*[1], *Hahn M*[1], *Heimann a*[1]; *nirav.patel2@sanofi.com*; *marek.lommatzsch@med.uni-rostock.de*
[1]*Sanofi;* [2]*University of Rostock;* [3]*IKF Pneumologie Mainz, Mainz, Germany;* [4]*Pneumologie Mittelrhein, Bendorf, Germany;* [5]*Allergologie, Lungen- und Bronchialheilkunde;* [6]*Klinik für Kinder- und Jugendliche;* [7]*Velocity Clinical Research;* [8]*Regeneron Pharmaceuticals Inc.*

394 Pooled data from phase II studies (AIRLEAF, CLAIRLEAF) of the dipeptidyl peptidase 1 (DPP1, or CatC) inhibitor verducatib in bronchiectasis

Shteinberg M[1], *Sauter W*[2], *Eleftheraki A*[3], *Chotirmall S*[4], *Flume P*[5], *Jain R*[6], *Morimoto K*[7], *O'Donnell A*[8], *Ringshausen F*[9], *Watz H*[10], *Xu J*[11], *Rauch J*[12], *Körsgen O*[3], *Mall M*[13], *Gupta A*[3], *Chalmers J*[14]; *michalsh@technion.ac.il*
[1]*Pulmonology Institute and Cystic Fibrosis Center, Carmel Medical Center, Haifa, Israel; Technion - Israel Institute of Technology, The B. Rappaport Faculty of Medicine, Haifa, Israel;* [2]*Boehringer Ingelheim International GmbH, Ingelheim am Rhein, Germany;* [3]*Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach an der Riss, Germany;* [4]*Lee Kong Chian School of Medicine, Nanyang Technological University, Singapore; Department of Respiratory and Critical Care Medicine, Tan Tock Seng Hospital, Singapore;* [5]*Medical University of South Carolina, Charleston, SC, United States of America;* [6]*Department of Internal Medicine, University of Texas Southwestern Medical Center, Dallas, TX, United States of America;* [7]*Fukujuji Hospital, Japan Anti-Tuberculosis Association, Tokyo, Japan;* [8]*Georgetown University Medical Center, Washington, DC, United States of America;* [9]*Department of Respiratory Medicine and Infectious Diseases, Hannover Medical School (MHH), Hannover, Germany; Biomedical Research in End-Stage and Obstructive Lung Disease Hannover (BREATH), German Center for Lung Research (DZL), Hannover, Germany; European Reference Network on Rare and Complex Respiratory Diseases (ERN-LUNG), Frankfurt, Germany;* [10]*Velocity Clinical Research Grosshansdorf GmbH, formerly Pulmonary Research Institute, LungenClinic, Airway Research Center North (ARCN), German Center for Lung Research (DZL), Grosshansdorf, Germany;* [11]*Tongji Hospital, Tongji University, Shanghai, China;* [12]*Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT, United States of America;* [13]*Department of Pediatric Respiratory Medicine, Immunology and Critical Care Medicine, Charité – Universitätsmedizin Berlin, Berlin, Germany; German Center for Lung Research (DZL), associated partner site Berlin, Berlin, Germany; German Center for Child and Adolescent Health (DZKJ), partner site Berlin, Berlin, Germany; Cluster of Excellence ImmunoPreCept, Charité - Universitätsmedizin Berlin, Berlin, Germany;* [14]*Division of Respiratory Medicine and Gastroenterology, University of Dundee, Dundee, United Kingdom*

395 Real-world use of solriamfetol for excessive daytime sleepiness in patients with obstructive sleep apnea in the US

Zhao Y[1], *Tran A*[2], *Varker H*[3], *Floam S*[4]; *yzhao@axsome.com*
[1]*Axsome Therapeutics, Inc., New York, NY, USA;* [2]*Merative, Ann Arbor, MI, USA;* [3]*Merative;* [4]*Axsome Therapeutics, Inc*

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409 Finding consensus on meaningful reporting measures for rheumatoid arthritis: Results from a modified Delphi study

Zuckerman A[1], Thomas K[2], Vest M[3], Rector A[4], DeClercq J[5]; autumn.zuckerman@vumc.org
[1]*Vanderbilt Specialty Pharmacy*; [2]*University of Illinois Chicago*; [3]ASHP; [4]*VA Tennessee Valley Healthcare System*; [5]*Vanderbilt University Medical Center*

410 Impact of expanding belzutifan to an integrated health-system specialty pharmacy

Renfro C[1], Looney B[2], Whitehead J[3], Faulkner C[1], Zuckerman A[4], DeClercq J[5], Choi L[6]; chelsea.renfro@vumc.org; brooke.d.looney@vumc.org
[1]*Vanderbilt Specialty Pharmacy, Vanderbilt Health*; [2]*Vanderbilt University Medical Center, Vanderbilt Specialty Pharmacy*; [3]VUMC; [4]*Vanderbilt Specialty Pharmacy*; [5]*Vanderbilt University Medical Center*; [6]*Vanderbilt University Medicine Center*

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