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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 2025. 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 2025. 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, Silver, and Bronze medals for the best abstracts submitted. The abstract reviewers for AMCP 2025 were as follows:

Peer Reviewers

Olajide Adekunle, MSc
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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, Silver, or Bronze medals.

Lockhart C, Dixon R, Venkataraman M, et al [C2] Real-world bevacizumab biosimilar uptake from 2018 to 2023 and outcomes among patients with non-small cell lung cancer and metastatic colorectal cancer using commercial and Medicare Advantage claims in the United States

Anatale-Tardiff L, Margiotta C, Swami S, et al [E18] Real-world trends in pharmacy utilization among commercially insured individuals treated with glucagon-like peptide-1 (GLP-1) receptor agonists, 2014-2024

Ganna S, Aparasu R, Khalid J, Tatar M [F2] Cost-Effectiveness of Dextromethorphan-Bupropion (Auvelity) Among Major Depressive Disorder Adult Patients

Quillen S, Yoo P [U17] Evaluating Medicaid brand-over-generic formulary strategies following the AMP cap removal

Tomassetti S, Kuypers N, Paulose J, et al [D3] Contemporary treatment patterns among real-world patients with paroxysmal nocturnal hemoglobinuria in the United States

Carlow D, Swift D, Rittgers-Simonds R, et al [E1] Association between tubeless automated insulin delivery and health care resource utilization and medical costs

Li J, Aparasu R [G9] Trends in Disease-Modifying Therapies Among Older Adults with Multiple Sclerosis over the Past Decade

Shamseddine N, Jones D, Mayo M, et al [K8] Determining clinically meaningful thresholds for patient-reported outcomes of pruritus in primary biliary cholangitis

Velez F, Brouwer E, Tan J [S1] Factors associated with post-discharge health care resource utilization following extremity arterial trauma treated with graft

Koenig M, Marjoram L, Huang Y, Cohen B, Anderson E [U1] Claims database analysis of health care resource utilization and associated medical costs in patients with Barth syndrome in the United States

Louie M, Hendrix N [U2] Payer Impacts of Revoked Accelerated Approvals in Oncology

Richardson T, Dellon E, McCormick D, Chan-Kai B, Pangrace M, Casebeer S [U3] Utilization Management Modifications Based on Regional Payer-Provider Roundtable Discussions

Gangoo-Dookhan T, Santibañez M, Pham H, et al [Z2] Evaluating the impact of a training-based program on social determinants of health for health care professionals

Jhamb S, Gauni R, Brastad S, Caron B [Z3] Evaluation and comparison of traditional approaches versus machine learning techniques for assessing resource utilization among polypharmacy members using real-world data

Wescott S, Gupta R, Haumschild R, et al [Z6] Managed Care Perspectives and Health Plan Best Practices in Food Allergy Management: AMCP Market Insights Program

Medal-Winning Abstracts

Shadman M, Fakhri B, Manzoor B, et al [C21] The Economic Impact of Treatment Sequences for Chronic Lymphocytic Leukemia (CLL) in the United States (US): Updated Results from a Cost of Care Sequencing Model for Patients with CLL

Wilson L, Hanna M, Nazar G, Pushkarna D, Breznen B [E2] Misdiagnoses of Autoimmune Type 1 Diabetes (T1D) or Latent Autoimmune Diabetes in Adults (LADA) as Type 2 Diabetes (T2D) in Adults: A Systematic Literature Review (SLR)

Son M, Edwards A, Burns B [E21] Yearly trends in payer coverage rates for GLP-1 receptor antagonists in weight loss

Barlev A, Princic N [G4] Real-World Health Care Resource Utilization in Stiff-Person Syndrome: 6-Year Claims Database Analysis of 352 Patients

Tran D, Mallick R, Patel B, et al [G17] Expected costs and costs per responder of Hizentra in comparison with other maintenance therapies for chronic inflammatory demyelinating polyneuropathy in the United States

Kogut S, Izzio K, Szozotka A [H8] Budget Impact of Biosimilar VEGF Inhibitors: Projected Medicare Part B Savings

Bazzazzadehgan S, Huang Y, Bhattacharya K, Yang Y, Agarwal S, Bentley J [M1] Comparative effectiveness of b/tsDMARDs in terms of opioid discontinuation among Medicare beneficiaries with rheumatoid arthritis

Thompson K, Hilgeman M, Urick B, Gleason P [U4] Medicare Member Drug Cost Predictive Model: Creation and Feature Engineering

Jhamb S, Brastad S, Gauni R, Caron B [Z4] Assessment of Clinical Characteristics and Resource Utilization in Members with Polypharmacy within a Commercially Insured Population

Motyka J, Patterson J, Salih R, Campbell J [C16] Orphan oncology drug development: implications for the Inflation Reduction Act's Orphan Drug Exclusion

Panjwani Q, Rowes J, Frazzitta M, et al [E3] Estimating the Impact of Utilizing the Lower of Glucose Management Indicator (GMI) with Hemoglobin A1c (HbA1c) within the Glycemic Status Assessment for Patients with Diabetes (GSD) Measure on Plan Performance

Greene S, Bali V, Coyle C, et al [I6] Identifying Patient Characteristics Associated with Guideline-Directed Medical Therapy Uptake and Health Care Resource Use in Patients Newly Diagnosed with Heart Failure with Reduced Ejection Fraction in the United States

Tejani M, Grossman J, Hocum B, et al [K6] The Budget Impact of the Value Regorafenib Delivers in the Treatment Landscape for Third- or Later-Line mCRC in the US

Seo S, Jungheim E, Yang M, et al [N6] Real-world utilization of gonadotropins and the associated cumulative live birth rates in the US: A retrospective claims database analysis

Arora H, Bennett K, Lowman C, Pandey A, Garg P [U5] A multi-faceted data science solution to assign Primary Care Providers (PCPs) to unassigned members by leveraging sophisticated algorithms to improve care coordination

Yoo P, Quillen S [U6] Quantifying the net financial impact of drug price reductions to manufacturers and payers

Platinum Award-Winning Abstracts

C2 Real-world bevacizumab biosimilar uptake from 2018 to 2023 and outcomes among patients with non-small cell lung cancer and metastatic colorectal cancer using commercial and Medicare Advantage claims in the United States

Lockhart C[1], *Dixon R*[2], *Venkataraman M*[2], *Barron J*[2], *Harris K*[3], *Pithua P*[4], *Roth J*[5], *Mendelsohn A*[6], *Yee G*[7], *Li M*[8]; *clockhart@bbcic.org*; *ruth.dixon@carelon.com*; *john.barron@carelon.com*

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BACKGROUND: The approval of biosimilars increased access to biologic therapies. Bevacizumab is used with various chemotherapy combinations for metastatic colorectal cancer (mCRC) and non-small cell lung cancer (NSCLC). With the launch of bevacizumab biosimilars in 2019, real-world evidence on patient access and uptake of biosimilars in a rapidly evolving market is scarce.

OBJECTIVE: We examined utilization of bevacizumab originator and available biosimilars among patients with mCRC and NSCLC, and the associated safety and survival outcomes.

METHODS: This non-interventional, retrospective study used de-identified data from Carelon Research's Healthcare Integrated Research Database (HIRD®) from 01 July 2017 to 31 March 2024 (study period) allowing for ≥6 months baseline period and ≥6 months of follow-up. Patient identification ended 30 September 2023. Statistical analysis was performed using the Instant Health Data (IHD®) analytics platform (Panalgo, Boston, MA). Survival outcomes between originator and biosimilar products were analyzed using Kaplan-Meier methodology.

RESULTS: Of 1,307 patients with NSCLC, 53.6% were female, 83.6% were white non-Hispanic/Latino, and median (IQR) age was 67 (59-76) years. Among 4,688 patients with mCRC, 43.4% were female, 78.6% were white non-Hispanic/Latino, and median (IQR) age was 59 (50-67) years. In the NSCLC cohort, the proportion of patients utilizing bevacizumab biosimilars increased from 0.0% in 2018 to 23.9% in 2023, while the proportion of patients utilizing originators decreased from 14.9% to 11.9%. In the mCRC cohort, the proportion of patients utilizing biosimilars rose from 0.0% in 2018 to 21.8% in 2023, while the proportion of patients utilizing originators fell from 22.9% to 7.4%. In the NSCLC cohort, hemorrhage was more common with biosimilars than originators (6.4% vs 4.7%, $p < 0.001$). Conversely, in the mCRC cohort, hemorrhage was more frequent with originators than biosimilars (9.9% vs 9.1%, $p = 0.008$). The median (95% CIs) overall survival times were 25.8 (23.3, 29.4) and 29.5 (28.4, 31.3) months for NSCLC, and mCRC, respectively.

CONCLUSIONS: Bevacizumab biosimilar uptake increased over time, while originator usage declined. Although adverse outcomes varied between cohorts, the efficacy and safety of bevacizumab biosimilars were found to be comparable with originators. Bevacizumab originators and biosimilars are used by similar patient profiles resulting in similar outcomes.

SPONSORSHIP: This study was sponsored by Biologics & Biosimilars Collective Intelligence Consortium (BBCIC)

E18 Real-world trends in pharmacy utilization among commercially insured individuals treated with glucagon-like peptide-1 (GLP-1) receptor agonists, 2014-2024

Coetzer H[1], *Anatale-Tardiff L*[1], *Margiotta C*[1], *Swami S*[2], *Adepoju B*[1], *Tomlin S*[1], *Kay J*[3], *Hashmi R*[4]; *henriette.coetzer@bluehealthintelligence.com*; *laura.anatale-tardiff@bluehealthintelligence.com*

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BACKGROUND: Nearly 42% of Americans are living with obesity and nearly 12% have type 2 diabetes mellitus (T2DM). The rapid increase in glucagon-like peptide-1 receptor agonist (GLP-1) use for T2DM and obesity has made them a primary driver of rising pharmacy costs for insurers. A clearer understanding of how GLP-1 initiation affects overall pharmacy utilization is essential to assess the additional costs for insurers.

OBJECTIVE: To describe trends in non-GLP-1 pharmacy utilization for individuals treated with GLP-1s.

METHODS: National pharmacy and medical claims data were used to identify individuals who initiated a GLP-1 product between 2014 and 2024 (cases). Cases and controls were

matched on initiation year-quarter, age, gender, continuous coverage, and obesity and/or diabetes diagnosis. We compared non-GLP-1 medication use and associated costs between cases and controls for the year prior to and three years following GLP-1 initiation.

RESULTS: Pharmacy costs remained higher in GLP-1 users (N = 1.1 million) than in controls (N = 2.6 million) over three years post initiation, even when excluding direct GLP-1 drug costs. Average non-GLP-1 annual pharmacy costs for cases were higher than controls by $1,449, $2,390, and $2,812 in years 1, 2, and 3, respectively. Although some of this additional utilization can be ascribed to common gastrointestinal side effects related to GLP-1 treatment, utilization increased over a broad range of medication categories. Compared to controls, the post-GLP-1 initiation prevalence of treatment was significantly higher for constipation and diarrhea (by 1.8% [p < 0.001]), nausea and vomiting (by 7.1% [p < 0.001]), gastroesophageal reflux disease (GERD) (by 5.8% [p < 0.001]), and GERD-related respiratory symptoms (by 5.2% [p < 0.001] for antitussives, beta adrenergics, nasal steroids, and antihistamines). The rate of side-effect–related treatment increased substantively with increased GLP-1 persistence. For example, GERD treatment rates were higher in cases than in controls (22%) and increased with GLP-1 persistence: 25%, 28%, and 32% for 0-12, 13-24, or 24+ months of GLP-1 use, respectively.

CONCLUSIONS: Side effects of GLP-1 treatment may necessitate additional drug intervention, contributing to additional pharmacy use and cost beyond direct GLP-1 medication costs. Payers and providers should consider the burden of side effect management when evaluating the suitability of these medications for prospective patients.

SPONSORSHIP: Blue Cross Blue Shield Association

F2 Cost-Effectiveness of Dextromethorphan-Bupropion (Auvelity) Among Major Depressive Disorder Adult Patients

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BACKGROUND: Major Depressive Disorder (MDD) is a debilitating mental health condition with significant treatment challenges, including high relapse rates and treatment resistance. First-line therapies include selective serotonin reuptake inhibitors (SSRIs) and selective norepinephrine reuptake inhibitors (SNRIs), but many patients fail to achieve remission, necessitating alternative treatments. Auvelity, a novel combination of dextromethorphan and bupropion, has been introduced as a potential second-line therapy for patients who have not responded to first-line treatments.

OBJECTIVE: This study evaluated the cost-effectiveness of Auvelity compared to standard treatments for MDD in the U.S.

METHODS: A cost-effectiveness analysis was conducted using a cohort-based decision tree model over a 12-month time horizon. The model compared Auvelity to standard care, which typically includes first-line SSRIs or SNRIs like citalopram or sertraline. The analysis was performed from the perspective of the U.S. health care system, incorporating remission and relapse rates derived from clinical trials and literature. The primary measure was the incremental cost-effectiveness ratio (ICER) per quality-adjusted life year (QALY) gained with a willingness-to-pay threshold of $100,000. Sensitivity analyses were performed, including tornado diagrams and two-way sensitivity analysis, to assess the robustness of the model.

RESULTS: Auvelity demonstrated higher effectiveness with a utility of 0.66 compared to 0.65 for standard care. With an incremental cost of $9,868.41, Auvelity resulted in an ICER of $518,107.86 per QALY gained. Sensitivity analyses indicated that annual price, along with the remission rate, was the most influential variable of the model. Additionally, Auvelity would be cost-effective if its annual price fell below $4,482.90, assuming similar remission rates.

CONCLUSIONS: While Auvelity offers a novel mechanism and slightly better remission outcomes, its high cost makes it less cost-effective than standard first-line therapies. Auvelity could be considered as a second-line therapy, particularly in treatment-resistant patients with favorable ICER. Further research into pricing and long-term outcomes is needed to better determine its place in clinical practice for MDD.

SPONSORSHIP: None

U17 Evaluating Medicaid brand-over-generic formulary strategies following the AMP cap removal

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IPD Analytics

BACKGROUND: The American Rescue Plan Act of 2021 removed the 100% average manufacturer price (AMP) cap for Medicaid rebates, effective January 1, 2024. Manufacturers are now required to pay the full additional rebate amount for drugs whose AMP has significantly outpaced the rate of inflation. Several manufacturers lowered the list price of established brand medications in late 2023 and early 2024.

OBJECTIVE: To estimate the change in Medicaid statutory rebates due to list price reductions and to identify any changes to brand-over-generic strategies to state Medicaid formularies.

METHODS: First Data Bank was used to identify brand drugs whose wholesale acquisition cost (WAC) decreased by at least 30% in December 2023 or January 2024. Medicaid statutory rebates were estimated for 2023 Q1 and Q2 and 2024 Q1 and Q2 by adding the basic rebate to the inflationary penalty, if applicable. Brand drugs without manufacturer-reported U.S. net sales or without generic or biosimilar competition in 2023 H1 were excluded. State Medicaid formularies from 2023 and 2024 for the 10 states with the largest Medicaid health care expenditures and a unified preferred drug list were reviewed for brand-over-generic strategies.

RESULTS: Twelve brand product lines with list price reductions were identified. Of those, five met criteria for inclusion: Advair (Diskus and HFA), Symbicort, Humalog (U-100 and 75-25 mix), NovoLog (U-100 and 70-30 mix), and Lantus. For all product lines, the estimated Medicaid statutory rebates decreased from 95% of WAC (ie, the AMP cap) in 2023 to less than 80% of WAC in 2024; four of the five product lines decreased to less than 60% of WAC. All brand drugs within the included product lines maintained their coverage status on all 10 state Medicaid formularies from 2023 to 2024.

CONCLUSIONS: Despite a decrease in estimated Medicaid statutory rebates following list price reductions, no changes to the brand-over-generic strategies of the 10 reviewed state Medicaid formularies were identified.

SPONSORSHIP: IPD Analytics

Professional Reviewed Abstracts

A00-B99 Certain Infectious and Parasitic Diseases

(eg, hepatitis C, HIV)

B1 Characteristics of individuals initiating cabotegravir long-acting for human immunodeficiency virus pre-exposure prophylaxis in the United States: results from the PrEPFACTS study

Metzner A[1], *Desai R*[2], *Herman G*[1], *Walko S*[1], *Martinez D*[1], *Shi S*[3], *Young-Xu L*[3], *DerSarkissian M*[3]; *raj.desai@analysisgroup.com*; *gabrielle.f.herman@viivhealthcare.com*
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BACKGROUND: APRETUDE (cabotegravir long-acting [CAB-LA]) was approved for human immunodeficiency virus (HIV) 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 the demographic and clinical characteristics of indv initiating CAB-LA, overall, and stratified by payer type (Commercial, Medicare, Medicaid).

METHODS: A retrospective cohort study was conducted using data from the Komodo Research Database (12/01/2020-09/30/2023). Indv 12 years of age and older who received at least 1 injection of CAB-LA after its approval (first 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 study included 1,202 indv (Commercial [n = 709; 59.0%]; Medicare [n = 48; 4.0%]; Medicaid [n = 444; 36.9%]) with a median age of 34 years (Commercial, 35; Medicare, 56; Medicaid, 32). Overall, 82.5% of indv were male (sex recorded by payer). Among those with recorded race (73.2% of sample), the majority were White (41.9%), followed by Black (29.9%) and Hispanic/Latino (24.3%). A larger proportion of Medicaid enrollees with known race were Black (42.7%). Indv were predominantly in the Northeast (47.6%) with commercially covered indv most likely to be in the South (39.8%). The most common comorbidities were anxiety disorders (31.2%), sexually transmitted infections [STIs] (22.8%), and hypertension (18.9%) [Commercial]; hypertension (45.8%), anxiety disorders (43.8%), and depressive disorders (33.3%) [Medicare]; substance-related and addictive disorders (29.7%), anxiety disorders (29.7%), and STIs (27.5%) [Medicaid]. Overall, the most frequently dispensed medications were systemic corticosteroids (15.9%), hormone replacement therapy (11.6%), and phosphodiesterase-5 inhibitors (6.5%). Overall, 27.5% of indv were new PrEP starters (72.5% received oral PrEP in baseline); 40.6% of indv switched from oral PrEP to CAB-LA within a month before index.

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 oral PrEP users in the general US population. Indv were most likely to have Commercial coverage and high proportions of psychiatric comorbidities across all payers. These findings can inform care of indv receiving CAB-LA, inclusive of possible comorbidities and concomitant medications.

SPONSORSHIP: ViiV Healthcare

B2 Enhancing Viral Load Suppression and Medication Adherence in Medicaid HIV Patients Through a Multidisciplinary MTM Pilot Program

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Community First Health Plans

BACKGROUND: Despite substantial improvements in HIV care, Texas continues to face significant challenges with HIV rates and viral suppression among people living with HIV (PLWH). In 2021, Texas saw an estimated 4,400 new HIV cases, and of those diagnosed, only about 62% achieved viral suppression, indicating the need for targeted interventions, especially within Medicaid populations. The Texas Health and Human Services Commission (HHSC) emphasizes increasing HIV viral suppression through quality performance measures, aiming for <200 copies/mL to reduce transmission risks and improve outcomes. This pilot study investigates an innovative Medication Therapy Management (MTM) program, leveraging health system integration, to enhance antiretroviral (ART) adherence and viral suppression among Medicaid members at Community First.

OBJECTIVE: This pilot study aimed to evaluate the impact of an MTM program on ART adherence and viral suppression rates among Medicaid-enrolled HIV patients within Community First.

METHODS: Identified eligible individuals through claims analysis with HIV and either a recent viral load >200 copies/mL or no documented viral load within the last year. The intervention included telehealth MTM visits by nurses under clinical pharmacist oversight, provider outreach, and other support services to facilitate care coordination. Baseline data for adherence was collected via claims data analysis, using the proportion of days covered (PDC) to gauge ART adherence. Data collection spanned from June 2023 to June 2024.

RESULTS: Of 13 members who qualified for the MTM program, 11 achieved viral suppression, defined as <200 copies/mL. Additionally, 90.9% of these members either maintained or improved their adherence, achieving a PDC above the 0.9 threshold for ART, consistent with the HHSC and Pharmacy Quality Alliance (PQA) quality measures. The intervention achieved an estimated 30.8% MTM member engagement rate, with 100% provider engagement from Community First's integrated health system, though provider coordination was less effective outside this system.

CONCLUSIONS: The pilot MTM program demonstrates that a multidisciplinary approach combining MTM and care coordination can significantly enhance ART adherence and viral suppression among Medicaid members. The collaborative model, combining MTM and health system integration, shows promise for scalability across other Community First lines of business. Future research should include expanded population health analytics and partnerships to address non-medical drivers of health, further supporting sustained viral suppression and improved ART adherence.

SPONSORSHIP: None

B3 Perceived barriers by those prescribed initial HIV pre-exposure prophylaxis: US pilot survey results

Patel K[1], *Sullivan P*[2], *Sung I*[1], *Zachry W*[3], *Mezzio D*[3], *Hsiao A*[3], *Bogart M*[3], *Showers P*[3], *Coaquira Castro J*[3]; *krisha.p.patel@walgreens.com*
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BACKGROUND: Despite pre-exposure prophylaxis (PrEP) availability for HIV-1 prevention, uptake remains low and inequities in uptake exist among individuals who need or want PrEP. Most research on access barriers affecting uptake has leveraged large claims and medical record databases to examine potential drivers of dispensation primarily at the pharmacy level.

OBJECTIVE: To conduct a cross-sectional survey to assess individuals' experienced psychosocial and structural barriers when receiving their first PrEP prescription.

METHODS: Adults without evidence of receiving HIV treatment and with an initial PrEP prescription in the Walgreens pharmacy database between August 1 and November 30, 2023, were invited to complete an electronic survey from March 19 to April 9, 2024. Individuals consented to participate and were compensated upon survey completion. The survey comprised 35 questions on topics including attitudes toward PrEP, out-of-pocket expenses, and prescription fill rejection reasons. Responses were compared between respondents who picked up their first PrEP prescription within 14 days (D14) versus those who did not pick up within 14 days (D>14) using Fisher's exact test (significance threshold P≤0.05), with no adjustments for multiple testing. Learnings gained from this pilot survey were applied for later phases of the survey study.

RESULTS: Of 274 eligible adults, 199 (73%) completed the survey and had linked dispensation data. Overall, most respondents indicated that their doctor explained PrEP in a way that they could understand (84%), that PrEP would protect them from HIV (92%), and that PrEP is safe to take (83%). Most respondents picked up their first PrEP prescription by day 14 (80%) and were male (80%). A higher proportion of D>14 respondents compared with D14 respondents were aged ≤29 (33% vs 24%) or ≥50 years (26% vs 21%), lived in the Midwest (36% vs 25%) or South regions (44% vs 32%), and paid cash for PrEP (46% vs 5%). D>14 respondents were more likely than D14 respondents to report problems with insurance processing or coverage (49% vs 16%, P<0.001). A higher proportion of D>14 respondents compared with D14 respondents reported difficulty in paying for PrEP (41% vs 29%) and that cost was very important in their decision to pick up PrEP (83% vs 67%).

CONCLUSIONS: Despite understanding and awareness of PrEP, respondents reported barriers with insurance coverage and out-of-pocket costs. Disparities were seen across age groups and geographic regions. These findings point to current unmet needs in the dispensation of PrEP among individuals who need or want PrEP.

SPONSORSHIP: Gilead Sciences, Inc.

B5 Trends in utilization and costs of oral pre-exposure prophylaxis (PrEP) for HIV prevention

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BACKGROUND: Pre-exposure prophylaxis (PrEP) is a crucial HIV prevention strategy, with two branded oral agents, Truvada (tenofovir disoproxil fumarate [TDF]/emtricitabine)

and Descovy (emtricitabine/tenofovir alafenamide [TAF]), approved for use by the US Food and Drug Administration (FDA) in 2012 and 2015. Most private insurance and Medicaid programs are required to cover PrEP services without cost sharing.

OBJECTIVE: This study aimed to examine trends in the utilization and costs of oral PrEP medications from 2018 to 2022, including the impact of Truvada becoming generic.

METHODS: A retrospective observational cross-sectional study, of patients with commercial or Medicaid insurance, was conducted using a comprehensive claims database from 2018 to 2022. Patients without HIV aged 13 to 64 prescribed oral PrEP were included. Those who received another antiviral on the same date as PrEP or had an HIV exposure diagnosis without subsequent PrEP or antiviral treatment were excluded. Outcomes of interest were trends in total cost of care (TCC) including medical and pharmacy costs and utilization. Trends and comparisons were assessed using Cochran-Armitage and chi-square tests, respectively. Statistical significance was at $p < 0.05$.

RESULTS: There was a significant linear increase trend in PrEP utilization between 2018 and 2022 ($p < 0.001$). Emtricitabine/tenofovir [TAF] utilization increased by 129.8%, from 17.3% in 2018 to 39.7% in 2022. In 2022, the generic form of tenofovir/emtricitabine (TDF) was the most prevalent (55.4%) compared to 39.7% for emtricitabine/tenofovir (TAF) and 5.0% for tenofovir/emtricitabine (TDF). A significant linear decrease trend was observed in average TCC from 2018 to 2022 ($p < 0.001$). The average TCC decreased by 56.7%, from $127,529 in 2018 to $55,179 in 2022. However, PrEP medication accounted for a majority of the total pharmacy cost (66% in 2018, 70% in 2022). In 2022, TCC for commercial patients were over 20% higher than Medicaid. Statistically significant differences were for patient characteristics (gender, race, region, and social determinants of health) between insurance type each year.

CONCLUSIONS: The findings highlight a growing trend in emtricitabine/tenofovir (TAF) utilization, and significant reduction in emtricitabine/tenofovir [TDF], replaced by the generic form. Average TCC decreased over time, but percentage of PrEP medications continues to be a high proportion of total pharmacy costs. Future studies are necessary to continue understanding TCC and utilization changes of oral PrEP as injectable PrEP was approved. PrEP needs to be affordable and utilized by those at risk.

SPONSORSHIP: None

B6 Comparative analysis of screening and preventative measures and health care resource utilization among people with HIV receiving long-acting cabotegravir plus rilpivirine or oral antiretroviral therapy in the US: the ABOVE study

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BACKGROUND: Clinic visits for administration of cabotegravir plus rilpivirine long-acting (CAB+RPV LA) may provide additional preventative health care opportunities for people with HIV (PWH).

OBJECTIVE: This retrospective study (ABOVE) compared rates of screening and preventative measures and health care resource utilization between PWH receiving CAB+RPV LA or oral antiretroviral therapy (ART).

METHODS: PWH on stable daily oral ART or initiating CAB+RPV LA were identified using administrative claims from Symphony Health Solutions (01/01/2020 - 8/31/2023). Index date was first CAB+RPV LA injection (01/01/2021 - 03/01/2023) or imputed for the oral ART cohort. Baseline characteristics were balanced using standardized mortality ratio (SMR) weighting. Rates of vaccinations, cancer and STI screenings, bone density tests, viral load and antiretroviral resistance testing, and all-cause and HIV-related hospitalizations and outpatient visits (excluding those associated with CAB+RPV LA administration) were compared during follow-up. Rate ratios (RRs) and 95% CIs were estimated using a doubly robust generalized linear model with a negative binomial distribution.

RESULTS: The study included 1,245 PWH in the CAB+RPV LA cohort and 58,644 (1,275 after weighting) in the oral ART cohort. Baseline characteristics were balanced after weighting (mean age 47 years, 24% females). Median follow-up was 392 days for CAB+RPV LA and 371 days for oral ART cohorts. While rates of preventative measures were generally low in both cohorts, the CAB+RPV LA cohort had higher rates of vaccinations (RR 1.25 [95% CI 1.18-1.33]), cancer screenings (RR 1.17 [95% CI 1.07-1.28]), STI screenings (RR 1.24 [95% CI 1.09-1.40]), and bone density tests (RR 2.37 [95% CI 1.64-3.42]) compared to the oral ART cohort (all $p < 0.001$). Viral load and resistance testing rates were similar between cohorts. The CAB+RPV LA cohort had higher rates of all-cause (RR 1.08 [95% CI 1.02-1.16]) and HIV-related (RR 1.38 [95% CI 1.23-1.54]) outpatient visits ($p < 0.001$), but lower rates of all-cause (RR 0.37 [95% CI 0.22-0.63]) and HIV-related (RR 0.40 [95% CI 0.19-0.86]) hospitalizations compared to the oral ART cohort ($p < 0.001$).

CONCLUSIONS: PWH switching from stable oral ART to long-acting ART had higher rates of key preventative measures, compared to those remaining on oral ART. Despite more frequent outpatient visit rates in the CAB+RPV LA cohort, hospitalization rates were lower, suggesting that more health care interactions likely improve outcomes for PWH. These data highlight the benefits of increased medical engagement for CAB+RPV LA.

SPONSORSHIP: ViiV Healthcare

B7 Health care resource use outcomes associated with antiretroviral resistance among US veterans with HIV

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BACKGROUND: Resistance-associated mutations (RAMs) to antiretroviral therapies (ART) remain a threat to HIV treatment.

OBJECTIVE: The objective of this study was to quantify the association between ART resistance and health care resource utilization (HCRU) in a nationwide database of US veterans.

METHODS: Retrospective medical and pharmacy claims data were extracted from the Veterans Affairs Informatics and Computing Infrastructure (VINCI). This analysis included veterans with HIV who received testing for RAMs within a VA health center between 2003 and 2023. Health care costs were measured after follow-up and costs were reported as per member per year and inflated to 2024 dollars.

RESULTS: 7,746 veterans had an interpretable resistance test result, of whom 5,871 had ≥1 RAM detected (resistance cohort). Age, gender, race, and Charlson comorbidity index were similar between cohorts. Veterans with resistance had a higher prevalence of hospitalization during follow-up (26.1%) vs the nonresistance cohort (21.3%, $p < 0.001$), and average length of stay was three days longer ($p < 0.001$). Total all-cause costs averaged $49,945 ± 69,861 per member per year for the resistance cohort compared to $45,476 ± 57,117 for the nonresistance cohort ($p = 0.037$). Inpatient costs were $16,846 ± 49,693 and outpatient costs were $13,674 ± 15,152 for the nonresistance cohort compared to $19,728 ± 59,267 and $14,103 ±26,438 for those with resistance ($p = 0.032$ and $p = 0.026$, respectively). Pharmacy costs were similar between the two cohorts ($16,315 ± 13,261 and $16,115 ± 13,340, respectively, $p = 0.569$), whereas HIV-specific pharmacy costs were higher for the nonresistance cohort ($14,298 ± 10,470 vs. $13,701 ± 11,490 in the resistance cohort, $p = 0.045$).

CONCLUSIONS: ART resistance was associated with greater HCRU and costs despite lower HIV pharmacy-related costs, driven by higher inpatient and outpatient costs and more frequent and longer hospital admissions.

SPONSORSHIP: This study was sponsored by Gilead Sciences. The content of this article is solely the responsibility of the authors and does not necessarily represent the official views of the US Department of Veterans Affairs, nor does mention of trade names, commercial products or organizations imply endorsement by the US government. This paper represents, in part, original research conducted using data from the Department of Veterans Affairs and is the result of work supported with resources and the use of facilities at the Dorn Research Institute, Columbia VA Health Care System, Columbia, South Carolina.

B11 Evaluation of Appropriateness of Nirmatrelvir/Ritonavir Prescribing Among Commercial Employer Groups: 2022-2024

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BACKGROUND: In December 2021, nirmatrelvir/ritonavir (Paxlovid) was approved for emergency use authorization (EUA) for patients at high risk for COVID-19 infection. In December 2023, the U.S. health care system began transitioning from government-subsidized medication to manufacturer-marketed nirmatrelvir/ritonavir at approximately $1,250 per treatment. Despite stable utilization, this transition resulted in increased plan spend from $0.01 to $0.67 PMPM during the first half of 2024. Treatment efficacy has been questioned as recent data indicate the time to alleviation of signs and symptoms of COVID-19 did not differ significantly between nirmatrelvir-ritonavir and placebo.

OBJECTIVE: To evaluate prescribing appropriateness, during and after EUA, of nirmatrelvir/ritonavir within commercial employer groups.

METHODS: Members aged >12 years were included if they had paid claims for nirmatrelvir/ritonavir from Q1 2022 to Q2 2024. The primary outcome was the appropriateness of use of nirmatrelvir/ritonavir, as defined by the number of claims for members with elevated risk, including high-risk disease and/or age >50 years. High-risk diseases were defined based on recommendations from the Centers for Disease Control and Prevention and were determined using pharmacy

claims. Secondary outcomes included multiple treatment occurrences and claims distribution by co-morbidity, gender, and age. Descriptive statistics were used to summarize the outcomes, utilization trends, and claims distributions.

RESULTS: We identified 1,268 members with a nirmatrelvir/ritonavir claim during the study period, accounting for 415,591 total claims and 1,343 for nirmatrelvir/ritonavir. By age, 42% (560) of claims were for members <50 years. Of all nirmatrelvir/ritonavir claims, 64% were for females and 36% for males. Nine percent (121 claims) of nirmatrelvir/ritonavir claims were inappropriately prescribed based on age and comorbidity. The top five comorbidities identified were cardiovascular disease, mental health, lung disease, diabetes, and cancer. Sixty-nine members had multiple treatment occurrences during the review period with the highest in females, aged 50-59 years.

CONCLUSIONS: Most claims for nirmatrelvir/ritonavir were prescribed in individuals at high risk for severe COVID-19 infection. However, at a significant cost per treatment, and with published clinical data showing no difference in alleviation of symptoms, the number of claims found to be prescribed inappropriately indicates an opportunity for clinical management and cost savings for employers.

SPONSORSHIP: None

C00-D49 Neoplasms

(eg, breast cancer, lung cancer, melanoma, multiple myeloma)

C1 Budget Impact of Circulating Tumor DNA Testing for Colon Cancer to Health Care Insurers

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BACKGROUND: Circulating tumor DNA (ctDNA) testing for colon cancer has been shown to provide cost savings to commercial health and Medicare Advantage plans in a recent budget impact analysis (Li et al., *JAMA Health Forum* 2024;5:e241270).

OBJECTIVE: To extend the budget impact analysis and assess the potential economic benefit of adopting ctDNA testing to health care insurers that provide commercial health, Medicare Advantage, and Medicaid coverages.

METHODS: The budget impact of adopting ctDNA testing was estimated as the difference in total cost of care when the use of adjuvant chemotherapy was guided by ctDNA testing (for patients aged 75 years and younger) vs by clinical evaluation (current standard of care). Total cost of care included cost of testing (if applicable), treatment, surveillance, and adverse events. Membership distribution among commercial health, Medicare Advantage, and Medicaid plans was based on the US census (Berdunov et al., *J Med Econ* 2023;26:973).

RESULTS: For a health care insurer with 5 million memberships, 233 patients with stage II colon cancer were expected to be eligible for ctDNA testing, including 113 in the commercial health plan, 91 patients in the Medicare Advantage plan, and 29 patients in the Medicaid plan. The average savings for each patient tested from the reduction in the use of adjuvant chemotherapy were expected to be $12,702 in the commercial plan, $2,293 in the Medicare Advantage plan, and $10,715 in the Medicaid plan (assuming cost of testing was at $3,500 per patient). If all eligible patients received ctDNA testing, the expected cost savings in the first year after testing would be $1,435,404 for the commercial health plan, $209,162 for the Medicare Advantage plan, and $306,420 for the Medicaid plan, totaling $1,950,986 for the health care insurer. If these results were extrapolated to the US population, the total savings would be $130 million per year.

CONCLUSIONS: Substantial cost savings are expected for a health care insurer when ctDNA testing is adopted to guide adjuvant chemotherapy for patients with stage II colon cancer.

SPONSORSHIP: Quest Diagnostics

C2 Real-world bevacizumab biosimilar uptake from 2018 to 2023 and outcomes among patients with non-small cell lung cancer and metastatic colorectal cancer using commercial and Medicare Advantage claims in the United States

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BACKGROUND: The approval of biosimilars increased access to biologic therapies. Bevacizumab is used with various chemotherapy combinations for metastatic colorectal cancer (mCRC) and non-small cell lung cancer (NSCLC). With the launch of bevacizumab biosimilars in 2019, real-world evidence on patient access and uptake of biosimilars in a rapidly evolving market is scarce.

OBJECTIVE: We examined utilization of bevacizumab originator and available biosimilars among patients with mCRC and NSCLC, and the associated safety and survival outcomes.

METHODS: This noninterventional, retrospective study used de-identified data from Carelon Research's Healthcare Integrated Research Database (HIRD®) from 01 July 2017 to 31 March 2024 (study period) allowing for ≥6 months baseline period and ≥6 months of follow-up. Patient identification ended 30 September 2023. Statistical analysis was performed using the Instant Health Data (IHD®) analytics platform (Panalgo, Boston, MA). Survival outcomes between originator and biosimilar products were analyzed using Kaplan-Meier methodology.

RESULTS: Of 1,307 patients with NSCLC, 53.6% were female, 83.6% were White non-Hispanic/Latino, and median (IQR) age was 67 (59-76) years. Among 4,688 patients with mCRC, 43.4% were female, 78.6% were White non-Hispanic/Latino, and median (IQR) age was 59 (50-67) years. In the NSCLC cohort, the proportion of patients utilizing bevacizumab biosimilars increased from 0.0% in 2018 to 23.9% in 2023, while the proportion of patients utilizing originators decreased from 14.9% to 11.9%. In the mCRC cohort, the proportion of patients utilizing biosimilars rose from 0.0% in 2018 to 21.8% in 2023, while the proportion of patients utilizing originators fell from 22.9% to 7.4%. In the NSCLC cohort, hemorrhage was more common with biosimilars than originators (6.4% vs 4.7%, $p < 0.001$). Conversely, in the mCRC cohort, hemorrhage was more frequent with originators than biosimilars (9.9% vs 9.1%, $p = 0.008$). The median (95% CIs) overall survival times were 25.8 (23.3-29.4) and 29.5 (28.4-31.3) months for NSCLC and mCRC, respectively.

CONCLUSIONS: Bevacizumab biosimilar uptake increased over time, while originator usage declined. Although adverse outcomes varied between cohorts, the efficacy and safety of bevacizumab biosimilars were found to be comparable with originators. Bevacizumab originators and biosimilars are used by similar patient profiles resulting in similar outcomes.

SPONSORSHIP: This study was sponsored by Biologics & Biosimilars Collective Intelligence Consortium (BBCIC).

C3 Integrating Named Entity Recognition to Improve Detection of Non-Small Cell Lung Cancer (NSCLC) and Evaluate Pain Scores in Clinical Notes

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BACKGROUND: NSCLC is the most common type of lung cancer, which is often associated with significant pain due to the disease or treatments. Effective NSCLC management requires accurate diagnosis and pain assessment, which impact treatment decisions and quality of life.

OBJECTIVE: This analysis aims to develop a Named Entity Recognition (NER) model that accurately identifies NSCLC cases and associated pain scores from unstructured clinical text, aiding in timely and effective patient care.

METHODS: We utilized Optum's de-identified clinical notes data between 2016 and 2023. These notes included diverse data including but not limited to provider notes (inpatient and outpatient), nursing logs, and pain management records. Diagnosis of NSCLC was confirmed using a combination of ICD-10 diagnosis codes along with mentions of NSCLC and its variations in the clinical notes. Mentions of pain score and its respective score was ensured in the notes via manual review (annotation) of 10% of the total sample following which NLP models were applied on the remaining set of notes. The NER model was trained using a deep learning approach integrating a Char CNNs - BiLSTM - CRF architecture for optimal entity recognition. The model was trained to identify specific medical entities related to NSCLC diagnosis and various pain assessment scales.

RESULTS: The NER model demonstrated robust performance with a precision of 89%, a recall of 95%, and an F1-score of 92% in identifying NSCLC entities. The model effectively extracted relevant entities corresponding to the diagnosis of NSCLC. Further, we will be looking at pain score among these patients and insights into the relationship between cancer progression and patient-reported pain levels.

CONCLUSIONS: The NER model developed in this study significantly enhances the extraction of essential data concerning NSCLC identification and pain assessment from clinical texts. By facilitating the accurate and timely identification of NSCLC and associated pain scores, the model supports a more tailored approach to patient care, potentially improving clinical outcomes and patient quality of life. Future efforts will aim to further enhance the precision of the model and expand its utility across additional cancer types and comprehensive symptom management.

SPONSORSHIP: None

C4 Exploring the Landscape of Non-Small Cell Lung Cancer: A Detailed Analysis of Disease Staging and Performance Status Using Named Entity Recognition

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BACKGROUND: NSCLC is a leading cause of cancer-related mortality globally, frequently diagnosed at an advanced stage with metastasis. Early detection of metastasis and

accurate assessment of patient performance status are essential for optimizing treatment strategies and improving outcomes.

OBJECTIVE: This study aims to develop and validate a Named Entity Recognition (NER) model to identify the various stages of non-small cell lung cancer (NSCLC) and assess the performance status of patients at each stage of the disease.

METHODS: Optum's de-identified clinical notes database was utilized to identify NSCLC patients between 2015 to 2020. Patients had ≥1 medical claim with an NSCLC (ICD-10) diagnosis code or evidence of NSCLC in their clinical notes. NSCLC stage, including stage narrative and Tumor-Node-Metastasis (TNM) staging, along with performance status and its respective score, was verified in the clinical notes through annotation of 10% of the total sample, and natural language processing (NLP) model was implemented on the remaining set of notes. The NER model was trained on a corpus of annotated clinical notes to identify and extract entities related to metastatic sites and performance statuses. It utilized a deep learning architecture, including Char CNNs - BiLSTM - CRF, to manage the complexity of medical language. The model's performance was evaluated using precision, recall, and F1-score metrics. Additionally, the correlation between identified metastatic sites, disease stage, and performance status was examined.

RESULTS: The NER model identified cancer stages with a precision of 97.2%, recall of 97.6%, and an F1-score of 97.4%. The most frequently detected metastatic sites were the brain, bones, liver, lungs, and the adrenal glands. Performance status, measured using the ECOG scale, significantly deteriorated with advancing disease stages. Stage IV patients with liver metastases exhibited the lowest performance status. The model effectively distinguished performance statuses between early-stage (I and II) and late-stage (III and IV) patients, aiding in targeted therapeutic approaches.

CONCLUSIONS: The resulting NER model demonstrates high accuracy in identifying cancer stages, detecting metastatic spread, and assessing performance status in NSCLC patients. This tool can aid in the timely and accurate stratification of patients, enabling personalized treatment plans and potentially improving clinical outcomes. Insights derived from the model's outputs could also inform clinical decision-making and resource allocation in oncology care settings.

SPONSORSHIP: None

C5 Treatment patterns, health care costs, and health care utilization in non-small cell lung cancer patients receiving sotorasib: A real-world analysis of US MarketScan insurance claims database

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BACKGROUND: In May 2021, sotorasib, a first-in-class oral targeted therapy for adult patients with KRAS G12C-mutated locally advanced or metastatic non-small-cell lung cancer (NSCLC) treated with prior systemic therapy, was approved in the US.

OBJECTIVE: To assess the real-world (RW) treatment patterns, health care costs (HCC), and health care resource utilization (HCRU) for patients with metastatic non-small-cell lung cancer (NSCLC) treated with sotorasib in second- or later-line therapy (2L+).

METHODS: Adult patients treated with sotorasib and having a prior diagnosis (Dx) of lung cancer were identified using the Merative® MarketScan claims database (until March 2023) in the US. First sotorasib prescription was considered the index date. Patients were continuously enrolled from 6 months prior to first Dx of lung cancer until at least 30 days after index date and received no medications for small cell lung cancer during the pre-index period. Key outcomes included medication adherence - proportion of days covered (PDC), time to next treatment (TTNT), HCC, and HCRU. HCC and HCRU were reported on a per-patient-per-month (PPPM) basis and also assessed over the baseline period (6 months prior to index date).

RESULTS: Among 88 patients that met all inclusion criteria, 74 (84%) patients used sotorasib as 2L+. The mean age was 65 years and 57% were females. Additionally, 53% received prior treatment (Tx) with platinum-based chemotherapy plus immune checkpoint inhibitors. The mean (SD) sotorasib PDC was 95% (12.2%) and median TTNT was 5.4 (range: 2.9-12.9) months. Baseline total (medical, pharmacy) and medical (inpatient, outpatient, emergency) HCC PPPM were $22,619 ($16,935) and $22,225 ($16,913), respectively, while total and medical HCC during sotorasib Tx period were $26,017 ($35,837) and $9,935 ($37,183) PPPM, respectively. Patients had 4.6 (5.7) outpatient, 0.13 (0.44) acute inpatient, and 0.13 (0.42) emergency visits PPPM during sotorasib Tx period.

CONCLUSIONS: The findings of this RW study suggest patients using sotorasib as a 2L+ targeted therapy for NSCLC in the US exhibit high adherence, TTNT similar to progression-free survival observed in clinical trials of sotorasib, and total HCC and HCRU comparable to those observed during pre-index treatment.

SPONSORSHIP: Amgen Inc

C6 Persistence and adherence of tepotinib in patients with metastatic non-small cell lung cancer (NSCLC) harboring mesenchymal-epithelial transition (MET) exon 14 skipping mutation

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BACKGROUND: Tepotinib, an oral MET inhibitor, is approved for metastatic non-small cell lung cancer (NSCLC) in patients with MET exon 14 (METex14) skipping mutation.

OBJECTIVE: While clinical trials have confirmed its efficacy, real-world data on treatment patterns, adherence, and persistence—critical for optimizing long-term outcomes—are limited.

METHODS: We performed an exploratory retrospective analysis using shipment data from Biologic Specialty Pharmacy from February 10, 2021, to August 2, 2024. Patients aged ≥50 years with NSCLC who received at least one shipment of tepotinib were included. The index date was the first active shipment, and patients were followed until death, loss of follow-up, or the end of the study. Persistence was measured by the total number of days supplied. Time to first discontinuation was analyzed using Kaplan-Meier methods, defining discontinuation as a treatment gap (>21 days), death, hospice care, patient refusal, or provider decision. Adherence was evaluated via the proportion of days covered (PDC), with adjusted PDC excluding treatment gaps, as prolonged gaps are generally not due to nonadherence according to clinical experts. Swimmer plots visualized individual treatment patterns, and subgroup results for patients with dose reductions (average daily dose ≤225 mg) are reported in a separate abstract.

RESULTS: The study included 389 patients with a mean age of 70.9 years and a median follow-up of 5.2 months (70%, 43%, 25%, and 16% at 3, 6, 9, and 12 months, respectively). Mean treatment persistence was 5.7 months (SD 6.3), and median persistence was 4.0 months (range: 2.0–7.0). Kaplan-Meier analysis showed that 63.0% of patients had not experienced discontinuation at 6 months, 39.5% at 12 months, and 31.2% at 21 months. The median time to first discontinuation was not reached, with 126 patients (32.4%) experiencing a discontinuation event. Primary reasons for discontinuation included treatment gaps (n = 77, 61%), provider decisions (n = 22, 18%), and death (n = 20, 16%). Unadjusted and adjusted PDC rates were 76.3% and 95.8%, respectively.

CONCLUSIONS: This real-world study of tepotinib in METex14 skipping NSCLC indicates substantial persistence and adherence, with many patients continuing treatment through the first year. Given the recent approval and increasing real-world use, further studies utilizing alternative data sources, such as claims, or electronic health records, are essential for understanding long-term outcomes and factors affecting treatment discontinuation.

SPONSORSHIP: EMD Serono (CrossRef Funder ID: 10.13039/100004755)

C7 Health care resource utilization in patients with non-squamous non-small cell lung cancer

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BACKGROUND: Non-squamous (NSQ) non-small cell lung cancer (NSCLC) poses a considerable clinical challenge due to its complex management and associated costs. Understanding the economic burden of NSQ NSCLC is critical to optimize resource allocation and improve patient care.

OBJECTIVE: To evaluate the impact of NSQ NSCLC on health care resource utilization (HCRU) and cost for second-line (2L) and third-line (3L) treatment settings.

METHODS: This was a real-world analysis of Optum Market Clarity database electronic health records and claims data in patients with NSQ NSCLC with stage ≥3B (locally advanced or metastatic) disease; patients were diagnosed in 2017 or later with ≥28 days of continuous enrollment after 2L therapy initiation. A peer-reviewed published algorithm was used to proxy patients' line of therapy (LoT), with a gap in treatment ≥120 days advancing the LoT (Hess et al. *Future Oncol*. 2021). All-cause HCRU and costs are reported as the number of visits (ie, office, outpatient, inpatient, and emergency room) and associated costs per patient per month (PPPM).

RESULTS: Of the 791 patients with NSQ NSCLC who initiated 2L treatment, 347 (44%) received immuno-oncology (IO) agents, 252 (32%) received chemo, 117 (15%) received chemo + IO, 69 (9%) received targeted agents (TA), and 6 (1%) received other regimens. Overall, the mean (SD) duration of continuous health plan enrollment was 228 (219) days, mean (SD) age at 2L start was 65 (10) years, 50% were female, 80% were White, and 13% were Black. Mean 2L all-cause number of visits and costs PPPM for office visits were 2.0 and $2,722 for chemo, 1.5 and $4,450 for chemo + IO, 2.0 and $5,396 for IO, 1.5 and $982 for TA; outpatient hospital visits were 2.1 and $2,439 for chemo, 1.9 and $2,327 for chemo + IO, 1.6 and $2,178 for IO, 1.3 and $1,460 for TA; inpatient hospital visits were 0.2 and $1,591 for chemo, 0.2 and $1,648 for chemo + IO, 0.1 and $1,289 for IO, 0.2 and $3,650 for TA; emergency

room visits were 0.3 and $365 for chemo, 0.3 and $368 for chemo + IO, 0.2 and $237 for IO, and 0.3 and $274 for TA. The 2L mean all-cause total medical cost PPPM was $13,391 for chemo, $24,519 for chemo + IO, $18,733 for IO, and $9,217 for TA. HCRU visits and cost trends were similar in 3L.

CONCLUSIONS: The total health care cost was high for all evaluated 2L therapies; while only 15% of patients received chemo + IO, those patients had the highest proportion of costs. Of visit types, office visits contributed to the highest proportion of health care costs.

SPONSORSHIP: AbbVie Inc.

C8 Real-world use of dose reductions for tepotinib in patients with metastatic non-small cell lung cancer (NSCLC) harboring mesenchymal-epithelial transition (MET) exon 14 skipping mutation

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BACKGROUND: Tepotinib is a targeted therapy for metastatic non-small cell lung cancer (NSCLC) with mesenchymal-epithelial transition (MET) exon 14 skipping mutations.

OBJECTIVE: This study examines the real-world use of dose reductions as a strategy to optimize patient outcomes.

METHODS: We conducted an exploratory retrospective analysis using biologic shipment data from February 10, 2021, to August 2, 2024. The study included patients aged ≥50 years with NSCLC who received at least one shipment of tepotinib. The index date was defined as the first active shipment, and patients were followed until death, loss to follow-up, or the end of the study. Treatment persistence and Kaplan-Meier methods were used to assess the duration of tepotinib, while adherence was measured by the proportion of days covered (PDC). This abstract focuses on a subgroup analysis of patients who decreased from the standard 450 mg daily dose to an average daily dose of ≤225 mg. The total treatment time on a reduced dose is also reported.

RESULTS: A total of 47 patients (12.1% of the full cohort) underwent dose reductions, with a mean age of 73.0 years and a median follow-up of 9.3 months (94%, 77%, 55%, and 38% at 3, 6, 9, and 12 months, respectively). Patients with dose reduction showed a higher mean persistence rate, 9.3 months (SD 7.3) versus the full cohort's 5.7 months (SD 6.3). The median persistence for the patients with dose reduction was 7.5 months (range: 4.3-12.0), while the full cohort had a median of 4.0 months (range: 2.0-7.0). The median time to first discontinuation was 4.0 months (95% CI 2.5-8.0). Kaplan-Meier analysis indicated that 41.1% of patients had not experienced a discontinuation event at 6 months, 17.7% at 12 months, and 10.6% at 21 months. Notably, 50% of total treatment time for these patients was spent on a reduced dose. Among the patients with dose reduction, 35 patients (74.5%) experienced a discontinuation event, primarily due to treatment gap (n = 30, 85.7%), provider decision (n = 3, 8.6%), and death (n = 2, 5.7%). The adjusted PDC for dose reducers was 95.1%, with all patients achieving adjusted PDC ≥80%.

CONCLUSIONS: This analysis underscores the real-world use of dose reductions for tepotinib patients since its approval. The observed dose reductions, along with sustained high persistence and adherence, indicate that some patients may be effectively maintained on a reduced dose of tepotinib. Further research is necessary to evaluate long-term outcomes and efficacy in patients on reduced doses.

SPONSORSHIP: EMD Serono (CrossRef Funder ID: 10.13039/100004755).

C9 Predicting Non-Small Cell Lung Cancer Risk: Utilizing a Polygenic Approach with US Cohort Data

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BACKGROUND: Non-small cell lung cancer (NSCLC) presents significant challenges due to its high mortality rate and late-stage diagnosis. Traditional risk assessment methods often fail to account for the complex genetic factors involved. Utilizing polygenic risk scores (PRS) that integrate multiple genetic variants offers a promising solution to enhance risk prediction accuracy. This approach has the potential to improve early detection, personalize treatment plans, and ultimately enhance patient outcomes by addressing the limitations of existing diagnostic tools.

OBJECTIVE: This study aims to develop and validate a predictive model for NSCLC risk by integrating PRS derived from Optum's Clinicogenomics data (OCD), which includes broad-panel next-generation sequencing (NGS) results and patient demographics. The goal is to identify key features that improve early detection.

METHODS: The Optum® Market Clarity Dataset was utilized to identify NSCLC patients between January 1, 2020, and October 30, 2024. Patients with ICD-10-CM codes for lung cancer (C34. and D02.2) were included if their data was present in

OCD and they had 12 months of continuous eligibility. A control cohort of breast cancer patients was created using similar inclusion and exclusion criteria for statistical validation of PRS scoring. Weights based on allele frequency were used to calculate the relative risk contribution, and the sum of weighted scores was employed to evaluate PRS. Logistic regression (LR) was conducted to validate the association between PRS and NSCLC status. The data was randomly divided into an 80:20 ratio for model training and testing. ROC/AUC curves and f1-scores were used for statistical validation.

RESULTS: The study cohort included a total of 20,339 patients. In the NSCLC cohort, EGFR, MET, and ALK exhibited the highest PRS of 270, with the L858R mutation in EGFR showing the strongest association, affecting 32% of NSCLC patients. A PRS of 270 in NSCLC indicates a higher cumulative genetic risk compared to the control cohort, indicating a greater genetic predisposition to NSCLC based on allele frequency. In the control cohort, the BRCA gene exhibited the highest PRS of 150. The association between PRS and NSCLC was determined using logistic regression, resulting in an AUC of 0.65.

CONCLUSIONS: Utilizing allele frequency percentages in combination with logistic regression offers a robust framework for evaluating polygenic risk scores in predicting NSCLC risk. This approach holds value for genetic risk stratification in both clinical and research settings.

SPONSORSHIP: None

C11 Real-world Outcomes for Pembrolizumab and Nivolumab Monotherapy in Patients with Metastatic or Unresectable Melanoma

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BACKGROUND: The immune checkpoint inhibitors pembrolizumab (pembro) and nivolumab (nivo) are utilized as monotherapies in the treatment of metastatic or unresectable melanoma. Pembro and nivo are FDA-approved immunotherapies with similar safety profiles and efficacy but differ in terms of dosing and frequency of administration.

OBJECTIVE: To compare adverse events and health care utilization between patients with metastatic or unresectable melanoma initiating first-line monotherapy with pembro or nivo using real-world data.

METHODS: This retrospective cohort study used claims and clinical data to evaluate patients receiving pembro or nivo as first-line monotherapy treatment for metastatic or unresectable melanoma diagnosed between January 2016 and November 2022 and having no prior systemic treatment. Patients were followed for at least 6 months after their first infusion of pembro or nivo. Confounding variables were balanced using weights (inverse probability of receiving the treatment). The presence of adverse events, discontinuation, time to discontinuation, all-cause and melanoma-specific health care utilization, and costs were compared.

RESULTS: After weighting, the analysis evaluated 2,305 patients (1,142 pembro and 1,163 nivo) who were 66 years old on average, mostly male (60%), and fully insured (80%) with commercial insurance (60%). Most patients had lymph nodes as the primary site of metastases (63%) and a median of 7 months between melanoma diagnosis and index date of treatment. Patients receiving pembro had statistically significant higher post-index incidence of pneumonitis (5% vs. 3%; p-value < 0.05), colitis (18% vs. 12%; p-value < 0.0001), and infusion-related adverse events (2% vs. 1%; p-value < 0.05) compared to patients receiving nivo. Discontinuation and time to discontinuation post-index was not statistically different across groups. Compared to patients receiving nivo, patients receiving pembro had significantly higher all-cause and melanoma-related health care utilization of inpatient services as well as higher melanoma-related health care costs.

CONCLUSIONS: According to NCCN guidelines, both pembro and nivo are considered preferred regimens and can be prescribed as first-line monotherapy for metastatic or unresectable melanoma. However, this real-world evidence suggests that melanoma patients receiving pembro may be more at risk of experiencing adverse events and incur more melanoma-related inpatient visits and costs. Further data will be needed to determine if these observations are consistent across other datasets or confirmed in prospective randomized controlled trials.

SPONSORSHIP: CarelonRx

C13 Cost-Effectiveness of Ribociclib (RIB) in Hormone Receptor–Positive/Human Epidermal Growth Factor Receptor 2–Negative (HR+/HER2–) Early Breast Cancer (EBC)

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BACKGROUND: Many patients (pts) with HR+/HER2– EBC experience recurrence despite treatment (tx) with adjuvant (adj) endocrine therapy; recurrences bear a substantial

cost and can impact life expectancy and quality of life. The cyclin-dependent kinase 4/6 inhibitor RIB + an aromatase inhibitor (AI) was FDA approved in Sept 2024 to reduce risk of recurrence among pts with any nodal involvement and pts with high-risk N0 disease, ≈30% of pts with HR+/HER2– EBC. At a 44.2-mo median follow-up, when all pts were off RIB, RIB + a nonsteroidal AI (NSAI) vs NSAI significantly improved invasive disease-free survival (iDFS; HR, 0.715 [0.609-0.840]) with a 4-yr landmark Δ of 4.9%.

OBJECTIVE: This analysis assessed cost-effectiveness of treating eligible pts with HR+/HER2– EBC with RIB+NSAI vs NSAI from a US third-party payer perspective.

METHODS: A Markov simulation model was developed to estimate costs and effectiveness of RIB+NSAI vs NSAI in NATALEE overall population over a lifetime time horizon, including 4 health states: invasive disease-free (IDF), locoregional recurrence (LR), distant recurrence (DR), and death. Transition probabilities between states were estimated using NATALEE iDFS data up to 4.5 y and parametric extrapolation afterward. Assumptions about tx efficacy waning and tx patterns in DR were informed by experts and literature. Direct medical costs associated with adj tx, LR and DR tx, disease and adverse event (AE) management, and terminal care costs were estimated based on NATALEE data and literature. Health state utilities were based on NATALEE EQ-5D-5L data; AE disutilities were based on literature. Lifetime costs, life-years (LYs), quality-adjusted LYs (QALYs), and incremental cost-effectiveness ratios (ICERs) between RIB+NSAI and NSAI were estimated. Scenario analyses were conducted to evaluate robustness of results.

RESULTS: Compared with NSAI, RIB+NSAI was estimated to extend survival by an average of 0.69 y and to extend QALYs by 0.68 y. RIB+NSAI was associated with lower costs of LR tx, DR tx, disease management in LR and DR, and terminal care, which substantially offset higher adj tx costs. Pts receiving RIB+NSAI incurred higher lifetime total costs ($800,052) vs those receiving NSAI ($769,757), with an increase at $30,295. The ICER per LY and QALY gained with RIB+NSAI vs NSAI was $43,784 and $44,789, respectively. Scenario analyses supported base-case findings, with all ICERs below $150,000/QALY.

CONCLUSIONS: This analysis supports that adj RIB+NSAI may offer a cost-effective option vs NSAI for reducing recurrence in pts with early-stage HR+/HER2– BC at high risk of recurrence.

SPONSORSHIP: Novartis Pharmaceuticals Corporation

C16 Orphan oncology drug development: implications for the Inflation Reduction Act's Orphan Drug Exclusion

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BACKGROUND: The Inflation Reduction Act (IRA) and the limited scope of its orphan drug exclusion (ODE), as interpreted by the Centers for Medicare and Medicaid Services (CMS), have raised concerns surrounding incentives for ongoing drug development into multiple rare diseases. Subsequent indications are common in orphan oncology drugs, which comprise a plurality of orphan drug designations and approvals.

OBJECTIVE: To describe the pathways and timelines of orphan oncology drug development, including both orphan designations and subsequent indications, and identify implications of the ODE by pathway among a cohort of recently approved orphan oncology drugs.

METHODS: Using FDA databases, we examined orphan designations and subsequent indications among oncology drugs first approved between 2008 and 2018. Drug-level designation, indication, and development timeline data were collected and categorized into six mutually exclusive and exhaustive development pathways. Development pathway types and timelines were summarized using median (IQR) and counts (percentages).

RESULTS: Of the 86 oncology drugs initially approved by the FDA from 2008 to 2018, 64 were initially approved in an orphan-designated condition (74.4%). Of the 64 drugs analyzed in our study, we found that clinical development into multiple rare cancers is more common than previously reported in indication-based analyses, with nearly two-thirds of drugs (n = 40, 62.5%) pursuing multiple designations. Only a third (n = 23, 35.9%) of the sample, representing two of the six common development pathways, would still qualify for the ODE as interpreted by CMS. In nearly all cases, drugs disqualified from the ODE would have been disqualified by a second orphan designation; in many cases, that designation remains unapproved or has been withdrawn.

CONCLUSIONS: Our research illustrates the complexity and diversity of development from designation to approval for initial and subsequent indications in orphan oncology drugs. The pathways of development observed here suggest shortcomings in the design of the ODE to align with the complex and lengthy process of orphan drug designations, development, and FDA approvals. The ODE has taken an initial step

toward preserving incentives for the development of new indications within the same orphan designation, a pathway followed by a fifth of the included drugs. However, these results amplify concerns that the ODE will disincentivize ongoing clinical research toward approvals in additional rare diseases.

SPONSORSHIP: National Pharmaceutical Council

C20 Health disparities in bladder cancer: A targeted literature review examining bladder cancer screening, diagnosis, treatment, and survival outcomes in the United States

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BACKGROUND: Bladder cancer (BC) is the sixth most common cancer in the United States with expected national expenditure of $11.6 billion by 2030. Health disparities exist within the BC, manifesting as differences based on sex, race, geographic region, and socioeconomic status.

OBJECTIVE: Achieving health equity has been long recognized as a top priority of the U.S. public health and health care institutions. Therefore, the objective of this study was to synthesize current evidence of health disparities among patients with BC in the U.S.

METHODS: A targeted literature review was conducted using PubMed® to identify health disparities in screening, diagnosis, treatment, and survival outcomes in BC patients in the U.S. Eligible articles were real-world studies published in English between January 1, 2018, and October 19, 2022. A template based on PICOT was used to extract relevant study information. After removing duplicates, abstracts were graded on a scale from 0 (information not pertinent and excluded) or 1 through 5 (from least to most relevant) by each member of the research team. The top-ranked abstracts with the highest average score and that met the above inclusion criteria were selected for full text review. Disparities based on gender and race and ethnicity were the highest priority for inclusion.

RESULTS: Out of 995 unique abstracts, 233 articles met selection criteria, of which 46 publications were selected. More studies reported results specifically for muscle invasive BC (MIBC; N = 15) than Non-MIBC (N = 7). Black patients and those with socioeconomic disadvantage are least likely to receive guideline-based treatment with neoadjuvant chemotherapy and radical cystectomy, undergo pelvic lymph node dissection at the time of cystectomy, have generally limited access to high-volume and academic treatment facilities, and present with more advanced disease. Overall, women received fewer cystoscopies than men. Both Black and female patients compared to their White and male counterparts have higher risks of mortality. Disparities related to education, socioeconomic status, environmental factors, and insurance types were also observed.

CONCLUSIONS: Health disparities within the BC population emerge as early as the screening and initial diagnosis stages and continue to affect survival outcomes. The systemic barriers faced by marginalized groups highlight the urgent need for improved health outcomes. This is critical as addressing social determinants of health has become a national priority of Healthy People 2030 initiative.

SPONSORSHIP: Janssen Scientific Affairs, LLC

C21 The Economic Impact of Treatment Sequences for Chronic Lymphocytic Leukemia (CLL) in the United States (US): Updated Results from a Cost of Care Sequencing Model for Patients with CLL

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BACKGROUND: The CLL treatment landscape has evolved in recent years with the US FDA approval of new oral targeted therapies (i.e., zanubrutinib [Zanu], pirtobrutinib [Pirto] accelerated approval).

OBJECTIVE: A cost-of-care model of CLL treatment sequences was updated to reflect this change.

METHODS: A partitioned survival model estimated the cumulative costs per patient with up to 3 lines of therapy, followed by best supportive care, for up to 10 years. FDA-approved treatment sequences (41 for patients without aberration [del 17p/TP53], 45 with aberration) recommended by NCCN guidelines and used in clinical practice were modeled. Sequences started with first-line fixed-duration venetoclax (V) + obinutuzumab (O) or Bruton Tyrosine Kinase inhibitor (BTKi)–based treat-to-progression regimens, including acalabrutinib (Acala), Acala+O, ibrutinib (Ibr), and Zanu. Costs included drug acquisition and administration, monitoring, tumor lysis syndrome prophylaxis (for V-based therapies), adverse event management, and terminal care. Efficacy and safety data were based on pivotal trials; cost data were obtained from public sources.

RESULTS: Sequences starting with V+O resulted in the lowest 10-year costs (average: $1.04 million [M]), at 52% lower

than sequences starting with BTKi-based regimens (averages: $2.17M [overall], $2.32M [Ibr], $2.22M [Acala+O], $2.05M [Acala], $2.03M [Zanu]). For patients with aberration, 10-year cost of V+O sequences (average: $1.44M) were 31% lower compared to BTKi-based sequences (averages: $2.07M [overall], $2.15M [Ibr], $2.16M [Acala+O], $1.89M [Acala], $2.07M [Zanu]). V retreatment often led to the most cost savings, while BTKi to BTKi sequencing led to the highest costs. The least costly sequences overall were V+O → Ibr → V+rituximab (R) ($1.02M) and V+O → Ibr → duvelisib (D) ($1.35M) for without and with aberration, respectively. In contrast, the costliest sequences were Ibr → Acala → Pirto ($2.38M) and Ibr → Zanu → Pirto ($2.27M) for patients without and with aberration, respectively. Similar trends were observed over 5 years, with the least costly sequence being V+O -> Zanu -> D ($0.57M without, $0.74M with aberration) and the most costly being Ibr -> Acala -> idelalisib+R ($1.25M without, $1.23M with aberration).

CONCLUSIONS: Sequences starting with fixed-duration V+O had considerably lower costs over 5 and 10 years (~50% lower for without del[17p]/TP53 mutation) compared to sequences starting with treat-to-progression BTKis. This cost difference was more pronounced in sequences with V retreatment relative to BTKi to BTKi sequencing.

SPONSORSHIP: AbbVie, Inc., and Genentech Inc.

C22 Economic Burden of Patients with DLBCL Who Progress on Third-line Therapy in the United States

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BACKGROUND: Relapsed/refractory diffuse large B-cell lymphoma (DLBCL) is associated with a poor prognosis and high costs. In the US, there are little real-world data on the economic burden of progression following third-line (3L) therapy in patients with DLBCL.

OBJECTIVE: To evaluate the economic burden of patients with DLBCL with and without progression following 3L therapy.

METHODS: This retrospective claims analysis of the MarketScan Commercial and Medicare Supplemental databases included adults aged ≥18 years diagnosed with DLBCL from 1/1/2014 to 9/30/2023 and receiving 3L therapy from 1/1/2017 to 9/30/2023. Patients with a history of other cancers were excluded. The progression cohort included patients who initiated a new chemotherapy regimen after discontinuing 3L chemotherapy, switched to a new chemotherapy, or underwent hematopoietic stem cell transplantation (HSCT) ≥30 days after 3L initiation date. The progression cohort was indexed at the earliest date of 4L initiation or HSCT. The non-progression cohort was randomly indexed based on the distribution of time from 3L start to index date for the progression cohort. Continuous plan enrollment of ≥6 months pre index and ≥30 days post index was required. All-cause health care resource utilization and costs (adjusted using 2023 CPI) were measured per patient per month (PPPM) among all patients and at 6 and 12 months post index (among patients with ≥6 and ≥12 months of follow-up).

RESULTS: Of the 160 included patients, the mean age of the progression (n = 103) and non-progression (n = 57) cohorts was 60 and 56 years; 49% and 32% of the cohorts were female. Most patients (progression: 69%; non-progression: 65%) had a CCI score ≥3. The median follow-up time was 10 and 8 months and the mean duration of 3L therapy was 5 and 6 months for the progression and non-progression cohorts. Mean total costs during the follow-up period were $199,693 higher ($285,799 vs $86,106; P<0.0001) and mean PPPM costs were $21,261 higher ($32,522 vs $11,261; P = 0.0001) for the progression vs the non-progression cohort. Mean total 6-month costs were $125,299 higher ($176,359 vs $51,060; P = 0.0002); mean total 12-month costs were $146,171 higher ($222,088 vs $75,917; P = 0.0037) for the progression vs the non-progression cohort.

CONCLUSIONS: Most costs (80%) incurred by progressors occurred during the first 6 months post progression. Mean total costs were approximately 3.3 times higher and PPPM costs approximately 2.9 times higher for patients who progressed compared with those not progressing following 3L therapy for DLBCL, demonstrating the high economic burden of this population.

SPONSORSHIP: Pfizer, Inc.

C23 Budget Impact of Fixed Treatment Duration Venetoclax in Combination with Obinutuzumab or Rituximab in Previously Untreated or Relapsed/Refractory Chronic Lymphocytic Leukemia Patients in the United States

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BACKGROUND: In 2018 and 2019, the United States (US) Food and Drug Administration approved fixed treatment duration venetoclax (VEN)+rituximab (R) and VEN+obinutuzumab (O) for relapsed/refractory (RR) and previously untreated (1L)

chronic lymphocytic leukemia (CLL) patients, respectively. In recent years, acalabrutinib (acala)±O, zanubrutinib (zanu), and pirtobrutinib (pirto) have also been approved but are treat-to-progression agents. Contemporary estimates of the effect of these changes on a payer's budget are lacking.

OBJECTIVE: To assess the total cost of care (TCC) and budget impact (BI) of introducing VEN+O/VEN+R for 1L/RR CLL treatment from the perspective of a mixed commercial/Medicare US health plan with 1,000,000 (1M) members.

METHODS: Two 3-year BI models were developed. Comparators in 1L CLL were O+chlorambucil (ClbO), fludarabine+cyclophosphamide+R (FCR), bendamustine+R (BR), ibrutinib (Ibr), Ibr+R, Ibr+O, acala±O, and zanu. Comparators in RR CLL were VEN, BR, Ibr, idelalisib+R (Idela+R), acala, zanu, and pirto. TCC included US-specific costs associated with treatment (i.e., drug, administration, and wastage), adverse events, routine care, and monitoring. Dosing and safety data were sourced from clinical trials and US package inserts. Drug costs (August 2024) were estimated based on the average wholesale acquisition cost reported in Truven Health Analytics Red Book®, and all other costs were based on published sources and inflated to 2023 US dollars. BI outcomes were presented on an absolute and per-member per-month (PMPM) basis. Sensitivity analyses (SA) explored uncertainty in influential parameters.

RESULTS: In 1L CLL, by year 3, the cumulative difference in TCC of VEN+O was -$381,898 vs Ibr, -$447,495 vs Ibr+R, -$461,417 vs Ibr+O, -$302,135 vs acala, -$382,345 vs acala+O, and -$291,016 vs zanu. Introducing VEN+O in a 1M-member health plan resulted in cost savings of $4.27 million over 3 years (PMPM -$0.12) relative to a scenario without VEN+O. In RR CLL, by year 3, the cumulative difference in TCC of VEN+R was -$353,040 vs pirto, -$189,307 vs Ibr, -$129,955 vs idela+R, -$115,687 vs VEN, -$108,033 vs acala, and -$94,528 vs zanu. Compared to a scenario without VEN+R, its introduction over 3 years resulted in cost savings of $1.17 million (PMPM -$0.03). In all SAs conducted, VEN+O/VEN+R remained cost-saving.

CONCLUSIONS: Introducing VEN+O/VEN+R in the 1L and RR treatment landscape resulted in cost savings due to its fixed treatment duration compared to targeted treat-to-progression therapies.

SPONSORSHIP: AbbVie, Inc., and Genentech, Inc.

C24 A systematic literature review (SLR) of multiple myeloma (MM) epidemiology literature: Trends in survival

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BACKGROUND: In recent decades, there has been a documented increase in the incidence of MM, a malignant neoplasm of plasma cells with a historically poor prognosis.

OBJECTIVE: Contextualize the impact of emerging treatments by describing the epidemiological profile of MM, focusing on mortality and survival statistics.

METHODS: Systematic searches for population-based, epidemiology studies from the United States (US), Australia, Canada, the United Kingdom, Germany, Italy, Spain, France, and Japan were conducted in MEDLINE and Embase (Jan 2012 to Mar 2024). Statistics from epidemiology registries (GLOBOCAN; US SEER) were also reviewed.

RESULTS: We included 67 studies with mortality or survival outcomes from the 12,089 records identified in the search, covering statistics from 1945 to 2021. The US had the most studies (n = 41). Across the SLR, country-level, age-adjusted MM-related mortality estimates varied from 1.0 death per 100,000 (2015, Japan) to 4.3/100,000 (1990, US). Age- and sex-stratified data show improving survival over time. Statistics from GLOBOCAN complement the SLR, revealing similar between-country heterogeneity in MM-related mortality rates and lower crude and global age-standardized mortality rates (gAMR) in Japan. Historical trends from GLOBOCAN also illustrate an increase in crude mortality rates (per 100,000) from 1990 to 2020 (3.2 vs 4.7 in males; 3.1 vs 3.8 in females) and decreasing gAMR (2.2 vs 1.7 in males; 1.5 vs 1.1 in females). Differences between increasing crude rates and decreasing gAMR may be attributable to the aging populations with concomitant improved therapies, respectively. In the US, SEER statistics highlight marked improvements in 5-year relative survival from 2000 (35.6%) to 2016 (61.1%), with a decline in age-adjusted mortality rates (per 100,000) from 3.8 in 2000 to 2.8 in 2022. Beyond geographical variability, age (≥65), sex (male), and race (African American) were consistent predictors of higher MM-related crude mortality rates across sources. The impact of these characteristics is compounding, and they should not be considered in isolation.

CONCLUSIONS: Our study found consistent evidence of improving survival, notwithstanding the global rise in

crude mortality rates. This SLR was part of a broader epidemiological analysis that found rising incidence rates. The combination of improved survival and increased incidence helps explain the increasing MM prevalence and, hence, rising burden of disease. These findings underscore the need for novel treatments to help improve patient survivorship.

SPONSORSHIP: Kite Pharma/Arcellx

C25 Economic Burden in Patients with CAR-T: Comparison of Idecabtagene Vicleucel with Ciltacabtagene Autoleucel

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BACKGROUND: Idecabtagene vicleucel (Ide-cel) and ciltacabtagene autoleucel (cilta-cel) are chimeric antigen receptor T-cell therapy (CAR-T) for treatment of relapsed or refractory multiple myeloma (MM). Little is known about their post-infusion economic burden in the real world.

OBJECTIVE: To evaluate and compare health care resource utilization (HCRU) and costs in MM patients who completed ide-cel or cilta-cel infusion.

METHODS: This retrospective study used administrative claims from the Optum Research Database combined with Transplant Prior Authorization Data to identify patients with MM who completed ide-cel or cilta-cel infusion during March 2021 to September 2023. Patient characteristics were assessed in the 3-month baseline prior to index date. Patients who received ide-cel or cilta-cel were compared on all-cause and CAR-T–related (medication, procedures, or clinically relevant events) HCRU and costs measured per patient per month (PPPM) in a variable post-infusion period.

RESULTS: Patients were followed up for 318±187 (mean ± standard deviation) days from ide-cel infusion (n = 58) and 206±121 days from cilta-cel infusion (n = 47). Demographics and baseline comorbidities were generally similar. Mean age was 63.1±9.5 years in ide-cel and 63.9±9.8 years in cilta-cel (p = 0.68); baseline National Cancer Institute Comorbidity Index score was 1.7±1.7 and 1.4±1.7 (p = 0.42), respectively. The number of PPPM all-cause ambulatory visits, emergency room visits, inpatient stays, and pharmacy fills in the post-infusion period did not differ significantly between the two groups. However, patients with ide-cel had a shorter inpatient stay than those with cilta-cel (2.4±3.2 vs 3.9±4.3 days, p = 0.033). All-cause total health care costs PPPM were significantly lower for ide-cel ($79,504±106,893 vs $132,051±124,021 for cilta-cel, p = 0.022). Compared to cilta-cel, patients with ide-cel had significantly lower PPPM all-cause medical costs ($77,691±107,277 vs $130,857±124,116, p = 0.021) and ambulatory visit costs ($9,828±18,519 vs $29,604±53,381, p = 0.002). Similar significant differences were found in PPPM CAR-T–related HCRU and costs. Total CAR-T–related costs made up 87.6% of all-cause costs for ide-cel and 88.7% of all-cause costs for cilta-cel. Plan-paid costs accounted for 99.6% of the total costs in patients with ide-cel and 99.8% in patients with cilta-cel.

CONCLUSIONS: In a real-world setting, patients with ide-cel had significantly lower post-infusion health care costs and shorter inpatient stays, compared to patients with cilta-cel.

SPONSORSHIP: Bristol Myers Squibb

C26 Budget impact of adding brentuximab vedotin + lenalidomide + rituximab as a later-line therapy for diffuse large B-cell lymphoma in the United States

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BACKGROUND: Relapsed/refractory diffuse large B-cell lymphoma (RR DLBCL) is associated with poor long-term survival; there is a need for safe and effective RR DLBCL treatments. In the phase 3 ECHELON-3 trial, patients with RR DLBCL treated with ≥2 prior lines of therapy were randomized to brentuximab vedotin (BV), a CD30-directed antibody drug conjugate, or placebo, both administered with lenalidomide (Len) and rituximab (R). BV compared with placebo demonstrated a statistically significant 37% reduction in the risk of death (hazard ratio, 0.629; 95% CI, 0.445-0.891; P = 0.0085), regardless of detectable CD30 expression (Kim et al, ASCO 2024; Abstract LBA7005).

OBJECTIVE: A budget impact model (BIM) was developed to estimate the budget impact of BV+Len+R for a hypothetical 1-million-member US health plan over 5 years. The base case includes adult patients with RR DLBCL following ≥2 prior lines of therapy who are ineligible for stem cell therapy or CAR-T therapy.

METHODS: The budget impact was calculated as the difference in total costs for formulary scenarios with and without BV+Len+R for RR DLBCL. The eligible population was based on SEER estimates of RR DLBCL incidence, including transformed DLBCL and high-grade B-cell lymphoma, and literature estimates for additional eligibility criteria. Drug and administration, health care resource utilization, adverse event, and subsequent treatment costs were included. A one-way sensitivity analysis was performed to identify major drivers of results.

RESULTS: For a hypothetical 1-million-member commercial health plan, 9 patients were estimated to receive third-line (3L; n = 7) or fourth-line (4L; n = 2) therapy with either BV+Len+R or a comparator. The per-member per-month (PMPM) budget impact of adding BV+Len+R was $0.001 to $0.004 over 5 years. For a hypothetical 1-million-member Medicare health plan, 36 patients were estimated to receive 3L (n = 29) or 4L (n = 7) therapy with BV+Len+R or a comparator. The PMPM budget impact of adding BV+Len+R was $0.005 to $0.017 over 5 years. In a hypothetical 1-million-member Medicaid health plan, 7 patients were estimated to receive 3L (n = 6) or 4L (n = 1) therapy with BV+Len+R or a comparator. The PMPM budget impact of adding BV+Len+R was $0.001 to $0.003 over 5 years. Key model drivers across all health plans included median number of BV+Len+R cycles and median overall survival with BV+Len+R.

CONCLUSIONS: Results from this BIM suggest that there is minimal budget impact over a 5-year time horizon following the addition of BV+Len+R to a drug formulary for treatment for RR DLBCL.

SPONSORSHIP: Pfizer, Inc.

D1 Real-world treatment patterns and economic burden among adult patients diagnosed with neurofibromatosis type 1 and plexiform neurofibromas (NF1-PN) in the United States

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BACKGROUND: Neurofibromatosis type 1 (NF1) is a progressive genetic condition with 25-30% of patients having plexiform neurofibromas (PN) that can cause pain and disfigurement. No pharmacological treatment is currently approved for adults with NF1-PN, and the disease burden is not well understood.

OBJECTIVE: This retrospective cohort study aimed to describe treatment patterns, health care resource utilization (HRU), and costs among adults with NF1-PN.

METHODS: Adults with a diagnosis of both NF1 and PN were identified from the Merative™ MarketScan® Commercial Claims Database (01/01/2016-12/31/2022) and matched to controls without NF1-PN on sociodemographic characteristics (1:5 ratio). Both cohorts required ≥12 months of continuous enrollment before and ≥3 months of follow-up after the index diagnosis (defined as latter of the NF1 or PN diagnosis by ICD-10 CM codes). Treatment patterns and all-cause and NF1-PN-specific HRU and costs were described during the follow-up period. All-cause HRU and costs were compared between patients and controls using generalized linear model with Poisson distribution and Tweedie distribution, respectively.

RESULTS: A total of 944 patients with NF1-PN were identified and matched to 4,720 controls. Mean age was 39.6 (standard deviation: 15.6) years and 60% were female. Over a mean follow-up of 25.8 months, 70% of NF1-PN patients used pain medications. Other common treatments included cytotoxic chemotherapy (29%), debulking surgeries (23%), radiotherapy (15%), and targeted therapies (e.g., MEK inhibitors) (5%). Patients with NF1-PN consistently exhibited significantly higher all-cause HRU compared to controls across all encounter settings (1.6 vs. 0.27 inpatient days per patient per year [PPPY], 18.8 vs. 9.1 outpatient visits PPPY, 0.80 vs. 0.53 emergency room visits PPPY), with adjusted incidence rate ratios of 1.4 to 4.2 (all $p < 0.001$). Among all-cause inpatient days and outpatient visits, 53% and 18% were attributable to NF1-PN. The average total health care costs were $34,398 PPPY for patients with NF1-PN, compared to $6,149 for controls. After adjustment, patients with NF1-PN had higher costs than controls across all settings with a total cost difference of $23,516 and a cost ratio of 4.3 ($p < 0.001$).

CONCLUSIONS: Adults with NF1-PN have substantial economic burden compared to those without NF1-PN, evidenced across all settings. With no approved pharmacological treatments available at the time the study was conducted, this real-world study reinforces the continued need for new treatments and interventions to effectively manage NF1-PN in the adult population.

SPONSORSHIP: Merck & Co., Inc.

D2 Impact of Geographic Location on Intravenous Iron Treatment Adherence in Urban, Rural, and Super Rural Regions

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BACKGROUND: Historically, patients living in urban areas have better access to care including improved medical facilities, providers, treatment, and transportation options. This can impact patients with iron deficiency anemia (IDA),

which affects >5 million people in the US. IDA is treated with oral iron; if ineffective or poorly tolerated, intravenous iron (IVI) is recommended. Depending on the IVI product and dose, the number of infusions per treatment course can vary. Older-generation IVI products typically require multiple low-dose infusions (~200 mg), while newer generations require fewer (≤2) infusions (500–1,000 mg).

OBJECTIVE: To explore differences in adherence to IVI products across urban, rural, and super rural regions among different health care plan types.

METHODS: This was a retrospective analysis of Medicaid, commercial, and Medicare administrative claims data from Komodo's Healthcare Map. Adult patients were diagnosed with IDA before their first IVI infusion (index date) and treated on or after January 1, 2020. Excluded patients had a history of dialysis or end-stage renal disease. IVI products evaluated were older generation (iron dextran, ferric gluconate, iron sucrose) and newer generation (ferumoxytol, ferric carboxymaltose, ferric derisomaltose). Adherence was defined as having received >1,000 mg of IVI within the 6-week period, inclusive of index date. Infusion location was categorized as urban, rural, or super rural according to CMS definition.

RESULTS: 464,009 patients were included in the analysis (Medicaid = 131,802; Commercial = 212,877; Medicare = 119,330). Across health care types, adherence was higher for patients treated with newer-generation IVI: ferumoxytol (n = 90,463; 83.3%), ferric carboxymaltose (n = 130,708; 81.5%), ferric derisomaltose (n = 8,001; 99.1%). Adherence was lower for patients treated with older-generation IVI: iron dextran (n = 43,466; 74.0%) ferric gluconate (n = 27,161; 10.5%), iron sucrose (n = 164,210; 37.0%). Mean adherence decreased from urban, rural, to super rural regions across different health care types: 62.1%, 59.7%, and 57.0%, respectively.

CONCLUSIONS: In all three analyses, as rurality increased, adherence decreased. Consistent across geographies, adherence rates were generally higher with newer-generation IVI products, especially in patients who received single-dose IVI. These data suggest that in addition to the number of doses needed for adequate iron replacement per treatment course, geographic health disparities further contribute to the observed differences.

SPONSORSHIP: Pharmacosmos Therapeutics Inc.

D3 Contemporary treatment patterns among real-world patients with paroxysmal nocturnal hemoglobinuria in the United States

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BACKGROUND: Treatment options have historically been limited for patients with paroxysmal nocturnal hemoglobinuria (PNH), a rare, life-threatening hematological disorder. Multiple new therapies have been approved in recent years, but the impact of these on the real-world treatment landscape is not yet well understood.

OBJECTIVE: The aim of this study was to describe contemporary treatment patterns among patients with PNH in the United States (US).

METHODS: This retrospective, observational cohort study used US closed (insurance provider records) and open claims data (health system and pharmacy records) from Komodo's Healthcare Map™. The study included adults with ≥2 claims with a PNH diagnosis between January 1, 2018, and June 14, 2024, and ≥2 consecutive claims for ≥1 complement-inhibitor (CI) therapy during the identification period (June 14, 2023, to June 14, 2024). The index date was the start date of the most recent CI therapy in the identification period and patients were classified into subgroups based on their index therapy: ravulizumab, eculizumab, pegcetacoplan, iptacopan, danicopan, or crovalimab. Patients were required to have continuous enrollment for ≥90 days prior to index.

RESULTS: Overall, 969 CI-treated patients were included (median age 49 years, 46% female, 42% White, 12% Black, 6% Asian, 9% Hispanic, and 57% covered by commercial insurance). The distribution of claims for the most recent CI therapy was as follows: ravulizumab (71%), eculizumab (14%), pegcetacoplan (10%), iptacopan (5%), danicopan (0.1%), and crovalimab (0%). Of the 3 recently approved CI therapies, iptacopan had the highest number of patients with claims (n = 44) and real-world data available; 1 patient had claims for danicopan and 0 did for crovalimab. Among the 44 patients with iptacopan claims, 8 (18%) were treatment-naive at iptacopan initiation; patients who had a claim for prior CI therapy were most commonly switching from ravulizumab (n = 23, 52%) or pegcetacoplan (n = 8, 18%).

CONCLUSIONS: This study provides insights into the current real-world treatment landscape among patients with PNH. Overall, 71% of patients received ravulizumab as their most recent CI therapy. The distribution of claims for the

recently approved therapies may reflect the timing of their approval within the identification period. However, following its approval less than one year ago, uptake of iptacopan among patients with PNH has been rapid in US real-world clinical practice, with 5% of patients in the study receiving iptacopan as their most recent therapy.

SPONSORSHIP: Novartis Pharmaceuticals Corporation

D4 Cost per responder analysis of iptacopan versus eculizumab and ravulizumab in treatment of paroxysmal nocturnal hemoglobinuria: implications for decision-making

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BACKGROUND: Paroxysmal nocturnal hemoglobinuria (PNH) is a rare severe blood disorder marked by hemolysis and thrombosis, imposing a lifelong burden on patients with unmet needs. Complement 5-inhibitors (C5is) eculizumab (ecu) and ravulizumab (ravu) have been historically utilized to treat PNH. Recently, iptacopan, the first-in-class oral factor B inhibitor of the alternative complement pathway, has been approved by the FDA. However, pharmacists, physicians, and payers may be unsure if hematological response to newer treatments provides sufficient value relative to existing C5is.

OBJECTIVE: Compare the average cost per responder in the US for iptacopan vs C5is (ecu, ravu, ecu biosimilar ABP959) among patients with PNH who are either (i) C5i-experienced (C5i-exp) with extravascular hemolysis or (ii) C5i-naive.

METHODS: A cost-per-responder comparison was conducted using data from prescribing information, clinical trials, and wholesale acquisition drug cost. Response was defined as the percent of transfusion-independent patients over 1 year. C5i-exp response was obtained from the APPLY-PNH trial for iptacopan and ravu/ecu, and C5i-naive response from the APPOINT-PNH trial and the external C5i control arm of the real-world APPEX cohort. ABP959 was assumed to have the same efficacy as ecu and 20% discounted drug cost. Given sustained response in the 48-week APPLY-PNH extension, efficacy was assumed to be maintained for one year, with an annual discontinuation rate applied. Costs were extrapolated to one year based on dosing and discontinuation. Number needed to treat (NNT) to achieve response compared to C5is was the inverse of iptacopan's incremental response rate. Average cost per responder was calculated by dividing the annual cost by response rate.

RESULTS: Annual iptacopan cost was $550,067 compared to $497,130 (ravu), $572,987 (ecu), and $459,145 (ABP 959). NNT was 1.5 for C5i-exp and 2.7 for C5i-naive. Among C5i-exp patients, iptacopan cost per responder was $1,360,296 less than ravu, $1,655,996 less than ecu, and $1,209,807 less than ABP959 (cost per responder: iptacopan = $589,769, ravu = $1,950,065, ecu = $2,245,765, ABP959 = $1,799,575). Among C5i-naive patients, iptacopan cost per responder was $283,197 less than ravu, $413,004 less than ecu, and $217,134 less than ABP959 (cost per responder: iptacopan = $572,849, ravu = $856,045, ecu = $985,853, ABP959 = $789,983).

CONCLUSIONS: Iptacopan is a cost-effective alternative to standard C5is among C5i-exp and C5i-naive patients with higher response rates and lower cost per responder.

SPONSORSHIP: Novartis Pharmaceuticals Corporation

D6 Resource utilization and economic burden among a cohort of patients with hemophilia with inhibitors in the United States

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BACKGROUND: Hemophilia is a rare bleeding disorder characterized by significant economic burden. Development of inhibitors against factor VIII and IX compromise treatment options and increase risk of bleeding and joint damage. Patients with inhibitors experience high direct costs of disease management. Prophylactic treatment is recommended to prevent bleeding episodes; however, at the time of this study, there were no Food and Drug Administration (FDA)–approved prophylactic options for patients with hemophilia B with inhibitors (PwHBwI) and only one prophylactic option for patients with hemophilia A with inhibitors (PwHAwI).

OBJECTIVE: To assess hemophilia-related costs and health care resource utilization (HCRU) in PwHAwI or PwHBwI in the United States (US).

METHODS: This was a descriptive, non-interventional, retrospective cohort study of medical and pharmacy claims data (Komodo Health claims database). The study period ran from Jan 1, 2016, to Dec 31, 2023. The cohort includes PwHAwI and PwHBwI on non-prophylactic and prophylactic treatment regimens, identified from medication claims and defined as 6 consecutive prescriptions with days' supply >7 days and no gaps of >60 days.

RESULTS: Data was collated from 100 patients, well distributed across the US with 12-32% in each geographical quadrant. The 84 PwHAwI and 16 PwHBwI had a median age of 23.0 and 21.8 years, respectively. Almost all patients were male (96% HAwI and 88% HBwI). Joint-related problems were reported for many patients (33% HAwI and 50% HBwI). Mean annualized bleeding rates (ABR) were 1.3 and 1.8 for PwHAwI and PwHBwI, respectively. 69% of PwHAwI (n = 58) and 75% (n = 12) of PwHBwI experienced ≥1 bleeding event. Of the 41 (49%) PwHAwI receiving prophylaxis, bleeds were experienced by almost half (n = 20), with a mean ABR among those with ≥1 bleed of 1.6. On an annualized basis, patients demonstrated significant HCRU. 26% of PwHAwI were hospitalized (mean duration of 6 days), all (100%) had outpatient visits, and 61% visited the emergency department (ED). 38% of PwHBwI were hospitalized (mean duration of 13 days), 94% had outpatient visits, and 63% visited the ED. Mean all-cause total costs (PwHAwI, $359,304; PwHBwI, $156,789) were largely composed of pharmacy costs for HA (57%) and medical costs for HB (97%).

CONCLUSIONS: Patients with hemophilia and inhibitors incur substantial economic burden. There is an urgent need for improved prophylactic options and targeted interventions to optimize patient care and mitigate costs.

SPONSORSHIP: Novo Nordisk

D8 Health Care Utilization and Costs Among Hereditary Angioedema Patients Receiving Long-Term Prophylaxis: Results of a Claims Database Analysis

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BACKGROUND: Most patients with hereditary angioedema (HAE) in the US are treated with non-androgen long-term prophylaxis (LTP) therapies. Currently, real-world data on health economic outcomes associated with LTP use is limited.

OBJECTIVE: This study assessed the impact of LTP on on-demand therapy claims, health care resource utilization, and total health care costs in patients with HAE using a national administrative claims database.

METHODS: Commercially insured patients from the IQVIA PharMetrics® Plus Database (Jan 2016 - Sept 2023) with ≥1 claim for non-androgen LTP, with ≥6 months of continuous enrollment before and ≥12 months following index date (first non-androgen LTP claim). The grace period was defined as 60 days for lanadelumab and 30 days for other LTP. Adherent: no prescription gap > grace period; non-adherent: ≥1 gap between refills > grace period; switchers: ≥1 non-index LTP claim. Annualized mean on-demand therapy claims, inpatient, outpatient, emergency room visits, home health visits, and costs were evaluated 12 months before and after index.

RESULTS: Of 334 LTP users (mean age 41.2 years; 70% female), 147 (44%) were adherent, 131 (39%) were non-adherent (including 74 who discontinued), and 56 (17%) switched. Overall, 67.7% of LTP users had ≥1 post-index on-demand therapy claim. Mean total HAE-related health care cost per patient per year was $173,543 pre-LTP and increased to $561,451 post-LTP, driven by LTP pharmacy costs ($406,405). Adherent users had a 267% increase in mean costs with the largest decrease in on-demand pharmacy costs (-$107,919). Non-adherent users had an increase in mean costs of 149% with the smallest increase in LTP costs ($219,900) and a slight reduction in on-demand costs (-$16,152). Switchers had an overall mean cost increase of 249%, driven by increases in LTP and on-demand pharmacy costs ($533,507 and $154,737, respectively).

CONCLUSIONS: Total HAE-related health care costs increased after LTP initiation, primarily driven by LTP pharmacy costs. Adherent users had the largest increase in total health care costs, driven by an increase in LTP pharmacy costs, which was partially offset by a decrease in on-demand medication costs. Non-adherent users had an increase in LTP pharmacy costs without a decrease in on-demand costs. LTP switchers had increases in both LTP and on-demand pharmacy costs, as well as medical costs.

SPONSORSHIP: This study was sponsored by KalVista Pharmaceuticals

D9 Long-Term Safety and Efficacy of Oral Deucrictibant for Treatment of Hereditary Angioedema Attacks: Results of the RAPIDe-2 Extension Study

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BACKGROUND: Hereditary angioedema (HAE) is a rare genetic condition caused by excess bradykinin production and characterized by painful, often debilitating, swelling attacks affecting the skin, gastrointestinal tract, and airways. Burden associated with parenteral administration of currently approved on-demand medications leads to treatment of a number of HAE attacks being delayed or forgone. An unmet need exists for on-demand oral therapies that are effective and well tolerated and may reduce the treatment burden, thus enabling prompt administration. In the RAPIDe-1 phase 2 trial (NCT04618211) deucrictibant immediate-release (IR) capsule reduced the time to onset of symptom relief and to resolution of HAE attacks vs placebo and was well tolerated.

OBJECTIVE: To evaluate the long-term safety and efficacy of deucrictibant IR capsule for treatment of repeat HAE attacks.

METHODS: RAPIDe-2 (NCT05396105) is an ongoing phase 2/3 extension study. Part A of RAPIDe-2 enrolls adult participants who completed RAPIDe-1. In the ongoing part A, participants continue self-administering the same double-blinded dose of deucrictibant IR capsule (10 mg, 20 mg, or 30 mg) received in RAPIDe-1 to treat qualifying HAE attacks. The Patient Global Impression of Change (PGI-C) and of Severity (PGI-S) were used to assess response to treatment with regard to symptom improvement and severity from the participant's perspective.

RESULTS: This Part A data cutoff (March 1, 2024) included 265 attacks treated with deucrictibant IR capsule by 17 participants (combined dose group results). At baseline, mean age was 43.9 years; 61.1% were female. Deucrictibant IR capsule was well tolerated, with no treatment-related treatment-emergent adverse events (TEAEs) and no TEAEs leading to treatment discontinuation. Median time (95% CI) to onset of symptom relief using PGI-C was 1.1 hours (1.0-1.2); 98.5% of attacks achieved this milestone by 12 hours. Median time to complete attack resolution using PGI-S was 11.5 hours (11.0-13.0); 85.8% of attacks achieved this milestone by 24 hours. Rescue medication was used in 4/265 (1.5%) attacks: in 3 instances after one dose of deucrictibant IR capsule, and in 1 instance after two doses.

CONCLUSIONS: Results of the RAPIDe-2 extension study provide evidence on the long-term safety and efficacy of deucrictibant IR capsule for treatment of repeat HAE attacks.

SPONSORSHIP: Pharvaris

D10 Long-Term Safety, Efficacy and Health-Related Quality of Life of Oral Deucrictibant for Prophylaxis in Hereditary Angioedema: Results of the CHAPTER-1 Open-Label Extension

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BACKGROUND: Hereditary angioedema (HAE) is a rare genetic condition caused by excess bradykinin production and characterized by painful, often debilitating, swelling attacks affecting the skin, gastrointestinal tract, and airways. People with HAE may experience high burden of illness and health care resource utilization. Despite the availability of approved therapies, an unmet need remains for additional prophylactic treatments combining injectable-like efficacy, a well-tolerated profile, and ease of administration. Deucrictibant is a selective, orally administered bradykinin B2 receptor antagonist under development for prophylactic and on-demand treatment of HAE attacks.

OBJECTIVE: To evaluate the long-term safety and efficacy of deucrictibant for prophylaxis of HAE attacks.

METHODS: In this ongoing open-label extension (OLE) of the phase 2 CHAPTER-1 trial (NCT05047185), 30 participants who had received deucrictibant 20 mg/day (N = 11), 40 mg/day (N = 10), or placebo (N = 9) during part 1 continued into part 2 and received deucrictibant 40 mg/day. Eligible participants were aged ≥18 and ≤75 years, were diagnosed with HAE-1/2, and had experienced ≥3 attacks within 3 months prior to screening or ≥2 attacks during screening (up to 8 weeks).

RESULTS: This part 2 data snapshot (cutoff: June 10, 2024) included 30 participants in the OLE who received deucrictibant 40 mg/day with a mean (standard deviation [SD]) treatment duration of 12.83 (5.03) months. Mean age at part 1 baseline was 39.1 years; 60% were female. Deucrictibant was well tolerated, with no treatment-related serious or severe treatment-emergent adverse events (TEAEs) and no TEAEs leading to study drug discontinuation, withdrawal, or death. The monthly attack rate was reduced by 93.0% in participants receiving deucrictibant 40 mg/day in the OLE (mean [SD]: 0.15 [0.25]) vs part 1 baseline (2.16 [1.36]). The mean (SD) monthly rate of "moderate and severe" attacks and attacks treated with on-demand medication in the OLE was 0.07 (0.03) and 0.07 (0.02), respectively. Health-related quality of life (HRQoL), assessed using Angioedema QoL Questionnaire (AE-QoL), showed a total mean score improvement of 28.2 points from part 1 baseline to week 62 (N = 14) in participants receiving deucrictibant 40 mg/day.

CONCLUSIONS: The results of the ongoing CHAPTER-1 OLE provide evidence on the long-term safety and efficacy of deucrictibant for prevention of HAE attacks. Consistent with clinical outcomes, clinically meaningful improvement in HRQoL was maintained through more than 1 year of treatment.

SPONSORSHIP: Pharvaris

E00-E90 Endocrine, Nutritional, and Metabolic Diseases

(eg, diabetes, growth hormone, lipids)

E1 Association between tubeless automated insulin delivery and health care resource utilization and medical costs

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BACKGROUND: The Omnipod 5 Automated Insulin Delivery (AID) System is cleared by the U.S. Food and Drug Administration for people with type 1 diabetes (T1D) ages two and older and type 2 diabetes (T2D) ages 18 and older. Prior studies demonstrated the clinical impact of Omnipod 5, but the impact on health care resource utilization (HCRU) and medical costs has not been studied.

OBJECTIVE: To compare medical HCRU and costs before and after initiation of Omnipod 5.

METHODS: Using the Optum Research Database of deidentified claims data, a retrospective analysis was conducted to identify commercial and Medicare Advantage patients that initiated Omnipod 5 (index date) between August 2022 and December 2022. Outcomes were compared in the 12 months prior to the index date versus the 12 months after and including index date. Users were required to be ≥2 years old, have continuous enrollment data available for the 24-month duration, and have ≥2 claims with diagnosis codes for T1D or T2D. All-cause and diabetes-related HCRU (ambulatory visits, emergency department [ED] visits, inpatient [IP] stays), hypoglycemic and hyperglycemic events, and associated costs were evaluated.

RESULTS: A total of 2,504 Omnipod 5 users were included in the study: mean age 42 years, predominately T1D (76%), commercially insured (70%), prior pump therapy (63%), and prior continuous glucose monitoring (92%). Mean baseline A1C was 7.8%. The proportion of users experiencing diabetes-related HCRU was lower post-initiation relative to pre-initiation for ED visits (12.1% vs 9.3%; $p<0.001$), IP stays (9.8%, 7.8% $p=0.005$), and hyperglycemic events (63.0% vs 59.4%; $p<0.001$). Similar results were observed for all-cause ED visits and IP stays. There were no differences in the mean count of HCRU for all-cause and diabetes-related HCRU overall, but mean (SD) counts of hypoglycemic and hyperglycemic events per patient were lower after initiation: 0.20 (1.2) vs 0.16 (0.8); $p=0.046$ and 2.4 (3.2) vs 2.2 (2.8); $p<0.001$, respectively. 12-month all-cause and diabetes-related medical costs ($K) were lower post-initiation (mean [SD]): 18.2 (37.1) vs 16.4 (39.1); $p=0.029$ and 8.6 (25.7) vs 6.4 (19.1); $p<0.001$, respectively.

CONCLUSIONS: Omnipod 5 was associated with reductions in users experiencing ED visits and IP stays, along with fewer hyper- and hypoglycemic events. A $2,138 decrease in mean diabetes-related medical costs was observed in the 12-month follow-up period. These real-world outcomes demonstrate the value Omnipod 5 offers payers and users.

SPONSORSHIP: Insulet Corporation

E2 Misdiagnoses of Autoimmune Type 1 Diabetes (T1D) or Latent Autoimmune Diabetes in Adults (LADA) as Type 2 Diabetes (T2D) in Adults: A Systematic Literature Review (SLR)

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BACKGROUND: Approximately 40% of adults (≥30 years) initially misdiagnosed with T2D may actually have autoimmune T1D or LADA. Such misdiagnoses represent critical missed opportunities for early intervention, potentially delaying disease progression and impacting treatment outcomes.

OBJECTIVE: To systematically review the prevalence of misdiagnoses of autoimmune T1D or LADA as T2D in adults ≥18 years of age.

METHODS: An SLR was conducted by searching MEDLINE® and Embase from database inception to April 3, 2024. Eligible observational studies reported the prevalence of misdiagnoses of autoimmune T1D or LADA as T2D among adults diagnosed with autoimmune T1D, LADA, or T2D. Data extraction included misdiagnoses percentages, diagnostic criteria used to correct misdiagnoses, and health care personnel involved in the diagnoses.

RESULTS: Of 5,874 records screened, 16 studies (10 cross-sectional, 5 retrospective, 1 case-control) were included. Study populations: autoimmune T1D (5), T2D (3), T1D and T2D (7), and LADA (1). Sample size: 10-38,344 (median: 316); patient age: 43-67 (median: 52.5 years). Patient surveys and past medical records were used among T1D/LADA patients and diagnostic tests among T2D patients to determine misdiagnoses. Misdiagnoses rates for autoimmune T1D as T2D ranged from 3% to 47% (median: 22%, 9 studies). Among clinically diagnosed autoimmune T1D (6 studies), rates ranged from 3% to 47% (median: 23%), and for clinically diagnosed T2D patients (2 studies), 4.6% and 12.5%. LADA misdiagnosed as T2D ranged from 4.2% to 8.3% (median: 5.6%).

An Australian study reported that endocrinologists were less likely to misdiagnose vs general practitioners (odds ratio 3.1 [95% CI 1.5-6.2]). To mitigate misdiagnoses, C-peptide and autoantibody (e.g., glutamic acid decarboxylase antibody [GADA], tyrosine phosphatase-related islet antigen2 [IA2], and zinc transporter 8 [ZnT8]) testing should be considered. Time to insulin initiation (within 1-3 years of diagnosis) should be considered, as a UK study found that misdiagnoses were significantly higher in patients with delayed (47%) vs early (3%) insulin initiation after diagnosis.

CONCLUSIONS: The prevalence of misdiagnoses of autoimmune T1D/LADA is common in clinical practice, although estimates varied across populations. This SLR highlights that enhanced provider education, diagnostic biomarkers (C-peptide, autoantibodies), and early-stage diagnosis are critical to delay the progression of autoimmune T1D and LADA.

SPONSORSHIP: Sanofi

E3 Estimating the Impact of Utilizing the Lower of Glucose Management Indicator (GMI) with Hemoglobin A1c (HbA1c) Within the Glycemic Status Assessment for Patients with Diabetes (GSD) Measure on Plan Performance

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BACKGROUND: Hemoglobin A1c (HbA1c) is an important metric used to assess quality of care for members with diabetes. Unfortunately, HbA1c levels can be affected by nonglycemic factors such as race, anemia, and age. Recently, the National Committee for Quality Assurance (NCQA) added the continuous glucose monitoring (CGM)–based GMI to the GSD Healthcare Effectiveness Data and Information Set (HEDIS) measure, which may reduce the impact of nonglycemic factors on perceived level of glucose control.

OBJECTIVE: To evaluate the impact of utilizing the lower value of a member's HbA1c or GMI would have on health plan performance for the GSD measure.

METHODS: A real-world dataset that combined data from administrative payor claims, FreeStyle Libre data housed in LibreView, and a large reference lab data set to extract GMI and HbA1c data. A total of 9,355 members were analyzed with diagnosis of type 1 or type 2 diabetes, age 18 to 75 years, HbA1c 5.7%-11%, and GMI range of 6.1%-10.7%. Members were analyzed for both numerator 1 (Glycemic status < 8%) and numerator 2 (Glycemic status > 9%) of the measure to determine the impact of the lower value of a member's paired HbA1c/GMI on the GSD measure compared to when only using HbA1c. Lastly, the impact of leveraging GMI was also analyzed at different thresholds of missing HbA1c by increasing population sizes in each of the denominators.

RESULTS: The three analyses comparing the use of the lower value of the paired HbA1c/GMI demonstrated that greater number of members were able to improve their glycemic status for numerator 1, numerator 2, and those with missing HbA1c values. For numerator 1 and numerator 2, there was a shift in cumulative compliance rates of 69.9% to 85.8% and 11% to 2.4% when using the lower paired value compared to HbA1c alone. By using the lower value of HbA1c/GMI, it was determined that measure performance can increase by 6-8%, improving the overall HEDIS performance rating. When stratifying results by race, Black individuals had the largest improvement in their glycemic status score by 20%.

CONCLUSIONS: Implementing the use of GMI derived from CGM in health plans HEDIS quality programs may help improve quality scores. Furthermore, the NCQA now requires GSD performance reporting by race and ethnicity, which provides more incentive to incorporate GMI in HEDIS quality programs due to the significant improvement in measure scores with emphasis on the Black population.

SPONSORSHIP: Abbott Diabetes Care

E4 Examining the Holy Grail of 80% Medication Adherence of the Newer Antidiabetic Agents: Cost Impacts of Higher Adherence

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BACKGROUND: There are efforts from clinical pharmacists to encourage medication adherence based on established improvement in clinical outcomes. Medicare star ratings are also affected by medication adherence. What are the cost implications of improvement beyond 80%?

OBJECTIVE: To evaluate the cost impacts of higher adherence of patients with diabetes taking GLP-1 or SGLT-2 medications.

METHODS: Patients in a large regional health plan, aged 50-80 years with diabetes and a history of cardiovascular diseases, were grouped into 3 groups based on their baseline 12-month adherence (PDC). Group 1 (PDC 70 to <80), Group 2 (PDC 80 to <90), and Group 3 (PDC ≥90). Per-member-per-month (PMPM) costs (total cost of care [TCC], pharmacy costs [PCs], medical costs [MCs]) were assessed for patients with index (GLP-1 or SGLT-2) fill in 2018. PMPM costs

12 months pre- and 24 months post of patients with commercial (CM) and Medicare (MC) insurance were assessed. We compared PMPM of those who moved from one group to a higher group with those who stayed in the same group.

RESULTS: There were 2,178 in the final sample (76% with CM and 24% with MC). Of these, there were pre vs post: (24% vs 6% in Group 1), (25% vs 13% in Group 2), (51% vs 71% in Group 3), and 11% fell below 70%. The following were the differences between post-pre differences of those who moved up and those who stayed within the group: Group 1 to Group 2 (TCC: $63; PCs: $82; MCs: -$20), Group 2 to Group 3 (TCC: -$233; PCs: $69; MCs: -$302), post-pre for those who stayed in Group 3 (TCC: $137; PCs: $159; MCs: -$22).

CONCLUSIONS: : Among patients 50-80 years with a history of cardiovascular disease, our findings suggest that medical cost decreases if patients with diabetes on GLP-1 and SGLT-2 improve their adherence beyond 80%; pharmacy cost increases, however, with TCC increases moving from 70-80% to 80-90%, but TCC decreases for those who move from 80-90% to above 90%.

SPONSORSHIP: None

E5 Evaluating the Impact of GLP-1 on Health Outcomes in Patients Using GLP-1 Receptor Agonists: Insights from Real-World Evidence

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BACKGROUND: Glucagon-like peptide-1 receptor agonists (GLP-1 RA) are used in the treatment of type 2 diabetes mellitus. They have been shown to improve glycemic control, promote weight loss, and reduce cardiovascular risk factors.

OBJECTIVE: This study aims to compare the burden of comorbidities before and after the initiation of GLP-1 RA treatment.

METHODS: A retrospective analysis was conducted using the Optum® Market Clarity Database, encompassing the period from January 1, 2018, to December 31, 2021. The study included adults aged 18 and above who had received at least one prescription for GLP-1 RA. The index date was defined as the earliest prescription of GLP-1 RA. Patients were required to have continuous enrollment for at least 12 months before and after the index date. The study compared the burden of comorbidities using the Charlson Comorbidity Index (CCI) scores pre- and post-initiation of GLP-1 RA treatment.

RESULTS: Out of 1,425,159 patients with at least one prescription for GLP-1 RA, 461,856 patients met the criteria of having continuous enrollment for at least 12 months before and after the index date. During the 12-month baseline period, the sample had an average CCI score of 1.37 (standard deviation 1.69), which increased to 1.50 (standard deviation 1.81) during the 12-month follow-up. Among patients with a baseline CCI score of 3 or higher and a high proportion of days covered (PDC) value above 0.8 during the 12-month follow-up, the average CCI score decreased to 3.56 (standard deviation 2.10) from 4.19 (standard deviation 1.51) over the same period. The paired t-test demonstrated a statistically significant difference ($p < 0.001$) in the CCI score before and after treatment.

CONCLUSIONS: The study's findings suggest that patients with higher CCI scores who adhere to GLP-1 RA treatment experience a reduction in the burden of comorbidities.

SPONSORSHIP: None

E6 Payer-Provider Risk-Sharing Agreements to Advance Continuous Glucose Monitoring–Based Care in Type 2 Diabetes

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BACKGROUND: Optimal diabetes management may be impeded by the underutilization of advances in care interventions, including continuous glucose monitoring (CGM). In addition, recent trends toward payment reform in the care of chronic conditions—including risk-sharing agreements—seek to mitigate quality-related barriers to optimal diabetes management.

OBJECTIVE: To identify current best practices and pragmatic risk-sharing agreement parameters for CGM regarding practice setting, target population, clinical measures, and adjacent personnel.

METHODS: An expert panel of 4 payer and 6 provider stakeholders was convened to discuss opportunities for CGM-based care management in risk-sharing agreements between payers and providers. The panelists were surveyed before two virtual roundtable meetings, during which pertinent clinical and trend data were shared.

RESULTS: All payer participants cited using interdisciplinary care management for T2D and 50% used a digital health platform, but only 25% featured an integrated CGM component. All payer participants responded that "fingerstick" glucose management was either inadequate or questionable for use in current care management programs for T2D. Conversely, 100% also responded that CGM would improve their care delivery solutions. Expert panelists outlined 3 key elements of risk-sharing agreements: agreement design,

realistic outcomes measures, and strategies to facilitate payer and provider participation.

CONCLUSIONS: The panel recommended that future programming and risk-sharing agreements focus on an appropriate patient population, attainable measures, and coordination among interdisciplinary personnel to facilitate successful and sustainable T2D management. The anticipated result of implementing these key elements of a risk-sharing agreement is improved clinical outcomes via the facilitation of care coordination, data reporting, and the implementation of interventions to address social determinants of health.

SPONSORSHIP: Dexcom

E7 Results of a Pharmacist-Directed Implementation of Professional Continuous Glucose Monitoring (proCGM) in Primary Care

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BACKGROUND: Ambulatory care pharmacists are well positioned to support professional use of continuous glucose monitoring (proCGM) in primary care.

OBJECTIVE: To evaluate a pharmacist-led initiative to implement proCGM in primary care.

METHODS: This initiative was conducted between August 2022 and July 2024 by the URI College of Pharmacy, the RI Department of Health, and the Care Transformation Collaborative of RI. Six pharmacists were selected to lead program implementation within their organizations, which included patient recruitment, placing sensors, reviewing results, and medication adjustment. Patients were included if one or more of the following criteria were met: hemoglobin A1c (A1c) above goal, discordant A1c and self-monitoring of blood glucose readings, hypoglycemia unawareness, and provider referral. We measured the short-term (3-6 months) post-proCGM change in A1c from baseline, and the proportion of patients who achieved ≥1 point reduction. These outcomes were evaluated by patient age, insurance, and practice site. Pre-post differences were assessed using paired t-tests and one-way ANOVA, and chi-square tests for proportions. Statistical analyses were performed with SAS 9.4. The project was approved by the URI IRB.

RESULTS: A total of 396 patients participated, with a range of 43 to 97 patients per site. The participants' mean baseline A1c was 9.35 (standard deviation 2.0), and the average duration of sensor placement was 12.7 days (SD 3.2). Most patients were between 50 and 69 years of age (55.1%). Medicare was the most frequent insurance type (41.4%), followed by commercial insurance (24.0%) and Medicaid (23.2%). The mean A1c following proCGM was 8.25, representing a 1.1 point reduction from baseline ($p < 0.0001$). There were no statistically significant differences in A1c reduction by age group or insurance type. Mean A1c reduction varied by practice site, ranging from -0.31 to -1.40 ($p = 0.003$). The proportion of patients who achieved ≥1 percentage point reduction in A1c was 42.5%, and this result was achieved by 51.6% of patients with commercial insurance, 47.8% of patients with Medicaid, 40.6% of patients with Medicare, and less than 30% of uninsured ($p < 0.001$). A1c reduction coincided with pharmacist-initiated medication changes, which occurred in 69.5% of patients.

CONCLUSIONS: Our findings support the role of ambulatory care pharmacists in the use of proCGM to improve glycemic control. Further study is needed to determine the optimal uses of pro-CGM given the expansion of personal CGM, and to assess impacts on patient outcomes and health system costs.

SPONSORSHIP: UnitedHealthcare RI Department of Health

E8 Value Impact and Evidence for Whole person care (VIEW) Model: Demonstrating the Value of an Automated Insulin Delivery System (AID) on Achieving HEDIS/ADA Glycemic Standards and Impact on CMS Star Rating

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BACKGROUND: Management of diabetes requires tight glycemic control to prevent downstream clinical and economic consequences. The VIEW model uses real world evidence to demonstrate the value of AID technology based on its impact on clinical quality measures, CMS star ratings, health care resource use, costs, and disparities in glycemic outcomes.

OBJECTIVE: The objective is to quantify the value of an AID compared to multiple daily injections (MDI) from a payer perspective, using the VIEW model. The value impact on glycemic outcomes and quality ratings were modeled for a population for type 1 and 2 diabetes (T1D, T2D).

METHODS: The model simulates an incremental 15% adoption of AID use from an MDI population with T1D and T2D across Commercial, Medicare, and Medicaid plans over a 1-year time horizon. Prevalence rates for T1D (0.55%) and T2D (8.58%) based on statistics from the Centers for Disease Control and Prevention were applied. The model assumed a mean baseline HbA1c of 8.3% for T1D and 8.5% for T2D,

based on real world evidence from an AID (t:slim X2 with Control-IQ technology). Clinical value impact was calculated by changes in American Diabetes Association (ADA) and NCQA Healthcare Effectiveness and Data Information Set (HEDIS) goal attainment. Thresholds for goal attainment were Hba1c <7% for ADA, HbA1c <8% (in control) for HEDIS, and 100% minus the percentage of beneficiaries with HbA1c >9% (poor control) for the CMS Star measure "C10 - Diabetes Care – Blood Sugar Controlled". The incremental quality bonus payment (QBP) for the change in the weighted C10 measure was calculated using the average monthly Medicare capitation rates for 2025, while holding performance of all other star measures constant. The model assumed a baseline raw overall/summary score (pre-rounded) of 3.72.

RESULTS: Based on a payer with 1 million lives, simulation results found relative improvements of HEDIS and ADA goal attainment were 7.7% and 13.0% for T1D and 21.1% and 16.0% for T2D, respectively. For Medicare, 2.2% more beneficiaries with blood sugar under control (100% minus HbA1c >9%), resulting in an increase to 3.75- and 4.0-star rating for raw and final overall/summary scores, respectively. The star rating improvement corresponded to an incremental QBP of $39.41 per beneficiary per month.

CONCLUSIONS: The VIEW model can be used to quantify the value impact of an AID technology from a payer perspective, using real world glycemic outcomes. The model found improvements in HEDIS/ADA goal attainment, higher star ratings, and greater QBP.

SPONSORSHIP: Tandem Diabetes Care

E9 Oral semaglutide adherence and associated risk factors in patients with type 2 diabetes in the United States

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BACKGROUND: In patients (pts) with type 2 diabetes (T2D), adherence to diabetes treatment has been associated with improved health outcomes. Oral semaglutide is the first and only oral glucagon-like peptide-1 analog approved for treatment of T2D.

OBJECTIVE: This real-world retrospective cohort study evaluated adherence to oral semaglutide and identified factors associated with lower adherence, with a focus on almost adherent pts.

METHODS: Data were obtained from Optum's de-identified Clinformatics® Data Mart Database from pts initiated on oral semaglutide with an index date (date of first fill) and continuous 12-month follow-up data between January 2018 and June 2023. Proportion of days covered (PDC) was used to assess adherence, with a stockpiling adjustment. PDC was evaluated separately for each quarter (Q) after the index date. Pts were categorized into non-adherent (PDC < 48%), almost adherent (48% ≤ PDC < 80%), and adherent (PDC ≥ 80%) groups, where almost adherence becomes adherence on one additional prescription fill at each follow-up quarter. Multinomial random-effects logistic regression was used to assess risk factors during baseline (12 months pre-index) and follow-up periods of adherence to oral semaglutide.

RESULTS: In total, 20,016 pts were identified and the mean quarterly PDC for Q1-4, respectively, was 78%, 53%, 46%, and 42%. In Q1, 59.8% of pts were adherent,18.5% were almost adherent, and 21.8% were non-adherent. By Q4, the proportion of pts who were adherent was 35.7%, almost adherent was 7.8%, and non-adherent was 56.5%. Compared with the adherent group, factors or variables associated with the almost adherent group included being Black (OR = 1.24; vs White), being Hispanic, (OR = 1.32; vs White), history of atherosclerotic cardiovascular disease (OR = 1.12), HbA1c levels ≥ 8% (OR = 1.15), presence of anxiety disorder (OR = 1.10), or insulin use on index (OR = 1.30). Variables associated with a lower likelihood of almost adherent vs adherent behavior included adherence for other T2D treatments at baseline (OR = 0.65), and polypharmacy (OR = 0.79) during the follow-up period. Risk factors for non-adherent vs adherent behaviors were similar for those associated with almost adherent vs adherent.

CONCLUSIONS: This study identified factors and variables associated with less adherent behavior to oral semaglutide. These findings can be used to improve pt adherence to oral semaglutide and form intervention programs in clinical practice.

SPONSORSHIP: Novo Nordisk Inc.

E10 Diagnostic journey of patients with type 1 diabetes with and without a prior type 2 diabetes misdiagnosis in a US managed care population

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BACKGROUND: Up to 40% of adults with type 1 diabetes (T1D) may initially be misdiagnosed with type 2 diabetes (T2D). The diagnostic journey in T1D patients is unclear.

OBJECTIVE: To assess the diagnostic journey of T1D patients with and without prior T2D diagnosis.

METHODS: This observational cohort study assessed administrative claims from the Carelon Healthcare Integrated Research Database between Oct 1, 2015, and Dec 31, 2023. Patients with ≥2 outpatient claims for T1D 30-183 days apart or ≥1 inpatient claim were identified. First T1D diagnosis was the index date. Patients required ≥12 months' continuous medical and pharmacy benefit prior to (baseline) and after index (follow-up). Patients with ≥2 T2D diagnoses or only 1 T1D diagnosis during 12-month follow-up, or secondary diabetes or pregnancy during 12-month baseline, were excluded. Diagnostic procedures in patients with and without prior T2D diagnoses were assessed descriptively and stratified by age.

RESULTS: Of 8,577 patients with a qualifying index T1D diagnosis, 2624 (31%) had ≥1 prior T2D diagnosis (41% female; mean age: 45 years; <18 years: 6%), and 5,953 (69%) had no prior T2D diagnosis (42% female; mean age: 27 years; <18 years: 46%). In patients with and without prior T2D diagnosis, 24% versus 2% (<18 years: 16% vs 1%; ≥18 years: 24% vs 3%) had a C-peptide test ordered, 72% versus 13% (<18 years: 65% vs 8%; ≥18 years: 72% vs 17%) had a hemoglobin A1C (HbA1c) test ordered; and 23% versus 2% (<18 years: 38% vs 2%; ≥18 years: 23% vs 3%) received an outpatient autoantibody (AA) test during the baseline period before T1D diagnosis; at index diagnosis, 4% versus 9% (<18 years: 8% vs 17%; ≥18 years: 4% vs 3%) received an outpatient AA test. Mean (SD) time to T1D diagnosis from first AA test in those with and without a prior T2D diagnosis was 61 (79) days versus 63 (93) days (<18 years: 38 [64] days vs 65 (101) days; ≥18 years: 63 [80] days vs 61 [88] days).

CONCLUSIONS: Relatively few patients received C-peptide, HbA1c, or AA tests during baseline; inpatient AA tests were not captured. C-peptide, HbA1c, and AA tests before T1D diagnosis were ordered more frequently for patients with a prior T2D diagnosis, likely due to physicians suspecting that their T2D diagnosis is incorrect; patients with no prior diabetes diagnosis were less likely to have had tests ordered. Increased diagnostic testing, in particular AA tests, during diabetes evaluation may facilitate correct T1D diagnosis, avoid delays in disease management, and improve outcomes.

SPONSORSHIP: Sanofi

E11 Treatment response and health care costs in the 180-day period after glucagon-like peptide-1 receptor agonist (GLP-1RA) initiation in patients with diabetes

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BACKGROUND: As studies have identified genetic variants associated with glycemic response to GLP-1RA, pharmacogenomic tests may be developed to assess how patients will respond to GLP-1RA therapy. Models to estimate the budget impact of pharmacogenomic tests require real-world data inputs for the proportion of patients with/without A1c response and short-term health care costs for responders and non-responders after GLP-1RA initiation.

OBJECTIVE: To assess the proportion of patients with diabetes who had A1c response and describe health care costs for responders and non-responders in the 180 days after initiating GLP-1RA.

METHODS: Using de-identified administrative claims data from the Optum Labs Data Warehouse, commercial and Medicare Advantage (MA) enrollees ≥18 y with ≥1 GLP-1RA from 07/01/2017 to 06/30/2023 were identified (index date = first GLP-1RA). Inclusion criteria were continuous enrollment in the 180-day baseline and 180-day follow-up periods, ≥1 baseline diabetes diagnosis, no baseline GLP-1RA claims, ≥1 baseline A1c, ≥1 A1c in follow-up days 91 to 180, and last baseline A1c ≥7.0%. The last A1c in follow-up days 91 to 180 was used to group patients as responders (<7.0%) or non-responders (≥7.0%). Health care costs were measured in the 180-day follow-up and adjusted to 2023 values. Imbalance in responders vs. non-responders was assessed with standardized difference (SMD); >0.10 was considered meaningful.

RESULTS: Of 55,835 identified patients (median 66 y, 64% MA), 38% were responders and 62% non-responders. Mean baseline A1c for responders vs. non-responders was 8.5% vs. 9.2% (SMD 0.51); mean last follow-up A1c was 6.3% vs. 8.4% (SMD 2.1). In the baseline period, 89% responders vs. 94% non-responders (SMD 0.17) used ≥1 non-GLP-1RA therapy; 15% vs. 18% (SMD 0.08) had a claim for ≥1 non-GLP-1RA therapy on index date. In follow-up days 91 to 180, more responders than non-responders continued GLP-1RA (81% vs. 66%, SMD 0.33), and 78% vs. 87% (SMD 0.25) used ≥1 non-GLP-1RA treatment. Follow-up total health care costs were similar for responders and non-responders (mean ± SD $14,735 ± 22,358 vs. $14,328 ± 18,746, SMD 0.02), as were pharmacy costs $8,418 ± 8,781 vs. $8,343 ± 8,762 (SMD 0.01) and medical costs $6,317 ± 20,002 vs. $5,985 ± 15,931 (SMD 0.02).

CONCLUSIONS: While A1c response was low (38% patients), health care costs were similar for responders

and non-responders in the 180-day period after initiating GLP-1RA. Further research is needed to assess costs for responders and non-responders over a longer follow-up and adjust for baseline characteristics.

SPONSORSHIP: Optum

E12 Risk-Stratified Cardiovascular Outcomes and Spend among Commercially Insured Members with Type 2 Diabetes using GLP-1 and SGLT2i compared to Other Antidiabetic Drugs

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BACKGROUND: Total U.S. estimated cost of diagnosed type 1 and type 2 diabetes (T2D) in 2022 was $413 billion. Glucagon-like peptide-1 receptor agonists (GLP-1) and sodium-glucose transporter 2 inhibitors (SGLT2i) with established cardiovascular (CV) benefit may offset medical costs by reducing service utilization and spend for major adverse CV events (MACE), such as stroke, heart failure, and myocardial infarction; however, literature suggests that reduction in medical costs may not outweigh the high pharmacy (Rx) benefit costs conferred by these drugs.

OBJECTIVE: Assess real-world odds of MACE and difference in all-cause spend for T2D members taking GLP-1 or SGLT2i v. Other Antidiabetic (OA) therapy (sulfonylurea or dipeptidyl peptidase-4 inhibitor [DPP4i]).

METHODS: Retrospective study of Blue Cross Blue Shield of Michigan (BCBSM) Rx and medical claims paid between 1/1/20 and 2/31/23, with index date 1/1/21-1/31/22. Commercial T2D members ≥18 years were continuously enrolled in medical and Rx coverage, and adherent to index drug (≥80% proportion of days covered post-index). Members were excluded if insulin use ≤180 days pre-index. Pairwise analysis cohorts: 1) GLP-1, 2) SGLT2i, and 3) OA; members were assigned by baseline atherosclerotic cardiovascular disease risk (ASCVD): 1) No ASCVD, 2) ASCVD. Statistical tests included propensity score matching (PSM) on baseline characteristics, logistic regression on odds of MACE, and difference-in-difference (DID) in all-cause spend.

RESULTS: Pre-PSM cohort sizes for GLP-1 (No ASCVD = 1,633, ASCVD = 198), SGLT2i (No ASCVD = 515, ASCVD = 94), OA (No ASCVD = 9,639, ASCVD = 1,212). Non-statistically significant lower odds of MACE in No ASCVD group for GLP-1 and SGLT2i v. OA: OR = 0.75, 95% CI: 0.50–1.14, and OR = 0.92, 95% CI: 0.51–1.64, respectively. Non-statistically significant odds of MACE in ASCVD group were similar for GLP-1 v. OA: OR = 1, 95% CI: 0.62–1.62, but higher for SGLT2i v. OA: OR = 1.23, 95% CI: 0.65–2.33. Significantly higher all-cause spend observed in No ASCVD group for GLP-1 v. OA; pre- v. post-index DID = $1,002 ($p < 0.0001$); however, higher for SGLT2i v. OA, DID = $102 ($p = 0.15$) was not statistically significant. Similarly, higher all-cause spend in ASCVD group for both GLP-1 and SGLT2i v. OA was not statistically significant (DID = $326, $p = 0.45$ and $707, $p = 0.26$, respectively).

CONCLUSIONS: 2-year odds of MACE were not significantly lower for GLP-1 or SGLT2i v. OA. Higher all-cause spend for GLP-1 and SGLT2i v. OA for No ASCVD and ASCVD groups was driven by greater Rx spend for GLP-1 and SGLT2i, suggesting medical spend was not offset due to high costs of GLP-1 and SGLT2i.

SPONSORSHIP: BCBSM

E13 Adherence to once-weekly injectable semaglutide and associated risk factors in patients with type 2 diabetes in the United States

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BACKGROUND: Once-weekly injectable semaglutide (sema OW) is a glucagon-like peptide-1 (GLP-1) analog available for the treatment of type 2 diabetes (T2D). Adherence to diabetes treatments among patients (pts) with T2D has been associated with improved health outcomes.

OBJECTIVE: To evaluate adherence to sema OW in pts with T2D in the US and identify factors associated with lower adherence, focusing on almost adherent pts.

METHODS: This retrospective real-world cohort study utilized data from pts that initiated sema OW (index date = date of first fill) in the US (January 2018 to June 2023), obtained from Optum's de-identified Clinformatics® Data Mart Database, over a 12-month follow-up period post-index, with continuous claims enrollment during this period required. Modified Proportion of Days Covered (mPDC) was used to assess adherence to sema OW, with a stockpiling and titration adjustment, and was evaluated separately for each quarter (Q) in the follow-up period. Pts were categorized into non-adherent (mPDC < 50%), almost adherent (50% ≤ mPDC < 80%), and adherent (mPDC ≥ 80%). Multinomial random-effects logistic regression was used to assess the associations of factors during baseline (12 months pre-index) or follow-up period with adherence to sema OW in each quarter.

RESULTS: In total, 70,693 pts were identified and the mean quarterly mPDC was 86%, 63%, 57%, and 53% for Q1–Q4, respectively. In Q1 and Q4, respectively, 71.0% and 43.2% of

pts were adherent, 16.8% and 12.4% were almost adherent, and 12.2% and 44.4% were non-adherent. Pts were more likely to be almost adherent than adherent if they were older (65–74 yrs, odds ratio [OR] = 1.11; 75+ yrs, OR = 1.24; vs <65 yrs), minority ethnicities (Black, OR = 1.23; Hispanic, OR = 1.21; vs White), lived outside the Northeast (South, OR = 1.23; West, OR = 1.15; Midwest, OR = 1.14), had HbA1c ≥8% (OR = 1.17), had anxiety disorder (OR = 1.06), had insulin use on index (OR = 1.10), had a history of atherosclerotic cardiovascular disease (OR = 1.06), were GLP-1 naive (OR = 1.20), or had T2D-related inpatient visits (OR = 1.05). Risk factors for non-adherent vs adherent pts were similar to those observed for almost adherent vs adherent. Variables associated with pts being more likely to be adherent vs almost adherent included year of index (2020, OR = 0.86; 2021, OR = 0.90; vs 2022), PDC ≥ 80% for other T2D treatments (OR = 0.69), polypharmacy (OR = 0.80), and obesity (OR = 0.95).

CONCLUSIONS: Several identified risk factors among pts with T2D who initiated sema OW could be used to formulate interventions to improve adherence to diabetes treatment.

SPONSORSHIP: Novo Nordisk Inc.

E14 Diagnostic setting of patients with type 1 diabetes and with or without prior type 2 diabetes misdiagnosis in a US managed care population

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BACKGROUND: Up to 40% of adults with type 1 diabetes (T1D) may initially be misdiagnosed with type 2 diabetes (T2D). The types of clinical providers diagnosing these patients are unclear.

OBJECTIVE: To assess the clinical providers diagnosing patients with T1D with and without prior T2D diagnosis.

METHODS: This observational cohort study analyzed administrative claims from the Carelon Healthcare Integrated Research Database between Oct 1, 2015, and Dec 31, 2023. Patients with ≥2 outpatient claims for T1D 30–183 days apart or ≥1 inpatient claim were identified. First T1D diagnosis was the index date. Patients required ≥12 months' continuous medical and pharmacy benefit prior to (baseline) and after index (follow-up). Patients with ≥2 T2D diagnoses or only 1 T1D diagnosis during 12-month follow-up, or secondary diabetes or pregnancy during 12-month baseline, were excluded. Diagnosing clinical providers at index were reported descriptively for T1D patients with and without prior T2D diagnosis (overall and by age).

RESULTS: Of 8577 patients with a qualifying index T1D diagnosis, 2624 (31%) had ≥1 prior T2D diagnosis (41% female; mean age: 45 years; <18 years: 6%); 5953 (69%) had no prior T2D diagnosis (42% female; mean age: 27 years; <18 years: 46%). Patients with and without prior T2D diagnosis were diagnosed with T1D by endocrinologists (28% vs 21%, respectively), primary care physicians (26% vs 26%, respectively), non-physician clinicians (14% vs 10%, respectively), or other physician specialties (eg, emergency medicine, critical care, pathology, sleep medicine, hematology/oncology, addiction medicine, pulmonology, surgery, cardiology) (29% vs 39%, respectively). In patients with T1D aged <18 years with and without prior T2D diagnosis, 48% versus 26% were diagnosed by endocrinologists, 8% versus 28% by primary care physicians, 14% versus 8% by non-physician clinicians, and 25% versus 34% by other physician specialties, respectively. In patients aged ≥18 years, 27% versus 25% were diagnosed by primary care physicians, 27% versus 17% by endocrinologists, 14% versus 12% by non-physician clinicians, and 29% versus 42% by other physician specialties, respectively.

CONCLUSIONS: Patients with a prior T2D diagnosis were most frequently diagnosed with T1D by endocrinologists or primary care physicians. Adults were most frequently diagnosed with T1D by primary care physicians while children were most frequently diagnosed with T1D by endocrinologists and primary care physicians. These findings may reflect coding or clinical errors in correctly diagnosing T1D.

SPONSORSHIP: Sanofi

E15 Senior Health Care Executive Consensus on Transforming Retinal Disease Management through Diabetes Care: AMCP Market Insights Program

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BACKGROUND: An AMCP Market Insights program, in partnership with Impact Education, LLC, was held virtually in September 2024. Chief medical and pharmacy officers and other health care executives attended to discuss the management of retinal diseases in patients with diabetes.

OBJECTIVE: To gain insights on how current health plan policies affect access to anti-VEGF treatments and the total cost of care; identify best practices in coverage policies for anti-VEGF agents; examine opportunities for innovative management of patients at higher risk of blindness; and understand the role of more durable treatment approaches in addressing social determinants of health (SDOH).

METHODS: The 11 health care executives from across the US, representing 18.4 million covered lives, were polled to understand consensus on statements regarding the management of retinal diseases in patients with diabetes. Consensus was defined as either a mean response of at least 3.3 or 100% of polling responses either "agree" or "strongly agree" on a 4-item Likert scale (1 = strongly disagree, 4 = strongly agree). Moderated panel discussions followed each poll to gather insights and contextualize the responses.

RESULTS: There was no consensus reached around treatment variation increasing the total cost of care (mean 3.10), anti-VEGF treatment cost concerns (mean 3.01), impact of coverage variation on treatment timeliness (mean 2.80), or more durable treatments addressing SDOH (mean 2.45). Consensus was reached on the importance of the ophthalmologist in managing patients with diabetes and retinal diseases who are at risk of blindness (mean 4.00) and timely access to treatment (mean 3.64). The executives shared a range of perspectives on the impact of current policies for anti-VEGF agents and reasons for not reaching consensus and stressed the importance of shared decision-making and patient education.

CONCLUSIONS: This AMCP Market Insights program discussion underscored the need for a multifaceted approach for patients with diabetes at risk for blindness due to retinal diseases that balances clinical efficacy, cost-effectiveness, and timely access to treatment, particularly considering the variability in current prescribing practices within the anti-VEGF therapeutic class. There was consensus from health care executives on the important role of ophthalmologists in managing patients at risk of blindness and the importance of timely access to appropriate treatments to prevent vision loss.

SPONSORSHIP: Regeneron Pharmaceuticals, Inc.

E16 Total cost of care of empagliflozin versus non-SGLT2i usual care among patients with cardio-renal-metabolic conditions

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BACKGROUND: Cardio-renal-metabolic (CRM) conditions, comprising cardiovascular disease, chronic kidney disease (CKD) and type 2 diabetes mellitus (T2D), frequently coexist. More than 1 in 4 US adults have ≥1 CRM condition, with nearly 1 in 10 having multiple conditions. Management of CRM conditions and associated complications places a clinical and financial burden on the health care system. Treatment guidelines for T2D, heart failure (HF), and CKD include the use of sodium-glucose cotransporter 2 inhibitors (SGLT2i). Evidence exists on the economic value of the SGLT2i class and specifically of empagliflozin for treating these CRM conditions. However, the economic value of empagliflozin from a total cost-of-care perspective has not been rigorously evaluated among these CRM conditions.

OBJECTIVE: Compare total costs of care among patients with ≥1 CRM condition (T2D, HF, and/or CKD), treated with empagliflozin versus non-SGLT2i usual care.

METHODS: A retrospective cohort study was conducted using Optum's de-identified Clinformatics® Data Mart Database from October 1, 2015, to December 31, 2023. Patients ≥18 years of age with ≥1 CRM condition within the 1 year of continuous baseline enrollment prior to their CRM treatment claim were included. Patients treated with empagliflozin were exact matched 1:1 to those receiving non-SGLT2i usual care per baseline CRM condition(s), key variables of demographics, comorbidity, and total costs, then further propensity score matched within 0.01 caliper. Total costs of care per patient per month (PPPM), including pharmacy and medical costs, were estimated over 1 year of follow-up censoring for death. Results were stratified by baseline CRM conditions.

RESULTS: A total of 20,982 patients treated with empagliflozin were matched to those treated with non-SGLT2i usual care. Within the CRM conditions, cost savings were generally observed among those with ≥2 CRM conditions treated with empagliflozin versus non-SGLT2i usual care. PPPM cost savings were greatest among those with all three CRM conditions (n = 3,100; $1,258); followed by HF and T2D only (n = 4,759; $589); and CKD and T2D only (n = 3,011; $103). Cost savings were also observed among a limited CKD only cohort (n = 121; $2,402).

CONCLUSIONS: From a total cost-of-care perspective, savings from treatment with empagliflozin increased with increasing CRM comorbidity. Patients with all 3 CRM conditions receiving empagliflozin had the greatest cost benefit compared to non-SGLT2i usual care. The clinical value of empagliflozin translates to a total cost of savings.

SPONSORSHIP: Boehringer Ingelheim Pharmaceuticals

E17 SGLT2 inhibitors: Retrospective assessment of the impact of a formulary change by an employer-sponsored health plan for a large academic medical center

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BACKGROUND: Sodium-glucose cotransporter-2 (SGLT2) inhibitors are indicated to improve glycemic control in patients diagnosed with type 2 diabetes mellitus. Each medication in the class also has other indications, such as heart failure and chronic kidney disease. In August 2023, Invokana (canagliflozin) and Invokamet (canagliflozin/metformin) were removed from the pharmacy benefit formulary by an employer-sponsored health plan for a large academic medical center, leaving Jardiance (empagliflozin) and Farxiga (dapagliflozin) as the preferred formulary SGLT2 inhibitor options. A clinical review was conducted to confirm that all indications for the drug class were adequately covered before the change was implemented.

OBJECTIVE: The objective of this project was to characterize utilization patterns prior to and after the formulary change, review therapy outcomes for members who were transitioned from canagliflozin in 2023, and discuss the implications of the findings on patient care and plan management.

METHODS: A retrospective analysis was conducted comparing SGLT2 inhibitor claims data from Jan 1 to April 30, 2023, to the same period in 2024. The plan's pharmacy benefit manager, Alluma, provided the claims data for each of the brand SGLT2 inhibitors. The following data was calculated for each brand SGLT2 inhibitor: percentage of overall claims and plan spend, percentage of utilizers that switched brands, and percentage of utilizers that switched drug classes. For utilizers who did not switch to any medication, a chart review was completed to understand why a change did not occur.

RESULTS: The majority of patients (57.1%) filled canagliflozin-containing products for the last time in August 2023. Most (83.8%) canagliflozin patients successfully switched to a formulary SGLT2 inhibitor. Following the formulary change, 67.6% of patient switched to empagliflozin and 16.2% switched to dapagliflozin. Some patients (6.7%) switched to other antidiabetic agents including agents in the biguanide, GLP-1 agonist, insulin, and sulfonylurea classes. The net plan cost savings due to the formulary change was estimated to be 17.0% of SGLT2 inhibitor plan costs per claim. There was an increase in total gross costs due to a 20.0% increase in claim volume.

CONCLUSIONS: The plan successfully implemented a SGLT2 inhibitor formulary change, resulting in cost savings without a significant negative impact on patient access or care.

SPONSORSHIP: Alluma

E18 Real-world trends in pharmacy utilization among commercially insured individuals treated with glucagon-like peptide-1 (GLP-1) receptor agonists, 2014-2024

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BACKGROUND: Nearly 42% of Americans are living with obesity and nearly 12% have type 2 diabetes mellitus (T2DM). The rapid increase in glucagon-like peptide-1 receptor agonist (GLP-1) use for T2DM and obesity has made them a primary driver of rising pharmacy costs for insurers. A clearer understanding of how GLP-1 initiation affects overall pharmacy utilization is essential to assess the additional costs for insurers.

OBJECTIVE: To describe trends in non-GLP-1 pharmacy utilization for individuals treated with GLP-1s.

METHODS: National pharmacy and medical claims data were used to identify individuals who initiated a GLP-1 product between 2014 and 2024 (cases). Cases and controls were matched on initiation year-quarter, age, gender, continuous coverage, and obesity and/or diabetes diagnosis. We compared non-GLP-1 medication use and associated costs between cases and controls for the year prior to and three years following GLP-1 initiation.

RESULTS: Pharmacy costs remained higher in GLP-1 users (N = 1.1 million) than in controls (N = 2.6 million) over three years post initiation, even when excluding direct GLP-1 drug costs. Average non-GLP-1 annual pharmacy costs for cases were higher than controls by $1,449, $2,390, and $2,812 in years 1, 2, and 3, respectively. Although some of this additional utilization can be ascribed to common gastrointestinal side effects related to GLP-1 treatment, utilization increased over a broad range of medication categories. Compared to controls, the post-GLP-1 initiation prevalence of treatment was significantly higher for constipation and diarrhea (by 1.8% [$p < 0.001$]), nausea and vomiting (by 7.1% [$p < 0.001$]), gastroesophageal reflux disease (GERD) (by 5.8% [$p < 0.001$]), and GERD-related respiratory symptoms (by 5.2% [$p < 0.001$] for antitussives, beta adrenergics,

nasal steroids, and antihistamines). The rate of side effect–related treatment increased substantively with increased GLP-1 persistence. For example, GERD treatment rates were higher in cases than in controls (22%) and increased with GLP-1 persistence: 25%, 28%, and 32% for 0-12, 13-24, or 24+ months of GLP-1 use, respectively.

CONCLUSIONS: Side effects of GLP-1 treatment may necessitate additional drug intervention, contributing to additional pharmacy use and cost beyond direct GLP-1 medication costs. Payers and providers should consider the burden of side-effect management when evaluating the suitability of these medications for prospective patients.

SPONSORSHIP: Blue Cross Blue Shield Association

E19 Budget impact model for commercial health plans after the implementation of weight loss benefit and with expanded FDA approval indications for GLP-1 agonists

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BACKGROUND: Along with lifestyle modifications, GLP-1 agonists are effective in managing diabetes (DM) and promoting weight loss (WL), resulting in sharp increases in demand and costs. New indications for Ozempic, Wegovy, and Zepbound continue to be approved, driving anticipated utilization. Many health plans without a WL benefit are considering its addition, alongside expanding FDA-approved indications for certain GLP-1s. However, estimating the financial impact of these decisions poses challenges.

OBJECTIVE: To investigate the budget impact (BI) for a commercial health plan without a WL benefit, focusing on future scenarios after adding this benefit and expanding selected GLP-1 indications, including major adverse cardiovascular events (MACE) prevention, obstructive sleep apnea (OSA), heart failure (HF), and diabetic nephropathy (DN).

METHODS: BI analyses were conducted for a hypothetical one-million-member commercial health plan without a WL benefit over a one-year period. In the base case scenario, the percentage of members utilizing GLP-1 agonists, stratified into DM and off-label WL usage, average fills per year, and costs per fill for each GLP-1, were estimated from claims data from MedImpact Inc. from July 2023 to June 2024. In the future scenario, where the plan implements a WL benefit by adding Wegovy, Saxenda, and Zepbound with expanding indications approved in the first year, the percentages of members utilizing GLP-1s for DM and WL were estimated based on trends from health plans with WL benefits. Estimates for members utilizing GLP-1s for MACE prevention, OSA, HF, and DN were based on public epidemiological data and expert sources.

RESULTS: The incremental costs per member per month (PMPM) for GLP-1s were $17.16 for DM management, $2.73 for WL management, and $0.67 for other indications during the first approval year. Total plan incremental costs PMPM were $16.25 for DM management, $2.45 for WL management, and $0.61 for other indications.

CONCLUSIONS: Integrating WL benefits and expanding indications for GLP-1 agonists could lead to significant changes in class costs. While WL costs may not rise significantly due to strict criteria for prior authorization and limited eligible prescribers, DM-related costs are projected to increase substantially. The GLP-1 with DM indication utilization is increasing, potentially due to off-label usage for WL, anticipated off-label usage for expanded indications, a shortage of GLP-1 with WL indications, and the lower cost of GLP-1 with DM indications compared to those with WL indications.

SPONSORSHIP: MedImpact

E20 Association between sodium intake and cardiorenal and cardiometabolic outcomes: A systematic review of the literature

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BACKGROUND: Global guidelines recommend a daily sodium intake of less than 2300 mg (less than 2000 mg for some guidelines) and ideally less than or equal to 1500 mg. Excess sodium intake correlates with increased risk of cardiovascular disease and other adverse health outcomes.

OBJECTIVE: A systematic review was performed to synthesize the published literature on associations between sodium intake and cardiorenal-cardiometabolic (CR-CM) outcomes.

METHODS: The systematic review followed PRISMA and Cochrane Handbook guidelines. Based on prespecified PICOS criteria, Embase, Medline, and Central databases were searched for English-language studies of adults (18 years of age or older) that described sodium intake and CR-CM outcomes published up to December 7, 2023. The number of studies that report a statistically significant association between higher/increased sodium intake and adverse CR-CM outcomes out of the total number of eligible studies is presented.

RESULTS: Of 20,523 publications screened, 146 studies (68 CR, 86 CM) met eligibility criteria. Studies were predominantly cohort (retrospective/prospective; n = 66) or cross-sectional (n = 64). Twenty-one studies were conducted in the US. Sodium intake was primarily estimated by 24-hour urinary excretion, followed by self-reported methods such as food frequency questionnaires. Fifty-seven of the 68 CR studies reported a statistically significant association between higher/increased sodium intake and adverse CR outcomes, including albuminuria (22/27 studies), proteinuria (5/5), decline in estimated glomerular filtration rate (eGFR; 13/17), and increased risk of kidney stones (2/5), chronic kidney disease progression (4/7), end-stage renal disease (ESRD; 3/6), and composite renal outcomes (eg, halving of eGFR, ESRD, and death; 7/8). Low risk of bias per Cochrane RoB2.0 and Newcastle-Ottawa Scale was assessed in 62/68 studies. Seventy-four of the 86 CM studies reported a statistically significant relationship between higher/increased sodium intake and adverse CM outcomes, including higher fasting plasma glucose level (7/10), lipid profile (18/23), waist circumference (13/15), and body mass index (34/40) and increased risk of non-alcoholic fatty liver disease (6/7), metabolic syndrome (12/13), diabetes (9/11), and obesity (15/16). Low risk of bias was assessed in 75/86 studies.

CONCLUSIONS: The current literature reinforces that higher relative to lower sodium intake is associated with an increased risk of adverse CR-CM outcomes. These findings support recommendations to reduce sodium consumption.

SPONSORSHIP: Jazz Pharmaceuticals

E21 Yearly trends in payer coverage rates for GLP-1 receptor antagonists in weight loss

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BACKGROUND: The prevalence of obesity in the U.S. has risen to 41.9%, sparking increased interest in pharmacological treatments, such as GLP-1 receptor agonists (GLP-1 RAs), originally developed for type 2 diabetes. Saxenda (liraglutide), Wegovy (semaglutide) and Zepbound (tirzepatide) are the GLP-1 RAs FDA approved for weight loss. These therapies have demonstrated efficacy in promoting weight loss, yet patients are facing access challenges such as prior authorizations (PAs) and limited coverage. This highlights the need to evaluate the payer coverage landscape and its impact on patient access to GLP-1 therapies.

OBJECTIVE: This study aims to assess changes in payer coverage and patient access to GLP-1 RA use in weight loss.

METHODS: The study was a descriptive retrospective analysis of Symphony Health Integrated Dataverse to compare yearly differences in coverage rates for new to treatment GLP-1 RAs for weight loss. Patients were included if they had ≥1 claims for a GLP-1 RA product and were new to treatment within the index period between 1/1/2021 and 6/30/2024. Primary endpoints were rejection rates, rejection rates due to PAs, abandonment rates, and pull-through rates. Secondary endpoints were patient out-of-pocket (OOP) cost and time to overcome PAs.

RESULTS: The analysis represented coverage of 3,400,315 patient lives and 8,318,205 claims. The overall rejection rate was 62.4%, while 31.1% of rejections were due to PAs and 42.1% were due to formulary exclusion. Yearly rejection rates were 74.0%, 64.9%, 61.3%, and 60.5%, respectively. Of the rejection rates, 23.8%, 30.6%, 35.1%, and 28.2% were due to PAs. Abandonment rates were 23.7%, 23.4%, 28.5%, and 17.3% and pull-through rates for PAs were 34.1%, 40.6%, 45.0%, and 37.8%, respectively. The median (min-max) overall OOP cost for patients who overcame PAs was 24.99 (0-4,919.59), while for patients who overcame PAs but did not fill the medication, OOP cost was 30 (0-8,715.19). The median time to overcome the PAs was 7 (0-21) days.

CONCLUSIONS: The analysis showed an annual decrease in overall rejection rates for GLP-1 RAs, suggesting a gradual increase in payer coverage for these medications. However, abandonment rates were inconclusive, which fluctuated year to year, indicating further analysis into contributing factors for patients not fulfilling their prescriptions. Additionally, the increase in pull-through rates during this period, despite a decline in 2024, highlights the dynamic nature of the GLP-1 RAs market and the need to monitor payer policies to understand patient access impacts.

SPONSORSHIP: Symphony Health

E22 Payer coverage trends of anti-obesity medications (AOMs) on commercial formularies

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BACKGROUND: The United States (US) Food and Drug Administration (FDA) has approved several medications for obesity. However, as demand rises for anti-obesity medications (AOMs), US payers are concerned about the associated budget impact and, as a result, are regularly assessing their coverage policies. To investigate AOM coverage trends, Cencora conducted research with US payers to understand how they are currently managing AOMs on commercial formularies and the challenges they face in this evolving

therapeutic space. For this research, AOMs refers to drugs that are specifically indicated for obesity.

OBJECTIVE: To understand how payers are currently managing anti-obesity medications on their commercial formularies and identify current formulary decision challenges.

METHODS: A web-based survey of US health care payers was conducted through Cencora's Managed Care Network research panel, in October 2024.

RESULTS: A total of 48 payers from health plans (n = 22), integrated delivery networks (n = 13), and pharmacy benefit managers (n = 13) completed the survey. On average, payers report only 31% of commercial members have coverage for AOMs. For payers who cover these drugs, 52% (n = 29) prefer Wegovy® and 44% (n = 27) prefer Zepbound®. Payers are using quantity limits, supplemental care programs, and prior authorization to manage AOMs. For payers whose organizations either are not currently covering AOMs in 2024 or do not plan to cover in 2025, 64% (n = 36) ranked cost as the main reason. Payers face several challenges in managing AOMs including high budget impact (92%) and lack of long-term data on sustained weight loss (79%). Payers who track obesity outcomes are seeing positive impacts of AOMs on body mass index (93%, n = 29) and weight loss (96%, n = 26). To further inform AOM coverage decisions, payers are interested in medical cost offsets data (81%) and real-world evidence (73%). In 2025, three-quarters of payers are expecting to cover Wegovy® and Zepbound® on their commercial formularies. Among payers who currently have opt-in rider policies for AOMs with their employer clients, 56% (n = 36) anticipate eventually moving AOMs to traditional commercial formulary placements.

CONCLUSIONS: On average, less than one-third of commercial members currently have coverage for AOMs. Payers are applying utilization management tools like quantity limits and supplemental care programs to control their access and manage costs. However, payers who track obesity outcomes are seeing positive impacts of AOMs. To further inform their coverage decisions, payers are interested in medical costs offset data and real-world evidence.

SPONSORSHIP: Cencora

E23 Two-Year Persistent Glucagon-Like Peptide-1 Agonist Obesity without Diabetes Treatment: Clinical Outcomes among Commercially Insured

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BACKGROUND: Obesity is a complex chronic condition with substantial impact on morbidity and mortality. Glucagon-like peptide-1 (GLP-1) products have demonstrated real-world effectiveness for glucose control and weight loss, but impacts on additional clinical outcomes have not been fully elucidated.

OBJECTIVE: To compare changes in clinical outcomes one year before and the second year after GLP-1 obesity treatment initiation among commercially insured obese members without diabetes mellitus (DM) who were persistent to GLP-1 therapy.

METHODS: Prime Therapeutics' integrated pharmacy and medical claims were used to identify members newly initiating a GLP-1 (index date) between 1/1/2021 and 12/31/2021 and continuously enrolled throughout the study period defined as three 365-day segments created from the member's index date: pre-period, year-one post-index period, and year-two post-index period. During the pre-period, members were required to have a medical claim indicating obesity, have no DM medical or pharmacy claims, and be aged 19+ years. Using the same criteria, a 3-to-1 matched GLP-1–naive control group was identified. Members were matched on characteristics and conditions. After matching, the cohort was limited to persistent GLP-1 users who did not have a 60-day gap in therapy over 730 days following index and their matched controls. Positive clinical outcomes included joint replacement, bariatric surgery, major adverse cardiovascular (CV) events (MACE), new diabetes diagnosis, and CV medication use; negative clinical outcomes included gastroparesis, cholecystitis, acute pancreatitis, intestinal obstruction, and acute kidney injury. All outcomes were reported as annual percent change in members with the outcome of interest between groups and across periods analyzed using difference-in-difference (DID) regression.

RESULTS: After matching, 3,046 GLP-1 therapy members met all study criteria, and of them, 436 were persistent with 1,249 members matched as controls. Mean age was 48 years and 84% were women. In year two, joint replacement increased in the GLP-1 group, with a DID of 1.7% (p = 0.023). New diabetes diagnosis was not lower in the GLP-1 group. All other positive and negative clinical outcomes were no different between groups.

CONCLUSIONS: In this real-world commercially insured cohort during the second year of persistent GLP-1 obesity

treatment, no favorable positive GLP-1 outcomes were seen compared to the matched control group with no GLP-1 negative clinical outcome signals. GLP-1 obesity treatment clinical event reductions among persistent members may take 2+ years.

SPONSORSHIP: Prime Therapeutics, LLC

E24 Real-world Two-Year Clinical Outcomes Following Initiation of Glucagon-Like Peptide-1 Agonists to Treat Obesity without Diabetes among a Commercially Insured Population

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BACKGROUND: Obesity is a complex chronic condition with substantial impact on morbidity and mortality. Glucagon-like peptide-1 (GLP-1) products have demonstrated real-world effectiveness in improving glucose control and weight loss among obese patients without diabetes mellitus (DM), but impacts on additional clinical outcomes have not been fully elucidated.

OBJECTIVE: To describe changes in clinical outcomes one year before and two years after GLP-1 obesity treatment initiation among commercially insured obese members without DM compared to a matched control group, regardless of treatment persistence.

METHODS: Prime Therapeutics' integrated pharmacy and medical claims were used to identify members newly initiating a GLP-1 (index date) between 1/1/2021 and 12/31/2021 and continuously enrolled throughout the study period, defined as three 365-day segments relative to index date: pre-period, year-one post-index period, and year-two post-index period. During the pre-period, members were required to have a medical claim indicating obesity, have no DM medical or pharmacy claims, and be aged 19+ years. Using the same criteria, a 3-to-1 matched control group was identified from members without a GLP-1 claim. Members were matched using a combined exact and propensity score matching approach. Clinical outcomes included joint replacement, new DM diagnosis, bariatric surgery, major adverse cardiovascular (CV) events, use of CV medications, gastroparesis, cholecystitis, acute pancreatitis, intestinal obstruction, and acute kidney injury. Annual percent change in members with the outcome of interest between groups and across periods was analyzed using difference-in-difference (DID) regression.

RESULTS: After matching, 3,046 GLP-1 and 8,653 control members met study criteria. Mean age was 46 years and 81% were women. New DM diagnosis was not lower in the GLP-1 group. Bariatric surgery was DID 0.7% higher among the GLP-1 group for year one ($p = 0.002$) and 1.6% for year two ($p < 0.001$). The rate of acute pancreatitis in year one compared to the pre-year was statistically higher for GLP-1-initiating members with a DID of 0.4% ($p = 0.019$). No other statistically significant changes were observed.

CONCLUSIONS: In this intent-to-treat real-world analysis, no improvement in clinical outcomes was seen over the two-year period. Compared to the matched control group, acute pancreatitis rates in year one for the GLP-1-treated group were significantly higher, resulting in number needed to harm of 1 in 250 treated GLP-1 utilizers. GLP-1 obesity treatment clinical event reductions among the general user population may take 2+ years.

SPONSORSHIP: Prime Therapeutics, LLC

E25 Real-world Two-Year Cost-effectiveness Assessment of Glucagon-Like Peptide-1 Agonists to Treat Obesity without Diabetes among a Commercially Insured Population

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BACKGROUND: High obesity prevalence and $1,000-a-month cost create widespread glucagon-like peptide-1 (GLP-1) treatment affordability concerns. Real-world evidence describing two-year GLP-1 cost-effectiveness for all GLP-1 obesity without diabetes mellitus (DM) treatment initiators is needed.

OBJECTIVE: To describe changes in annual total cost of care (TCC) one year before and two years after GLP-1 obesity treatment initiation among commercially insured members without DM compared to a matched control group, regardless of treatment persistence.

METHODS: Prime Therapeutics' integrated pharmacy and medical claims database was used to identify members newly initiating a GLP-1 (index date) between 1/1/2021 and 12/31/2021 and continuously enrolled throughout the study period, defined as three 365-day segments relative to index date: pre-period, year-one post, and year-two post. During the pre-period, members were required to have a medical claim indicating obesity, have no DM medical or pharmacy claim, and be aged 19+ years. Using the same criteria, a 3-to-1 matched control group was identified from members without a GLP-1 claim. Members were matched using a combined exact and propensity score matching approach. Annual TCC was calculated for each study period by summing medical and pharmacy claim paid allowed amounts

after all network provider discounts were applied and included member share. TCC changes between groups and across periods were analyzed using difference-in-difference (DID) regression.

RESULTS: After matching, 3,046 GLP-1 therapy members and 8,653 control group members met all study criteria. Mean age was 46 years and 81% were women. Across the three study periods, TCC for GLP-1 utilizers averaged $12,695, $20,165, and $18,507 in the pre-year, year one, and year two, respectively, and $11,406, $11,882, and $13,012 for controls. The TCC DID for GLP-1-treated members was $6,994 (p<.0001) higher in year one vs. pre-year and $4,206 (p<.0001) higher in year two vs. pre-year. Lower rates of GLP-1 therapy persistence in year two compared to year one explain the difference in TCC DID estimates; there were no differences in medical spending DID across post-years.

CONCLUSIONS: This real-world GLP-1 intent-to-treat study found a significant $11,200 average per-member TCC investment in the first two years following GLP-1 obesity treatment initiation for members without DM. No differences in annual medical spend trends were observed between groups. A substantial GLP-1 obesity treatment investment should be expected during the first two years, with unknown future medical cost offsets.

SPONSORSHIP: Prime Therapeutics, LLC

E26 Two-Year Persistent Glucagon-Like Peptide-1 Agonist Obesity without Diabetes Treatment: Cost-effectiveness among Commercially Insured

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BACKGROUND: High obesity prevalence and $1,000-a-month cost create widespread glucagon-like peptide-1 (GLP-1) treatment affordability concerns. Real-world evidence describing two-year persistent GLP-1 therapy cost-effectiveness for treating obesity without diabetes is needed.

OBJECTIVE: To describe changes in annual total cost of care (TCC) one year before and two years after GLP-1 obesity treatment initiation among commercially insured members without DM who were persistent to GLP-1 therapy.

METHODS: Prime Therapeutics' integrated pharmacy and medical claims database was used to identify members newly initiating a GLP-1 (index date) between 1/1/2021 and 12/31/2021 and continuously enrolled during the study period defined as three 365-day segments created from the member's index date: pre-period, year-one post-index, and year-two post-index. During the pre-period, members were required to have an obesity medical claim, have no DM medical or pharmacy claims, and be aged 19+ years. Using the same criteria, a 3-to-1 matched GLP-1–naive control group was identified. Members were matched on characteristics and conditions using a combined exact and propensity score matching approach. After matching, the cohort was limited to persistent GLP-1 users who did not have a 60-day gap in therapy over 730 days following index and their matched controls. Annual TCC was calculated for each study period by summing medical and pharmacy claim paid allowed amounts. TCC changes between groups and across periods were analyzed using difference-in-difference (DID) regression.

RESULTS: After matching, 3,046 GLP-1 therapy members met all study criteria, and of them, 436 were persistent with 1,249 members matched as controls. Mean age was 48 years and 84% were women. Across the three study periods, TCC for GLP-1 utilizers averaged $14,418, $28,309, and $27,909 in the pre-year, year one, and year two, respectively, and $13,457, $12,314, and $13,863 for controls. The TCC DID estimate for GLP-1–treated members vs. controls was $15,034 (p<.0001) higher in year one vs. pre-year and $13,085 (p<.0001) higher in year two vs. pre-year. There were no differences in medical spending DID findings.

CONCLUSIONS: This real-world GLP-1 study found a significant $26,118 average per-member TCC investment in the first two years following GLP-1 obesity treatment initiation for members without DM who were persistent to therapy. No differences in annual medical spend trends were observed between groups. A substantial two-year GLP-1 obesity treatment cost investment should be expected with unknown future medical cost avoidance.

SPONSORSHIP: Prime Therapeutics, LLC

E27 Demographic and Clinical Characteristics of Mississippi Medicaid Members Initiating GLP-1 Receptor Agonists for Obesity Management

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BACKGROUND: Beginning July 2023, semaglutide (Wegovy®) and liraglutide (Saxenda®), GLP-1 receptor agonists, were added to Mississippi Medicaid preferred drug list as anti-obesity agents. Limited evidence exists about the demographic and clinical characteristics of individuals

initiating these medications within the Mississippi Medicaid population.

OBJECTIVE: The objective of this study was to describe the demographic and clinical characteristics of Mississippi Medicaid members who initiated semaglutide or liraglutide for obesity management.

METHODS: This descriptive study utilized Mississippi Medicaid administrative claims data from July 2022 to June 2024. The study population included all members who initiated semaglutide or liraglutide between July 2023 and June 2024 and had continuous enrollment for one year pre-initiation (baseline period). Demographic and clinical characteristics were assessed during the baseline period. Hypertension, hyperlipidemia, and diabetes were identified if a member had both a diagnosis and medication use during the baseline period. Other clinical characteristics were assessed based on presence of medical claims with their diagnosis codes.

RESULTS: A total of 1,818 members were identified with the majority initiating semaglutide (89.82%). The cohort was predominantly female (89.49%), with 46.53% of initiators identifying as Black and 39.71% as White. Most initiators had an obesity diagnosis (95.16%). The most prevalent comorbidities identified in the baseline period were hypertension (43.07%), prediabetes (19.51%), sleep apnea (17.6%), hyperlipidemia (13.09%), and diabetes (11.5%). Additionally, nearly 26% of members had a history of antidiabetic medication use during the baseline period. Demographic and clinical characteristics were similar among semaglutide and liraglutide initiators. Age stratification revealed a higher proportion of male initiators (38.22%) among teens compared to adults (7.25%). Adults exhibited a higher prevalence of comorbidities such as hypertension (46.65% vs. 12.57%) and hyperlipidemia (14.44% vs. 1.57%) compared to the teen initiators, indicating more complex health profiles in the adult population using GLP-1 receptor agonists for obesity management.

CONCLUSIONS: This descriptive analysis of Mississippi Medicaid members initiating GLP-1 receptor agonists for obesity management reveals notable demographic differences, with a predominance of female and Black initiators. Comorbidities were more prevalent in adult initiators as compared to teen initiators.

SPONSORSHIP: This study is funded by the Mississippi Division of Medicaid.

E32 Real world evidence of the effect of GLP-1 receptor agonist treatment on the adherence and persistence of second-generation antipsychotics using administrative claims data

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BACKGROUND: Second-generation antipsychotics (SGA) are associated with high risk of weight gain especially during the first 6 months of treatment initiation. The effect of GLP-1RA on SGA adherence is crucial as weight gain is a key factor contributing to non-adherence of SGA.

OBJECTIVE: To examine the effect of concurrent GLP-1RA treatment on the adherence and persistence of SGA.

METHODS: A retrospective cohort study was conducted using MarketScan commercial and Medicaid insurance data from 01/01/2017 to 12/31/2019. Patients who were continuously enrolled 90 days prior to and 180 days after the initiation of GLP-1 RA (index date) were identified. Patients on concurrent SGA and GLP-1RA were identified as having at least 1 GLP-1RA claim and at least 30 days' overlap between SGA and GLP-1RA. Concurrent users were matched 1:4 with SGA patients, not on any hypoglycemic drugs (control), using prescription time distribution matching. Patients were followed to 180 days post index date to estimate the SGA adherence and persistence. Adherence was measured as proportion of days covered (PDC) whereas persistence was calculated as the number of days of medication filled before a 60-day gap. Propensity score analysis using IPT weights was applied to adjust for the patient demographics, comorbidities, and comedications.

RESULTS: In commercial data, 675 concurrent users were matched to 2,700 controls. Concurrent users had higher prevalence of DM type 2 (58.57% vs 9.1%), DM type 1 (3.3% vs 0.8%), antidiabetic medication (65.9% vs 10.3%), and anti-obesity medication (19.03% vs 6.3%) during the 90-day pre-index period (p<.001). Persistence (140.4 vs 107.9 days) and PDC (78.5% vs 70.2%) were higher in concurrent users (p<.0001). Propensity score adjustment indicated that the PDC for SGA at 180 days was 9.94% higher and persistence was 34.04 days higher in concurrent users compared to nonusers. In Medicaid data, 1,489 concurrent users were matched to 5,956 controls, with users having a significantly higher proportion of patients with DM type 2 (80.2% vs 17.34%), DM type 1 (4.6% vs 1.3%), antidiabetic medication (79.85% vs 15.86%), and anti-obesity medication (16.1% vs 7.5%). Persistence (147.6 vs 118.4 days) and PDC (78.8% vs 69.9%) were higher in concurrent users (p<.0001). PSM-adjusted analysis indicated that the PDC for SGA is 9.67%

higher and persistence was 28.6 days higher in concurrent users compared to nonusers.

CONCLUSIONS: SGA adherence and persistence were significantly higher in GLP-1RA users compared to nonusers. The addition of GLP-1RA greatly increases the adherence to SGA, enhancing patient engagement and improving long-term compliance.

SPONSORSHIP: None

E33 A post-hoc analysis of Balance assessing all-cause health care resource utilization in patients with familial chylomicronemia syndrome by history of acute pancreatitis

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BACKGROUND: Familial chylomicronemia syndrome (FCS) is a rare genetic disorder with high morbidity and increased acute pancreatitis risk. The randomized, placebo-controlled, phase 3 Balance study assessed olezarsen vs placebo in patients with FCS.

OBJECTIVE: This post-hoc analysis of the Balance study examined adjudicated acute pancreatitis (AP) risk and health care resource utilization (HRU) in FCS patients based on AP history.

METHODS: Patients were randomized to olezarsen 50 mg or 80 mg (evaluated by dose as well as pooled olezarsen [50 mg + 80 mg]) or placebo. AP events were adjudicated according to Atlanta AP classification. Kaplan-Meier analysis was used to assess time to first AP occurrence and negative binomial regression to evaluate associations between treatment and AP. Adjusted rates of all-cause hospitalizations and emergency room (ER) visits, plus total inpatient days and length of hospital stay (LOS), from weeks 1 to 53 were calculated. Results were stratified by 10-year AP history (≥1 record vs no record).

RESULTS: Patients' characteristics were similar across placebo (n = 23) and olezarsen 50 mg (n = 21) and 80 mg (n = 22) arms. No AP events were reported in patients without AP history (0/11 pooled olezarsen; 0/8 placebo). Of those with AP history, 1 patient in each olezarsen arm experienced an AP event (50 mg 1/15 [7%]; 80 mg 1/17 [6%]) vs 7 of 15 (47%) patients with placebo; at week 53, the probability of not experiencing AP was 0.93 (95% CI: 0.73, 1.00) for patients on olezarsen (pooled) and 0.51 (95% CI: 0.23, 1.00) for placebo. In patients with AP history, the mean hospitalization rate ratio for the pooled olezarsen arms vs placebo was 0.13 ($p = 0.0013$), indicating that olezarsen-treated patients had 87% lower hospitalization rates vs placebo. Total inpatient days were 8.75 days lower with olezarsen than placebo ($p = 0.0074$). No statistically significant reduction was observed for ER visits. In patients with no AP history, no statistical difference in HRU was observed. Adjusted LOS in the pooled olezarsen group was 57% (mean rate ratio 0.43) shorter than placebo and was ~2.3 times longer with AP history vs without. Results by dose showed similar trends.

CONCLUSIONS: Although previous AP history is known to increase risk of subsequent AP events and HRU, in the Balance study olezarsen is associated with reduced all-cause HRU vs placebo in patients with FCS. Limitations include small sample size and a limited duration of follow-up of 1 year. Further studies in larger real-world settings are needed to provide additional evidence of these results.

SPONSORSHIP: Ionis

E34 Real-world effectiveness of bempedoic acid and bempedoic acid plus ezetimibe on LDL-C in patients with or without prior statin use

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BACKGROUND: Bempedoic acid (BA) alone and in combination with ezetimibe (BA+EZE) have demonstrated LDL-C lowering in clinical trials of adults with primary hyperlipidemia at high risk for or with cardiovascular disease, including in patients partially or completely statin intolerant. The real-world impact of BA and BA+EZE on LDL-C outcomes in patients with no statin history has yet to be evaluated.

OBJECTIVE: To assess the effectiveness of BA and BA+EZE on LDL-C reduction by evidence of prior statin use in a real-world cohort.

METHODS: This retrospective study used deidentified data from the Veradigm Network EHR linked to claims from Komodo Health to identify adults with ≥1 pharmacy claim for BA or BA+EZE between 03/01/2020 and 03/15/2024 (first pharmacy claim = index date). Adults were required to have EHR/claims activity ≥6 months prior to and ≥12 months post-index with ≥1 LDL-C lab on or before the index date and ≥2 LDL-C labs post-index, including 1 lab result within ±60 days of 12 months post-index. BA+EZE patients with evidence of ezetimibe use within 6 weeks prior to index were excluded. LDL-C was captured at baseline (closest value to but not after index), 3 months (±30 days), 6 months (±60 days), and 12 months (±60 days). Patients were stratified by statin history (evidence vs no evidence of statin use in the prior 12 months).

RESULTS: Of 900 BA patients meeting the inclusion criteria, 376 (41.8%) had no evidence of prior statin use. Of 615 BA+EZE patients, 224 (36.4%) had no evidence of prior statin use. For both BA and BA+EZE, patients with no prior statin use were slightly older, more likely to be female, and more likely to have higher baseline LDL-C levels as compared to patients with prior statin use. Across all cohorts, there was a clinically relevant shift in the proportion of patients with LDL-C <70 mg/dL and <100 mg/dL from baseline to 3 months that was sustained at 12 months. The magnitude of change was greatest in patients with no prior statin use: the proportion of BA patients with LDL-C <100 mg/dL increased 3-fold from baseline to 3 months (11.2% to 37.0%) and 2.5-fold for BA+EZE patients (24.9% to 63.4%). Median LDL-C reduction from baseline to 3, 6, and 12 months was -24.2%, -23.5%, and -20.8% for BA patients with no prior statin use and 36.7%, 33.8%, and -27.3% for BA+EZE patients with no prior statin use.

CONCLUSIONS: Patients taking BA or BA+EZE showed early and sustained LDL-C reduction and attainment levels <100 mg/dL, with the greatest improvements seen in patients with no evidence of prior statin use.

SPONSORSHIP: Esperion Therapeutics, Inc.

E35 Real-World Impact of Elexacaftor/Tezacaftor/Ivacaftor Initiation on Health Care Resource Utilization, Costs, and Pulmonary Exacerbations among Mississippi Medicaid Beneficiaries with Cystic Fibrosis

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BACKGROUND: Cystic fibrosis (CF) is a life-limiting genetic disorder that significantly impacts patients' quality of life and health care resource utilization (HCRU). Elexacaftor/Tezacaftor/Ivacaftor (ETI) is a novel CF transmembrane conductance regulator (CFTR) modulator therapy that has shown promising results in clinical trials.

OBJECTIVE: This study aimed to evaluate the real-world impact of ETI initiation on HCRU, associated costs, and pulmonary exacerbations (PEx) among Mississippi Medicaid beneficiaries with CF.

METHODS: This cohort study was conducted using 2018-2023 Mississippi Medicaid administrative claims data. Beneficiaries aged ≥6 years who initiated ETI between October 2019 and December 2022 were included. Outcomes compared between the 1-year pre-ETI initiation period (baseline) and post-ETI initiation period (follow-up) included all-cause HCRU, all-cause health care costs (medical and pharmacy), and CF PEx events. Mean (standard deviation [SD]) and median (interquartile range [IQR]) were reported. Wilcoxon signed-rank tests were conducted to test for significant differences between pre- and post-initiation periods. Subgroup analysis was performed based on prior use of other CFTR modulators.

RESULTS: Of the 96 eligible beneficiaries, 41.6% were aged 6-11 years, 54.1% were male, and 61.4% were White. Following ETI initiation, median medical costs decreased significantly from $3,720.8 [IQR: 1,144.42 to 13,655.82] to $2,685.7 [IQR: 1,274.4 to 6,839.5] (p<0.0001). Median pharmacy costs, however, increased substantially from $243,841.8 [IQR: 75,213.6 to 395,418.9] to $469,809.4 [IQR: 354,468.7 to 615,583.8] (p<0.0001), resulting in higher median total health care costs in the follow-up period, $262,511.8 [IQR: 81,329.4 to 418,553.5] compared to $471,584.8 [IQR: 359,146.0 to 619,768.1] (p<0.0001). The mean number of inpatient visits per patient decreased from 0.62 [SD: 1.46] to 0.11 [SD: 0.40] (p<0.0001), while changes in outpatient and emergency department visits were not statistically significant. The mean number of PEx events per patient decreased from 2.58 [SD: 3.85] to 1.10 [SD: 2.11] (p<0.0001). Similar trends were observed in subgroups with and without prior CFTR modulator use.

CONCLUSIONS: In this cohort of Medicaid beneficiaries with CF, ETI treatment was associated with significant reductions in acute care utilization and PEx events, despite increased overall costs due to higher pharmacy expenses. These findings suggest that ETI may improve disease management and potentially long-term benefits for CF patients.

SPONSORSHIP: Mississippi Division of Medicaid

F00-F99 Mental and Behavioral Disorders

(eg, antipsychotics, bipolar disorder, depression, schizophrenia)

F1 Open Access to Antipsychotics in State Medicaid Programs: The Effect on Health Care Resource Utilization and Costs Among Patients with Serious Mental Illness

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BACKGROUND: Medicaid provides crucial coverage for mental health treatments, including prescription medications for individuals with serious mental illness (SMI). To manage rising drug costs, many states have implemented utilization management programs such as prior authorization and step therapy for antipsychotics (APs). However, these restrictions may delay care and worsen outcomes for SMI patients, who often require complex, individualized treatment.

OBJECTIVE: This study compared outcomes among patients with SMI accessing APs through state Medicaid programs with open access (OA) policies (Michigan) for APs, vs five state Medicaid programs without OA policies (California, Colorado, Florida, Illinois, Wisconsin).

METHODS: Retrospective study using Kythera Medicaid data (1/1/2016 to 12/31/2023) compared outcomes for patients with SMI (inclusion criteria: >18 years old; >1 AP pharmacy claim during the identification period 1/1/2017 to 12/31/2022 [index date]; >1 claim with an SMI diagnosis 12 months pre index date; continuous medical/pharmacy benefits 12 months pre/post index date) in states with/without OA. Outcomes included SMI-related hospital admissions, length of stay, emergency department (ED) and outpatient visits, and costs (inpatient, outpatient, ED, pharmacy, and total).

RESULTS: A greater percentage of Medicaid beneficiaries had SMI in Michigan than in other states. After PSM, the proportion of AP users with SMI-related hospitalizations was higher in California (18.25% vs 9.47%, p<.0001), Colorado (11.41% vs 7.33%, p=.0004), Florida (19.70% vs 10.17%, p<.0001), Illinois (23.57% vs 8.79, p<.0001), and Wisconsin (15.21% vs 10.02%, p=.0046) than Michigan. Length of stay was lower in Michigan than California, Colorado, and Illinois. SMI-related inpatient costs were significantly lower in Michigan, although pharmacy costs were higher. SMI-related total costs in all states except Colorado were higher vs Michigan.

CONCLUSIONS: State Medicaid programs without OA to APs were associated with higher rates of SMI-related resource use and cost compared to Michigan. Policymakers should consider the potential downstream cost implication of restrictive access policies and evaluate whether OA could result in better health outcomes and cost savings for Medicaid programs.

SPONSORSHIP: Funded by Otsuka Pharmaceutical Development & Commercialization Inc. (Princeton, NJ, USA)

F2 Cost-Effectiveness of Dextromethorphan-Bupropion (Auvelity) Among Major Depressive Disorder Adult Patients

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BACKGROUND: Major depressive disorder (MDD) is a debilitating mental health condition with significant treatment challenges, including high relapse rates and treatment resistance. First-line therapies include selective serotonin reuptake inhibitors (SSRIs) and selective norepinephrine reuptake inhibitors (SNRIs), but many patients fail to achieve remission, necessitating alternative treatments. Auvelity, a novel combination of dextromethorphan and bupropion, has been introduced as a potential second-line therapy for patients who have not responded to first-line treatments.

OBJECTIVE: This study evaluated the cost-effectiveness of Auvelity compared to standard treatments for MDD in the U.S.

METHODS: A cost-effectiveness analysis was conducted using a cohort-based decision tree model over a 12-month time horizon. The model compared Auvelity to standard care, which typically includes first-line SSRIs or SNRIs like citalopram or sertraline. The analysis was performed from the perspective of the U.S. health care system, incorporating remission and relapse rates derived from clinical trials and literature. The primary measure was the incremental cost-effectiveness ratio (ICER) per quality-adjusted life-year (QALY) gained with a willingness-to-pay threshold of $100,000. Sensitivity analyses were performed, including tornado diagrams and two-way sensitivity analysis, to assess the robustness of the model.

RESULTS: Auvelity demonstrated higher effectiveness with a utility of 0.66 compared to 0.65 for standard care. With an incremental cost of $9,868.41, Auvelity resulted in an ICER of $518,107.86 per QALY gained. Sensitivity analyses indicated

that annual price, along with the remission rate, were the most influential variables of the model. Additionally, Auvelity would be cost-effective if its annual price fell below $4,482.90, assuming similar remission rates.

CONCLUSIONS: While Auvelity offers a novel mechanism and slightly better remission outcomes, its high cost makes it less cost-effective than standard first-line therapies. Auvelity could be considered as a second-line therapy, particularly in treatment-resistant patients with favorable ICER. Further research into pricing and long-term outcomes is needed to better determine its place in clinical practice for MDD.

SPONSORSHIP: None

F3 Examining Physicians' Behaviors Regarding Buprenorphine Prescribing for Opioid Use Disorder

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BACKGROUND: The opioid crisis remains a significant public health issue in the U.S., affecting 2.1 million Americans. Buprenorphine, a highly effective treatment for opioid use disorder (OUD), reduces mortality and improves recovery outcomes. However, prior literature shows buprenorphine prescribing is influenced by physicians' perceptions and behaviors. Understanding these perceptions and behaviors is critical to enhancing access to buprenorphine by patients with OUD.

OBJECTIVE: The objective of this study was to explore California physicians' behaviors concerning buprenorphine prescribing for OUD. Upon a thorough review of the literature, our study aimed to identify key challenges to guide policymakers in improving buprenorphine access and enhancing OUD treatment effectiveness in California.

METHODS: A cross-sectional online survey via Qualtrics was conducted among California physicians from various specialties related to buprenorphine prescribing for OUD. Out of 21,498 delivered questionnaires, 101 completed responses were collected. The questionnaire assessed prescribers' perceptions regarding the complexity of the prescribing process for buprenorphine, training requirements, DEA interference, and patient demand using a 5-point Likert scale. Data were analyzed using descriptive and inferential statistics, including Wilcoxon Signed Ranks and Kruskal-Wallis tests, to explore demographic variations in behaviors.

RESULTS: Of the respondents, 66.3% were male and 31.7% were female, with 66.3% identifying as White, 20.8% as Asian, and the remainder as other racial minorities. Most respondents reported a lack of demand for buprenorphine treatment (mean = 2.3 ± 1.3), and many disagreed that access to naloxone in overdose cases was sufficient (mean = 2.3 ± 1). The majority of physicians did not express significant concern about DEA interference (mean = 2.4 ± 0.9), and believed stigma did not prevent them from treating OUD (mean = 4.2 ± 1). Male physicians found buprenorphine training more challenging than females. Physicians practicing in suburban areas expressed higher DEA concerns compared to those in urban areas. Additionally, DATA Waiver holders felt more supported and trained than those without the waiver ($p < 0.05$).

CONCLUSIONS: This study highlights California physicians' perceptions in prescribing buprenorphine for OUD. Challenges related to required training to prescribe buprenorphine suggest a need to lessen the burden. Also, concerns regarding DEA regulations in suburban areas, and access to naloxone in overdose cases, call for policy considerations.

SPONSORSHIP: None

F4 A Retrospective Analysis of Health Care Resource Utilization Associated With Use of Extended-Release Naltrexone Among Medicaid Patients With Opioid Dependence

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BACKGROUND: A limited number of real-world studies of Vivitrol® (extended-release naltrexone, XR-NTX) treatment have examined the effect of XR-NTX persistence on subsequent health care resource utilization (HCRU) in individuals diagnosed with opioid dependence (OD).

OBJECTIVE: To examine the association between XR-NTX persistence and HCRU among Medicaid patients with an OD diagnosis.

METHODS: Using the Merative® MarketScan® Multi-State Medicaid Database, adults with ≥1 medical claim containing an OD diagnosis between 7/1/2010 and 12/31/2021 and ≥6 months of continuous medical and pharmacy enrollment prior to the first observed OD diagnosis were included. Patients were categorized as receiving exactly 1, ≥2, ≥3, ≥4, ≥5, or ≥6 consecutive XR-NTX injections based on receipt of an injection every 18-38 days. Marginal structural models (MSM) were used to evaluate average monthly HCRU for each XR-NTX injection category, adjusting for potential confounding.

RESULTS: 17,678 patients (mean [SD] age, 33.5 [9.4] years; 46.7% male; 67.5% White; mean [SD] time from diagnosis to XR-NTX initiation, 8.5 [9.9] months) met inclusion criteria and received ≥1 XR-NTX injection, 50.9% of whom received

≥2 consecutive injections during follow-up. MSM estimated that receipt of ≥2 consecutive injections would lead to a 15% decrease in the weighted rate of monthly all-cause emergency department visits, versus receiving 1 injection; the weighted rate was further decreased among patients with more consecutive injections (27% reduction in patients with ≥6 injections). A similar trend was observed with monthly inpatient admissions and number of inpatient days. In a sensitivity analysis separating inpatient hospital, residential treatment, and psychiatric admissions, the weighted rate of inpatient hospital admissions was 34% lower if patients received ≥2 injections and 53% lower if patients received ≥6 injections. In contrast, MSM-estimated monthly outpatient visits increased (44% and 56% if patients received ≥2 and ≥6 injections, respectively) and outpatient pharmacy prescriptions increased (24% and 37% if patients received ≥2 and ≥6 injections, respectively) with increasing persistence.

CONCLUSIONS: Receipt of ≥2 XR-NTX injections was associated with reductions in acute care utilization and increases in outpatient HCRU, versus OD patients who received 1 XR-NTX injection. Increased treatment persistence and the shift in HCRU from acute to outpatient settings may reflect improved patient engagement, an important prognostic indicator for improved, long-term outcomes.

SPONSORSHIP: Alkermes, Inc.

F5 Evaluation of economic burden due to mental health issues associated with opioid crisis: A retrospective analysis in the US

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BACKGROUND: The opioid crisis is deeply intertwined with various mental health issues that contribute to the deterioration of health, which can even lead to mortality. With the rising prevalence of opioid use disorder (OUD) in the US, it becomes evident that many individuals turn to opioids as a coping mechanism for untreated and inadequately managed mental health issues. In addition to declining health conditions, an opioid crisis can cause substantial economic burden with surging health care cost and hospitalization.

OBJECTIVE: To determine if mental health issues are a major cause of opioid overdose in the US, and evaluate the associated costs (medical and pharmacy costs) and health care resource utilization due to opioid overdose.

METHODS: An exploratory retrospective analysis was conducted using Optum® Market Clarity database, with integrated claims and electronic health records (EHR) data. An identification period from 1st January 2019 till 30th June 2023 was considered, with the index event defined as the first claim for opioid overdose/opioid poisoning. A 12-month continuous eligibility was considered for the baseline and follow-up period. Patients with mental health issues were evaluated during the baseline, while total costs (medical and pharmacy costs) and health care resource utilization were considered for the follow-up period including the index date. ICD-10-CM codes were used for mental health issues (major depressive disorder, stress, depression, and anxiety) and opioid poisoning. CPT codes were used for place of services (POS).

RESULTS: Based on the final cohort of 49,570 patients with opioid overdose, it was observed that around 60% of patients had mental disorders in the pre-index period. Regarding POS visits, 41% visits were to the outpatient hospitals, while emergency (ER) and inpatient hospital visits were 33% and 26%, respectively. The average annual medical and pharmacy cost per patient amounted to $69,849, and $10,492, respectively.

CONCLUSIONS: The interplay between mental health crises and opioid overdoses is a critical public health concern that has significant implications for health care resource utilization and associated costs. This underscores the urgent need for integrated care approaches that address both mental health and substance use issues simultaneously. This study will be developed further using natural language processing (NLP) in unstructured EHR data to provide a more precise and in-depth analysis.

SPONSORSHIP: None

F6 Impact of Out-of-Pocket Costs on Initial Medication Adherence in Major Depressive Disorder

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BACKGROUND: Initial medication adherence (IMA) is critical in managing major depressive disorder (MDD) and achieving long-term clinical outcomes. Although various clinical and demographic factors affecting adherence are well documented, the role of out-of-pocket (OOP) costs in influencing IMA remains unexplored in MDD patients.

OBJECTIVE: To examine the impact of OOP costs on IMA in patients initiating antidepressant therapy.

METHODS: A retrospective cohort study using the Merative MarketScan commercial claims data from 2017 to 2019 was conducted involving adults (≥18 years) diagnosed with MDD and newly prescribed selective serotonin reuptake inhibitors (SSRIs) or serotonin-norepinephrine reuptake

inhibitors (SNRIs). IMA was measured for the first three months after the index date, with adherence calculated using the proportion of days covered (PDC) with a threshold of 80% for optimal adherence. OOP costs included copay, coinsurance, and deductible payment, which were then categorized into three levels: <$100, $100-$500, and >$500. Covariates were measured 6 months prior to the index date and included age, gender, region, antidepressant medication (ADM) class, comorbidities, health care utilization, and medication count. Descriptive analyses were used to examine OOP costs, IMA, and the study sample. Multivariable logistic regression was used to examine the impact of OOP on optimal IMA after controlling for baseline factors.

RESULTS: The study cohort consisted of 397,727 MDD patients initiating first-line SSRIs or SNRIs, with 60.71% having optimal IMA (PDC ≥80%). Most patients were aged 18-34 years (39.53%), female (70.11%), and from the southern region (46.46%). With respect to OOP, 88.71% of patients had OOP costs <$100, 10.61% of patients had OOP costs $100-$500, and 0.69% of patients had OOP costs >$500. Compared to OOP costs <$100, OOP costs >$500 were significantly associated with lower optimal IMA (adjusted odds ratios [aOR]: 0.85, 95% CI: 0.79-0.92). Interestingly, patients with OOP costs of $100-$500 were found to have marginally higher IMA compared to patients with OOP costs <$100 (aOR: 1.04, 95% CI: 1.02-1.07).

CONCLUSIONS: OOP prescription costs greater than $500 adversely affected the IMA in MDD, suggesting the importance of financial barriers in early treatment adherence. Strategies such as formulary coverage, lower copays, and value-based models may mitigate the patient burden and help in improving IMA and associated outcomes in MDD.

SPONSORSHIP: None

F7 Treatment patterns and health care resource utilization of patients early in schizophrenia illness initiating aripiprazole lauroxil versus oral aripiprazole: a retrospective claims-based study

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BACKGROUND: Optimal treatment of patients with schizophrenia who are early in illness has the potential to provide long-term benefits. Long-acting injectable (LAI) antipsychotics may improve outcomes in this population.

OBJECTIVE: Compare real-world treatment patterns and health care resource utilization (HCRU) among early-in-illness patients with schizophrenia initiating the LAI aripiprazole lauroxil (AL) versus oral aripiprazole (OA).

METHODS: This retrospective analysis used MarketScan US administrative claims data (January 1, 2016, to June 30, 2022). Adults aged 18-40 years with a first observed diagnosis of schizophrenia on or after January 1, 2017, no antipsychotic claims within 12 months before diagnosis, 2 or more AL or OA claims (the first within 1 year of first schizophrenia diagnosis code), and continuous plan enrollment 12 or more months before and after their first (index) AL or OA claim were eligible. Adherence (proportion of days covered), persistence, and HCRU (proportion with at least 1 visit; visits per patient per month [PPPM]) were compared between 1:1 propensity score–matched cohorts.

RESULTS: Early-in-illness patients initiating AL (n = 131) had a mean age of 27.2 years; 38.9% were female (OA: n = 1,222, 27.2 years, 47.1% female). In matched early-in-illness cohorts, greater adherence and longer persistence were observed for AL versus OA (both P<0.0001). Odds of 1 or more all-cause emergency department (ED) visits were significantly reduced for AL versus OA (odds ratio [95% CI], 0.59 [0.36-0.96]). All-cause inpatient and ED visits PPPM were significantly reduced with AL versus OA (rate ratios [95% CI], 0.63 [0.45-0.83] and 0.60 [0.43-0.78], respectively), as were mental health–related inpatient (0.63 [0.45-0.84]) and ED visits PPPM (0.50 [0.35-0.69]).

CONCLUSIONS: Early-in-illness patients with schizophrenia initiating AL versus OA in real-world treatment settings were more persistent and adherent to treatment and had significantly lower acute HCRU. Initiating AL versus OA early in schizophrenia treatment may reduce the likelihood of acute care events.

SPONSORSHIP: Alkermes, Inc.

F8 Health Care Resource Utilization in Schizophrenia: Assessing the Role of Cognitive Impairments and Negative Symptoms

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BACKGROUND: Schizophrenia is a chronic and debilitating condition characterized by positive and negative symptoms, as well as cognitive impairments (CI). Negative symptoms (NS), such as avolition and blunted affect, disrupt daily activities, emotional expression, and social functioning, while CI affects memory, attention, and executive functioning. Both NS and CI are persistent features of schizophrenia and have

been associated with increased health care resource utilization (HCRU), although this relationship has not been well quantified using real-world data.

OBJECTIVE: This study aims to assess the real-world impact of NS and CI on HCRU in patients with schizophrenia in the United States.

METHODS: This US retrospective cohort study used electronic health records (EHR) linked to administrative claims data from January 2016 through February 2023. Adult patients (≥18 years) with at least two schizophrenia diagnosis codes were included. CI and NS were identified by natural language processing (NLP). Patient characteristics were assessed in the 12 months preceding the index date (first documented schizophrenia diagnosis). HCRU (e.g., inpatient, outpatient, emergency room, and pharmacy) was measured over the 12 months after index date. A negative binomial regression model was applied to calculate adjusted estimates for inpatient admissions.

RESULTS: The study used EHR data from 79,326 schizophrenia patients. 18.9% had documented NS, and 25.2% had documented CI. An association was observed between the number of clinical notes and the documented NS or CI percentages. Specifically, in patients with over 50 notes, 41.5% had documented NS and 52.3% had documented CI. Avolition was the most common NS (44%), followed by blunted affect (42%). The most common CI was "Reasoning & Problem Solving - Executive Functioning" (70.4%). In the EHR-linked claims data subset (n = 11,293), 22.1% had documented CI and 17.5% had documented NS. Patients with documented CI or NS had longer hospital stays per patient per year (PPPY) than those without (17.4 vs 15.4 days for documented CI; 18.6 vs 15.3 days for documented NS). Adjusted any inpatient admissions PPPY were higher for patients with documented CI (0.38 vs 0.32) and documented NS (0.36 vs 0.32), with all comparisons being statistically significant ($p < 0.05$).

CONCLUSIONS: CI and NS significantly increase HCRU in patients with schizophrenia. These findings highlight the need for targeted interventions to address CI and NS in order to reduce the health care burden and improve outcomes for these patients.

SPONSORSHIP: This project is sponsored by Boehringer Ingelheim.

F9 Outcomes and practice patterns of long-acting injectable vs oral antipsychotics among patients with bipolar disorder in the United States

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BACKGROUND: Bipolar I disorder (BD-I) is a chronic, disabling condition associated with manic and depressive episodes, often accompanied by severe psychosocial dysfunction. Patients with BD-I are at risk of psychiatric hospitalization.

OBJECTIVE: To examine practice patterns, rehospitalization rates, and risk of rehospitalization of hospitalized patients with BD-I who use long-acting injectable antipsychotics (LAI) compared with patients who use oral antipsychotics (OAP).

METHODS: This retrospective cohort study included adults hospitalized with BD-I diagnosis between Jan 1, 2021, and Jun 30, 2023, in the Premier Healthcare Database. Eligible patients had a ≥3-month baseline/follow-up period prior to and after index date (defined as discharge date of the first hospitalization with a BD-I diagnosis). Patients were grouped based on discharge medication at index hospitalization; patients in the LAI cohort and second-generation (SG) LAI sub-cohort were propensity-score matched (1:4) to the patients in the OAP cohort. BD-I–related rehospitalization rates within 30, 60, and 90 days following index hospitalization were calculated, with rehospitalization risk assessed using Cox proportional hazards modeling.

RESULTS: Of 98,088 eligible patients with ≥1 BD-I–related hospitalizations, 78,942 (80.5%) were given antipsychotics at discharge, of whom 2.4% were given an LAI. After matching, 9,244 and 2,311 patients discharged on OAP and LAI and 4,572 and 1,143 discharged on OAP and SG LAI, respectively, were included (mean age, 38 years; 50% male). Most patients (94%) were under the care of a psychiatrist, and 23% used antipsychotics at baseline. BD-I–related rehospitalization rates within 30, 60, and 90 days were 4%, 6%, and 7% among the LAI group compared with 5%, 7%, and 9% among the OAP group (P values: .033, .030, .064), respectively. The hazard ratios of BD-I–related rehospitalization within 30, 60 and 90 days were 0.78 (95% CI, 0.63-0.98, P = .034), 0.82 (95% CI, 0.68-0.98, P = .033), and 0.86 (95% CI, 0.73-1.01, P = .067) between those discharged on LAI vs OAP and were 0.65 (95% CI, 0.47-0.91, P = .012), 0.69 (95% CI, 0.53-0.91, P = .009), and 0.74 (95% CI, 0.58-0.95, P = .016) between those discharged on SG LAI vs OAP.

CONCLUSIONS: In adult patients with BD-I, LAI (primarily SG) administration was associated with a lower rate and

risk of BD-I–related rehospitalization. However, the low discharge rates with LAIs suggest that they are underused in BD-I management. These results underscore the benefits of LAIs and highlight their potential role in managing BD-I.

SPONSORSHIP: Teva Branded Pharmaceutical Products R&D, Inc.

F10 Counting the costs of schizophrenia treatment: drug acquisition costs do not tell the whole story

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BACKGROUND: Schizophrenia is a serious, chronic mental illness that results in considerable disability. Patients cycle through many antipsychotic treatments due to limited efficacy and adverse events (AEs), including movement disorders and metabolic issues, which can limit their use. Many of these AEs are persistent and contribute to high annual treatment costs.

OBJECTIVE: To estimate the drug and AE costs associated with treating adults with schizophrenia in the second-line setting and beyond (2L+).

METHODS: A Microsoft Excel® cost calculator with a 3-year time horizon was developed to assess the drug acquisition, drug administration, and AE management costs associated with the treatment of schizophrenia for a hypothetical US payer (weighted across Medicare, Medicaid, and Commercial plan types). The tool tracked a single patient's journey across 2L and subsequent therapy. Costs associated with first-line (1L) treatment were also explored in a scenario analysis. Treatments included in the tool were generic second-generation antipsychotics with an average market share of ≥3% across plan types. Select branded agents (cariprazine, lumateperone, brexpiprazole, and olanzapine/samidorphan) and the long-acting injectables (LAIs) were also included. The AEs included are key cost drivers in schizophrenia: metabolic syndrome, diabetes, cardiovascular disease (CVD), and tardive dyskinesia (TD).

RESULTS: Drug acquisition costs for a single patient over 3 years ranged from $9,352 to $19,799 for oral generic therapies and from $37,152 to $47,280 for oral branded therapies. AE management costs over 3 years for a single patient ranged from $4,066 to $6,838 for oral generic therapies and from $2,426 to $4,349 for oral branded therapies. A scenario analysis considering 1L as the initial line of therapy found similar results. Sensitivity analyses indicated results were sensitive to LAI-related inputs (as LAIs made up the largest drug acquisition costs) and costs associated with the management of TD and metabolic syndrome.

CONCLUSIONS: The results suggest that the treatment of schizophrenia can be costly and wide-ranging, with branded agents costing up to approximately $51,663 over 3 years. Rates of select AEs, metabolic syndrome, CVD, diabetes, and TD appear to be drivers of costs across schizophrenia treatments, especially notable in generic agents (accounting for approximately 26% of total mean cost). These findings support the need for effective and safe treatment options for schizophrenia that minimize the burden of AEs.

SPONSORSHIP: Bristol Myers Squibb

F11 Budget impact analysis of xanomeline and trospium chloride for the treatment of adults with schizophrenia in the US

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BACKGROUND: Schizophrenia is a severe, lifelong mental disorder causing significant disability. Current standard of care involves antipsychotic agents that block dopamine receptors in the brain and are linked to costly, chronic adverse events (AEs) such as movement and metabolic disorders. Xanomeline and trospium chloride (X/T) was approved by the FDA in September 2024 for the treatment of adults with schizophrenia. Unlike traditional dopaminergic antipsychotics, X/T targets muscarinic receptors and has demonstrated lower rates of chronic AEs.

OBJECTIVE: To estimate the budget impact of X/T as a second-line (2L) therapy for adults with schizophrenia.

METHODS: A Microsoft Excel® model with a 3-year time horizon was developed to assess the budget impact of introducing X/T to a hypothetical 1-million-member US health plan weighted across Medicare, Medicaid, and Commercial plan types. The model tracked a cohort of eligible patients, defined by payer-specific epidemiology estimates, across 2L and subsequent therapy, and first line (1L) therapy in a scenario analysis. Patients were assigned to either X/T or a second-generation antipsychotic based on market share distributions informed by IQVIA anonymous patient-level data. One scenario analysis focused on select branded treatment options (cariprazine, lumateperone, brexpiprazole, and olanzapine/samidorphan). The model included drug acquisition, drug administration, and AE management costs. Key AEs considered were metabolic syndrome, diabetes, cardiovascular disease, and tardive dyskinesia. Treatment costs

were estimated before and after introducing X/T; the cost difference indicated the budget impact associated with X/T.

RESULTS: For a hypothetical 1-million-member health plan, introducing X/T as a 2L treatment results in estimated annual additional costs of $195,920 and $1,107,171 from Year 1 through Year 3. X/T results in a per-member per-month (PMPM) budget impact ranging from $0.016 in Year 1 to $0.091 in Year 3. Results were similar in a scenario considering 1L X/T use. Estimated PMPM was lower with a comparator basket limited to branded treatments but with no discontinuation from 2L therapy onto subsequent treatment. Sensitivity analysis indicated results were sensitive to schizophrenia epidemiology inputs and X/T acquisition costs.

CONCLUSIONS: Introducing X/T as a 2L therapy for adults with schizophrenia in a hypothetical health plan is projected to incur a modest PMPM budget impact. Costs are influenced by schizophrenia epidemiology and X/T acquisition costs.

SPONSORSHIP: Bristol Myers Squibb

F12 Cognitive Impairments in Schizophrenia: Association with Health Care Utilization, Comorbidities, Adherence, and Mortality in a Veterans Affairs Cohort

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BACKGROUND: Schizophrenia is a mental health disorder characterized by disruptions in thought processes, perceptions, emotional responsiveness, and social interactions. Cognitive impairments (CI), affecting over 80% of patients, significantly impact memory and thinking skills. Previous research has demonstrated an association between CI and increased health care resource utilization (HCRU) and mortality.

OBJECTIVE: This study aims to evaluate the impact of CI on HCRU, antipsychotic adherence, comorbidities, and mortality among patients with schizophrenia receiving care at Veterans Affairs (VA) facilities.

METHODS: This retrospective cohort study utilized administrative claims data from July 1, 2000, to December 31, 2022, across the US. The study population included patients diagnosed with schizophrenia who had at least 12 months of data before and after diagnosis. Propensity score matching was applied based on the date of first schizophrenia diagnosis, age, sex, race, BMI, and Charlson Comorbidity Index. Statistical analyses were conducted to assess differences between groups with and without CI in terms of HCRU, antipsychotic adherence, comorbidities, and mortality. Proportion of days covered (PDC) was used to assess the antipsychotic adherence.

RESULTS: The study identified 58,776 patients with schizophrenia, of whom 21.5% (n = 12,639) had documented CI. After matching, the CI group showed significantly higher HCRU. Patients with CI had approximately four times the rate of hospitalizations per month (1.05 vs. 0.24) and three times the rate of emergency department visits per month (0.60 vs. 0.19). Adherence to first-generation antipsychotics was significantly lower in the CI group (59.6% vs. 64.3%), as was adherence to second-generation antipsychotics (53.1% vs. 55.1%). Additionally, patients with CI had higher rates of alcohol abuse or dependence (44.0% vs. 19.9%), suicidal ideation (10.8% vs. 2.8%), and cannabis use (11.5% vs. 3.9%). Mortality rates were also significantly higher in the CI group, with 1-year (5.7%) and 5-year mortality rates (14.4%) being 1.4 and 1.2 times higher, respectively, compared to 4.2% and 12.3% in the non-CI group ($p < 0.05$ for all comparisons).

CONCLUSIONS: These findings highlight the substantial burden of CI among patients with schizophrenia, particularly regarding increased HCRU, lower antipsychotic adherence, and higher rates of comorbidities and mortality. The results underscore the need for targeted interventions to address the unique health challenges faced by patients with CI in schizophrenia.

SPONSORSHIP: This project was funded by Boehringer Ingelheim Pharmaceuticals, Inc.

F19 Impact of a digital cognitive behavioral therapy program (Daylight) for anxiety on health care costs, a real-world evaluation at a population scale

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BACKGROUND: Generalized anxiety disorder (GAD) is common, with symptoms affecting nearly one in five adults in the US. GAD leads to significant impairments in daily functioning, decreased productivity, and increased health care claims. These complaints often co-occur with mental health disorders and chronic conditions, exacerbating their impact on individuals. GAD also places a significant economic burden on health care systems and payers. Cognitive behavioral therapy (CBT) is a recommended first-line treatment, but access can be difficult. Daylight, a digital CBT solution, offers

an effective way to enhance accessibility and may reduce higher health care costs associated with GAD.

OBJECTIVE: To evaluate US health care costs in a large sample of individuals who used Daylight for GAD compared with a matched control.

METHODS: This retrospective cohort study used Kythera commercial insurance and Medicare administrative claims data. We identified those who used Daylight (digital CBT) with at least 12 months of baseline (pre-Daylight) and follow-up (post-Daylight) claims data. The control group was formed from nationally representative claimants (~3.6 million patients), consisting of individuals who were managing anxiety difficulties (ICD-10 code and/or medication) and who did not use Daylight. Controls were matched on age, gender, state, comorbidities, and treatment index year, using 1:1 exact matching. The primary outcome was change in total health care costs, including pharmacy and medical claims (e.g., inpatient, outpatient, ER). Between-group comparisons were assessed using difference-in-difference regression, adjusting for utilization.

RESULTS: 323 individuals who used Daylight were successfully matched with 323 controls. Cohorts were demographically representative including age (42 years) and gender (28% male). Average costs at baseline were $6,852 and $7,230 in the treatment and control groups, respectively. Costs decreased at 12 months for the treatment group to $6,449 and increased for the control group to $8,689. The difference-in-difference effect found a 27.2% reduction in total costs (p>0.1), representing annual savings of $1,863 on average per person for those who used Daylight. Savings were similar when adjusting for health care utilization, year, and comorbidities. Reductions were also observed for both pharmacy (26%) and medical (25%) claim costs.

CONCLUSIONS: Daylight was associated with reductions in total health care costs among US individuals. Findings suggest that scaling access to Daylight to further individuals could lead to substantial cost savings.

SPONSORSHIP: Big Health Inc.

F20 Real-world treatment patterns, health care resource utilization, and costs for Medicaid patients with a postpartum depression diagnosis

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BACKGROUND: Postpartum depression (PPD) is a serious, common condition associated with pregnancy and childbirth, but treatment can be suboptimal.

OBJECTIVE: This study assessed PPD treatment patterns (pharmacotherapy use/duration), health care resource utilization (HCRU), and costs among Medicaid enrollees, who represent nearly half of US births.

METHODS: This study used medical and pharmacy Medicaid claims from the Kythera database. Treatment patterns (discontinuing, switching, or adding on pharmacotherapy), HCRU and costs were assessed for distinct pregnancy episodes resulting in live birth and/or stillbirth, with end-of-pregnancy date from 7/1/2016 to 12/31/2022 and continuous enrollment for 6 mo before and 12 mo after initial PPD diagnosis. PPD diagnosis was defined as ≥1 claim with a PPD code, or ≥1 inpatient or ≥2 outpatient claims with major depressive disorder (MDD) codes, during the third trimester and 12 mo after end of pregnancy. Exclusion criteria included MDD diagnosis ≥6 mo before pregnancy and manic episode/bipolar disorder during the study period (1/1/2016 to 12/31/2023). Pregnancy episodes were separated into those with a PPD diagnosis and those with live birth and/or stillbirth without a PPD diagnosis during the same period.

RESULTS: 91,178 pregnancy episodes with a PPD diagnosis were identified. Of these, 33,883 (37.2%) episodes had available pharmacy claims, among which two-thirds (66.9%) received pharmacotherapy for PPD. Among these, within 1 year of diagnosis, 59.7% discontinued a pharmacologic treatment for any reason, 67.7% added adjunctive pharmacotherapy, and 20.8% switched pharmacotherapies. Mean time from pharmacotherapy initiation to discontinuation, add-on, or switch was 48.1, 46.5, and 87.5 days, respectively. Pregnancy episodes with a PPD diagnosis had higher mean annual HCRU vs. 1,077,220 episodes without a PPD diagnosis (mean number of all-cause visits: 9.0 vs 4.1 [outpatient]; 0.6 vs 0.4 [inpatient]; 0.8 vs 0.4 [emergency department]). Mean annual total all-cause health care costs were higher among episodes with a PPD diagnosis vs. those without ($21,868 vs $11,374).

CONCLUSIONS: Among Medicaid claims, most pregnancy episodes defined as having a PPD diagnosis with available pharmacy claims were associated with pharmacotherapy changes, potentially suggesting commonly used pharmacological treatments for PPD available through 2023 may not have provided optimal results. Higher HCRU and costs accrued among those with a PPD diagnosis suggest a substantial resource and economic burden associated with PPD.

SPONSORSHIP: Sage Therapeutics, Inc.; Biogen, Inc.

F21 Health care cost savings with digital cognitive behavioral therapy for insomnia (Sleepio), a real-world evaluation at a population scale

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BACKGROUND: Insomnia, affecting up to one-third of US adults, poses significant challenges to health and productivity, with an estimated economic burden of up to $100 billion annually. Cognitive behavioral therapy for insomnia (CBT-I) is the recommended first-line treatment; however, access is limited due to a shortage of trained therapists. Sleepio, a digital CBT-I solution, offers an effective alternative that could enhance accessibility and potentially reduce higher health care costs associated with insomnia. Real-world data can help demonstrate the impact of Sleepio at scale.

OBJECTIVE: To estimate the impact on health care costs of using Sleepio for insomnia and sleep difficulty, based on a large sample of individuals compared with matched controls.

METHODS: This retrospective cohort study used Kythera commercial insurance and Medicare administrative claims data. We identified those who used Sleepio (digital CBT-I) with at least 12 months of baseline (pre-Sleepio) and follow-up (post-Sleepio) claims data. The control group was formed from nationally representative claimants (~1.3 million), consisting of individuals who were managing sleep difficulties (ICD-10 code and/or medication) and who did not use Sleepio. Controls were matched on age, gender, state, comorbidities, and treatment index year, using 1:1 exact matching. The primary outcome was change in total health care costs, including pharmacy and medical claims (e.g., inpatient, outpatient, ER). Between-group comparisons were assessed using difference-in-difference regression, adjusting for baseline utilization (total claims).

RESULTS: 11,027 individuals who used Sleepio were successfully matched with 10,770 controls before and after Sleepio or prescription index event. Cohorts were demographically representative for age (44 years) and gender (34% male). Use of Sleepio was associated with an annual saving of $2,083 ($p<0.001$) per person, which equates to 42% of baseline total costs. Savings were similar and remained significant when adjusting for health care utilization, year, and comorbidities. Reductions were observed for both pharmacy (46%, $p<0.001$) and medical (15%, $p>0.1$) claim costs.

CONCLUSIONS: Sleepio was associated with significant reductions in total health care costs among US individuals, relative to patients managing sleep difficulties using medication. Findings suggest that implementing Sleepio at scale could lead to substantial cost savings and value for health care payers, relative to the current standard of care, while improving access to effective insomnia treatment.

SPONSORSHIP: This work was supported by Big Health Inc.

F22 Developing an Algorithm for Postpartum Depression Prediction: Integrating Clinical Notes and Claims Data

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BACKGROUND: Postpartum depression (PPD) is a significant mental health issue affecting women after childbirth, with potential adverse effects on both the mother and child. Early detection and intervention are crucial for improving outcomes and reducing the burden of PPD.

OBJECTIVE: This study aims to develop an algorithm that predicts postpartum depression using a combination of claims and clinical notes data. The goal is to enhance early detection and intervention for individuals at risk of developing PPD.

METHODS: A total of 186,517 pregnant patients (the first occurrence of a pregnancy event is index event) were identified in the Optum® de-identified Market Clarity database from January 1, 2018, to December 31, 2023. Among them, 39,318 patients were diagnosed with PPD within the 12-month post-index period (Cases). Patients were required to have continuous enrollment in the health plan for 6 months before the index event and 12 months after. Clinical notes within the 9-month post-index period were analyzed for PPD-related symptoms, including mood-related ("sadness," "hopelessness," "anxiety"), behavior-related ("substance abuse," "smoking"), and social factors ("lack of social support", "marital conflict," "financial stress," "domestic violence"). Controls were selected from female patients who showed no signs of postpartum depression in the 12-month post-index period. Case-control matching was performed using covariates to eliminate confounding effects.

RESULTS: Logistic regression, XG Boost, and random forest algorithms were utilized to build the prediction model, which was trained and tested using a matched patient pool of Cases and Controls. The model demonstrated approximately 50% accuracy in identifying patients at risk of postpartum depression. Further evaluation of the model's predictive performance will be conducted using AUC/ROC analysis.

CONCLUSIONS: The developed algorithm shows promise in improving early detection and intervention for at-risk individuals, leading to better outcomes in the prevention and management of postpartum depression. Integrating clinical notes and claims data can enhance the accuracy of PPD prediction, ultimately benefiting patients and health care providers.

SPONSORSHIP: None

G00-G99 Diseases of the Nervous System

(eg, migraine, multiple sclerosis, restless leg, seizures, sleep apnea)

G1 Distribution of claims by payer type and proportion entering Medicare by age at onset for patients with Friedreich ataxia based on real-world medical claims data

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BACKGROUND: Friedreich ataxia (FA) is a rare genetic condition with progressive neurological impairment leading to loss of ambulatory function, cardiomyopathy, heart failure, and death. Patients with FA are eligible for expedited review and access to Medicare based on their loss of ambulatory function and disability. Natural history studies have provided significant insights on the progression of FA. However, we are not aware of studies evaluating the relative burden across payer types and the age of Medicare entry.

OBJECTIVE: The objective of this study was to quantify the distribution of claims by payer type prior to FA onset, FA onset to FA diagnosis, and post FA diagnosis, as well as the age at first Medicare claim for FA based on real-world data from US medical claims.

METHODS: Retrospective cohort study of de-identified claims from October 2015 to March 2024. Cohort required ≥1 year claims history prior to the first claim for FA onset symptoms, FA diagnosis, or Medicare entry and was stratified based on age at FA onset: 0-7, 8-14, 15-24, 25-39, and 40+ years. Key endpoints included the distribution of medical claims prior to the first claim for FA onset symptoms or comorbid conditions, from FA onset to FA diagnosis, and post FA diagnosis, presented as the percentage of patients entering Medicare by age at onset.

RESULTS: The cohort included 608 patients, with median age at FA onset of 22 years (range, 1-88). Prior to FA onset symptoms, 48.9%, 38.4%, and 0.3% of medical claims were from commercial payers, Medicaid, and Medicare, respectively. From the time of FA onset to diagnosis, commercial claims decreased to 42.6%, with Medicaid and Medicare increasing to 41.2% and 7.4%, respectively. Post FA diagnosis, this trend continued with 33.2%, 44.3%, and 14.0% from commercial, Medicaid, and Medicare, respectively. Subgroup analysis separating patients entering Medicare by age of onset (0-7, 8-14, 15-24, 25-39, and 40+ years) shows that 5.8%, 0.9%, 3.4%, 12%, and 27% enter Medicare prior to onset of symptoms, respectively, and the percentage with Medicare claims at any time during observation were 7.6%, 1.7%, 17.8%, 20.2%, and 45.6%, respectively.

CONCLUSIONS: Commercial payers cover the largest percentage of claims prior to onset of FA. However, this decreases steadily with patient claims shifting to Medicaid and Medicare as FA symptoms, and comorbid conditions, begin and further shift over to Medicare and Medicaid after they are first diagnosed with FA.

SPONSORSHIP: Biogen, Inc.

G2 Enhancing Treatment Adherence Monitoring in Huntington's Disease Through Natural Language Processing (NLP) and Named Entity Recognition (NER): Insights from Patient Narratives

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BACKGROUND: Huntington's disease (HD) is a neurodegenerative disorder characterized by motor, cognitive, and psychiatric symptoms. Monitoring treatment adherence in HD is crucial for optimizing patient outcomes and disease management.

OBJECTIVE: This study aims to utilize NER and NLP techniques to extract valuable insights from patient narratives (unstructured data) regarding medication adherence, therapy attendance, and lifestyle modifications. By analyzing these narratives, we can identify patterns and barriers to adherence, ultimately improving treatment outcomes in Huntington's disease.

METHODS: Huntington's disease patients were identified from the Optum® Market Clarity Dataset, which links medical and pharmacy claims with electronic health record (EHR) data using ICD-9 and ICD-10 codes. Patients between the ages of 20 and 40 years, with continuous eligibility for 3 years before the index date and at least 2 outpatient diagnoses falling 30 days apart or one inpatient diagnosis, were included. Patients without symptoms, associated comorbidities, and prior claims of HD in the pre-index period were excluded. NLP techniques, including text classification, entity recognition, sentiment analysis, and pattern identification, were employed for accurate treatment prediction.

RESULTS: Among approximately 12,000 identified HD patients, males were more commonly affected by HD, with a male to female ratio of approximately 1.2:1. Most patients experienced symptom onset between the ages of 35 and 44 years. The adherence rate with deutetrabenazine for HD patients was 62.5%, with a mean proportion of days covered (PDC) of 76.7% (SD 28.2%; median 92.8%) during the 6-month study period. For patients with tardive dyskinesia (TD), the adherence rate was 46.7%, with a mean PDC of 65.7% (SD 30.2%; median 72.8%). Analysis revealed common barriers to adherence, such as forgetfulness and side effects, and identified patterns of improved adherence with family support and reminders.

CONCLUSIONS: By leveraging NLP techniques, relevant information regarding medication adherence, therapy attendance, and lifestyle modifications can be extracted from patient narratives. Analyzing these narratives enables health care providers to identify patterns and challenges that patients face in adhering to their treatment plans. Additionally, sentiments and emotions expressed in the narratives provide valuable insights into patient experiences. This information can guide the development of personalized interventions and support systems to improve treatment outcomes in Huntington's disease.

SPONSORSHIP: None

G4 Real-World Health Care Resource Utilization in Stiff-Person Syndrome: 6-Year Claims Database Analysis of 352 Patients

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BACKGROUND: Stiff-person syndrome (SPS) is a rare, progressive neurological autoimmune disease in which autoreactive B cells play a pathogenic role, resulting in disability and impaired mobility. Symptoms of SPS overlap with other neurological disorders, leading to potential delayed diagnoses. Current treatments targeting B cell–driven mechanisms like intravenous immunoglobulin (IVIG) and rituximab (RTX) are costly, with limited response in SPS. Currently, real-world data for patients with SPS are limited.

OBJECTIVE: To investigate the health care resource utilization (HCRU) and cost for US patients with SPS.

METHODS: Patients diagnosed with SPS (ICD-10-CM code G25.82) were selected from Merative MarketScan Commercial and Medicare administrative claims databases (1/1/2017 to 12/31/2023). Eligible patients had ≥2 claims for IVIG or ≥1 claim for RTX on/after SPS diagnosis (earliest diagnosis = index). HCRU and costs were measured per patient per month (PPPM) during a variable-length follow-up (≥30 days) until database disenrollment or study end (12/31/2023). Costs were adjusted to 2023 dollars using the medical component of the consumer price index.

RESULTS: Of 352 patients included in the analysis, 73% (n = 256) were female. The mean (SD) age was 49.6 (13.4) years. Patients were well distributed across US regions. Post-index (mean follow-up 2.4 years) clinical characteristics confirmed the cohort was representative of a general SPS population. Common SPS-related symptoms included anxiety (53%), joint deformities/arthralgia (52%), and limb/back stiffness/spasms (49%). Use of other SPS-related treatments were reported, such as benzodiazepines (71%) and muscle relaxants (70%). The mean (SD) Charlson Comorbidity Index score was 2.2 (2.0), indicative of increased 10-year mortality risk. The mean (SD) PPPM all-cause total HCRU and costs were $16,731 ($16,115). Of these costs $1,587 ($5,617) were for inpatient admissions, $11,485 ($11,849) for outpatient admissions, and $3,659 ($7,891) for pharmacy costs. Notably, of the $16,731 total PPPM costs, a mean of $10,224 was specifically associated with IVIG/RTX treatments. During the study period, 130 patients (37%) had at least one inpatient admission, with a mean (SD) cost per admission of $35,785 ($37,703).

CONCLUSIONS: HCRU and costs for US patients with SPS receiving IVIG/RTX are high ($200,772 per patient per year), alongside ongoing reported disease-related symptoms. These findings suggest a notable SPS disease burden, demonstrating unmet needs for improved treatment options.

SPONSORSHIP: Kyverna Therapeutics, Inc.

G5 Employee Care Partners of Spouses with Parkinson's Disease: Analysis of Direct Medical, Rx, and Total Costs and Lost Time

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BACKGROUND: Parkinson's is the second-most common neurodegenerative disease in the US, with nearly 1M people living with Parkinson's disease (PD) and 1.2M expected by 2030. While overall incidence increases with age, ~4% of people with PD are diagnosed during their working years, before age 50. Parkinson's costs for employers include heath care benefits for employees and dependent spouses and indirect costs for employee caregivers (CGs) including unpaid time off for Family Medical Leaves (FMLs) and paid Discretionary Incidental Time-off (DITO) to care for spouse patients (PAT).

OBJECTIVE: To examine the annual changes of employees with spouses with PD (CG), per member per month (PMPM) costs from medical and Rx claims for CGs and PATs, and the CG leaves due to FML and DITO.

METHODS: Retrospective analysis of the Workpartners Research Reference Database (RRDb, 2018-2022). PATs with PD (ICD-10 = G20). PATs and CGs had >1 year continuous data following PATs initial Dx (IndexYear) and were analyzed based on IndexYear. The following outcomes were reported based on the condition and IndexYear: FML claims files, days missed under DITO and FML; PMPM MED and Rx costs (CGs, PATs) and total (TOT) costs (CGs, PATs). The % and trends of PATs PMPM MED, RX, and TOT costs were also examined.

RESULTS: We identified 1,772 CG of PATs with PD (36.2% of PATs female). From 2018 to 2022 the number of new pairs increased 166% and average PAT age decreased from 61.2 to 58.7 years. FML claims were filed by 13% of the CGs with average FML days / year increasing from 6.9 to 18.4 days before dropping to 16.9 in 2022. Mean DITO lost time increased from 20.7 to 35.2 days per year (medians 20.5-35d). The PATs mean PMPM Med costs decreased from $2,446 to $1,445, Rx costs increased from $537 to $581, and TOT costs decreased from $2,982 to $2,027. CG mean Med costs were relatively stable (average $974, range $843-$1,069), Rx costs increased from $199 to $335, and TOT costs were relatively stable (average $1,226, range $1,143-$1,355). PAT averaged 68.1% of the PMPM (CG+PAT) MED (58.6%-70.9%), 70.6% of Rx (65.2-77.4%), and 68.7% of TOT direct (59.9%-75.9%) costs.

CONCLUSIONS: Although Parkinson's disease is often considered a disease of the elderly, the number of working age persons diagnosed with Parkinsons disease is increasing. Only through understanding both direct and indirect costs can employers develop programs to support employees, thereby mitigating the impact on both the bottom line and work performance.

SPONSORSHIP: None

G6 Comparing real-world therapeutic dose attainment and dosing trends of valbenazine and deutetrabenazine among patients with tardive dyskinesia (TD) in a US claims database

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BACKGROUND: TD is a movement disorder associated with prolonged exposure to dopamine receptor blocking agents. There are 2 FDA-approved, guideline-recommended treatments: valbenazine and deutetrabenazine (VBZ; DTBZ). In phase 3 clinical trials, all VBZ doses (40-80 mg) showed efficacy in treating TD, while DTBZ doses of below 24 mg/day did not; as such, therapeutic dosing thresholds are set at 40 and 24 mg/day, respectively.

OBJECTIVE: To compare real-world dosing trends and therapeutic dose attainment in patients with TD initiated on VBZ or DTBZ.

METHODS: A retrospective cohort study used linked data from IQVIA's longitudinal prescription and professional fee claims US databases. Adults with TD were indexed at VMAT2i initiation (7/1/22 to 1/31/24) and stratified into VBZ, DTBZ twice daily (BID), or DTBZ extended release (XR) cohorts. Patient characteristics were assessed during a 6-month baseline period and outcomes assessed during a 6-month follow-up period. Patients with Huntington's disease were excluded. Monthly dosing trends and therapeutic dose attainment were compared between VBZ vs each DTBZ cohort. Doses were rounded to the nearest dosage form.

RESULTS: A total of 3,527 patients initiated VBZ, 2,166 DTBZ BID, and 326 DTBZ XR. Baseline characteristics were similar across cohorts; median age was 61-62 years and 66%-73% were female. As the initial dosage strength of VBZ is effective, all VBZ patients reached a therapeutic dose. Significantly fewer DTBZ patients reached a therapeutic dose within 6 months (BID: 47.5%, $P < 0.001$; XR: 54.3%, $P < 0.001$); for those who did, it took on average 3-4 weeks to attain (BID: mean [SD], 24 d [38]; XR: 22 d [30]). Nearly 10% of DTBZ patients were unable to maintain a therapeutic dose (BID: 8.5%; XR: 9.6%). Among patients that did not switch agents

or discontinue during follow-up, significantly more DTBZ patients had ≥1 dose change compared to VBZ (VBZ: 33.7%; BID: 48.1%; XR: 54.0%; both P < 0.001).

CONCLUSIONS: To our knowledge, this is the first study to apply efficacy thresholds based on TD trial results to real-world dosing data. Roughly half of DTBZ-treated patients were unable to reach the therapeutic threshold within 6 months, and significantly more DTBZ patients experienced a dose change or were unable to maintain a therapeutic dose. More research is needed to investigate why patients were unable to reach this threshold (eg, tolerability, titration difficulty, effectiveness) and the economic, clinical, and humanistic consequences of subtherapeutic VMAT2i dosing in TD.

SPONSORSHIP: Neurocrine Biosciences, Inc.

G7 Improvements in functional domains, socio-emotional domains, and activities of daily living (ADLs) following valbenazine treatment in 315 patients with tardive dyskinesia (TD): real-world data from a chart extraction and clinician survey

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BACKGROUND: TD is a movement disorder characterized by repetitive and involuntary movements. Prior research suggests TD impairs social and physical functioning, which may be improved with valbenazine treatment.

OBJECTIVE: To update and expand upon a previously conducted survey and chart extraction study on TD burden and clinician-reported improvement with treatment across various areas.

METHODS: Clinicians reported data for patients who started valbenazine between 1/1/24 and 6/30/24, completed ≥2 months of treatment, and had ≥1 follow-up visit. Questions on burden and improvement were based on patient chart data and physician recall.

RESULTS: Interim data were previously reported. Final analyses included responses from 128 clinicians caring for 315 patients taking valbenazine. Mean patient age was 51 years; 53% were female. The most common underlying psychiatric diagnoses were schizophrenia (37%), bipolar disorder (35%), major depressive disorder (24%), generalized anxiety disorder (23%), and schizoaffective disorder (17%). TD severity was severe in 12%, moderate 53%, mild 29%, minimal 5%, and none 1%. At the survey time, 96% had experienced TD improvement (any level) after initiating valbenazine; of those patients (n = 303), 88% experienced improvement in ≤4 weeks. TD had an impact on overall functional ability for 92% of patients. The most commonly impacted areas were social and emotional domains, ADLs (eating, using utensils), and mouth/throat function. Among those impacted (n = 291), 72% improved in overall functional status. Improvements in emotional and social activities and ADLs were attributed to improved movement symptoms in 75%-79% of patients and improved psychiatric status in 49%-54% of patients. TD impacted independence for 88% of patients; of those, 84% experienced greater independence with valbenazine. This was attributed to improved movement symptoms in 86% of patients and psychiatric status in 51%. For those with available information on antipsychotic adherence (n = 220), 50% experienced improved adherence.

CONCLUSIONS: Real-world, valbenazine-treated TD patients experienced improvement in functional, social, emotional, and physical aspects of their lives, irrespective of TD severity. Data on independence, ADLs, antipsychotic medication adherence, and attribution of improvement to movement and/or psychiatric status add new information to prior analyses in functional and quality of life improvements beyond movement symptoms.

SPONSORSHIP: Neurocrine Biosciences, Inc.

G8 Developing and Validating a Natural Language Processing (NLP) and Named Entity Recognition (NER) Algorithm for Classifying Alzheimer's Disease (AD) and Related Dementia Patients: Insights from Electronic Health Records Data (EHR)

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BACKGROUND: The prevalence of dementia is projected to triple globally in the next three decades due to increased life expectancy. Identifying modifiable risk factors for dementia presents an opportunity for early detection and targeted interventions that can potentially prevent the onset of dementia.

OBJECTIVE: This study aims to develop and validate an algorithm for classifying Alzheimer's disease and related dementia patients using NLP and NER techniques applied to electronic health records (EHR) data. The goal is to enable early identification and facilitate the development of interventions and treatments to prevent subsequent dementia.

METHODS: A total of 108,714 patients aged 61 years and older were included from Optum's de-identified EHR database. AD patients were identified using ICD-9 and ICD-10 codes from 2010 to 2017. NER was employed to extract symptom information from free-text narratives in EHRs written by various health care providers across different clinical specialties.

The extracted symptom information was then utilized for disease classification. Model performance was evaluated using accuracy, sensitivity, specificity, and area under the curve (AUC) score.

RESULTS: Age, coronary heart disease, stroke, hearing loss, hypertension, and myocardial infarction were identified as highly significant contributors ($p < 0.001$) to the development of AD. Coronary heart disease exhibited the highest relative risk (RR: 1.9), followed by stroke (RR: 1.4), among all other comorbidities in relation to dementia. Additionally, African Americans had the highest relative risk (RR: 1.1) among racial groups for developing dementia.

CONCLUSIONS: This study demonstrates the effectiveness of the transformer model in accurately classifying AD using categorical and ordinal data. As the field progresses, integrating emerging biomarker measures and exploring novel imaging modalities will further enhance the capabilities of deep learning models in AD research and diagnosis. The algorithm developed in this study has the potential to contribute to early identification and intervention strategies for preventing dementia.

SPONSORSHIP: None

G9 Trends in Disease-Modifying Therapies Among Older Adults with Multiple Sclerosis over the Past Decade

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BACKGROUND: Although multiple sclerosis (MS) can cause significant non-traumatic disability and diminished health-related quality of life, patients with MS have comparable survival and life expectancy to that of non-MS patients. The number of older adults with MS has been increasing over the past few decades. However, there is a significant literature gap in the US regarding older adults with MS and the extent of disease-modifying therapy (DMT) use in older adults based on nationally representative data.

OBJECTIVE: To describe older adults with MS and their use of DMTs from 2011 and 2021.

METHODS: This cross-sectional study used multi-year Medicare Part A, B, and D claims data to examine older adults (age >65) with MS and their utilization of DMTs from 2011 to 2021. Diagnosis of MS was defined by ≥1 medical claim with an *International Classification of Diseases* code of 340 or G35. DMTs including interferon-beta, glatiramer acetate, teriflunomide, dimethyl fumarate, fingolimod, natalizumab, ocrelizumab, and ofatumumab were assessed. Descriptive analyses were used to examine the utilization rates further stratified by demographic variables such as age group, sex, race, and ethnicity.

RESULTS: The study found that the number of older adults with MS increased from 59,479 in 2011 to 99,502 in 2021, an increase of 67.3% in 11 years. Among adults with MS, 26.8% received at least one prescription for DMTs. From 2011 to 2021, DMT utilization among older adults with MS increased by 225%. The most frequently prescribed DMTs in older adults were interferon-beta and glatiramer acetate. Older adults prescribed DMTs were predominantly female (77.5%) and between the ages of 66 and 70 (72.5%). Meanwhile, most patients were White (89.3%), followed by African American (7.1%). The utilization rate of DMTs remained stable within each of the demographic groups.

CONCLUSIONS: The use of DMTs among older adults with MS increased over two-fold between 2011 and 2021. With the increasing availability of new and highly efficacious DMTs, there is a strong need to evaluate the DMT-associated treatment outcomes in older adults with MS.

SPONSORSHIP: Agency for Healthcare Research and Quality (R01HS029501; PI: Aparasu)

G10 Comparative Effectiveness in Multiple Sclerosis Patients Using Generic and Branded Glatiramer Acetate

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BACKGROUND: In 2015, Glatopa was the first U.S. Food and Drug Administration (FDA)–approved generic (Glatiramer Acetate [GA]) of Copaxone for multiple sclerosis (MS) management. GA is classified as a non-biologic complex medication, and this FDA approval was based on rigorous structural and functional characterization rather than clinical trial evidence. However, the comparative effectiveness profile of Glatopa vs. Copaxone remains limited.

OBJECTIVE: To compare the effectiveness of Glatopa and Copaxone in reducing relapses in patients with MS.

METHODS: A retrospective claims study was conducted using the 2017-2019 Merative MarketScan Commercial Claims data. The cohort included adults aged 18-64 years diagnosed with MS who initiated Glatopa or Copaxone between July 1, 2017, and June 30, 2019. The index was the first eligible prescription, with a 6-month washout period. Patients were required to have ≥6 months of continuous enrollment in both baseline and follow-up periods. MS relapse was identified using a claims-based relapse algorithm. The inverse probability of treatment weighting (IPTW) based on the Cox proportional hazards (CPH) regression model was

conducted to evaluate the time to first relapse between Glatopa and Copaxone users.

RESULTS: Among 3,193 MS patients who initiated GA, 21% (n = 668) initiated Glatopa, while 79% (n = 2,525) received Copaxone. The majority of the Glatopa cohort were middle age (35-44, 29.8%), were predominantly female (78.4%), received their index prescription in 2019 (54.4%), and enrolled with Preferred Provider Organization (PPO) health insurance plans (52.2%). About 12.4% (n = 395) of the study cohort experienced ≥1 MS relapse during the follow-up period. There was no significant difference in the extent of relapse between Glatopa and Copaxone users (11.9% vs. 12.5%; p = 0.9445). Similarly, the median time to experience the first relapse (74 days [29-112] vs. 66 days [23-119]; p = 0.8257) did not differ between the two groups. The IPTW-based CPH regression revealed no significant difference in time to the first MS relapse (adjusted hazard ratio [aHR], 0.93; 95% CI, 0.81-1.08) between Glatopa and Copaxone users.

CONCLUSIONS: This real-world study found that MS patients who initiated Glatopa had comparable effectiveness outcomes when compared to patients on Copaxone. Future studies should examine the comparative safety to provide the overall risk-benefit profile of Glatopa vs. Copaxone as well as the cost-effectiveness evaluation for informing clinical and policy decision-making.

SPONSORSHIP: None.

G11 Treatment Persistence With Cladribine Tablets in Patients With Multiple Sclerosis Aged <50 and ≥50 Years: A Cross-Sectional Survey of US Patients Enrolled in the MS LifeLines Patient Support Program

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BACKGROUND: Cladribine tablets (CladT) are one of the few disease-modifying therapies (DMTs) that have been studied in patients up to age 65 years in a pivotal study (CLARITY) and may be a viable treatment option for patients with multiple sclerosis (MS) aged ≥50 years.

OBJECTIVE: To evaluate patient-reported CladT treatment persistence among patients with MS aged <50 and ≥50 years participating in the MS LifeLines patient survey.

METHODS: Enrollees from MS LifeLines completed the cross-sectional survey in July and August 2022 and were included if they self-reported physician-diagnosed relapsing MS, were aged ≥18 years, and received ≥1 dose of CladT. Information collected included demographics, clinical characteristics, MS-related medical history, prior DMTs, CladT completion rate (defined as receiving the full 2-year course), treatment persistence (defined as completing the full 2-year course without any switches or discontinuations), and switching. Findings were analyzed descriptively. A sensitivity analysis was conducted among patients with ≥2 years of follow-up.

RESULTS: A total of 329 participants aged <50 years and 273 participants aged ≥50 years were included in the analyses (<50 years vs ≥50 years: mean [SD] age 38.7 [6.9] vs 58.7 [6.1] years; 83.6% vs 79.1% female; 70.5% vs 84.6% White, 11.9% vs 3.7% Black/African American, 9.1% vs 4.4% Hispanic; 94.8% vs 78.4% relapsing-remitting MS). The average time from CladT initiation until the survey was 17.6 months for patients <50 years old and 19.0 months for patients ≥50 years old (P = 0.102). At the time of the survey, compared to patients aged <50 years, those aged ≥50 years had similar rates of treatment persistence (ie, completing 1 course within <18 months since initiation of CladT or the full 2-year course; 87.5% vs 83.9%, respectively, P = 0.200), completion of the full course of CladT (49.2% vs 49.8%, respectively, P = 0.880), and treatment switching (4.0% vs 5.5%, respectively; P = 0.371). The sensitivity analysis, which included patients with ≥2 years' follow-up, showed high rates of treatment completion (<50 years vs ≥50 years: 88.2% vs 86.0%, P = 0.662) and treatment persistence (83.9% vs 77.4%, P = 0.265) and low rates of treatment switches in both age groups (7.5% vs 12.9%, respectively; P = 0.226).

CONCLUSIONS: In the MS Lifelines patient survey, patients aged ≥50 years demonstrated comparable treatment persistence with CladT, with similarly low rates of switching, relative to those <50 years. These findings contribute to the growing evidence supporting the use of CladT in patients aged ≥50 years.

SPONSORSHIP: EMD Serono (CrossRefFunder ID: 10.13039/100004755)

G12 All-cause Health Care Resource Use and Cost of care among OSA patients by BMI categories using Medicare EMR/Claims database

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BACKGROUND: Obstructive sleep apnea (OSA) is associated with a high economic burden. Nonetheless, the relationship between body weight status and economic burden of OSA is not known.

OBJECTIVE: The goal of this study was to describe cost of care and health care resource utilization (HCRU) by body mass index (BMI) categories among Medicare enrollees with OSA.

METHODS: Optum Market Clarity, an electronic health record (EHR) linked with claims database, was used to identify adults with Medicare with two medical claims for OSA between 10/1/2015 and 12/31/2021. The index date was 1/1/2022; patients were required to have continuous enrollment 1 year before (baseline) and 1 year after the index date (follow-up). Study cohorts were classified as normal weight, overweight, class I obesity, class II obesity, or class III obesity, based on their BMI reported in EHR in 2022. Linear trends in annual all-cause HCRU and all-cause costs in 2022 across BMI categories were examined using regressions with BMI categories included as a continuous independent variable.

RESULTS: 36,930 individuals were included. Of these, 6.8% were classified as normal weight, 22.8% as overweight, 28.6% as class I obesity, 21.2% as class II obesity, and 20.5% as class III obesity. Rising trends were observed for proportions of non-Hispanic Black, those from the Midwest region, and those with baseline comorbid conditions such as hypertension, type 2 diabetes, asthma, and osteoarthritis with increasing BMI class. The number of all-cause outpatient visits, emergency room (ER) visits, inpatient stays, pharmacy fills, and medication counts increased as BMI increased (all $p<0.05$). No such trends were observed between obesity status and the number of office visits ($p>0.05$). All-cause medical, pharmacy, and total health care costs also increased as BMI increased (all $p<0.001$). In addition, cost of ER visits among those with ER visits increased as BMI increased ($p = 0.009$).

CONCLUSIONS: Higher HCRU and costs were observed in patients with OSA with Medicare insurance who were within higher BMI categories compared to those in lower BMI categories.

SPONSORSHIP: Eli Lilly and Company

G13 Resource Utilization among Patients with Epilepsy: A Five-Year Comprehensive Analysis of Trends in the US

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BACKGROUND: Epilepsy is a chronic neurological disorder characterized by recurrent seizures, impacting approximately 65 million people worldwide. It significantly affects patients' quality of life and health care systems, leading to frequent hospitalizations, emergency visits, and long-term treatment costs. Effective management is crucial to reduce health care resource utilization.

OBJECTIVE: This study aims to evaluate trends in all-cause and epilepsy-specific health care resource utilization in the US.

METHODS: Patients with a diagnosis of epilepsy and recurrent seizures were identified in the Optum® Market Clarity database from January 1, 2017, to June 30, 2022. The index date was defined as the first prescription for epilepsy treatment. Patients were included if they had received epilepsy medications within the past 12 months before the index date and were continuously enrolled for at least 24 months afterward, with at least one prescription during the 12-month post-index period. Patients without an epilepsy diagnosis or prescriptions were excluded. Demographic characteristics and hospital visits were analyzed, stratifying patient data by demographics and treatment stage (pre-treatment and post-treatment).

RESULTS: A total of 115,562 patients met the selection criteria. The average age was 39 years, with 54.1% being female. Overall, all-cause hospitalizations decreased by 6% after treatment initiation, with no reduction in outpatient visits. The post-treatment group showed a declining trend in both inpatient (6%) and emergency room (ER) visits (9%) compared to the pre-treatment group. Both male and female post-treatment groups demonstrated reductions in ER visits (8% and 9%, respectively) and inpatient visits (5% and 6%). Across age categories, the post-treatment group exhibited reduced ER visits: 10% for patients aged up to 10 years, 8% for 11-25 years, 8% for 46-55 years, 9% for 56-65 years, and 13% for those aged ≥65 years. Patients aged 56-65 years and ≥65 years also had lower inpatient visits by 8% and 13%, respectively.

CONCLUSIONS: This study demonstrates a reduction in health care resource utilization for patients with epilepsy during the post-treatment stage. Our findings support that initiating epilepsy treatment not only improves patient management but also reduces stress and urgent care needs across all age groups.

SPONSORSHIP: None

G14 All-cause Health Care Resource Use and Cost of Care by Body Mass Index among OSA Patients enrolled in Commercial Plans

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BACKGROUND: The economic burden of obstructive sleep apnea (OSA) is high. However, whether economic burden of patients with OSA differs by body weight status is not known.

OBJECTIVE: The objective of this study was to describe all-cause health care resource utilization (HCRU) and all-cause

cost of care by body weight status in individuals with OSA who were enrolled in commercial health plans.

METHODS: Commercial health plan enrollees who had two medical claims for OSA between 10/1/2015 and 12/31/2021 in Optum's Market Clarity linked electronic health record (EHR) and administrative claims database were included in the study. Index date was 1/1/2022; patients were required to have continuous enrollment during 1 year prior to (baseline) and 1 year after the index date (follow-up). Patients were classified based on body mass index (BMI) reported in 2022 within EHR records as normal weight, overweight, class I obesity, class II obesity, or class III obesity. Linear trends in annual all-cause HCRU and all-cause costs in 2022 across BMI classes were examined using regressions with BMI classes included as a continuous independent variable.

RESULTS: 89,673 patients met study criteria, with 4,246 (4.7%) classified as normal weight, 16,529 (18.4%) as overweight, 24,845 (27.7%) as class I obesity, 20,888 (23.3%) as class II obesity, and 23,165 (25.8%) as class III obesity. Individuals with OSA and obesity were younger, were more likely to be non-Hispanic Black and from the Midwest region, and had higher rates of hypertension, type 2 diabetes, asthma, and osteoarthritis at baseline (all $p < 0.001$). Higher number of all-cause outpatient visits, emergency room (ER) visits, pharmacy fill, and medication counts and lower number of office visits were observed with higher BMI classes (all $p < 0.001$). Similarly, higher all-cause medical, pharmacy, total health care costs, and ER costs (among those with ER visits) were observed with higher BMI classes (all $p < 0.001$).

CONCLUSIONS: Higher HCRU and costs were observed with higher BMI categories among those with OSA and enrolled in commercial health plans.

SPONSORSHIP: Eli Lilly and Company

G15 The cost-effectiveness of tirzepatide in the treatment of moderate-to-severe obstructive sleep apnea in patients with obesity

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BACKGROUND: Two SURMOUNT-OSA trials evaluated the effectiveness of tirzepatide (TZP) treatment for moderate-to-severe obstructive sleep apnea (OSA) in patients with obesity. Patients who received TZP had statistically significant reduction in the apnea-hypopnea index (AHI) compared to placebo. Despite the demonstrated clinical effectiveness, the cost-effectiveness of TZP for treatment of OSA is unknown.

OBJECTIVE: Estimate the cost-effectiveness of TZP versus lifestyle modification (LSM) for moderate-to-severe OSA in adult patients with obesity in the US.

METHODS: An individual-level simulation cost-effectiveness model assessing TZP as treatment for obesity and overweight was adapted to consider treatment of moderate-to-severe OSA in patients with obesity. TZP was compared to LSM over a lifetime time horizon, with cost and health outcomes discounted 3% annually. For each comparator, 1,000 patients from the Sleep Health Heart Study who met key selected SURMOUNT-OSA inclusion criteria were simulated. Treatment effect on AHI, BMI, and other cardiometabolic factors was based on the efficacy estimand data from SURMOUNT-OSA. The model predicts the onset of cardiovascular (CV) events and type II diabetes (T2D) using the patient's current health status and published risk equations. Mortality due to fatal CV events and non-CV death was included; non-CV death was estimated based on US lifetables adjusted to exclude CV-related deaths. The severity of OSA influences non-CV mortality and risk of CV events, thereby increasing overall mortality rates as OSA worsens. The model includes costs related to TZP and LSM treatment, concomitant treatment including wakefulness agents, subsequent surgeries to treat OSA, CV events, and T2D and its complications. Quality of life is linked to patients' AHI, BMI, history of CV events, and complications of T2D. A scenario analysis was conducted comparing TZP to no treatment, where patients assigned to no treatment experienced no improvement in AHI or cardiometabolic parameters.

RESULTS: In the comparison against LSM, TZP was predicted to yield 0.52 additional life-years and 0.64 additional QALYs at an incremental cost of $42,023, translating to an ICER of $65,796 per QALY. Patients treated with TZP were predicted to spend an additional 3.53 years in remission (defined as AHI < 5 events / hour) versus those who received LSM.

CONCLUSIONS: With an estimated ICER below $100,000 per QALY, TZP may be considered a cost-effective alternative to LSM for moderate-to-severe OSA.

SPONSORSHIP: This study was sponsored by Eli Lilly.

G16 Comparative Efficacy of AXS-07 vs. Gepants for Acute Treatment of Migraine: A Network Meta-Analysis

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BACKGROUND: AXS-07 is a novel, oral, rapidly absorbed, multi-mechanistic investigational medicine to treat migraine, consisting of MoSEIC™ (Molecular Solubility Enhanced Inclusion Complex) meloxicam and rizatriptan. The MOMENTUM (NCT0389600) phase 3 randomized, double-blind, single-dose, placebo-controlled trial demonstrated the efficacy and safety of AXS-07 in the acute treatment of migraine, with or without aura, in adults with a history of inadequate response to prior treatments.

OBJECTIVE: To compare the efficacy of AXS-07 with gepants (rimegepant, ubrogepant, zavegepant) approved for acute migraine treatment in the United States using a network meta-analysis (NMA).

METHODS: The analysis included MOMENTUM and 7 placebo-controlled phase 3 trials of the comparator drugs. A fixed-effects Bayesian NMA was conducted focusing on 2-hour and 2- to 24-hour pain relief and pain freedom, absence of most bothersome symptoms (MBS), ability to perform normal activities at 2 hours, and use of rescue medications from 2 to 24 hours. Results were summarized with odds ratios (OR) and 95% credible intervals (CIs).

RESULTS: Compared to rimegepant, ubrogepant, and zavegepant, participants treated with AXS-07 were more likely to achieve 2-hour pain relief (OR [95% CI]: 1.06 [0.73-1.53], 1.10 [0.75-1.61], 1.33 [0.91-1.96]), 2-hour pain freedom (1.96 [1.07-3.78], 1.98 [1.07-3.89], 2.07 [1.13-4.06]), sustained 2- to 24-hour pain relief (1.11 [0.77-1.62], 1.02 [0.69-1.52], 1.66 [1.13-2.45]), and sustained 2- to 24-hour pain freedom (1.66 [0.85-3.51], 2.07 [1.04-4.46], 2.25 [1.14-4.83]). AXS-07 also showed greater absence of MBS (1.15 [0.78-1.73], 1.11 [0.73-1.69], 1.26 [0.84-1.92]), improved ability to perform normal activities at 2 hours (1.03 [0.68-1.58], 1.18 [0.77-1.82], 1.16 [0.75-1.81]), and reduced use of rescue medications from 2 to 24 hours (0.84 [0.57-1.23], 0.68 [0.43-1.10], 0.47 [0.32-0.71]).

CONCLUSIONS: The NMA favors AXS-07 over rimegepant, ubrogepant, and zavegepant for acute migraine. AXS-07 is particularly effective in achieving 2-hour and 2- to 24-hour sustained pain freedom, offering a promising therapeutic alternative for patients with inadequate response to prior treatments.

SPONSORSHIP: Axsome Therapeutics, Inc.

G17 Expected costs and costs per responder of Hizentra in comparison with other maintenance therapies for chronic inflammatory demyelinating polyneuropathy in the United States

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BACKGROUND: Hizentra (HIZ) is a human subcutaneous immunoglobulin (SCIg) approved as a maintenance therapy for long-term treatment of chronic inflammatory demyelinating polyneuropathy (CIDP).

OBJECTIVE: To assess the (a) expected overall cost and (b) expected costs per responder (CPR) of HIZ 0.2 g/kg and HIZ 0.4 g/kg versus new entrants (efgartigimod: Vyvgart Hytrulo [VYV] and facilitated SCIg: HyQvia [HYQ]) for maintenance treatment of CIDP in adult patients from a United States (US) health care system perspective.

METHODS: A 1000-patient cohort-level Markov model was used for the economic analysis. The model included five health states—Initial maintenance status, Non-responder, Responder, Disabled, and Death—and was run over 5 years using a 4-week cycle length and 3% annual discount rate. Treatment efficacy was based on transition probabilities (TPs) of relapse rates in the maintenance period (weeks 0-24) from a network meta-analysis of respective published trials. For weeks 25 and beyond, a TP of relapse was calculated from weeks 25-48 of ADHERE (VYV Phase 3 trial) and applied for all treatments. The TP of returning from Non-Responder to the Responder health state was based on published relapse management efficacy from the HIZ PATH open-label extension and the ICE study. The relapse management strategy for each therapy was based on its drug label but was absent from the label for new entrants. Costs were obtained from US sources. Scenario analyses tested alternative model assumptions, including intravenous immunoglobulin (IVIg) rescue therapy for HYQ and VYV, and a lower annual drug cost of $450,000 for VYV.

RESULTS: In the base case, HIZ 0.2 g/kg had the lowest total expected costs ($886.44 million [M]) while VYV had the highest ($2.71 billion) The expected number of responders was highest for HIZ 0.2 g/kg (n = 811) and HIZ 0.4 g/kg (n = 894) versus 637 responders each for both new entrants, due to lack of their labeled relapse management. HIZ 0.2 g/kg had the lowest expected CPR ($1.09M), followed by HYQ ($1.41M) and HIZ 0.4 g/kg ($1.72M). In the scenarios permitting IVIg rescue therapy, the number of responders increased for HYQ (n = 888) and VYV (n = 891), reducing each treatment's CPR. However, VYV consistently had the highest

expected CPR (base case: $4.25M) versus other treatments, even in the reduced annual drug cost scenario ($2.36M).

CONCLUSIONS: Initiating maintenance therapy with HIZ overall is expected to result in the highest number of responders and, for HIZ 0.2 g/kg, the lowest CPR over new entrants.

SPONSORSHIP: CSL Behring.

G18 Disease severity and health care resource utilization for chronic inflammatory demyelinating polyradiculoneuropathy and multifocal motor neuropathy: Results from an integrated database

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BACKGROUND: Chronic inflammatory demyelinating polyradiculoneuropathy (CIDP) and multifocal motor neuropathy (MMN) are rare neuromuscular diseases characterized by muscle weakness and/or sensory loss.

OBJECTIVE: To analyze health care resource utilization (HCRU) and all-cause health plan paid amount by disease severity for patients with CIDP or MMN using patient-reported outcome measures.

METHODS: A mixed-method study surveyed US adult patients diagnosed with CIDP or MMN with open medical/pharmacy claims and ICD-10 codes of G61.81 or G61.82. Included patients had claims data available ≥1 year before and after the index diagnosis date. Inflammatory Neuropathy Cause and Treatment (INCAT) scores were used to categorize patients by overall level of impairment as follows: minimal manifestations, mild, moderate, or severe.

RESULTS: Overall, 56 patients with CIDP and 13 patients with MMN were included; median follow-up times from index diagnosis were 43 months (for CIDP) and 54 months (for MMN). Per INCAT, 68% of patients with CIDP and 62% of patients with MMN were categorized as having moderate/severe impairment. All-cause paid amount 1 year after CIDP diagnosis was available for 46 patients with CIDP, of whom 14 had intravenous immunoglobulin (IVIG) paid amount available. IVIG paid amount accounted for 96% of the all-cause paid amount. One year after their CIDP diagnosis, patients with severe impairment had more hospitalizations (4.5 vs 1.5) and higher median IVIG paid amount than those with mild impairment ($125,538 vs $80,248). IVIG paid amount 1 year after MMN diagnosis was available for only 1 patient ($64,982).

CONCLUSIONS: More severe impairment among patients with CIDP is associated with higher HCRU and costs. Results for patients with MMN were inconclusive due to limited sample size.

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G19 Epidemiology, Patient Characteristics, Real-World Treatment Patterns, and Outcomes for Patients with Multifocal Motor Neuropathy (MMN)

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BACKGROUND: MMN is a rare and progressive nerve disorder characterized by asymmetrical limb weakness due to motor nerve conduction blocks. Patient characteristics, treatment patterns, and economic burden of MMN are not well established.

OBJECTIVE: To examine epidemiology, diagnostic and treatment patterns, health care resource utilization (HCRU), and health care costs associated with MMN in patients enrolled in a United States Medicare Advantage plan.

METHODS: This retrospective observational claims study included Humana Research Database enrollees (18-89 years) with ≥2 medical claims and diagnosis of MMN (January 2017 to June 2022). Individuals with evidence of prevalent MMN, CIDP, ALS, or immunosuppressant use were excluded. Index date was the date of the first MMN diagnosis. Descriptive outcomes were assessed during 12-month pre-index and post-index periods.

RESULTS: Patients (N = 248) with newly diagnosed MMN were identified (mean [SD] age: 68.9 [10.3] years; 53.6% male); 59.7% were diagnosed by a primary care provider. Diagnostic procedures used included (pre-/post-index %) spinal MRI (21.4/18.1), nerve conduction studies (19.8/14.5), and electromyography (17.7/15.3). Anticonvulsants, pain medications, steroids, and muscle relaxants were used pre- and post-index. Post-index, 5.2% of patients received intravenous immunoglobulin (IVIG). Mean (SD) time to initiation was 63.1 (52.2) days, with an average of 6.5 (5.4) administrations, 28.7 (22.9) days between treatments, and 147.5 (133.9) days total treatment duration. Pre-index, 23.8% of patients had ≥1 inpatient stay, and mean length of stay (LOS) per patient with an inpatient stay was 12.7 (SD 14.5) days;

post-index, 27.8% of patients had ≥1 inpatient stay, with a mean LOS per patient with an inpatient stay of 13.4 (SD 16.2) days. Telehealth services were utilized by 18.5% of patients pre-index and 28.6% of patients post-index; 43.1% (pre-index) and 46.8% (post-index) of patients had ≥1 emergency department (ED) visit. Median spending (pre-/post-index) was $11,299/$16,074 for total health care, $1374/$1701 for pharmacy, and $6745/$10,630 for medical.

CONCLUSIONS: All-cause HCRU and health care costs revealed that patients with MMN experienced inpatient hospitalizations and ED encounters before and after diagnosis. Since only a few patients were treated with IVIG after diagnosis, there is a significant opportunity to identify potential barriers to appropriate use of IVIGs in the MMN population.

SPONSORSHIP: Takeda Pharmaceuticals USA, Inc., Cambridge, MA, USA, funded the study and writing support.

G25 Dosing Patterns and Persistence on Cannabidiol (CBD): Insights From US Specialty Pharmacy Data

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BACKGROUND: A plant-derived highly purified pharmaceutical formulation of CBD (Epidiolex®, 100 mg/mL oral solution) is approved in the US for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS), Dravet syndrome (DS), or tuberous sclerosis complex (TSC) in patients aged ≥1 year. The recommended maintenance dosage is 10-20 mg/kg/day for LGS and DS and 25 mg/kg/day for TSC.

OBJECTIVE: To characterize real-world dosing patterns and persistence on CBD.

METHODS: We analyzed patient-level, de-identified US specialty pharmacy (SP) fill records for new CBD users from November 15, 2018, to July 12, 2023. Dosage was derived from patient weight, quantity dispensed, and days' supply. Discontinuation was defined as a 60-day supply gap; patients with continuous supply beyond July 12, 2023, were censored at their last recorded day of supply. Persistence (initial CBD pharmacy fill through discontinuation/censoring) was analyzed via Kaplan-Meier method.

RESULTS: We identified 19,444 new users. The overall probability of persistence at 12 months was 69.9%. The distributions of the starting dosages at ≤5, >5-10, >10-15, >15-20, >20-25, and >25 mg/kg/day were 16.8%, 53.7%, 19.7%, 5.7%, 2.3%, and 1.7%, respectively. The proportions shifted over time toward higher doses, reaching 4.0%, 18.8%, 25.6%, 28.6%, 15.9%, and 6.9%, respectively, at 12 months. Cumulatively, during their initial continuous treatment period and up to 12 months, 66.1% of treatment months were at doses >10; 38.7%, >15; and 15.6%, >20 mg/kg/day. Risk for discontinuation was highest in the second month of treatment.

CONCLUSIONS: Based on US SP data, most patients at 12 months were taking dosages >15 mg/kg/day. Long-term persistence on CBD may be associated with dose optimization over time, representing a balance between tolerability and seizure reduction.

SPONSORSHIP: Jazz Pharmaceuticals, Inc.

G26 Economic Evaluations of FcRn Inhibitors in Generalized Myasthenia Gravis

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BACKGROUND: Generalized myasthenia gravis (gMG) is a rare autoimmune disorder affecting the neuromuscular junction. Two Fc receptor (FcRn)–targeting therapies, efgartigimod (EFG) and rozanolixizumab (ROZ), have been approved in the U.S. EFG (available in both intravenous [IV] and subcutaneous [SC]) is an engineered Fc fragment that selectively binds to FcRn to reduce immunoglobulin G (IgG) levels, whereas ROZ (available only in IV) is a monoclonal antibody that targets FcRn to reduce IgG levels. Both therapies follow individualized dosing with variable vial consumption based on patient weight and clinical evaluation. These dose variations may create uncertainty for health plans to forecast treatment budgets. Evaluating the economic value of these therapies, based on reliable treatment cycle and patient weight estimates, can provide critical insights to budget planning.

OBJECTIVE: To estimate the annual costs and costs per improved outcome (CPIO) for FcRn-targeting therapies with weight-based and/or individualized dosing in gMG.

METHODS: Annual costs for EFG IV, SC, and ROZ were estimated based on treatment cycles and patient weights. The primary and sensitivity analyses accounted for variations in both patient weight distributions and the number of treatment cycles. To estimate the CPIO, a Bayesian NMA was conducted for novel gMG treatments including EFG IV, SC, and ROZ. Efficacy outcomes included ≥3- and ≥5-point reductions in Myasthenia Gravis-Activities of Daily Living (MG-ADL) and Quantitative Myasthenia Gravis (QMG) scores. NMA results were used to estimate CPIO for each treatment vs. placebo, with costs in 2024 USD.

RESULTS: In the primary analysis, EFG IV and SC had similar annual costs ($299,053 and $296,532, respectively), both lower than ROZ ($326,520). Across the four efficacy outcomes evaluated, EFG IV and SC showed comparable CPIO vs. placebo. ROZ had significantly higher CPIO compared to EFG IV or SC for achieving ≥3- and ≥5-point reductions in QMG and ≥5-point reductions in MG-ADL ($1,731,176, $904,159, $1,100,698, respectively). Although ROZ had the highest CPIO for achieving ≥3-point reductions in MG-ADL, this difference was not statistically significant compared to EFG IV or SC. Sensitivity analyses yielded consistent results.

CONCLUSIONS: Considering real-world weight distributions and individualized dosing schedule, EFG IV and SC demonstrated lower annual costs and lower CPIOs compared to ROZ, suggesting they may offer more favorable economic value in the treatment of gMG.

SPONSORSHIP: argenx, Inc.

G27 Effectiveness and safety of low-sodium oxybate in participants with narcolepsy and idiopathic hypersomnia: top-line results from the phase 4 DUET study

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BACKGROUND: Low-sodium oxybate (LXB, Xywav®) is approved by the US Food and Drug Administration to treat excessive daytime sleepiness (EDS) or cataplexy in patients ≥7 years of age with narcolepsy and idiopathic hypersomnia (IH) in adults.

OBJECTIVE: Jazz DUET (Develop hypersomnia Understanding by Evaluating low-sodium oxybate Treatment) is a phase 4, prospective, multicenter, single-arm, open-label study (NCT05875974) of the effectiveness of LXB treatment on EDS, sleep architecture and disruption (measured by polysomnography [PSG]), and functional outcomes in participants with narcolepsy or IH (separate cohorts).

METHODS: DUET comprised a screening period (2-week washout for current oxybate users), 8-day baseline (BL) period, 2- to 8-week LXB titration period, 2-week stable-dose period (SDP), 8-day end-of-treatment period (EOT), and 2-week safety follow-up. The primary endpoint for narcolepsy was change in Epworth Sleepiness Scale (ESS) score from BL to EOT; key secondary endpoints included 3 PSG parameters. The primary endpoint for IH was change in ESS score; the key secondary endpoint was change in Idiopathic Hypersomnia Severity Scale (IHSS). Additional endpoints included Patient Global Impression of Change (PGIc)–overall symptoms (both cohorts) and PGIc–sleep inertia (IH).

RESULTS: Fifty-five narcolepsy and 46 IH participants enrolled and took ≥1 dose of LXB after BL. Most participants (narcolepsy and IH, respectively) were female (72.7%; 80.0%) and White (80.0%; 85.0%). For narcolepsy, least-squares mean (LSM) (SE) change from BL to EOT in ESS score was –7.7 (0.9), P<0.0001 (N = 34). LSM (SE) changes for total shifts from deeper to lighter stages of sleep, N3 sleep duration (minutes), and number of awakenings were –13.1 (3.0), P<0.0001; 45.0 (8.8), P<0.0001; and –3.2 (0.9), P = 0.0015, respectively (N = 34 each). Most participants reported improvement on the PGIc–overall (93.3%; N = 30). For IH, LSM (SE) changes in ESS (N = 40) and IHSS (N = 36) were –8.4 (0.7), P<0.0001 and –15.5 (1.5), P<0.0001, respectively. Most participants reported improvement on the PGIc–overall (94.6%; N = 37) and PGIc–sleep inertia (81.1%; N = 37). For IH, there was 1 serious adverse event of hypoxia (concurrent with influenza) unrelated to study drug, which resolved. Common TEAEs included nausea, dizziness, and headache.

CONCLUSIONS: Participants with narcolepsy taking LXB had improvements in sleepiness (ESS scores) and narcolepsy symptom severity, reduced sleep stage shifts, increased deep sleep (N3), and fewer awakenings. Participants with IH had improvements in ESS scores, sleep inertia, and IH symptom severity.

SPONSORSHIP: Jazz Pharmaceuticals

H00-H95 Diseases of the Eye and Adnexa

(eg, macular degeneration)

H1 Addressing the gaps in dry eye disease: A review of current and emerging treatments with new mechanisms of action

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BACKGROUND: Dry eye disease (DED) is a prevalent ocular condition marked by discomfort, visual disturbance, and ocular surface damage. New options have opened the treatment landscape beyond anti-inflammatories, but substantial unmet needs remain. Acoltremon ophthalmic solution 0.003% (ACO) is an investigational drug with a distinct mechanism of action (MOA) seeking FDA approval to treat the signs and symptoms of DED.

OBJECTIVE: This study assessed treatment patterns including utilization, adherence, and satisfaction with prescription therapies to identify persistent unmet needs affecting US patients and evaluates, based on MOA and clinical profile, the potential for ACO to impact treatment paradigms.

METHODS: A literature review was conducted (10/2019 to present) to identify real-world evidence (RWE) for established immunomodulator therapies (lifitegrast, cyclosporine) and recent entrants (Tyrvaya [a neuromodulator] and Miebo [anti-evaporative]). Claims database analyses, patient and physician surveys, or clinical trials reporting outcomes of interest were included.

RESULTS: Recent surveys report one in three patients experience inadequate symptom control and prolonged time to onset using existing therapies. Large database analyses indicate discontinuation rates between 64.4% and 90.7% for cyclosporine and lifitegrast. Although RWE is limited for the more recent entrants, literature suggests the treatment regimens may be burdensome or inconvenient for some patients (eg, contact lens users). ACO contains a topical transient receptor potential melastatin 8 agonist, which increases tear production and may help to address these gaps. In recent phase 3 clinical trials (COMET-2 and COMET-3), ACO demonstrated a rapid significant increase in tear production vs vehicle (VEH). The primary endpoint (proportion of subjects attaining ≥10 mm increase in unanesthetized Schirmer score) at day 14 was met in both studies: 42.6% vs 8.2% and 53.2% vs 14.4%, ACO vs VEH ($P < 0.0001$). Tear production was observed as early as day 1 and through day 90, yielding treatment differences of 26.7% to 43.8% vs VEH ($P < 0.0001$). Total and inferior corneal staining (used to detect corneal damage) and DED symptoms decreased numerically from baseline with ACO across all timepoints in both trials.

CONCLUSIONS: Findings suggest ongoing unmet needs in DED relating to optimizing adherence to treatment and clinical outcomes. Data support ACO as a potential option to treat the signs and symptoms of DED, offering a medication with a new MoA to help address gaps.

SPONSORSHIP: Alcon

H2 Treatment Patterns Among Medicare Advantage Plan Beneficiaries Diagnosed with Neovascular Age-Related Macular Degeneration Who Initiated Faricimab Treatment

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BACKGROUND: Faricimab, a novel intraocular bispecific antibody, binds angiopoietin-2 and vascular endothelial growth factor (VEGF)-A and is indicated for treatment of neovascular age-related macular degeneration (nAMD), a leading cause of vision loss in the US. Real-world evidence of treatment patterns and clinical outcomes of faricimab is growing; this is the first claims-based study evaluating treatment patterns among nAMD patients initiating faricimab within routine clinical practice.

OBJECTIVE: To evaluate real-world health care resource utilizations and treatment patterns among nAMD patients initiated on faricimab in a large population enrolled in Medicare Advantage (MA).

METHODS: All patients aged ≥65 years, diagnosed with nAMD and newly initiated faricimab, were identified in claims data from Humana MA plans (study period: 2/7/2022 to 8/31/2023). Index date was the date of the first faricimab claim during the study period. Continuous enrollment in medical and pharmacy benefit plans during the 12-month pre- and post-index period was required. Baseline demographic and clinical characteristics were described. Treatment patterns were evaluated during the pre- and post-index period among unilaterally treated patients. Results were stratified for prior aVEGF (anti-VEGF)-experienced vs -naive patients using pre-index aVEGF claims.

RESULTS: Among 5,368 patients with faricimab claims, 2,542 nAMD patients met sample selection criteria, and 94.1% were aVEGF experienced. Mean (SD) age was 78.6 (5.6) years, 59.6% were female, and 93.9% were White patients. The mean (SD) baseline Elixhauser comorbidity score was 2.6 (2.2). At pre-index, 71.7% aVEGF-experienced patients had ≥5 prior aVEGF injections, and 62.7% were previously treated with aflibercept. At post-index, mean (95% CI) number of faricimab injections was 6.1 (5.9-6.3) for experienced and 5.0 (4.4-5.6) for naive patients. Among experienced patients, mean (95% CI) injection intervals increased from 47.0 (46.0-48.0) days on prior aVEGF agents to 53.0 (52.0-53.8) days on faricimab ($P < 0.0001$). Among experienced patients, ophthalmologist visits per patient per month decreased from 0.70 (0.69-0.71) to 0.62 (0.61-0.63) ($P < 0.0001$) after switching to faricimab.

CONCLUSIONS: The vast majority of nAMD patients initiating faricimab were previously treated with aVEGF agents, and switching to faricimab was associated with longer treatment intervals and fewer ophthalmologist visits. Further research is needed to understand the impact on longer-term clinical and treatment-related outcomes including health care resource use.

SPONSORSHIP: None

H3 Real-world evidence of treatment burden linked to long-term visual outcomes in patients with neovascular age-related macular degeneration receiving anti-VEGF therapy

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BACKGROUND: Treatment of neovascular age-related macular degeneration (nAMD) can be burdensome for patients as it requires repeated intravitreal injections. This study addresses the current gap in data examining long-term treatment patterns and visual outcomes in patients with nAMD.

OBJECTIVE: To assess the burden of intravitreal anti-VEGF treatment, including non-persistence and loss to follow-up (LTFU) rates, and their link with visual acuity (VA) in patients with nAMD.

METHODS: Patients ≥50 years with nAMD and initiated on anti-VEGF therapy were identified using the Vestrum Health database (n = 85,657 eyes). Number of injections, rate of non-persistence (no treatment for 6 months after last injection), LTFU, and best-corrected VA (BCVA) outcomes were assessed up to 60 months.

RESULTS: Mean number of injections was 7.5 in year 1 (median = 8, Q3 = 9), 4.8 in year 3, and 4.6 in year 5. Higher numbers of injections (>7.5, 8, and 9) were all linearly associated with better BCVA outcomes over the 5-year period versus fewer injections ($p < 0.01$). By the end of year 5, 47% of patients were non-persistent and 32% were LTFU. Lower index BCVA was associated with greater likelihood of non-persistence and LTFU within the first 3 years of treatment compared with higher index BCVA ($p < 0.001$).

CONCLUSIONS: A high number of injections in the first year was associated with better BCVA outcomes vs fewer injections over a 5-year period. Ensuring consistent anti-VEGF therapy over time, especially in the first year, leads to better visual outcomes; however, many patients did not remain on therapy.

SPONSORSHIP: AbbVie and REGENXBIO Inc.

H4 Treatment Patterns Among Medicare Advantage Plan Beneficiaries Diagnosed with Diabetic Macular Edema Who Initiated Faricimab Treatment

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BACKGROUND: Faricimab is the first bispecific monoclonal antibody administered intraocularly and indicated for treatment of diabetic macular edema (DME), the leading cause of blindness among patients with diabetes mellitus. Real-world evidence of treatment patterns and clinical outcomes of faricimab is growing; this is the first claims-based study evaluating treatment patterns among DME patients initiating faricimab within routine clinical practice.

OBJECTIVE: To evaluate the real-world health care resource utilizations and treatment patterns of patients with DME initiated on faricimab in a large population enrolled in Medicare Advantage (MA).

METHODS: Patients aged ≥65 years, diagnosed with DME and newly initiated faricimab, were identified in claims data from Humana MA plans (study period: 2/7/2022 to 8/31/2023). Index date was the date of the first faricimab claim during the study period. Continuous enrollment in medical and pharmacy benefit plans during the 12-month pre- and post-index period was required. Baseline demographic and clinical characteristics were described. Treatment patterns were evaluated during pre- and post-index period among unilaterally treated patients. Results were stratified for prior aVEGF (anti-VEGF)-experienced vs -naive patients using pre-index aVEGF claims.

RESULTS: Among 5,368 patients with faricimab claims, 559 DME patients met sample selection criteria, and 88.9% were aVEGF experienced. The mean (SD) age was 73.0 (5.5) years, 53.1% were female, and 67.6% were White patients. The mean (SD) baseline Elixhauser comorbidity score was 4.1 (2.2). At pre-index, 67.3% aVEGF-experienced patients had ≥5 prior aVEGF injections, with 57.4% previously treated with aflibercept. At post-index, mean (95% CI) faricimab injections were 6.0 (5.5-6.5) for experienced and 4.8 (3.7-5.9) for naive patients. Among experienced patients, mean (95% CI) injection interval increased from 45.0 (42.5-47.3) days on prior aVEGF agents to 51.0 (48.0-53.4) days on faricimab ($P = 0.003$). Among naive patients, the mean (95% CI) injection interval was 53.0 (46.0-60.4) days. Among experienced patients, ophthalmologist visits decreased from 0.69 (0.66-0.72) per patient per month (PMPM) to 0.61 (0.58-0.64) PMPM ($P<0.0001$) after switching to faricimab.

CONCLUSIONS: The vast majority of DME patients initiating faricimab were previously treated with anti-VEGF agents,

and switching to faricimab was associated with longer treatment intervals and fewer ophthalmologist visits. Further study of treatment-related and clinical outcomes over long-term follow-up will help establish outcomes in routine clinical practice.

SPONSORSHIP: None

H6 Real-World Evidence of Usual Care and Binocular Treatment for Amblyopia: Results from the IRIS and PUPiL Registry

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BACKGROUND: Amblyopia, neurological suppression of visual stimuli from an eye, is typically treated via monocular part time occlusion (PTO) of the stronger eye. This treatment does not resolve amblyopia in a majority of patients, evidenced both in clinical trials and in the real world via clinical data collected from the IRIS® Registry. Luminopia, a digital binocular treatment for amblyopia, has shown effect in multiple clinical trials and real-world data is available for analysis via the PUPiL Registry (NCT06429280).

OBJECTIVE: Evaluate real world evidence from the IRIS and PUPiL Registries in similar patients to characterize change in best-corrected visual acuity (BCVA) over time for children under usual care and those on Luminopia.

METHODS: Children matched in age and amblyopia were evaluated from both Registries. For the PUPiL Registry, inclusion criteria also included 12+ weeks of Luminopia usage. IRIS Registry was analyzed from prior publications. Change in lines of BCVA from baseline to most recent follow-up visit available was analyzed. Sub-groups within the PUPiL Registry based on prior amblyopia treatment were evaluated.

RESULTS: In the IRIS Registry, 442,854 patients qualified for analysis. Children aged 3-6 years gained 1.9 lines in BCVA over 2.3 years of PTO (n = 45,079); children aged 7-12 years gained 0.8 lines over 2.6 years (n = 58,323). In the PUPiL Registry, 289 children qualified for analysis. Children aged 3-6 years gained 1.3 (95% CI: 1.0-1.5, n = 124) lines BCVA and 7-12 year olds gained 0.9 lines (0.7-1.2, n = 153), both over 8 months of follow-up. 79% of 3- to 6-year-olds and 86% of 7- to 12-year-olds received amblyopia treatment prior to Luminopia for 1.6 and 2.5 years, respectively, a vast majority of which was patching. In these prior-treated groups, 3- to 6-year-olds improved by 1.1 lines (0.8-1.3) and 7- to 12-year-olds by 0.9 lines (0.6-1.1) in BCVA over 8 months. Children without any prior amblyopia treatment improved 2.1 (1.6-2.6) and 1.2 lines (0.3-2.1) 8 months after starting Luminopia in the younger and older groups, respectively.

CONCLUSIONS: Children on Luminopia in the PUPiL Registry experienced similar or greater BCVA improvement of the amblyopic eye in less time than those receiving PTO in the IRIS Registry. Prior-treated children switched to Luminopia experienced additional BCVA gains. Younger children in both registries improved more than older children, with older children on Luminopia gaining more vision, even after switching from other treatments. A shorter duration of follow-up data was available for the PUPiL Registry; further research with longer term data is warranted.

SPONSORSHIP: Luminopia, Inc.

H7 Evaluating the Impact of Luxturna Gene Therapy on Vision Preservation and Disease Progression in Patients with RPE65 Mutation–Associated Inherited Vision Loss: A Retrospective Analysis of Claims and Electronic Health Records (EHR) in the US

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Optum

BACKGROUND: RPE65 mutation–associated inherited vision loss is a rare genetic disorder causing severe visual impairment. Mutations in both copies of the RPE65 gene disrupt retinal function, leading to progressive vision loss and blindness. Early intervention is crucial for preserving vision.

OBJECTIVE: This study aims to investigate the impact of Luxturna, a novel gene therapy drug, on patients with inherited vision loss caused by mutations in both copies of the RPE65 gene. The research aims to provide insights into the potential effects of Luxturna on vision preservation and slowing down disease progression.

METHODS: A retrospective study was conducted using the Optum® Market Clarity Dataset, focusing on patients with claims or EHR records for Luxturna between January 1, 2017, and March 31, 2024. Patients were identified using specific NDC (71394006501, 71394041501, 71394071601) and HCPCS (J3398) codes. The index event was defined as the first claim or EHR record for Luxturna. Analysis covered a 6-month pre-index period and an 18-month post-index period. Natural language processing was used to assess family history, changes in vision, and outcomes of mobility and visual tests such as multi luminance mobility testing, full-field light sensitivity threshold testing, visual acuity testing, visual field testing, light sensitivity testing, and other tests along with developmental and educational needs status.

RESULTS: The study included 58 patients with a claim or EHR for Luxturna. Clinical notes for 13 patients were analyzed to

understand the state of vision pre and post Luxturna therapy, which showcased improvement in vision post Luxturna therapy. Provider specialty analysis revealed a significant decrease in patient visits to ophthalmology specialists, from 40% pre-therapy to 20% post-therapy ($p < 0.0001$). Further evaluation of Luxturna's impact on health care resource utilization and cost is planned.

CONCLUSIONS: Luxturna, novel gene therapy approved by the US FDA in December 2017 aiming to help the cells in the retina to function better and slow down the progression of the disease, has demonstrated encouraging outcomes.

SPONSORSHIP: None

H8 Budget Impact of Biosimilar VEGF Inhibitors: Projected Medicare Part B Savings

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BACKGROUND: Vascular endothelial growth factor (VEGF) inhibitors are an increasingly utilized therapy for retinal diseases, and a top spending category for Medicare Part B.

OBJECTIVE: To estimate the cost savings to Medicare Part B associated with the increased utilization of biosimilar ranibizumab, and future biosimilar versions of aflibercept.

METHODS: We conducted a budget impact analysis projecting a treatment environment where biosimilar versions of ranibizumab and aflibercept are available. Utilization and expenditure data for brand ranibizumab and aflibercept were derived from the 2022 Medicare Part B Spending by Drug Databases, providing a baseline market mix. A projected new treatment environment comprised a market mix where 50% of brand ranibizumab and aflibercept use switched to biosimilars priced at 65% of the average expenditure per claim for the brand product. The percent utilization of other therapies was presumed to continue unchanged. Cost savings were estimated by applying the difference between the mean cost per claim for brand ranibizumab and the published wholesale acquisition cost for biosimilar ranibizumab. The cost of future aflibercept biosimilars was estimated as the percent cost difference for biosimilar ranibizumab applied to the mean spending per claim for brand aflibercept. Sensitivity analyses assessed variation in the uptake of biosimilar ranibizumab and aflibercept (range 30%-70%) and cost reductions for biosimilars that ranged from 45% to 85% of the per-claim brand spending.

RESULTS: In the base case, the annual estimated Medicare Part B savings associated with 50% biosimilar utilization was $139.2 million for ranibizumab and $619.8 million for aflibercept, for total annual savings of $759 million. Results of sensitivity analyses of 30%-70% market utilization yielded an estimated annual savings of $83-$194 million for ranibizumab and $371-$867 million for aflibercept. Sensitivity analyses exploring a 45% and 85% reduction in the cost per claim for biosimilars yielded an estimated annual savings of $59-$218 million for ranibizumab and $265-$974 million for aflibercept. Limitations of the analysis include the assumption that biosimilar versions of aflibercept will enter the US market (currently halted by patent lawsuits), and lack of information about discounts provided by manufacturers.

CONCLUSIONS: Growth in utilization of biosimilar VEGF inhibitors offers substantial potential for cost savings for Medicare Part B, and will be driven by the magnitude of price reduction and the extent of biosimilar utilization.

SPONSORSHIP: AscellaHealth

I00-I99 Diseases of the Circulatory System

(eg, atrial fibrillation, pulmonary hypertension)

I1 Aldosterone dysregulation is a risk factor for hypertension and chronic kidney disease: BREAKTHROUGH Risk Study

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BACKGROUND: Aldosterone dysregulation (AD) has been associated with increased risk of hypertension (HTN) and chronic kidney disease (CKD), but the levels at which dysregulated aldosterone becomes associated with HTN and CKD have not been established.

OBJECTIVE: (1) To evaluate the association between plasma aldosterone and risk of HTN at multiple aldosterone levels. (2) To evaluate the association between plasma aldosterone and risk of CKD at multiple aldosterone levels.

METHODS: Patients with plasma aldosterone measured during 2013-2023 were identified from the TriNetX Dataworks-USA Network, a de-identified, federated network of electronic medical records. The first aldosterone measurement meeting eligibility criteria was the index event: ≥18 years old, systolic blood pressure (SBP) during 12-month follow-up, low renin (≤1 ng/mL/hr) during 12-month baseline, and no pregnancy within 40 weeks. The adjusted odds ratio (AOR) of HTN (the first SBP ≥130 mm Hg measure) during

the 12-month follow-up was established between patients with aldosterone ≥5 and <5 ng/dL. The AOR of stage 2 HTN (SBP ≥140 mm Hg) and the AOR of CKD (by ICD diagnosis, or eGFR ≤60 mL/min/1.73 m^2) during the 12-month follow-up between patients with aldosterone ≥5 and <5 ng/dL, ≥10 and <10 ng/dL, and ≥15 and <15 ng/dL was also analyzed. Adjustment factors for each model included age, sex, race, ethnicity, and T2DM during the 12-month baseline.

RESULTS: The study's eligibility criteria identified 1,334 patients with plasma aldosterone. The AOR of HTN (SBP ≥130 mm Hg) was 2.01 (95% CI 1.38-2.92) between patients with and without excess aldosterone at threshold of ≥5 ng/dL. The AOR of stage 2 HTN (SBP ≥140 mm Hg) was 1.31 (95% CI 0.98-1.76), 1.37 (95% CI 1.02-1.84), and 1.47 (95% CI 1.03-2.00) between patients with and without excess aldosterone at thresholds of ≥5 ng/dL, ≥10 ng/dL, and ≥15 ng/dL, respectively. The AOR of CKD was 1.05 (95% CI 0.80-1.36), 1.49 (95% CI 1.15-1.92), and 1.84 (95% CI 1.36-2.49) between patients with and without excess aldosterone at thresholds of ≥5 ng/dL, ≥10 ng/dL, and ≥15 ng/dL, respectively.

CONCLUSIONS: Aldosterone dysregulation (at thresholds of ≥15 ng/dL) was a known risk factor for HTN and CKD. This study shows that even lower levels (at thresholds of ≥10 ng/dL or ≥5 ng/dL) are a risk factor. Identification of patients with AD is important for the management of HTN and CKD.

SPONSORSHIP: AstraZeneca

15 Cost-effectiveness of bempedoic acid (BA) in high-cardiovascular (CV)-risk patients: Insights from the CLEAR Outcomes trial

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BACKGROUND: CLEAR Outcomes demonstrated bempedoic acid (BA) reduced low-density lipoprotein cholesterol (LDL-C) by 25.9 mg/dL and the risk of major adverse cardiovascular events (MACE-4) by 13% in high-cardiovascular-risk patients, unable or unwilling to take guideline-recommended statin doses. The cost-effectiveness of use of BA is unknown.

OBJECTIVE: To determine the cost-effectiveness of BA.

METHODS: CLEAR Outcomes randomized 13,970 patients with, or at high risk for, cardiovascular disease, with hypercholesterolemia and intolerant of statins to treatment with BA or placebo daily. A Markov model estimated cost-effectiveness of BA versus standard of care alone to reduce cardiovascular risk from a US third-party payer perspective. Baseline MACE risk was estimated by applying individual patient characteristics to the Reynolds Risk Score (primary prevention) and the SMART-2 risk equation (secondary prevention). Treatment benefit was extrapolated over a lifetime horizon using on-treatment hazard ratios (HR) for individual MACE components from CLEAR Outcomes. Model outcomes included costs, MACE, life-years (LY), quality-adjusted life-years (QALYs), and the incremental cost-effectiveness ratio (ICER). Scenario analyses included alternate costs of BA and modeling the effects of the fixed-dose combination with ezetimibe on LDL-C reduction and predicted MACE.

RESULTS: BA treatment (wholesale acquisition cost $396/month) was estimated to reduce total lifetime MACE (1.53 vs 1.95 per patient) compared to standard of care alone. Over a lifetime horizon, BA treatment was associated with increased costs (incremental $23,235) and improved LYs (incremental 0.23) and QALYs (incremental 0.34), resulting in a ICER of $68,252 per QALY gained. BA had a 76% likelihood of costing less than $100,000 per QALY and being more effective in reducing CV risk compared with standard of care when using the list price. Reduction in the cost of BA by 25% resulted in lower incremental total costs for BA and an ICER of $41,313 per QALY gained. Modeling the effects of the fixed-dose combination of BA and ezetimibe resulted in a more favorable ICER of $39,141 per QALY gained.

CONCLUSIONS: The use of BA to lower cardiovascular risk in patients with or at high risk for CVD meets commonly used cost-effectiveness thresholds.

SPONSORSHIP: Esperion Therapeutics, Inc.

16 Identifying Patient Characteristics Associated with Guideline-Directed Medical Therapy Uptake and Health Care Resource Use in Patients Newly Diagnosed with Heart Failure with Reduced Ejection Fraction in the United States

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BACKGROUND: Guideline-directed medical therapy (GDMT) provides proven benefits for patients with heart failure with reduced ejection fraction (HFrEF), but most eligible US patients receive suboptimal treatment. GDMT in HFrEF includes one drug from each of four drug classes: ACEi/ARBs/ARNi, beta-blockers, MRAs, and SGLT2 inhibitors ("quadruple therapy"). Identifying sociodemographic factors (SDF) linked to lower GDMT uptake and higher health

care resource utilization (HRU) may help inform GDMT implementation strategies.

OBJECTIVE: To describe GDMT use in newly diagnosed HFrEF patients in the US, and assess associations between SDF, GDMT improvement, and HRU.

METHODS: Newly diagnosed patients with HFrEF (Jan 2017 to Sep 2021) were identified in Optum's Clinformatics® Database. Baseline characteristics and GDMT were assessed 12 months pre-diagnosis. SDF included depression, substance abuse, cardiologist or internist care, education, housing, income, and household size. GDMT improvement was defined as initiating ≥2 additional GDMT classes within one month post-diagnosis or adding ≥1 class for patients already on ≥2 classes. Outcomes analyzed within 12 months post-diagnosis were all-cause and heart failure (HF)–related hospitalizations. Associations between SDF, GDMT improvement, and HRU were assessed using logistic and negative binomial models, adjusted for age, diagnosis year, and comorbidities.

RESULTS: Among 230,664 patients (mean age 73.8 years, 41.5% female, 69.6% White), 36.0% had no GDMT exposure pre-diagnosis, with 30.6% on mono, 22.9% on dual, 4.3% on triple, and 0.6% on quadruple therapy. One month post-diagnosis, these percentages shifted to 19.5%, 25.8%, 35.3%, 11.1%, and 2.7%, respectively, with only 12.5% improving GDMT use. Depression, substance abuse, lack of cardiologist/internist care, and living alone were associated with lower odds of GDMT improvement (odds ratios: 0.79, 0.83, 0.54, 0.89, respectively; all $p<0.05$). Substance abuse and living alone were also associated with increased risk for all-cause hospitalizations (incidence rate ratio [IRR]: 1.61, 1.35, respectively; all $p<0.05$) and HF-related hospitalizations (IRR: 1.27, 1.31, respectively; all $p<0.05$).

CONCLUSIONS: Utilization of GDMT for HFrEF remains suboptimal, with low rates of GDMT initiation early after HF diagnosis. SDF such as substance abuse and living alone are linked to lower GDMT uptake and higher hospitalizations. These data can inform targeted interventions to improve GDMT use and outcomes in high-risk patients with HFrEF.

SPONSORSHIP: Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

17 Cost-effectiveness of empagliflozin for heart failure patients across the spectrum of ejection fraction in the United States

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BACKGROUND: Heart failure (HF) is a chronic condition that significantly impacts patients' quality of life and poses substantial burden on the health care system. The EMPEROR-Reduced and EMPEROR-Preserved trials demonstrated the efficacy and safety of empagliflozin when added to standard of care (SoC) for HF patients across the spectrum of ejection fraction (EF). The cost-effectiveness of empagliflozin for HF patients across the spectrum of EF in the United States (US) has not yet been reported.

OBJECTIVE: Evaluate the cost-effectiveness of empagliflozin + SoC versus SoC alone for treating HF patients across the spectrum of EF in the US.

METHODS: This cost-effectiveness analysis combined the results from the two pre-existing Markov models, developed from the EMPEROR-Reduced and EMPEROR-Preserved trails, from the Commercial perspective over a lifetime horizon. Population weighting was performed for the aggregated health and cost model outcomes, i.e., life-years (LYs), quality-adjusted life-years (QALYs), and total health care costs based on the proportion of HF patients with reduced EF in the Get With The Guidelines-HF registry (Hamo et al., 2021). Costs were expressed in 2024 US dollars, inflated from prior years using the medical component of the US consumer price index. To execute a probabilistic sensitivity analysis (PSA), the probabilistic results from each model were sampled according to the proportion of each HF phenotype. Subgroup analyses were conducted for patients with/without type 2 diabetes mellitus (T2DM) and patients older/younger than 65 years at baseline, to examine how HF patients' baseline characteristics affect cost-effectiveness.

RESULTS: Empagliflozin + SoC compared to SoC alone added 0.13 LYs (6.52 vs 6.39) and 0.15 QALYs (4.71 vs 4.56) at an incremental cost of $20,781 ($115,673 vs $94,892) for HF patients across the spectrum of EF over a lifetime horizon. The incremental cost-effectiveness ratio (ICER) was $139,280/QALY. In PSA, ICER was $133,936/QALY, with a 60% likelihood of empagliflozin + SoC being cost-effective compared to SoC alone at a $150,000/QALY threshold. Subgroup analyses confirmed that empagliflozin + SoC remained cost-effective across all subgroups, in line with the main analysis. The

model predicted ICERs of $149,219/QALY and $127,017/QALY for patients with/without T2DM, and $138,760/QALY and $137,213/QALY for patients older/younger than 65 years.

CONCLUSIONS: Empagliflozin is a clinically efficacious and cost-effective treatment option for HF patients across the spectrum of EF in the US from the Commercial perspective.

SPONSORSHIP: Boehringer Ingelheim Pharmaceuticals, Inc

18 Medication Adherence and Adverse Drug Effects Across Patients with Obstructive Hypertrophic Cardiomyopathy Receiving Pharmacotherapy

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BACKGROUND: Traditional pharmacologic management of symptomatic obstructive hypertrophic cardiomyopathy (oHCM) includes beta blockers (BB), calcium channel blockers (CCB), or combination therapy with disopyramide. These agents may provide symptomatic relief due to left ventricular outflow tract obstruction, but use is generally limited by tolerability. While disease-modifying therapies for oHCM are emerging, rates of adverse drug effects (ADEs) and adherence for generic pharmacotherapy are not well described.

OBJECTIVE: To evaluate incidence of ADEs and medication adherence in oHCM patients using the Symphony real-world claims database.

METHODS: Retrospective study of adults diagnosed with oHCM in the US from 2016 to 2024. Eligible patients had ≥2 claims for oHCM (ICD-10 I42.1) >30 days apart (index date first oHCM claim), 1-year pre-index continuous enrollment, and treatment with a BB, CCB, and/or disopyramide after diagnosis. Patients with Fabry disease, amyloidosis, and any oHCM treatment 1 year prior to index were excluded. Medication adherence was assessed by proportion of days covered (PDC) and with a threshold of 0.80 considered adherent. Incidence rates (IR) of ADEs were evaluated per 100 person-years using generalized linear models with Poisson distribution. Adherence as measured by PDC (mean ± standard deviation; percent adherent) and ADEs (mean [95% confidence interval]) were reported at 2 years.

RESULTS: Among 20,539 patients with oHCM (mean age 60.3 ± 13.5 years; 53.1% female; 35.0% reside in South), the majority were receiving BB (66.8%) at index diagnosis, followed by CCB (20.7%), BB+CCB (10.1%), and disopyramide (1.1%). At 2 years, mean PDC was 0.55 ± 0.33, with 67% of patients having a PDC <0.80. Adherence was highest among patients receiving BB+CCB (0.58 ± 0.31), followed by BB (0.56 ± 0.33), CCB (0.49 ± 0.33), and disopyramide (0.33 ± 0.28). Following oHCM diagnosis, 2,449 (27.4%) patients developed an ADE after receiving a new pharmacotherapy. The most common ADEs include shortness of breath (IR: 15.5 [14.8-16.2]), tiredness (IR: 6.7 [6.3-7.1]), dizziness (IR: 6.4 [6.0-6.8]), fatigue (IR: 5.5 [5.2-5.9]), and nausea (IR: 5.0 [4.7-5.4]). Other ADEs reported in <5% of patients included bradycardia, depression, diarrhea, edema, headache, hypotension, rash, constipation, and syncope.

CONCLUSIONS: Most patients with symptomatic oHCM were nonadherent to standard pharmacotherapy, with more than 1 in 4 patients reporting ADEs. These findings highlight the urgent need for safe, effective, and less burdensome pharmacologic treatments for oHCM.

SPONSORSHIP: Cytokinetics, Inc.

19 Budget impact of etripamil for the treatment of paroxysmal supraventricular tachycardia (PSVT) in the United States

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BACKGROUND: Paroxysmal supraventricular tachycardia (PSVT) is a heart rhythm disorder characterized by episodes of regular tachyarrhythmia with abrupt onset, often requiring treatment in a hospital setting. Etripamil is a rapidly absorbed, non-dihydropyridine L-type calcium channel blocker currently under investigation for intranasal self-administration to terminate acute episodes of PSVT.

OBJECTIVE: To estimate the budget impact of including etripamil in a drug formulary during the first 3 years after market entry from a commercial US payer perspective.

METHODS: A model was developed in Microsoft Excel to assess differences in health care costs in a hypothetical 1-million-member commercial health plan over a 3-year period. The model considered a scenario with etripamil post-market entry versus the scenario without etripamil. The model considered drug acquisition costs and costs associated with inpatient, emergency department, outpatient hospital, and catheter ablation use. PSVT-eligible patients, visit rates, and visit costs were obtained from published literature and ICD-9/ICD-10 administrative claims databases. Reductions in health resource use were based upon the phase 3 NODE-301,RAPID, and NODE-303 trials as well as qualitative research with physicians. Market

uptake for etripamil was assumed at 10%, 25%, and 55% based upon physician qualitative research. All costs were reported undiscounted in 2024 USD. One-way sensitivity analyses were conducted for each hypothetical health plan with inputs varied by ±10%.

RESULTS: An estimated 1,900 adult patients in the health plan were eligible for etripamil treatment each year. Over 3 years, the etripamil scenario was associated with an estimated 73 fewer inpatient hospital admissions, 159 fewer emergency department visits, 85 fewer outpatient hospital visits, and 36 fewer catheter ablations. The total drug acquisition and administration costs were $592,800, $1,490,892, and $3,299,642 during years 1-3, respectively. The incremental per-member per-month budget impact in a commercial plan was $0.01 in Year 1 and $0.03 in Year 3. Results were sensitive to the number of yearly treated episodes, etripamil packs per episode, and etripamil pack costs, as well as rate and cost of inpatient admissions.

CONCLUSIONS: The introduction of etripamil is associated with minimal, balanced budget impact in a commercial health plan over 3 years, with drug acquisition costs offset by reductions in emergency department, inpatient, outpatient hospital, and catheter ablation use.

SPONSORSHIP: Milestone Pharmaceuticals Inc.

I10 Emergency department visits and inpatient admissions for atrial fibrillation in the United States (US): 2015-2019

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BACKGROUND: Atrial fibrillation (AF) is the most common form of cardiac arrhythmia. Symptoms include irregular heartbeat, palpitations, lightheadedness, fatigue, shortness of breath, and chest pain. Self-management options are limited, and patients may seek treatment for acute AF episodes in the emergency department (ED) and may also be hospitalized for AF management. ED visits for AF increased 30.7% from 2007 to 2014, although an increasing proportion of these visits did not require inpatient (IP) admission. AF is increasingly prevalent, but its impact on ED visits and IP admissions in more recent years is not known.

OBJECTIVE: Examine trends in ED visits and IP admissions for AF in the United States since 2014.

METHODS: This repeated cross-sectional analysis used ED visit and IP admission data from Healthcare Cost and Utilization Project (HCUP)'s Nationwide Emergency Department Sample (NEDS) and Nationwide Inpatient Sample (NIS) databases (2015-2019) to examine ED visits and IP admissions with a principal diagnosis of AF (International Classification of Diseases, Ninth Revision, Clinical Modification [ICD-9-CM]: 427.31; ICD-10-CM: I48.0x; I48.1x; I48.2x, I48.91) without secondary Atrial Flutter (ICD-9-CM: 427.32; ICD-10-CM: I48.3x, I48.4x, I48.92) for adults aged ≥18 years. Annual numbers of ED visits and IP admissions were calculated using AHRQ weighted estimates that reflect national estimates. ED visits that resulted in admission to the same hospital were also evaluated.

RESULTS: ED visits for AF in the US continued to increase from 2015 to 2019, rising 8.9%, from 550,334 (95% CI: 517,844-582824) in 2015 to 599,251 (95% CI: 564,958-633,543) in 2019. Rates of increase were similar for older (≥65 y) and younger (18-64 y) patients. Mean age ranged from 69.6 to 69.8 y, with 50.6% to 52.0% of visits for females. The proportion of ED visits that resulted in admission to the hospital decreased over the study period, from 52.7% in 2015 to 44.5% in 2019, although IP admissions for AF increased 2%, from 365,835 (95% CI: 352,064-379,606) in 2015 to 372,900 (95% CI: 358,330-387,470) in 2019. IP admission numbers declined 7.0% for patients aged 18-64 y but increased 5.7% for older patients aged ≥65 y.

CONCLUSIONS: Annual ED visits for AF have continued to increase since 2014, while ED visits that result in admission have continued to decline. IP admissions have grown more slowly, with declines among younger adults and increases among older adults. Interventions that reduce the need for an ED visit for AF may benefit patients and may be associated with cost reductions.

SPONSORSHIP: Milestone Pharmaceuticals Inc.

I11 Health Care Resource Utilization and Costs of Non-Obstructive Hypertrophic Cardiomyopathy in the United States

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BACKGROUND: Approximately one-third of patients with hypertrophic cardiomyopathy (HCM) are non-obstructive (nHCM). There are limited data evaluating health care resource utilization (HRU) and costs of care for patients with nHCM.

OBJECTIVE: To quantify annual disease-related HRU and costs pre and post HCM diagnosis using Optum medical and pharmacy claims and electronic medical record data.

METHODS: Retrospective cohort study of adults diagnosed with nHCM in the US from January 2013 to December 2021. Eligible patients had ≥2 claims for nHCM (ICD-9 and-10) at least 30 days apart (index date = first nHCM claim), and 6-months pre- and 12-months post-index continuous enrollment. Patients with evidence of Fabry disease, amyloidosis, pharmacological treatment for HCM, or septal reduction therapy were excluded. HCM-related HRU and costs ($2022 CPI adjusted) were reported at baseline and 1-year follow-up for medical (ambulatory: office [OV] visits, outpatient [OP] visits), emergency room (ER) visits, inpatient admissions (IP), and pharmacy. HRU were presented as n (%) of patients with ≥1 visit, and costs were reported as mean ± standard deviation (SD).

RESULTS: Among 9,842 patients with nHCM, 54% were male and mean age was 61 ± 16 years (74% non-Hispanic White; 42% reside in Midwest). The majority had Commercial insurance (50%), followed by Medicare (28%), Medicaid (8%), and Other insurance (14%). Proportion of patients with HCM-related HRU increased from baseline to 1-year follow-up for ambulatory (10% vs 84%), OV (8% vs 70%), OP (4% vs 39%), ER visits (2% vs 11%), IP admissions (3% vs 12%), and pharmacy (9% vs 10%). Total medical costs increased at 1-year follow-up ($3,666 ± $42,802 vs $12,715 ± $40,381; p<0.001), including ambulatory ($227 ± $3,078 vs $2,963 ± $12,627; p<0.001), OV ($27 ± $130 vs $441 ± $1,226; p<0.001), OP ($200 ± $3,055 vs $2,522 ± $12,472; p<0.001), and other medical costs ($189 ± $2,628 vs $1,873 ± $8,816; p<0.001). Costs of IP admissions ($3,232 ± $42,388 to $7,708 ± $36,127; p<0.01) and ER visits ($17 ± $250 vs $171 ± $911; p<0.001) also increased at follow-up. Differences in pharmacy costs ($6 ± $63 vs. $7 ± $61; p = 0.28) increased but were generally very low.

CONCLUSIONS: In a large, national cohort of nHCM patients, disease-related HRU and costs across all categories increased over a 1-year period, driven by medical costs and IP admissions. A diagnosis of nHCM carries a notable cost of care and future interventions to reduce this burden for patients with nHCM is warranted.

SPONSORSHIP: Cytokinetics, Inc.

J00-J99 Diseases of the Respiratory System

(eg, asthma, COPD, rhinitis)

J2 Real-world outcomes following dupilumab initiation among patients with chronic rhinosinusitis with nasal polyps

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BACKGROUND: Biologics are emerging treatments for uncontrolled chronic rhinosinusitis with nasal polyps (CRSwNP), with FDA-approved dupilumab being the most frequently used. Dupilumab is also approved for patients with moderate to severe (M-S) asthma. However, there is limited real-world outcome data on dupilumab among patients with CRSwNP, including for patients with and without comorbid M-S asthma.

OBJECTIVE: To evaluate the real-world utilization of oral corticosteroids (OCS), antibiotics, and nasal polyp (NP) surgeries in the 24 months after dupilumab initiation, and to examine the occurrence of dupilumab discontinuation in patients with CRSwNP with and without M-S asthma.

METHODS: This retrospective cohort study analyzed data from the US IQVIA longitudinal prescription and medical claims databases. Patients were included if they were adults who had received ≥2 separate diagnoses (≥30 days apart) of CRSwNP, had received ≥2 consecutive doses of dupilumab from July 2019 to June 2022, and had data for ≥12 months before dupilumab initiation (baseline) and for ≥24 months after dupilumab initiation (index date). Results for other approved biologics were not analyzed owing to insufficient sample sizes.

RESULTS: In total, 1,983 patients with CRSwNP received dupilumab, among whom 41% had M-S asthma at baseline. In the 24-month follow-up period, 68.1% of dupilumab recipients

with CRSwNP and M-S asthma had ≥1 all-cause OCS use (≥2 OCS uses: months 1-12, 29.8%; months 13-24, 26.5%), and 75.3% had ≥1 all-cause antibiotic use; 6.3% of patients without NP surgery before dupilumab initiation (n = 599) had ≥1 NP surgery during follow-up. Among dupilumab recipients with CRSwNP but no M-S asthma diagnosis, 60.8% of patients had ≥1 all-cause OCS use (≥2 OCS uses: months 1-12, 21.7%; months 13-24, 23.5%), and 77.7% had ≥1 antibiotic use; 6.6% of patients without NP surgery before dupilumab initiation (n = 1,173) had ≥1 NP surgery during follow-up. The percentage of patients with CRSwNP with and without M-S asthma who discontinued dupilumab in the 24 months after initiation was 42.6% and 50.0%, respectively.

CONCLUSIONS: OCS and antibiotic usage among patients with CRSwNP remained substantial in the 24 months after starting dupilumab, regardless of comorbid M-S asthma. These results indicate a need for additional treatment options for disease control.

SPONSORSHIP: AstraZeneca/Amgen.

J4 Impact of non–cystic fibrosis bronchiectasis on health care resource utilization and direct medical costs of select comorbid conditions

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BACKGROUND: The clinical and economic burden of non–cystic fibrosis bronchiectasis (NCFBE) on patients and health care systems has been characterized in previous studies. While it is known that patients with NCFBE often have comorbidities, the impact of NCFBE on health care resource utilization (HCRU) and direct medical costs associated with these comorbidities is unknown.

OBJECTIVE: To assess the complexity and incremental burden of managing certain comorbid diseases (chronic obstructive pulmonary disease [COPD], asthma, or rheumatoid arthritis [RA]) in patients with NCFBE.

METHODS: This retrospective cohort study, using administrative claims data from the Merative™ MarketScan® database, included adult patients (≥18 years) with a diagnosis of COPD, asthma, or RA between 1 Jan 2017 and 31 Dec 2021 (identification period); within these cohorts, patients with a diagnosis of NCFBE (claim with a diagnosis of bronchiectasis; patients with cystic fibrosis excluded) were compared with controls (COPD, asthma, or RA with no claim with bronchiectasis) using 1:1 propensity score matching (1:2 for RA due to cohort size) to balance patient characteristics. Index was a randomly selected date within the identification period after diagnosis criteria were met for each study group. Patients had continuous enrollment ≥12 months prior to and after index and were followed until loss of follow-up or study end date (31 Dec 2022). Proportions and per-person per-year (PPPY) comorbid disease-specific inpatient, outpatient, emergency room (ER) visits, and direct medical costs were reported.

RESULTS: Following propensity score matching, 4,291 patients with COPD, 2,460 with asthma, and 566 with RA, all of whom had NCFBE, and the corresponding controls were included. In patients with COPD, proportions with COPD-related inpatient (4.5% vs 3.1%), outpatient (66.5% vs 56.8%), and ER visits (7.5% vs 5.8%), and direct medical costs ($1,384 vs $1,107), were significantly higher within the matched NCFBE cohort than controls. In patients with asthma, asthma-related outpatient visits (52.0% vs 41.1%) and direct medical costs ($489 vs $221) were significantly higher within the matched NCFBE cohort. In patients with RA, RA-specific PPPY outpatient (5.1 vs 3.9) and specialist visits (3.5 vs 2.5), and outpatient costs ($6,787 vs $3,821), were significantly higher within the matched NCFBE cohort ($P < 0.05$ vs controls for all comparisons).

CONCLUSIONS: NCFBE increases the complexity of managing patients with comorbid disease and is associated with higher comorbid disease–related HCRU and costs.

SPONSORSHIP: Insmed Incorporated

J5 Identification of Payer Knowledge Gaps and Collaborative Opportunities for Improved Outcomes in Moderate to Severe Asthma

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BACKGROUND: Moderate to severe asthma presents significant clinical and economic challenges, often due to complex treatment regimens. Effective management requires collaboration between managed care professionals and clinicians, yet differing priorities and knowledge gaps can hinder progress. This program explores challenges and opportunities for improving treatment access through stakeholder collaboration.

OBJECTIVE: To describe challenges and opportunities to improve access to appropriate and timely treatment of moderate to severe asthma through managed care and clinician collaborations.

METHODS: A series of virtual roundtables were conducted with managed care professionals, clinicians, and patient advocates recruited from a proprietary database in June 2024. Participants provided quantitative data via polling

and discussed opportunities to improve care for patients with moderate to severe asthma. Polling responses and roundtable transcripts were analyzed to identify priorities, knowledge gaps, and collaborative opportunities.

RESULTS: Insights from 18 participants were evaluated following the roundtables. The managed care professionals (n = 8) represented health plans, PBMs, IDNs, and employer groups. The clinicians (n = 8) had over 162 years of combined experience in their respective specialties, and the patient representatives (n = 2) had more than 40 years of experience in the asthma community. Clinicians identified the high cost of medications as the most significant challenge in managing patients with moderate to severe asthma. Managed care professionals had mixed perspectives, while the patient representatives unanimously ranked access to specialty care as the most significant challenge. There was low agreement among the three groups around what payers could do to improve the quality of care for moderate to severe asthma. The participants also had differing perspectives on the effectiveness of expanding coverage for asthma treatments. Additionally, eight payer knowledge gaps were identified, such as understanding the benefits of biologics for disease control and reducing the need for corticosteroids, and four collaborative opportunities between clinicians and managed care professionals were recommended.

CONCLUSIONS: Several opportunities exist to address knowledge gaps and barriers that prevent patients with moderate to severe asthma from effective treatment. Addressing the identified gaps in payer knowledge and exploring collaborative efforts may help support improvement in the quality of care for patients with moderate to severe asthma.

SPONSORSHIP: Regeneron Pharmaceuticals, Inc., and Sanofi

J6 Frequency, duration, and cost of suspected exacerbations among patients with non–cystic fibrosis bronchiectasis

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BACKGROUND: Studies of non–cystic fibrosis bronchiectasis (NCFBE) from claims databases use a fixed period to denote the start and end of an exacerbation, which limits assessment of exacerbation duration and characteristics.

OBJECTIVE: To apply a novel cost-based algorithm to characterize frequency, duration, health care resource use, and cost of suspected exacerbations in patients with NCFBE.

METHODS: This retrospective cohort study used Merative® MarketScan® Commercial Claims and Encounters database 01 Jan 2016 to 31 Dec 2022. Patients ≥18 years were identified as having NCFBE if they had ≥2 outpatient claims or ≥1 inpatient claim with bronchiectasis and no claims for cystic fibrosis. Patients had ≥12 months continuous enrollment before (baseline) and ≥12 months after (follow-up) index (first bronchiectasis claim). The threshold for a suspected exacerbation was based on a composite score of a) weeks with high-cost increase from baseline and b) high absolute weekly cost during follow-up. Exacerbation duration was defined as the period with statistically significantly higher weekly cost difference in follow-up than mean baseline weekly cost. Sensitivity analyses assessed if suspected exacerbations were associated with traditional claims-based exacerbation definitions.

RESULTS: Of 9,005 patients, 6,033 patients (3,239 commercial; 2,794 Medicare) had 49,750 suspected exacerbations (32,330 commercial; 17,420 Medicare) during mean (SD) 2.7 (1.3) years of follow-up. Mean (SD) exacerbation duration of was 3.4 (8.6) weeks (3.3 [8.2] commercial; 3.7 [9.3] Medicare). During follow-up 83% patients had ≥3 suspected exacerbations (89% commercial; 75% Medicare) and 67% patients needed hospitalizations/IV antibiotic treatment (58% commercial; 78% Medicare). Mean respiratory costs were higher for the first suspected exacerbation episode ($3,332 commercial; $3,069 Medicare; mean [SD] duration 3.6 [10.0] weeks) than the second ($1,500 commercial; $1,393 Medicare; duration 3.8 [10.4] weeks). Annual respiratory costs were higher for patients with vs without suspected exacerbations ($14,116 vs $3,390). In sensitivity analysis, 95.7% patients and 51.0% suspected exacerbations met the traditional claims-based exacerbation definition.

CONCLUSIONS: This novel cost-based approach identified suspected exacerbations that frequently lasted >3 weeks, with commercial and Medicare beneficiaries having similar patterns and duration. Patients with suspected exacerbations had higher respiratory costs than those without, with the first suspected exacerbation being the most expensive.

SPONSORSHIP: Insmed Incorporated

J7 Health care resource utilization in patients with non–cystic fibrosis bronchiectasis treated with brensocatib vs placebo: An analysis of the ASPEN trial

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BACKGROUND: Non–cystic fibrosis bronchiectasis (NCFBE) is a chronic, progressive inflammatory respiratory disease. Neutrophilic inflammation plays a key role in the pathophysiology of NCFBE. Neutrophil serine proteases (NSPs) are associated with disease progression and poorer clinical outcomes. The phase 3, randomized, double-blind ASPEN study (NCT04594369) evaluated the impact of brensocatib, an oral, selective, competitive, reversible inhibitor of dipeptidyl peptidase 1 that prevents activation of NSPs, on adjudicated pulmonary exacerbations (PEx) over 52 weeks vs placebo.

OBJECTIVE: To review key primary and secondary endpoint data and contextualize the clinical benefit of brensocatib by assessing its impact on hospitalization.

METHODS: ASPEN enrolled patients with NCFBE and history of PEx in the 12 months prior to screening (adults [18-85 years], ≥2; adolescents [12 to <18 years], ≥1). Patients were randomized to once-daily brensocatib (10 or 25 mg) or matched placebo for 52 weeks (adults, 1:1:1; adolescents, 2:2:1). Endpoints were annualized PEx rate, time to first PEx, rate of severe PEx, change in post-bronchodilator forced expiratory volume in 1 second (FEV1) and forced vital capacity (FVC), and change in Quality of Life-BE (QOL-B) Respiratory Symptoms Domain score.

RESULTS: In total, 583, 575, and 563 patients received brensocatib 10 mg, 25 mg, and placebo, respectively. The annualized rate of adjudicated PEx over 52 weeks vs placebo was significantly reduced by brensocatib 10 mg (RR 0.79 [95% CI, 0.68-0.92, P = 0.0019]) and 25 mg (0.81 [0.69-0.94; P = 0.0046]). Time to first PEx was significantly prolonged (HR 0.81 [95% CI, 0.70-0.95; P = 0.0100]; 0.83 [0.70-0.97; P = 0.0182]) and odds of remaining PEx-free were significantly increased (OR 1.41 [95% CI, 1.11-1.81; P = 0.0059]; 1.40 [1.10-1.79; P = 0.0074]) with brensocatib 10 and 25 mg vs placebo. The 25-mg dose significantly reduced FEV1 decline vs placebo (difference: 38 mL, P = 0.0054). Other secondary endpoints were not significant. Rates of adverse events were similar with brensocatib 10 mg (78%), 25 mg (77%), and placebo (80%). Fewer patients with brensocatib 10 and 25 mg had ≥1 NCFBE-related hospitalization vs placebo (38 [6.5%], 42 [7.3%], 55 [9.8%], respectively) and the number of NCFBE-related hospitalizations was lower in brensocatib arms (57, 57, and 88, respectively).

CONCLUSIONS: Brensocatib-treated patients had significant reductions in annualized rate of PEx vs placebo. Brensocatib was associated with fewer NCFBE-related hospitalizations vs placebo, providing added evidence of clinical and economic impacts for patients living with NCFBE.

SPONSORSHIP: Insmed Incorporated

J11 Real-World Health Care Resource Utilization and Costs Associated with Acute Exacerbations Among Patients with Fibrosing Interstitial Lung Disease in the United States

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BACKGROUND: Acute exacerbations (AEx) in fibrosing interstitial lung disease (ILD) are characterized by worsening dyspnea, cough, and hypoxia. The diagnosis relies on a combination of radiological and clinical findings. AEx carry significant morbidity and mortality risks. Currently, there is limited understanding of the economic burden associated with AEx among the fibrosing ILD population in the United States.

OBJECTIVE: This study aims to evaluate the health care resource utilization (HCRU) and costs associated with AEx among patients with fibrosing ILD in the real-world setting.

METHODS: This non-interventional retrospective cohort study was conducted using the Optum® Market Clarity database from 01 January 2016 through 30 September 2022. Adult patients with ≥2 fibrosing ILD diagnoses on different dates within 365 days were included. A claims-based AEx algorithm was used to identify and classify patients into two cohorts: patients who have experienced AEx (AEx cohort) and those who have not yet experienced AEx (no-AEx cohort) following the ILD diagnosis. The index date for the AEx cohort was the first AEx episode date. For the no-AEx cohort, it was assigned by sampling from the distribution of the times between the fibrosing ILD diagnosis date and the index date in the AEx cohort. The cohorts were propensity score matched 1:1 based on covariates measured 12 months prior to the index date. Patients were followed until the earlier of health plan

disenrollment, death, or end of study period (follow-up period). HCRU and costs were measured during the follow-up period and reported as per patient per month (PPPM).

RESULTS: A total of 8,104 AEx patients were successfully matched to no-AEx patients. The AEx cohort incurred significantly higher total all-cause health care costs compared to the no-AEx cohort, median (interquartile range [IQR]) total costs ($7,935 [$3,223-$18,798] vs. $4,674 [$1,659-$12,149] PPPM, p<0.05). These costs were primarily driven by medical costs, particularly costs related to inpatient visits. A higher proportion of the AEx cohort had at least one inpatient visit (92.4% vs. 77.3%), with significantly higher median [IQR] all-cause inpatient visits (0.34 [0.13-0.77] vs. 0.16 [0.03-0.45], p<0.05) PPPM. Similar trends were observed in fibrosing ILD–related HCRU and costs.

CONCLUSIONS: Our study demonstrates that patients with fibrosing ILD who experience AEx have higher incremental HCRU and costs compared to those without AEx. These findings suggest that reducing the rate of AEx could alleviate the economic burden among patients with fibrosing ILD.

SPONSORSHIP: The study was funded by Boehringer Ingelheim.

K00-K93 Diseases of the Digestive System

(eg, Crohn disease, ulcerative colitis)

K1 Survey of Health Plan Coverage of Guideline- and Expert-Recommended Treatments in Eosinophilic Esophagitis (EoE)

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BACKGROUND: Guideline- and expert-recommended treatment of EoE includes diet elimination therapy, proton pump inhibitors (PPIs), swallowed corticosteroids, elemental formula, and, recently, FDA-approved biologic therapy. Historically, most treatments were prescribed off-label or were available over the counter, leading to potential gaps in medication use history/claims data and therefore potential challenges in meeting coverage criteria for newer therapies.

OBJECTIVE: Gain regional insights from managed care professionals related to the implementation of guideline and expert recommendations on EoE.

METHODS: A survey containing multiple-choice, open-ended, and Likert scale rating questions was fielded by Impact Education, LLC, between January and May 2024 from a network of managed care professionals from the AMCP Affiliates in California, Northwest (West), and Mid-Atlantic. All survey respondents were required to attest to having influence over formulary and/or other clinical management decisions within their organization.

RESULTS: Across respondents from the West (n = 33) and the Mid-Atlantic (n = 48) regions, it was reported that their organizations represent over 145 million covered lives. Most respondents were pharmacists (West 88%, Mid-Atlantic 84%). The survey reported coverage for PPIs for EoE was slightly higher in the Mid-Atlantic (65%) compared to the West (64%). For swallowed corticosteroids, coverage was more commonly reported in the Mid-Atlantic (51%) than in the West (45%). And coverage for elemental formulas was low in both the West (33%) and Mid-Atlantic (31%). The reported coverage for the FDA-approved biologic, dupilumab, was slightly higher in the West (55%) compared to the Mid-Atlantic (53%). A significant proportion of payers reported prior authorization (PA) criteria for dupilumab requiring a trial and failure of either a PPI or swallowed corticosteroids for coverage (West 73%, Mid-Atlantic 79%).

CONCLUSIONS: Across both regional surveys, coverage for guideline- and expert-recommended treatments for EoE was consistent but limited. Coverage for biologics often requires a prior trial and failure of either a PPI or swallowed corticosteroid. The findings highlight the need to consider guideline and expert recommendations and existing coverage status of first-line therapies during coverage policy development for new treatments.

SPONSORSHIP: Regeneron Pharmaceuticals, Inc., and Sanofi

K2 The burden of illness of gastroesophageal adenocarcinoma

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BACKGROUND: Adenocarcinomas of the stomach, esophagus, and gastroesophageal (GE) junction are collectively termed gastroesophageal adenocarcinoma (GEA). Combined data on GEA burden is limited.

OBJECTIVE: This study aimed to synthesize the epidemiology, clinical and humanistic burden, and unmet need

in the treatment and care of patients with HER2-positive advanced/metastatic GEA.

METHODS: A targeted literature review was conducted using Embase, MEDLINE®, the Cochrane Library, and web searches to identify studies assessing the burden of GEA.

RESULTS: In the US, an estimated 47,000 new cases of GE cancer are expected in 2024, accounting for around 2.4% of cancer diagnoses; approximately 88% of these are GEA. GE cancer incidence and mortality rates are 2-4 times higher in males than females, and evidence suggests gastric cancer incidence is increasing in people <60 years old. Up to 71% of GE cancers are diagnosed at regional or distant metastatic stages. Once the disease is locally advanced/unresectable, it is mostly incurable. Approximately 25% of patients with GEA have HER2-positive tumors; however, there is still a gap in testing for HER2 status, as 20% of GEA patients go untested for HER2 before treatment. The National Comprehensive Cancer Network® recommends trastuzumab + fluoropyrimidine and a platinum agent with/without pembrolizumab as first-line (1L) treatment for metastatic HER2-positive GEA. However, real-world studies suggest that HER2-targeted therapies are underused as only 80% of confirmed HER2-positive patients receive them. Advanced/metastatic GEA patients experience substantially reduced health-related quality of life (HRQoL), with a cross-sectional study reporting their Functional Assessment of Cancer Therapy - General scores as 57.5 compared with 80.1 in US age-matched healthy controls. Symptoms at GEA diagnosis include weight loss, gastrointestinal (GI) bleeding, dysphagia, anemia, and fatigue. Fatigue, dysphagia, and pain have the biggest impact on HRQoL and are experienced by up to 84% of GEA patients. Other GI symptoms such as diarrhea occur in approximately 54% of patients and can be associated with cytotoxic and targeted therapies. Current 1L treatment may not improve global HRQoL; while some symptom scales improve, diarrhea scores significantly worsen.

CONCLUSIONS: GEA is often diagnosed at advanced stages with high humanistic burden. There is high unmet need with current 1L treatments, which do not provide long-term HRQoL improvement. Increasing HER2 testing coverage and improving access to more efficacious 1L targeted agents could improve patient HRQoL.

SPONSORSHIP: Jazz Pharmaceuticals

K3 Impact of advanced therapy utilization management criteria on health care resource utilization and cost among patients with ulcerative colitis in the United States

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BACKGROUND: Health plans and pharmacy benefit managers (PBMs) implement formulary restrictions including drug exclusions, prior authorization (PA), and step therapy (ST) requirements to ensure appropriate medication utilization and control costs. In patients with ulcerative colitis (UC), these payer practices may lead to coverage denials and rejected payments for advanced therapy medications, thus contributing to delays in necessary treatment, poor patient outcomes, and higher health care resource utilization (HCRU) and outpatient medical costs.

OBJECTIVE: To describe formulary restrictions for UC advanced therapies and compare HCRU and costs between patients with paid and rejected claims for an advanced therapy.

METHODS: Adult UC patients with a paid (i.e., filled) or rejected claim due to a formulary restriction (PA, ST, or non-coverage status) for an advanced therapy between October 2019 and July 2022 were identified from IQVIA's Formulary Impact Analyzer. Two cohorts were defined based on payment of the first advanced therapy claim (index date). Eligible patients had commercial, health exchange, or Medicare insurance and linkage to IQVIA Professional Fee Claims with their health plan/PBM present in MMIT Formulary Data. HCRU, cost, and corticosteroid use in the 12 months including and following the index date (the post-index) were compared between cohorts using chi-square tests for proportions and t-tests for means.

RESULTS: In total, 726 patients made up the paid cohort (mean age: 51.4 years; 53% female; 64% commercial payer) and 3,879 patients made up the rejected cohort (mean age: 48.6 years; 51% female; 75% commercial payer). Most had health plans/PBMs with a PA policy (paid: 81%; rejected: 71%) and/or ST requirements for the index therapy (71%; 63%). Rejection reasons were non-coverage (34%), PA (65%), and ST (1%). Post-index mean outpatient medical costs, both all-cause ($2,876 vs $5,524; $p<0.01$) and UC-related ($1,859 vs $4,265; $p<0.01$), were lower for patients in the paid cohort. All-cause and UC-related inpatient stays and ER visits were comparable between cohorts (all $p>0.05$). The mean number of UC-related outpatient physician visits was greater in the rejected cohort (3.1 vs 3.5; $p=0.01$); mean number of

UC prescriptions was greater in the paid cohort (7.2 vs 4.0; p < 0.01). Fewer patients in the paid cohort had post-index corticosteroid use (59% vs 63%; p = 0.02).

CONCLUSIONS: Higher outpatient medical costs, number of outpatient physician visits, and corticosteroid use were observed among patients with rejected claims for advanced therapies.

SPONSORSHIP: This study was funded by Eli Lilly and Company

K6 The Budget Impact of the Value Regorafenib Delivers in the Treatment Landscape for Third- or Later-Line mCRC in the US

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BACKGROUND: Since regorafenib's approval in 2012 for third- or later-line (3L+) treatment of metastatic colorectal cancer (mCRC), newer therapies such as fruquintinib monotherapy and trifluridine/tipiracil plus bevacizumab have emerged.

OBJECTIVE: This analysis evaluates the budget impact of retaining regorafenib in the current mCRC treatment landscape.

METHODS: A budget-impact model was developed to compare costs with and without regorafenib in the market from a U.S. commercial payer perspective over 1 year. Regorafenib was analyzed using a mix of two dosing strategies: 25% of standard dose based on CORRECT trial (Grothey A, et al. 2013) and 75% of dose escalation based on ReDOS trial (Bekaii-Saab TS, et al. 2019). Comparators included fruquintinib monotherapy, trifluridine/tipiracil monotherapy or plus bevacizumab, and other standard treatments to reflect the current landscape. Eligible patient numbers were estimated through epidemiology calculations based on mCRC incidence and prevalence. Cost inputs included drug acquisition, administration costs, and adverse event (AE) management costs, sourced from pivotal trials, literature, and publicly available cost databases. Market share assumptions were based on real-world research. The budget impact was analyzed as cost per member per month (PMPM), with one-way sensitivity analyses to identify key cost drivers and evaluate alternative scenarios including health care resource use (HRU) costs.

RESULTS: For a hypothetical health plan with 1 million members, 26 patients were estimated to be eligible for treatment over 1 year. Retaining regorafenib in the 3L+ mCRC treatment landscape resulted in a 7% budget decrease of $215,152 over 1 year. The PMPM cost with regorafenib was $0.23 compared to $0.25 without it, resulting in cost savings PMPM of -$0.02. Drug acquisition costs were the largest expense, followed by treatment administration and AE management. Including HRU in the analysis did not significantly affect the budget impact.

CONCLUSIONS: The analysis suggests that retaining regorafenib in the 3L+ mCRC treatment landscape would be slightly budget saving for a U.S. commercial health plan.

SPONSORSHIP: Research funded by Bayer.

K7 MASH clinical and health care burden in England 2011 to 2020: an estimation using routinely collected health care data

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BACKGROUND: Approximately one quarter of individuals with metabolic dysfunction–associated steatotic liver disease will progress to metabolic dysfunction–associated steatohepatitis (MASH). MASH increases the risk of end-stage liver disease (ESLD), cardiovascular complications, and death.

OBJECTIVE: To characterize patients with MASH in England and estimate associated health care resource use (HCRU) and costs, with stratification by progression to ESLD.

METHODS: Using a retrospective cohort study design, adults diagnosed with MASH between 2011 and 2020 were included from the Clinical Practice Research Datalink Aurum dataset linked to the Hospital Episode Statistics and death registrations. Rates of progression to ESLD during follow-up were estimated. Annualized all-cause HCRU activity and costs in primary and secondary care were calculated. Generalized linear models (GLM) were used to estimate the incremental cost for those who progressed to ESLD, specifically compensated cirrhosis (CC), and decompensated cirrhosis (DCC), adjusted for Charlson Comorbidity Index score and follow-up time.

RESULTS: 2,696 patients with MASH were included, with a mean (SD) age of 56 (15) years, and patients had a mean available follow-up of 4 years. At baseline, 61.8% (n = 1,667) were overweight/obese, 40.9% (n = 1,104) had type 2 diabetes (T2D), and 19.2% (n = 517) had cardiovascular disease. During observed follow-up, 13.2% (n = 356) patients progressed to

ESLD, the majority to CC (n = 234) or DCC (n = 174). Among all patients with MASH, the mean number of primary care consultations was 16.8 per patient per year (PPPY); inpatient admissions was 1.3 PPPY; outpatient appointments was 5.8 PPPY; and emergency care attendances was 0.5 PPPY. There were more inpatient admissions (1.8 vs 1.0 PPPY) and outpatient appointments (7.3 vs 4.8 PPPY) in patients who also had T2D than among those without T2D. Similarly, patients who progressed to CC or DCC had more inpatient admissions (2.4 vs 1.1 PPPY, respectively) and outpatient appointments (9.9 vs 5.2 PPPY) than those who did not progress. The incremental mean primary and secondary care costs for progression to CC was £7,500 (95% CI: £4,075–£10,924) and for DCC was £18,376 (95% CI: £12,874–£25,706), compared with £9,977 in non-progressed.

CONCLUSIONS: Analysis shows that HCRU and costs among patients with MASH are high, particularly for those with cardiometabolic comorbidities, such as T2D, or who progress to ESLD. Efforts to detect MASH early and slow its progression could reduce health care burden.

SPONSORSHIP: Madrigal Pharmaceuticals, Inc.

K8 Determining clinically meaningful thresholds for patient-reported outcomes of pruritus in primary biliary cholangitis

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BACKGROUND: Patients with primary biliary cholangitis (PBC) experience pruritus, which can negatively impact health-related quality of life. Elafibranor, an approved peroxisome proliferator-activated receptor (PPAR) agonist exerting effects on PPARα and PPARδ, demonstrated significant efficacy in patients with PBC in the phase III ELATIVE® trial.

OBJECTIVE: This analysis estimated and applied clinically meaningful thresholds (CMTs) for changes in patient-reported outcome (PRO) measures of pruritus.

METHODS: In ELATIVE® (NCT04526665), patients were randomized 2:1 to elafibranor or placebo. Pruritus was assessed using the PBC Worst Itch Numeric Rating Scale (WI-NRS), the PBC-40 Itch domain, and the 5-D Itch questionnaire, with score ranges of 0-10, 0-15, and 5-25, respectively; higher scores indicate more severe/impactful pruritus. Distribution (using statistical properties of the data) and anchor (using external measures for reference) based approaches determined within-patient and between-group (elafibranor vs placebo) CMTs for these PRO scales using data from baseline (BL) to Week (Wk) 52 in patients with moderate to severe pruritus (WI-NRS ≥4) at BL. Patient Global Impression of Severity scores were used as the primary anchor, with evidence triangulated to identify single CMT values and ranges. Relevant CMTs were applied in responder analyses at Wks 52, 104, and 130.

RESULTS: Of 161 patients, 66 (41.0%) had WI-NRS ≥4 at BL (elafibranor: 44; placebo: 22). In these patients, the within-patient CMTs for WI-NRS, PBC-40 Itch domain, and 5-D Itch were –1.8, –2.0, and –4.5 points, respectively. The between-group CMTs were –1.7, –1.7, and –3.6 points, respectively. In patients with WI-NRS ≥4 receiving elafibranor, the least squares (LS) mean changes from BL to Wk 52 in WI-NRS and PBC-40 Itch domain were –1.9 and –2.5, exceeding the within-patient CMTs. The LS mean change from BL in 5-D Itch was –4.2, slightly lower than, but close to, this measure's CMT. Proportions of patients reaching within-patient CMTs were consistently greater when receiving elafibranor vs placebo: WI-NRS (–2 points): 43.2% vs 36.4%; PBC-40 Itch domain (–2 points): 57.1% vs. 25.0%; 5-D Itch (–5 points): 45.2% vs 25.0%. Trends were sustained or further improved to Wk 130.

CONCLUSIONS: Treatment with elafibranor led to clinically meaningful changes in pruritus PRO scores in patients with moderate to severe pruritus in ELATIVE®, as measured by WI-NRS and PBC-40 Itch domain. Almost double the number of patients receiving elafibranor vs placebo achieved the 5-D Itch CMT.

SPONSORSHIP: Ipsen and GENFIT.

K9 Episodic and Long-Term Costs of Acute Pancreatitis Requiring Hospitalization Among Adults in US Clinical Practice

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BACKGROUND: Acute pancreatitis (AP) is associated with significant morbidity, mortality, and economic costs. While most patients fully recover following the acute phase of illness, some develop long-term complications that require additional medical care.

OBJECTIVE: The objective of this real-world study was to estimate short- and long-term costs of AP requiring hospitalization among adults in US clinical practice, on an overall basis and within subgroups defined by cause of AP.

METHODS: A retrospective cohort design and data spanning January 2013 through December 2019 from the Merative MarketScan Research Databases (Commercial Claims and Encounters, Medicare Supplemental and Coordination of Benefits, and Labs) were employed. The study population comprised adults hospitalized for AP (first admission = index admission) and was considered overall, as well as by AP cause (alcohol-induced [AI], biliary-induced [BI], drug-induced [DI], cause unknown [CU], multiple causes [MC]). Study measures included AP-related health care utilization/expenditures (2019 USD) during the short-term episode (index admission + encounters separated by <30 days) and long-term follow-up period (1 year from end of episode). AP-related encounters were identified based on claims with a diagnosis code for AP or an AP-related complication (e.g., organ failure, sepsis). Study measures were summarized using means, percentages, and 95% confidence intervals (CI); long-term measures were adjusted for differential follow-up.

RESULTS: Study population totaled 5,051 patients hospitalized for AP (AI = 21%, BI = 36%, DI = 5%, CU = 35%, MC = 4%); mean age ranged from 50 years (AI) to 55 years (BI), 2% (CU) to 7% (MC) had a history of AP, and mean baseline triglyceride level ranged from 169 mg/dL (BI) to 291 mg/dL (CU). AP with necrosis ranged from 6% (MC) to 8% (BI), 19% (BI) to 26% (MC) had organ failure, 6% (DI) to 16% (MC) had sepsis, and 9% (DI) to 19% (MC) had systemic inflammatory response syndrome. During long-term follow-up, 5% (BI) to 15% (AI) of patients had a recurrent AP event, and 10% (BI) to 25% (MC) developed chronic pancreatitis. Mean AP-related expenditures ranged from $22,963 (DI) to $37,733 (MC) during the short-term episode, and from $9,614 (DI) to $20,657 (MC) during the long-term follow-up period; total AP-related expenditures thus ranged from $32,577 (DI) to $58,390 (MC).

CONCLUSIONS: The cost of AP requiring hospitalization is high, for the treatment of both acute disease and associated long-term complications, which underscores the potential economic benefits from the prevention of this condition.

SPONSORSHIP: Ionis Pharmaceuticals

L00-L99 Diseases of the Skin and Subcutaneous Tissue

(eg, eczema, psoriasis)

L1 Real-world clinical experience with ruxolitinib cream vs systemic therapies in patients with moderate atopic dermatitis in the United States

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BACKGROUND: Ruxolitinib (Janus kinase [JAK] 1 and JAK2 inhibitor) cream demonstrated clinical benefit as a monotherapy and was well tolerated in clinical trials of patients with mild to moderate atopic dermatitis (AD). Similar findings have been reported in subanalyses of patients with moderate and/or more extensive disease.

OBJECTIVE: To examine real-world treatment outcomes among patients with moderate AD following the use of ruxolitinib cream or systemic therapies.

METHODS: Physician-reported data from the Adelphi AD Disease-Specific Programme (wave III; August 2022 to March 2023) were used to describe treatment outcomes in adults with moderate AD. Patients were identified using physician-reported disease severity at the initiation of current treatments, which included 4 mutually exclusive cohorts of patients who were treated with ruxolitinib cream, systemic immunosuppressants, oral JAK inhibitors (JAKi), or biologics.

RESULTS: A total of 619 adults with moderate AD were included in this analysis (ruxolitinib cream, n = 122; systemic immunosuppressants, n = 80; oral JAKi, n = 264; biologics, n = 153). The mean age was 39.1 years, 50% of patients were female, 79% were White, and the mean AD duration was 4.1 years. The mean treatment duration was 7.4 months with ruxolitinib cream, 27.0 months with systemic immunosuppressants, 12.2 months with oral JAKi, and 14.0 months with biologics. The mean affected body surface area (BSA) while on treatment was reduced from 16.5% to 8.5% with ruxolitinib cream, 25.6% to 16.8% with systemic immunosuppressants, 20.9% to 8.1% with oral JAKi, and 20.4% to 9.2% with biologics. Nearly half of patients treated with ruxolitinib cream (48.4%) experienced a reduction in physician-reported disease severity vs 6.3% of those treated with systemic immunosuppressants, 51.5% with oral JAKi, and 46.4% with biologics. BSA reductions and disease severity improvements were generally similar among cohorts when the sample was further limited to patients with a baseline BSA of ≤20%.

CONCLUSIONS: Physician-reported clinical outcomes show that ruxolitinib cream provided substantial reductions in both the extent and severity of moderate AD. These data also suggest that patients with moderate AD may experience similar clinical benefits from ruxolitinib cream monotherapy as compared with oral JAKi and biologics.

SPONSORSHIP: Incyte Corporation

L2 Synergistic adherence improvement seen with multi-modal clinical support offerings

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BACKGROUND: Clinical support via diverse communication modes (i.e., telephonic, digital) can optimize engagement. We sought to understand the incremental impact on adherence through providing multi-modal engagement opportunities for clinical support in a pilot program.

OBJECTIVE: To understand the impact of moderate or maximal clinical engagement in both telehealth education/coaching and/or smart sharps device with companion digital app on patient adherence.

METHODS: An integrated clinical pharmacy and PBM claims dataset was used to monitor outcomes from our study population. Patients aged 18-89 years, with continuous eligibility, initiating dupilumab between 7/1/23 and 12/31/2023 were included. At first fill, patients were offered enrollment in both live telehealth education at scheduled intervals and an FDA-approved digital adherence app and "smart sharps" system with clinical support calls triggered by device alerts. Engagement in one or both adherence support modes was measured over the first 6 months of treatment. Primary outcome was 6-month proportion of days covered (PDC) compared across unengaged, moderately engaged (participated in either telephonic or digital offering), and maximally engaged (participated in both available offerings) cohorts. Bivariate comparisons were made with Student's t-test, ANOVA, and chi-square tests. Multi variable linear regression was used to measure impact of the program on PDC controlling for age and gender of patients.

RESULTS: In the lead-in period, 14,552 patients started therapy. The unengaged cohort (n = 9,402, 45.6% male, 41.94 mean age) averaged 74.3% PDC*, moderately engaged cohort (n = 3,889, 42.8% male, 43.67 mean age) averaged 79.6% PDC*, and maximally engaged cohort (n = 1,261, 39.0% male, 42.48 mean age) had 83.1% PDC* (*p < 0.0001). Controlling for age and gender, moderately and maximally engaged patients had increased PDC of 5.2% and 8.8%, respectively.

CONCLUSIONS: In a sample of new dupilumab patients with varying degrees of clinical engagement (unengaged, moderately engaged, maximally engaged), those maximally engaged in both solutions achieved 8.8% higher* PDC vs unengaged patients, and those moderately engaged in one clinical support solution via their preferred mode performed 5.2% higher* vs unengaged patients, controlling for age and gender differences between groups (*p < 0.0001). Our results demonstrate that providing complementary clinical adherence support offerings and engaging patients in multi-modal (telephonic and digital) solutions promotes more robust adherence maintenance in new-to-therapy patients.

SPONSORSHIP: Evernorth Health Services

M00-M99 Diseases of the Musculoskeletal System and Connective Tissue

(eg, osteoarthritis, osteoporosis, rheumatoid arthritis)

M1 Comparative effectiveness of b/tsDMARDs in terms of opioid discontinuation among Medicare beneficiaries with rheumatoid arthritis

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BACKGROUND: Pain is the most prevalent patient-reported outcome among individuals with rheumatoid arthritis (RA), often managed with long-term opioid therapy (LTOT). However, evidence supporting the efficacy and safety of LTOT in RA remains limited. Given the inflammatory nature of RA pain, biologic or targeted synthetic disease-modifying antirheumatic drugs (b/tsDMARDs) may offer pain relief, potentially facilitating opioid discontinuation.

OBJECTIVE: This study examined the rate of opioid discontinuation among Medicare beneficiaries with RA who newly initiated b/tsDMARDs, including tumor necrosis factor inhibitors (TNFi bDMARDs), non-TNFi bDMARDs, and Janus kinase inhibitors (JAKi).

METHODS: Using 5% Medicare claims data from 2012 to 2020, we identified Medicare beneficiaries diagnosed with RA, who initiated b/tsDMARDs (first prescription = index date) with continuous enrollment during a 12-month baseline period. Beneficiaries were also required to have at least 45 days of opioid possession in the 90 days preceding the index date. Follow-up continued until opioid discontinuation (defined as a gap of more than 90 days in opioid possession) or censoring. To adjust for baseline covariate imbalances across the three b/tsDMARDs comparator groups, we employed inverse probability weighting (IPTW) with generalized propensity scores estimated using generalized boosted models (GBM). Cox proportional hazards modeling incorporating the GBM-derived IPTWs was applied to evaluate opioid discontinuation rates across b/tsDMARDs, with reference to JAKi initiators.

RESULTS: The cohort consisted of 1,428 individuals with RA (mean [SD] age 63.87 [12.30]; 77.73% female). TNFi initiators made up the majority (866, 60.64%), followed by non-TNFi bDMARDs (479, 33.54%) and JAKi (83, 5.81%) initiators. A total of 285 individuals (19.96%) discontinued opioids during the follow-up period. In the Cox model incorporating GBM-derived IPTWs, TNFi bDMARDs (adjusted HR [95% CI] = 1.06 [0.78-1.42]), and non-TNFi bDMARDs (aHR [95% CI] = 0.99 [0.72-1.36]) had similar rates of opioid discontinuation compared to JAKi.

CONCLUSIONS: Among Medicare beneficiaries with RA, TNFi and non-TNFi bDMARDs were associated with similar impact on opioid discontinuation as JAK inhibitors. Future research is needed to evaluate the comparative effectiveness of these b/tsDMARDs in terms of pain control in patients with RA.

SPONSORSHIP: This study was supported by a grant from the NIH, National Institute on Drug Abuse: R15DA046036 (PI: Dr Yang).

M2 Real-World Patient Profile, Persistence, and Adherence Data on Early Hyrimoz® Utilization: A Retrospective Claims-Based Analysis

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BACKGROUND: Adalimumab (ADA)-adaz (Hyrimoz®), was launched in July 2023, and formulary changes in April 2024 favored biosimilar options. Thus, it is important to understand the real-world experience of biosimilar ADA adoption, including patient and utilization characteristics.

OBJECTIVE: To describe the characteristics and treatment history of patients initiating ADA-adaz. Secondarily, to evaluate preliminary persistence and adherence to ADA-adaz.

METHODS: A retrospective cohort study of patients initiating ADA-adaz was conducted using open and closed claims from Komodo Research Data (KRD+; 01/2016 to 05/2024). The index date was the first ADA-adaz prescription; continuous data availability for ≥12 months prior to index (baseline period) was required. For persistence and adherence analyses, continuous health plan enrollment for ≥3 months post-index was required. Persistence was defined as time from index to earliest of switch or discontinuation (45-day gap). Censoring occurred at the earliest of end of data, end of health plan enrollment, or death. Adherence was defined as the proportion of days covered (PDC) while on treatment.

RESULTS: A total of 23,737 eligible patients initiating ADA-adaz were observed, 53.5% initiating in April 2024. Median age was 49.0 years, 59.4% were female, 73.5% were White, and 91.0% were covered by Commercial insurance. Patients received ADA-adaz primarily for rheumatoid arthritis (33.0%), Crohn's disease (23.2%), and psoriatic arthritis (15.7%). The most common baseline comorbidities were hyperlipidemia (29.2%), hypertension (29.0%), anxiety (22.8%), and osteoarthritis (21.4%). In the 12-month baseline period, 93.2% had prior biologic treatment, with 98.2% receiving reference ADA and 83.0% being treated with biologics for 6-12 months. Other baseline treatments included corticosteroids (52.3%), nonsteroidal anti-inflammatory drugs (NSAIDs; 35.4%), and disease-modifying antirheumatic drugs (DMARDs; 34.6%). A total of 1,108 (4.7%) patients were included in the preliminary persistence and adherence analyses. Persistence at 3 months was 65.7% and average PDC was 93.9% while on ADA-adaz.

CONCLUSIONS: This analysis of early ADA-adaz adopters shows a high rate of prior ADA use, highlighting a transition to biosimilars in treatment-experienced patients. Lower persistence was largely driven by switching to other ADA treatments, suggesting formulary-driven transitions rather than treatment discontinuation; adherence on ADA-adaz was high. As more real-world data becomes available, further studies with longer follow-up are needed to assess utilization patterns and long-term outcomes.

SPONSORSHIP: Sandoz Inc.

M3 Clinical and out-of-pocket cost outcomes of patients with rheumatoid arthritis who switched to biosimilar adalimumab-atto from reference product adalimumab

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BACKGROUND: Adalimumab-atto was the first biosimilar of reference product (RP) adalimumab to launch in the US in early 2023. Adalimumab products are biologic disease-modifying antirheumatic drugs (DMARD) used in inflammatory conditions such as rheumatoid arthritis (RA). No studies to date have evaluated outcomes of US patients who switched from RP to biosimilar adalimumab.

OBJECTIVE: To evaluate clinical and out-of-pocket cost (OOP) outcomes of patients with RA who switched from RP to biosimilar adalimumab.

METHODS: This was a retrospective, matched cohort study of adults with RA from Kaiser Permanente (KP) California and Colorado who switched from RP adalimumab to biosimilar adalimumab-atto in 03/2023 to 06/2023 (biosimilar group) or continuously received RP adalimumab (control group). The index date was the first dispense date of adalimumab-atto or a random dispense date of RP adalimumab in 01/2010 to 09/2022. The biosimilar and control groups were matched 1:1 with propensity score matching. Patients were followed until 1 year after the index date, discontinuation of biosimilar/RP adalimumab, end of KP membership, or death—whichever came first. A composite effectiveness measure of disease worsening (defined by increased glucocorticoid use, switch to an alternative DMARD due to loss of response, or RA-related emergency department/hospital admission) was analyzed using a noninferiority test with upper margin of 5%. A crude incidence rate of safety outcomes including serious infection, cancer, or switch to an alternative DMARD due to injection-site reaction/rash was calculated. The OOP outcome was the change in average patient contribution for adalimumab per month during follow-up.

RESULTS: There were 1,172 patients in each study group. The mean overall age was 58 ± 13 years, 78% were female, 63% had commercial prescription coverage, and 60% had ≥2 years of RP adalimumab history at baseline. The outcome of disease worsening occurred in 24.8% and 31.0% of patients in the biosimilar and control groups, respectively ($p < 0.01$ for non-inferiority). The crude safety rate per 100 person-years was 5.6 and 7.2 in the biosimilar and control groups, respectively ($p = 0.21$). Patients in the biosimilar group had a statistically significantly greater decrease in monthly adalimumab OOP ($p < 0.01$).

CONCLUSIONS: Among patients with RA, biosimilar adalimumab-atto demonstrated similar effectiveness and safety as RP adalimumab after 1 year of follow-up. Patient OOP costs were lower in those who switched to the biosimilar.

SPONSORSHIP: Kaiser Permanente

M4 Contemporary economic burden of gout flare for overall and high-cost episodes: A comparative real-world study in the USA

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BACKGROUND: Gout, the most common inflammatory arthritis, represents a significant economic burden in the USA, with the annual cost and health care resource utilization varying significantly based on disease severity, age, and treatment refractory status.

OBJECTIVE: To build a comparative analysis of gout flares for high-cost and overall episodes, based on total flare care cost (pharmacy and medical cost) by site of care and physician specialty, provider-based treatment encounters, and associated comorbidities.

METHODS: A retrospective study of commercial enrollees from Optum's de-identified normative health information (dNHI) database (2016-2024) was conducted. A total of 178,509 gout patients with 425,008 flare episodes were identified, aged ≥18 years, with 3 months pre-index and 12 months post-index continuous eligibility and without gout flare in the pre-index period. Frequency of gout flares was calculated in the post-index period. Standard cost per episode was calculated during the 30 days following the onset of a flare for each episode and stratified by physician specialty and site of care. Deciles were created based on total flare cost per episode, where the top 5% decile constituted the high-cost episodes.

RESULTS: Males aged 50-59 years had the highest proportion of gout flares. The mean flare frequency was 4 vs 2.3 in the high-cost group vs overall. Mean total cost per overall episode was $1,393 for overall flares and $18,287 for high-cost flares. Inpatient acute site of care accounted for the highest average medical cost per overall episode ($6,438), whereas emergency room (ER) visits were estimated with the highest average medical cost per high-cost episodes ($13,085). Among the provider specialties, 43% and 35% of overall and high-cost gout episodes were associated with family

practitioner visits. Only 9% and 11% of visits to rheumatologists were observed for overall and high-cost episodes, respectively. Hypertension and dyslipidemia were the top comorbidities observed during the pre-index period.

CONCLUSIONS: This study highlights the considerable economic impact of gout flares, with the average cost of the top 5% most expensive flares being $18,287 per episode. Gout-related costs and resource use were higher in patients with frequent flares, suggesting a significant cost to payers and health care systems that have gout management plans to reduce flare frequency. To mitigate this financial strain, there is a pressing need for cost-effective treatment options that manage gout flares and reduce avoidable expensive medical care such as hospitalizations and ER visits.

SPONSORSHIP: ANI Pharmaceuticals, Inc.

M5 Cost-effectiveness analysis of SI-6603 for lumbar disc herniation in the United States

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BACKGROUND: Lumbar disc herniation (LDH) affects 2-3% of the population in the United States (US). It is a leading cause of radicular leg pain, resulting in disability and impacting work productivity and quality of life. Initial treatment of LDH is conservative, often followed by epidural steroid injection if ineffective. Surgeries are required for many patients who do not respond to either treatment. SI-6603, a minimally invasive one-time intradiscal injection, has been approved in Japan for LDH; a US phase 3 trial (NCT03607838) has demonstrated the efficacy and safety of SI-6603 compared to Sham.

OBJECTIVE: To evaluate the cost-effectiveness of SI-6603 for LDH from a US payer perspective.

METHODS: A cost-effectiveness analysis (CEA) was conducted to estimate costs, quality-adjusted life-years (QALYs), and incremental cost-effectiveness ratio (ICER) over 3 years for SI-6603 vs Sham for patients with LDH who had failed conservative treatment, and/or ESI, and had not received surgery. Efficacy measures (responders with at least 50% improvement in worst leg pain, occurrence of surgery, Work Productivity and Activity Impairment) and utility scores (EQ-5D) came from the US trial. Surgery costs, LDH-related medical and pharmacy costs, and drug price assumptions for SI-6603 were included in the base case. A scenario analysis of including indirect costs due to work productivity loss was performed. Costs were estimated in 2024 US dollars. Given the short model time horizon, discounts were not considered.

RESULTS: Compared to Sham, SI-6603 was estimated to result in cost savings of $1,335 in LDH-related medical and pharmacy costs (SI-6603: $5,350; Sham: $6,684) and $1,233 in surgery costs (SI-6603: $1,116; Sham: $2,349) over 3 years per patient. The QALY gain of SI-6603 vs Sham was 0.14 (SI-6603: 2.43; Sham: 2.28). SI-6603 was cost-effective compared to Sham when priced up to $16,000, with an ICER per QALY gained below the $100,000 willingness-to-pay threshold, and up to $23,000 with an ICER per QALY gained below the $150,000 threshold. In the scenario analysis, SI-6603 was estimated to provide cost savings of $8,929 in indirect costs (SI-6603: $52,782; Sham: $61,711), compared to Sham, and it was cost-effective when priced up to $25,000, with an ICER per QALY gained below the $100,000 threshold.

CONCLUSIONS: SI-6603 provides a cost-effective treatment option for patients with LDH when the drug price is within a certain range. This cost effectiveness may result from savings in LDH-related medical and pharmacy costs, surgery costs, and indirect costs.

SPONSORSHIP: Ferring Pharmaceuticals, Inc.

N00-N99 Diseases of the Genitourinary System

(eg, chronic kidney disease)

N3 Medication initiation and discontinuation patterns among Medicare Fee-For-Service beneficiaries with chronic kidney disease and comorbid conditions

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BACKGROUND: Low initiation and high discontinuation rates of pharmacologic therapy have been observed in patients with chronic kidney disease (CKD). Despite the considerable burden of cardio-renal-metabolic conditions in the Medicare Fee-For-Service (FFS) patients with CKD, limited evidence exists on treatment patterns among this population.

OBJECTIVE: To evaluate the initiation and discontinuation patterns of medication classes recommended for patients with CKD and cardiometabolic comorbidities.

METHODS: Medicare FFS beneficiaries with newly diagnosed CKD (index date = CKD diagnosis date) from Jan 2015 through Dec 2022 with 12 months of baseline and ≥12 months and ≤60 months of follow-up were identified. Patients were categorized into mutually exclusive cohorts based on baseline comorbidities: CKD only, CKD+T2D,

CKD+HF, CKD+T2D+HF. Medication classes included angiotensin-converting enzyme inhibitors (ACEi), angiotensin II receptor blockers (ARB), diuretics, glucagon-like peptide-1 receptor agonists (GLP-1), mineralocorticoid receptor antagonists (MRA), and sodium-glucose co-transporter-2 inhibitors (SGLT2i). Initiation was examined in those without the medication class in the baseline. Discontinuation of treatment was defined as a gap of ≥30 days. Persistence was measured as time to discontinuation. Descriptive statistics were used to summarize study variables, and Kaplan-Meier analyses estimated time-to-event outcomes.

RESULTS: A total of 2,260,075 Medicare FFS beneficiaries were identified (mean [SD] age: 78.3 [7.7] years; female: 59.1%); 56.5% with CKD only, 7.2% with CKD+HF, 30.9% with CKD+T2D, and 5.4% with CKD+HF+T2D. In the CKD only cohort, 12-month initiation for ACEi, ARB, diuretics, GLP-1, MRA, and SGLT2i was 4.5%, 4.6%, 11.1%, 0.09%, 1.5%, and 0.13%, respectively. At 12 months, highest initiation for all medication classes was observed in CKD+HF+T2D, followed by CKD+HF, CKD+T2D, and CKD only, except for GLP-1 and SGLT2i, which were higher in CKD+T2D than CKD+HF ($p < 0.001$ for all). By 12 months, discontinuation in all cohorts was >45% for all medication classes. In the CKD only cohort, >50% discontinued ACEi, ARB, diuretics, GLP-1, MRA, and SGLT2i by 7.4, 15.5, 4.2, 5.4, 7.0, and 10.0 months, respectively.

CONCLUSIONS: Treatment initiation and persistence were low among Medicare FFS beneficiaries with CKD and cardiometabolic comorbidities. This study underscores the need to increase initiation and continuation of guideline recommended treatments in CKD among Medicare FFS beneficiaries, which may lead to improved patient outcomes and reduced health care costs.

SPONSORSHIP: Boehringer Ingelheim Pharmaceuticals, Inc.

N4 Serious adverse events (SAEs), health care resource utilization (HCRU), and costs in chemotherapy-naive patients (pts) with metastatic castration-resistant prostate cancer (mCRPC) from Surveillance, Epidemiology, and End Results (SEER)–Medicare data

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BACKGROUND: Pts with mCRPC constitute a vulnerable population who have often received multiple prior treatments and have aggressive disease. While androgen receptor pathway inhibitor (ARPI) and/or taxane therapies have advanced mCRPC treatment and become standard of care, they are not without side effects, which impact not only pts but also the health care system.

OBJECTIVE: To determine the SAEs, HCRU, and costs among pts with mCRPC who were chemotherapy-naive and had received one prior ARPI.

METHODS: This retrospective, observational study was based on US SEER-Medicare data from Jan 1, 2009, to Dec 31, 2019. Adult men with mCRPC pretreated with one ARPI who went on to receive a second ARPI (ARPI cohort) or a taxane (taxane cohort) were included. The index date was the initiation of either the second ARPI or the taxane. Pts who had received poly(ADP-ribose) polymerase inhibitors, immunotherapy, radiation, biologics, or other chemotherapy within the past 12 months were excluded. SAEs were identified when an AE was the primary diagnosis code on a hospitalization or emergency room claim. Rates of SAEs were analyzed descriptively. Inverse probability of treatment weighting–adjusted HCRU and costs were reported per patient per month (PPPM).

RESULTS: The final study population included 923 pts (ARPI cohort: 714 [77%] pts; taxane cohort: 209 [23%] pts). Overall, 48% of pts experienced ≥1 new-onset SAE during the follow-up period (ARPI cohort: 42%; taxane cohort: 66%). The most common SAEs were general (e.g., fatigue, pain), musculoskeletal, and cardiac SAEs in both cohorts. The mean length of SAE-associated hospitalization was 8 days (ARPI cohort: 8 days; taxane cohort: 5 days) and the mean SAE-associated cost was $92,112 (ARPI cohort: $84,687; taxane cohort: $110,424). Overall, 84% of pts had ≥1 inpatient hospitalization in the first year of follow-up (ARPI cohort: 85%; taxane cohort: 81%). The mean total all-cause health care cost was $14,302 PPPM (ARPI cohort: $12,542; taxane cohort: $19,556); all cost components were higher in the taxane vs ARPI cohort ($p < 0.0001$). The 1-year total all-cause health care cost was $171,621 per patient.

CONCLUSIONS: This study demonstrates that pts with mCRPC who have received prior ARPIs are at considerable risk of SAEs while receiving commonly used therapies. HCRU and costs were high, with about 8/10 pts needing hospitalization and 1-year total health care costs of >$170K. SAEs were a key driver of costs, with a mean cost of >$90K per SAE episode. Overall, the results indicate an unmet need for treatments with a better safety profile for these pts.

SPONSORSHIP: Novartis Pharmaceuticals Corporation

N5 Evaluating hospitalization rates for darolutamide in patients with metastatic hormone-sensitive prostate cancer: Insights from ARANOTE trial

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BACKGROUND: ARANOTE was a randomized double-blind, placebo-controlled trial designed to evaluate the efficacy and safety of darolutamide combined with androgen deprivation therapy (ADT) in patients with metastatic hormone-sensitive prostate cancer (mHSPC). A total of 669 patients were randomly assigned to receive either 600 mg of darolutamide twice daily or a matching placebo alongside ADT.

OBJECTIVE: To analyze clinical trial data from ARANOTE to assess the impact of adding darolutamide to ADT on hospitalization rates in comparison to placebo plus ADT.

METHODS: Hospitalization rates were assessed using negative binomial regression, with treatment included as a covariate. An offset term was incorporated to account for time at risk, defined as the duration until the onset of radiographic progression-free survival (rPFS). We estimated both all-cause hospitalization rates and rates of grade 3 or higher hospitalization for each treatment arm. The analysis focused on treatment-emergent adverse events (TEAEs). No duplicates were found in the dataset. Data analysis was conducted using R software.

RESULTS: Approximately 22% of patients required hospitalization at least once during treatment in ARANOTE, including those receiving darolutamide and placebo. The treatment coefficient for darolutamide was 0.005 (P = 0.983), suggesting that the addition of darolutamide to androgen deprivation therapy (ADT) is comparable to hospitalization rates of placebo. Annual all-cause hospitalization rates found that the darolutamide group had a hospitalization rate of 0.426 (95% CI: 0.174-1.039), compared to a rate of 0.424 (95% CI: 0.278-0.646) in the placebo group. This indicates there is no meaningful numerical difference in hospitalization rates between the two groups. For grade 3 or higher adverse events, the darolutamide group reported a rate of 0.771 per year (95% CI: 0.361-1.645), while the placebo group had a rate of 0.847 per year (95% CI: 0.591-1.215), indicating a numerical reduction of approximately 9% in the rate of these adverse events in the darolutamide group compared to the placebo group.

CONCLUSIONS: Darolutamide was associated with an all-cause hospitalization rate that was similar to that of the placebo group. Additionally, the darolutamide group experienced a lower rate of hospitalizations due to grade 3 or higher AE. There was no statistically significant difference in hospitalization rates between the darolutamide and placebo groups.

SPONSORSHIP: Bayer Healthcare LLC

N6 Real-world utilization of gonadotropins and the associated cumulative live birth rates in the US: A retrospective claims database analysis

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BACKGROUND: Highly Purified Human Menopausal gonadotropin (HP-HMG), follitropin alfa, and follitropin beta are gonadotropins approved in the US for follicle stimulation and pregnancy in ovulatory women during an assisted reproductive technology cycle.

OBJECTIVE: To assess the real-world utilization of gonadotropins and associated cumulative live birth rates (CLBR) in women diagnosed with infertility in the US.

METHODS: Women aged 18-42 years diagnosed with infertility (ICD-10: N97) who received subsequent gonadotropins were identified in the IQVIA PharMetrics® Plus database (01/2016 to 06/2022). Patients were grouped by their first gonadotropin treatment: HP-HMG monotherapy, follitropin alfa monotherapy, follitropin beta monotherapy, or combinations of HP-HMG with follitropin alfa or follitropin beta (mixed protocol). The index date was earliest date of gonadotropin use. Patient characteristics were assessed during the 6 months pre-index (baseline period). CLBR were compared between cohorts in unadjusted and adjusted analyses (logistic regression adjusting for baseline characteristics).

RESULTS: Of 14,174 women identified, the mean (standard deviation [SD]) age was 34.7 (4.1) years. Prior to the index date, 7.1% had endometriosis and 17.7% had polycystic ovary syndrome. From 2016 to 2021, there was increased use of mixed protocol (60.1% to 71.2%) and HP-HMG monotherapy (4.3% to 5.7%), and decreased use of follitropin alfa monotherapy (21.7% to 11.4%) and follitropin beta monotherapy (13.9% to 11.6%). Unadjusted CLBRs were highest in the HP-HMG group (45.4%), followed by mixed protocol (44.5%), follitropin alfa (39.7%), and follitropin beta (38.5%). After adjusting for baseline characteristics, the odds of achieving a live birth were significantly higher in the mixed protocol group versus the

follitropin alfa (OR 1.31) and follitropin beta groups (OR 1.36; both p<0.001). The HP-HMG group also had significantly higher live birth odds compared to the follitropin alfa (OR 1.28, p=0.004) and follitropin beta groups (OR 1.34, p=0.001). There was no significant difference in CLBR between follitropin alfa and follitropin beta groups (OR 1.04, p=0.566).

CONCLUSIONS: The real-world utilization of HP-HMG, as monotherapy or in a mixed protocol, has increased over time in women with infertility in the US. HP-HMG used in a mixed protocol or as monotherapy were associated with a significantly higher CLBR compared to follitropin alfa or follitropin beta monotherapy.

SPONSORSHIP: Ferring Pharmaceuticals, Inc.

N7 Comparative efficacy of elinzanetant versus other non-hormonal therapies for the treatment of moderate to severe vasomotor symptoms associated with menopause: a network meta-analysis

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BACKGROUND: Elinzanetant is a novel, non-hormonal selective dual NK-1,3 receptor antagonist investigated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.

OBJECTIVE: To compare the efficacy of elinzanetant versus other non-hormonal treatments (nHT) in alleviating VMS.

METHODS: A systematic literature review identified randomized controlled trials (RCTs) from Medline, Embase, and Cochrane up to August 2024. This included phase 2/3/4 RCTs investigating approved or off-label use of nHT in women with natural menopause, and reporting results from baseline to week 12 in VMS frequency and severity, sleep disturbances, and the Menopause-Specific Quality of Life (MENQoL). Treatments were compared using Bayesian network meta-analysis (NMA). Results were presented as mean differences (MD) or odds ratios (OR), with 95% Bayesian credible intervals.

RESULTS: Seventeen RCTs were qualified: 3 assessing elinzanetant (EZN), 2 paroxetine 7.5mg (PRX), 4 gabapentin 1,200-1,800 mg (GABA), 3 fezolinetant 45 mg (FEZO), and 5 desvenlafaxine 50-200 mg (DVS). EZN showed a statistically significant greater reduction in daily VMS frequency compared to PRX (MD = -2.11 [-3.31, -0.92]), DVS (MD: -2.77 to -1.72), and GABA (MD: -2.22 to -2.31), and a favorable numerical trend versus FEZO (MD = -0.98 [-2.14, 0.18]). The proportion of patients with ≥50% reduction in VMS frequency was statistically significantly higher for EZN compared to DVS 100 mg (OR = 1.52 [1.03, 2.24]) and PRX (OR = 2.20 [1.49, 3.28]), and comparable to DVS 150 mg and FEZO. EZN was associated with a statistically significantly greater reduction in VMS severity versus DVS 50 mg (MD = -0.37 [-0.56, -0.17]), and no statistically significant differences versus other treatments. EZN reduced nighttime awakenings statistically significantly more effectively than PRX (MD = -0.82 [-1.26, -0.39]) and all DVS regimens. EZN also statistically significantly improved PROMIS SD 8b raw score versus FEZO (MD = -2.67 [-3.92, -1.42]), and showed a favorable numerical trend for reduction of the insomnia severity index versus GABA 1,800 mg (MD = -1.46 [-3.03, 0.11]). Change in MENQoL did not significantly differ between various nHT.

CONCLUSIONS: EZN demonstrated effectiveness in reducing the frequency and severity of VMS and was statistically significantly better at improving sleep quality among nHT, rendering it a potentially optimal non-hormonal alternative for managing VMS.

SPONSORSHIP: Bayer

O1 The cost infertility therapy for women with a history of hysteroscopic adhesiolysis, as compared to those with other or no previous uterine surgeries

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BACKGROUND: Intrauterine adhesions (IUAs) can result from trauma to the endometrium, most commonly following uterine surgery. These IUAs, and their treatment via hysteroscopic adhesiolysis (HA), can lead to reduced fertility and detrimental obstetrical outcomes for both the mother and the infant. We sought to quantify the economic burden of IUAs through their association with infertility.

OBJECTIVE: Compare the infertility-related economic costs of three cohorts of women, including those with a history of HA, history of other uterine surgery, and those with no historical uterine surgery.

METHODS: We conducted a retrospective analysis of a closed claims database to identify health care resource use and costs for women with >6 months of continuous enrollment in each of the three cohorts of interest. This was restricted to eight US states where infertility service coverage is mandated. We used propensity-score matching (PSM) to reduce confounding between the three cohorts, which were analyzed over a period of 41 months.

RESULTS: Our analysis covered 594 patients in each cohort after PSM. Total costs of infertility evaluation and management were $1,488,373 ($2,506 / woman) in the cohort of women with a history of HA, $259,360 ($408 / woman) among the cohort with prior uterine procedures, and $40,136 ($68 / woman) for women with no historical uterine procedures.

CONCLUSIONS: Women who underwent hysteroscopic adhesiolysis were found to have greatly increased use of health care services for infertility evaluation and management, primarily IVF. Therefore, surgeons should look to prevent intrauterine trauma, which may lead to IUAs, wherever feasible.

SPONSORSHIP: Rejoni Inc., Axtria Inc.

Q1 Comparative Analysis of Total Hospital Charges and Length of Stay by Insurance Type and Diagnosis-Related Group in Patients with Congenital Malformation Syndromes Predominantly Associated with Short Stature

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BACKGROUND: Congenital malformation syndromes predominantly associated with short stature (CMSPASS) include conditions such as Prader-Willi syndrome (PWS) and Alazami syndrome. The economic and social implications of these disorders are significant, involving both direct health care costs and indirect expenses related to caregiving and quality of life. Understanding the factors that influence health care utilization and costs is essential for improving care strategies.

OBJECTIVE: This study aims to compare total hospital charges and length of stay among patients with CMSPASS, focusing on variations by insurance type and Diagnosis-Related Group (DRG).

METHODS: We utilized the National Inpatient Sample (NIS) 2019 dataset from the Healthcare Cost and Utilization Project (HCUP), employing a retrospective cross-sectional study design. Inpatient discharges of patients diagnosed with CMSPASS (ICD-10 code Q87.1) were identified, and DRG version 36 was used to classify the top 10 DRG codes within this cohort based on net spend. Mean and standard deviation for both length of stay and total charges were calculated by payer type and DRG code, alongside baseline characteristics of the cohort.

RESULTS: Our analysis identified 1,044 discharges of CMSPASS patients in 2019, with a mean age of 22 years; 50% were female, and 63% were White, followed by Hispanic and Black patients. Medicaid insured 42% of discharges, followed by private insurance (33%) and Medicare (22%). Medicaid patients experienced the longest length of stay (9.6 days) and incurred the highest total charges ($121,977), whereas Medicare patients had a shorter stay (6.7 days) and approximately half the total charges. Notably, neonatal death or transfer to acute care incurred the highest net spend at $7.5 million, with respiratory and cardiac-related DRGs accounting for net spends of $8.1 million and $6.7 million, respectively.

CONCLUSIONS: This study highlights that variations in insurance types and reasons for hospitalization significantly affect health care costs and length of stay for patients with CMSPASS.

SPONSORSHIP: None

Q2 Capturing the burden of Prader-Willi syndrome on patients and the health care system: A real-world analysis of United States claims data

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BACKGROUND: Prader-Willi syndrome (PWS) is a rare genetic disorder with a median age of death of 23 years per a recent analysis of IQVIA US claims data (McCandless et al., 2020). In 2017, Butler et al concluded that individuals with PWS show heightened hyperphagia-related mortality (e.g., high rates of choking, accidents, and gastrointestinal perforation), which contribute to one-third of all US reported deaths in PWS.

OBJECTIVE: This analysis aims to describe key health care services that drive the economic burden of PWS by examining the volume of ambulance-related and palliative services.

METHODS: Observational retrospective analysis was performed on a de-identified US closed-claims dataset (2021-2023). Patients (pts) with ≥2 claims with a diagnosis of PWS (Q87.11) >2 weeks apart were included in the study. In this cross-sectional analysis, patients were assigned to one of five age groups (<12, 12-23, 24-35, 36-47, 48-59 years). Diagnoses and services (srvs) codes occurring during this three-year period were included. Statistics were descriptive.

RESULTS: A total of 3685 pts were included in this study (<12: 33.2%; 12-23: 30.5%; 24-35: 17.2%; 36-47: 9.5%; 48-59: 7.1%). Ambulance-related services were frequent in all age groups; <12 group generated 19,156 srvs (16.0/pt, 33.7/pt with ≥1 srv), 12-23 group: 16,246 srvs (14.4 srv/pt, 27.9 srv/pt with ≥1 srv), 24-35 group generated 13,303 srvs (21.0/pt; 34.7/pt with ≥1 srv), 36-48: 6,452 srvs (18.4/pt; 29.2/pt with ≥1 srv), and 48-59: 4,938 srvs (19.0/pt; 28.4/pt with ≥1 srv). For palliative services, the 12-23 (1,090 srvs, 0.97/pt, 21.0/pt with ≥1 srv) and 24-35 (849 srvs, 1.3/pt, 19.7/pt with ≥1 srv) age groups generated the most palliative srvs. The 36-48 (319 srvs, 0.9/pt,

10.3/pt with ≥1 srv) and 48-60 (94 srvs, 0.4/pt, 3.9/pt with ≥1 srv) age groups generated fewer.

CONCLUSIONS: These results build upon analysis by Butler et al (2017) and others, demonstrating the significant health care resource utilization and burden of PWS based on morbidity and mortality signals, such as ambulatory and palliative services. This disease burden is most prominent in younger patients, but does not decrease with age, despite diminishing population size. Utilization of ambulatory and palliative services in this population provides insight into the burden associated with heightened PWS mortality. This real-world analysis reinforces existing PWS literature, validating previously reported findings with evidence from US claims data on the considerable burden and mortality of PWS on patients and the US health care system.

SPONSORSHIP: Soleno Therapeutics, Inc

S1 Factors associated with post-discharge health care resource utilization following extremity arterial trauma treated with graft

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BACKGROUND: Extremity arterial trauma is one of the most severe types of trauma, and requires immediate attention to preserve life, limb, and function. Vascular trauma complications can be severe in nature, but their impact on post-discharge costs is not yet fully understood.

OBJECTIVE: To understand factors associated with patient costs in the 18 months after hospitalization for extremity arterial trauma patients receiving a graft.

METHODS: Patients were identified from the PINC AI Healthcare Database linked with Inovalon claims database who had ≥1 ICD-10-CM code for an extremity arterial injury between 01/01/2018 and 03/31/2023, were ≥18 years old, and underwent open vascular repair with a graft identified with ICD-10-PCS and CPT codes. Total medical costs for the 6 and 18 months after discharge were analyzed as unadjusted and adjusted with a two-part model (logit and GLM with gamma distribution). Costs were adjusted for age, gender, graft type, concomitant injuries (orthopedic fracture, vein or nerve injury), pre- and post-discharge complications (infection, amputation, thrombectomy, aneurysm, fasciotomy, rhabdomyolysis), and use of services (≥1 inpatient, outpatient, or ER).

RESULTS: The search identified 964 unique patients, 74% of whom received autologous vein, 14% synthetic graft, 6% non-autologous vein, and 6% multiple types of grafts. The majority of costs (75%) occurred in the 6 months after discharge and averaged $70,222 (SD: $292,706), increasing to $93,639 (SD: $380,774) at 18 months. After adjusting for age, sex, and graft type, pre-discharge conduit infection was associated with $382,953 ($p < 0.01$) additional costs at 6 months after discharge, orthopedic fracture with $136,395 ($p < 0.01$), and amputation with $40,947 ($p = 0.57$). Other pre-discharge complications were associated with lower post-discharge costs: thrombectomy ($p > 0.05$), aneurysm ($p < 0.05$), fasciotomy ($p > 0.05$), and rhabdomyolysis ($p > 0.05$). Post-discharge aneurysm was associated with $310,758 ($p < 0.01$) in additional costs, infection with $205,592 ($p < 0.01$), thrombectomy with $192,101 ($p < 0.01$), and amputation with $105,397 ($p = 0.57$). At 18 months, variables associated with the highest cost were ≥1 ER claim ($538,429; $p < 0.05$), pre-discharge conduit infection ($415,260; $p < 0.01$), aneurysm ($248,168; $p < 0.05$), and post-discharge conduit infection ($244,333; $p < 0.01$).

CONCLUSIONS: Complications such as infection and amputation occurring before and after discharge were associated with higher post-discharge costs. These results highlight the importance of preventing in-hospital complications in this patient population.

SPONSORSHIP: Humacyte Global, Inc.

S2 Health care utilization rates after hospital discharge for extremity arterial trauma patients treated with graft repair

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BACKGROUND: The gold standard medical care for patients with extremity arterial trauma is autologous vein. A comparison of the health care utilization between patients with and without saphenous vein available is imperative to understanding the unmet need that may be present in this patient population.

OBJECTIVE: To describe the frequency of post-discharge health care visits for patients with extremity arterial trauma treated with different graft types.

METHODS: A retrospective data analysis was conducted using the linked PINC AI Healthcare Database and Inovalon insurance database. The study included patients aged ≥18 years with extremity arterial trauma (ICD-10-CM), who underwent vascular repair with a graft between 01/01/2018 and 03/31/2023 and had 18 months of follow-up data. Patients were grouped by graft type using ICD-10-PCS codes (autologous, synthetic, non-autologous other, or multiple types). All inpatient, outpatient, and emergency room (ER) visits after the initial hospital discharge were identified, capturing the number patients using care and incidence rate of visits per patient.

RESULTS: The search identified 922 graft recipients, and most received autologous vein (74%), followed by synthetic graft (14%), non-autologous other (6%), and multiple types (6%). At 6 months after discharge, the incidence rate for hospitalizations, ER, and outpatient visits was lowest for the autologous group (0.0410, 0.0307, and 0.3031 events per patient, respectively), compared with synthetic (0.2205, 0.0630, and 0.6220), non-autologous other (0.1667, 0.0185, and 1.1481), and multiple types (0.1207, 0.1724, and 1.6379). At 18 months the incidence of inpatient stays among autologous graft recipients (0.0454 stays per patient) was 85.2% lower compared to those treated with synthetic graft (0.3071), 77.7% lower compared to those treated with non-autologous other (0.2037), and 89.9% lower than those treated with multiple types (0.4483). Similarly, the incidence of ER visits (0.0351) was 62.8%, 5.1%, and 94.0% lower compared to synthetic (0.0945), non-autologous other (0.0370), and multiple type recipients (0.5862), while the incidence of outpatient visits (0.4187) was 78.4%, 80.0%, and 85.8% lower vs synthetic (1.9370), non-autologous other (2.0926), and multiple type recipients (2.9483).

CONCLUSIONS: When compared to other graft types, 18-month post-discharge health care resource use was markedly lower among autologous vein recipients. These results provide evidence of an unmet need in patients with extremity arterial trauma requiring graft repair that extends well beyond the acute care episode.

SPONSORSHIP: Humacyte Global, Inc.

T1 Analyzing Clinical Notes to Map Traumatic Brain Injury and Assess Risky Substance Use or Substance Use Disorder Based on Affected Brain Regions

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BACKGROUND: Traumatic brain injuries (TBIs) present a significant risk for developing risky substance use or substance use disorder. This study found that traumatic brain injuries (TBIs) in patients aged ≤40 years are associated with a risk of developing risky substance use or substance use disorder. To analyze the correlation between the location of brain injury and subsequent addiction risk, providing insights for personalized treatment in the correlation between the location of the brain injury and subsequent addiction risk can help inform personalized treatment and prevention strategies.

OBJECTIVE: The study aims to analyze the correlation between the location of the brain injury and the subsequent risk of developing risky substance use or substance use disorder, providing insights for more personalized treatment and prevention strategies.

METHODS: We conducted a retrospective study using Optum® Market Clarity. Patients aged ≤40 years with ICD-10 diagnosis codes (S07. *, S09. *, S36. *, S46. *, S00. *) for TBI (Index Event) between January 1, 2018, and December 31, 2020 (N=2,422,309). Patient clinical notes were extracted and annotated to identify mentions of injury to specific brain regions like frontal, parietal, temporal lobes, etc. Literature reviews and clinical expertise were used to determine key terms that were searched in the clinical notes. Generative AI was used to increase the accuracy and speed of customizing clinical notes data. Risky substance use or substance abuse (including opioids, alcohol, cannabis, methamphetamine, and cocaine) was assessed within the 4-year post-index period. To reduce the confounding effects of demographic factors and comorbidities, propensity score matching was performed using age, gender, region, and Charlson comorbidity score. The relationship between the location of the brain injury and the subsequent risk of addiction was assessed in the PSM-matched populations.

RESULTS: A total of 57,407 patients with TBI followed by risky substance use were included in the study. The analysis revealed a significant correlation ($p < 0.05$) between the anatomical location of the brain injury and the subsequent risk of addiction. Further analysis will be conducted to determine the odds of engaging in risky addictive behaviors after TBI.

CONCLUSIONS: These findings highlight the potential for using clinical notes to accurately identify brain injury locations, otherwise missing from claims data, as well as emphasize the need for targeted behavioral interventions in individuals with brain injuries to mitigate the risk of addiction.

SPONSORSHIP: None

U00-U99 Codes for Special Purposes and AMCP Unclassified Abstracts

(eg, benefit management, care management, multidisease studies, pharmacist services, Part D, specialty pharmacy, star ratings)

U1 Claims database analysis of health care resource utilization and associated medical costs in patients with Barth syndrome in the United States

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BACKGROUND: Barth syndrome (BTHS) is a serious, ultra-rare genetic disorder with an estimated prevalence of ~1 in 1,000,000 male births. The US FDA has accepted a New Drug Application for elamipretide in patients with BTHS. To support reimbursement, the economic evaluation of elamipretide is necessary; however, compiling such data for orphan drugs is difficult. One direct method to measure disease burden of rare diseases is overall cost and health care resource utilization (HCRU).

OBJECTIVE: We assessed HCRU and associated costs in the United States by conducting a claims database analysis.

METHODS: Claims containing the ICD-10 diagnostic code for BTHS (E78.71) were examined using Healthcare Cost and Utilization Project (HCUP) data from the National (Nationwide) Inpatient Sample (NIS) (combined 2020-2021 data) and the Kids' Inpatient Database (KID) (2019 data). Major complications or comorbidities (MCC), patient age, length of stay, total charge, and total cost per claim were examined. Case Mix Index (CMI) was assessed to measure the complexity and severity of patient cases. Median and average data were compared to better understand outliers.

RESULTS: There were 65 claims for BTHS in the KID and NIS databases. Greater than 400 diagnostic codes were reported, demonstrating a significant number of comorbidities. Common claims in the databases included dilated cardiomyopathy (n = 25), dehydration (n = 20), neutropenia (n = 19), and heart transplant status (n = 16). NIS data included 47 different Medicare Severity Diagnosis-Related Groups (MS-DRGs). Of those, 24 were MCCs (including ventilator MS-DRGs). In the NIS, average length of stay (ALOS) was 8.2 days (median at 3.0 days). In KID, ALOS was 14.8 days (median at 6.0 days). Charge amounts show similar results. Average total charge per claim in NIS was $127,324 (median value $52,345). In KID, average total charge per claim was $218,789 (median value $45,927). Costs tracked similarly. average hospital cost per claim in NIS was $32,702 (median value $17,326). The KID average total cost per claim was $62,596 (median, $13,647). CMI (a severity metric) averaged 2.01 in NIS (median value 1.37). In KID, average CMI was 1.59 (median value 1.03). (Higher values indicate more severity.)

CONCLUSIONS: Data extrapolated during this claims database analysis demonstrated that patients with diagnostic codes linked to BTHS are complex patients with a high percentage of complications. This high degree of complexity in patients with BTHS can become significant, necessitating a high level of HCRU and associated costs in the inpatient setting.

SPONSORSHIP: Stealth BioTherapeutics, LLC

U2 Payer Impacts of Revoked Accelerated Approvals in Oncology

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BACKGROUND: The FDA's Accelerated Approval (AA) Program expedites drug approval for serious conditions based on surrogate endpoints with subsequent confirmatory trials. If confirmatory trials demonstrate a clinical benefit, traditional approval of the drug is granted. Recently, numerous drugs have received AA for indications that are later withdrawn. Because of CMS requirements for the coverage of oncology medication based on Local Coverage Determination, this incurs unnecessary expense to payers.

OBJECTIVE: To evaluate the number of drugs granted AA for oncology indications in the previous 5 years that were subsequently withdrawn and to understand the financial implications from a payer perspective.

METHODS: We searched the FDA website for oncology AAs that were subsequently withdrawn using the Drug Approvals and Databases. Withdrawal of these indications were verified by the drug's prescribing information and FDA approval letter. Finally, we used wholesale acquisition costs (WAC), combined with conservative estimates of utilization over the period during which each drug was marketed under an AA, to approximate payer costs.

RESULTS: From February 2020 to October 2024, 20 drugs for 26 indications were identified that were granted AA for an oncology indication by the FDA and AA subsequently withdrawn. This represents 40% of confirmed (withdrawn/full approval) oncology indications for the same time period. For 9 drugs (10 indications), AA withdrawal led to removal of the drug from the marketplace. Almost half of indications

(46%) were for blood cancers and over 75% of the withdrawn indications were initially approved based on response rates. The mean time in the marketplace for the indication was 43.8 months and mean monthly cost/drug was $20,200. Using conservative estimates for the Medicare population, one utilizer/month for each identified AA translates to drug expenditures in excess of $500,000 per month or 6 million dollars annually exclusive of administration costs.

CONCLUSIONS: Drugs approved for oncology indications by AA can burden patients and payers with unnecessary cost when these drugs fail to demonstrate adequate benefit in confirmatory trials. High drug expenditures of government health care dollars for oncology medications may be avoidable with approvals based on higher quality data and clinically meaningful endpoints, a need underscored by Medicare plans exiting the marketplace. AA criteria may need to be reevaluated in light of the costs involved.

SPONSORSHIP: None

U3 Utilization Management Modifications Based on Regional Payer-Provider Roundtable Discussions

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BACKGROUND: Utilization management (UM) strategies can cause administrative challenges for patients and providers and may impact timeliness to prescribed treatment. This study explores recommendations for improving UM programs through open communication between provider specialists and managed care decision makers.

OBJECTIVE: To outline opportunities and develop recommendations by sharing insights on clinical evidence and health plan UM strategies through an open communication channel between clinical specialists and managed care decision makers.

METHODS: Two virtual roundtables were held in the western region with managed care professionals and provider specialists, recruited from a proprietary database, for high-cost conditions (eosinophilic esophagitis [EoE] and retinal disease), on October 3 and 23, 2023, respectively. Participants provided quantitative data via polling and discussed recommendations to improve UM strategies that can lead to effective and timely treatment for both diseases. Follow-up interviews were conducted with managed care attendees 6 months later to access UM changes.

RESULTS: Insights from 8 managed care professionals and 7 clinicians (4 gastroenterologists, 1 allergist, and 2 retina specialists) were evaluated following the roundtables. EoE clinicians identified the physical, social, mental, and financial impacts on patients and families. Managed care professionals were generally unaware of the EoE lived experience and most were not aware of challenges with prescribing recommended treatments. Retina specialists noted a high PA approval rate for anti-VEGFs, but the process can delay appropriate treatment by weeks. Step therapy was generally viewed as acceptable among both stakeholders, but the initial PA to access the first agent is cumbersome for providers. For EoE, a regional health plan changed PA criteria from a two-step before approving biologic therapy to a one-step. A health system implemented the first gold-carding policy for a retina specialist group based on historical prescribing patterns in line with preferred formulary agents and plans to gold card an additional group.

CONCLUSIONS: Open communication between managed care professionals and clinical specialists proved an effective approach to address barriers to timely treatment. The 6-month post modifications made demonstrate that informed and collaborative discussions lead to meaningful improvements in care delivery. The findings suggest that continued engagement between stakeholders is valuable for evolving UM strategies to better support both patients and providers.

SPONSORSHIP: Regeneron Pharmaceuticals, Inc., and Sanofi

U4 Medicare Member Drug Cost Predictive Model: Creation and Feature Engineering

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BACKGROUND: Key changes to Medicare Part D as a result of the Inflation Reduction Act (IRA) include an out-of-pocket annual cap of $2,000 for members start in 2025. This increases liability for Part D plan sponsors and creates incentives for plans to identify members likely to exceed this cap.

OBJECTIVE: Create a predictive model to identify members enrolled in Medicare Part D who are at risk of large increases in prescription drug spending over the next 12 months, referred to as Rapid Risers.

METHODS: Model training data included medical and pharmacy claims from 2.5 million Medicare members during 10/1/2021 to 9/30/2023. Over 300 different member level prediction features were created for the model, including demographics, eligibility, chronic conditions, general health and comorbidity indexes, medication adherence, medical spend, drug spend, claim details, and Medicare-specific

information such as low-income subsidy, dual eligibility, disability, hospice, and ESRD. Multiple model types were tested, and performance was judged by root mean squared error (RMSE) where a lower number (i.e., predicted value variance from actual) is better, since the most important scenario being predicted member future cost and a member rapidly rising in cost. The model benchmark was previous 12 months member drug spending to predict future drug spending. In addition, rapid riser was judged by F5 classification, which prioritized reducing false negative predictions with values from 0 to 1, with closer to 1 being better.

RESULTS: About 450,000 members were included for prediction. The test data showed a mean previous total Part D drug spend in the prior 12 months of $2,869 and median of $486. The best performing model type was Random Forest. The models outperformed the benchmark for the primary performance metrics, with model RMSE of $8,899 vs $9,683 and F5 of 0.65 vs 0.61. Key prediction features identified included previous 12-month total drug spend, predicted drug cost assuming full adherence, use of GLP-1 product, pharmacy count, and specialty drug & brand drug utilization.

CONCLUSIONS: A Part D drug cost member predictive model was successfully created using integrated medical and pharmacy claims data. The model performed better than using the member's prior year drug spend. The model features, including the rapid drug spend riser indicator, medical conditions, and extensive member-specific characteristics, may be used by managed care pharmacists for care management strategies to predict high-cost members and optimize drug therapy in the context of IRA-related Medicare changes.

SPONSORSHIP: Prime Therapeutics, LLC

U5 A multi-faceted data science solution to assign Primary Care Providers (PCPs) to unassigned members by leveraging sophisticated algorithms to improve care coordination.

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BACKGROUND: The role of preventive services in controlling health outcomes and cost in managed care is well established. Underutilization of preventive services often leads to delayed treatments and higher emergency care costs. In a recent analysis of our managed care health plans, we have observed that ~17% of members lack an assigned PCP, and ~4% of those with assigned PCPs do not maintain an active relationship.

OBJECTIVE: To build a model to recommend a list of PCPs for a member, each having a higher propensity of acceptance by the member. This model is data-centric, leveraging key member and provider features.

METHODS: We used enrollment and medical claims data for 510k "non-engaging members" (2023-2024) who did not actively engage with PCPs. The solution has three components: (1) Identify members similar to non-engaging members. (2) Maximize the provider pool for recommendations. (3) Optimize recommendations by accounting for perceived capacity. A machine learning–based algorithm identified similarity between members without a PCP and those with assigned PCPs. To maximize the recommended list of PCPs, we compare the set of PCPs identified through claim attribution model for an assigned member (having similarity score >80%) with the entire PCP pool. Coupled with a ranking system, which incorporates demographic, enrollment, and clinical features, helps evaluate suitability of the recommended PCP. To ensure proportionate distribution of members across PCPs, a capacity module was implemented. This module continuously refines the allocation process, ensuring PCPs' time is optimally utilized.

RESULTS: The claim attribution system provides real-world evidence where a PCP claim is identified for non-engaging members across 20 test groups, suggesting an improvement in PCP allocation by one-third (~30%) compared with random visits by members previously. Following this success, the algorithm showed potential to be scaled up and applied across 28k policy groups, promising significant improvements in matching members with suitable providers.

CONCLUSIONS: The current approach suggests that members who are recommended a PCP derived from a member provider feature mix model is better suited than random allocation. This process helps better engagement and enables timely health care intervention. Further analysis on impact of this on health outcomes and cost will provide critical insights on long-term impact of this in managed care.

SPONSORSHIP: Optum

U6 Quantifying the net financial impact of drug price reductions to manufacturers and payers

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BACKGROUND: Drug price reductions have emerged in recent years as a response to public scrutiny of manufacturer drug pricing strategies. Recent regulatory changes have further incentivized manufacturers to lower list prices to avoid certain penalties. The subsequent financial impact

of these price reductions to manufacturers and payers has not been broadly researched.

OBJECTIVE: To describe year-over-year changes in manufacturer net revenues for drugs with significant list price reductions and assess implications these price changes had for payers.

METHODS: Brand drugs with WAC price reductions of over 30% from January 2023 to January 2024 were identified for inclusion, limiting our analyses to drugs where product-level US net revenues were available. Discounts were estimated by comparing the calculated gross sales (WAC * units dispensed from IQVIA) with company reported net sales. Medicaid rebates were estimated using the higher of the statutory rebate of AMP or AMP less best price and, if applicable, adding an additional rebate equal to AMP less baseline AMP increased by inflation.

RESULTS: Of 12 brand product lines identified with price decreases, 6 met study criteria for inclusion in the analysis. Despite the significant reduction in list prices, all brands demonstrated an increase in net revenue per unit in 1H2024 compared with 1H2023. Changes in utilization for these products were associated with greater net revenues, often inversely correlated. In comparison with 1H2023, during 1H2024, the percent change in utilization/percent change in net revenues were as follows: Advair -58%/-24%, Symbicort -28%/+38%, Lantus +14%/+49%, Levemir -53%/+237%, Novolog -13%/+16%, and Humalog -11%/+54%. These changes were driven by a reduction in total discounts, which was most significant in the Medicaid line of business. We estimate the changes in Medicaid rebates from 2023 to 2024 for these drugs were as follows: Advair -39%, Symbicort -68%, Lantus -37%, Levemir -74%, Novolog -74%, and Humalog -14%. Decreases in Medicaid discounts appear to have been driven by the removal of inflationary penalties accumulated by the drugs due to the list price decreases.

CONCLUSIONS: Drastic reductions in list prices may decrease the total discounts provided for medications, which can improve the unit profitability of the drug for the manufacturer. Conversely, the reductions in total discounts may disproportionately impact the Medicaid line of business and increase the net plan paid amounts for these drugs.

SPONSORSHIP: IPD Analytics

U7 Artificial intelligence–supported evidence synthesis for reimbursement decision-making

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BACKGROUND: Evidence synthesis plays a critical role in reimbursement, allowing health technology assessment (HTA) agencies, payers, pharmacy benefit managers, and managed care organizations to make informed decisions. Systematic literature reviews (SLRs) serve as an unbiased process for synthesizing efficacy, safety, and pharmacoeconomic evidence. As SLRs are resource-intensive, augmentation with artificial intelligence (AI) is of great interest; however, limited clarity exists on whether AI-supported SLRs will gain acceptance among reimbursement authorities.

OBJECTIVE: The study's objective was to evaluate how reimbursement decision-makers regard the use of AI-supported SLRs.

METHODS: First, a targeted literature review (TLR) was conducted in Embase and MEDLINE (January 2019-October 2024). The search terms included AI, natural language processing, large language model, and machine learning combined with terms from reimbursement authorities, particularly HTA agencies, given their rigorous SLR standards. Supplemental searches (January 2019-October 2024) were conducted to identify relevant evidence in policy documents. Second, the insights from the TLR informed the development of a survey to determine how reimbursement authorities regard the use of AI in SLRs.

RESULTS: The TLR found that most reimbursement authorities do not mention using AI for SLRs. Exceptions are the National Institute for Health and Care Excellence and the Institute for Quality and Efficiency in Health Care, which do provide recommendations on the use of AI for SLRs. The survey was completed by reimbursement decision-makers across Europe and the United States, including a member of the Institute for Clinical and Economic Review (ICER) and a health plan. Most respondents were somewhat familiar with the use of AI in SLRs and thought AI could improve efficiency. In the United States, the level of familiarity was greater with ICER than with the health plan. However, reimbursement decision-makers were not convinced that AI would improve SLR quality and thought manufacturers should not be primarily responsible for developing or validating AI tools for SLRs.

CONCLUSIONS: Reimbursement decision-makers agreed that AI could benefit SLR production by serving as an assistant rather than a human replacement. Transparency and reliability were judged key factors to consider when

incorporating AI for SLRs in reimbursement decision-making. A multistakeholder effort will be required to ensure quality and realize efficiency gains associated with AI-supported SLRs for reimbursement decision-making.

SPONSORSHIP: OPEN Health

U8 Payer trends in clinical evaluation, financial management, and patient support for orphan drugs

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BACKGROUND: The increasing number of orphan drug approvals poses both clinical and financial challenges for health care payers. In response, payers are evolving their strategies for evaluation and management for orphan drugs, which may impact patient access to treatment for rare diseases.

OBJECTIVE: To understand how payers are managing the clinical and economic challenges associated with orphan drugs.

METHODS: A survey was conducted with payer decision-makers recruited from a proprietary database of market-access decision-makers from May to June 2024. Respondents were asked about their experiences and activities in the orphan disease space, including tactics to manage affordability and utilization of drugs to treat orphan diseases.

RESULTS: Managing the impact of orphan drugs on the affordability of the overall benefit was identified as one of the greatest challenges for payers in rare disease, with 76% of respondents describing it as the top challenge. With respect to the clinical evaluation of orphan drugs, payers noted that the top challenges include lack of outcomes data (80%), lack of long-term data (68%), and use of surrogate endpoints (44%). Payers are increasingly utilizing subject matter expert (SME)/key opinion leader (KOL) input (88%), manufacturer dossiers (76%), and ICER clinical evaluations (76%) to guide formulary decisions on orphan drugs. Payers are seeking to limit their financial exposure to the cost of orphan drugs through use of reinsurance (60%), outcomes-based rebates (32%), and milestone-based rebates (32%). Payers primarily support their rare disease patients through use of care management programs (96%), medication adherence programs (76%), and behavioral health programs (72%).

CONCLUSIONS: Payers are seeking to implement a multipronged approach to orphan drug management that includes in-depth clinical evaluation of orphan drug products, financial strategies to mitigate financial risks and uncertainties, and wrap-around patient support.

SPONSORSHIP: Precision AQ

U9 Value assessment information (VAI) sources: Surveying payer perceptions and utilization

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BACKGROUND: United States (US) payers have increasingly utilized VAI to support and guide their pricing and formulary decisions. Given the significance of these decisions on patient access, it is essential to understand the current VAI sources payers utilize.

OBJECTIVE: To identify trends in the use of VAI in payer organizations, including training material development and relevant sources for formulary decision-making.

METHODS: Double-blinded, web-based survey of US health care payers was conducted through Cencora's Managed Care Network research panel, in June and July 2024.

RESULTS: A total of 51 advisors from health plans (n=26), pharmacy benefit managers (n=13), and integrated delivery networks (n=12) participated in the survey. The most cited roles responsible for reviewing VAI were pharmacy directors (92%), pharmacy and therapeutics committee members (65%), clinical pharmacists (57%), and medical directors (51%). The majority of payers indicated that training resources for reviewers of VAI were developed internally (69%), while less than 33% received externally sourced training resources from either the National Comprehensive Cancer Network (NCCN) or the Institute for Clinical and Economic Review (ICER). When assessing the utilization of VAI sources, payers reported that NCCN Evidence Blocks (65%) and specialty society guidelines (63%) were very/extremely useful for informing coverage and formulary decisions. In the past 24 months, payers indicated that most coverage and formulary decisions were informed by specialty society guidelines (45%), NCCN Evidence Blocks (41%), and Academy of Managed Care Pharmacy (AMCP) dossiers (30%). The most common VAI sources used for clinical data included specialty society guidelines (73%), NCCN Evidence Blocks (71%), and AMCP dossiers (69%), while the most common VAI sources for economic data were ICER Evidence Reports (86%) and AMCP dossiers (55%). To make VAI more useful for future decision-making, payers recommended more comparisons with new/relevant drugs (92%) and cost-effectiveness inputs that better reflect the real world (80%).

CONCLUSIONS: More than two-thirds of payer respondents report developing training resources for reviewing VAI internally, thus reflecting recognition by payer organizations of the value of VAI and its application. Payers utilize a range of VAI sources to guide decision-making; however, the perception of the relevance and utility of these sources

differs across organizations. Payers recommended several opportunities to optimize current VAI sources.

SPONSORSHIP: Cencora

U10 An Indirect Treatment Comparison of COVID-19 Next-Generation mRNA-1283 Vaccine and BNT162b2 Vaccine Against COVID-19 Symptomatic Infections in the US

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BACKGROUND: COVID-19 continues to significantly burden US health care systems in terms of number of cases, severity, and resource utilization, especially among adults aged ≥65 years. mRNA-1283 is a next-generation COVID-19 mRNA vaccine with potential for better protection. Primary results of the pivotal Phase 3 randomized controlled trial (RCT) NextCOVE comparing bivalent (ancestral/Omicron BA.4/5) versions of the original COVID-19 mRNA-1273 and of the mRNA-1283 vaccines have recently become available. However, no head-to-head trials comparing mRNA-1283 with COVID-19 BNT162b2 vaccine currently exist.

OBJECTIVE: This analysis aimed to compare the effectiveness of bivalent vaccines mRNA-1283 and BNT162b2.

METHODS: A comprehensive feasibility assessment of an indirect treatment comparison (ITC) was conducted, including a structured targeted literature review to identify published RCTs and real-world evidence (RWE) studies comparing the bivalent mRNA-1273 and BNT162b2 vaccines. A large retrospective RWE study, Kopel et al. 2023, which compared the relative vaccine effectiveness (rVE) of mRNA-1273 and BNT162b2, was identified as suitable for performing an anchored ITC using the Bucher method, with mRNA-1273 as the anchor. The analysis was conducted for different age groups, and sensitivity analyses with alternative outcome definitions were performed.

RESULTS: A comparison of the study designs of NextCOVE and Kopel showed they were comparable to support a robust ITC despite cross-study differences (e.g., study type, geographic regions, time periods, duration of follow-up, vaccination and infection history, and COVID-19 definitions). Based on the Bucher method, the main analyses showed that among participants aged ≥18 years, the rVE against symptomatic COVID-19 of mRNA-1283 vs. BNT162b2 was 15.3% (95% CI: 4.7-24.8%, p = 0.003). In the ≥65 age group, the rVE was 22.8% (95% CI: 3.7-38.1%, p = 0.011). Multiple sensitivity analyses confirmed the robustness of these estimates.

CONCLUSIONS: This ITC demonstrated consistently that next-generation mRNA-1283 is statistically significantly more effective in preventing symptomatic COVID-19 than BNT162b2, with the greatest effect among those aged ≥65. Cross-study differences introduce complexities that must be considered when interpreting these results, but consistent findings across multiple sensitivity analyses suggest the results are robust. These data can help inform policymakers, providers, and payers in decision-making and in recommending COVID-19 vaccination.

SPONSORSHIP: This study was sponsored by Moderna, Inc.

U11 Association of Copay Assistance Utilization with List and Net Price of Medicines

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BACKGROUND: Copay assistance programs can reduce patients' out-of-pocket costs for their medications. However, there is a belief that these programs may lead to higher medication prices. Despite this belief, there is limited real-world evidence on the association between copay assistance utilization and medication prices.

OBJECTIVE: To assess the correlation between copay assistance utilization and medication prices (list and net).

METHODS: Claims from the IQVIA Longitudinal Access and Adjudication Data (LAAD) were assessed for immunology medications from 2018 to 2023. To be included, patients had to have 3+ claims for the same medication in a given year and be under the age of 65 and commercially insured. Years in which generic or biosimilar options were available for a given medication were excluded to help isolate any effects on pricing to copay assistance. Copay assistance utilization was defined as the proportion of patients using a copay card on any claim in a given year for a given medication out of the overall number of patients prescribed that medication in that year. Medication prices, including annual wholesale acquisition cost (WAC, used as list price) and estimated net prices, were obtained from SSR Health. To standardize across products, annual percentage changes in medication prices were calculated. Correlations between prior-year copay assistance utilization and annual percentage change in medication prices (list and net) were estimated by calculating Spearman's rank correlation coefficient.

RESULTS: Using claims from 396,162 patients prescribed 16 different immunology medications, copay assistance

utilization and average list price increased over time whereas average net price decreased. In 2023, no statistically significant correlation was observed between the copay assistance utilization of medications and their average list ($r = -0.15$, $p = 0.61$) or net ($r = -0.09$, $p = 0.77$) price in the same year. Further, no statistically significant correlation was observed between the annual percentage change in list ($r = 0.2$, $p = 0.12$) or net ($r = 0.04$, $p = 0.77$) price and the 1-year lagged annual change in copay assistance utilization, when all years were analyzed.

CONCLUSIONS: In an analysis of claims of immunology medications, no correlation was seen between prior-year copay assistance utilization and change in list or net price, suggesting that copay assistance utilization may not drive subsequent changes in prices. More research that examines this association in other therapeutic areas and types of medicines is needed.

SPONSORSHIP: Genentech, Inc.

U12 Closing the gap? Comparison of Medicare-negotiated maximum fair prices with European drug prices

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BACKGROUND: Enacted in 2022, the Inflation Reduction Act (IRA) includes provisions to reduce Medicare spending through inflation price caps, Part D redesign, and direct price negotiation with manufacturers. The negotiated prices (maximum fair prices) for the first 10 Part D drugs will take effect in 2026 and include discounts ranging from 38% to 79% compared with 2023 prices. However, the full impact of the IRA on US drug pricing and the potential effects of the IRA on European drug pricing remain unclear.

OBJECTIVE: To evaluate the impact of the IRA on both US and global drug pricing through a comparative analysis of drug pricing and generic availability in the US, UK, and EU4 (Germany, France, Italy, and Spain).

METHODS: Drug prices were retrieved from country-specific databases, and the availability of generics was reviewed through searches of regulatory websites. Monthly Medicare maximum fair prices in the US were compared with current prices in the UK and EU4.

RESULTS: For 9 of the 10 drugs with a maximum fair price (Januvia, Fiasp/NovoLog/NovoRapid insulin products, Farxiga/Forxiga, Enbrel, Jardiance, Xarelto, Eliquis, Entresto, and Imbruvica), US Medicare prices were still higher than all included European countries regardless of the availability of generic products. Stelara was the only drug for which the US Medicare maximum fair price fell below the price in any country (approximately 25% below the price in Germany and approximately 10% below that in Italy).

CONCLUSIONS: Despite substantial discounts provided by Medicare price negotiations, the maximum fair prices in the US remain higher than those in the UK and EU4, irrespective of generic availability.

SPONSORSHIP: OPEN Health

U13 Impact of self-funded versus fully insured commercial health plans on patient drug liability

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BACKGROUND: Several states are considering policies to address concerns on patient affordability of drugs, including examining the impact of health plan benefit design. Commercial health plans typically fall into one of two categories: fully insured (FI) plans (state-regulated) and self-funded (SF) plans (federally regulated). Employers who choose to self-fund have more control over their benefits; however, little is known on how benefit designs and cost sharing differ between SF and FI health plans.

OBJECTIVE: Describe differences in benefit design and resulting patient drug liability for SF vs FI plans.

METHODS: A retrospective analysis of pharmacy and medical claims (2018-2022) for patients on select drugs in the IQVIA PharMetrics Plus database was conducted to assess patient liability and cost sharing types (copays, deductibles and coinsurance). Twenty drugs used to treat rheumatoid arthritis, psoriasis, multiple sclerosis, and cancer were included based on the list of those eligible for review by state prescription drug affordability boards. NDC codes were grouped by drug and dosage strength. Patients were required to have at least 3 claims throughout a calendar year for a unique drug-NDC grouping and be continuously enrolled in an SF or FI plan throughout at least one calendar year to be included in the study. Two-part models consisting of a logistic regression for the likelihood of non-zero patient drug liability and a log-linked gamma regression for non-zero patient drug liability were used, with plan type (SF or FI) as the exposure of interest and adjusted for baseline characteristics.

RESULTS: 174,761 patients were included, with 62% of patients in FI health plans. SF plans had a 1.7 greater odds of having copays (OR 1.73 [1.69, 1.77]) but a 33% lower odds of having coinsurance (OR 0.67 [0.65, 0.69]). SF plans were more likely (OR 1.79 [1.72, 1.86]) to have non-zero patient drug liability compared with FI plans; however, claims with non-zero

patient drug liability were 21% (20%, 22%) less compared with FI plans. The effect of being enrolled in an SF plan on patients' total annual drug liability was a $245 (95% CI: $227 to $262) decrease relative to those enrolled in an FI plan. Per the mean annual patient drug liability of $1500 in the cohort, this represents a 16% decrease in patient drug liability.

CONCLUSIONS: FI (state-regulated) health plans are associated with less generous cost-sharing benefit designs; thus, there is an opportunity for state-level benefit design reform legislation to improve patient affordability and increase equitable benefit designs between health plan types.

SPONSORSHIP: Genentech, Inc.

U14 Understanding health care decision-maker sentiments: Using natural language processing to predict formulary coverage outcomes

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BACKGROUND: Sentiment analysis, a natural language processing (NLP) technique, evaluates whether textual data convey a positive, negative, neutral, or mixed sentiment. While NLP has been used extensively in e-commerce and other areas, limited research has explored whether health care decision-maker (HCDM) sentiments about a product can predict formulary coverage outcomes.

OBJECTIVE: To use NLP to classify HCDM perceptions on the clinical efficacy (N = 8,696 responses), economic value (N = 8,548 responses), and patient value (N = 8,695 responses) of Food and Drug Administration (FDA)–approved products and evaluate how well these sentiments predict the following formulary coverage outcomes: formulary priority level and formulary preference.

METHODS: Open-ended HCDM survey responses from FormularyDecisions surveys were collected between June 16, 2022, and June 16, 2024, to obtain feedback on the following attributes of FDA-approved products: clinical efficacy, economic value, and patient value. NLP classified responses on these attributes as positive, negative, neutral, or mixed sentiment. Further data analysis assessed how each attribute's sentiment type influenced a product's formulary coverage outcomes and which attribute's overall sentiment distribution was most predictive of formulary coverage outcomes.

RESULTS: Regression analyses suggested that the sentiment type for clinical efficacy, economic value, and patient value significantly predicted formulary priority level and formulary preference ($p < 0.05$). Specifically, the mixed sentiment type, relative to neutral, for all 3 product attributes was the strongest predictor of more favorable formulary priority level and formulary preference. Among the 3 attributes' overall sentiment distribution, the patient value model had the best fit in predicting formulary coverage outcomes; however, the low McFadden pseudo R-squared values for all attributes' sentiment distribution models indicated limited ability to predict formulary coverage outcomes.

CONCLUSIONS: HCDM responses with mixed sentiments on a product's clinical efficacy, economic value, and patient value were associated with more favorable formulary coverage outcomes. Mixed sentiments, reflecting a more balanced assessment of a product, could serve as a potential indicator for formulary coverage, pending further validation. However, the limited model fit for all attributes' sentiment distribution suggested the involvement of additional factors influencing formulary coverage outcomes, highlighting the need for further research.

SPONSORSHIP: Cencora

U15 Subsequent Indications in Personalized Medicine: Potential Implications of the Drug Price Negotiation Program on Clinical Development

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BACKGROUND: Recent research suggests the Inflation Reduction Act's (IRA) Drug Price Negotiation Program (DPNP) may reduce incentives for drug manufacturers to invest in post-approval clinical trials exploring subsequent drug indications. The potential impact on personalized medicines (PMs), which target specific biological markers to guide individual treatment across therapeutic areas for narrower patient populations with unmet needs, remains unexplored.

OBJECTIVE: Describe the clinical development landscape for therapeutic PMs between 2014 and 2019 and illustrate the potential unintended consequences of the 2022 IRA DPNP on manufacturer investment toward subsequent indications.

METHODS: This cross-sectional analysis evaluated PMs approved as new molecular entities (NMEs) or through Biologic License Applications (BLAs) by the Food and Drug Administration (FDA) from 2014 to 2019. A list of PMs was compiled from the Personalized Medicine Coalition's annual reports, while FDA approval event data were sourced from Citeline Pharmaprojects. For each drug, we recorded the dates of initial and subsequent approvals. The timing of subsequent indications relative to a drug's initial FDA approval and the approval immediately preceding it (e.g., from 1st to

2nd subsequent indication) were calculated for each of a PM's first five subsequent indications.

RESULTS: From 2014 to 2019, the FDA approved 261 NMEs, of which 252 (96.6%) were therapeutic NMEs. Of the therapeutic NMEs, 80 (31.7%) were PMs. Of these, 52 (65.0%) were multi-indication PMs with one or more subsequent indications approved, and 61 (76.3%) were small-molecule drugs. The median time between FDA approvals for indications was highest between the first and second subsequent indication at 2.2 years (IQR: 1.2, 3.7). Across all multi-indication PMs, the median time to the most recent approval for a subsequent indication was 4.9 years (IQR: 3.0, 7.0). Approximately one-quarter (23.7%) of multi-indication small-molecule drugs were approved for their most recent subsequent indication after the time when they would be DPNP-eligible.

CONCLUSIONS: To date, most PMs are small molecules, making them subject to earlier DPNP selection. A substantial portion of a drug's indications are identified post-approval, often years after initial approval. The IRA alters the landscape of economic incentives for multiple indications by accelerating anticipated price erosion, previously associated with loss of patent exclusivity. These findings suggest that the development of subsequent indications for PMs may be at risk under the DPNP, potentially impacting future innovation.

SPONSORSHIP: None

U16 Assessing the impact of socioeconomic disparities on access to immuno-oncology treatments

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BACKGROUND: Cancer immuno-oncology (IO) use has expanded across tumor types; however, disparities persist in patient access to care across the United States.

OBJECTIVE: To understand the association of disparities in socioeconomic factors and social determinants of health (SDoH) on patient access to IO treatment for advanced renal cell carcinoma (aRCC), metastatic non–small cell lung cancer (mNSCLC), metastatic melanoma (mMEL), and advanced colorectal cancer (aCRC).

METHODS: This retrospective cohort study was conducted from January 2012 to March 2023. Patients in this analysis were diagnosed with aRCC, mNSCLC, mMEL, or aCRC. Final analysis included patients diagnosed after earliest FDA approval of nivolumab; patient index periods differed by tumor type. Data were extracted from the Optum Research database linked to socioeconomic status, SDoH, and prior authorization databases. Study variables were analyzed with descriptive statistics. Overall survival was estimated with Kaplan-Meier analyses. Predictors of receipt of IO were identified with multivariable analyses by tumor type.

RESULTS: In total, 32,500 patients were eligible (mNSCLC, 41%; aCRC, 37%; mMEL, 13%; aRCC, 9%), with 46% of patients at any academic center and 48% at any non-academic center (missing center data in 6%). Median overall survival was significantly longer in patients who received IO vs those who did not (P<0.001). Overall, the distributions of SDoH were generally similar across tumor types. Per multivariable-adjusted analysis of each tumor type, race, ethnicity, and age were not important predictors of access to IO. Greater distance from treating provider resulted in lower access to care in patients with mNSCLC (odds ratio [OR], 0.79; 95% confidence interval [CI], 0.71-0.88; 5 to <10 miles); a consistent trend was seen across other tumor types. Increased number of comorbidities was associated with lower odds of receiving IO in patients with aRCC and mNSCLC. Medicare Advantage Part D patients were less likely to receive IO vs commercially insured patients for aRCC (OR, 0.69; 95% CI, 0.52-0.90), mNSCLC (OR, 0.69; 95% CI, 0.60-0.80), mMEL (OR, 0.53; 95% CI, 0.42-0.68), and aCRC (OR, 0.76; 95% CI, 0.65-0.89).

CONCLUSIONS: This study revealed significant predictors of decreased access to IO therapy across several tumor types, particularly distance from the treating provider. The introduction of subcutaneous IO formulations may provide an alternative option for patients with challenges in receiving optimal treatment.

SPONSORSHIP: Bristol Myers Squibb.

U17 Evaluating Medicaid brand-over-generic formulary strategies following the AMP cap removal

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BACKGROUND: The American Rescue Plan Act of 2021 removed the 100% average manufacturer price (AMP) cap for Medicaid rebates, effective January 1, 2024. Manufacturers are now required to pay the full additional rebate amount for drugs whose AMP has significantly outpaced the rate of inflation. Several manufacturers lowered the list price of established brand medications in late 2023 and early 2024.

OBJECTIVE: To estimate the change in Medicaid statutory rebates due to list price reductions and to identify any changes to brand-over-generic strategies to state Medicaid formularies.

METHODS: First Data Bank was used to identify brand drugs whose wholesale acquisition cost (WAC) decreased by at least 30% in December 2023 or January 2024. Medicaid statutory rebates were estimated for 2023 Q1 and Q2 and 2024 Q1 and Q2 by adding the basic rebate to the inflationary penalty, if applicable. Brand drugs without manufacturer-reported U.S. net sales or without generic or biosimilar competition in 2023 H1 were excluded. State Medicaid formularies from 2023 and 2024 for the 10 states with the largest Medicaid health care expenditures and a unified preferred drug list were reviewed for brand-over-generic strategies.

RESULTS: Twelve brand product lines with list price reductions were identified. Of those, five met criteria for inclusion: Advair (Diskus and HFA), Symbicort, Humalog (U-100 and 75-25 mix), NovoLog (U-100 and 70-30 mix), and Lantus. For all product lines, the estimated Medicaid statutory rebates decreased from 95% of WAC (i.e., the AMP cap) in 2023 to less than 80% of WAC in 2024; four of the five product lines decreased to less than 60% of WAC. All brand drugs within the included product lines maintained their coverage status on all 10 state Medicaid formularies from 2023 to 2024.

CONCLUSIONS: Despite a decrease in estimated Medicaid statutory rebates following list price reductions, no changes to the brand-over-generic strategies of the 10 reviewed state Medicaid formularies were identified.

SPONSORSHIP: IPD Analytics

U18 Split Decisions: Assessing Large Language Model Efficacy in Simulating P&T Committee Dynamics and Decision-Making Processes

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BACKGROUND: The Pharmacy and Therapeutics (P&T) committee is responsible for managing an organization's drug formulary system, and decisions are based on each member's vote. Committee dynamics vary between organizations based on member composition, plan design, number of covered lives, and insurance segment. The unpredictability of potential pitfalls during the formulary decision-making process often leaves manufacturers unable to address them until a financial impact is already felt. Preparation for P&T discussions can be very time-consuming and requires forethought to predict and manage challenges from various stakeholders.

OBJECTIVE: To evaluate the capabilities of a large language model (LLM) to simulate a P&T committee discussion and provide actionable insights.

METHODS: Cencora's internal proprietary generative artificial intelligence platform was used to create a P&T committee meeting simulation. The platform allows for custom configurations (personas) and leverages a privately deployed instance of OpenAI's GPT-4o. For this evaluation, we developed the persona Split, capable of simulating distinct perspectives for P&T meeting simulations.

RESULTS: The LLM generated committee discussions with 10 comments from each member, a summary, and a recommendation from the chair that aligned with the consensus from the dialogue. The response time was quick, with each simulation taking 1-2 minutes to generate. Members maintained assigned personality attributes and offered perspectives consistent with designated traits. The simulation was cost-efficient, with the LLM less than $1 per month per active user. Limitations included virtual personas having difficulty contributing opinions that directly addressed previous statements from other members during disagreements. Contributions were sometimes limited by subject matter expertise and professional background, and clinical subtleties were not consistently considered by all members when necessary.

CONCLUSIONS: P&T committee simulations can potentially enhance the efficiency of the process by providing insights and recommendations to committee members more quickly. They can also help manufacturers predict formulary decisions at any point in the drug's lifecycle. Further research is needed to explore how LLMs can impact decision-making across various health organizations. As stated herein, the evaluation was supported by Cencora's proprietary AI platform, which was used in accordance with Cencora's AI policies, and reviewed by a human.

SPONSORSHIP: None

U19 Real-world disease burden and health care resource utilization for patients with Barth syndrome throughout their lifespan

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BACKGROUND: Barth syndrome (BTHS) is a rare X-linked genetic disorder with an estimated prevalence of approximately 1 in 1,000,000 male births. The US Food and Drug Administration has accepted a New Drug Application, supported by positive clinical trial data, for elamipretide in patients with BTHS. To support reimbursement following regulatory approval, the economic evaluation of

elamipretide will become necessary. However, compiling such data for ultra-orphan drugs is difficult.

OBJECTIVE: We assessed real-world data on health care resource utilization extrapolated from patient cases in the medical literature to increase our understanding of the cost of BTHS based on its burden of disease and health care resource utilization in patients.

METHODS: A search of the published medical literature (PubMed) and patient reports and abstracts/presentations (Google) identified individual case studies used to assess the burden of disease and potential cost of BTHS throughout a patient's lifespan. Key buckets of health care expenditures (i.e., medical procedures, interventions, medications, hospitalizations, and outpatient visits) were identified from the cases. Real-world disease burden and health care resource utilization for infant, adolescent, and adult patients with BTHS were summarized.

RESULTS: Most affected individuals with BTHS presented with symptoms in infancy, including cardiac issues (specifically cardiomyopathy), skeletal muscle and eating disorders, neutropenia, and prepubertal growth delay. The BTHS diagnostic journey for patients with BTHS is difficult, with the majority of patients having not been diagnosed until after the development of cardiomyopathy or until a family member is diagnosed, even in symptomatic patients. Of the living individuals known to have BTHS, a high proportion experience heart failure, with some requiring heart transplantation. One patient, who died at 28 years of age, had 47 hospitalizations (total of 564 days), 57 procedures under anesthesia (including gastrostomy, defibrillator implantation, and bone marrow aspiration), 16 central lines, weekly physician appointments, multiple daily medications, and tube feedings. Many patients have comorbid anxiety that requires treatment due to the BTHS diagnosis.

CONCLUSIONS: Health economic evaluations for rare diseases are scarce. With a noteworthy absence of pharmacoeconomic evidence, a review of the published case report data for patients with BTHS from the medical literature effectually demonstrates that it is a costly disease associated with high disease burden and excessive health care resource utilization.

SPONSORSHIP: Stealth BioTherapeutics

U20 Optimize Member Engagement in a Managed Care Setup: A Real-World Data–Driven, Member Persona–Based Solution to Enhance Care Coordination Between High-Risk Members and Care Managers

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BACKGROUND: Targeted care management for high-risk managed care members (acuity levels exceeding 4) is associated with substantial costs of critical care. However, implementing improved care services can reduce hospital visits by nearly 11% and, in turn, decrease Medicare spending by approximately 6% for high-risk enrollees. Our exploratory work (not published) has revealed low engagement rates between members and care managers. This may be attributed to inconsistencies in contact details and challenges in providing timely responses. Additionally, our findings indicate that care outreach often lacks the empathy and support that these members require.

OBJECTIVE: To improve member engagement and support from care managers in a cohort of high-risk enrollees by implementing targeted care management interventions.

METHODS: Member enrollment data for nearly 3.1M members and medical claims between Jan 2021 and Jun 2024 were analyzed. We included members unreachable by phone or chat, those who had no digital footprints, and non-participants in company surveys during a managed care episode. A model was developed using member contact information provided at enrollment, and all previous responses to digital outreaches. These data points were analyzed using an algorithm to determine the optimal time and method to reach each member. The algorithm placed greater importance on recent responses to predict members' preferred communication channels and timing for contact. In addition, various datasets including clinical history, engagement patterns, social determinants of health (SDOH), and member demographics were utilized to ensure personalization and customization for individual members. By identifying relevant cohorts of member groups within the data, care managers were able to tailor messaging for improved engagement.

RESULTS: The engagement rate for high-risk enrollees has experienced a notable uplift of 17%, surpassing the initial rate of 40%, while engagement for young adults (≤25) rose to 50%. Furthermore, around half of the targeted critical members were able to establish timely contact with their

care managers within 45 days, enabling proactive interventions and effective care coordination.

CONCLUSIONS: By tailoring messages to individual member personas, engagement levels improved considerably. A key factor in the program's success is the customization of interventions to meet specific member needs, along with ongoing engagement through effective communication channels. This approach enables members to better manage their conditions, leading to reduced hospitalizations in terms of both frequency and severity.

SPONSORSHIP: Optum

U21 AI-Assisted Medication Management Platform for Hyper-Polypharmacy Patients to Reduce Health Care Expenditure in the US

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BACKGROUND: Polypharmacy and hyper-polypharmacy are defined as the concurrent intake of ≥5-9 and ≥10 medications, respectively. Both have been associated with poor health outcomes in older adults and at-risk younger individuals and cost at least $50 billion to the US health plan. More than 40% of the patients aged ≥65 years can be categorized as either polypharmacy or hyper-polypharmacy. More than half of these senior patients develop adverse drug reactions (ADRs), leading to considerable expenses, and can be associated with up to 30% of hospitalizations. Leveraging AI-assisted platforms to identify at-risk patients can improve patient outcomes and can reduce ADR-associated treatment costs.

OBJECTIVE: We compared the ability of an AI-assisted medication management platform with a conventional approach to identify at-risk hyper-polypharmacy patients from the US and to determine their impact on costs associated with ADR treatment.

METHODS: De-identified patient data from Optum Market Clarity database were utilized to identify patients aged ≥65 years, who received ≤5 prescription medications between January 1, 2023, and December 31, 2023, for ≥120 days. Both conventional and AI-assisted approaches were utilized to identify the patients. Demographics, prescription medications, ADRs, emergency room (ER) visits, hospitalizations, and associated costs were assessed to evaluate the effectiveness of the two approaches. Treatment costs were determined by implementing intervention programs on identified populations.

RESULTS: A total of 26,277 patient records were included in the study. The AI approach not only efficiently identified patients with hyper-polypharmacy but also identified the patients who were at a higher risk of ER admission. Further, around 80% of hyper-polypharmacy patients identified by the AI approach were unique and were not identified by the conventional approach. Patients identified by the AI-assisted approach exhibited up to a 6% reduction in hospitalization rates, and a 2.6 times reduction in ER visits due to ADRs, when compared to conventional approach patients.

CONCLUSIONS: The AI-assisted platform demonstrated a reduction in both ER visits and hospitalizations, leading to significant cost savings. The AI-assisted approach could effectively identify at-risk hyper-polypharmacy patients in advance, thereby mitigating negative health outcomes. Consequently, payers can anticipate substantial savings by reducing health care utilization through the implementation of this innovative platform.

SPONSORSHIP: None

Z00-Z99 Factors Influencing Health Status and Contact With Health Services

Z1 Formulary coverage for recently approved 505(b)(2) drugs at leading commercial plans

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BACKGROUND: Drugs approved under a 505(b)(2) new drug application (NDA) may be a new chemical entity such as a prodrug. They may also be approved drugs with changes made to aspects such as dosage form, route of administration, dosing regimen, strength, or formulation. 505(b)(2) drugs are not considered generics and not regarded as therapeutically equivalent to products with the same active ingredient in the Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book). Attitudes about 505(b)(2) drugs vary among different managed care decision makers.

OBJECTIVE: Quantify formulary coverage of 505(b)(2) drugs at leading commercial plans. Identify differences in coverage between plans and also between standard and priority review drugs.

METHODS: We researched Food and Drug Administration (FDA) approvals and identified pharmacy benefit, 505(b)(2) drugs with proprietary names that were approved in 2023. We accessed Decision Resource Group's Fingertip Formulary to determine the formulary status at the top 10 non-government commercial plans.

RESULTS: In 2023, FDA approved fifty-eight 505(b)(2) drugs. Thirty-two new 505(b)(2) drugs had proprietary names (brand names) that were different from their established names (generic names). Fourteen of these drugs were pharmacy benefit drugs that appeared in the Fingertip Formulary database. These include Alvaiz (eltrombopag tablets), Atorvaliq (atorvastatin), Austedo XR (deutetrabenazine), Cabtreo (clindamycin phosphate, benzoyl peroxide, and adapalene), Coxanto (oxaprozin), Iwilfin (eflornithine) , Likmez (metronidazole), Liqrev (sildenafil), Lodoco (colchicine), Motpoly XR (lacosamide), Opvee (nalmefene HCL), Rextovy (zavegepant), Vevye (cyclosporine), and Zituvio (sitagliptin). Overall commercial plan coverage for 505(b)(2) drugs was 42%. For 505(b)(2) drugs that received priority review status from FDA, commercial plan coverage was higher at 57%. Coverage of 505(b)(2) drugs varied widely between plans. One plan covered 100% of 505(b)(2) drugs. Two other plans covered 7% of 505(b)(2) drugs. These 2 plans did not cover any of the priority review drugs involved.

CONCLUSIONS: Most of the top commercial plans covered 505(b)(2) drugs that received priority review from FDA. Overall, less than half of 505(b)(2) drugs were covered by the top commercial insurers. Stronger supporting evidence for formulary inclusion of 505(b)(2) drugs may be needed.

SPONSORSHIP: None

Z2 Evaluating the impact of a training-based program on social determinants of health for health care professionals

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BACKGROUND: Social determinants of health (SDOH) are non-medical factors that significantly influence patients' health outcomes. SDOH include factors such as economic stability, education, health literacy, and access to quality health care. Suboptimal health literacy can lead to poorer health outcomes and higher mortality rates. As such, training health care professionals (HCPs) on SDOH is essential in reducing disparities and improving patient outcomes. Integrating SDOH training into continuing health care education enhances HCPs' abilities to address diverse patient needs and promotes health equity, especially among marginalized populations.

OBJECTIVE: The primary objective of this study was to evaluate the impact of training HCPs on SDOH at 4 clinical practice sites in Florida and Puerto Rico using validated Agency for Healthcare Research and Quality (AHRQ) Health Literacy tools.

METHODS: This was a 9-week training program conducted over Zoom, with 8 weekly lunch-and-learn didactic workshops and targeted focus sessions during the final week. The AHRQ's interactive training modules titled "SHARE Approach Workshop" were used to teach HCPs strategies to integrate shared decision making and effective interpersonal communication strategies into their everyday clinical practice. Participants completed pre-post surveys assessing demographics and awareness of SDOH principles. Significance was set at $p < 0.05$ and Cytel's Xact software package was used for statistical analyses.

RESULTS: A total of 27 HCPs (including case managers, nurses, pharmacists/interns, physicians, and social workers) completed both pre-post surveys. Descriptive statistics showed 85.2% of participants were female, and 63.0% were ≤40 years old. One-third (33%) of participants were White, 18.5% Black, and 37% Hispanic; 74.1% spoke English as their first language. Half were licensed for ≤5 years while 29.6% were licensed to practice for ≥16 years. Paired t-tests showed significant improvements post-training in implementing the SHARE approach ($p < 0.006$), patient-centered outcomes ($p < 0.035$), health-literate communication ($p < 0.030$), cultural competency ($p < 0.003$), and effective communication for patients with barriers ($p < 0.004$).

CONCLUSIONS: This study demonstrated the need to train HCPs on SDOH, further validated the SHARE approach as an effective educational tool, and recognized challenges associated with different clinical practice environments and regions. Participants showed significant improvement in patient-centered outcomes, health-literate communication, and cultural competency.

SPONSORSHIP: AMCP Foundation/Takeda Pharmaceuticals

Z3 Evaluation and comparison of traditional approaches versus machine learning techniques for assessing resource utilization among polypharmacy members using real-world data

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BACKGROUND: Several studies have been published to assess resource utilization among polypharmacy members but lack comparison of rule-based approaches compared to machine learning (ML) approaches with integrated data.

This study aims to evaluate resource utilization among polypharmacy members by comparing traditional methods with machine learning algorithms.

OBJECTIVE: Evaluate resource utilization among polypharmacy members by leveraging integrated data, utilizing both rule-based algorithms and ML-based predictive analytics.

METHODS: Members were identified using two linked administrative claims databases—pharmacy and medical—covering the period from July 1, 2022, to December 31, 2023. Two XGBoost models were developed to identify members at risk for (a) polypharmacy and (b) ER visits. Members were compared with a rule-based approach using criteria: age ≥18 years and ≥5 chronic medications filled in the last 120 days.

RESULTS: A total of 170,976 members were identified and stratified into three categories: poly minor (38%), poly major (18%), and hyper polypharmacy (45%). The key features included sociodemographic details (e.g., gender, age), co-morbid conditions (e.g., cardiovascular disease, hyperlipidemia, pain and inflammation), and medication-related factors (e.g., days' supply, chronic medication use). Subsequently, another model was developed to predict the risk of events (ER visits or hospitalizations), which identified 33% (n = 4,373) of poly minor, 18% (n = 2,378) of poly major, and 48% (n = 6,321) of hyper polypharmacy members at risk. Notably, 79% of members were not identified with the rule-based approach, resulting in identification of 4,976 additional hyper polypharmacy members. Members had 36% and 49% higher medical spend compared to those identified by rule-based approach. Based on model, average ER visits and hospitalizations were 85.4% vs. 85.5% and 13.8% vs. 21.2% among the poly major and hyper poly population, respectively. The model demonstrated an accuracy of 0.92, a precision of 0.85, and a ROC-AUC of 0.96 for both the hyper polypharmacy and poly major cohorts.

CONCLUSIONS: The ML-based approach has shown promising results in identifying high-risk polypharmacy members with the addition of integrated medical data. In future studies, analysis coupled with medical data would be ideal to identify the highest-risk members to reduce resource utilization costs and to improve health outcomes. However, further research on larger datasets is necessary to generalize these findings.

SPONSORSHIP: None

Z4 Assessment of Clinical Characteristics and Resource Utilization in Members with Polypharmacy within a Commercially Insured Population

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BACKGROUND: While polypharmacy is often necessary for individuals managing multiple complex health conditions, it also poses significant risks, such as adverse drug reactions, increased hospitalizations, and higher health care costs. Understanding these risks is crucial for comprehensive assessment of polypharmacy's impact on resource utilization within health care systems and for reducing cost.

OBJECTIVE: Assess the impact of polypharmacy on resource utilization using Real-World Data.

METHODS: For this analysis, members were identified using two administrative claims databases—pharmacy and medical—covering the period from January 1 to June 30, 2023. A unique key was used to map both databases. Members aged 18 years and older were included. Descriptive analysis was conducted to assess the demographic and clinical characteristics of these members.

RESULTS: A sample of 330,000 members were identified, of which 20,614 members were identified with polypharmacy (defined as taking more than five medications) for at least 120 days. These members were further categorized into hyper polypharmacy (more than 10 drugs) and polypharmacy major (five to nine drugs). The mean age of the members was 51 years, with 52% being female. On average, each member used nine medications, and 20% were on high-risk medications, 52% with mental health medications, and 68% were on medications that could induce falls. The top five conditions among polypharmacy members were hypertension (61.3%), type 2 diabetes mellitus (26.7%), hyperlipidemia (18.1%), sleep apnea (16.8%), and upper respiratory infections (15.9%). Resource utilization was as follows: 91-96% for office visits, 11-18% for ER visits, and 3-6% for hospitalizations among poly major and hyper poly members, receptively. There were 85% of polypharmacy members with inpatient stays up to 1-5 days and 35% with inpatient stays up to 6-15 days.

CONCLUSIONS: Most of the individuals identified with polypharmacy were middle-aged and above having multiple chronic conditions. Higher resource utilization was observed among polypharmacy members compared to those without polypharmacy. This highlights the need for intervention programs targeting at-risk members to facilitate deprescribing and reduce avoidable hospitalizations.

SPONSORSHIP: None.

Z5 A Descriptive Study of Medication Adherence within a Full Coverage Value-Based Insurance Design Versus a Traditional Benefit Design for Marketplace Plan Members in the Intermountain Region

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BACKGROUND: As health care costs continue to rise, medical and pharmacy benefit managers must find innovative, meaningful ways to manage health care expenses effectively. Like the plan benefits mandated by the Affordable Care Act (ACA) for preventive products and services, some health plans have decided to implement a more comprehensive plan benefit under its Value-Based Insurance Design (VBID). Health plans with this unique VBID allow its members to access a wide array of high-value chronic medications pre-deductible with at least partial coverage, with the intent of stimulating a healthier population and reducing financial burden on health care systems. However, more studies assessing the impact of full coverage VBID (fcVBID) on medication adherence and overall health care costs are needed.

OBJECTIVE: To observe the impact of fcVBID on the medication adherence of chronic medications, as measured by proportion of days covered (PDC), compared to traditional benefit design for Marketplace plan members.

METHODS: This descriptive study used pharmacy administrative claims data from two regional health plans' Marketplace members enrolled between 1/1/2022 and 12/31/2023. The study included all chronic medications intended for long-term use covered under fcVBID. Drugs covered under ACA, which are also available pre-deductible at zero cost to members, were excluded due to risk of confounding. Additionally, insulins and rescue inhalers were excluded to mitigate risk for inaccurate adherence data due to their inherent fluctuation in usage and dosage. PDC was the primary outcome measure compared for each study arm that was further stratified by drug class.

RESULTS: PDCs for fcVBID versus traditional benefit design were as follows: Overall – 78% vs 68%; CGM Sensors – 92% vs 85%; Antiasthmatics – 69% vs 67%; Anticoagulants/Antiplatelets – 89% vs 83%; Antihypertensives – 83% vs 73%; Antihyperlipidemics – 87% vs 79%; Antiarrhythmics – 89% vs 83%; Antidepressants – 84% vs 76%; Bisphosphonates – 87% vs 80%

CONCLUSIONS: The expansive fcVBID plan benefit that allows plan members better access to essential chronic medications seems to be positively correlated with a more compliant population. Plan members receiving the fcVBID benefit were shown to have greater adherence across all chronic drug categories compared to members with a traditional benefit design. To better understand the value of fcVBID plan benefits and the implications for outcomes, additional studies comparing total drug and medical costs are needed.

SPONSORSHIP: None

Z6 Managed Care Perspectives and Health Plan Best Practices in Food Allergy Management: AMCP Market Insights Program

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BACKGROUND: Food allergies affect approximately 8% of the U.S. population and management typically involves dietary restrictions, emergency preparedness, and treating accidental exposures. While avoiding allergens is crucial, newer treatments such as omalizumab and peanut allergen oral immunotherapy (OIT) can reduce the response to one or more allergens following accidental exposure. However, the costs and complex dosing regimens for treatments can pose significant challenges for both patients and payers.

OBJECTIVE: To gain insights from a multi-phase program focused on identifying health plan best practices for managing immunoglobulin E (IgE)–mediated food allergies. The research explored the evolving landscape of food allergy management, particularly in relation to newly approved biologic treatments.

METHODS: A three-step program approach included (1) a national survey of managed care professionals, (2) in-depth interviews with managed care experts, and (3) a virtual roundtable discussion of findings with a clinical expert and managed care experts. Survey respondents were required to declare knowledge of and influence over formulary and/or other clinical management decisions for medications in their organization to participate. The managed care experts were chosen for their professional roles and diverse expertise in food allergy management.

RESULTS: From the 6 interviewed managed care professionals and 61 responses to the national survey, eight health plan best practices were identified. Both phases 1 and 2 outlined a need for increased education on the mechanisms of IgE-mediated food allergies to guide clinical and policy decisions. Additionally, in phase 3, clinical and managed care professionals provided implementation details around the best practices including the development of evidence-based coverage policies for biologic therapies and ensuring emergency medications like epinephrine are accessible and affordable. There was also an emphasis on flexibility in policy implementation to reduce treatment barriers for patients while maintaining a focus on safety, efficacy, and cost-effectiveness.

CONCLUSIONS: These AMCP Market Insights program findings provide insights into the opportunities for managed care to support the development of clear, evidence-based coverage policies that can help ensure timely and appropriate treatment of IgE-mediated food allergies.

SPONSORSHIP: Genentech

Student Poster Titles and Presenters

B12 Determinants of HIV preexposure prophylaxis adherence and continuation among individuals with Texas Medicaid

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B13 Prevalence and correlates of alcohol use disorder diagnosis among HIV preexposure prophylaxis users with Medicaid

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B14 Antiretroviral therapy adherence after removal of the cost barrier

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B15 Longitudinal Trajectories of HIV Preexposure Prophylaxis Adherence and Their Association with Alcohol Use Disorder Treatment

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B16 Association Between Alcohol Use Disorder Diagnoses and HIV Preexposure Prophylaxis Adherence and Continuation

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B17 Infection Prevention and Control Staffing Across Free-Standing Hospitals and Multi-Facility Systems: Insights from a National Study

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C35 Impact of Race and Ethnicity on Outcomes in Patients with Hormone Receptor–Positive Breast Cancer Treated with CDK 4/6 Inhibitors

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C36 Adherence to recommended cardiac monitoring in breast cancer patients prescribed ribociclib

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C37 Analysis of current and future genetic testing for breast and ovarian cancer and its impact on patient care

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C38 Medical and Non-Medical Determinants of Cancer- and Cardiovascular-Related Mortality among Texas Residents with Cancer

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C39 Trends in Health Care Costs Over a Decade Among Patients with Cancer and Cardiometabolic Comorbidities

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C40 Efficacy of combined radioligand and systemic therapies in neuroendocrine tumors: a systematic review

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C41 Assessing health care costs and utilization trends among CAR T-cell therapy recipients

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D16 What are the mechanisms, efficacy, challenges, and future directions of CAR T-cell therapy in treating leukemia for patients with recurring cancer?

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D17 Identifying patient characteristics correlated with complement inhibitor treatment switch patterns in paroxysmal nocturnal hemoglobinuria

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D18 Comparative Analysis of Sickle Cell Anemia Medications for Use in Pediatric Patients

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D19 Potential Antisense Therapeutics for Multiple Myeloma

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D20 Real-world clinical outcomes of an adalimumab biosimilar transition program

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E36 A real-world comparative analysis of utilizers versus non-utilizers of glucagon-like peptide 1 receptor agonists among Medicare patients with type 2 diabetes mellitus

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E37 A retrospective review of background therapy utilization trends of cystic fibrosis (CF) patients initiating Trikafta (elexacaftor/tezacaftor/ivacaftor)

Patel M[1], *Needham C*[1], *Hoyceanyls R*[2], *Sourounis E*[3], *Perea R*[4], *Kachar B*[1], *Grover R*[1]; *Monali.Patel4@cvshealth.com*
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E38 Addressing the Missing Link in Comprehensive Care: Advocating for Psychotherapy as an Adjunct Treatment in Cachexia

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E39 Adherence and economic outcome evaluations of a value-based insurance design program in a Medicare Advantage plan population

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E40 Association of Social Determinants of Health (SDOH) with Primary and Cost-Related Medication Nonadherence Among Adult Patients with Diabetes

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E41 Descriptive analysis of health care outcomes and costs in type 2 diabetes: Evaluating continuous glucose monitoring and self-monitoring blood glucose among HealthPartners commercially insured members

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E42 Effectiveness of an information systems–driven, pharmacist-led program for optimizing glucagon-like peptide-1 receptor agonist utilization in ambulatory care

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E43 Effects of Medicare's insulin $35 cap on adherence rates

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E44 Evaluating the economic and health outcomes of continuous glucose monitors in diabetes management

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E45 Impact of a drug utilization review therapeutic duplication edit on glucagon-like peptide-1 medication utilization: Reducing overlap, ensuring appropriate therapy, and lowering costs in Medicaid and Marketplace populations

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E46 Impact of GLP-1 Receptor Agonists on Glycemic Control and Weight in Type 2 Diabetes: Real-World Evidence from a Retrospective Cohort Study

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E47 Impact of pharmacist management on glycemic control in patients with uncontrolled type 2 diabetes on insulin with personal continuous glucose monitors

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E48 Impact of various utilization management on per-member per-month spending for glucagon-like peptide-1 receptor agonists (GLP-1 RAs)

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E49 Marginal Health Care Expenditure Burden Among U.S. Civilian Noninstitutionalized Individuals with Type 2 Diabetes Mellitus: 2013-2022

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E50 Medication adherence for diabetes medications (MAD) quality measure and correlation to A1c and other diabetes measures in a Medicare Advantage population

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E51 Bexagliflozin: A Systematic Review of the Discovery, Mechanism, Metabolism, and Pharmacology

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E52 Comparison of clinical outcomes over 24 months in patients who discontinued GLP-1 RAs matched to patients who continued GLP-1 RAs

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E53 Changes in GLP-1 prescribing patterns for T2DM in response to American Diabetes Association guideline changes®

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E54 Group-based trajectory modeling to identify longitudinal patterns and predictors of adherence to concomitant triple therapy (oral antidiabetics, RAS antagonists, statins) in older adults under managed care

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E55 Investigating the mechanisms of microplastic exposure and endocrine-disrupting chemicals on male reproductive diseases

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E56 An evaluation of real-world persistence, adherence, and effectiveness of GLP-1 medications for treatment of overweight and obesity in a Medicaid population

Meyer K[1], *McVeigh M*[2], *Boss K*[3], *Chiara A*[4], *Pomfret T*[1], *Semmel K*[2], *Nicolas D*[5], *Bacon R*[1], *Alper C*[1], *Clements K*[6], *Lenz K*[2]; *katelyn.meyer3@umassmed.edu*
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E57 Assessing the Potential Impact of Scarce Resource Allocation Guidance on Prescribing of GLP-1 Medications Among Veterans for Weight Management in the Veterans Affairs (VA)

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E58 Effect of Concurrent Metformin Treatment on the Adherence and Persistence of Second-Generation Antipsychotics in Nondiabetic Patients

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E59 GLP-1 Utilization in Weight Management: An Analysis of Adherence, Persistence, and Outcomes by Sociodemographics

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E60 Off-label continuous glucose monitor use in a commercial population and its impact on anti-obesity medication utilization and weight loss surgeries: a retrospective analysis

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E61 Reconsidering Semaglutide Use for Chronic Obesity in Patients of Asian Descent: A Critical Review

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E62 Effect of Initial Combination Therapy vs. Step-Therapy on Adherence and Persistence in Drug-Naïve Type 2 Diabetes Patients

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E63 Evaluating Time to Treatment Intensification Among Drug Naïve Type 2 Diabetes Patients: A Comparison of Initial Combination Therapy vs. Step-therapy Approaches

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F23 Comparative costs, outcomes, and health care resource utilization among commercially insured members with opioid use disorder (OUD) for those with naloxone and without naloxone

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F24 Comparison of the clinical and economic outcomes between oral and injectable buprenorphine in patients with opioid use disorder

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F25 Patterns of Opioid and Benzodiazepine Prescriptions with or without Gabapentin in an Oklahoma Medicaid Population from 2020 to 2024

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F26 Comparative Efficacy of Talking Therapy and Medication in Schizophrenia: A Systematic Review

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F27 Assessing anticholinergic medication use in older adults by analyzing trends from 2023 patient and provider data

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F28 Unmanaged Depression and Chronic Disease Medication Adherence in Medicare Advantage Beneficiaries: A Novel Claims-Based Analysis

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F29 Assessing the Efficacy and Drug-Drug Interactions of Kava, Valerian, and Ashwagandha in Psychiatric Pharmacy Practice

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F30 Comparing the effectiveness of dopamine antagonists in the restoration of desensitized dopamine receptors due to technology overuse

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F31 Rate and Predictors of Mental Health Services Utilization Among Adults with Anxiety in the United States After COVID-19

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G32 A Systematic Review of Cholinesterase Inhibitors and Amyloid-Beta Pathway–Targeting Biologics in the Treatment of Early-Stage Alzheimer Disease

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G33 Utilizing predictive analytics to understand patient adherence to therapy within the pharmacy hub space

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G34 Calcitonin gene–related peptide gepants compared to monoclonal antibodies and their impact on health care resource utilization

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G35 Comparative analysis of prescribing patterns for narcolepsy in the U.S.: A focus on European guidelines

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G36 Prior Authorization Criteria Analysis for Chronic Migraine

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G37 Validating Gene Maps for Pathway and Target Discovery Using AlphaFold and Deep Learning Models

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G38 Medication adherence in myasthenia gravis: Exploring patient characteristics and treatment

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G39 Investigating the Role of KCNB1 Channel in Hypothalamic Function and Metabolic Regulation: Implications for Leptin Sensitivity and Obesity

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H9 Factors Associated with GLP-1 Receptor Agonist Utilization in Medicare Patients with Diabetic Retinopathy

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H10 Treatment Journey of Age-Related Macular Degeneration and Diabetic Macular Edema Patients: Analyzing Bevacizumab Persistence and Therapy Switching

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H11 Understanding Real-World Evidence for Safety, Efficacy, and Adherence of Anti–Vascular Endothelial Growth Factor in Wet Age-Related Macular Degeneration: A Scoping Review

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I17 Evaluation of the impact of a clinical pharmacist-led patient engagement program on cost savings

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I18 Comparison of 1-Year Costs Between Oral Antiplatelet Agents following ST-Elevation Myocardial Infarction Treated with Percutaneous Coronary Intervention

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I19 Marginal Health Care Expenditure Burden Among U.S. Civilian Noninstitutionalized Individuals with Heart Failure: 2018-2022

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I20 Uptake of guideline-directed medical therapy for heart failure with reduced ejection fraction and its impact on health care resource utilization in a commercially insured population

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I21 Impact of a mail-based intervention on adherence to direct oral anticoagulants among Medicare and Medicaid beneficiaries

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J12 Variability in Adherence to Biologics in the Treatment of Moderate to Severe Asthma

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J13 Analysis of the Impact of GLP-1 Receptor Agonists (GLP-1 RAs) on Asthma Medication Utilization on Members within a Commercial Population

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J14 Descriptive analysis of inhaled corticosteroid-formoterol utilization trends and the impact of wildfires on the asthma medication ratio

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J15 Impact of Value-Based Insurance Design on Primary Non-Adherence of Inhalers in Patients with Asthma and/or COPD in an Employee Health Plan

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K10 Comparative Health Care Costs of Biologics in Inflammatory Bowel Disease: Analyzing Standard vs Escalated Dosing Intervals of Adalimumab, Ustekinumab, and Vedolizumab

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K11 Comparative Effectiveness of Entecavir vs Tenofovir in Patients with Chronic Hepatitis B: A Systematic Literature Review

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L17 The Impact of Phototherapy in Atopic Dermatitis and Psoriasis: A Retrospective Claims Analysis

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L18 Psoriasis and psoriatic arthritis cross-sectional trends in treatment

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L19 Cost-effectiveness of a policy-based intervention to prevent melanoma in the United States

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M9 Examining Racial and Ethnic Disparities in Health Care Expenditure Among Older Adults with Arthritis in the United States

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M10 Toward Improving Adherence to Diet Therapy/Recommendations in Osteoarthritis Patients at National Orthopedic Hospital, Lagos, Nigeria

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M11 Exploring Quality of Life and Racial and Ethnic Disparities Associated With Joint Pain Burden in Older Individuals

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T2 Utilizing PET Imaging for Monitoring Off-Target Nanocarrier Accumulation and Enhancing Safety in Managed Cancer Care

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U27 AI-Driven Predictive Modeling to Identify High-Risk Diabetic Populations in Need of Mental Health Services

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U28 An Examination of Alternative Payment Models (APMs) and Access of Novel Oncology Products

Salih R[1], *Jash R*[1], *Patel D*[1], *Wong E*[2], *Quintero V*[3], *Jurasik T*[1], *Torres S*[3], *York J*[4]; *rks180@pharmacy.rutgers.edu*
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U29 Analysis of monoclonal antibody DDC product advancement in the last 18 years to optimize drug development design in order to enhance patient access, adherence, and therapeutic benefit

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U30 Anticholinergic polypharmacy: A deprescribing program to improve safe medication use in older adults

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U31 Artificial intelligence–driven optimization of medical versus pharmacy benefit strategies for cost efficiency

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U32 Assessing Knowledge, Attitudes, and Willingness to Prescribe Biosimilars Among Texas Health Care Providers: Identifying Educational Needs

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U33 Assessing Return on Investment of SGLT2 Inhibitors and GLP-1 Agonists: A Descriptive Analysis on Utilization

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U34 Assessing the effectiveness of telephonic and printed patient education materials on medication adverse event reporting and therapy discontinuation

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U35 Association of a therapeutic interchange program on medication adherence among Medicare beneficiaries

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U36 Building Bridges to Better Health for Hypertensive Patients with Social Determinants of Health Barriers: Empowering Community Pharmacies to Optimize Blood Pressure Control and Address Nutrient Deficiencies

Duan H[1], *Dickey K*[1], *Enghauser A*[1], *Medina Z*[1], *Steele S*[1], *Chen A*[2]; *huanyun.duan@caresource.com*
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U37 Duration of Concurrent Oxycodone and Serotonin Reuptake Inhibitors Use and the Risk of Opioid-Related Overdose in Commercially Insured Patients

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U38 Evaluating Therapeutic and Economic Outcomes of Targeted Biologic Dose De-Escalation Interventions in a Managed Care Setting

Farrow J[1], *LaBeau S*[1], *Hollingsworth B*[1], *Nash J*[1], *Barrett K*[1], *Kelley C*[2]; *jlh0087@auburn.edu*
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U39 Evaluating ICD Codes on Pharmacy Claim Submissions: Are They Reliable?

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U40 Evaluating Payer-Manufacturer Value-Based Contracts: Outcomes, Perceptions, and Artificial Intelligence Utilization

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U41 Evaluating the impact of enhanced cooler return services for rare cold chain medications based on environmental, financial, and patient perspectives

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U42 Evaluating the Impact of Switching from Humira to Humira Biosimilars: A Retrospective Claims Analysis

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U43 Examining the Predictor of Prostate Cancer Diagnosis in the United States

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U44 Identifying utilization trends for intravenous immunoglobulin across a health plan

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U45 Impact of biosimilar strategies on cost savings and utilization trends of adalimumab products among United States health plans

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U46 Impact of compliance packaging on adherence rates in a multistate health plan: a prospective chart review study

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U47 Impact of medication automatic refill programs on patient adherence and health care utilization in outpatient settings: a systematic literature review

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U48 Impact of Omalizumab on Adjunct Therapies for Allergic Asthma and Food Allergies in Middle Market Employer Groups

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U49 Inflation Reduction Act and its impact on Medicare Part D benefits in one plan's service area

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U50 Influenza and COVID-19 vaccination rates among Medicare members with chronic kidney disease and type 2 diabetes

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U51 Insights into health care professionals' educational preferences: findings from a national survey

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U52 Medicare beneficiaries' plan selection decisions in response to in-person vs telephone-delivered counseling services: a trend analysis

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U53 Medication adherence in previously non-adherent Medicare beneficiaries

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U54 Perceived Value and Utility in the Academy of Managed Care Pharmacy (AMCP) Foundation Pharmacy & Therapeutics (P&T) Competition: Insights through Rasch Analysis

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U55 Population health pharmacist–led deprescribing among Medicare Advantage value-based patients with polypharmacy concerns

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U56 Preliminary Real-World Evidence on the Pharmacy Benefit Uptake of Biosimilar Products for Self-Insured Employers

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U57 Rapamycin: a new frontier in age-related disease management and its future in formulary

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U58 Real-World Outcomes of Plan Coverage Design and Member Cost Share Structure on Preventive Services and Medication Utilization

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U59 Reimagining managed care pharmacy: a shift toward integrated patient-centric solutions

Vohra M[1], *Dave K*[1]; *mv660@sacrletmail.rutgers.edu*
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U60 Removing financial barriers for essential medications: a retrospective claims analysis

Hodgen N[1], *Loya H*[2], *Faustgen B*[1], *Berg H*[1], *Beauvais J*[1]; *nicholas_hodgen@uhc.com*
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U61 Subjective norms and perceived behavioral control associated with fentanyl test strip provision by Alabama community pharmacists: a cross-sectional survey

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U62 The effectiveness of high-touch versus moderate-touch pharmacies in bridging care gaps for HEDIS measures: a retrospective study

Adigwe A[1], *Famutimi D*[1], *Coleman A*[1], *Nguyen K*[1]; *ann.adigwe@carelon.com*
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U63 The impact of patient familiarity with their pharmacy care team on medication adherence and communication effectiveness in disease management

Lepro K[1], *Puc M*[1], *Gabriel C*[1], *Abramson A*[1], *Koerner P*[1], *Jastrab A*[1], *King K*[1], *Faris R*[1]; *klepro@pantherxrare.com*
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U64 Unlocking the Wonders of Black Seed: Nature's Miraculous Secret Revealed

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U65 Value-Based Purchasing of Cell and Gene Therapies Between Pharmaceutical Manufacturers and Managed Care Organizations in the United States

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Z7 A contemporary analysis of use, clinical outcomes, and costs of robotic-assisted, laparoscopic, and open partial nephrectomy using the National Inpatient Sample

Lin M[1], *Kimani M*[1], *Lallas C*[1], *Davis R*[1], *Ghosh A*[1], *Moeller P*[1], *Keith S*[1], *Maio V*[1]; *meng-hsuan.lin@jefferson.edu*
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Z8 Prevention Pays: Impact of reducing cost barriers on hospitalizations and ER visits

El-Sharif Y[1], *Mann A*[1], *Riggs C*[1], *Le N*[2], *Park C*[3]; *yasmineelsharif@gmail.com*
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Z9 Retrospective Analysis of Buprenorphine/ Naloxone Dosing in Adolescents with Opioid Use Disorder

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Z10 Comparing Characteristics of Mail Order Utilizers Before and After COVID-19

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Z12 Using Employer Data to Identify Potential Health Inequities Relating to Pharmaceutical Access and Utilization in a Self-Insured Population

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Z13 Evaluating the Role of Drug Pricing Tiers in Shaping Health Care Outcomes for Older Patients

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Z14 Social determinants of health: How health inequities impact medication adherence

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Z15 Improved clinical outcomes and reduced costs associated with mail-to-prescriber duplicate therapy deprescribing interventions

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Encore Poster Titles and Presenters

B8 US socioeconomic disparities and geographic variations in HIV pre-exposure prophylaxis providers

Tao L[1], Yang J[2], Nguyen C[3], Gruber J[4], Baker K[2], Green J[2], Khoshabafard D[2], Brown G[2], Zachry W[2]; Li.tao@gilead.com
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B9 The influence of racialized economic segregation on unmet HIV prevention needs in the real world

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B10 Optimizing Maribavir Management: Role of a Health System Specialty Pharmacy in Access, Monitoring, and Waste Reduction

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C10 Beamion LUNG-1 and LUNG-2: The zongertinib clinical program in patients with non-small cell lung cancer and HER2 mutations

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C12 Real-world treatment patterns and clinical conditions of patients with basal cell carcinoma who received sonidegib or vismodegib treatment

Lebwohl M[1], Rigel D[2], Eroglu Z[3], Squittieri N[4], Gupta D[5], Zanardo E[5], Huynh L[5], Yenikomshian M[5], Barghout V[6], Ferro T[7], Patel K[8]; lebwohl@aol.com; Kunal.patel@sunpharma.com
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C14 Clinical Characteristics and Treatment Persistence in US Patients with HR+/HER2-, Node-Positive Early Breast Cancer Treated with Abemaciclib: Real-World Study from First Year After Approval

Hudson K[1], Gathirua-Mwangi W[2], Cui Z[2], Richey M[3], Grimes B[2], Wang J[3], Liepa A[2], Brechtelsbauer E[2], Volodarsky R[2], Moreira K[3], Soliman H[4], Pin J[2]; Kathryn.Hudson@usoncology.com; j.pin@lilly.com
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C15 Imlunestrant, an Oral Selective Estrogen Receptor Degrader, as Monotherapy and Combined with Abemaciclib, for Patients with ER+, HER2- Advanced Breast Cancer, Pretreated with Endocrine Therapy: Results of the Phase 3 EMBER-3 trial

Jhaveri K[1], *Neven P*[2], *Casalnuovo M*[3], *Kim S*[4], *Tokunaga E*[5], *Aftimos P*[6], *Saura C*[7], *O'Shaughnessy J*[8], *Harbeck N*[9], *Carey L*[10], *Curigliano G*[11], *Llombart-Cussac A*[12], *Lim E*[13], *García Tinoco M*[14], *Sohn J*[15], *Mattar A*[16], *Zhang Q*[17], *Huang C*[18], *Hung C*[19], *Rodriguez J*[20], *Ruiz Borrego M*[21], *Nakamura R*[22], *Pradhan K*[23], *Smyth L*[23], *Bidard F*[24], *Foxx-Lupo W*[23]; *jhaverik@mskcc.org*; *foxx_lupo_william@lilly.com*

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C17 Overall survival in patients with metastatic castration-sensitive prostate cancer treated with apalutamide versus abiraterone acetate: a head-to-head analysis of real-world patients in the United States

Bilen M[1], *Lowentritt B*[2], *Khilfeh I*[3], *Rossi C*[4], *Du S*[3], *Kinkead F*[4], *Diaz L*[4], *Pilon D*[4], *Ellis L*[3], *Shore N*[5]; *mehmet.a.bilen@emory.edu*; *blowentritt@chesuro.com*

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C18 Real-world head-to-head analysis of overall survival in patients with metastatic castration-sensitive prostate cancer initiated on apalutamide versus enzalutamide in the United States

Bilen M[1], *Shore N*[2], *Lowentritt B*[3], *Khilfeh I*[4], *Rossi C*[5], *Du S*[4], *Kinkead F*[5], *Diaz L*[5], *Pilon D*[5], *Ellis L*[4]; *mehmet.a.bilen@emory.edu*; *nshore@auclinics.com*

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C19 Real-world treatment patterns for patients with high-risk biochemically recurrent nonmetastatic castration-sensitive prostate cancer

Freedland S[1], *Ribbands A*[2], *Butcher J*[2], *Brown T*[2], *Russell D*[3], *Bland C*[4], *Touya M*[5], *Ivanova J*[3]; *stephen.freedland@cshs.org*; *jasmina.ivanova@pfizer.com*

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C27 A retrospective analysis of US commercial and Medicare closed-claims databases to evaluate real-world characteristics and treatment patterns of patients with diffuse large B-cell lymphoma (2017-2023)

Phillips T[1], *Zhou Z*[2], *Gutierrez C*[3], *Shao A*[3], *Boyd M*[3], *Noshad S*[3], *Hohlbauch A*[4], *Liu N*[5], *Repetny K*[5], *Fanale M*[5], *Mitchell B*[5], *Davis E*[6], *Burke J*[7]; *tphillips@coh.org*; *nicholas.g.liu@gmail.com*

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C28 A systematic literature review of clinical outcomes in patients with relapsed or refractory diffuse large B-cell lymphoma treated in the third-line or later setting

Bandy S[1], *Wu A*[1], *Gratie D*[1], *Horblyuk R*[1], *Repetny K*[2], *Fanale M*[2], *Mitchell B*[2], *Davis E*[3], *Liu N*[2]; *sarah.bandy@aesara.com*
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C29 Association of patient-reported outcomes (PROs) with red blood cell (RBC) transfusion reduction and rise in hemoglobin (Hb) with imetelstat (IME) in RBC transfusion-dependent (TD) lower-risk myelodysplastic syndromes (LR-MDS) in the IMerge trial

Sekeres M[1], *Santini V*[2], *Zeidan A*[3], *Platzbecker U*[4], *Komrokji R*[5], *Díez Campelo M*[6], *Fenaux P*[7], *Savona M*[8], *Madanat Y*[9], *Valcárcel D*[10], *Regnault A*[11], *Creel K*[11], *Sengupta N*[12], *Dougherty S*[13], *Shah S*[13], *Sun L*[13], *Wan Y*[13], *Navada S*[13], *Oliva E*[14]; *msekeres@med.miami.edu*; *snavada@geron.com*
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C30 Cost-effectiveness evaluation of Bruton tyrosine kinase inhibitor (BTKi) treatments among Medicare patients with chronic lymphocytic leukemia (CLL) in first-line (1L) and relapsed/refractory (R/R) settings

Crawford S[1], *Li H*[2], *Srivastava B*[2], *Martin P*[3], *Gahn J*[3], *Bacchus S*[2], *Ryan O*[2], *Salkar M*[2]; *samuel.crawford@abbvie.com*
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C31 Impact of prior treatments (tx) on the clinical activity of imetelstat (IME) in transfusion-dependent (TD) patients (pts) with erythropoiesis-stimulating agent (ESA)–relapsed or refractory/ineligible lower-risk myelodysplastic syndromes (LR-MDS)

Platzbecker U[1], *Santini V*[2], *Zeidan A*[3], *Sekeres M*[4], *Fenaux P*[5], *Raza A*[6], *Mittelman M*[7], *Thépot S*[8], *Buckstein R*[9], *Germing U*[10], *Madanat Y*[11], *Díez Campelo M*[12], *Valcárcel D*[13], *Jonášová A*[14], *Dougherty S*[15], *Shah S*[15], *Xia Q*[15], *Sun L*[15], *Navada S*[15], *Savona M*[16], *Komrokji R*[17]; *uwe.platzbecker@medizin.uni-leipzig.de*; *snavada@geron.com*
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C32 Real-world treatment patterns and characteristics of patients with diffuse large B-cell lymphoma (DLBCL): A retrospective analysis of US claims (2017-2024)

Burke J[1], *Zhou Z*[2], *Gutierrez C*[3], *Shao A*[3], *Boyd M*[3], *Noshad S*[3], *Hohlbauch A*[4], *Liu N*[5], *Repetny K*[5], *Fanale M*[5], *Mitchell B*[5], *Davis E*[6], *Phillips T*[7]; *John.Burke@USOncology.com*
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C33 Safety, pharmacokinetics (PK), and clinical activity of imetelstat (IME) plus ruxolitinib (RUX) in patients (pts) with intermediate (INT)-1, INT-2, or high-risk (HR) myelofibrosis (MF): updates from the ongoing, open-label phase 1/1B IMproveMF trial

Mascarenhas J[1], *Otoukesh S*[2], *Bradley T*[3], *Scott B*[4], *Yimer H*[5], *Dougherty S*[6], *Peng L*[6], *Huang F*[7], *Wan Y*[6], *Feller F*[8], *Rodolf V*[7], *Ho H*[8], *Berry T*[7], *Kuykendall A*[9]; *john.mascarenhas@mssm.edu*; *tberry@geron.com*
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C34 Updated Results and Longer Follow-Up From the AUGMENT-101 Phase 2 Study of Revumenib in all Patients With Relapsed or Refractory (R/R) KMT2Ar Acute Leukemia

Aldoss I[1], *Issa G*[2], *Blachly J*[3], *Thirman M*[4], *Mannis G*[5], *Arellano M*[6], *DiPersio J*[7], *Traer E*[8], *Zwaan C*[9], *Shukla N*[10], *Cuglievan B*[2], *Grove C*[11], *Greenwood M*[12], *McMahon C*[13], *Perl A*[14], *Stone R*[15], *Papayannidis C*[16], *Dickens D*[17], *Montesinos P*[18], *Mantzaris I*[19], *Kovacsovics T*[20], *Shami P*[21], *Yu L*[22], *Bagley R*[22], *McNeer N*[23], *Stein E*[10]; *ialdoss@coh.org*
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D7 Cost comparison of ruxolitinib and momelotinib in patients with myelofibrosis and anemia

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D11 Comorbidities and Risk of In-Hospital Mortality Contribute to Clinical Burden of WHIM Syndrome: A Retrospective Data Claims Analysis of Patients with Clinical Symptoms Consistent with WHIM Syndrome in the United States

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D12 International Clinical Consensus on Leukocyte Adhesion Deficiency-I: A Modified Delphi Analysis

Bailey M[1], *Heimall J*[2], *Gonzalez Granado L*[3], *Booth C*[4], *Carter P*[5], *Matthews E*[5], *Chitty-Lopez M*[1], *Prockop S*[6], *Gennery A*[7], *Leiding J*[8]; *mbailey@rocketpharma.com*
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D13 Patients with WHIM Syndrome Experience High Rates of Infection and Health Care Utilization: A Retrospective Data Claims Analysis of Patients with Clinical Symptoms Consistent with WHIM Syndrome in the United States

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D14 Real-World Safety Assessment of Treatment of Chronic Inflammatory Demyelinating Polyneuropathy with Subcutaneous IgPro20

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D15 Safety of Decade-Plus Use of IgPro20 in the Real World: Post-Marketing Pharmacovigilance Report

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E28 Clinical Characteristics of Individuals with Overweight/Obesity Predictive of Health Care Costs

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E29 Health Care Resource Utilization (HCRU) and Economic Burden of Obesity or Overweight with Comorbidities in the US: A Systematic Literature Review (SLR)

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E30 Real-World Use of Tirzepatide in People with Obesity or Overweight: Merative Claims Database Results

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E31 Work Loss Among Privately Insured Employees with Obesity and Obstructive Sleep Apnea in the US

Shinde S[1], *Varnado O*[1], *Lew C*[2], *Jerry M*[2], *Liao B*[1], *Akers J*[3]; *shinde_shraddha@lilly.com*; *JOSHUA.AKERS@LILLY.COM*
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F13 Changes in Quality of Life for Schizophrenia Outpatients Receiving the Muscarinic Agonist Xanomeline and Trospium Chloride: Findings of a Qualitative Interview-Based Study

Weiden P[1], *Saucier C*[2], *Horan W*[3], *Foster A*[2], *Sauder C*[4], *LaGasse K*[2], *Jackson K*[2], *Rucker S*[2], *Henderson C*[3], *Kaul I*[4]; *peter@pjweiden.com*
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F14 Health care resource utilization 12 months following initiation of olanzapine/samidorphan: real-world assessment of patients with schizophrenia

Cutler A[1], *Panchmatia H*[2], *Hughes A*[3], *Doane M*[4], *Oyedeji H*[5], *Jain R*[6]; *hemangi.panchmatia@alkermes.com*
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F15 Long-Term Safety and Efficacy of Xanomeline and Trospium Chloride in Schizophrenia: Results from the 52-Week, Open-Label EMERGENT-4 Trial

Kaul I[1], *Claxton A*[1], *Sauder C*[1], *Patel T*[1], *Chaturvedi S*[1], *Zhu H*[1], *Marcus R*[2], *Sawchak S*[1], *Wilbanks J*[2], *Brannan S*[2]; *Inder.Kaul@bms.com*
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F16 Long-Term Safety, Tolerability, and Efficacy of Xanomeline and Trospium Chloride in People With Schizophrenia: Results From the 52-Week, Open-Label EMERGENT-5 Trial

Kaul I[1], *Claxton A*[1], *Sauder C*[1], *Sawchak S*[1], *Patel T*[1], *Chaturvedi S*[1], *Zhu H*[1], *Boland P*[1], *Raj E*[1]; *Inder.Kaul@bms.com*
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F17 Treatment patterns and health care resource utilization of patients with schizophrenia prescribed aripiprazole lauroxil versus oral aripiprazole: a retrospective claims-based study

Kane J[1], *Barthel A*[2], *Liang C*[2], *Wang Z*[2], *Nagelhout E*[2], *Strand L*[3], *Doane M*[4], *Grebla R*[4]; *lauren.strand@alkermes.com*
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F18 Health care resource utilization 12 months following initiation of olanzapine/samidorphan: real-world assessment of patients with bipolar I disorder

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G3 Referral Patterns for Patients With Amyotrophic Lateral Sclerosis Enrolled in a US-Based Administrative Claims Database

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G20 Efficacy and safety of subcutaneous efgartigimod PH20 in chronic inflammatory demyelinating polyneuropathy: ADHERE trial subgroup analysis

Allen J[1], *Lewis R*[2], *Querol L*[3], *Hussain Y*[4], *Gwathmey K*[5], *Suresh N*[6], *Guptill J*[7], *Hofman E*[7], *Van Hoorick B*[7], *Mole T*[7], *Kuwabara S*[8], *Basta I*[9], *Jefferson M*[7], *van Doorn P*[10]; *jaallen@umn.edu*; *mjefferson@argenx.com*
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G21 Decreased Cost Utilization with Lidocaine Topical System 1.8% Compared to Lidocaine 5% Patch: A Retrospective Claims Analysis

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G22 Changes in intravenous or subcutaneous immunoglobulin usage before and after efgartigimod initiation in patients with myasthenia gravis

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G23 Hospitalization outcomes after efgartigimod initiation in patients with myasthenia gravis

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G24 Real-world reduction in oral glucocorticoid utilization at 1 year following efgartigimod initiation

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G28 Health care resource utilization in cognitively unimpaired individuals up to 5 years prior to amyloid PET for A4 vs LEARN eligibility

Chandler J[1], *Kubisiak J*[2], *Lee A*[2], *Holdridge K*[1], *Robinson R*[1], *Yaari R*[1], *Rafii M*[3], *Aisen P*[3], *Sperling R*[4], *Shepherd M*[1]; *chandler_julie_m@lilly.com*; *shepherd_michael_e@lilly.com*
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G30 Lecanemab Use in the United States: A Real-World Observational Study

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H5 Real-world durability and safety of suprachoroidal triamcinolone acetonide injectable suspension for uveitic macular edema

Emami-Naeini P[1], *Garcia K*[2], *Talwar A*[3], *Brevetti T*[3], *Borkar D*[4], *Nair A*[3]; *parisaemami@gmail.com*; *ashna.talwar@bausch.com*; *abhishek.nair@bausch.com*
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I2 Impact of RBT-1 on post-operative complication rates and costs for cardiac surgery

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I3 Heart Failure–Related Health Care Resource Utilization and Cost of Care Associated With Different IV Iron Treatments in Medicare Patients With Heart Failure and Iron Deficiency/Iron Deficiency Anemia Using a Real-World Database

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I4 Real-World Persistency on Tafamidis: An Analysis of US Insurance Claims Data

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I12 Clinical application of biomarkers in obstructive HCM: insights from SEQUOIA-HCM

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I13 Global Remodeling Changes with Aficamten in Patients with Obstructive Hypertrophic Cardiomyopathy: An Analysis of the SEQUOIA-HCM Trial

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I14 Association between elevated lipoprotein(a) and cardiovascular events and mortality in a nationally representative sample of US Medicare, Medicaid, and commercial enrollees with ASCVD

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I15 Elevated lipoprotein(a) increases cardiovascular-related health care resources utilization and costs among US Medicare, Medicaid, and commercial enrollees with ASCVD

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I16 Impact of RBT-1, a novel treatment to reduce post-operative complication rates and costs for coronary artery bypass graft (CABG) surgery

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J1 Baseline asthma burden of patients who initiated dupilumab in the RAPID registry, stratified by dose of inhaled corticosteroid

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J3 Predictive characteristics of sinonasal surgery in patients with chronic rhinosinusitis with nasal polyps from a large US physician network database

Han J[1], *Sabban A*[2], *Black R*[3], *Nadler B*[4], *Stanford R*[3], *Corbett M*[5], *Gandhi A*[5], *Radwan A*[6], *Jacob-Nara J*[5], *Solouki S*[5], *Nash S*[6], *Subramaniam A*[7], *Rosenberg S*[2]; *mdjosephhan@gmail.com*; *arun.subramaniam@sanofi.com*
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J8 Effectiveness of Biologics in Asthma: Comparing Real-World Evidence

Adams S[1], *Maselli D*[2], *Durg S*[3], *Dubucq H*[4], *Ritter J*[5], *Pandit-Abid N*[6], *Ledanois O*[7], *Wang Z*[8], *Cheng W*[6]; *adamssg@uthscsa.edu*; *janet.ritter@sanofi.com*
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J9 Efficacy and Safety of Dupilumab in Patients with Chronic Obstructive Pulmonary Disease and Type 2 Inflammation: Pooled Analysis of BOREAS and NOTUS Trials

Anson I[1], *Bhatt S*[2], *Rabe K*[3], *Hanania N*[4], *Vogelmeier C*[5], *Bafadhel M*[6], *Christenson S*[7], *Papi A*[8], *Singh D*[9], *Laws E*[10], *Akinlade B*[11], *Maloney J*[11], *Bansal A*[11], *Abdulai R*[12], *Robinson L*[13]; *lane.anson@sanofi.com*; *sbhatt@uabmc.edu*
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J10 Exacerbations and health care resource utilization in patients with chronic obstructive pulmonary disease with an eosinophilic phenotype: a US claims analysis

Narendra D[1], *Paczkowski R*[2], *Park J*[2], *Mu G*[2], *Kumar A*[2], *Kolterer S*[2], *Igboekwe E*[2], *Noorduyn S*[2], *Yang S*[2]; *Dharani.Narendra@bcm.edu*
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K5 Improvement in fatigue with mirikizumab therapy and associations with clinical outcomes in patients with moderately to severely active Crohn disease: Results from the PHASE 3 VIVID-1 study

Bossuyt P[1], *Regueiro M*[2], *Fisher M*[3], *Traxler K*[4], *Yu G*[4], *Protic M*[4], *Tsilkos K*[4], *Vadhariya A*[4], *Hisamatsu T*[5], *Juillerat P*[6], *Wallem A*[4]; *peter.bossuyt@imelda.be*; *wallem_alexandra@lilly.com*
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L3 Achievement of No-to-Minimal Itch and Sleep Improvement with Tapinarof Cream 1% Once Daily in Two Pivotal Phase 3 Trials in Adults and Children Down to 2 Years of Age with Atopic Dermatitis

Tallman A[1], *Simpson E*[2], *Siri D*[3], *Chovatiya R*[4], *Shahriari M*[5], *Burnette A*[6], *Craiglow B*[7], *Brown P*[8]; *simpsone@ohsu.edu*
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L4 Integrated safety analysis of abrocitinib in 3,848 patients with moderate to severe atopic dermatitis: data from more than 7,000 patient-years with up to 4.5 years of exposure

Simpson E[1], *Gutermuth J*[2], *de Bruin-Weller M*[3], *Chan G*[4], *Chittuluru K*[5], *Koppensteiner H*[6], *Fan H*[7], *Alderfer J*[5], *Vyas S*[8], *Gutierrez G*[9]; *simpsone@ohsu.edu*; *Gabriela.Gutierrez@pfizer.com*
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L5 Lebrikizumab improves atopic dermatitis and quality of life in patients with moderate to severe atopic dermatitis previously treated with dupilumab: Results from the ADapt Trial

Silverberg J[1], *Ackerman L*[2], *Bagel J*[3], *Stein Gold L*[4], *Blauvelt A*[5], *Rosmarin D*[6], *Chovatiya R*[7], *Zirwas M*[8], *Yosipovitch G*[9], *Waibel J*[10], *E. Murase J*[11], *Lockshin B*[12], *Weisman J*[13], *Reck Atwater A*[14], *Harris C*[15], *Proper J*[15], *Silk M*[14], *Pierce E*[14], *Lucia Buziqui Piruzeli M*[14], *Montmayeur S*[14], *Schuster C*[14], *Zhong J*[16], *Jose Rueda M*[15], *Pillai S*[14], *Simpson E*[17]; *jonathanisilverberg@gmail.com*; *evangeline.pierce@lilly.com*
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L6 Matching-adjusted indirect comparison of efficacy in patients with moderate to severe atopic dermatitis treated with lebrikizumab plus topical corticosteroids versus dupilumab plus topical corticosteroids

Chovatiya R[1], *Kircik L*[2], *Binamer Y*[3], *Puig L*[4], *Torres T*[5], *Akmaz B*[6], *Dossenbach M*[7], *Gallo G*[7], *Yang C*[7], *Ding Y*[7], *Cho Y*[8], *Luy I*[9]; *Raj.chovatiya@gmail.com*; *irene.luy@lilly.com*
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L7 Stringent efficacy response of skin clearance and itch-free state with abrocitinib 100 mg versus dupilumab in patients with moderate to severe atopic dermatitis: a post hoc analysis of JADE COMPARE

Weidinger S[1], *Silverberg J*[2], *Makris M*[3], *Bunick C*[4], *Zirwas M*[5], *Issa N*[6], *Alderfer J*[7], *Bhambri A*[7], *Biswas P*[8], *Güler E*[9], *Selfridge A*[8], *Waltzer A*[8]; *Stephan.Weidinger@uksh.de*; *Aaron.Waltzer@pfizer.com*
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L8 Skin Clearance, Treatment Response off Therapy, and Safety of Tapinarof Cream 1% Once Daily: Results from ADORING 3, a 48-Week Phase 3 Trial in Adults and Children Down to 2 Years of Age with Atopic Dermatitis

Tallman A[1], *Bissonnette R*[2], *Stein Gold L*[3], *Kircik L*[4], *Simpson E*[5], *Eichenfield L*[6], *Browning J*[7], *Hebert A*[8], *Alexis A*[9], *Soong W*[10], *Piscitelli S*[11], *Rubenstein D*[11], *Brown P*[12], *Silverberg J*[13]; *rbissonnette@innovaderm.com*
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L9 Real-world effectiveness and quality-of-life outcomes of tildrakizumab for moderate to severe plaque psoriasis in the United States: A systematic literature review and meta-analysis

Gottlieb S[1], *Farberg A*[2], *Bhatia N*[3], *Fazeli M*[4], *Hofer K*[4], *Lam O*[4], *Barghout V*[5], *Mathew J*[6], *Ferro T*[6]; *scottgott@aol.com; Jacob.Mathew@sunpharma.com*
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L10 A discrete choice experiment to assess clinician preferences for the treatment of alopecia areata

Del Rosso J[1], *Pariser D*[2], *Bhatia N*[3], *Harshaw Q*[4], *Deering K*[4], *Barghout V*[5], *Ferro T*[6]; *jqdelrosso@yahoo.com; Thomas.Ferro@sunpharma.com*
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L11 Patient preference among Janus kinase inhibitors for the treatment of alopecia areata

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L12 Efficacy and safety of clascoterone cream 1% in patients with acne with skin of color: 16-week interim analysis

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L13 Efficacy and safety of roflumilast foam 0.3% in patients with psoriasis of the scalp and body in the phase 3 ARRECTOR trial

Higham R[1], Gooderham M[2], Bagel J[3], DuBois J[4], Kircik L[5], Lockshin B[6], Papp K[7], Soung J[8], Krupa D[9], Burnett P[9], Berk D[9], Chu D[9]; rhigham@arcutis.com; mgooderham@centrefordermatology.com
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L14 Global Delphi consensus on treatment goals for generalized pustular psoriasis

Barker J[1], Casanova E[2], Choon S[3], Foley P[4], Fujita H[5], Gonzalez C[6], Gooderham M[7], Marrakchi S[8], Puig L[9], Romiti R[10], Thaci D[11], Zheng M[12], Strober B[13]; jonathan.barker@kcl.ac.uk
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L15 Patient-reported outcomes with roflumilast foam 0.3% in patients with psoriasis of the scalp and body in the phase 3 ARRECTOR trial

Stephenson B[1], Gooderham M[2], Bagel J[3], Forman S[4], Kircik L[5], Wiseman M[6], Lockshin B[7], Soung J[8], Krupa D[9], Kato S[10], Berk D[9], Chu D[9]; bstephenson@arcutis.com; mgooderham@centrefordermatology.com
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L16 Roflumilast foam 0.3% in patients with psoriasis of the scalp and body in the phase 3 ARRECTOR trial: secondary efficacy and patient-reported outcomes

Moran T[1], Gooderham M[2], Alonso-Llamazares J[3], Bagel J[4], Bhatia N[5], Bukhalo M[6], DuBois J[7], Ferris L[8], Green L[9], Kircik L[10], Lockshin B[11], Loo W[12], Papp K[13], Soung J[14], Snyder S[15], Kato S[16], Krupa D[17], Burnett P[17], Berk D[17], Chu D[17]; tmoran@arcutis.com; mgooderham@centrefordermatology.com
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M6 Cardiac MRI outcomes in patients with Duchenne muscular dystrophy treated with delandistrogene moxeparvovec: Findings from EMBARK Part 1

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M7 Efficacy and safety of apitegromab in individuals with type 2 and type 3 spinal muscular atrophy evaluated in the phase 3 SAPPHIRE trial

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M8 Muscle MRI outcomes in patients with Duchenne muscular dystrophy treated with delandistrogene moxeparvovec: Findings from EMBARK Part 1

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N1 A phase 1/2 trial of zigakibart in IgA nephropathy

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N2 ALIGN subgroup analyses: clinically meaningful urine protein-creatinine ratio reductions seen across subgroups

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O2 A Cost-Effectiveness Analysis of Intrauterine Spacers Used to Prevent the Formation of Intrauterine Adhesions Following Endometrial Cavity Surgery

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R1 Identifying opportunities to improve evaluation for hematuria in a large health system

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U22 Comparing rates of turnaround time, adherence, and persistence among patients at Vanderbilt Specialty Pharmacy compared to external specialty pharmacies

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U23 Defining quality in digital therapeutics (DTx): A landscape and gaps analysis

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U24 Effect of elinzanetant for the treatment of vasomotor symptoms associated with menopause across BMI and smoking history subgroups: pooled data from two phase 3 studies

Pinkerton J[1], *Simon J*[2], *Joff H*[3], *Maki P*[4], *Nappi R*[5], *Panay N*[6], *Soares C*[7], *Thurston R*[8], *Lu C*[9], *Djordjevic S*[10], *Haberland C*[11], *Zuurman L*[10]; *jsimon@intimmedicine.com*; *lineke.zuurman@bayer.com*
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U25 Efficacy of elinzanetant for the treatment of vasomotor symptoms associated with menopause: pooled data from two phase 3 studies

Pinkerton J[1], *Simon J*[2], *Joff H*[3], *Maki P*[4], *Nappi R*[5], *Panay N*[6], *Soares C*[7], *Thurston R*[8], *Ahlers C*[9], *Djordjevic S*[10], *Haberland C*[11], *Zuurman L*[10]; *jsimon@intimmedicine.com*; *joffe.hadine@gmail.com*
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U26 Patient attitudes and beliefs toward deprescribing 5-Aminosalicylates in patients with inflammatory bowel disease on concomitant advanced therapy: A qualitative analysis

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