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SUPPLEMENT

Poster Abstracts

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SUPPLEMENT POLICY STATEMENT

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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 2024. 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

Seventy-eight reviewers and 4 JMCP editors completed the review process for AMCP 2024. 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 2024 were as follows:

Peer Reviewers

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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.

Karishma Shelley, PharmD, MS [C11] Development of a predictive administrative claims–based algorithm for melanoma stage classification

Roy Thomas, PharmD [E6] Improvements in glycemic control in people with diabetes in an employer health initiative offering continuous glucose monitors (CGMs) as a pharmacy benefit

Jessica Duchen, MPH [E13] Learnings from linking electronic medical record patient cohorts with consumer SDOH data

Vikash K. Verma, MBA [G5] Impact of Zolgensma in health care utilization in patients with spinal muscular atrophy in the United States: A retrospective claims and electronic health records analysis

Dylan Mezzio, PharmD, MS [B8] Characteristics and drivers of initial prescription dispensation among individuals newly prescribed oral preexposure prophylaxis for HIV-1

Mayank Raturi, PhD [C35] Variation in racial and payer impact on multiple myeloma mortality and receipt of therapeutic interventions: A 5-year cross-sectional HCUP analysis

Sonia R. Talwar, PharmD [D3] Intravenous iron treatment considerations in patients with non–dialysis-dependent chronic kidney disease

Scott Leslie, PhD [E44] Real-world first-year cost-effectiveness assessment of glucagon-like peptide-1 agonists to treat nondiabetes obesity

Nicholas J. Friedlander, PharmD [G17] Promoting generic multiple sclerosis drug utilization and drug cost savings with a managed care pharmacist outreach program

Shelagh M. Szabo, MSc [K13] Evaluating the cost of care and disease progression among patients with nonalcoholic steatohepatitis (NASH): A US cohort study

Kamal Kant Mangla, BTech [K16] Liver fibrosis is associated with economic burden related to cardiovascular disease in patients with nonalcoholic steatohepatitis: The unCoVer-NASH longitudinal cohort study

Yifei Dai, PhD [M18] A digital behavioral therapy for fibromyalgia progressively improves clinical outcomes: Results of the PROSPER-FM randomized clinical trial

Medal-Winning Abstracts

Alice Hsiao, PharmD [B5] Prevalence of renal and bone risk factors and nucleos(t)ide inhibitor treatment among US patients with chronic hepatitis B

Sophia Li, MPH [C31] Health resource utilization (HRU) in patients (pts) with multiple myeloma (MM) and cytogenetic abnormalities in the relapsed/refractory (R/R) setting: Results using the Flatiron electronic health record (EHR) claims linked dataset

Dee Lin, PharmD, MS [D20] Identification of high-grade cytokine release syndrome in retrospective databases

Shailaja Daral, MD, MBA [E3] Impact estimation of patients' cost sharing on drug adherence in the context of the Inflation Reduction Act

Duy Do, PhD [E34] Association between glucagon-like peptide-1 (GLP-1) receptor agonist use and health care resource utilization among US adults

Kristen Ricchetti-Masterson, PhD [M14] Agreement and accuracy of ambulatory definitions in Duchenne muscular dystrophy (DMD): A cross-sectional analysis using the Cooperative International Neuromuscular Research Group (CINRG) registry

Kyle A. Noonan, PharmD [U16] Payer perspectives of cell therapy and gene therapy treatment paradigms for an inherited retinal disorder

Maria Sallee, PharmD Student [U24] Differences in opioid utilization metrics among beneficiaries enrolled in Mississippi Medicaid using claims-linked PMP data vs claims data only

Jessica Duchen, MPH [U26] Insights to payer perspectives on the Inflation Reduction Act: A survey of US payers

Peter Kardel [D17] Rate of cytokine release syndrome in CAR-T for Medicare Fee-for-Service beneficiaries: Analysis of more than 3 years of claims

Anny C. Wong [E7] SGLT2i as early treatment in type 2 diabetes mellitus: A systematic review of real-world studies

Gabriela Samayoa [E42] Impact of Ozempic vs Wegovy on osteoarthritis risk in patients with obesity: A retrospective cohort study

Scott Leslie [E43] Real-world adherence and persistence to glucagon-like peptide-1 receptor agonists among nondiabetic commercially insured adults with obesity

Lauren Isenman [F28] The effect of Ozempic vs Wegovy vs Mounjaro on the incidence of alcohol and substance use disorder in patients with obesity

Sari W. Grossman [G21] Reduction in medical and pharmaceutical costs in US patients treated with eptinezumab for migraine prevention: A retrospective cohort study

Sarah J. Billups [I2] Impact of a population-based hypertension outreach program with pharmacist consultation on clinical inertia and blood pressure control

Medal-Winning Abstracts

Kristel Griffith [I8] Budget impact of bempedoic acid for prevention of major cardiovascular events (MACEs) in patients at high risk for or with established atherosclerotic cardiovascular disease (ASCVD) in the United States

Jinan Liu [L4] Does ruxolitinib cream reduce corticosteroid and biologic use in patients with a history of moderate to severe atopic dermatitis?

Stefanie L. Pitts [M17] The impact of safety labeling changes on parathyroid hormone analog utilization and persistence

Lauren Isenman [O1] Socioeconomic status and postpartum depression among commercial health insurance enrollees

Gary Rice [U10] Contemporary insights into patient and provider perceptions of and barriers to biosimilar use from the Biosim.care Web App

Platinum Award-Winning Abstracts

C11 Development of a predictive administrative claims–based algorithm for melanoma stage classification

Karishma Shelley, PharmD, MS, Josh Linton, PharmD, Lisa Rosenblatt, MD, MPH, Ella Xiaoyan Du, MESC, Sophie Gao, MS, Manasvi Sundar, MPH, Sophie A. Kitchen, MSc, Keith A. Betts, PhD
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BACKGROUND: Identifying melanoma stage in administrative claims data is challenging because of the lack of clinical information.

OBJECTIVE: To develop and validate a claims-based algorithm to predict disease stage for patients (pts) with melanoma.

METHODS: Surveillance, Epidemiology, and End Results data provide a "gold standard" for developing a stage inference algorithm, as they contain reliable tumor staging at diagnosis, abstracted from hospital medical records. This study used the linked Surveillance, Epidemiology, and End Results–Medicare data (2012-2018). Pts aged 65 years and older diagnosed with stage I-IV cutaneous melanoma who had continuous Medicare enrollment for at least 12 months before and 6 months (follow-up period) after initial melanoma diagnosis (index date) were selected. The study sample was split into a training cohort (70%) and a test cohort (30%). A decision-tree model was developed using the CART method to predict American Joint Committee on Cancer (7th edition) disease stages (ie, I-II, III, and IV). Stage categories were determined based on similarities in treatment practice. Model performance was evaluated using sensitivity, specificity, precision, and negative predictive value. In the primary analysis, patient demographics and clinical characteristics available from Medicare claims were included as candidate predictors. Considering rapid shifts in the treatment landscape of melanoma, a sensitivity analysis was conducted by excluding treatment-related predictors.

RESULTS: A total of 8,314 pts with melanoma were included (7,549 stage I/II, 562 stage III, and 203 stage IV). The study population was predominantly White (93.7%) and male (59.4%), with a mean age of 76 years. The presence of the following claims during the follow-up period were selected in the final decision tree as predictors: "any metastasis," "lung metastasis," "lymph node (LN) metastasis," "sentinel LN biopsy," "ipilimumab," and "pembrolizumab." The model demonstrated a precision of 98% in predicting stage I/II, 73.5% in stage III, and 86.7% in stage IV. In the sensitivity analysis excluding treatment, "skin excision" was added as a predictor to the final decision tree, and the model had similar predictive performance.

CONCLUSIONS: The tree-based algorithms demonstrated high accuracy in predicting melanoma stages, particularly in stage I/II, based on demographic and clinical characteristics captured in the Medicare data. These findings suggest that tree-based algorithms offer a viable approach to predict melanoma stage by leveraging administrative claims–based data within the Medicare population, potentially laying the groundwork for broader application in other claims databases.

SPONSORSHIP: Bristol Myers Squibb.

E13 Learnings from linking electronic medical record patient cohorts with consumer SDOH data

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BACKGROUND: Social determinants of health (SDOH) are the conditions in which people are born, live, work, and age and are estimated to drive up to 80% of health outcomes.

OBJECTIVE: To link patient- and household-level SDOH characteristics from consumer data to select electronic medical record (EMR) disease cohorts identifying traditionally unavailable SDOH measures for inclusion in real-world data analysis.

METHODS: EMR encounter records from community health care providers between 01/01/2016 and 12/31/2021 and SDOH for calendar year 2022 including demographics, socioeconomic, and household information were used (CHRONOS. 2017-2023. Forian, Inc. https://forian.com). Both data sources are Health Insurance Portability and Accountability Act of 1996 compliant and linked by a unique anonymized patient identifier. Patients aged 18 years and

older with evidence of HIV, chronic kidney disease (CKD), heart failure (HF), type 2 diabetes (DM2), and metastatic prostate cancer (mPC) were identified using EMR diagnosis code (*International Classification of Diseases, Tenth Revision, Clinical Modification* [ICD-10-CM], ICD-9-CM, Snomed) prior to linking to SDOH data. Patients were considered overlapped if there was at least 1 record in SDOH data and at least 1 record with a diagnosis of interest in EMR. Descriptive statistics of SDOH measures were evaluated for age, sex, race, and custom-defined composite measures for household status (marital status; household size; children in the home) and household economic status (economic stability indicator [ESI], household income). ESI ranges from 0 to 30 with higher numbers indicating less economic stability.

RESULTS: 2,573,469 EMR patients (17.5%) had a linkable SDOH and ranged from 19.8% of patients with mPC to 34.3% of patients with HIV. Racial diversity was greatest among patients with advanced CKD or HIV and lowest among those with mPC or HF. Patients with HIV were most likely to be single living in a household without children, whereas patients with HF and those with mPC were most likely to be aged older than 65 years and living alone. Most patients lived in households with annual incomes below the US median ($75,000). Of those with household incomes above the median, 47% of patients with HIV, 36% of those with DM2, 33% of those with HF, 32% of those with CKD, and 28% of those with mPC were found to have ESI values greater than 10, indicating low economic stability relative to household income.

CONCLUSIONS: SDOH measures provide insight into disease-specific patient cohorts beyond demographic data available in EMR alone. Composite measures and interactions can be derived to provide deeper understanding of care patterns and health outcomes. Including patient- and household-level rather than geographic-level SDOH measures may remove additional variability and bias when measuring the impact on health outcomes and costs.

SPONSORSHIP: Magnolia Market Access.

E6 Improvements in glycemic control in people with diabetes in an employer health initiative offering continuous glucose monitors (CGMs) as a pharmacy benefit

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BACKGROUND: Metro Nashville Public Schools, a large Tennessee school system with a focus on workplace health programs, implemented a policy change in May of 2022 covering continuous glucose monitors (CGMs) through the pharmacy benefit without prior authorization requirements. Covering CGMs through the pharmacy vs medical benefit resulted in a 2-fold increase in CGM use, but the clinical outcomes were unknown.

OBJECTIVE: To evaluate the change in clinical outcomes from expanded access to CGM in people with diabetes.

METHODS: Adults with type 1 (T1D) and type 2 (T2D) diabetes (aged 18-64 years) with hemoglobin A1c and average glucose levels prior to starting CGM and at follow-up were included in the analysis. The main outcomes were changes in A1c and average glucose. Secondary measures included percentages of participants meeting Healthcare Effectiveness Data and Information Set (HEDIS; <8.0%) and American Diabetes Association (ADA; <7.0%) treatment targets.

RESULTS: Of the total participants (n = 184) who met the inclusion criteria, 23% (n = 43) were T1D and 77% (n = 141) were T2D. Participants were 65% White, 25% Black, and 10% all other. Of the participants with T2D, 40% were not treated with insulin. In participants with T1D, A1c improved by 0.3% from 7.8% at baseline to 7.5% at follow-up ($P = 0.11$). The cohort with T2D had a 0.9% improvement in A1c from 8.3% at baseline to 7.4% at follow-up ($P < 0.001$). Overall, average glucose improved by 24.1 mg/dL from 175.0 mg/dL at baseline to 150.9 mg/dL at follow-up ($P < 0.001$). The percentage of participants meeting the HEDIS target of A1c < 8.0% increased from 52% (n = 95) at baseline to 73% (n = 134) at follow-up. The percentage of participants meeting the ADA target of A1c < 7.0% increased from 27% (n = 50) at baseline to 45% (n = 83) at follow-up.

CONCLUSIONS: Expanded access to CGM by a large employer through the pharmacy benefit without prior authorization requirements increased CGM use and was associated with clinically meaningful improvements in A1c and average glucose in employees and their dependents with diabetes. This improvement in glycemic control was associated with an approximately 41% and 67% increase in the number of participants achieving HEDIS (<8.0%) and ADA (<7.0%) treatment goals, respectively.

SPONSORSHIP: None.

G5 Impact of Zolgensma in health care utilization in patients with spinal muscular atrophy in the United States: A retrospective claims and electronic health records analysis

Vikash K. Verma, MBA, *Ina Kukreja*, MBA, *Gursimran Basra*, MCA, *Abhimanyu Roy*, MBA, *Shailaja Daral*, MD, MBA
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BACKGROUND: Spinal muscular atrophy (SMA) is a rare genetic disease, which affects 1 in 10,000 live births in the United States. SMA is a motor neuron disease and has several subtypes based on the onset of age and severity. SMA type I is the most severe, requiring numerous hospitalizations and having a 95% fatality rate. Infants with SMA do not live beyond their second year. Zolgensma was first gene therapy approved by the US Food and Drug Administration in May 2019 for treatment in patients with SMA aged younger than 2 years.

OBJECTIVE: To evaluate health care utilization in patients with SMA after Zolgensma therapy.

METHODS: Using the Optum deidentified data from Market Clarity, a retrospective analysis was conducted from June 1, 2020, to June 30, 2022. A cohort was created using *International Classification of Diseases, Tenth Revision* codes (G12.0, G12.1, G12.8, G12.9) for patients with SMA. The index event was defined as the first claim for SMA diagnosis. Selection criteria included patients who had at least 2 SMA-related claims 30 days apart and had received Zolgensma. Patients with other motor neuron diseases (G12.2) were excluded from this study. Index date was defined as the date of Zolgensma administration. A 12-month period is used as the pre-and post-index period to evaluate health care utilization before and after Zolgensma treatment in patients with SMA.

RESULTS: Of the 716 patients identified with SMA during our study period, a substantial majority (n = 615) patients were administered Zolgensma. Our observations revealed a significant reduction in health care utilization following the administration of Zolgensma. Specifically, the average length of hospital stay notably decreased from 9.67 days to 5.58 days, indicating the potential effectiveness of the treatment. To further enhance our understanding of Zolgensma's impact on health care utilization, we plan to evaluate more comprehensive parameters. These include the frequency of inpatient admissions, visits to the emergency department, and the necessity for intensive care unit admissions, with or without the need for ventilator support

CONCLUSIONS: Zolgensma, a pioneering gene therapy for SMA, has demonstrated encouraging outcomes. There has been a noteworthy reduction in the average length of hospital stay for patients with SMA following the administration of Zolgensma, underscoring the treatment's potential effectiveness.

SPONSORSHIP: Optum.

Professional Reviewed Abstracts

A00-B99 Certain Infectious and Parasitic Diseases

(eg, hepatitis C, HIV)

A1 Budget impact analysis of VOWST oral spores (VOS, formerly SER-109) for prevention of recurrent *Clostridioides difficile* infection (CDI) in the United States

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BACKGROUND: *Clostridioides difficile* infection (CDI) may result in debilitating and life-threatening complications. Recurrence of CDI remains a management challenge and increases the burden on health care systems. VOS (fecal microbiota spores, live-brpk, formerly SER-109) is an orally administered microbiome therapeutic US Food and Drug Administration approved for prevention of recurrent CDI (rCDI) following antibacterial treatment of rCDI in patients aged 18 years and older.

OBJECTIVE: To assess the budget impact of VOS inclusion in a health plan's formulary for the prevention of rCDI in the United States.

METHODS: A budget impact model was developed in Microsoft Excel. Epidemiology data, baseline recurrence risk, treatment costs, and recurrence costs were obtained from published literature. Reduction in risk of recurrence with VOS was obtained from the phase 3 ECOSPOR III clinical trial. A scenario with VOS uptake was compared with a scenario of standard of care alone. VOS uptake was assumed to be 10%, 20%, 30%, and 40% for recurrences 1-4, respectively, based on market share estimates. The model estimated recurrences, deaths, and per-member per-month (PMPM) costs from a third-party payer perspective for a hypothetical 1-million-member health plan over a 1-year horizon. Costs were reported undiscounted in 2023 US dollars. One-way sensitivity analyses and VOS uptake scenario analyses were conducted.

RESULTS: For a 1-million-member plan, an estimated 225 individuals with an initial rCDI were modeled. In the base-case analysis, the introduction of VOS was estimated to avert 27 recurrences and 0.30 deaths. VOS was expected to increase pharmacy costs ($0.0820 PMPM). However, pharmacy costs were offset by reductions in cost of recurrence (-$0.0856 PMPM) and a decrease in total costs (-$0.0035 PMPM). Results were sensitive to variation in cost of recurrence, risk reduction for VOS, and baseline risk of recurrence; however, total PMPM costs did not exceed $0.03 in any parameter variation. Scenario analyses showed the greater and earlier the uptake of VOS, the more subsequent recurrences were avoided, and the greater the cost savings.

CONCLUSIONS: Treatment with VOS has been shown to substantially reduce recurrences for patients with rCDI compared with standard of care alone. This study illustrates that VOS is a cost-saving treatment despite increasing pharmacy costs, due to greater reductions in recurrence costs. Furthermore, treating with VOS in earlier recurrences leads to greater cost savings. As such, VOS provides both clinical and economic value to a US health plan.

SPONSORSHIP: Aimmune Therapeutics, a Nestlé Health Science company.

B1 Claims algorithms: A tool for identifying immunocompromised adults at increased risk of herpes zoster

Stempniewicz N[1], *Steffens A*[2], *DuCharme M*[2], *Zhu Y*[2], *Gallagher S*[2], *Poston S*[1], *Singer D*[1]; *nikita.x.stempniewicz@gsk.com*
[1]GSK; [2]*Optum Life Sciences*

BACKGROUND: Individuals with immunocompromising conditions or treatments are at increased herpes zoster (HZ) risk compared with the general population. Previous retrospective claims studies have defined algorithms to identify immunocompromised (IC) adults.

OBJECTIVE: To implement a range of claims-based algorithms in a common database, describe patient characteristics for each IC cohort, and estimate HZ incidence and compare it with HZ incidence in an immunocompetent cohort.

METHODS: Five algorithms identified from a literature review were applied to administrative claims data for individuals

with Medicare Advantage and commercial insurance in the United States. Adults (aged ≥18 years) with at least 1 claim for an immunosuppressive therapy or at least 1 claim with a diagnosis for an immunocompromising condition between October 2016 and September 2022 were assigned to up to 5 non–mutually-exclusive IC cohorts and indexed on the first algorithm-qualifying claim for each cohort. Individuals not meeting criteria for any of the IC cohorts were included in an immunocompetent cohort and assigned a random index date. Individuals included had at least 12 months of pre-index continuous enrollment for baseline, no HZ vaccine prior to index, and no baseline HZ diagnosis. Patient characteristics were measured during baseline. Follow-up started on the index date until the earlier of an incident HZ diagnosis or censoring event (HZ vaccination, disenrollment, death, or end of the study period). HZ incidence rates in each IC cohort were compared with HZ incidence rates in the immunocompetent cohort using generalized linear models.

RESULTS: Immunocompromised cohorts included between 1,164,999 and 4,240,161 individuals, mean (SD) age was between 54 (18) and 65 (15) years, and mean (SD) Charlson Comorbidity Index was between 0.8 (1.4) and 1.9 (2.4). HZ incidence rates in the IC cohorts ranged from 11.9 to 16.3 per 1,000 person-years. Among 6,987,087 individuals in the immunocompetent cohort, mean (SD) age was 43 (17) years, mean (SD) Charlson Comorbidity Index was 0.1 (0.6), and HZ incidence was 3.5 per 1,000 person-years. HZ incidence rates were higher in each IC cohort compared with HZ incidence rates in the immunocompetent cohort, and adjusted incidence rate ratios (95% CI) ranged from 2.06 (2.03-2.09) to 2.72 (2.68-2.76).

CONCLUSIONS: Immunocompromised cohorts varied in size and patient characteristics, and each algorithm identified populations at increased HZ risk. Claims algorithms may be useful for identifying at-risk patients for prevention strategies.

SPONSORSHIP: GlaxoSmithKline Biologicals SA (GSK study identifier: VEO-000374).

B2 Risk of herpes zoster among adults initiating immunosuppressive therapies in the United States

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[1]GSK; [2]*Optum Life Sciences*

BACKGROUND: Recombinant zoster vaccine (RZV) is recommended by the Advisory Committee on Immunization Practices (ACIP) for prevention of herpes zoster (HZ) in adults aged 50 years and older and those aged 19 years and older who are or will be at an increased risk of HZ owing to immunodeficiency or immunosuppression caused by known disease or therapy. Although previous studies focused on narrow disease populations or immunosuppressive (IS) medications in patients with specific conditions, there remains a gap regarding HZ risk associated with IS medication use among a broader population.

OBJECTIVE: To describe the incidence of HZ among US adults initiating IS medications overall, by medication class, and by time-varying immunosuppression status.

METHODS: This was a retrospective cohort study of commercial and Medicare Advantage with Part D health plan members using October 2015 to December 2022 administrative claims data. Adults aged 18 years and older, with at least 1 claim for an IS medication and continuous enrollment for at least 12 months prior to the first IS medication fill (index date), were eligible. Outcomes included HZ diagnosis and HZ-related complications following IS medication initiation, and patients were followed until the earlier of HZ diagnosis, HZ vaccination, pregnancy, end of enrollment or study period, or death. HZ incidence rates (IRs) per 1,000 person-years were calculated overall and stratified by baseline characteristics, medication class, and time-varying immunosuppression status during follow-up.

RESULTS: Overall, 528,283 US adults initiating IS therapy were identified, with 17,822 HZ cases observed, corresponding to an overall IR of 18.2 (95% CI = 17.90-18.43). Incidence was lower in non-Hispanic Black adults, similar across COVID-19 time periods, but increased with age and was higher in females. Incidence was also higher among those initiating Janus kinase inhibitors (IR = 30.5; 95% CI = 25.03-36.90), rituximab (IR = 27.8; 95% CI = 25.20-30.57), or cyclophosphamide (IR = 27.5; 95% CI = 19.27-38.10). In periods when patients were not on IS medication, the IR was 13.7 (95% CI = 13.37-14.07), whereas the IRs were 18.6 (95% CI = 18.17-18.99) and 32.0 (95% CI = 31.06-33.04) in periods where either 1 or multiple IS medication classes were used, respectively.

CONCLUSIONS: Consideration for HZ vaccination should be made when IS medications are being initiated. These results provide guidance on which drug classes could signal to providers the patients who are appropriate for HZ vaccination upon IS medication initiation.

SPONSORSHIP: GlaxoSmithKline Biologicals SA (GSK study identifier: VEO-000613).

B3 Health care resource utilization and economic burden of herpes zoster in people with HIV: A retrospective cohort study

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[1]*GSK*; [2]*Optum Life Sciences*; [3]*ViiV Healthcare*

BACKGROUND: Herpes zoster (HZ) typically involves a painful dermatomal rash and can increase health care resource utilization (HRU) and costs. People with HIV (PWH) are at increased risk of HZ.

OBJECTIVE: To estimate and compare HRU and costs in PWH and HZ and PWH only.

METHODS: This retrospective cohort study used administrative claims data for individuals with Medicare Advantage with Part D and commercial insurance (Optum Research Database) between October 2015 and March 2022. Adults (aged ≥18 years) with HIV were identified based on *International Classification of Diseases, Tenth Revision, Clinical Modification* diagnosis codes. Those with an HZ diagnosis (marking the index date) were assigned to a PWH+HZ cohort, and those without were assigned to a PWH-only cohort (index dates were randomly assigned to a date after an HIV diagnosis and 12 months of continuous enrollment [CE]). Patients included had at least 12 months of baseline CE, at least 1 month of follow-up CE, and no baseline HZ diagnosis or HZ vaccine. Patient characteristics were measured during baseline. PWH+HZ were propensity score matched 1:4 to PWH-only with at least as much follow-up. Propensity scores were calculated using logistic regression with cohort as the outcome and baseline characteristics as predictors. All-cause HRU and cost outcomes were assessed in the 1 month post-index, and the 3 months post-index for matched sets with sufficient follow-up time. Outcomes were compared using z-tests with robust SEs.

RESULTS: After matching, 1,078 and 4,312 patients were included in the PWH+HZ and PWH-only cohorts, respectively. No significant differences were observed in baseline characteristics between the matched cohorts, with similar mean (SD) age (53 [13] years), mean (SD) baseline costs ($54,608 [$63,217] vs $54,270 [$60,502]), and percent male (75 vs. 76%). In the 1 month post-index, mean (SD) HRU was higher in the PWH+HZ vs PWH-only cohort ($P<0.001$) for ambulatory visits (3.4 [4.0] vs 2.0 [3.6]), emergency department visits (0.42 [1.04] vs 0.15 [0.66]), inpatient admissions (0.09 [0.32] vs 0.03 [0.19]), and pharmacy fills (5.8 [4.6] vs 4.1 [4.4]). Mean (SD) 1-month costs were also higher ($P<0.001$) in the PWH+HZ ($7,904 [$30,161]) vs PWH-only cohort ($4,829 [$11,673]). Among matched sets with at least 3 months of follow-up (92% of overall cohorts), higher HRU and costs were also observed in the PWH+HZ compared with PWH-only cohort in the 3 months post-index ($P<0.001$).

CONCLUSIONS: HZ is associated with increased HRU and costs among people with HIV. HZ prevention may be important to consider in this population.

SPONSORSHIP: GlaxoSmithKline Biologicals SA (GSK study identifier: VEO-000373).

B4 Health care resource utilization and economic burden of herpes zoster in patients with multiple sclerosis: A retrospective cohort study

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BACKGROUND: Herpes zoster (HZ) is characterized by a painful dermatomal rash and is associated with increased health care resource utilization (HRU) and costs. Adults with multiple sclerosis (MS) may be at increased risk of HZ. The increased HRU and costs associated with HZ among adults with MS in the United States is unknown.

OBJECTIVE: To estimate HRU and costs in patients with both MS and HZ in comparison with patients with MS only.

METHODS: This retrospective cohort study used an administrative claims database with commercial and Medicare Advantage with Part D data. Adults (aged ≥18 years) with MS were identified between October 2015 and March 2022 based on *International Classification of Diseases, Tenth Revision, Clinical Modification* diagnosis codes. Patients with an HZ diagnosis (index date) were assigned to an MS+HZ cohort, or MS-only cohort if not (index dates were randomly assigned to a date after an MS diagnosis and 12 months of continuous enrollment [CE]). Patients included had at least 12 months of baseline CE, at least 1 month of follow-up CE, and no baseline HZ diagnosis or HZ vaccine. Patient characteristics were measured during baseline. Patients with MS+HZ were propensity score matched 1:4 to patients with MS-only with at least as much follow-up time. Propensity scores were calculated using logistic regression with cohort as the outcome and baseline characteristics as predictors. All-cause HRU and cost outcomes were assessed in the 1 month post-index, and the 3 months post-index for matched sets with sufficient follow-up time. Outcomes were compared using z-tests with robust SEs.

RESULTS: After matching, 1,860 and 7,440 patients were included in the MS+HZ and MS-only cohorts, respectively. Matched cohorts were well balanced on baseline characteristics, with similar mean (SD) age (58 [13] years), percent female (79%), and mean baseline costs ($58,238 vs $60,026).

At 1 month post-index, mean (SD) HRU was higher in the MS+HZ vs MS-only cohort ($P<0.001$) for ambulatory visits (3.8 [3.8] vs 2.5 [3.9]), emergency department visits (0.28 [0.81] vs 0.12 [0.52]), and inpatient admissions (0.05 [0.23] vs 0.03 [0.17]). Mean (SD) total costs at 1 month post-index were also higher ($P<0.001$) in the MS+HZ cohort ($5,991 [$15,814]) vs MS-only cohort ($4,674 [$9,450]). Higher HRU and costs in the MS+HZ vs MS-only cohort were also observed at 3 months post-index ($P<0.001$), among the 94% of matched sets with at least 3 months of follow-up.

CONCLUSIONS: Patients with MS and HZ had higher HRU and costs than those with MS only, suggesting a need to consider HZ prevention in this population.

SPONSORSHIP: GlaxoSmithKline Biologicals SA (GSK study identifier: VEO-000373).

B5 Prevalence of renal and bone risk factors and nucleos(t)ide inhibitor treatment among US patients with chronic hepatitis B

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BACKGROUND: Chronic hepatitis B (CHB) can lead to complications including cirrhosis, end-stage liver disease, hepatocellular carcinoma, and death. This study evaluated demographic characteristics and prevalence of renal and bone comorbidities/risk factors, including chronic kidney disease (CKD) and osteopenia/osteoporosis (OP), among patients with CHB.

OBJECTIVE: To describe the prevalence of renal and bone risk factors and nucleos(t)ide inhibitor (NI) treatment among those with CHB.

METHODS: This study evaluated retrospective claims data from Optum's deidentified ClinFormatics Data Mart database between January 1, 2016, and December 31, 2022. Commercially and Medicare-insured adult patients (aged ≥18 years) with a confirmed diagnosis of CHB (at least 1 inpatient or 2 outpatient *International Classification of Diseases, Tenth Revision* codes at least 30 days apart) who met continuous enrollment criteria and had no evidence of HIV infection were included. Descriptive analyses were carried out to estimate the prevalence of CKD, OP, related risk factors, and NI treatment experience.

RESULTS: 14,863 patients with CHB meeting eligibility were identified, of whom a majority were aged older than 50 years (70.0%), male (52.7%), and Asian (51.2%). Among those aged older than 64 years, 89.3% were Medicare insured and 10.7% were commercially insured. Less than one-third (29.9%) of patients had evidence of NI treatment during the observation period, with tenofovir disoproxil fumarate being most common (16.5%), followed by entecavir (12.5%) and tenofovir alafenamide (8.1%). One-quarter (25.8%) of the population had CKD, with 6.7% of patients diagnosed with CKD stage IV or end-stage renal disease. Most patients with CHB had a comorbidity- or medication-related risk factor for CKD, such as hypertension (60.8%), vitamin D deficiency (41.2%), and chronic nonsteroidal anti-inflammatory drug use (25.7%). More than one-quarter (26.9%) of the CHB population had a diagnosis or evidence of treatment for OP. Bone-related risk factors were prevalent, with diabetes mellitus (32.7%) and statin use (35.7%) being especially common. The overall prevalence of renal- and bone-related comorbidities and risk factors was similar among patients treated with NIs.

CONCLUSIONS: This study demonstrates the persistent high prevalence of comorbidities in the CHB population. These complex patients had a high comorbidity burden, and most had at least 1 risk factor for CKD. Although NIs are preferred treatment options for CHB, fewer than one-third had a history of NI treatment. These findings are relevant for considering CHB treatment options, particularly their renal and bone impact, to minimize comorbidities and complications.

SPONSORSHIP: Gilead Sciences.

B6 Improving adherence to HIV PREP via a PBM- driven educational intervention

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BACKGROUND: Pre-exposure prophylaxis (PrEP) reduces the risk of getting HIV from sex by approximately 99% and reduces the risk of getting HIV from injection drug use by at least 74%. Using PrEP and condoms and having low-risk sex can all effectively reduce risk, but combining prevention strategies may be even more effective. For any prevention strategy to work, it must be used correctly and consistently. Also, for every HIV infection that is prevented, an estimated $360,000 is avoided. However, a high level of prevention efficacy requires a high level of adherence to daily medication (>95%).

OBJECTIVE: To (1) improve adherence to HIV PrEP therapy via a pharmacy benefit management (PBM)–driven educational intervention aimed at physicians and pharmacists to educate on current HIV PrEP guidelines and (2) identify barriers to adherence.

METHODS: A quasi-experimental pre-/post-study design. Data were obtained through a retrospective drug utilization analysis of pharmacy claims from commercial insurers. The percentage of prescription days covered

(PDC) was determined. Adherence to PrEP was defined as compliant with at least 95% PDC. Education was provided to a total of 9 physicians and 3 pharmacists that provide HIV PrEP treatment to a total of 55 members. The proportion of adherent patients was determined for 3 periods: (1) before and (2) after the HIV PrEP 2021 guideline update (pre-intervention) and (3) after provider education (post-intervention).

RESULTS: We observed a gradual increase in the proportion of patients that were adherent to HIV PrEP when compared with baseline (37.8%), after guideline publication (57.9%), and after educational intervention (62.7%). During the pre-intervention period (before and after the publication of the 2021 HIV PrEP guidelines) nonadherence to HIV PrEP was 62% and 42%, respectively. The major adherence barrier reported was related to a lack of patient knowledge regarding the efficacy of HIV PrEP at optimal adherence rates.

CONCLUSIONS: Clinical educational outreach may provide an effective strategy to improve knowledge regarding the efficacy of HIV PrEP when adherence is optimal. Payers need to be aware of the significant cost avoidance associated with preventing HIV infection that is achievable via optimal adherence rates. Pharmacy benefit management interventions have a strategic role in promoting educational campaigns regarding updates to HIV PrEP guidelines, the importance of adherence in achieving optimal HIV PREP efficacy, and the significant cost avoidance associated with these educational efforts.

SPONSORSHIP: MC-Rx.

B7 Switching between preexposure prophylaxis regimens for HIV-1 prevention in the United States: A real-world study, 2021-2022

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BACKGROUND: Adherence to pre-exposure prophylaxis (PrEP) is critical to ensure its effectiveness in preventing HIV-1 infection.

OBJECTIVE: To understand how modality could impact PrEP use and adherence, we examined utilization and switching patterns for oral and injectable PrEP regimens from 2021 to 2022.

METHODS: HIV-1 negative and PrEP-naive individuals who initiated emtricitabine (F)/tenofovir disoproxil fumarate (TDF), F/tenofovir alafenamide (TAF), generic F/TDF (gF/TDF), or injectable cabotegravir (CAB) after January 2021 were identified from the IQVIA Real-World Longitudinal Prescriptions and Diagnosis Database. Transgender men and women were identified by an algorithm incorporating claims for gender dysphoria and gender-affirming surgery/hormone therapy. Individuals not identified as transgender were classified as cisgender men or women. Switching patterns between CAB and oral PrEP regimens were described in individuals who initiated PrEP after January 2021. Utilization patterns of different PrEP regimens among individuals who were PrEP naive prior to January 1, 2022, were described in a subgroup analysis conducted between January 1, 2022, and December 31, 2022.

RESULTS: Among 415,905 individuals who initiated PrEP after January 2021, 3,258 (0.8%) received CAB and the rest had oral regimens. A higher proportion of cis- and transgender women received CAB vs oral PrEP compared with cis- and transgender men, as did those with a history of renal and bone comorbidities. Of those individuals who received CAB between 2021 and 2022, 1,236 (38%) had CAB as their first prescription. Among individuals who switched to CAB, 2,022 (62%) switched from oral PrEP; 397 (20%) switched back to oral PrEP within 6 months. Those switching back had a 3.8% and 4.5% increase in 30- and 60-day adherence to oral PrEP (by proportion of days covered), respectively, compared with pre-switch levels. In the subgroup of individuals who were PrEP naive prior to January 2022 (n=123,807), 0.8% initiated CAB and the remainder initiated oral PrEP (33.3% F/TAF, 4.2% F/TDF, and 61.7% gF/TDF). Between January and December 2022, 0.3%-0.5% of those who initiated oral PrEP switched to CAB.

CONCLUSIONS: Between 2021 and 2022, most individuals initiated oral PrEP; however, switches were observed between oral and injectable regimens. Alternative PrEP modalities can support use when oral regimens do not meet individual needs or preferences. Further studies are needed to describe factors that would drive a switch.

SPONSORSHIP: Gilead Sciences, Inc.

B8 Characteristics and drivers of initial prescription dispensation among individuals newly prescribed oral preexposure prophylaxis for HIV-1

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BACKGROUND: The Ending the HIV Epidemic in the US (EHE) initiative aims to reduce new HIV-1 cases by 90% from 2017 to 2030. Pre-exposure prophylaxis (PrEP) is a key HIV-1 prevention strategy. In 2021, there were 32,100 new HIV-1 diagnoses in the United States; however, PrEP use in those who could benefit was only 30%, despite efforts to

increase prescribing. Understanding barriers to initial PrEP uptake from a population-health perspective is important to achieve EHE goals.

OBJECTIVE: To describe characteristics and potential drivers of PrEP prescription (Rx) initiation from a large, nationally representative, US retail pharmacy chain database.

METHODS: Retrospective analyses of Walgreens Pharmacy data (1/1/2020 to 12/31/2022) were conducted. Oral PrEP Rxs (F/TAF and F/TDF) were identified by generic product identifier and National Drug Code numbers; Rxs for HIV-1 treatment were excluded. Analyses included adults aged ≥18 years with at least 1 PrEP Rx (2021-2022) with no observed PrEP Rxs in 2020. Descriptive statistics, including out-of-pocket (OOP) costs and rejection reasons of first PrEP Rxs, are presented by processing and pickup status: filled and dispensed in less than or equal to 14 days, dispensed in more than 14 days, filled but not dispensed, or unfilled.

RESULTS: Between 2021 and 2022, 143,315 adults (male, 80%), had a first oral PrEP Rx written, most were in Southern states (36%), and those with PrEP Drug Assistance Programs (56%). Of those first Rxs, 74% were dispensed in less than or equal to 14 days, 9% in more than 14 days, 6% filled but not dispensed, and 11% were unfilled. Primary payment categories for first Rxs written were commercial insurance (62%), government (19%), and cash/other (19%). Overall, 23% had at least 1 Rx rejection, and of these, 19% were never dispensed. Among first PrEP Rxs, Rxs dispensed in less than or equal to 14 days, dispensed in more than 14 days, filled but not dispensed, and unfilled, respectively, the most common reasons for rejection were product/service not covered plan/benefit exclusion (38%, 36%, 35%, 31%, 49%), prior authorization required (21%, 19%, 22%, 20%, 31%), and plan limitations exceeded (45%, 48%, 48%, 52%, 24%). Average OOP costs were $341 for Rxs filled but not dispensed, compared with $6 for those dispensed in less than or equal to 14 days.

CONCLUSIONS: One in four first oral PrEP Rxs were not filled within 14 days; of those unfilled, rejection due to requirement for prior authorization was notably higher (31%) compared with Rxs dispensed within 14 days (19%). Mean OOP costs were considerably higher for Rxs filled but not dispensed than those dispensed in less than or equal to 14 days. Barriers to PrEP access exist in the pharmacy setting even after prescribing, highlighting the need to improve access and achieve EHE goals.

SPONSORSHIP: Gilead Sciences, Inc.

B9 Social determinants of health in a real-world adult HIV population: ICD-10-CM and consumer-linked data identification

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BACKGROUND: Social determinants of health (SDOH) are the conditions in which people are born, live, work, and age.

OBJECTIVE: To describe SDOH measures in a real-world HIV population through linkage with consumer data and *International Classification of Diseases, Tenth Revision, Clinical Modification* (ICD-10-CM) ICD-10-CM Z-codes available in medical closed claims (CC).

METHODS: CC from commercially insured enrollees between 01/01/2016 and 12/31/2021 and SDOH for calendar year 2022 including demographics, socioeconomic, and household information were used (CHRONOS. 2017-2023. Forian, Inc., Newtown, PA. https://forian.com). Both data sources are Health Insurance Portability and Accountability Act of 1996 compliant and linked by a unique anonymized patient identifier. Patients aged 18 years and older diagnosed with HIV (ICD-10-CM: B20*, Z21) were identified in CC prior to linking to SDOH data. Patients counted as overlapped if there was at least 1 record in SDOH data and at least 1 claim with HIV diagnosis in CC. Descriptive statistics of SDOH measures were evaluated for age, sex, race, and custom-defined composite measures for household status (marital status; household size; children in the home) and household economic status (economic stability indicator, household income). Economic stability indicator ranges from 0 to 30 with higher numbers indicating less economic stability. SDOH measures identified in CC using ICD-10-CM Z-codes (Z55-Z65, Z72, Z74) were summarized.

RESULTS: In CC, 69,897 (40.4%) unique patients with HIV were linked to SDOH records. Mean age was 44.4 (±12.6) years, and 77.2% were male. Patients were 58.7% White, 24.6% Black, 13.5% Hispanic, and 1.6% Asian. 77.8% had at least a college degree. 55.3% were single living in homes without children. Most patients lived in households with low economic stability (80.6%), even with high incomes reported (53.4% with >$100k annual income). Among linked patients with HIV, 17,559 (25.1%) had at least 1 record with an SDOH Z-code. The most common were problems related to lifestyle (Z72), problems related to care provider dependency (Z74), and other problems related to primary support group (Z63). At max digit specificity, the most common were tobacco use (Z72.0), high-risk heterosexual behavior (Z72.51), and high-risk homosexual behavior (Z72.52).

CONCLUSIONS: In this study, SDOH factors potentially influencing HIV care patterns, health outcomes, and health care costs were identified in medical claims and linked consumer data. These can be used in propensity score development or as covariates to remove additional bias when evaluating the impact of treatment on health outcomes or, in the case of Z-codes, allow for informative subset analyses. The creation of SDOH composite measures may provide deeper insights into HEOR results.

SPONSORSHIP: Magnolia Market Access.

B10 Influence of formulary coverage on dispensing status of HIV-1 preexposure prophylaxis regimens in the United States

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BACKGROUND: Despite effective HIV-1 prevention options, barriers to pre-exposure prophylaxis (PrEP) uptake persist.

OBJECTIVE: To assess the influence of formulary factors on the dispensing status of US PrEP claims using a prescriptions-claims database.

METHODS: Claims data for daily oral brand emtricitabine (F)/tenofovir disoproxil fumarate (TDF), generic F/TDF (gF/TDF), F/tenofovir alafenamide (TAF), and injectable cabotegravir (CAB) for PrEP from January 2021 to July 2023 for adults aged 18 years and older were obtained from the IQVIA Longitudinal Access and Adjudication Dataset. Claims for HIV-1 treatment, HIV-1 postexposure prophylaxis, and hepatitis B were excluded. Formulary coverage was evaluated by reasons for claim rejections, dispensing status (claim has been filled and paid), payer types, and copay costs. Transgender men and women were identified by an algorithm incorporating claims for gender dysphoria and gender-affirming surgery or hormone therapy. Individuals not identified as transgender were classified as cisgender men/women. Logistic regression was used to estimate the likelihood of dispensing PrEP claims by demographic and formulary characteristics.

RESULTS: More than 4 million PrEP claims were assessed, with significant variations in the likelihood of dispensation. Claims for older individuals had a higher probability of dispensation; each 5-year age increment corresponded to a 6% rise in odds of dispensing. Although most PrEP claims were for cisgender men, cisgender women and transgender individuals had lower odds of dispensing. Medicare claims were more likely, and Medicaid claims less likely, to be dispensed vs commercial insurance claims. Compared with gF/TDF, the likelihood of dispensing was similar for F/TAF, whereas CAB or brand F/TDF were associated with 65%-80% lower odds of dispensing. Odds of PrEP dispensing decreased by 41%-88% when individuals had out-of-pocket costs. Reasons for claim rejections varied by PrEP regimen. A substantial proportion of rejections were due to noncoverage of product/individual for brand F/TDF (47%) and CAB (60%), with a comparatively low 23% for F/TAF. Prior authorization requirements accounted for an average of 12% of all PrEP claims rejections (F/TAF, 18%; other regimens, 5%-10%). The prevalence of refill restrictions was relatively high (15%) for F/TAF and gF/TDF, but low (<6%) for other PrEP regimen claims.

CONCLUSIONS: Our study highlights the sizable influence of formulary coverage on the dispensing status of PrEP claims. These findings emphasize the need to increase PrEP use by addressing prior authorization requirements and out-of-pocket costs.

SPONSORSHIP: Gilead Sciences, Inc.

B13 Burden of refractory/resistant cytomegalovirus or cytomegalovirus drug intolerance in hematopoietic stem cell transplant recipients: US subgroup analysis

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BACKGROUND: Contemporary, real-world data on managing cytomegalovirus (CMV) infection following hematopoietic stem cell transplant (HSCT) are limited.

OBJECTIVE: To generate real-world data on CMV burden in HSCT recipients with refractory/resistant CMV or intolerance to current therapies (RRI) from the US cohort of the multinational OTUS study.

METHODS: This subgroup analysis of a retrospective study included pooled data from 4 US transplant centers from patients (pts) aged 18 years or older with RRI CMV who required at least 1 anti-CMV agent. Eligible pts had to have available data for at least 12 months after the CMV index date (RRI CMV identification date) or until death (whichever was first). CMV index episode: first CMV episode where pts were considered RRI after HSCT. CMV treatment patterns, clinical outcomes, and health care resource utilization data were analyzed descriptively.

RESULTS: For the 138 US pts analyzed (median age: 55 years), median time from transplant to first CMV episode was 30.5 days. After HSCT, there were 199 CMV episodes. At CMV index episode, 94 pts had refractory CMV, 8 had resistant CMV,

and 65 were intolerant (not mutually exclusive). Valganciclovir was the most often used anti-CMV agent (81.2% of pts), followed by foscarnet (56.5%) and ganciclovir (50.7%); 76.1% of pts received at least 2 therapies. All pts had at least 1 anti-CMV therapy dose change/discontinuation during CMV RRI episodes; CMV infection/disease resolution resulted in dose change/discontinuation in less than 40% of pts per therapy. After RRI identification, 42.8% of pts had myelosuppression events; 55.2% (37/67) of events were neutropenia. CMV index episode clearance (determined by PI) was achieved by 59.4% of pts (median time: 61.0 days). CMV recurred in 31.2% of pts (median time from end of index CMV episode to start of recurrent CMV episode: 36.0 days); 55.8% of pts achieved clearance of recurrent CMV episodes. After HSCT, 3.6% of pts had graft failure and 60.1% experienced at least 1 graft-versus-host disease event; 57.2% had at least 1 acute graft-versus-host disease event. All-cause mortality was 42.0%; mortality 1 year after RRI identification was 30.4%. Overall, 29.7% of pts reported at least 1 CMV-related hospitalization; most hospitalizations (79.3%) occurred during an RRI CMV episode.

CONCLUSIONS: Although several anti-CMV therapies are available in real-world settings, many patients with RRI CMV after HSCT did not achieve viremia clearance and experienced high rates of recurrence and adverse outcomes (eg, myelosuppression and mortality). Novel therapies with improved safety profiles are needed to achieve and maintain CMV clearance.

SPONSORSHIP: Study and medical writing support from Caudex funded by Takeda Development Center Americas, Inc.

B14 Burden of refractory/resistant cytomegalovirus or cytomegalovirus drug intolerance in solid organ transplant recipients: US subgroup analysis

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BACKGROUND: Current real-world data on management and outcomes of cytomegalovirus (CMV) infection after solid organ transplant (SOT) are limited. The multinational CMV Outcomes, Treatment Patterns and Healthcare Resource Utilization study collected data to describe the burden of refractory/resistant CMV infection or intolerance to alternative anti-CMV therapies (RRI) in SOT recipients.

OBJECTIVE: To provide real-world evidence regarding treatment (tx) patterns, clinical outcomes, and disease burden in patients (pts) with post-transplant difficult-to-treat CMV infection in a US cohort.

METHODS: This was a subgroup analysis of a retrospective study of adult SOT recipients with RRI CMV. Across 5 US transplant centers, eligible pts received SOT after January 1, 2014, and were treated with at least 1 anti-CMV therapy for RRI CMV. Pts needed to have available data for at least 12 months after the CMV index date (date of first RRI identification after SOT) or until death (whichever came first). Anti-CMV tx patterns, clinical outcomes, and hospitalizations were descriptively analyzed.

RESULTS: Data were evaluated from 106 pts in the United States. The median time (Q1-Q3) from transplant to first CMV episode was 197.5 (115-254) days. 89.6% of pts developed RRI CMV during their first CMV episode. During the first RRI CMV episode, pts were identified as intolerant to anti-CMV therapies (50.9%) or having refractory CMV (35.8%) or resistant CMV (34.0%) (not mutually exclusive). Valganciclovir (VGCV) was the most commonly used therapy for primary (78/83 [94.0%]) and secondary prophylaxis (24/35 [68.6%]). During tx, 87.7% and 26.4% of pts received VGCV and foscarnet, respectively; 66.3% of pts received at least 2 anti-CMV therapies. During the first RRI CMV episode, 56.0% of myelosuppression events were associated with VGCV use after RRI identification; tx discontinuations/dose adjustments occurred in 82.7% of pts on VGCV and 59.6% of pts on ganciclovir. During the first RRI CMV episode, 18.9% of pts failed to achieve viremia clearance. CMV recurred in 23.6% of pts. Of 106 pts, 53 (50.0%) had CMV-related hospitalizations with/without emergency department visits. Of 13 (12.3%) pts with graft loss, 11 had graft loss after first RRI identification. All-cause mortality was 17.0%; mortality 1 year after RRI identification was 7.5%.

CONCLUSIONS: This study showed that many pts did not achieve CMV clearance during the first RRI episode and had CMV recurrence and/or adverse outcomes. New therapies that achieve and sustain CMV clearance without tx-associated toxicities are needed.

SPONSORSHIP: Study and medical writing support from Caudex was funded by Takeda Development Center Americas, Inc.

C00-D49 Neoplasms

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

C1 Adverse event costs associated with systemic therapies for metastatic colorectal cancer previously treated with oxaliplatin- and irinotecan-based chemotherapy therapy in the United States

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BACKGROUND: Systemic therapies such as fruquintinib, regorafenib, and trifluridine/tipiracil (T/T) have demonstrated survival benefits vs best supportive care (BSC) in patients with metastatic colorectal cancer (mCRC) previously treated with oxaliplatin- and irinotecan-based chemotherapy (OIC). However, there is limited evidence on their relative safety profiles and adverse event (AE)–related cost burden, which has previously been identified as a driver of health care resource use and costs in the United States.

OBJECTIVE: To compare the AE management costs of fruquintinib, regorafenib, T/T and T/T+bevacizumab (T/T+bev) for mCRC previously treated with OIC, from US Commercial and Medicare payer perspectives.

METHODS: A cost-consequence model was developed to calculate the per-patient and per-patient per-month AE costs using the incidence of grade 3/4 AEs occurring in greater than or equal to 5% of patients, the corresponding AE management costs, and the mean duration of each treatment. AE rates and treatment duration were obtained from individual patient data from FRESCO and FRESCO-2 for fruquintinib, from RECOURSE and SUNLIGHT for T/T, CORRECT for regorafenib, and SUNLIGHT for T/T+bev. AE costs were obtained from the 2020 Healthcare Cost and Utilization Project for the Commercial perspective (inflated to 2023) and the FY2023 Medicare Acute Inpatient Prospective Payment System Fee Schedule for the Medicare perspective. Anchored comparisons of AE costs were calculated for fruquintinib, regorafenib, and T/T using a difference-in-differences approach over the entire treatment period with BSC as common reference.

RESULTS: From the commercial perspective, per-patient (per-patient per-month) AE costs were as follows: $4,015 ($814) and $4,253 ($1,053) for fruquintinib based on FRESCO and FRESCO-2, respectively; $8,181 ($2,922) for regorafenib; $17,110 ($5,858) and $9,851 ($2,475) for T/T based on RECOURSE and SUNLIGHT, respectively; and $11,620 ($1,226) for T/T+bev. In anchored comparisons with BSC as common reference, difference-in-differences over the entire treatment period also resulted in lower AE cost for fruquintinib based on FRESCO (and FRESCO-2) vs regorafenib: –$1,910 (–$2,239) and vs T/T based on RECOURSE: –$11,427 (–$11,756). These results were consistent from the Medicare perspective.

CONCLUSIONS: Based on the cost-consequence model results, fruquintinib was associated with lower AE management costs compared with regorafenib, T/T, and T/T+bev for patients with mCRC previously treated with OIC, which should be considered in treatment and formulary decision-making.

SPONSORSHIP: Takeda Pharmaceuticals America, Inc.

C2 Health care resource utilization and financial burden of adverse events with current first-line therapies among patients with HER2-negative metastatic gastric or gastroesophageal junction cancers in the United States

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BACKGROUND: New therapies have emerged for patients with human epidermal growth factor receptor 2–negative metastatic gastric or gastroesophageal junction cancers (mG/GEJC). Although these therapies provide promising efficacy, it is important to understand the impact of adverse events (AEs) that result from real-world usage.

OBJECTIVE: The goal of this study was to determine the health care–related burden of AEs from available first-line (1L) therapies for patients with mG/GEJC.

METHODS: The US Medicare Fee-For-Service (MFFS) and IQVIA PharMetrics Plus closed-claims commercial insurance (COMI) databases were analyzed from January 2016 to December 2021 for patients with human epidermal growth factor receptor 2–negative mG/GEJC, at least 1 systemic therapy, and evidence of 1L treatment completion. Patient demographics, comorbidities, and disease characteristics were analyzed (6 months prior to 1L initiation [index date]). Health care resource utilization (HRU) and costs were adjusted for patient characteristics, treatments, and other AEs to reflect incremental change associated with specific AEs during the 1L treatment period (index date to 1L end).

RESULTS: Overall, 6,503 patients with MFFS and 955 patients with COMI were included; on 1L, 75% and 79% had AEs of any severity, respectively. Of patients who had AEs on 1L, most had GEJC (69%, MFFS and COMI) and National Cancer Institute comorbidity index less than 1 (62% MFFS and 89% COMI). The most common AEs of any severity across both MFFS and COMI patients comprised nausea/vomiting (≥44%), anemia (≥39%), and fatigue/lethargy/asthenia (≥26%); the most common severe AEs included anemia (≥12%), nausea/vomiting (≥8%), and thrombocytopenia (≥7%). Incremental HRU in 1L increased markedly in outpatient additional visits regardless of coverage for most patients experiencing AEs of interest, ranging from −0.9 to 1.5 (any severity) and −0.8 to 0.5 (severe) additional visits for patients with MFFS and −1.0 to 4.4 (any severity) and 1.1 to 3.9 (severe) additional visits for those with COMI. Incremental costs in 1L treatment increased for most AEs of interest (costs ranged from approximately $700 to $13,000 [any severity] and $9,000 to $17 000 [severe] for patients with MFFS and approximately $2,000 to $22,000 [any severity] and $31,000 to $49,000 [severe] for patients with COMI). Overall, costs were mainly driven by outpatient visits.

CONCLUSIONS: Common AEs occurring on treatment with currently available therapies pose a substantial burden on the health care system with increased HRU and cost, regardless of severity. This highlights the need for enhanced prophylactic, monitoring, and management strategies for AEs to reduce HRU and economic burden.

SPONSORSHIP: Astellas Pharma Inc.

C3 Real-world treatment and testing patterns for advanced/metastatic gastric cancer/gastroesophageal junction cancer/esophageal adenocarcinoma in the United States: Results from the Flatiron Health database

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BACKGROUND: In CheckMate 649 (NCT02872116), nivolumab + fluoropyrimidine and platinum-based chemotherapy (NIVO+chemo) showed overall survival and progression-free survival benefit vs chemo alone in patients with advanced/metastatic gastric cancer/gastroesophageal junction cancer/esophageal adenocarcinoma (adv/met GC/GEJC/EAC). NIVO+chemo received US Food and Drug Administration approval in April 2021 as first-line (1L) treatment in patients with adv/met GC/GEJC/EAC regardless of programmed death-ligand 1 (PD-L1) status. Currently, data on real-world NIVO+chemo use and PD-L1 testing patterns in the 1L setting in patients with adv/met GC/GEJC/EAC are limited.

OBJECTIVE: To describe real-world treatment patterns, baseline demographics and clinical characteristics, and PD-L1 testing trends among patients diagnosed with adv/met GC/GEJC/EAC on/after April 1, 2021, using the Flatiron Health database.

METHODS: A retrospective observational study of adults diagnosed with adv/met GC/GEJC/EAC between April 1, 2021, and April 30, 2023, was conducted using electronic health records. Patients aged 18 years and older with at least 1 month of follow-up data from index (date of first adv/met GC/GEJC/EAC diagnosis) were included. Patients with human epidermal growth factor receptor 2–positive disease, evidence of receiving trastuzumab or an experimental drug, or diagnosis of other primary cancers prior to index were excluded.

RESULTS: A total of 1,607 patients met the eligibility criteria and were diagnosed on/after April 1, 2021. The median age at index was 70.0 years, 73.7% of patients were male, and the median follow-up time from diagnosis was 6.7 months. The proportion of patients receiving 1L treatment was 73.4% (n = 1,179). Among patients receiving 1L treatment, only 22.3% (n = 263) received NIVO+chemo and 67.0% (n = 790) received chemo only. Overall, 55.9% (n = 898) of patients received PD-L1 CPS testing. Among patients receiving 1L chemo-only treatments (n = 790), 54.2% received PDL1 CPS testing and 21.1% had a CPS greater than or equal to 5; among patients receiving immune-oncology–based treatments (n = 362), 74.0% received PD-L1 CPS testing and 38.4% had a CPS greater than or equal to 5.

CONCLUSIONS: The majority of patients with adv/met GC/GEJC/EAC received chemo-only regimens in the 1L setting. Among patients receiving 1L chemo only, approximately one-fifth had CPS greater than or equal to 5 and a large proportion of patients remained untested for PD-L1 CPS. These results highlight an opportunity for patients to potentially benefit from 1L immune-oncology+chemo. Additional analyses are needed to explore long-term outcomes in the real-world setting in this patient population. Further education is needed to raise awareness of the approved 1L treatment options available for patients with adv/met GC/GEJC/EAC regardless of PD-L1 status.

SPONSORSHIP: BMS.

C5 State-level opportunities for advancing biomarker testing in patients with advanced non–small cell lung cancer (aNSCLC) with fully insured commercial health plans

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BACKGROUND: Biomarker testing in advanced non–small cell lung cancer (aNSCLC) has grown, with guidelines now recommending comprehensive testing with multigene panel tests (MGPT). Although states have recently advanced legislation to improve access to testing in state-regulated health plans, comparisons with other plan types are needed to assess variation in access and use.

OBJECTIVE: To compare biomarker testing in fully insured (FI) vs self-funded (SF) plans.

METHODS: A retrospective analysis (2018-2022) of medical and pharmacy claims using IQVIA PharMetrics Plus database was used to assess upfront biomarker testing (≤60 days of aNSCLC diagnosis) trends by patients' health plan type (FI vs SF) and state. Patients' biomarker testing was categorized as having claims for MGPT, single gene testing only, or no testing. Adjusted logistic regression was used to assess the association between health plan type and testing, whereas differences within states were assessed by chi-square tests.

RESULTS: The analysis included 4,424 FI patients with aNSCLC and 4,871 SF patients with aNSCLC. Overall testing rates were similar between FI and SF (85.0% vs 86.3%, $P = 0.06$); however, FI patients had a lower proportion of claims for MGPT (11.0% vs 17.6%, $P \leq 0.01$). FI patients had a 12% lower odds of receiving upfront testing compared with SF patients (odds ratio [OR] [95% CI) = 0.88 [0.78-0.99], $P = 0.03$), which persisted across the study period (all time interactions: $P > 0.05$). Furthermore, the odds of upfront MGPT were 42% lower for FI vs SF (OR [95% CI) = 0.58 [0.51-0.66], $P < 0.01$); this effect also stayed consistent over time (all time interactions: $P > 0.05$). States with below 80% testing rates among FI patients included Iowa (16/24, 66.7%), Minnesota (112/171, 65.5%), New Jersey (22/31, 71.0%), Oregon (25/37, 67.6%), and South Carolina (102/134, 76.1%). States where upfront testing was lower in the FI vs SF included Florida (82.2% vs 88%, $P = 0.04$) and Iowa (66.7% vs 94.7%, $P = 0.01$). Claims for upfront MGPT in the FI population were low across all states, with Massachusetts (31/112, 27.7%) and Connecticut (12/50, 24.0%) on the high end of the range, whereas Florida (40/523, 7.6%) and Washington (3/48, 6.2%) were among states on the lower end. Upfront MGPT in FI patients were less than or equal to 50% of that of SF patients in Florida (7.6% vs 16.0%, $P < 0.01$), North Carolina (6.9% vs 14.0%, $P = 0.02$), and Tennessee (11.0% vs 22.0%, $P = 0.02$), whereas claims for MGPT (vs single gene testing only) were lower for FI vs SF in Indiana (11.9% vs 22.7%, $P = 0.048$).

CONCLUSIONS: Patients in FI plans were less likely to have upfront testing and upfront MGPT than those in SF plans, with varying levels of differences across states. This evidence suggests that there is opportunity for state-level legislation to improve access to testing.

SPONSORSHIP: Genentech, Inc.

C6 Health care costs and unmet needs among patients treated for EGFR-mutated advanced or metastatic non–small cell lung cancer

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BACKGROUND: Approximately 19%-24% of patients with non–small cell lung cancer (NSCLC) have an epidermal growth factor receptor mutation (EGFRm). Osimertinib (OSI) has shown improved outcomes in first-line (1L) treatment of EGFRm advanced NSCLC relative to other EGFR-tyrosine kinase inhibitors (EGFR-TKIs), but it is associated with higher costs, and progression on OSI poses a challenge for treatment of these patients. Cost implications of current EGFRm treatments are of interest to US population health decision-makers.

OBJECTIVE: To describe health care costs by line of therapy (LOT) among patients with EGFRm advanced NSCLC initiating 1L treatment.

METHODS: IBM MarketScan Research Databases (1/1/2010 to 1/31/2023) were used to analyze adult patients with advanced NSCLC, identified based on a diagnosis for lung cancer (LC) and initiation of 1L therapy or diagnosis of metastases within 30 days of the first LC diagnosis. All patients were required to initiate an EGFR-TKI during any LOT on or after 4/18/2018 (date of OSI approval) to proxy EGFRm status. Per-patient per-month (PPPM) all-cause health care costs were described by LOT (ie, 1L, second line [2L], and third line [3L]) among all patients and among subgroups of patients treated or not treated with OSI in 1L.

RESULTS: A total of 409 patients with EGFRm advanced NSCLC were analyzed (mean age at 1L initiation: 60.5 years; 70.2% female). In 1L, 72.9% initiated OSI (2L: 45.9%; 3L: 41.2%), 21.0% initiated chemotherapy (2L: 30.0%; 3L: 36.5%), 4.6% initiated another EGFR-TKI (2L: 12.9%; 3L: 12.9%), and 1.5% initiated immunotherapy (2L: 11.2%; 3L: 9.4%). Among

all EGFRm patients, mean LOT duration was 10.2 months (1L), 8.7 months (2L), and 8.0 months (3L) and mean all-cause health care costs PPPM were $27,751 (1L), $28,971 (2L; n = 170), and $31,251 (3L; n = 85). Among patients treated with OSI monotherapy in 1L (n = 279), mean PPPM costs were $27,610 (1L), $35,501 (2L; n = 67), and $36,618 (3L; n = 33). Of the patients who were not treated with OSI in 1L (n = 111), 77.5% initiated chemotherapy, 17.1% initiated another EGFR-TKI, and 5.4% initiated immunotherapy in 1L, with mean PPPM costs of $28,552 (1L), $24,074 (2L; n = 99), and $25,887 (3L; n = 50).

CONCLUSIONS: Among patients with EGFRm advanced NSCLC initiating 1L therapy, each successive LOT was shorter and more costly, including among those treated with 1L OSI. Approximately 1 in 10 patients received treatments that are not guideline recommended (ie, immunotherapy) in 2L+. Targeted 1L therapies with greater efficacy and more durable responses are needed to delay costly disease progression in EGFRm advanced NSCLC.

SPONSORSHIP: Janssen Scientific Affairs.

C7 Real-world treatment treatment patterns and health care resource utilization (HCRU) in patients (pts) with advanced/metastatic non–small cell lung cancer (a/mNSCLC) who have successfully completed first-line (1L) therapy

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BACKGROUND: Patients (pts) with a/mNSCLC who successfully complete first-line (1L) therapy with platinum-based chemo, pemetrexed, and/or pembrolizumab (pembro) are candidates for 1L maintenance therapy (1LMT). Real-world data on 1LMT for these pts are limited.

OBJECTIVE: To describe treatment patterns, clinical outcomes, and health care resource utilization for pts with a/mNSCLC who achieved stable disease or complete or partial response (SD/CR/PR) on completion of 1L therapy.

METHODS: This retrospective chart review study used physician-provided data collected via an electronic case report form from the United States, Canada, United Kingdom, Italy, Spain, France, and Germany. Pts (aged ≥18 years) were eligible if they had a/mNSCLC and achieved SD/CR/PR with 1L platinum-based chemo+immunotherapy (IO). The index date was defined as 1L completion date. Pts were followed from index to disease progression, death, second-line therapy initiation, or last physician contact.

RESULTS: In all, 285 physicians provided data for 942 pts; 680 (72.2%) pts initiated 1LMT and 262 (27.8%) pts did not. Among pts initiating 1LMT, pembro monotherapy (mono) was the most used 1LMT (53.4%), followed by pembro+pemetrexed (27.7%). The most common reason for not initiating 1LMT was patient preference (46.2%). Compared with pts who did not initiate 1LMT, pts who initiated 1LMT were older ($P < 0.01$) and more likely to have nonsquamous histology, metastatic disease at diagnosis, and shorter disease duration at index ($P < 0.001$ for all). Although overall survival was similar across both groups, progression-free survival was longer in pts who received 1LMT than in those who did not (17.7 vs 7.1 months; adjusted progression-free survival hazard ratio = 0.63 [95% CI = 0.41-0.85]). Median time to discontinuation was 20.0 months for IO mono; among pts who received 1LMT pembro+pemetrexed, median time to discontinuation was 9.0 months for pemetrexed vs 11.0 months for pembro. Disease progression was the primary reason for discontinuation of any 1LMT (65.5%). Prior to progression, pts who received 1LMT had a significantly lower mean (standard deviation) number of hospitalizations per year (0.3 ± 1.0 vs 1.2 ± 8.1; $P < 0.01$) and shorter mean length of stay (0.22 ± 0.89 vs 0.53 ± 2.43 days per month; $P < 0.01$) vs those who did not. However, pts who initiated 1LMT had significantly higher outpatient visits per month (mean ± standard deviation = 1.7 ± 1.4 vs 1.0 ± 0.9; $P < 0.001$), including visits with an oncologist (0.8 ± 0.7 vs 0.4 ± 0.4; $P < 0.001$), nurse (0.5 ± 0.6 vs 0.3 ± 0.4; $P < 0.001$), or general practitioner (0.4 ± 0.6 vs 0.3 ± 0.3; $P < 0.01$). Mean emergency department visits per month and hospice days per month were similar between groups.

CONCLUSIONS: Among the selected pts with a/mNSCLC who achieved SD/CR/PR with 1L therapy, 1LMT provided a clinical benefit while not substantially increasing health care resource utilization.

SPONSORSHIP: GSK.

C8 The economic impact of disease recurrence in resected non–small cell lung cancer

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BACKGROUND: Several new regimens are approved or in development for patients with surgically resectable

non–small cell lung cancer (rNSCLC) that may delay or prevent recurrence following surgery.

OBJECTIVE: To describe the historic cost associated with disease recurrence in rNSCLC.

METHODS: This observational cohort study used the Optum Clinformatics Data Mart database, which includes commercial and Medicare Advantage claims data. Adult patients were included if they had evidence of NSCLC diagnosis, surgical resection within 4 months of diagnosis, no evidence of metastasis 6 months prior to diagnosis (baseline) or 90 days after diagnosis, and continuous plan enrollment in baseline and 1 month after diagnosis (unless deceased) between July 2017 and February 2023. Patients were excluded for evidence of cancer in the baseline period, clinical trial participation, or osimertinib use (evidence of epidermal growth factor receptor mutant disease). The index date was defined as the NSCLC diagnosis date. Recurrence was defined as evidence of metastasis, new treatment after 180-day treatment-free period following a systemic agent, end-of-life care, or death. Treatment patterns, recurrence rates, health care resource use, and costs were measured using descriptive statistics.

RESULTS: A total of 10,563 patients met study inclusion criteria. The median age was 71 years, 41.2% were male, 85.8% had Medicare, and the median number of comorbidities was 1.4. In addition to surgery, 211 (2.0%) received neoadjuvant therapy and 2,145 (20.3%) received adjuvant therapy. During the time analyzed, chemotherapy was the most common adjuvant or neoadjuvant regimen, and only 282 patients received IO agents. With a median follow-up of 22.1 months, 2,842 patients (26.9%) had evidence of recurrence. Among patients who recurred, median time to recurrence was 9.6 months from surgery. The mean per-patient per-month (PPPM) all cause health care cost was $16,498 (SD = $15,545) from 1 month prior to diagnosis to recurrence and increased to $25,007 ($101,189) per month after recurrence. Among patients who did not recur, the mean PPPM cost was $10,292 ($8,217) from 1 month before diagnosis to 12 months after surgery. This declined to a mean PPPM cost of $3,160 ($4,877) from 12 months after surgery to end of follow-up.

CONCLUSIONS: There is a high cost associated with recurrence in rNSCLC, which often occurs within 12 months following surgery. This should be considered when evaluating the cost of new treatments that may delay or prevent recurrence.

SPONSORSHIP: AstraZeneca Pharmaceuticals LP.

C10 Pharmacist-tailored monitoring for patients initiating encorafenib and binimetinib combination therapy

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BACKGROUND: Combination therapy with protein kinase B-raf (BRAF) inhibitor, encorafenib, and mitogen-activated extracellular kinase inhibitor, binimetinib, is approved for the treatment of BRAF V600E or V600K unresectable or metastatic melanoma. This combination is associated with adverse events (AEs) that can lead to therapy changes (treatment holds, dose reductions, or discontinuations) early in treatment.

OBJECTIVE: To assess the impact of pharmacist-tailored monitoring on therapy changes during the first 90 days after encorafenib and binimetinib initiation.

METHODS: This was a single-center, pre-/postintervention study of adult patients, not part of a clinical trial, initiating encorafenib and binimetinib filled through the center's specialty pharmacy or manufacturer assistance program from July 2018 to December 2019 and April 2021 to December 2022. In April 2021, a tailored monitoring program was implemented where patients received counseling and a welcome kit at therapy initiation, followed by 6 monitoring calls over the first 90 days aligned with expected AE onset. Descriptive statistics were used to compare rates of treatment interruptions, dose reductions, and discontinuations before/after tailored monitoring implementation. Specific AE and pharmacist intervention frequency were also described.

RESULTS: Preintervention (n = 18) (first throughout) and postintervention (n = 19) (second throughout) populations were White (100%) and male (50%, 63%), with a median age of 55 [IQR = 43-65] and 59 [IQR = 51-68] years and median disease duration of 1.6 [IQR = 0.8-3.1] and 1.0 [IQR = 0.4-2.6] years. Cancer stage at time of diagnosis was more advanced (stage 4) in the postintervention arm (55%, 95%). There were more patients with at least 1 treatment interruption (44%, 58%), dose reduction (39%, 47%), and discontinuation (11%, 26%) in the postintervention arm. Dose increases, after a reduction, occurred twice in the postintervention group, but not in the preintervention group. At day 7 after initiating therapy, 44% of preintervention and 84% of postintervention patients reported at least 1 AE. The most reported AEs were fatigue (56%, 68%), nausea (44%, 74%), and diarrhea (17%, 47%). After intervention, all patients (n = 19) received

pharmacist interventions, with patient education (95%) and supportive therapy (68%) being the most frequent.

CONCLUSIONS: This study supports the recommendation to follow up with patients 7-14 days after oral anticancer medication initiation. More studies are needed to evaluate the benefit of increased pharmacist monitoring after the first 2 weeks of therapy.

SPONSORSHIP: Supported by a grant from Pfizer, Inc.

C11 Development of a predictive administrative claims–based algorithm for melanoma stage classification

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BACKGROUND: Identifying melanoma stage in administrative claims data is challenging because of the lack of clinical information.

OBJECTIVE: To develop and validate a claims-based algorithm to predict disease stage for patients (pts) with melanoma.

METHODS: Surveillance, Epidemiology, and End Results data provide a "gold standard" for developing a stage inference algorithm, as they contain reliable tumor staging at diagnosis, abstracted from hospital medical records. This study used the linked Surveillance, Epidemiology, and End Results–Medicare data (2012-2018). Pts aged 65 years and older diagnosed with stage I-IV cutaneous melanoma who had continuous Medicare enrollment for at least 12 months before and 6 months (follow-up period) after initial melanoma diagnosis (index date) were selected. The study sample was split into a training cohort (70%) and a test cohort (30%). A decision-tree model was developed using the CART method to predict American Joint Committee on Cancer (7th edition) disease stages (ie, I-II, III, and IV). Stage categories were determined based on similarities in treatment practice. Model performance was evaluated using sensitivity, specificity, precision, and negative predictive value. In the primary analysis, patient demographics and clinical characteristics available from Medicare claims were included as candidate predictors. Considering rapid shifts in the treatment landscape of melanoma, a sensitivity analysis was conducted by excluding treatment-related predictors.

RESULTS: A total of 8,314 pts with melanoma were included (7,549 stage I/II, 562 stage III, and 203 stage IV). The study population was predominantly White (93.7%) and male (59.4%), with a mean age of 76 years. The presence of the following claims during the follow-up period were selected in the final decision tree as predictors: "any metastasis," "lung metastasis," "lymph node (LN) metastasis," "sentinel LN biopsy," "ipilimumab," and "pembrolizumab." The model demonstrated a precision of 98% in predicting stage I/II, 73.5% in stage III, and 86.7% in stage IV. In the sensitivity analysis excluding treatment, "skin excision" was added as a predictor to the final decision tree, and the model had similar predictive performance.

CONCLUSIONS: The tree-based algorithms demonstrated high accuracy in predicting melanoma stages, particularly in stage I/II, based on demographic and clinical characteristics captured in the Medicare data. These findings suggest that tree-based algorithms offer a viable approach to predict melanoma stage by leveraging administrative claims–based data within the Medicare population, potentially laying the groundwork for broader application in other claims databases.

SPONSORSHIP: Bristol Myers Squibb.

C12 Cost-per-outcome analysis of nivolumab plus relatlimab vs BRAF/MEK inhibitor combinations for first-line treatment of patients with BRAF-mutant advanced melanoma

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BACKGROUND: Although nivolumab plus relatlimab (NIVO+RELA) and several BRAF/MEK inhibitor (BRAF/MEKi) combinations are approved for the treatment of BRAF-mutant advanced melanoma, there is limited evidence comparing long-term efficacy and costs between NIVO+RELA and BRAF/MEKi therapies.

OBJECTIVE: To compare total health care costs, cost per life-year (LY), and cost per progression-free LY (PFLY) of NIVO+RELA vs dabrafenib plus trametinib (DAB+TRAM), encorafenib plus binimetinib (ENCO+BINI), and vemurafenib plus cobimetinib (VEM+COBI) as first-line (1L) treatments for BRAF-mutant advanced melanoma across a 48-month horizon.

METHODS: Patients with previously untreated, BRAF-mutant, unresectable or metastatic melanoma from the following trials were included in the study: RELATIVITY-047 (NIVO+RELA arm; n = 136), pooled COMBI-d and COMBI-v (DAB+TRAM arm; n = 211 and 352), COLUMBUS (ENCO+BINI arm; n = 192), and coBRIM (VEM+COBI arm; n = 247). Pairwise matching-adjusted indirect comparisons were conducted separately for NIVO+RELA vs each BRAF/MEKi therapy to

estimate progression-free survival, overall survival, and treatment duration over a 48-month horizon. Total health care costs included drug acquisition and administration costs, disease management costs, subsequent treatment costs, and adverse event management costs. Cost per LY and cost per PFLY for each arm were estimated by dividing the total health care costs by the LYs and PFLYs, respectively. Costs were based on a US third-party payer perspective.

RESULTS: In pairwise comparisons and after matching, total health care costs were lower for NIVO+RELA vs DAB+TRAM ($357,121 vs $530,907), ENCO+BINI ($406,787 vs $546,402), and VEM+COBI ($353,758 vs $356,346) at 48 months. Drug acquisition and administration costs were the main drivers of cost differences. LYs trended higher with NIVO+RELA vs DAB+TRAM (2.83 vs 2.41), ENCO+BINI (2.82 vs 2.51), and VEM+COBI (2.82 vs 2.30). PFLYs trended higher with NIVO+RELA vs DAB+TRAM (1.64 vs 1.62) and VEM+COBI (1.80 vs 1.63). PFLYs trended lower for NIVO+RELA vs ENCO+BINI (1.59 vs 1.68). Cost per LY was lower for NIVO+RELA vs DAB+TRAM ($126,414 vs $220,293), ENCO+BINI ($144,038 vs $217,980), and VEM+COBI ($125,372 vs $154,765). Cost per PFLY was lower for NIVO+RELA vs DAB+TRAM ($217,757 vs $327,047), ENCO+BINI ($255,707 vs $325,401), and VEM+COBI ($196,532 vs $218,060).

CONCLUSIONS: NIVO+RELA is a more cost-saving 1L treatment option for BRAF-mutant advanced melanoma compared with DAB+TRAM, ENCO+BINI, and VEM+COBI. These results support the use of NIVO+RELA in this patient population.

SPONSORSHIP: Bristol Myers Squibb.

C14 Impact of genetic test–based counseling on health care utilization and cost among female patients with breast cancer

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BACKGROUND: The role of genetic testing (GT) and tumor profiling in cancer treatment is pivotal, providing crucial information about cancer metastasis risk, treatment outcomes, and targeted treatment options. Current literature primarily focuses on germline cancer susceptibility testing, while the rates of somatic tumor profiling and health care utilization (HCRU) costs related to genetic test–based counseling (GC) remain underexplored. A thorough understanding of GC distribution among patients with breast cancer (BC) can help identify disparities and direct targeted interventions for enhanced outcomes.

OBJECTIVE: To summarize demographic characteristics and compare HCRU among 2 cohorts, namely, patients with BC with GT and GC, and patients with BC with GT but without GC.

METHODS: The Optum deidentified Market Clarity Dataset was used to assess GC and tumor profiling among female patients with BC in the United States between January 1, 2020, and March 30, 2021, and with continuous 12-month eligibility. Two diagnosis codes with a 90-day gap were used to confirm BC diagnosis. A GT cohort (n = 14,896) was considered to create final cohorts based on GC presence (n = 2,897) and absence (n = 11,999). Variables including sex, age, self-reported race, ethnicity, insurance type, and total cost were descriptively summarized. Differences in proportions of molecular testing across subgroups were evaluated using a chi-square test of homogeneity.

RESULTS: The median age at BC diagnosis was 56 years. Testing proportions varied significantly among all demographic subgroups ($P < 0.0001$). Patients with commercial insurance were more likely to receive testing, especially those in their 30s, 40s, and 50s, compared with older patients (23% vs 14%). Notably, higher testing proportions were observed among Asian and Black patients vs White patients. In the GT with GC cohort, most patients were tested for surgical pathology, including biopsy. The average costs per patient within 12 months post-index procedure were $83,910 and $71,078 for the GT with GC and GT without GC cohorts, respectively.

CONCLUSIONS: Genetic counselor involvement during the initial cancer progression phase is associated with higher costs. This study emphasizes multiple areas for improvement in molecular testing disparities and underscores the opportunity to investigate outcomes related to GC.

SPONSORSHIP: Optum.

C15 Budget impact analysis of fam-trastuzumab deruxtecan-nxki (T-DXd) for the treatment of unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-low breast cancer in the United States

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BACKGROUND: Fam-trastuzumab deruxtecan-nxki (T-DXd) is the first approved human epidermal growth factor receptor 2 (HER2)–targeted treatment for adult patients with HER2-low (IHC 1+ or IHC 2+/ISH–) unresectable or metastatic breast cancer (mBC) who have received a prior chemotherapy in the metastatic setting or developed recurrence during or within 6 months of completing adjuvant chemotherapy. In DESTINY-Breast04, T-DXd demonstrated

greater clinical efficacy compared with physician choice of chemotherapy (median PFS = 9.9 vs 5.1 months). Considering the importance of comprehensively evaluating new cancer treatments, information on budgetary impact of T-DXd may be valuable to health care decision-makers.

OBJECTIVE: To estimate the budget impact of including T-DXd in a drug formulary for the treatment of patients with HER2-low mBC who have received prior chemotherapy from a commercial payer perspective in the United States.

METHODS: A budget impact model was developed to assess differences in total health care costs before and after adding T-DXd in a drug formulary of a hypothetical 10-million-member plan. The model considered drug acquisition and administration costs, monitoring costs, adverse event (AE) treatment costs, and health care costs after disease progression over 2 years (reported in 2023 USD). Published sources were used to estimate the number of eligible patients and obtain clinical efficacy and safety information for T-DXd and other commonly used treatments. Market shares for T-DXd and alternative treatments were assumed based on forecasting assumptions and retrospective chart review study. One-way sensitivity analyses were performed by varying model inputs by ±20%.

RESULTS: 756 patients with HER2-low mBC (517 hormone receptor positive and 239 hormone receptor negative) were estimated to be eligible for T-DXd. The total incremental per-member per-month budget for treating patient with T-DXd was $0.0287 over 2 years including cost offsets/savings of $0.0147. These savings were attributable to delayed disease progression and reduction in AE management costs due to T-DXd. In one-way sensitivity analyses, results ranged from $0.0108 to $0.0520 and were most sensitive to average body weight of the targeted population and T-DXd drug price.

CONCLUSIONS: This study provides important information on overall economic impact of treating patients with T-DXd. The cost savings associated with delayed disease progression and reduced AEs due to T-DXd were evident in the first 2 years and are likely to increase over time.

SPONSORSHIP: Daiichi Sankyo, Inc and AstraZeneca, Plc.

C18 The real-world value of medically integrated dispensing

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BACKGROUND: Medically integrated dispensing (MID) is the practice of processing prescriptions onsite at the physician practices. MID has been shown to provide benefits for all stakeholders. Patient care can be coordinated through the electronic medical record, which enables the physician to communicate therapy adjustments in real time and the pharmacist to timely fill appropriate therapy. Pharmacists can also evaluate issues that affect therapy adherence and intervene proactively. All this tends to reduce drug waste and the cost to the payers.

OBJECTIVE: To demonstrate the value of MID in oncology by measuring adherence to orally administered oncolytic drugs in 3 cancers.

METHODS: This is a retrospective study of adult patients treated with Xtandi (enzalutamide) or Zytiga (abiraterone acetate) for prostate cancer, Ibrance (palbociclib) for breast cancer, or Imbruvica (ibrutinib) for chronic lymphocytic leukemia in the period from July 2016 to November 2020. Pharmacy claims and dispensing data were collected from Hematology-Oncology Associates of Central New York. The study groups were as follows: "MI," comprising the patients who filled all their prescriptions at the Hematology-Oncology Associates of Central New York pharmacies, and "non-MI," consisting of patients who filled prescriptions off-site as well. Therapy adherence was measured by calculating the medication possession ratio (MPR) separately for each target drug for which the patient had 2+ prescriptions. The numerator was capped at the number of days in the follow-up period, because MPR is overinflated if patients obtain early refills. The standardized mean difference of the adjusted MPR was used to quantify the difference between the 2 study groups. The value higher than 20% was considered as meaningful.

RESULTS: The study groups (134 patients in total) were split by the target drug, with the numbers of MI and non-MI patients as follows: palbociclib (47:14), ibrutinib (30:9), enzalutamide (7:10), and abiraterone acetate (6:11). The mean age ranged between 71 and 79 years across the subgroups. The standardized mean difference between the MI and non-MI subgroups was as follows: palbociclib (21%), ibrutinib (53%), enzalutamide (57%), and abiraterone acetate (37%).

CONCLUSIONS: Oral oncolytic therapy adherence was meaningfully higher in the MI group when compared with the non-MI group for all 4 drugs evaluated. This finding held in the sensitivity analysis with follow-up periods of 6 and 12 months. Although this result suggests benefits of MID in oncology, larger studies with more sites, more drugs, and additional metrics are needed.

SPONSORSHIP: None.

C20 Assessing racial disparities in specialty drug treatment utilization and outcomes in patients with ovarian cancer: Insights from real-world evidence

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BACKGROUND: Women's health is a paramount concern in contemporary health care, with particular attention being paid to disparities in cancer care. Ovarian cancer (OC), the second most frequent gynecologic cancer and a leading cause of gynecologic malignancy–related deaths in the United States, poses specific challenges. The advent of specialty drugs, particularly PARPi therapy, has transformed OC treatment. This study aims to examine disparities in treatment use and outcomes among women with OC from diverse racial and ethnic backgrounds and socioeconomic status (SES) factors.

OBJECTIVE: To assess any racial and ethnic disparities in the use, initiation, and outcomes of PARPi therapy in patients with OC.

METHODS: A retrospective analysis was conducted using the Optum deidentified Market Clarity Dataset, which integrates claims and electronic health records of patients. Patients with OC aged 18 years and older were identified using *International Classification of Diseases, Ninth Revision* (ICD-9) (183x) and ICD-10 (C56x) codes, with a study period from January 1, 2015, to September 30, 2021. The index event was defined as the first OC diagnosis (clinical or claims). Only newly diagnosed patients with continuous medical and pharmacy eligibility, or continuous clinical activity of before 12 months and after index date, until the disenrollment from the health plan, end of study period, or death were taken into consideration. The study evaluated any racial disparities in (1) use of PARPi therapy for OC, (2) time to initiation of PARPi treatment, and (3) place of service utilization outcomes. Comparison of outcomes across different races was performed using Kaplan-Meier estimator.

RESULTS: Out of 46,626 identified new patients with OC, 2,795 patients received targeted PARPi therapy. The racial distribution was as follows: White 73.52%, Black 6.69%, Asian 2.83%, and Hispanic 4.65%. Kaplan-Meier analysis estimated a total of 32,925 White and 4,263 Black patients with OC at day zero. Analysis revealed a statistically significant difference ($P < 0.0001$) in patients receiving the PARPi therapy in White vs Black patients: 4% vs 2.9% at 2 years, 5.8% vs 3.9% at 3 years, 6.8% vs 4.8% at 4 years, and 7.4% vs 5.1% at 5 years, respectively. Outcomes among different SES groups will be analyzed further.

CONCLUSIONS: This real-world data study highlights the existence of racial disparities in treatment use and outcomes among Black and White patients with OC. The findings emphasize the need for targeted interventions to address these disparities and improve outcomes for all women with OC.

SPONSORSHIP: Optum.

C21 Health care resource use and costs for metastatic prostate cancer before and after progression to castration resistance

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BACKGROUND: Although patients with metastatic hormone-sensitive prostate cancer (mHSPC) generally have a better prognosis compared with those with metastatic castration-resistant prostate cancer (mCRPC), limited real-world studies evaluating the health care resource use (HRU) and cost burden associated with disease progression exist.

OBJECTIVE: To compare all-cause and prostate cancer (PC)–related HRU and health care costs (payer perspective) among patients with metastatic PC before and after progression to castration resistance (CR) using a large health plan claims database.

METHODS: US adults who progressed from mHSPC to mCRPC between 01/2011 and 12/2021 were identified from IQVIA PharMetrics Plus. Patient characteristics were assessed during the 6 months before first evidence of CR (index date). Wilcoxon signed rank tests were used to compare HRU (inpatient admissions, emergency department [ED] visits, and outpatient [OP] visits) and health care costs (total, medical, and pharmacy; 2022 USD) between the 6-month periods before (pre-mCRPC period) and after the index date (mCRPC period).

RESULTS: Among the 883 commercially insured patients from the database included in the analysis, mean [SD] age was 52.1 [2.3] years, and mean [SD] Charlson Comorbidity Index was 5.8 [1.9]. Compared with the pre-mCRPC period, during the mCRPC period, patients had significantly higher HRU in terms of number of all-cause (mean [SD] = 21.0 [16.0] vs 17.8 [12.8]; $P < 0.001$) and PC-related (mean [SD] = 15.9 [14.8] vs 12.4 [10.5]; $P < 0.001$) OP visits. The number of patients with ED visits (n [%] = 116 [13.1%] vs 84 [9.5%]; $P < 0.01$) was also higher for PC-related HRU during mCRPC. During the

mCRPC period, patients had significantly ($P<0.001$) higher all-cause total costs (86,003 [83,661] vs 42,953 [55,056]), higher pharmacy costs (37,795 [44,019] vs 6,849 [16,277]), and higher medical costs (48,208 [72,054] vs 36,104 [51,929]; driven by higher OP costs). During the mCRPC period, patients also had significantly higher PC-related medical costs (38,026 [57,306] vs 28,162 [42,750]; $P<0.001$), explained by higher OP and ED costs.

CONCLUSIONS: Among patients with metastatic PC, progression to CR was associated with significantly greater HRU in terms of OP visits (all-cause, PC-related) and ED visits (PC-related). Progression was also associated with both higher medical costs (all-cause, PC-related) and pharmacy costs. The study highlights the need for therapies with optimal risk-benefit profiles for appropriate treatment intensification to minimize HRU and cost burden overall, and especially the increase in both on progression to mCRPC.

SPONSORSHIP: Bayer HealthCare Pharmaceuticals Inc.

C22 Differences in health care costs by risk classification for patients with localized prostate cancer treated with radical prostatectomy in SEER-Medicare

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BACKGROUND: Radical prostatectomy (RP) is a definitive treatment option for patients (pts) with localized prostate cancer (LPC) or locally advanced prostate cancer. Limited information exists on the long-term health care costs of these pts, particularly those with different risk status.

OBJECTIVE: To examine real-world health care costs for US pts with LPC, high-risk (HR)-LPC, or low/intermediate-risk (LIR)-LPC who had prior RP.

METHODS: Pts with LPC having RP as initial definitive therapy within 6 months of LPC diagnosis and aged 65 years and older were identified in the Surveillance, Epidemiology, and End Results (SEER)–Medicare linked registry-claims data (2012-2019) and categorized as HR or LIR per National Comprehensive Cancer Network criteria. Demographic and clinical characteristics were summarized for each cohort in the 12 months prior to index (RP date). All-cause paid costs (2021 Dollars) were summarized (per patient per year [PPPY]) and compared using unpaired t-tests. For pts with HR-LPC with documented metastasis, all-cause health costs during the 1 year before metastasis and (up to) 1 year after metastasis were also compared.

RESULTS: Of 6,476 pts meeting inclusion criteria, 51.5% (N = 3,333) were HR-LPC and 48.5% (N = 3,143) were LIR-LPC. In both groups, mean age at RP was ~70 years, 90% were White, and mean follow-up time was greater than 45 months. In the 12 months before RP, mean all-cause PPPY costs for HR-LPC were $1,077 higher vs LIR-LPC ($9,926 vs $8,849; $P<0.001$). After RP, mean all-cause PPPY costs for HR-LPC vs LIR-LPC were $6,216 higher ($21,703 vs $15,487; $P<0.0001$), driven by $4,106 higher outpatient costs ($P<0.001$). Mean PPPY costs for HR-LPC vs LIR-LPC were also $1,967 higher ($P<0.001$) for adjuvant external beam radiation therapy and $280 higher ($P<0.001$) for androgen deprivation therapy. For pts with HR-LPC with documented metastasis (N = 489), all-cause PPPY costs up to 1 year after metastasis were $32,900 higher vs 1 year before metastasis ($52,542 vs $19,642; $P<0.0001$) vs LIR-LPC, driven by $11,358 higher inpatient costs and $13,938 higher outpatient costs ($P<0.001$ for both).

CONCLUSIONS: This real-world study observed higher health care costs in pts with HR-LPC relative to LIR-LPC, which increased substantially after RP. Moreover, within HR-LPC, development of metastasis was associated with significant incremental cost burden. These findings underscore the need for more effective treatment options to slow disease progression and reduce disease relapse and future incremental costs, particularly for pts with HR-LPC.

SPONSORSHIP: Janssen Scientific Affairs, LLC.

C23 Trends and trajectories of real-world treatment intensification for men with metastatic hormone-sensitive prostate cancer (mHSPC) in the United States

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BACKGROUND: The metastatic hormone-sensitive prostate cancer (mHSPC) treatment landscape has evolved with new approvals, most recently of chemo-hormonal triple therapy, and guidelines updates such as those from the National Comprehensive Cancer Network and American Society of Clinical Oncology. However, real-world data (RWD) showed continued prevalent use of nonrecommended regimens such as androgen deprivation therapy (ADT) monotherapy and first-generation androgen receptor inhibitor (ARI) + ADT.

OBJECTIVE: To evaluate mHSPC treatment trends and trajectories for alignment with National Comprehensive Cancer Network and American Society of Clinical Oncology guidelines and patient needs in contemporary clinical practice.

METHODS: Retrospective chart review data on patients with mHSPC, collected online from US physician participants of the Ipsos Global Oncology Monitor, were used to descriptively analyze treatment utilization rates, physician-reported likelihood of prescribing current therapy in the next 6 months, and patient characteristics, from moving quarterly totals from January 2021 to August 2023.

RESULTS: RWD on the reported patients with mHSPC showed that, over the study period, use of ADT monotherapy decreased (69.6% to 34.5%) but continued to be a leading treatment while novel ARI (nARI)+ADT increased steadily (8.0% to 38.8%). Utilization also increased but to lesser extents for other hormonal therapies including abiraterone (Abi)+ADT (7.2% to 17.1%), ARI+ADT (3.5% to 4.6%), and chemo-hormonal triple therapy (0% to 1.2%), predominantly with darolutamide. Use of docetaxel+ADT decreased (6.6% to 2.2%). In terms of physician prescribing expectations for the next 6 months, reported as study period averages, ADT monotherapy had the highest likelihood of staying the same with marginal net change expected (+1.1%). Triple therapy had the lowest likelihood of staying the same with the greatest net increase expected (+10.8%). Among the study sample of patients with mHSPC, rates of high prostate cancer risk classification increased while good baseline function (Eastern Cooperative Oncology Group score 0) decreased over the study period.

CONCLUSIONS: Although mHSPC treatment trends have started to converge toward guidelines in terms of increased use of recommended combination therapies, RWD shows that nonrecommended therapy persists, primarily as use of ADT monotherapy. Among patients with mHSPC in the sample, high-risk classification increased and Eastern Cooperative Oncology Group 0 baseline function decreased. These findings highlight the need for therapies with favorable benefit-risk profiles for timely treatment intensification and guideline-based care.

SPONSORSHIP: Bayer Healthcare Pharmaceuticals.

C25 Real-world outcomes in patients with locally advanced or metastatic urothelial carcinoma by maintenance eligibility

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BACKGROUND: First-line (1L) platinum-based chemotherapy (PBT) is recommended for patients with locally advanced or metastatic urothelial carcinoma (Ia/mUC). Avelumab maintenance (maintA) is recommended for patients without disease progression following 1L PBT. Real-world (RW) data on the proportion of patients initiating 1L PBT who remain progression-free and eligible for maintA are limited, and outcomes among patients who are ineligible for maintA are uncertain.

OBJECTIVE: To assess the proportion of patients with Ia/mUC initiating 1L PBT who were eligible for maintA and RW outcomes among maintA-eligible and -ineligible patients.

METHODS: A retrospective, observational study was conducted using the US nationwide Flatiron Health longitudinal electronic health record–derived database comprising deidentified patient-level structured and unstructured data. Adults with Ia/mUC who received at least 1 dose of 1L PBT between April 2020 and January 2022 were included. The proportion of patients eligible for maintA, defined as complete response, partial response, or stable disease following 1L PBT, was estimated and clinical outcomes were assessed for maintA-eligible and -ineligible patients.

RESULTS: Of 336 patients with Ia/mUC treated with 1L PBT, 186 (55%) received a cisplatin-based regimen and 150 (45%) received a carboplatin-based regimen. 181 (54%) were maintA-eligible, and 138 (41%) maintA-ineligible (17 not evaluable). Of 181 maintA-eligible patients, 67 (37%; 20% of 1L PBT treated) received maintA. Median overall survival (mOS) among all 1L PBT-treated patients was 15.0 (95% CI = 12.2-19.6) months. mOS among maintA-ineligible patients was 8.0 (95% CI = 6.7-10.3) months, whereas mOS among maintA-eligible patients (including 37% who received maintA) was 27.6 (95% CI = 23.4-NA) months.

CONCLUSIONS: In this RW study, approximately half of patients were maintA-eligible and one-fifth received it. RW OS remains short for the overall 1L PBT–treated population, particularly due to the limited OS seen in maintA-ineligible patients. These results highlight the continued unmet need for new treatment options in patients with Ia/mUC.

SPONSORSHIP: Seagen Inc. and Astellas Pharma Inc.

C26 Budget impact analysis of nadofaragene firadenovec (Adstiladrin) for the treatment of high-grade, Bacillus Calmette-Guerin–unresponsive nonmuscle invasive bladder cancer in the United States

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BACKGROUND: Bladder cancer is the most common urinary tract cancer and the sixth most common cancer overall in

the United States, with 75% restricted to the superficial layers of the bladder, termed non–muscle-invasive bladder cancer (NMIBC). Adstiladrin, a replication-deficient adenovirus, is approved by the US Food and Drug Administration (FDA) for the treatment of high-grade Bacillus Calmette-Guerin (BCG)–unresponsive NMIBC with carcinoma in situ with or without papillary tumors (CIS±Ta/T1).

OBJECTIVE: To estimate the budget impact (BI) of Adstiladrin during the first 3 years following the market entry from a US payer perspective.

METHODS: The BI was estimated by comparing costs under the market scenario with Adstiladrin vs that without Adstiladrin for adults with high-grade BCG-unresponsive NMIBC with CIS±Ta/T1. Other available treatments either FDA approved or used in real-world setting in the analysis includedvalrubicin,mitomycinC,gemcitabine,BCG+interferon-alpha, and pembrolizumab. The model adopted an incidence approach and considered the costs of drug and administration, adverse events (AEs), surveillance and disease management, and subsequent cystectomy. The budget impact over 3 years was calculated in 2023 US dollars. One-way sensitivity analyses were performed.

RESULTS: In a 1-million-member plan, 2.1 patients were estimated to have high-grade BCG-unresponsive NMIBC with CIS±Ta/T1 annually. The entry of Adstiladrin ($60,000/instillation) was estimated to increase the total plan budget by $4,507, $22,499, and $63,388 assuming 2%, 10%, and 30% of patients received Adstiladrin over 1-3 years, respectively. On the per-member per-month (PMPM) basis, the BI was $0.0004, $0.0019, and $0.0053. The scenario with Adstiladrin was associated with higher drug and administration costs (difference at $0.0004 to $0.0064 PMPM; $5,241 to $76,611 total plan over years 1-3), while partially offset by decreased costs of AEs (difference at –$26 to –$526 total plan), surveillance and disease management (difference at –$0.0001 to –$0.0008 PMPM; –$549 to –$10,101 total plan), and cystectomy (difference at –$0.0000 to –$0.0002 PMPM; –$159 to –$2,596 total plan). The model results remained robust in sensitivity analyses.

CONCLUSIONS: Adstiladrin has minimal BI for US payers over a 3-year period, well below PMPM-based notions of high or even moderate BI. Improved efficacy and safety profiles of Adstiladrin are associated with reduced costs of AEs, surveillance and disease management, and cystectomy, which partially offset the higher drug cost.

SPONSORSHIP: Ferring Pharmaceuticals, Inc.

C29 The impact of routine cancer screening on socioeconomic disparities in cancer diagnosis stages

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BACKGROUND: Individuals with limited access to medical care, including routine cancer screening, may have disparate cancer outcomes.

OBJECTIVE: To investigate the relationships between routine cancer screenings, incidence and stage of cancer diagnosis, and residence in medically underserved areas.

METHODS: Claims data were collected for a population with commercial insurance through either high-risk plans or small-employer group insurance. Cancer incidence, rate of cancer screening, frequency of physician visits, and stage of cancer diagnosis, along with participant demographics and comorbidities, were extracted. Participants were categorized based on their residence in low-income/medical professional health shortage areas or nonshortage areas.

RESULTS: We obtained claims data for 68,767 people aged 18 years and older who participated in plans between 2018 and 2022, of whom 28,774 were aged 50 years or older. Of those aged 50 years or older, 12,074 were in medically underserved areas (MU) by zip code and the balance in areas with adequate medical service (MS). Over a 4-year period, 37.6% of the MU population and 38.5% of the MS population had 1 or more claims for cancer screening. Over the observation period, 6.6% of the population was newly diagnosed with cancer, with 8.7% diagnosed in the MU population and 5.2% in the MS ($P < 0.01$). 20.6% of newly diagnosed cancers in the overall population were stage 3 or 4. Among those participating in screening, 1.0% of the MU population and 0.6% of the MS population were diagnosed with stage III and IV cancer, representing 21.2% and 20.4% of those with stageable cancers, respectively. Among those not participating in screening, however, late-stage diagnoses represented a higher proportion of stageable cancers in the MU population: 3.4% of the MU population and 1.2% of the MS population were diagnosed with stage III and IV cancer, representing 33.8% and 20.7% of those with stageable cancers, respectively ($P < 0.01$).

CONCLUSIONS: In a population of individuals with commercial health plans, disparities in cancer incidence and stage at diagnosis were observed between MU and MS areas. Among those who do not participate in cancer screening, individuals in MU areas are significantly more likely to be diagnosed with late-stage cancer than individuals in MS

areas, whereas no difference was observed in those who participate in cancer screening. Understanding the relation between availability of medical services, individual screening decisions, and cancer diagnosis is essential in helping bridge the overall gap in cancer care.

SPONSORSHIP: GRAIL, LLC.

C30 Real-world treatment patterns and clinical outcomes among patients with gastroenteropancreatic neuroendocrine tumors treated with 177Lu-dotatate in the United States

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BACKGROUND: 177Lu-Dotatate was approved for the treatment of advanced gastroenteropancreatic neuroendocrine tumors (GEP-NETs) in the United States in 2018. To date, few data have been published on the patterns of use or associated outcomes in patients receiving this therapy in real-world clinical practice.

OBJECTIVE: To examine real-world patient characteristics, treatment patterns, and clinical outcomes among patients with GEP-NETs treated with 177Lu-Dotatate in the United States.

METHODS: This retrospective cohort study used Flatiron Health electronic health record data from 01/01/2011 to 07/31/2021. Included patients were adults (aged ≥18 years) with at least 1 diagnosis code for a GEP-NET who had received at least 1 somatostatin analog on or after their GEP-NET diagnosis date as well as 177Lu-Dotatate at any time. Treatment patterns were evaluated descriptively. The Kaplan-Meier method was used to evaluate time to next therapy (TTNT) and overall survival (OS) from the start of 177Lu-Dotatate.

RESULTS: Of the 316 patients (mean age 64 years, 53% male) eligible for the study, 3 (1%) received 177Lu-Dotatate as first-line therapy, 138 (44%) as second-line (2L), 49 (16%) as third-line, 42 (13%) as fourth-line, and 35 (11%) as fifth-line. The median time from GEP-NET diagnosis to the start of 2L 177Lu-Dotatate was 1.8 years, and the majority (61%) of patients received 2L 177Lu-Dotatate in combination with a somatostatin analog. Among all patients treated with 177Lu-Dotatate, the median TTNT was 7.8 months, and at 2 years after treatment initiation, the median OS had not yet been reached. OS was 90% at 1 year and 77% by 2 years after treatment initiation.

CONCLUSIONS: This real-world study demonstrates that the highest proportion of adult patients with GEP-NETs who received 177Lu-Dotatate did so at 2L. 177Lu-Dotatate appeared to be associated with benefits in terms of both TTNT and OS.

SPONSORSHIP: Novartis Pharmaceuticals Corporation.

C31 Health resource utilization (HRU) in patients (pts) with multiple myeloma (MM) and cytogenetic abnormalities in the relapsed/refractory (R/R) setting: results using the Flatiron electronic health record (EHR) claims linked dataset

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BACKGROUND: As the treatment landscape for multiple myeloma (MM) evolves and cytogenetic abnormalities become important tools to guide MM therapy in later lines of treatment (LOTs), a better understanding of health care resource utilization (HRU) by LOT and type of cytogenetic abnormalities is needed.

OBJECTIVE: To describe HRU by LOT in patients (pts) with MM who had at least 3 LOTs and cytogenetic abnormalities.

METHODS: We analyzed pts aged 18 years and older with MM (diagnosed between January 1, 2013, and February 28, 2022) with at least 3 LOTs documented in the Flatiron Health electronic health record–derived deidentified database. Flatiron Health data were linked to deidentified claims data from the Komodo Healthcare Map. Pts had to be continuously enrolled in a closed claims medical and pharmacy health plan for at least 3 months before and after index. Pts who enrolled in clinical trials were excluded. HRU by LOT was evaluated in all eligible pts and in 4 subsets: pts with t(11;14)+ MM and pts with 0, 1, or 2+ high-risk genetic abnormalities.

RESULTS: Among 374 pts with MM, 52 were t(11;14)+, and 148, 125, and 101 pts had 0, 1, and 2+ high-risk genetic abnormalities, respectively. Mean (SD) age at MM diagnosis across all pts was 65 (11) years; all subsets had reported similar baseline characteristics to the full cohort. In the third-line (3L; n = 374), fourth-line (4L; n = 191), and fifth-line+ (5L+; n = 93) subsets, 41%, 44%, and 61% of pts had at least 1 inpatient visit, with a mean (SD) of 3.9 (9.3), 3.9 (12.5), and 6.6 (10.9) visits/year, respectively. For emergency department visits in the 3L, 4L, and 5L+ subsets, 27%, 26%, and 37% of pts had at least 1 visit/year, with a mean (SD) of 1.1 (4.1), 0.6 (1.5), and

1.2 (3.0) visits/year, respectively. The proportion of pts with at least 1 outpatient visit was similar across LOT, but the mean (SD) visits/year increased from 68 (63), to 75 (63), to 81 (62), respective to increasing LOT. Among all pts continuing on 4L and 5L+ treatment, there was a slight increase in HRU. Similar trends in HRU were observed in the t(11;14)+ and the 0, 1, and 2+ high-risk abnormalities subgroups.

CONCLUSIONS: Contrary to the notion that treatment of pts with increasing numbers of high-risk abnormalities leads to greater HRU, large differences in HRU based on abnormalities were not observed. HRU in our study was consistent with published data in this setting (Gupta, ASCO 2022). Our research sets a baseline for HRU in relapsed/refractory MM based on LOT, high-risk abnormalities, and the presence of t(11;14), which may be amenable to targeted oral therapy. Further work is needed to evaluate payer and patient-facing costs based on these factors, as precision medicine tactics continue to emerge for MM.

SPONSORSHIP: Genentech, Inc.

C32 Estimation of postinfusion costs of care for patients with relapsed and refractory multiple myeloma who received idecabtagene vicleucel in the KarMMa-3 clinical trial

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BACKGROUND: Idecabtagene vicleucel (ide-cel), a B-cell maturation antigen-directed chimeric antigen receptor T-cell therapy, has demonstrated frequent, deep, and durable responses in triple-class–exposed patients with relapsed/refractory multiple myeloma (RRMM) in the KarMMa trial (NCT03361748) and superior progression-free survival vs standard regiments in the randomized phase 3 clinical trial KarMMa-3 (NCT03651128). Prior research suggests high economic burden among patients with RRMM (Madduri D, et al. *Future Oncol* 2020).

OBJECTIVE: To evaluate health care resource utilization (HCRU) and estimate cost of care across a 1-year time period for ide-cel–treated patients in the KarMMa-3 study.

METHODS: Patient-level KarMMa-3 HCRU data, including hospitalizations and length of stay (standard inpatient [IP] and intensive care unit [ICU] days), diagnostics (eg, imaging), procedures (eg, dialysis), and medications (eg, adverse event management) excluding ide-cel, were retrospectively analyzed from ide-cel infusion through 1-year follow-up. Postinfusion costs were estimated using a micro-costing methodology in which HCRU were identified and unit costs from public databases or literature (adjusted to 2022 USD) were applied to each HCRU. Average total cost by ide-cel postinfusion month was calculated among patients with ongoing status and aggregated.`1111

RESULTS: Among 225 patients treated with ide-cel, most were male (62.7%), White (68.9%), and non-Hispanic/Latino (75.1%) and had a mean (SD) age of 61.9 (8.9) years. The estimated mean 1-year postinfusion total cost of care was $104,926. Most (63.7%) costs were incurred in month 1 after infusion and were primarily driven by facility costs, namely, IP hospitalizations and ICU stays. Almost all patients (99.6%) had an IP stay (trial protocol required ≥15 days IP stay after infusion unless admitted to the ICU, which may not reflect real-world practice). Mean (SD) length of stay was 18.7 (10.1) days for IP hospitalizations and 1.2 (6.0) days for ICU stays. Total length of stay ranged 14 to 90 days with a mean (SD) of 19.9 (12.9) days. Most patients received corticosteroids either with tocilizumab (70.2%) or alone (11.6%), and few required vasopressors (9.3%), dialysis (2.2%), intubation (2.7%), or an ICU stay (8.4%).

CONCLUSIONS: Postinfusion costs among patients receiving ide-cel in the KarMMa-3 trial were mostly incurred during month 1 and facility-related. Compared with other RRMM therapies, the mean estimated 1-year total ide-cel postinfusion cost of $104,926 is substantially less costly, likely due to reduced HCRU following the initial treatment period.

SPONSORSHIP: Bristol Myers Squibb.

C33 Cost-per-responder analysis for patients with relapsed or refractory multiple myeloma treated with talquetamab compared with usual care

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BACKGROUND: Most patients with multiple myeloma (MM) will ultimately relapse and experience multiple lines of therapy (LOTs). Patients with relapsed/refractory MM (RRMM), who had at least 4 prior LOTs, including those with triple-class exposure, often have high clinical and economic burdens due to a lack of effective therapies and poor disease control. In the United States, talquetamab (Tal) is a newly approved bispecific GRPC5D-directed CD3 T-cell engager indicated for the treatment of patients with RRMM who have received at least 4 prior LOTs. Tal has demonstrated a high overall response rate (ORR) for heavily

treated patients with RRMM, yet little is known about the cost for such response.

OBJECTIVE: To evaluate cost per responder for patients with RRMM receiving Tal on weekly (QW) and biweekly (Q2W) dosing schedules compared with those receiving usual care.

METHODS: Cost per responder was calculated by dividing the total cost by the ORR. Total cost for patients receiving Tal included the cost of Tal (based on 85 kg, as the weight of a typical patient in the United States with MM), inpatient cost, adverse event management cost after step-up hospitalization, outpatient administrative and supportive care cost, and subsequent therapy cost. The duration of treatment for Tal was based on progression-free survival. Cost of usual care was the all-cause health care costs from the 2022 study by Jagannath et al on patients with RRMM who had received at least 4 prior LOTs, including triple-class exposure, and was inflated to January 2023. ORR was based on the indirect treatment comparison between Tal (MonumenTAL-1 study) and real-world physician's choice from the LocoMMotion study (ORR: Tal QW, 74.1%; Tal Q2W, 71.7%; usual care, 28.5%).

RESULTS: The total costs of care for Tal QW and Q2W were as follows: $327,987 and $341,217 over 6 months; $521,567 and $551,350 over 12 months, respectively. The total costs for usual care were $217,996 over 6 months and $435,993 over 12 months. Costs per responder for Tal QW and Q2W were $ 442,627 and $446,781 over 6 months and $703,869 and $754,241 over 12 months. Costs per responder for usual care were $764,900 per 6 months and $1,529,800 per 12 months. The incremental costs per additional responder of Tal QW and Q2W vs usual care were $241,207 and $285,233 at 6 months and $187,663 and $267,031 at 12 months.

CONCLUSIONS: In patients with RRMM who had at least 4 prior LOTs, Tal represents an effective treatment to achieve response, with lower cost per responder than usual care.

SPONSORSHIP: Janssen Scientific Affairs, LLC.

C34 Real-world treatment patterns after discontinuation of venetoclax or BTKis among older US Medicare beneficiaries with chronic lymphocytic leukemia in the front-line setting

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BACKGROUND: Venetoclax (VEN) and BTK inhibitors (BTKi) are key treatment options for patients (pts) with chronic lymphocytic leukemia (CLL) in the front-line (1L) setting, yet little real-world evidence exists comparing these agents.

OBJECTIVE: To compare treatment patterns and hospitalization after discontinuation of 1L VEN or 1L BTKi in a national sample of older US Medicare beneficiaries with CLL.

METHODS: Using 2016-2021 100% Medicare Parts A, B, and D claims, we identified fee-for-service senior Medicare beneficiaries with CLL initiating VEN in combination with obinutuzumab (VenO group) or an available BTKi treatment (BTKi group) in the 1L setting between 6/1/2019 and 6/30/2020 (index date = first Rx fill date). Discontinuation was defined as a consecutive 90-day gap in index treatment from date of its initiation until the end of 18 months of follow-up. The rate and type of subsequent CLL treatment initiated, rates of restart of index agent, and rates of all-cause and CLL-related hospitalization were assessed.

RESULTS: We identified 193 VenO pts and 1,577 BTKi pts. Over 18 months of follow-up, 597 (37.9%) BTKi pts discontinued their index treatment and 57 (29.5%) VenO pts discontinued treatment prior to the expected fixed duration treatment period (336 days). More than half (n = 102) of VenO pts stopped treatment after completing the fixed duration period. Pts who discontinued a BTKi did so within a median 3.6 months. Few pts (n < 11) who discontinued VenO initiated another CLL treatment over a median follow-up period of 0.5 years. In contrast, 39.0% of discontinuers in the BTKi group had evidence of subsequent CLL treatment over a median 1.2-year postdiscontinuation follow-up period. The median time to next treatment was 1.2 months. Common post-BTKi regimens initiated were BCL-2 regimens (35.6%), another BTKi regimen (31.8%), traditional chemotherapy regimens (14.6%), anti-CD20 monotherapy (9.9%), or other (8.2%). Among BTKi discontinuers, 13.1% restarted index BTKi treatment after their initial discontinuation. The rate of all-cause and CLL-related hospitalization after discontinuation was lower for VenO compared with the BTKi group (16.4% vs 40.2% and 11.9% vs 35.2%, respectively).

CONCLUSIONS: In this real-world study of older pts with CLL in the United States, most pts treated with 1L VenO received fixed duration therapy and did not initiate subsequent CLL treatment. Conversely, 38% of pts on 1L BTKi discontinued their index treatment at a median of 3.6 months, and nearly 40% of these pts initiated another CLL treatment.

SPONSORSHIP: AbbVie Genentech.

C35 Variation in racial and payer impact on multiple myeloma mortality and receipt of therapeutic interventions: A 5-year cross-sectional HCUP analysis

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BACKGROUND: Multiple myeloma (MM), a hematologic malignancy, results from abnormal plasma cell proliferation in the bone marrow. In 2021, the American Cancer Society projected 34,000 new MM diagnoses. Black Americans face a 2-fold higher MM incidence and mortality compared with White Americans. Recent research (2008-2017) highlights significant racial disparities in MM epidemiology and management. We seek to further this research to 2020 and study the impact of other factors such as payer type.

OBJECTIVE: To determine the impact of racial disparities, patient characteristics, and payer types on receipt of MM therapeutic procedures and hospital mortality.

METHODS: An aggregated multiyear retrospective study design was conducted using Healthcare Cost and Utilization Project (HCUP) databases (2016-2020). MM hospitalizations (age ≥18 years) were identified with *International Classification of Diseases, Tenth Revision, Clinical Modification* code C90.0. Regression analyses were used to examine the relationship between patients' racial characteristics, demographics, hospital characteristics on procedures performed (including extraction of bone marrow, chemotherapy, blood transfusion, and stem cell transplant), use of an intensive care unit (ICU), and hospital outcomes (mortality).

RESULTS: A total of 20,742 MM hospitalizations were analyzed across 5 years. The mean age at hospitalization was 65.4 ± 11.4 years, with a higher prevalence of MM in male patients (55.9%). The majority of patients were White (57.9%), followed by Black (22.7%) and then Hispanic (9.2%). Multivariate regression analysis revealed that Black patients had a 29% lower likelihood of receiving stem cell transplants than White patients (odds ratio [OR] = 0.71, $P < 0.001$], whereas their odds of receiving blood transfusions were 73% higher (OR = 1.73, $P < 0.001$). Inpatient chemotherapy utilization in Black patients aligned with the other racial groups. Hispanic patients used the ICU significantly more, with ORs twice those of White or Black patients ($P = 0.00815$). A significant disparity in mortality rates was observed, with Black individuals having 21% higher odds of mortality compared with White or Hispanic patients (OR = 1.21, $P < 0.0162$). Furthermore, impact of Payer types (Medicare, Medicaid, and private insurance) independently and significantly impacted MM mortality and receipt of stem cell transplant procedures.

CONCLUSIONS: Despite MM therapy advancements, care disparities persist for Black and Hispanic patients, with higher hospitalization and mortality rates. Further research is needed to determine the relationship between social determinants of health, insurance coverage, and racial variations for MM.

SPONSORSHIP: None.

D3 Intravenous iron treatment considerations in patients with non–dialysis-dependent chronic kidney disease

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BACKGROUND: Chronic kidney disease (CKD) affects 37 million people in the United States. Anemia is a common complication of CKD, with iron deficiency anemia (IDA) resulting from functional or absolute iron deficiency. In individuals with non–dialysis-dependent CKD (NDD-CKD) and IDA who do not respond to or tolerate oral iron, the 2012 Kidney Disease Improving Global Outcomes guideline suggests using intravenous iron (IVI) for iron repletion. An initial course of 1,000 mg is common practice. Depending on the iron preparation, full repletion necessitates 1 to 10 infusions. Some institutional or insurance coverage policies restrict the use of certain IVI products based on drug cost alone, ignoring other aspects that can impact treatment.

OBJECTIVE: To understand the incidence of incomplete treatment with IVI in patients with NDD-CKD.

METHODS: A retrospective analysis of Medicare administrative claims data from Komodo's Healthcare Map included patients diagnosed with NDD-CKD and IDA prior to the date of first IVI infusion (index date) and treated with an IVI product from 1/1/2020 to 9/30/2022. Patients with end-stage renal disease or receiving hemodialysis were excluded. IVI products evaluated were iron dextran, iron sucrose, sodium ferric gluconate, ferric carboxymaltose, ferric derisomaltose, and ferumoxytol. Incomplete treatment (discordance) was defined as having received less than 1,000 mg of IVI within the 6-week period, including the index date.

RESULTS: 6,210 patients were included in this study. Patients had an average age of 75.4 years (86.6% of patients were aged >65 years), and 60.7% of patients identified as female. The Charlson Comorbidity Index was similar among the IVI cohorts, an average of 5.9. CKD stages were stratified by last *International Classification of Diseases, Tenth Revision* code as follows: stage 1 (n = 51; 0.82%), stage 2 (n = 315;

5.07%), stage 3 (n = 3,446; 55.5%), stage 4 (n = 1,325; 21.3%), and stage 5 (n = 83; 1.34%). Discordance to IVI therapy was seen in 34.9% of patients overall and as follows for patients receiving each IVI product: 43.5% (iron dextran), 70.7% (iron sucrose), 95.7% (sodium ferric gluconate), 23.1% (ferric carboxymaltose), 2.3% (ferric derisomaltose), and 18.6% (ferumoxytol).

CONCLUSIONS: Overall, discordance was more frequent for IVI products requiring multiple infusions. Even IVI products requiring only 2 infusions resulted in more than 1 out of 6 patients being discordant. Incomplete treatment with IVI hinders guideline-directed anemia management for patients with IDA and NDD-CKD. These data should provide impetus for institutional and insurance coverage policies on IVI to have a holistic consideration, including the rates of inadequate treatment and product preference.

SPONSORSHIP: Pharmacosmos Therapeutics Inc.

D4 Management of iron deficiency anemia in oncology: Intravenous iron discordance in patients with cancer

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BACKGROUND: Anemia is a common hematological manifestation of cancer, with iron deficiency anemia (IDA) often a main contributor caused by a variety of factors (eg, chemotherapy, blood loss after surgery, malnutrition, and malabsorption). IDA may be managed with intravenous iron (IVI). Published guidelines recommend IVI ranging from 1 to 10 infusions per treatment course, totaling approximately 1,000 mg for most IVI products. Some payors restrict the use of IVI based on drug cost alone, ignoring infusion schedules and resulting in incomplete treatment that can contribute toward overall patient outcomes and cost.

OBJECTIVE: To evaluate incomplete treatment among IVI products in patients with cancer.

METHODS: A retrospective analysis of commercial administrative claims data from Komodo's Healthcare Map included patients diagnosed with cancer and IDA prior to the index date (date of first IVI infusion) and treated with an IVI product from 01/01/2020 to 09/30/2022. IVI products evaluated were iron dextran, iron sucrose, sodium ferric gluconate, ferric carboxymaltose, ferric derisomaltose, and ferumoxytol. Patients were followed for 6 months from the index date, inclusive. Iron deficit was unknown. Discordance, a surrogate marker for nonadherence, was defined as having received less than 1,000 mg of IV iron over 6 weeks.

RESULTS: In total, 28,856 patients were included in this study. Patients had an average age of 51.6 years, and 78.1% of patients identified as female. The Charlson Comorbidity Index was similar among the cohorts, an average of 3.2. Discordance to IVI therapy was 33.4% overall and for each IVI product: 29.6% (iron dextran), 72.9% (iron sucrose), 92.3% (sodium ferric gluconate), 0.4% (ferric derisomaltose), 18.0% (ferric carboxymaltose), and 16.1% (ferumoxytol).

CONCLUSIONS: Overall, the more infusions required, the greater discordance to an IV iron treatment course. Even IV irons that may require only 2 infusions per label resulted in patient discordance. Patients with cancer- and chemotherapy-induced IDA who do not receive the full IVI treatment course can potentially experience undertreatment, which can adversely impact patient outcomes. These data should inform payors of the potential for discordance to IVI treatment, thereby potentially impacting management of IDA in patients with cancer. Policies with unencumbered access to a single-dose option may help mitigate this issue.

SPONSORSHIP: Pharmacosmos Therapeutics Inc.

D5 Mortgage pricing can shield US payors from the high upfront costs of emerging ultra-expensive therapies: A hypothetical case of gene therapy

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BACKGROUND: Recent advancements in gene therapy have introduced curative treatments with substantial budgetary implications. Although they offer significant value, their high upfront costs necessitate innovative payment approaches.

OBJECTIVE: To explore the application of mortgage-based pricing (MBP) as a potential payment approach for US payors in the context of gene therapy for severe sickle cell disease.

METHODS: We conducted a budget impact analysis of providing gene therapy coverage for children diagnosed with severe sickle cell disease, from the US private and public payor's perspectives. We compared the adoption of gene therapy under one-time payment (OTP) vs MBP. We assumed patients who underwent gene therapy would either be cured or experience treatment failure. We used a base-case MBP time horizon of 5 years to demonstrate how annual payment installments can mitigate high upfront costs. One-way and probabilistic sensitivity analyses were conducted to assess the robustness of model results to parameter uncertainties.

RESULTS: Over a 5-year time horizon, standard care cost a total of $0.2M. Coverage of gene therapy cost $21.4M with OTP and $19.8M with MBP under the private payor scenario. In the public payor scenario, standard care cost $1.3M, whereas coverage of the therapy cost $137.8M with OTP and $127.7M with MBP. The incremental cost savings with MBP vs OTP was $1.6M and $10.0M under the private and public payor scenarios, respectively, translating into per-capita cost savings of $0.1M and $1.1M, respectively. Annual market diffusion rate of gene therapy treatment had the most significant impact on results, followed by fraction of insured children enrolled in the plan. Findings remained robust to uncertainties in model input parameter values.

CONCLUSIONS: Real-world implementation of payment models like MBP is likely to involve combinations of strategies based on factors like patient demographics and evolving market dynamics. Our analysis illustrates the importance of addressing treatment affordability without compromising the inherent value provided by such expensive therapies. Although simply lowering drug prices may be an immediate solution, it overlooks the importance of adequately compensating innovators for the value generated by new treatments. MBP reconciles affordability with the therapy's intrinsic worth but also necessitates considerations of patient-enrollee debt portability. In settings and health care systems with constrained budgets, such as low- and middle-income countries, MBP could be a particularly valuable approach for expanding access to new treatments and promoting health equity.

SPONSORSHIP: None.

D6 Evaluation of costs of treatment with complement inhibitors in paroxysmal nocturnal hemoglobinuria in commercial claims

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BACKGROUND: Eculizumab (ECU) and ravulizumab (RAVU) are current treatment options for paroxysmal nocturnal hemoglobinuria (PNH).

OBJECTIVE: To evaluate the costs of treatment with ECU and RAVU in PNH from a US commercial payer perspective.

METHODS: Medical claims of patients with PNH (*International Classification of Diseases, Tenth Revision, Clinical Modification* code D59.5) with procedure codes for ECU (Healthcare Common Procedure Coding System [HCPCS] code J1300) or RAVU (HCPCS code J1303) were used to assess real-world treatment costs (2011-2022) and mean rate difference between reimbursement in commercial claims and average selling price (ASP) based on ASP drug pricing from Centers for Medicare & Medicaid Services (2020-2022) of ECU and RAVU. Total annual real-world treatment costs in commercial claims, ASP (in 2023), ASP-based reimbursement in commercial claims (in 2023), and wholesale acquisition cost (WAC; in 2023) based on Merative Micromedex RED BOOK were assessed for ECU and RAVU. For cost calculations, total number of doses were based on label-recommended dosing schedules of ECU and RAVU, assuming a mean body weight of 70 kg for RAVU.

RESULTS: For ECU, total annual real-world treatment costs was $642,790 for the first and $636,943 for subsequent years in commercial claims. Mean rate difference of reimbursement was 7.46% above ASP, with 51.2% of commercial claims having been reimbursed above ASP+6.0%. Total annual ASP was estimated at $510,029 for the first and $497,279 for subsequent years, with higher total annual ASP-based reimbursement of $548,101 for the first and $534,399 for subsequent years in commercial claims. Total annual WAC was estimated at $521,832 for the first year and $508,786 for subsequent years. For RAVU, total annual real-world treatment costs were $590,229 for the first and $548,476 for subsequent years in commercial claims. Mean rate difference of reimbursement was 7.9% above ASP, with 39.6% of commercial claims having been reimbursed above ASP+6.0%. Total annual ASP was estimated at $470,524 for the first and $414,061 for subsequent years, with higher annual ASP-based reimbursement of $507,603 for the first and $446,691 for subsequent years in commercial claims. Total annual WAC was estimated at $480,301 for the first year and $422,665 for subsequent years.

CONCLUSIONS: From a US commercial payer perspective, average ASP-based reimbursement of ECU and RAVU was ASP+7.5% and ASP+7.9%, respectively. More than 50% of commercial claims for ECU and approximately 40% for RAVU were reimbursed above ASP+6.0%. Total annual real-world treatment costs in commercial claims for ECU and RAVU in PNH exceeded the annual WAC.

SPONSORSHIP: Novartis.

D7 Patient advocacy–led educational sessions for payer professionals yields increased confidence and planned change in sickle cell disease

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BACKGROUND: In 2022 and 2023, Impact Education, LLC, collaborated with Sick Cells to enhance their annual Coverage for SCD Summit. Sick Cells is a patient advocacy organization focused on amplifying the voices of the sickle cell disease (SCD) community. The educational sessions were designed to meet the unique needs of managed care professionals, focusing on efficacy and safety data of traditional treatments and the ongoing exploration of novel treatment strategies, including gene therapies. Payers need to understand SCD treatments to fulfill their responsibilities in managing costs, improving quality of care, and ensuring access to effective treatments for patients with SCD, as it is a life-shortening blood disorder.

OBJECTIVE: To demonstrate educational outcomes following 2 managed care professional–focused accredited sessions in SCD.

METHODS: In 2022, a panel of 4 key opinion leaders from the SCD community, payer, and hematology fields participated in the accredited session on improving equity and affordability of SCD therapies. In 2023, another panel of 4 key opinion leaders representing the same areas of expertise presented on opportunities to improve equity, affordability, and appropriate treatment access for patients with SCD. Pre- and postassessment of participants' knowledge and intent to change behavior were collected.

RESULTS: Over 2 years, a total of 214 participated in these sessions, with 79 completing both the pre- and postprogram surveys to obtain credit. Between both programs, a total of 42% of respondents (n = 79) plan to implement changes in their practice based on the information presented. Confidence of completers to implement changes was also high for each program. In 2022, 91% (n = 49) of the learners indicated that they were "somewhat confident" to "very confident" in their ability to implement and/or recommend patient-centered care and services that support appropriate treatment, coverage, and access for patients with SCD. In 2023, 70% (n = 30) in the postsurvey indicated that they were "somewhat confident" to "very confident" in their ability to implement and/or recommend evidence-based formulary management strategies for SCD.

CONCLUSIONS: Patient advocacy–driven educational sessions for payer professionals have resulted in heightened confidence and a commitment to change in the management of SCD. The implementation of comprehensive payer-focused education over time has proved to be an effective approach for bolstering the confidence of managed care professionals in the management of rare diseases, as exemplified by the results achieved in SCD.

SPONSORSHIP: Sick Cells.

D14 Understanding the real-world health care resource utilization and costs of severe hemophilia A without inhibitors among adults treated with long-term prophylaxis in the United States by payer type

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BACKGROUND: Health care resource utilization (HRU) can vary by payer type.

OBJECTIVE: To estimate HRU and costs of US people with severe hemophilia A (PwSHA) managed with prophylaxis by payer type.

METHODS: Adult male PwSHA, without inhibitors or transfusion-transmitted infections (hepatitis B or C virus, or HIV), managed with prophylaxis in the American Thrombosis and Hemostasis Network dataset between 1/1/2017 and 1/1/2023 were stratified by primary payer (commercial, Medicaid, and Medicare). HRU (hemophilia treatment center visits; treatment utilization of extended half-life [EHL] and standard half-life [SHL] FVIII therapies, and nonfactor replacement therapies [NFRT]) and clinical outcomes (annualized bleeding rate; target joints) were described. Annualized treatment costs were based on wholesaler acquisition cost for commercial insurance, average sales price for Medicare, and state maximum allowable costs or equivalent for Medicaid. Upper/lower 2.5% of utilization and costs were trimmed for outliers.

RESULTS: 757 PwSHA on commercial insurance, 388 on Medicaid, and 54 on Medicare were analyzed. Mean age was similar for commercial and Medicaid (27.8 and 25.8 years) and older (35.9 years) for Medicare, with weight, which is used for dosing differing (mean: 86.4, 82.2, and 93.3 kg, respectively). Annual hemophilia treatment center visits (mean: 1.3-1.4) and comprehensive care visits (mean: 0.7-0.9) were similar across payers, as were clinical outcomes. Use of prophylaxis treatments was similar, with at least 40% using NFRT in each group, followed by SHL and EHL products. Dosing was generally consistent, with mean annualized doses for EHL of 5,388 IU/kg for commercial, 5,512

Medicaid, and 5,495 IU/kg Medicare; SHL of 5,873 IU/kg for commercial, 5,588 IU/kg Medicaid, and 6,432 IU/kg Medicare; and NFRT of 77.6-81.8 mg/kg across insurances. Annual treatment costs for FVIII therapy varied by payer type. Mean costs based on weight and dosing were estimated to be $859,519 (commercial), $762,471 (Medicaid), $768,528 (Medicare) for SHL and to be $1,118,010 (commercial), $968,836 (Medicaid), $1,005,629 (Medicare) for EHL. Costs for NFRT were more similar, with median costs of $769,170 (commercial), $735,935 (Medicaid), and $754,149 (Medicare). Medicare utilization and costs were based on small sample sizes.

CONCLUSIONS: HRU, including treatment utilization, and clinical outcomes for PwSHA without inhibitors treated with prophylaxis were consistent regardless of primary payer (commercial, Medicaid, or Medicare). Annual treatment costs were similar for NFRT by payer type and more variable for FVIII products.

SPONSORSHIP: BioMarin Pharmaceutical Inc.

D16 Estimating the financial impact of introducing momelotinib as a treatment option for adult patients with intermediate- or high-risk myelofibrosis with anemia from a US commercial and Medicare payer perspective

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BACKGROUND: Anemia and transfusion dependence in patients (pts) with myelofibrosis (MF) are associated with poor prognosis and increased medical costs. Although Janus kinase inhibitors (JAKi) approved for MF provide spleen and symptom improvements, they may induce or worsen anemia. Momelotinib (MMB) is a JAK1, JAK2, and ACVR1 inhibitor that demonstrated spleen, symptom, and anemia benefits across 3 phase 3 trials.

OBJECTIVE: To estimate the 3-year projected budget impact resulting from the potential market entrance of MMB for pts with intermediate- or high-risk MF with anemia.

METHODS: A budget impact model (BIM) was developed using 2 payer perspectives, US commercial and Medicare, to estimate the financial impact of introducing MMB as a treatment option for JAKi-naive or -experienced adult pts with intermediate-1, intermediate-2, or high-risk MF (per Dynamic International Prognostic Scoring System-plus risk score) with anemia. The budget impact was calculated as the difference between the total costs associated with the current market without MMB, including, ruxolitinib, fedratinib, pacritinib, and other best available therapies, and a proposed market with MMB introduced over 3 years. Costs for the current and proposed scenarios were estimated by applying clinical inputs from patient-level trial data, market share estimates of current treatments, and cost inputs including treatment-, disease-, and transfusion-related costs derived from IBM RED BOOK Micromedex and in the literature.

RESULTS: For 1 million pts from combined commercial and Medicare plans, the estimated average budget impact over the 3 years was $314,222, $644.73 per patient treated with MMB per month and $0.026 per member per month. The budget impact was mainly influenced by the acquisition costs per year of MMB and ruxolitinib and the proportion of pts with confirmed anemia in the JAKi-experienced population. The introduction of MMB resulted in savings in transfusion status-related disease management costs, which over 3 years decreased by an average of $113,694 per year. There was an estimated total reduction of 119 transfusions over 3 years or an average of 40 fewer transfusions each year. In scenarios with higher utilization of ruxolitinib plus luspatercept, the budget impact of MMB was further decreased.

CONCLUSIONS: The introduction of MMB resulted in a small positive budget impact. The higher acquisition cost of MMB that drives the budget impact was partially offset by savings due to reduced transfusion-related costs.

SPONSORSHIP: GSK plc.

D17 Rate of cytokine release syndrome in CAR-T for Medicare Fee-for-Service beneficiaries: Analysis of more than 3 years of claims

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BACKGROUND: Cytokine release syndrome (CRS) is the most observed chimeric antigen receptor T-cell therapy (CAR-T)–associated toxicity. CRS has been shown to lead to various negative and life-threatening outcomes. Various published works have found the rate of CRS to be from 37% to 93%. The wide range is likely due to studying on small sample sizes (eg, <50) and dependent on the different scoring/grading of CRS symptoms. CRS received a specific *International Classification of Diseases, Tenth Revision* diagnosis code in October 2020. Since then, to our knowledge, no published literature exists that summarizes system-wide occurrence of CRS over the 3+ years since the introduction of the CRS diagnosis.

OBJECTIVE: To identify the rate of CRS within CAR-T Medicare fee-for-service beneficiaries, determine whether

administration of CAR-T in the inpatient or outpatient setting has higher rates of CRS, and evaluate potential predictors of CRS.

METHODS: This analysis used the 100% Medicare Research Identifiable Files from Q3 2020 through Q4 2022. Beneficiaries were identified on their first occurrence of CAR-T in either the inpatient or outpatient setting. Beneficiaries were required to have continuous eligibility in Medicare Parts A and B for 3 months after discharge from their index CAR-T claim. Demographic information (age, race, dual-eligibility status, etc.) was obtained from the Master Beneficiary Summary Files.

RESULTS: After applying inclusion and exclusion criteria, 2,733 CAR-T episodes were selected for the analysis. The rate of CRS was 68% overall. Of the beneficiaries with CRS, 10.9% (n = 204) died within 3 months of the CAR-T procedure, which was equivalent to the mortality rate of non-CRS (10.7%). The rate of CRS was significantly lower for beneficiaries receiving CAR-T in the outpatient setting compared with inpatient (57% vs 69%, Fisher's exact, $P < 0.0001$). Interestingly, the rate CRS for nonclinical trials was significantly higher than that for clinical trials (72% vs 63%, Fisher's exact, $P < 0.0001$).

CONCLUSIONS: CAR-T continues to expand into new products and indications, and CRS continues to be an important clinical variable in CAR-T treatment. Now that the CRS diagnosis code has been present for more than 3 years, this analysis suggests that we now have the statistical power to find important predictors of CRS, which can help providers mitigate treatment hurdles and improve patient outcomes. These factors will also become increasingly important as CAR-T administration moves into the outpatient setting.

SPONSORSHIP: None.

D19 An update to the ICER lupus nephritis model evaluating the cost-effectiveness of voclosporin for the treatment of lupus nephritis in the United States

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BACKGROUND: Lupus nephritis (LN) is a severe manifestation of systemic lupus erythematosus, and approximately 30% of patients with LN develop end-stage kidney disease (ESKD). The main treatment goal for LN is preservation of kidney function, with early decreases in proteinuria resulting in improved long-term outcomes. Voclosporin (VCS), a second-generation calcineurin inhibitor, was approved in the United States in 2021 for the treatment of adults with active LN in combination with background immunosuppression. The AURORA 1 study found the addition of VCS to mycophenolate mofetil and low-dose glucocorticoids yielded significant reductions in proteinuria. The Institute for Clinical and Economic Review (ICER) published an economic model of LN progression in 2021 to estimate the impact and cost-effectiveness of therapies incorporating data from clinical trials and published literature. From a US health care perspective, VCS was cost-effective at $149,000 per quality-adjusted life-year (QALY) and $132,000 per equal value of life-years gained. At the time of model development, however, VCS was not yet approved in the United States and the cost of treating patients with LN with ESKD was not well captured in the literature.

OBJECTIVE: To evaluate the cost-effectiveness of VCS given the emergence of new data.

METHODS: The ICER LN model was accessed by subscription on the ICER Analytics Platform. It uses a short-term trial-based Markov model and long-term extrapolation using partitioned survival modeling data assuming adults with LN start with active disease followed by transitions to complete renal response, partial renal response, kidney failure, or death. In this updated analysis, drug cost reflected the 2023 price of VCS and duration of VCS treatment for nonresponders reflected the approved product labeling. Health care payer costs were based on recently published Optum claims data representing costs covered by a commercial payer and including costs of an LN population based on disease activity and ESKD.

RESULTS: Using the economic LN model developed by ICER and the updated inputs reflecting the latest evidence, the incremental cost per QALY for voclosporin was $99,791 and per equal value of life-years gained was $88,037.

CONCLUSIONS: Economic modeling of LN evaluated the cost-effectiveness of VCS. Following the inclusion of updated data in the model, VCS was found to be cost-effective, substantially below the ICER published willingness to pay threshold of $150,000/QALY. These results are consistent with the original ICER evaluation with VCS continuing to be a cost-effective treatment for LN.

SPONSORSHIP: Aurinia Pharmaceuticals Inc.

D20 Identification of high-grade cytokine release syndrome in retrospective databases

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BACKGROUND: Understanding real-world (RW) adverse events is crucial to support evidence-based medicine. Cytokine release syndrome (CRS) is common in novel cancer therapies, such as chimeric antigen receptor T-cell (CAR-T) or bispecific therapies. *International Classification of Diseases* (ICD) codes (D89.83x) for CRS were introduced in 2020 with subcodes for severity: low-grade ([LG] grade 1, D89.831) or high-grade ([HG] grade ≥2, D89.832-D89.835). However, the code for an unspecified grade (D89.839) is used frequently, which poses challenges when evaluating the CRS severity in retrospective RW data.

OBJECTIVE: To identify indicators of HG CRS among patients receiving a therapy associated with CRS in RW databases.

METHODS: Using Premier Healthcare chargemaster data (1/1/2020 to 9/30/2021), adults with a diagnosis of LG or HG CRS during a hospitalization where blinatumomab or CAR-T was administered were identified. A least absolute shrinkage and selection operator regression model was developed to identify indicators of HG CRS, as observed during the hospitalization. Candidate indicators were informed by descriptive analyses and clinical advice, and included age, gender, length of stay, comorbidities, symptoms, and management. Performance of the model was evaluated using the area under the receiver operating characteristic curve (AUC). The model was validated in 2 additional data sources: electronic health records (EHR) and administrative claims.

RESULTS: 133 hospitalizations for CRS were analyzed (81 LG, 52 HG). Differences were observed in the prevalence of hypotension (16% LG vs 42% HG), positive pressure (including mechanical ventilation, 7% vs 23%), tocilizumab (43% vs 67%), and vasopressors (1% vs 17%). The least absolute shrinkage and selection operator model identified these 4 (as a multivariable model) as indicators of HG CRS (AUC = 75%, acceptable performance). In EHR, a lower proportion of patients with LG CRS (n = 11) than HG CRS (n = 15) had hypotension (18% vs 67%), tocilizumab (64% vs 73%), and vasopressors (36% vs 47%). In claims (n = 16 LG, 12 HG), these indicators were rarely observed. The AUC was 70% in EHR (acceptable performance) and 60% in claims (less than acceptable performance).

CONCLUSIONS: Among patients with an ICD code of CRS, use of vasopressors, positive pressure, and tocilizumab and having hypotension were indicators of HG CRS. The model performed moderately well in hospital chargemaster and EHR data. These indicators can inform CRS severity in RW data, which is critical for treatment decision-making, especially given the high proportion of patients with codes for unspecified CRS grade.

SPONSORSHIP: Janssen Scientific Affairs, LLC.

D21 Comparison of real-world health care resource utilization and costs among patients with hereditary angioedema on lanadelumab or berotralstat long-term prophylaxis

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BACKGROUND: Hereditary angioedema (HAE) is a rare autosomal dominant disorder characterized by unpredictable swelling attacks. Treatment includes on-demand therapy for acute attacks and long-term prophylaxis (LTP). Payers seek to manage costs in HAE due to high-budget impact on a per-patient basis. Lanadelumab and berotralstat are approved for LTP in patients (pts) with HAE. Understanding the real-world costs of LTP can help inform payers regarding management of the HAE population.

OBJECTIVE: To describe real-world health care resource utilization (HCRU) and health care costs among pts persistent on lanadelumab or berotralstat.

METHODS: This was a retrospective, observational study of health care insurance claims data from Merative MarketScan Databases between July 1, 2017, and July 31, 2023, among pts with HAE who initiated lanadelumab or berotralstat and were persistent for at least 18 and at least 6 months, respectively. Persistence was defined as treatment without a gap for at least 60 days of lanadelumab and at least 30 days for berotralstat. Required length of persistence varied because of the more recent approval of berotralstat and lack of flexible dosing after 6 months. Hospital admissions, emergency department (ED) visits, and health care costs were described. Covariate balancing propensity score inverse probability of treatment weighting was performed using sex, baseline costs, and baseline on-demand prescriptions

to balance characteristics believed to be associated with the outcome of interest.

RESULTS: This analysis included weighted data from 32 pts each in the lanadelumab and berotralstat cohorts. A higher proportion of berotralstat pts had a hospital admission during 6 months on LTP (9.4%) than those on lanadelumab during months 0-6 (4.0%), 7-12 (1.8%), and 13-18 (2.0%). Mean inpatient costs were higher for pts on berotralstat ($3,720) than lanadelumab (months 0-6: $218; 7-12: $1,206; 13-18: $1,113). A higher proportion of berotralstat pts had an ED visit (21.9%) than lanadelumab pts during months 0-6 (14.0%), 7-12 (8.0%), and 13-18 (17.9%). Mean total health care costs (medical + outpatient pharmacy) were similar for berotralstat ($384,303) and lanadelumab ($382,562) during months 0-6 but were reduced in months 7-12 ($326,049) and 13-18 ($289,907) for lanadelumab. Mean acute treatment costs were also higher among berotralstat pts ($60,451) than during months 0-6 ($46,336), 7-12 ($37,578), and 13-18 ($23,968) of lanadelumab treatment.

CONCLUSIONS: These real-world findings suggest lower HCRU and health care costs among pts with HAE persistent on lanadelumab for at least 18 months than those persistent on berotralstat for at least 6 months.

SPONSORSHIP: Takeda Pharmaceuticals USA, Inc.

D22 Clinical burden and health care resource utilization among commercially insured adults with IgG4-RD in the United States

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BACKGROUND: IgG4-related disease (IgG4-RD) is a systemic autoimmune condition that causes fibro-inflammation and may result in multiorgan damage. Although increasingly recognized, little is known about the burden of this disease.

OBJECTIVE: To assess the clinical and economic burden of IgG4-RD in the United States.

METHODS: Commercially insured adults with IgG4-RD were identified (IQVIA PharMetrics Plus data; 01/01/2011 to 06/30/2022) using a validated algorithm. The index date was defined as the date of the first observed IgG4-RD–related diagnosis code. The baseline and follow-up periods were defined as the 12 months before and after the index date, respectively. Demographic characteristics were described on the index date. Clinical characteristics, IgG4-RD-related treatments, all-cause health care resource utilization (HRU), and all-cause health care costs (2022 USD) were described during the baseline and follow-up periods. Mean ± SD was reported for all continuous variables.

RESULTS: A total of 295 patients with IgG4-RD (aged 49.8 ± 12.5 years, 50.5% female) were included in the study. After diagnosis, the most frequently observed IgG4-RD-related comorbidities were hypertension (31.5%), hyperlipidemia (22.4%), and type 2 diabetes (17.3%). Based on coding patterns, the most common organ manifestations were pancreas (32.9%), biliary (27.8%), and sialadenitis (6.8%). The majority of patients (87.8%) received a treatment for IgG4-RD after diagnosis, with prednisone (71.5%), rituximab (20.7%), and azathioprine (17.6%) being the most common. Annual all-cause HRU and health care costs were substantial before diagnosis and further increased after diagnosis. Before diagnosis, patients had 30.4 ± 24.4 outpatient (OP) visits (18.4 ± 15.6 office visits, 12.0 ± 14.1 nonoffice visits) and 22.7% had at least 1 inpatient (IP) admission (length of stay = 9.0 ± 10.7 days). After diagnosis, this increased to 40.7 ± 26.4 OP visits (22.0 ± 18.1 office visits; 18.7 ± 16.3 nonoffice visits) and 35.3% of patients had at least 1 IP admission (length of stay = 10.6 ± 12.4 days). All-cause health care costs were 1.5 times higher after diagnosis compared with before diagnosis ($69,753 ± $83,413 vs $45,844 ± $92,097, respectively), which was driven by both increased OP and increased IP costs.

CONCLUSIONS: This study provides important insights into the high clinical and economic burden observed in patients with IgG4-RD. These findings highlight the need for better detection, treatment, and management of this complex and understudied disease to reduce the burden on health care systems and improve patient outcomes.

SPONSORSHIP: Horizon Therapeutics (now Amgen Inc.).

E00-E90 Endocrine, Nutritional, and Metabolic Diseases

(eg, diabetes, growth hormone, lipids)

E2 The impact of interchangeability on biosimilar insulin glargine use and spending in Medicaid

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BACKGROUND: Insulin glargine is one of the most widely prescribed and expensive drugs for diabetes, accounting for a significant portion of Medicaid spending. However, little is known about how state Medicaid programs responded

to the introduction of an interchangeable biosimilar, which would allow pharmacists to substitute without prescriber approval in most states.

OBJECTIVE: To investigate the impact of the first interchangeable biosimilar for insulin glargine on spending and use of state Medicaid programs in the United States.

METHODS: We used Medicaid state drug use data to examine cost and market share of insulin glargine products from 2020 to 2022. We collected quarterly data on the number of units and total amount reimbursed for all insulin glargine products. We calculated market share as the proportion of units out of the total units reimbursed for insulin glargine in each state and quarter. We also estimated the cost per unit for Lantus and the interchangeable biosimilar after applying an adjustment for minimum statutory rebate amounts required under Medicaid. We reported variation in biosimilar market share by state program and used segmented regression analysis with Stata software to test for changes in biosimilar market share following the introduction of the first interchangeable biosimilar in Q4 2021.

RESULTS: Insulin glargine biosimilars had 48% market share in Q1 2020 with a downward trend of 2.2% per quarter as use shifted to reference products ($P < 0.01$). However, after introduction of an interchangeable biosimilar, this trend reversed, and the biosimilar market share grew by 2.8% per quarter through Q4 2022 ($P < 0.01$). We estimated that entry of an interchangeable biosimilar saved $60.6 million for Medicaid programs between Q4 2021 and Q4 2022, or approximately 5% of Medicaid spending on insulin glargine. Despite these savings, we observed significant variation in interchangeable biosimilar use across state Medicaid programs, which ranged from 0% to 93% in quarterly market share (mean = 9.1%, SD = 17.9%) with 6 states reporting no interchangeable biosimilar use in 2022.

CONCLUSIONS: The introduction of an interchangeable biosimilar for insulin glargine helped reverse the declining trend of the biosimilar market share and generated substantial savings for Medicaid programs. However, use of interchangeable biosimilars varied widely across states, suggesting the need for more education and incentives to promote their adoption.

SPONSORSHIP: None.

E3 Impact estimation of patients' cost sharing on drug adherence in the context of the Inflation Reduction Act

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BACKGROUND: High cost of novel drugs, with increasing prices for consumer goods, may lead to cost-related medication nonadherence. Because the introduction of the Inflation Reduction Act would empower the Department of Health and Human Services to negotiate drug prices for selected novel drugs as well as limit copays for insulin under Medicare Part D, prescription abandonment rates are expected to decrease for patients with prescribed novel drugs.

OBJECTIVE: To build a model for assessing the relationship between patients' cost-sharing and medication adherence for antidiabetic novel drugs with no generics, using historical data. The study aims at predicting whether the effect of decreased cost-sharing can shift the financial burden of patients, leading to increased medication adherence. Because the high cost of some novel antidiabetic drugs is a concern for many, the model is built on patients with diabetes who are under such medications.

METHODS: A total of 4,986 patients were identified as incident patients with diabetes from January 1, 2019, to December 31, 2022. Patients' continuous eligibility criteria were considered for 12 months pre-index and 18-months post-index period. Proportion of days covered (PDC) was used as a measure of medication adherence. Ordinary least square regression technique was used to find the effect of cost-sharing, comorbidities, days of supply, quantity disbursed for the concerned antidiabetic drugs, and demographic factors on drug adherence. Adjusted R-square was applied to predict model accuracy.

RESULTS: Descriptive bivariate plots suggested symmetric distribution of adherence, and it was found to be negatively correlated with cost-sharing by patients. The ordinary least square regression analysis established a good fit regression model with ~80% accuracy. Cost-sharing, patients' age, and other comorbidities were statistically significant ($P < 0.05$) predictors for PDC. The overall trend showed an inverse relationship between PDC and cost-sharing. However, when analyzing the effect of cost-sharing on adherence for different subgroups, we noted a wide variation in measured effects, which is possibly a result of different comorbid conditions.

CONCLUSIONS: Our analysis suggests a negative relation between drug adherence and patients' cost-share. However,

this relation can be affected by other factors, such as the patients' underlying comorbidities. Based on the overall results, it may be inferred that managed care decision-makers should carefully consider the negative implications of high cost-sharing of novel drugs on adherence. In this context, the Inflation Reduction Act can help in mitigating this issue to an appreciable extent.

SPONSORSHIP: Optum.

E4 HEDIS and ADA glycemic goals achieved by Control-IQ technology users with type 1 and type 2 diabetes

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BACKGROUND: Glycemic control in patients with type 1 and 2 diabetes (PwT1D, PwT2D) is critical to reduce morbidity and mortality. National glycemic standards include the Healthcare Effectiveness Data and Information Set (HEDIS) metric to identify hemoglobin A1c control as less than 8.0% and the American Diabetes Association (ADA) target A1c goal of less than 7%. Glucose management indicator (GMI) is a recognized surrogate for A1c when sufficient data are provided (≥14 days and ≥70% continuous glucose monitoring use). The t:slim X2 insulin pump with Control-IQ technology ("Control-IQ technology") is an advanced hybrid closed-loop system that predicts blood sugar and automates insulin delivery.

OBJECTIVE: To assess performance of Control-IQ technology using HEDIS and ADA thresholds for glycemic control.

METHODS: This retrospective analysis evaluated glycemic data among newly initiated Control-IQ technology users in the United States from 1/1/20 to 6/14/23, following prior therapy of multiple daily injections. Patients had to have at least 70% continuous glucose monitoring use in the last 3 months of a 1-year period after Control-IQ technology initiation and baseline A1c. Results were stratified by diabetes type, payer type, and baseline A1c. GMI was calculated using the last 3 months, where GMI = 3.31 + 0.02392 × [mean glucose in mg/dL], and compared with baseline A1c. Changes in glycemic outcomes and proportion of patients meeting national thresholds were analyzed using paired t-test and chi-square tests.

RESULTS: Analysis included 11,040 users, 88.8% (n = 9,803) PwT1D and 11.2% (n = 1,237) PwT2D. For PwT1D, glycemic improvements (mean [SD]) were as follows: –1.0% [1.7] $P < 0.0001$ overall, –3.2% [1.7] $P < 0.0001$ for baseline A1c greater than 9%, and by payer type: Medicare: –0.9% [1.3], Medicaid: –1.0% [1.7], Commercial: –1.0% [1.8], Cash: –1.2% [1.8], all $P < 0.0001$. Proportion meeting standards increased from 49.9% to 87.6% ($P < 0.0001$) for HEDIS control and 22.7% to 35.2% ($P < 0.0001$) for ADA target. For PwT2D, glycemic improvements were as follows: –1.2% [1.5] $P < 0.0001$ for all, –2.9% [1.5] $P < 0.0001$ for baseline A1c greater than 9%, and by payer type, Medicare: –0.9% [1.2], Medicaid: –1.5% [1.8], Commercial: –1.3% [1.6], Cash: –1.6% [1.3], all $P < 0.0001$ except Cash was not calculated owing to small samples. Proportion meeting standards increased from 43.5% to 86.5% ($P < 0.0001$) for HEDIS control and 14.6% to 38.5% ($P < 0.0001$) for ADA target.

CONCLUSIONS: Control-IQ technology improved HEDIS and ADA outcomes for PwT1D and PwT2D. Improvements were seen across all payer types with the largest improvement seen in patients with the highest A1c at baseline.

SPONSORSHIP: Tandem Diabetes Care.

E5 Dose escalation of once-weekly semaglutide in patients with type 2 diabetes and uncontrolled hemoglobin A1c in the United States

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BACKGROUND: Real-world dose escalation data for once-weekly (OW) semaglutide is limited.

OBJECTIVE: To describe dose escalation and patient (pt) escalation factors for OW semaglutide in US adults with type 2 diabetes (T2D) and uncontrolled hemoglobin A1c.

METHODS: This was a retrospective cohort study using Optum Clinformatics Data Mart (01/01/2017 to 12/31/2022) in pts with T2D and A1c greater than or equal to 9.0%, who newly initiated OW semaglutide. Index date was the initiation date of OW semaglutide. The primary outcome was time to dose escalation (1 mg) and quarterly highest dose over a 2-year follow-up. In pts with at least 2 claims of 1 mg, pt factors associated with rapid (increase to 1 mg within 2 months), timely (increase to 1 mg between 2 and 12 months), and slow (increase to 1 mg between 12 and 24 months) escalation were explored.

RESULTS: 2,311 pts were included. Mean (SD) age was 60.2 (11.5) years and 52.2% were male. In the 2-year follow-up, 1,419 (61.4%) pts increased to 1 mg post-index and mean (SD) time to reaching the 1 mg dose increase was 174.6 (191.1) days. An increase to 1 mg was seen in 908 (39.3%) pts at least 2 months post-index and mean (SD) time to increase was 266.8 (182.3) days. Except for the last 3 quarters of year 2, at least 8% of pts were receiving a dose of 0.25 mg. The proportion of

pts with the highest dose of 0.5 mg were in year 1 quarter 1 (62.4%), with a steady decrease thereafter. The highest dose of 1 mg peaked in year 2 quarter 1. The proportion of pts with no prescription steadily increased during follow-up. In pts with at least 2 claims of 1 mg (n = 1,303), rapid, timely, and slow escalation was reported in 499 (38.3%), 607 (46.6%), and 197 (15.1%) pts, respectively. Pt baseline factors associated with rapid vs timely dose escalation were higher sodium-glucose co-transporter 2 inhibitor use (33.3% vs 27.5%), higher prior use of other GLP-1RA (33.1% vs 23.6%), and mean longer time from A1c measurement to index date (31.2 vs 26.1 days); $P < 0.05$ for all. Baseline factors associated with slow vs timely escalation were mean lower diabetes complications severity index (1.55 vs 1.92), lower use of insulin (basal insulin: 37.6% vs 47.6%; other insulin: 16.2% vs 26.0%), and lower prior use of other GLP-1RA (13.7% vs 23.6%); $P < 0.05$ for all.

CONCLUSIONS: In pts with poorly controlled T2D who newly initiated OW semaglutide, 38.6% of pts did not reach a dose of 1 mg over a 2-year follow up period. This indicates that a significant proportion of pts remained on sub-maintenance dose and experienced slow dose escalation. In these high-risk, high-burden pts, a focus on timely dose escalation to manage T2D may be warranted.

SPONSORSHIP: Novo Nordisk Inc.

E6 Improvements in glycemic control in people with diabetes in an employer health initiative offering continuous glucose monitors (CGMs) as a pharmacy benefit

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BACKGROUND: Metro Nashville Public Schools, a large Tennessee school system with a focus on workplace health programs, implemented a policy change in May of 2022 covering continuous glucose monitors (CGMs) through the pharmacy benefit without prior authorization requirements. Covering CGMs through the pharmacy vs medical benefit resulted in a 2-fold increase in CGM use, but the clinical outcomes were unknown.

OBJECTIVE: To evaluate the change in clinical outcomes from expanded access to CGM in people with diabetes.

METHODS: Adults with type 1 (T1D) and type 2 (T2D) diabetes (aged 18-64 years) with hemoglobin A1c and average glucose levels prior to starting CGM and at follow-up were included in the analysis. The main outcomes were changes in A1c and average glucose. Secondary measures included percentages of participants meeting Healthcare Effectiveness Data and Information Set (HEDIS; <8.0%) and American Diabetes Association (ADA; <7.0%) treatment targets.

RESULTS: Of the total participants (n = 184) who met the inclusion criteria, 23% (n = 43) were T1D and 77% (n = 141) were T2D. Participants were 65% White, 25% Black, and 10% all other. Of the participants with T2D, 40% were not treated with insulin. In participants with T1D, A1c improved by 0.3% from 7.8% at baseline to 7.5% at follow-up ($P = 0.11$). The cohort with T2D had a 0.9% improvement in A1c from 8.3% at baseline to 7.4% at follow-up ($P < 0.001$). Overall, average glucose improved by 24.1 mg/dL from 175.0 mg/dL at baseline to 150.9 mg/dL at follow-up ($P < 0.001$). The percentage of participants meeting the HEDIS target of A1c < 8.0% increased from 52% (n = 95) at baseline to 73% (n = 134) at follow-up. The percentage of participants meeting the ADA target of A1c < 7.0% increased from 27% (n = 50) at baseline to 45% (n = 83) at follow-up.

CONCLUSIONS: Expanded access to CGM by a large employer through the pharmacy benefit without prior authorization requirements increased CGM use and was associated with clinically meaningful improvements in A1c and average glucose in employees and their dependents with diabetes. This improvement in glycemic control was associated with an approximately 41% and 67% increase in the number of participants achieving HEDIS (<8.0%) and ADA (<7.0%) treatment goals, respectively.

SPONSORSHIP: None.

E7 SGLT2i as early treatment in type 2 diabetes mellitus: A systematic review of real-world studies

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BACKGROUND: Sodium-glucose cotransporter 2 inhibitors (SGLT2is) are an effective treatment option for individuals with type 2 diabetes (T2D), for glucose lowering and cardiovascular benefits. Systematic reviews have summarized safety and efficacy data from SGLT2i trials, particularly for those with more advanced T2D and/or comorbid diseases. As trial-based data from individuals treated with SGLT2is early in their disease course are limited, estimates from real-world studies are needed. However, a synthesis of real-world data on early use of SGLT2i among individuals with T2D is lacking.

OBJECTIVE: To synthesize estimates of the effectiveness of early use of SGLT2i, as first- or second-line treatment, compared with other glucose-lowering drugs (oGLDs) among those with T2D.

METHODS: A systematic review using study-specific PICOS criteria was conducted using MEDLINE, Embase, and the Northern Light database, focusing on evidence comparing SGLT2is with oGLDs from the last 10 years. Outcomes included hospitalization for heart failure (HHF), myocardial infarction (MI), and mortality. Early use was defined as first- or second-line treatment. Propensity score–matched studies reporting hazard ratios (HRs) with 95% CIs were retained. Data were tabulated by comparator and line of therapy.

RESULTS: From 2,672 abstracts, 5 studies were included. SGLT2i-treated sample sizes ranged from 2,020 to 21,688. Three studies reported significantly lower HHF among those on SGLT2i vs oGLD, with HRs from 0.35 (95% CI = 0.13-0.89) to 0.78 (95% CI = 0.63-0.97). One of 3 studies reported a significantly lower risk of MI among those on SGLT2i vs at least 1 Ogld (HR = 0.65 [95% CI = 0.55-0.77]); 2 studies reported directionally supportive but nonsignificant results with HRs from 0.70 (95% CI = 0.48-1.00) to 0.94 (95% CI = 0.67-1.33). Two of 3 studies reported significantly lower mortality among those on SGLT2is vs at least 1 oGLD, with HRs from 0.30 (95% CI = 0.20-0.46) to 1.00 (95% CI = 0.57-1.74). Two studies were conducted in first-line settings, and although comparisons generally favored SGLT2is vs oGLDs, most results were nonsignificant.

CONCLUSIONS: This review suggests early treatment with SGLT2is for T2D may be associated with lower risk of HHF, mortality, and MI vs oGLDs. Comparing results across studies was complicated by study heterogeneity. Sufficiently powered real-world studies are needed to further examine these associations.

SPONSORSHIP: Boehringer Ingelheim.

E8 Cost-effectiveness analysis of flash glucose monitoring for glucose self-management by people with type 2 diabetes mellitus on basal insulin therapy: A US Medicaid perspective

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BACKGROUND: For people living with type 2 diabetes mellitus (T2DM), effective glucose management is important to help reduce disease burden, complications, and health care utilization. Glucose monitoring is an essential component of patient self-management to help reach and maintain targeted glucose and glycated hemoglobin A1c levels. The FreeStyle Libre system (FSL) is an intermittently scanned continuous glucose monitor that helps reduce the burden of self-monitoring of blood glucose (SMBG).

OBJECTIVE: To assess the cost-effectiveness of FSL, compared with SMBG, in individuals with T2DM insured through state Medicaid programs and using basal insulin.

METHODS: A patient-level microsimulation model was used to compare FSL with SMBG for a population of 10,000 patients. A 10-year horizon was used, with an annual discount rate of 3.0% for costs and utilities. Model population characteristics were based on US national epidemiology data. Patient outcomes were based on published clinical trials and real-world studies. Annual costs, reflective of 2023 values, included FSL and SMBG acquisition costs and the costs of treating diabetic complications, severe hypoglycemia, and diabetic ketoacidosis. The effect of FSL was modeled as a persistent 1.1% reduction in A1c relative to SMBG, based on US real-world evidence. Disutilities were based on published clinical trials and other relevant literature. The primary outcome was cost per quality-adjusted life-year (QALY) gained. Sensitivity analyses were performed to test the validity of model results when accounting for plausible variation of inputs.

RESULTS: In the base-case analysis, FSL was dominant to SMBG, providing more QALYs (6.18 vs 5.97) at a lower cost ($70,137 vs $71,809) over the 10-year time horizon. A $10,456 increase in glucose monitoring costs was offset by a $12,127 mean reduction in treatment costs, reflecting reductions in severe hypoglycemia, diabetic ketoacidosis, and diabetes-related complications, particularly renal failure, myocardial infarction, and congestive heart failure. Scenario analyses were consistent with base-case results, and the incremental cost-effectiveness ratio for FSL vs SMBG ranged from dominant to cost-effective. In probabilistic analysis, FSL was 100% likely to be cost-effective at a willingness-to-pay threshold of $50,000/QALY.

CONCLUSIONS: From the perspective of the US Medicaid program, FSL is cost-effective compared with SMBG for patients with T2DM on basal insulin therapy.

SPONSORSHIP: Abbott Diabetes Care.

E9 Health plan best practices highlight opportunities for enhancing patient outcomes in diabetes through continuous glucose monitoring

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BACKGROUND: The expanding use of continuous glucose monitoring (CGM) has been transformative in diabetes care, providing valuable real-time data and insights for diabetes management. Coverage in type 2 diabetes (T2D) has

increased, reaching a broader population of patients with diabetes who are recommended for CGM per clinical guidelines. To understand the opportunity for health plans to support improved patient outcomes with CGM, AMCP and Impact Education, LLC, sponsored a multifaceted program to identify best practices.

OBJECTIVE: To summarize health plan best practices for CGM to support managed care and payer professionals in making collaborative, evidence-based decisions to optimize outcomes among patients with diabetes.

METHODS: The program consisted of expert interviews (n = 7), a national payer survey (n = 63), and an expert panel workshop with clinical experts and managed care stakeholders (n = 9). The best practice recommendations were identified through expert interviews from commercial and public payer health plans and further refined with the data from a national survey. Additional insights and real-world examples around coverage and access to CGMs were collected during a live, virtual moderated workshop.

RESULTS: Five health plan best practices were identified and validated during the program's stages. A large proportion of the national survey participants (70%) affirmed covering CGM for guideline-recommended populations or beyond. Payers ranked improvements in A1c reduction as the greatest benefit of CGM, followed by improvements in advanced measures such as time in range and enhanced patient self-management. Although reduced provider burden is an important consideration, the primary benefit of pharmacy coverage of CGM is improved access to care for patients. Pharmacists were also identified as having a key role in offering patient education on CGMs, such as how to use the devices, interpret the reports produced, and adjust insulin dosing. Creating opportunities for patient education and engagement, referral for broader disease management, and supporting adherence as a way to improve outcomes and reduce costs were also identified through these activities.

CONCLUSIONS: CGM has implications for managed care pharmacy, as it represents a transformative technology in diabetes management. Managed care professionals play a key role in the administration and coordination of drug benefits with the goal of optimizing health outcomes and controlling health care costs and will benefit from understanding current best practices.

SPONSORSHIP: Dexcom, Inc., Medical Affairs.

E10 Impact of utilization management of continuous glucose monitors in a commercial population

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BACKGROUND: Continuous glucose monitors (CGMs) are devices used to measure glucose levels and trends over time. CGMs have risen in use and are now commonly available as a pharmacy benefit. Health plan formulary management balances patient access and a health plan's responsibility to be cost-effective stewards of health care dollars. CGMs have been observed to be used off label in patients who do not require frequent glucose monitoring and in patients that do not have diabetes. To ensure cost-effective coverage for patients who meet the labeled indications, utilization management criteria were implemented in July 2023 for point-of-sale lookback for at least 1 insulin fill within the past 6 months.

OBJECTIVE: To evaluate the impact of utilization management criteria on the volume of CGM dispensed under the pharmacy benefit, total cost of care, and the volume of prior authorization requests.

METHODS: A retrospective analysis was conducted using Priority Health medical and pharmacy paid claims for commercial health plan patients who filled a CGM through the pharmacy benefit during the pre- and postmanagement period (90 days before and after the insulin lookback was implemented). To account for sensor life varying among these disposable products, the total quantity of CGM sensors dispensed was converted to sensor days supply in each period.

RESULTS: A total of 4,158 patients were identified as filling a CGM component within either period. Days supply of sensors filled in the 90 days after implementation decreased by 26.7%. Prior authorization requests for coverage of sensors in the postimplementation period increased by 182% (an additional 287 requests over the prior period). In review of total cost of care, more than half (53%) of members showed a decline in total allowed amounts between time periods, with a 6% overall decline in total cost of care for all members within the dataset.

CONCLUSIONS: An observed increase in off-label use of CGMs led to the implementation of utilization management criteria. Retrospective review of claims data showed that an insulin use requirement significantly reduced the volume of CGMs dispensed under the pharmacy benefit and was associated with a decline in total cost of care. Volume of prior authorization requests increased, but the insulin lookback

was found to be adequate as an automated measure for the majority of cases. Utilization management strategies should continue to be evaluated for coverage of CGMs to ensure cost-effective care.

SPONSORSHIP: None.

E11 Assessing racial disparities in health care resource utilization and medical expenditure in patients with diabetes, congestive heart failure, and chronic kidney disease: Insights from real-world evidence

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BACKGROUND: Diabetes mellitus (DM), chronic kidney disease (CKD), and congestive heart failure (CHF) present significant public health challenges. However, a comprehensive understanding of long-term patterns of racial disparities in these diseases remains limited.

OBJECTIVE: To evaluate health disparities across different racial and ethnic groups by examining medical costs and health care resource utilization (HCRU) in patients with DM, CHF, and CKD.

METHODS: A retrospective analysis was conducted using the Optum deidentified Market Clarity Dataset, which integrates claims and electronic health records of patients. Three patient cohorts were examined, representing DM, CHF, and CKD. The study period ranged from January 1, 2016, to December 31, 2020, with patients identified between January 1, 2017, and December 31, 2019, included. All-cause average medical cost (ACAMC) and all-cause HCRU were evaluated over a 12-month follow-up period. Only patients with no diagnosis of DM, CHF, and CKD in the preceding 12 months from the index date for the respective cohorts were included. Comparison of outcomes across different race and socioeconomic status groups was performed using Kruskal-Wallis post hoc statistical test.

RESULTS: In the DM cohort (n = 225,006), significant differences were observed in ACAMC between White and Black patients ($16,930 vs $17,421, $P < 0.0001$) and HCRU across various setting (emergency department [ED], inpatient [IP], office/clinics, and outpatient [OP]) ($P < 0.0001$). In the CHF cohort (n = 131,658), significant differences were found in ACAMC ($43,549 vs $42,678) and HCRU across various settings (ED, IP, office/clinic, and OP) ($P < 0.0001$) between White and Black patients. Similarly, in the CKD cohort (n = 173,449), significant differences were noted in ACAMC ($29,793 vs $26,955) and HCRU across multiple settings (ED, IP, OP, SNF, and office/clinics) between White and Black patients.

CONCLUSIONS: This real-world evidence analysis reveals disparities in health care resource utilization and medical expenditure among patients with DM, CHF, and CKD across different racial and ethnic groups. These findings underscore the need for further investigation into the factors contributing to these disparities and the development of targeted interventions to address them. Policy reforms focused on equitable access to care can help mitigate these disparities and improve health outcomes for all patients affected by these chronic diseases.

SPONSORSHIP: Optum.

E12 Increased burden of diabetic ketoacidosis among pediatric patients with type 1 diabetes using Medicaid in the United States

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BACKGROUND: In the United States, clinical (or stage 3) type 1 diabetes (T1D) affects 244,000 children and adolescents (aged <20 years [yr]). Children with T1D require lifelong, intensive treatment including exogenous insulin and metabolic monitoring to avoid long-term complications. Poor control can lead to increased costs due to emergency department (ED) care or hospitalization related to diabetic ketoacidosis (DKA). Despite therapeutic advances, soaring treatment costs pose challenges to managing T1D. Recent data on health care resource utilization (HRU) in pediatric patients (pts) with T1D are limited.

OBJECTIVE: To examine the clinical and HRU burden of T1D among real-world pediatric pts in the United States after clinical T1D diagnosis.

METHODS: This retrospective cohort study analyzed pediatric pts (aged <18 yr; subgroups: 0-5, 6-12, and 13-17 yr) newly diagnosed with T1D from January 1, 2015, to June 30, 2018, in Merative MarketScan data. Pts with at least 2 medical claims with T1D diagnosis codes, at least 30 days apart, and continuous health plan eligibility for at least 1 yr prior to initial T1D diagnosis (index) were included. HRU was analyzed based on health plan type: commercial health plan (CHP) and Medicaid. Baseline characteristics and study outcomes were summarized using descriptive statistics.

RESULTS: Newly diagnosed pediatric pts with T1D (n = 5,245; 4,092 in CHP, mean [SD] age = 10.5 [4.3] yr; 1,153 in Medicaid, 11.1 [4.1] yr) were analyzed. Medicaid had a higher proportion

of female pts than CHP (51.4% vs 44.5%; P < 0.05). Although baseline comorbidities were low, Medicaid patients had greater baseline comorbidities (with mean [SD] Charlson Comorbidity Index [CCI] in CHP 0.22 [0.52], and in Medicaid 0.45 [0.70]; P < 0.05). A higher proportion of Medicaid pts had CCI greater than or equal to 1 (35.0% vs 18.9%; P < 0.05). Medicaid patients also experienced DKA less than or equal to 3 months (mos) after initial clinical diagnosis among 0- to 5-yr-olds (CHPs = 29.1%; Medicaid = 35.5%). The proportion with DKA greater than 12 mos after diagnosis was 2.5 times higher in Medicaid patients (14.4% vs 5.8%). Medicaid pts also experienced greater DKA-related hospitalizations (CHPs = 27.2%; Medicaid = 28.9%) and ED visits (CHPs = 28.8%; Medicaid = 31.7%) and were among the top 6 services pts used (>27.0%).

CONCLUSIONS: Pediatric pts enrolled in Medicaid experienced higher rates of DKA events in pts aged younger than 5 yr after initial clinical diagnosis of T1D compared with those with CHP. During the greater than 12 mos after diagnosis, DKA events were 2.5 times higher in people with T1D who have Medicaid coverage. This suggests an increased DKA-related clinical and HRU burden for T1D management in pts who used Medicaid.

SPONSORSHIP: Sanofi.

E13 Learnings from linking electronic medical record patient cohorts with consumer SDOH data

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BACKGROUND: Social determinants of health (SDOH) are the conditions in which people are born, live, work, and age and are estimated to drive up to 80% of health outcomes.

OBJECTIVE: To link patient- and household-level SDOH characteristics from consumer data to select electronic medical record (EMR) disease cohorts identifying traditionally unavailable SDOH measures for inclusion in real-world data analysis.

METHODS: EMR encounter records from community health care providers between 01/01/2016 and 12/31/2021 and SDOH for calendar year 2022 including demographics, socioeconomic, and household information were used (CHRONOS. 2017-2023. Forian, Inc. https://forian.com). Both data sources are Health Insurance Portability and Accountability Act of 1996 compliant and linked by a unique anonymized patient identifier. Patients aged 18 years and older with evidence of HIV, chronic kidney disease (CKD), heart failure (HF), type 2 diabetes (DM2), and metastatic prostate cancer (mPC) were identified using EMR diagnosis code (*International Classification of Diseases, Tenth Revision, Clinical Modification* [ICD-10-CM], ICD-9-CM, Snomed) prior to linking to SDOH data. Patients were considered overlapped if there was at least 1 record in SDOH data and at least 1 record with a diagnosis of interest in EMR. Descriptive statistics of SDOH measures were evaluated for age, sex, race, and custom-defined composite measures for household status (marital status; household size; children in the home) and household economic status (economic stability indicator [ESI], household income). ESI ranges from 0 to 30 with higher numbers indicating less economic stability.

RESULTS: 2,573,469 EMR patients (17.5%) had a linkable SDOH and ranged from 19.8% of patients with mPC to 34.3% of patients with HIV. Racial diversity was greatest among patients with advanced CKD or HIV and lowest among those with mPC or HF. Patients with HIV were most likely to be single living in a household without children, whereas patients with HF and those with mPC were most likely to be aged older than 65 years and living alone. Most patients lived in households with annual incomes below the US median ($75,000). Of those with household incomes above the median, 47% of patients with HIV, 36% of those with DM2, 33% of those with HF, 32% of those with CKD, and 28% of those with mPC were found to have ESI values greater than 10, indicating low economic stability relative to household income.

CONCLUSIONS: SDOH measures provide insight into disease-specific patient cohorts beyond demographic data available in EMR alone. Composite measures and interactions can be derived to provide deeper understanding of care patterns and health outcomes. Including patient- and household-level rather than geographic-level SDOH measures may remove additional variability and bias when measuring the impact on health outcomes and costs.

SPONSORSHIP: Magnolia Market Access.

E34 Association between glucagon-like peptide-1 (GLP-1) receptor agonist use and health care resource utilization among US adults

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BACKGROUND: Glucagon-like peptide 1 (GLP-1) agonists have become attractive therapies for patients with type 2 diabetes (T2D) and/or obesity. Nonetheless, little is known about the association between GLP-1 agonist use and health care resource utilization.

OBJECTIVE: To examine whether GLP-1 agonist use is associated with emergency department (ED), inpatient, and outpatient visits for any medical indication, as well as for

cardiovascular disease (CVD)–related and gastrointestinal (GI)-related indications.

METHODS: This study included 769,631 patients aged 18 years and older in the Komodo Healthcare Map who had at least 1 GLP-1 agonist fill between January 2019 and March 2022 and had continuous enrollment for 12 months or longer before and after the index fill. Patients were followed until they switched to a different GLP-1 agonist, they discontinued GLP-1 treatment, or the end of the 12-month follow-up period, whichever occurred first. Health care resource utilization and clinical characteristics were measured in the baseline and follow-up periods. A self-control approach was used to compare resource utilization between the follow-up and baseline periods within a patient. Poisson regression with individual fixed-effect was used. The length of baseline and follow-up period was included as an offset. Analyses were conducted separately by type of GLP-1 used (eg, dulaglutide, semaglutide, liraglutide, exenatide, and others).

RESULTS: Patients were on GLP-1 treatment for, on average, 262 days. In fully adjusted Poisson models, the rate of health care resource utilization increased significantly following the initiation of any type of GLP-1 agonists, as compared with that in the baseline. Among dulaglutide users, the initiation of such medication was associated with an increase in the rates of overall ED, inpatient, and outpatient visits by 1.05 (95% CI = 1.04-1.06], 1.07 [1.04-1.09], and 1.13 [1.13-1.14] times, respectively. Similar findings were observed for CVD-related and GI-related health care resource utilization among patients who initiated any type of GLP-1. Findings were similar when stratifying by patients' baseline comorbidity (eg, T2D and/or obesity).

CONCLUSIONS: GLP-1 agonist use was associated with a significant increase in the rate of health care resource utilization for any medical indication, as well as for CVD-related and GI-related indications. Given the wide use of these drugs, additional efforts should focus on monitoring side effects associated with GLP-1 agonists to avoid unnecessary/avoidable health care resource utilization.

SPONSORSHIP: None.

E41 Adherence and persistency analysis of glucagon-like peptide-1 receptor agonist therapy for weight loss

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BACKGROUND: Obesity is a serious health crisis affecting more than 40% of adults in the United States. Minimum weight loss of 5% has demonstrated lower incidence of weight-related complications and lower annual health care expenditures. GLP-1 receptor agonist (GLP-1) products for weight loss, such as liraglutide and semaglutide, represent the newest class of antiobesity medications (AOMs). GLP-1 is the most used AOM owing to its established weight loss benefit and emerging evidence demonstrating cardiovascular risk reduction in patients without type 2 diabetes. However, literature suggests significant weight regain and worsened cardiovascular outcomes after GLP-1 is discontinued, which suggests that chronic, consistent therapy is necessary for long-term benefits. There are limited real-world data to assess adherence and persistency patterns among members with weight loss GLP-1.

OBJECTIVE: To evaluate adherence and persistency for members with weight loss GLP-1 (liraglutide, semaglutide).

METHODS: This was a retrospective analysis of Blue Cross Blue Shield of Michigan commercial insured members with a pharmacy claim starting weight loss GLP-1 in 2021 (index date). Members were continuously enrolled with Blue Cross Blue Shield of Michigan pharmacy coverage throughout the post-index period. Adherence (proportion of days covered ≥80%) and persistency (no more than one >60-day gap in day supply between GLP-1 fills or no discontinuation >60 days prior to post-index end) were assessed 12 and 18 months post-index.

RESULTS: A total of 2,426 members met inclusion criteria for 12-month post-index evaluation: liraglutide (n = 1,629), semaglutide (n = 623), and mixed liraglutide/semaglutide (n = 174). Average age was 45 years, and 80.5% were female. The majority of members (73.1%; n = 1,773) were nonadherent. For the adherent members (n = 653), the semaglutide cohort demonstrated the highest average proportion of days covered (94.1%) vs liraglutide (91.5%) vs mixed (92.3%). Most members were not persistent with therapy (66.9%; n = 1,622). Of this group, 77.1% (n = 1,251) also discontinued therapy. For the 18-month post-index analysis (N = 1,931), a smaller proportion was adherent (16.9%; n = 326) and persistent (19.4%; n = 375).

CONCLUSIONS: The majority of members in this study demonstrated nonadherence and lack of persistency to weight loss GLP-1, which also appeared to decrease further over time. These insights on adherence and persistency to weight loss GLP-1 will better inform payers regarding the importance of leveraging management strategies to ensure optimal use.

SPONSORSHIP: BCBSM.

E42 Impact of Ozempic vs Wegovy on osteoarthritis risk in patients with obesity: A retrospective cohort study

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BACKGROUND: Osteoarthritis (OA) is a prevalent degenerative joint disorder. Although the effect of obesity on OA is well documented, less is known about the effect of approved antiobesity medications (AOMs) such as Ozempic or Wegovy. To date, no studies have analyzed the effect of Ozempic and Wegovy, both of which are formulations of semaglutide, on users' risk of developing OA.

OBJECTIVE: To determine the impact of Ozempic vs Wegovy on the risk of OA in patients with obesity in the United States.

METHODS: We conducted a retrospective cohort study using Kythera Medicare data from January 2020 to August 2022. Two cohorts of patients with obesity were identified: those taking Ozempic and those taking Wegovy. Patients in each of the groups had at least 1 pharmacy claim for Ozempic or Wegovy, had at least 1 claim with a diagnosis of obesity prior to the index date, and had continuous medical and pharmacy benefits for 12 months pre-index date. Patients were excluded during baseline if they were prescribed obesity medications and had 1 or more claims for OA, had more than 1 claim of obesity medication on the same index date, and were aged 99 years or older. We also compared results by AOM vs non-AOM users. Cox regression was applied to determine the risk of OA; the presence of OA was determined using diagnosis codes at outpatient and inpatient visits. Multivariate analysis was used to adjust for demographic variables and comorbidities.

RESULTS: Patients in the Ozempic cohort were older (72.08 vs 70.93, $P<0.0001$) and significantly less likely to live in a region of high socioeconomic status (33.50% vs 40.72%, $P=0.0065$). Ozempic users also had higher prevalences of congestive heart failure (14.35% vs 6.96%, $P=0.0001$), hypertension (81.97% vs 73.04%, $P<0.0001$), peripheral vascular disease (13.34% vs 6.67%, $P=0.0003$), and diabetes (82.03% vs 22.03%, $P<0.0001$). The Ozempic cohort had a lower OA risk than the Wegovy group after adjusting for demographic and clinical factors. However, Cox regression showed that this difference was not statistically significant (hazard ratio = 0.90; $P=0.4341$).

CONCLUSIONS: The absence of a statistically significant difference in the risk of OA between Ozempic users and Wegovy users demonstrates that one medication is no more effective than the other for the prevention of OA. However, when we compared patients with obesity on medication vs those not receiving medication, Cox regression demonstrated a 10% risk reduction ($P<0.0001$) in OA; therefore, we can conclude that AOMs do help in reducing the risk of OA.

SPONSORSHIP: None.

E43 Real-world adherence and persistence to glucagon-like peptide-1 receptor agonists among nondiabetic commercially insured adults with obesity

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BACKGROUND: In 2015, the US Food and Drug Administration approved the first glucagon-like peptide-1 agonist (GLP-1) product, liraglutide injection, for obesity treatment, followed by semaglutide injection in 2022. GLP-1 obesity treatment clinical trials report significant weight loss (6.1%-17.4%) and medication adherence at greater than 90%. GLP-1 use and costs during 2023 have increased dramatically in part due to increased obesity treatment. Little is known about the real-world GLP-1 obesity treatment adherence and persistency.

OBJECTIVE: To measure adherence and persistence to GLP-1 therapy in a real-world cohort of members without diabetes using these drugs for the treatment of obesity.

METHODS: Prime Therapeutics' integrated pharmacy and medical claims data from 16 million commercially insured members were used to identify members with a GLP-1 pharmacy claim (index date) between 1/1/2021 and 12/31/2021, with continuous enrollment 1 year before (pre-period) and after (post-period) the index date, and no GLP-1 drug claim in the pre-period. During the pre-period, members were required to have a medical claim indicating obesity without a diabetes diagnosis or diabetes drug claim and to be aged 19 years or older. Adherence was measured as the proportion of days covered (PDC) in the post-period, and members with a PDC greater than or equal to 80% were considered adherent. Persistence was measured as no 60-day-or-longer gap between a claim days supply ending and a subsequent claim fill date in the post-period. GLP-1 product switching was allowed.

RESULTS: 4,070 commercially insured members with obesity newly initiating GLP-1 therapy met all study criteria. The mean age was 46 years and 81% were female. Overall GLP-1 persistency was 47% at 180 days and 32% at 1 year. The highest and lowest persistency rates at 1 year were observed for semaglutide 0.5-2 mg injection (47%) and liraglutide (19%),

respectively. Average PDC was 51%, with 27% of members adherent to therapy, and 8.5% switched GLP-1 drugs.

CONCLUSIONS: This real-world analysis of GLP-1 products used for weight loss, among individuals with obesity without diabetes, found poor 1-year persistence and adherence, as compared with clinical trials data. Low adherence and persistence may be due to adverse effects, lack of perceived benefit, member cost share, and drug shortages. Participation in a comprehensive weight loss treatment program, including a care manager, may improve GLP-1 therapy persistency. Additional research is needed to understand the reasons for treatment discontinuation and long-term cost-effectiveness of these products.

SPONSORSHIP: Prime Therapeutics, LLC.

E44 Real-world first-year cost-effectiveness assessment of glucagon-like peptide-1 agonists to treat nondiabetes obesity

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BACKGROUND: Glucagon-like peptide-1 agonist (GLP-1) products to treat type 2 diabetes mellitus (T2DM) have been on the market since 2005, with weight loss US Food and Drug Administration indications added in 2015. In the fall of 2022, social media influencers expounded GLP-1 weight loss attributes, resulting in substantial use and cost increases. Little real-world evidence describes the first-year GLP-1 cost-effectiveness for treating obesity without diabetes.

OBJECTIVE: To describe changes in total cost of care (TCC) 1 year before and after initiation of GLP-1 treatment among commercially insured members with obesity, without diabetes, compared with a concurrent matched control group.

METHODS: Prime Therapeutics' integrated pharmacy and medical claims database was used to identify members newly initiating a GLP-1 (index date), defined as no use in prior year, between 1/1/2021 and 12/31/2021 and continuously enrolled 1 year before (pre-period) and after (post-period) the index date. During the pre-period, members were required to have a medical claim indicating obesity without a T2DM diagnosis or diabetes drug claim and be aged 19 years or older. Using the same criteria, a 3-to-1 matched control group was identified from members without a GLP-1 claim. Members were matched on characteristics and conditions using a combined exact and propensity score matching approach. TCC was calculated as the sum of allowed pharmacy and medical costs. Difference-in-difference (DID) regression using pre-post TTC changes assessed GLP-1 treatment cost-effectiveness.

RESULTS: 3,887 GLP-1 therapy members and 11,392 control group members met all study criteria after matching. Mean age was 47 years and 82% were women. GLP-1 group mean TCC increased from $12,776 to $19,931, a $7,155 (56%) increase, and for controls from $11,369 to $11,391, a $22 (0.2%) increase. Mean medical costs for the GLP-1 group increased from $9,950 to $10,960, a $1,010 (10%) increase, and for controls from $9,294 to $8,818, a $476 (5%) decrease. DID regressions found the GLP-1 group had significantly higher per-member annual TCC and medical spending at $7,132 ($P < 0.01$) and $1,487 ($P < 0.01$).

CONCLUSIONS: These real-world findings found a significant $7,132 TCC investment, in year 1, for each member newly initiating a GLP-1 for weight loss without T2DM. No medical cost offset was seen; instead, the GLP-1 treatment medical cost increased significantly $1,487 per person. These findings can aid in development of evidence-based GLP-1 weight loss management programs, pharmaceutical manufacturer value-based contracts, and health insurance benefit designs.

SPONSORSHIP: Prime Therapeutics, LLC.

E45 The effect of approved obesity medications on obesity's cardiovascular related comorbidities

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BACKGROUND: Obesity and its comorbidities, including cardiovascular disease (CVD), are major causes of morbidity and mortality in the United States. More than 70% of American adults aged 20 years and older are obese or overweight. Studies have shown that Ozempic, Wegovy, and tirzepatide have the potential to reduce body weight substantially. Little is known on the effect of antiobesity medications (AOMs) on CVD among patients with obesity.

OBJECTIVE: To compare the effect of Ozempic, Wegovy, and tirzepatide on CVD in patients with obesity in the United States.

METHODS: We used Kythera Medicare claims data from 2020 to 2022 in this retrospective cohort study. Identified patients were diagnosed with obesity before the index date and had at least 1 pharmacy claim for Ozempic, Wegovy, or tirzepatide between January 2021 and August 2022 (first claim = index date). These patients were then assigned to 1 of 3 cohorts based on the AOM they used. The study included patients who were aged younger than 99 years, had continuous medical and pharmacy benefits, did not receive any AOM or have a CVD claim during the 12 months before

the index date, and did not have more than 1 claim for an AOM on the same index date. We applied Cox regression to determine the risk of CVD and used diagnosis codes at outpatient and inpatient visits to determine the presence of CVD. Multivariate analysis was used to adjust for demographic variables and comorbidities.

RESULTS: A total of 5,926 patients who were treated with AOM were identified, which includes Ozempic (5,404 patients), Wegovy (375 patients), and tirzepatide (147 patients). We analyzed the data and found that patients treated with Wegovy had a 12% lower risk (hazard ratio = 0.88, *P* = 0.391) of developing CVD compared with those treated with Ozempic. Moreover, patients treated with tirzepatide had a 2% lower risk (hazard ratio = 0.98, *P* = 0.919). However, our findings were not statistically significant.

CONCLUSIONS: After comparing 3 groups of patients treated with AOMs, we found no significant differences between treatment with Ozempic, Wegovy, or tirzepatide on CVD. Therefore, all of the analyzed treatments affect CVD similarly among patients with obesity.

SPONSORSHIP: None.

E46 Total cost of care health economic model for comparison of weight loss interventions

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BACKGROUND: Second-generation (2G) antiobesity medications (AOMs) in clinical trials have led to significant weight loss (WL), and more than 40% of Americans meet the clinical guidelines for treatment. Commercial health plan coverage includes weight loss surgery (WLS) or lifestyle management (LSM) for some patients with obesity, and 2G-AOMs could provide a cost-effective alternative. However, 2G-AOMs were first approved in 2021, so limited real-world data (RWD) exist regarding cost outcomes associated with use. A health economic model to predict payer total cost of care (TCOC) and patient clinical outcomes under different scenarios allows payers to plan in the absence of RWD to understand clinical and financial outcomes related to expanding access to 2G-AOMs.

OBJECTIVE: To create a TCOC model to forecast total medical and pharmacy costs related to modality-specific WL: AOM, WLS or LSM. This model was developed from a payer perspective to understand the potential budget impact and mitigate financial risks of including 2G-AOMs in a formulary, in addition to 1G-AOMs, WLS and LSM.

METHODS: The eligible patient population included patients with obesity class 3 or 2 with weight-related comorbidities. Model inputs were obtained from literature and administrative claims. Modules were eligible population size, market dynamics, costs, and probability of WL for each comparator. Costs included intervention costs and annual all-cause health care (HC) costs for patients, stratified by no WL, minimal WL (5% to <15% body mass index [BMI] reduction), or significant WL (≥15% BMI reduction). 1-year results were presented from a US commercial payer perspective with no discounting.

RESULTS: Claims-based analyses demonstrated that significant WL (≥15% BMI) was needed before reductions in HC costs were realized. Therefore, key drivers of TCOC included the probability of an intervention resulting in significant WL, the cost of each intervention, and market uptake. Sensitivity analyses with increased AOM costs, increased significant WL on AOM, and increased AOM market share led to budget impact results ranging from cost saving to ~15% increase in TCOC.

CONCLUSIONS: Modeling frameworks offer payers and/or pharmacy benefit managers insights into the value of prior authorization requirements, initial and continued coverage, and clinical outreach programs. Our analysis demonstrated cost offsets but did not show TCOC savings, even among the significant WL subset. RWD on 2G-AOMs are rapidly changing, especially as patient access is expanding. The TCOC model allows for integration of emerging evidence, and understanding how increased member demand for 2G-AOMs will impact overall plan spending.

SPONSORSHIP: Optum Life Sciences.

E47 Changes in health care costs among beneficiaries without diabetes initiating GLP-1 agonists in Mississippi Medicaid

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BACKGROUND: Glucagon-like peptide-1 (GLP-1) receptor agonists were initially developed as a treatment for type 2 diabetes but have also demonstrated metabolic and cardiovascular benefits including weight loss. Obesity has been associated with increased health and economic burdens for individuals. Although clinical evidence exists supporting the use of GLP-1s in managing obesity, real-world evidence demonstrating their impact on health care costs in this population is limited.

OBJECTIVE: To capture changes in health care costs before and after GLP-1 initiation among Mississippi Medicaid

beneficiaries initiated on GLP-1s without the presence of a diabetes diagnosis in claims data.

METHODS: Mississippi Medicaid administrative claims data were used to identify GLP-1 initiators between January 1, 2019, and June 30, 2021. Those with a diabetes diagnosis in claims data during a 1-year look-back period were excluded, and only those with continuous enrollment 12 months pre- and post-index GLP-1 claim with full benefits were included in the study. A single-group, aggregate-level interrupted time series (ITS) study design was used to examine the impact of GLP-1 initiation on health care costs. Health care cost data (pharmacy, medical, and total) for the study population were aggregated by month and used for the ITS analysis.

RESULTS: A total of 173 Medicaid beneficiaries were included in the study. Most beneficiaries were aged 18-50 years (78.0%), female (86.1%), and Black (57.8%). Prior to GLP-1 initiation, the average monthly pharmacy cost was estimated at $169, medical cost was $485, and average total health care cost was $654. The results of the ITS analysis showed that at GLP-1 initiation, pharmacy costs increased by $737 and total costs increased by $845 (both $P < 0.0001$). Over the 12 months after GLP-1 initiation, pharmacy costs fell by more than $51 per month ($P < 0.0001$) and total health care costs by $69 per month ($P = 0.0007$). For medical costs, the decreasing trend change after GLP-1 initiation difference was not statistically significant.

CONCLUSIONS: This study demonstrated that the initiation of GLP-1s resulted in a significant increase in pharmacy and total health care costs immediately after initiation, but over the 12 months after initiation, these costs significantly decreased monthly. By the end of the 12-month postinitiation period, a comparison of actual costs with the counterfactual estimates showed that although pharmacy costs were elevated, medical costs decreased, resulting in a total health care cost that was only slightly higher than the counterfactual estimate.

SPONSORSHIP: Mississippi Division of Medicaid.

F00-F99 Mental and Behavioral Disorders

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

F1 Evaluating the value of adding early psychotherapy to pharmacotherapy for major depressive disorder using a continuous-time patient-level simulation model

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BACKGROUND: Real-world evidence indicates that most patients receiving treatment for major depressive disorder (MDD) cycle through different selective serotonin reuptake inhibitors (SSRIs) following their initial diagnosis, without receiving psychotherapy. The combination of psychotherapy and pharmacotherapy for MDD treatment, especially adding psychotherapy early in treatment, is more costly but may lead to better outcomes, raising questions about the cost-effectiveness of combination therapy.

OBJECTIVE: To examine—using a continuous-time individual-patient simulation (CT-IPS) model—outcomes, costs, and cost-effectiveness of combination therapy with SSRI plus psychotherapy from the second through fourth line, compared with using SSRIs through 4 lines of therapy for adults (aged 18-64 years) newly diagnosed with MDD in the United States.

METHODS: The model included 3 health states—nonresponse, complete response (CR), and partial response—and was used to examine clinical and economic outcomes over a 5-year time horizon. Clinical outcomes include percentage that achieve remission in 5 years, time to achieve CR, and months in CR. Economic outcomes include direct treatment costs, other health care costs, productivity loss, and transportation costs. Costs are discounted at 3% annually and adjusted to 2021 dollars.

RESULTS: Combination therapy with SSRI plus psychotherapy from the second line results in a higher likelihood of achieving remission within 5 years after diagnosis than using SSRIs for all 4 lines of treatment (84.0% vs 79.5%); quicker achievement of CR (5.2 vs 6.5 months); and longer time spent in CR (27.4 vs 24.2 months). Over 5 years, average treatment costs for combination therapy were $30,211 compared with $964 for SSRIs, respectively. Additionally, combination therapy resulted in lower average productivity loss vs SSRIs only ($61,969 vs $54,380), higher transportation costs ($761 vs

$356), and higher total costs ($130,202 vs $104,879). Cost-effectiveness was estimated as $103,829 per remission for combination therapy vs $94,315 per remission for SSRIs only.

CONCLUSIONS: Although combination therapy of SSRI plus psychotherapy leads to better outcomes, it is associated with higher cost per remission compared with using SSRIs only. This may be due to the relatively low prices of generic SSRIs and our assumption of two 45-minute psychotherapy sessions per week. Health care systems should explore whether less costly forms of psychotherapy can achieve similar outcomes but at lower cost.

SPONSORSHIP: None.

F4 Dementia: Uncovering insights from physician notes using cognitive assessments

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BACKGROUND: Dementia is a broad term encompassing various cognitive impairments that interfere with an individual's daily life. In 2022, the annual cost of dementia care exceeded $300 billion, thus straining health care systems, families, and care providers.

OBJECTIVE: To identify patients with dementia using cognitive assessment tools (CAT) and assess the cost differences by severity of cognitive decline.

METHODS: Incident patients with dementia aged 65 years and older were identified in the year 2018 using *International Classification of Diseases, Tenth Revision* diagnosis codes from the Optum deidentified Market Clarity Database. Patients with 2 confirmed outpatient diagnoses (30 days apart) or 1 confirmed inpatient diagnosis were included. Index event was defined as the first documented diagnosis of dementia in claims/electronic health records. 12 months pre- and post-index medical and pharmacy eligibility was ensured. Mentions of CAT (MMSE, MOCA, SLUMS) along with their respective scores was observed in structured and unstructured data. CAT score was used to classify the severity of dementia as mild, moderate, and severe. We observed dementia-specific standardized medical cost over a period of 12 months. Kruskal-Wallis statistical test was applied to compare the cost differences. Further, we will explore the pharmacy cost, comorbidity profile, and sign and symptoms that a patient presents with based on the severity of dementia.

RESULTS: Out of the total 101,126 patients, CAT with mention of score was found in 3% and 9% in structured and unstructured data, respectively. Of these, 24%, 21%, 32%, and 23% patients had normal, mild, moderate, and severe scores of CAT, respectively. A sex-based comparison revealed a contrast between mild (13% vs 9%) and severe (14% vs 9%) CAT score in female and male patients, respectively. The average medical cost for dementia was highest in the severe as compared with the mild category ($5,621 vs $3,409). Further, a significant increase in cost ($P < 0.001$) was observed in White patients from mild ($2,314) to severe ($4,656) cognitive decline. A similar trend was observed in the Black population from mild ($2,349) to severe ($5,640), respectively.

CONCLUSIONS: Our study demonstrated the importance of CAT in patients with dementia. Early identification of these patients and timely interventions can help reduce the disease as well as the economic burden on health care systems, caregivers, and society. The findings from this study can also be used for policy making and health care planning where more allocation of resources can be provided for dementia care and services based on cognitive impairment.

SPONSORSHIP: Optum.

F6 Opioid treatment programs, health care resource utilization, and health care costs among patients initiating treatment with buprenorphine extended-release

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BACKGROUND: The economic burden of opioid use disorder (OUD) is high, and health care resource utilization (HCRU) and costs associated with different opioid treatment programs (OTPs) have not been extensively studied.

OBJECTIVE: To describe the use of buprenorphine extended-release (BUP-XR), HCRU, and costs across OTPs among patients initiating treatment with BUP-XR.

METHODS: This retrospective longitudinal study used PharMetrics Plus claims data. Adult patients with OUD initiating treatment with BUP-XR between March 1, 2019, and December 31, 2020 (initiation date = index date), were identified. Baseline clinical characteristics were evaluated during the 12 months pre-index, and OTP use, MOUD adherence, and opioid-related HCRU and costs were evaluated during the 12 months post-index. HCRU and costs were reported by index OTP (residential treatment program [RTP], office-based outpatient treatment [OBOT], intensive outpatient program [IOP]) and by OTP during follow-up (OBOT only, multiple OTP). Results were descriptive.

RESULTS: 798 patients were treated with BUP-XR in an RTP (n = 20), OBOT (n = 636), IOP (n = 108), or undefined OTP

(n = 34) at index. During follow-up, 522 were treated in an OBOT only and 235 in multiple OTPs. The mean number of BUP-XR administrations during follow-up was as follows: 3.8 injections for index RTP patients, 6.0 for index OBOT, 4.5 for index IOP, and 5.8 for undefined. Index OBOT patients were more likely to receive more than 1 BUP-XR injection than index RTP patients (83.2% vs 55.0%). Index OBOT had the longest mean time from first to second BUP-XR injection of 42 days, followed by index IOP with 41 days and finally index RTP and undefined with 36 days. Of patients with more than 1 BUP-XR injection, index IOP had the shortest average time from first to last injection, of 181 days, followed by index RTP with 198 days, undefined with 205 days, and index OBOT with 210 days. Overall, patients with index OBOT had lower HCRU and health care costs than patients with index RTP or index IOP.

CONCLUSIONS: OUD patients started in index OBOT appeared to have greater utilization and continuation of BUP-XR compared with patients started in an RTP and IOP. Although results are unadjusted to reflect differences in patient profiles, a trend toward lower HCRU and health care costs was observed in index OBOT patients.

SPONSORSHIP: Funding for this study was provided by Indivior. Courtney Flynn, William Mullen, and Sabrina Gaiazov are full-time employees for Indivior. Nicole Fusco and Eileen Farrelly are full-time employees for Cencora.

F7 Simulating different switch rates of once-monthly (PP1M) and once-every-3-months (PP3M) paliperidone palmitate to once-every-6-months paliperidone palmitate (PP6M) for the management of schizophrenia in Medicare: A budget impact model (BIM)

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BACKGROUND: The prevalence of schizophrenia in the United States is estimated to be between 0.25% and 1.1%, where approximately half of those affected are covered under Medicare. The economic burden of schizophrenia is substantial, with the average Medicare beneficiary with schizophrenia incurring $23,662 in annual total health care costs in 2019. Most of these beneficiaries are prescribed oral antipsychotics, with overall adherence to antipsychotics being reported high. However, the high rates of hospitalizations and readmissions with long length of stay suggest that adherence may be overestimated. Once-every-6-months paliperidone palmitate (PP6M) is a long-acting injectable antipsychotic with the longest dosing interval of any antipsychotic, indicated for adults with schizophrenia stabilized on once-monthly (PP1M) or once-every-3-months paliperidone palmitate (PP3M). The recent 2-year real-world open-label extension study showed 96.1% of patients on PP6M remained relapse free after stabilization, demonstrating its benefit in the treatment of schizophrenia. Using the open-label extension results and simulating different switch rates of patients on PP1M and PP3M to PP6M, we estimated the budgetary impact from a Medicare perspective.

OBJECTIVE: To estimate the budget impact of different switch rates of PP1M and PP3M to PP6M for the management of schizophrenia in Medicare.

METHODS: A Medicare-perspective budget impact model (BIM) was developed to estimate health care costs of PP6M in a 64-million-member Medicare plan over 5 years. Model inputs included schizophrenia prevalence, relapse rates, treatment transition and adherence rates, drug acquisition costs, administration costs, and relapse costs. The incremental annual and 5-year cumulative per-treated-patient per-year (PTPPY) costs and per-member per-month (PMPM) costs were calculated.

RESULTS: An annual market share shift of 3% from PP1M and 6% from PP3M to PP6M is projected to result in a 5-year cumulative incremental budget impact of $37.18 PTPPY or $0.0024 PMPM. Increase in market share shift to 5% from PP1M and 10% from PP3M resulted in an increased PTPPY of $143.53 or $0.0091 PMPM. The improved treatment adherence and less frequent administration of PP6M led to reduced relapses and administration costs, which partially offset the drug cost increase associated with better adherence.

CONCLUSIONS: Increased switch rates from PP1M and PP3M to PP6M in Medicare for adults with schizophrenia are projected to have minimal budget impact. Population health decision-makers who assess different treatment options for patients with schizophrenia can benefit more with this long-acting injectable antipsychotic with the longest dosing interval and may improve treatment adherence in patients with schizophrenia.

SPONSORSHIP: Johnson and Johnson.

F8 Efficacy and safety of KarXT (xanomeline and trospium) in schizophrenia: Pooled results from the randomized, double-blind, placebo-controlled EMERGENT trials

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BACKGROUND: KarXT (xanomeline and trospium chloride) is a dual M1/M4 preferring muscarinic receptor agonist that lacks direct D2 dopamine receptor binding being developed for the treatment of schizophrenia.

OBJECTIVE: To evaluate the efficacy and safety of KarXT in the treatment of acute psychosis in people with schizophrenia using pooled data from the EMERGENT-1 (NCT03697252), EMERGENT-2 (NCT04659161), and EMERGENT-3 (NCT04738123) trials.

METHODS: Data from the EMERGENT trials were pooled and efficacy and safety analyses were conducted in the modified intent-to-treat and safety populations, respectively. In each trial, the primary efficacy endpoint was change from baseline to week 5 vs placebo in PANSS total score. Additionally, change from baseline to week 5 in PANSS positive subscale, PANSS negative subscale, and Clinical Global Impressions-Severity scores were secondary endpoints. Safety assessment included monitoring for spontaneous adverse events (AEs) after the first dose of trial drug until the time of discharge on day 35.

RESULTS: Across trials, KarXT (n = 314) was associated with a significantly greater reduction in PANSS total score at week 5 vs placebo (n = 326) (KarXT, −19.4; placebo, −9.6; $P < 0.0001$; Cohen's d, 0.65). At week 5, KarXT was also associated with a significantly greater reduction than placebo in PANSS positive subscale (KarXT, −6.3; placebo, −3.1), PANSS negative subscale (KarXT, −3.0; placebo, −1.3), and Clinical Global Impressions-Severity scores (KarXT, −1.1; placebo, −0.5), all $P < 0.0001$. In the pooled analyses for safety, 51.8% in the KarXT group (n = 340) reported at least 1 treatment-related AE compared with 29.4% in the placebo group (n = 343). The treatment-related AEs occurring in greater than or equal to 5% of participants receiving KarXT and at a rate at least twice that observed in placebo were nausea (17.1% vs 3.2%), constipation (15.0% vs 5.2%), dyspepsia (12.1% vs 2.3%), vomiting (10.9% vs 0.9%), and dry mouth (5.0% vs 1.5%). The most common treatment-related AEs in the KarXT group were mild or moderate in intensity and mostly transient. Overall discontinuation rates (27.6% vs 22.7%) and rates of discontinuation due to treatment-emergent AEs (5.6% vs 4.7%) were similar between the KarXT and placebo groups.

CONCLUSIONS: In pooled analyses from the EMERGENT trials, KarXT demonstrated statistically significant improvements across efficacy measures with consistent and robust effect sizes and was generally well tolerated. These findings support the potential of KarXT to be first in a new class of medications to treat schizophrenia based on muscarinic receptor agonism and without any direct dopamine D2 receptor blocking activity.

SPONSORSHIP: Karuna Therapeutics.

F9 Open access for mental health medication: Impact on state Medicaid budgets

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BACKGROUND: Some state Medicaid programs implement formulary restrictions, including prior authorization or step edits, for antipsychotics (APs), which may lead to delays in getting the right drug to the right patient quickly. States with open access (OA) policies for APs may realize revenue increases due to additional supplemental rebates and decreased health care resource utilization.

OBJECTIVE: To compare mental health–related outcomes among patients with serious mental illness (SMI) in state Medicaid programs with (Michigan, MI) and without (Pennsylvania, PA) OA to AP medications.

METHODS: Adults from Kythera Labs Medicaid dataset (2016 to 2023) were included if they had at least 1 pharmacy claim for APs during the identification period (04/01/2016 to 12/31/2021; treatment initiation date), had continuous medical and pharmacy benefits for 3 months pre-/12 months post-index, and had at least 1 claim with a diagnosis of SMI. Patients in PA and MI were matched 1:1 on demographic and clinical characteristics, and a subset of patients taking non-preferred (eg, restricted) APs in PA were also matched to patients taking the same APs in MI.

RESULTS: A total of 7,487 AP users from each state were identified and matched for analysis. Patients in PA had higher SMI-related utilization than those in MI, including hospital admissions (17.23% vs 8.59%, $P < 0.0001$), length of stay (3.11 vs 1.16, $P < 0.0001$), and outpatient visits (50.55% vs 47.16%, $P < 0.0001$). Corresponding SMI-related total cost ($6,466.38 vs $5,577.47, $P = 0.0002$), inpatient cost ($1,615.68 vs $486.13, $P < 0.0001$), and outpatient cost ($970.94 vs $706.48, $P = 0.0002$) were also higher in PA, but SMI-related pharmacy

cost was lower in PA ($3,631.27 vs $4,159.96, $P < 0.0001$). After matching patients with SMI who received nonpreferred APs in PA (n = 667) to a cohort in MI, results were similar. SMI-related hospital admissions (22.34% vs 11.09%, $P < 0.0001$), length of stay (4.44 vs 1.40, $P = 0.0001$), and outpatient visits (55.17% vs 46.93%, $P = 0.0026$) were higher in PA, as was inpatient cost ($3,001.43 vs $1,111.13, $P = 0.0230$). Pharmacy cost was lower in PA than MI ($3,003.79 vs $3,906.40, $P = 0.0099$).

CONCLUSIONS: Although pharmacy costs were slightly lower in PA, total, inpatient, and outpatient costs were higher. SMI-related inpatient and outpatient utilization were also lower in MI, a state with OA to APs. This example of states with and without OA to APs may indicate that OA policies have little effect on state budget but improve patient outcomes and should therefore be implemented.

SPONSORSHIP: Otsuka Pharmaceutical Development & Commercialization, Inc.

F10 Pooled analysis of EPS-like symptoms in the EMERGENT program of KarXT in schizophrenia

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BACKGROUND: Dopamine-D2 receptor blockade can induce extrapyramidal symptoms (EPS) and contributes to the side-effect burden of approved antipsychotics. Although atypical antipsychotics (AAs) have lowered the overall prevalence and severity of antipsychotic-induced EPS, there is still an increased risk of hospitalization and health care resource utilization due to these AEs. Patients with EPS induced by AAs have nearly twice the rate of schizophrenia-related hospitalizations and almost double the schizophrenia-related health care costs when compared with those without EPS. New treatment options that minimize the risk of EPS may reduce this overall economic and patient burden.

OBJECTIVE: To characterize rates of new-onset EPS associated with KarXT (xanomeline and trospium chloride), an investigational medicine that contains a dual M1/M4 preferring muscarinic receptor agonist that lacks direct D2 dopamine receptor binding and is being developed for the treatment of schizophrenia.

METHODS: EMERGENT-1 (NCT03697252), EMERGENT-2 (NCT04659161), and EMERGENT-3 (NCT04738123) were 5-week, randomized, double-blind, placebo-controlled, inpatient trials in people with schizophrenia. Data from the 3 trials were pooled for this analysis. Treatment-emergent AEs (TEAEs) associated with EPS from the safety populations, defined as all participants who received more than 1 dose of trial medication, were pooled. EPS was assessed by examining change from baseline to week 5 on the Simpson-Angus Scale, Barnes Akathisia Rating Scale, and Abnormal Involuntary Movement Scale.

RESULTS: In the pooled safety analyses, the rate of TEAEs associated with EPS was 3.2% in the KarXT group (n = 340) vs 0.9% in the placebo group (n = 343). Dystonia, dyskinesia, and extrapyramidal disorder TEAEs were reported by only 1 subject each (0.3%) in the KarXT group. Akathisia was reported in 2.4% of the KarXT group vs 0.9 % in the placebo group. Overall rates of akathisia TEAEs deemed related to trial drug were 0.6% in the KarXT group vs 0.3% in the placebo group. Most EPS TEAEs were reported as mild and resolved. The mean ± SD EPS Scale changes in the KarXT group from baseline to week 5 were also assessed (Simpson-Angus Scale [−0.1 ± 0.6], Barnes Akathisia Rating Scale [−0.1 ± 0.9], or Abnormal Involuntary Movement Scale [0.0 ± 0.7]).

CONCLUSIONS: The incidence of EPS-related TEAEs with KarXT was low and not associated with increased scores on EPS scales across 5 weeks of treatment. These results, combined with the robust efficacy of KarXT in trials to date, suggest that KarXT's novel mechanism of action may provide therapeutic benefit in the absence of EPS frequently associated with currently available antipsychotics.

SPONSORSHIP: Karuna Therapeutics.

F11 Potential impact of KarXT (xanomeline and trospium) on negative symptoms in acute schizophrenia: An analysis of pooled data from 3 trials

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BACKGROUND: Schizophrenia is a severe mental illness, characterized by positive, negative, and cognitive symptoms. Negative symptoms may be clinically relevant in up to 60% of patients and have been associated with a greater likelihood of hospital admission, longer inpatient duration, and an increased likelihood of readmission after discharge. A real-world study found patients with negative symptoms have significantly higher estimated mean annual total cost ($55,864 vs $43,385; $P < 0.001$) than those without negative symptoms. Currently available treatments have limited effect on negative symptoms.

OBJECTIVE: To analyze the potential impact of KarXT (xanomeline and trospium chloride) on negative symptoms of schizophrenia. KarXT is a dual M1/M4 preferring muscarinic receptor agonist that lacks direct D2 dopamine

receptor binding being developed for the treatment of schizophrenia.

METHODS: Data were pooled from the phase 2 EMERGENT-1 (NCT03697252) and the phase 3 EMERGENT-2 and EMERGENT-3 (NCT04659161, NCT04738123) trials of KarXT in acute inpatients with schizophrenia that used identical 5-week randomized, double-blind, placebo-controlled designs. A subset of participants with prominent negative symptoms were identified using PANSS Marder Negative Symptoms score greater than or equal to 24, PANSS Mohr positive score less than or equal to 19, and scores of greater than or equal to 4 on at least 2 of 3 PANSS items (blunted affect, social withdrawal, lack of spontaneity/flow of conversation). Mixed model for repeated measures analyses were used to evaluate changes from baseline to week 5 in PANSS-Marder Negative Symptoms.

RESULTS: In the pooled analyses of these 3 trials (n = 640), PANSS-Marder Negative Symptom scores showed statistically significant reduction in those treated with KarXT compared with placebo at week 5 (–1.97, $P < 0.0001$; Cohen's d = 0.42). Ten percent of the pooled sample (n = 64) met criteria for having prominent negative symptoms at baseline. Within this subgroup, there was a statistically significant reduction in PANSS-Marder Negative Symptom scores in the KarXT group compared with placebo (–4.71, $P < 0.0001$; Cohen's d = 1.18). Further, the KarXT effect remained statistically significant after accounting for changes in positive symptoms, depression/anxiety, disorganization, or hostility.

CONCLUSIONS: Across pooled analyses from the EMERGENT trials, including a subset of participants with prominent negative symptoms, KarXT demonstrated statistically significant improvement in negative symptoms. These are exploratory findings and support further investigation with additional studies.

SPONSORSHIP: Karuna Therapeutics.

F12 Economic burden of cognitive impairment among patients with schizophrenia using US Medical Expenditure Panel Survey data

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BACKGROUND: Cognitive impairment is a key symptom domain in schizophrenia, affecting attention, memory, motor speed, executive function, and social cognition. Cognitive impairment negatively impacts instrumental and role functioning. The broader economic burden of cognitive impairment including health care resource utilization (HCRU) and costs remains unclear.

OBJECTIVE: To evaluate the impact of cognitive impairment on HCRU and costs among patients with schizophrenia.

METHODS: This cross-sectional study used 1997-2021 Medical Expenditure Panel Survey data, a nationally representative survey of US noninstitutionalized individuals. Adults (aged ≥18 years) with schizophrenia were included in this study. Cognitive impairment was defined using 2 variables: cognitive limitations (CL; ie, interference of daily activities through [1] confusion/memory loss or [2] problems making decisions or [3] requiring supervision for own safety; data available 1997-2021) and cognitive difficulties (CD; ie, difficulty concentrating, remembering, or making decisions; data available 2013-2021). Regression models were adjusted by age, sex, race, and ethnicity. All analyses accounted for the complex survey design of the Medical Expenditure Panel Survey.

RESULTS: Of 1,827 surveyed adults with schizophrenia (mean age: 45.6 years, 56.7% male), representing 661,243 US individuals, 57.6% reported CL and 53.5% reported CD. Individuals with CL had higher annual incidence of inpatient visits (23.2% vs 17.0%, $P < 0.01$) and emergency department visits (31.6% vs 22.1%, $P < 0.01$) and nearly 55.0% higher ($P < 0.01$) annual total health care costs than those without CL. They also faced a 43.1% ($P < 0.01$) greater per-capita annual wage loss due to unemployment than those without CL. Individuals with CL had $5,118 ($P < 0.01$) higher total direct health care costs compared with those without CL, in the adjusted regression models on log-transformed costs. Further, CL was associated with increased odds of inpatient visits (adjusted odds ratio = 1.5, 95% = 1.1-2.1) and emergency department visits (adjusted odds ratio = 1.6, 95% CI = 1.2-2.2). Consistently, individuals with CD had increased HCRU, annual total health care costs, and per-capita annual wage loss than those without CD.

CONCLUSIONS: Cognitive impairment was reported in more than half of adults with schizophrenia and was associated with significantly increased HCRU as well as direct and indirect costs. These findings illustrate high burden and unmet need for managing cognitive impairment in patients with schizophrenia with opportunities to improve treatments and outcomes.

SPONSORSHIP: Boehringer-Ingelheim Pharmaceutical Co.

F13 Treatment patterns and outcomes from OASIS: Observational Study of Long-Acting Injectables in Schizophrenia

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BACKGROUND: OASIS (NCT03919994) was a prospective, observational study assessing real-world outcomes associated with initiating atypical long-acting injectable (aLAI) antipsychotics.

OBJECTIVE: To describe treatment patterns and key outcomes observed in OASIS.

METHODS: Adults (aged ≥18 years) with schizophrenia who newly initiated aLAI antipsychotics (aripiprazole lauroxil, aripiprazole monohydrate, paliperidone palmitate, or risperidone) were evaluated for up to 12 months at the clinicians' discretion. Reasons for initiation, duration of use, and rates of switching/discontinuation were assessed. Outcomes included Clinical Global Impressions-Severity, Clinician-Rated Dimensions of Psychosis Severity Scale individual symptom, and patient-reported Glasgow Antipsychotic Side-Effect Scale total scores.

RESULTS: The most common reasons for aLAI antipsychotic initiation were persistent psychotic symptoms and adherence challenges. Mean (SD) time on treatment was 210.0 (145.3) days (median = 200); 73.7% of patients remained on their index aLAI antipsychotic, 8.7% and 9.4% switched to new aLAI or oral antipsychotics, respectively, and 8.3% discontinued. Of 277 enrolled patients, 130 (46.9%) completed the study. Most study visits were planned/scheduled vs crisis visits. Mean (SD) baseline Clinical Global Impressions-Severity score was 4.2 (1.1), indicating moderate illness severity; individual symptoms were mild (mean [SD] Clinician-Rated Dimensions of Psychosis Severity Scale delusions score = 2.0 [1.3]; hallucinations = 1.9 [1.4]; negative symptoms = 1.6 [1.3]) at baseline and remained stable after index aLAI antipsychotic initiation. Antipsychotic side effects were generally absent or mild at baseline (mean [SD] Glasgow Antipsychotic Side-Effect Scale total score = 10.7 [10.3]) and over follow-up.

CONCLUSIONS: In OASIS, most patients remained on their index aLAI antipsychotic. Among those with available data, outcomes were stable over up to 12 months' follow-up.

SPONSORSHIP: Alkermes, Inc.

F14 Baseline demographics and clinical characteristics from OASIS: Observational Study of Long-Acting Injectables in Schizophrenia

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BACKGROUND: Despite their availability, there is limited understanding of the "real-world" use of atypical long-acting injectable (aLAI) antipsychotics in schizophrenia. The prospective, observational OASIS study (NCT03919994) evaluated outcomes associated with the use of aLAI antipsychotics in routine care to address these knowledge gaps.

OBJECTIVE: To describe OASIS design and characteristics of patients and treatment setting.

METHODS: Adults (aged ≥18 years) with schizophrenia who newly initiated 1 of 4 aLAI antipsychotics (aripiprazole lauroxil, aripiprazole monohydrate, paliperidone palmitate, or risperidone) across 44 sites were eligible. Patients were evaluated for 12 months or less after enrollment at the clinicians' discretion.

RESULTS: Patients with schizophrenia (N = 277; mean [SD] age = 37.7 [14.9] years) were mostly male (65.7%), White (47.3%), unemployed (53.1%) or on disability (27.1%), and insured by Medicaid (46.9%) or Medicare (30.3%). Mean (SD) time since diagnosis was 11.9 (12.5) years. Baseline illness severity was moderate (mean [SD] Clinical Global Impressions of Severity score = 4.21 [1.06]). Only 34.7% of patients reported antipsychotic use in the 12 months before enrollment, most commonly with oral antipsychotics. Most patients were treated in community mental health clinics (46.2%) or private

practices (45.1%); 63.9% initiated aLAIs as outpatients. Travel was a frequent challenge to accessing care.

CONCLUSIONS: Patients initiating aLAI antipsychotics in OASIS had moderate baseline illness severity and were mostly treated as outpatients. Despite symptoms present, only approximately one-third of patients used an antipsychotic in the 12 months before aLAI initiation. These findings from a real-world study increase our understanding of the role of aLAI antipsychotics in schizophrenia.

SPONSORSHIP: Alkermes, Inc.

F17 Health care resource utilization following 6 months of treatment with olanzapine/samidorphan: Real-world assessment of patients with schizophrenia or bipolar I disorder

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BACKGROUND: Long-term pharmacotherapy is recommended for treating schizophrenia (SZ) and bipolar I disorder (BD-I), but the adverse effects of atypical antipsychotic medications, such as weight gain, contribute to suboptimal treatment adherence. The combination of olanzapine and samidorphan (OLZ/SAM) provides the established antipsychotic efficacy of olanzapine while mitigating olanzapine-associated weight gain. In real-world settings, treatment with OLZ/SAM may be associated with reductions in health care resource utilization (HCRU).

OBJECTIVE: To examine the impact of initiating treatment with OLZ/SAM on HCRU among patients with SZ or BD-I.

METHODS: This retrospective analysis used administrative claims data from April 19, 2021, to December 31, 2022, from Komodo Healthcare Map. Adult patients aged 18 years and older with SZ or BD-I who had continuous enrollment at least 6 months before (baseline) and after (follow-up) OLZ/SAM initiation were eligible. HCRU outcomes included inpatient (IP) admissions and lengths of stay and emergency department (ED) and outpatient (OP) visits; outcomes were compared between the 6-month baseline and follow-up periods.

RESULTS: Included patients (SZ: n = 855; BD-I: n = 691) had a mean age of ~40 years (percent female: SZ = 47%; BD-I = 69%). Among both the SZ and BD-I cohorts, the proportions of patients with all-cause IP admissions and ED visits significantly decreased (IP: $P < 0.001$; ED: $P < 0.05$), as did the proportions with mental health–related IP admissions and ED visits (IP: $P < 0.001$; ED: $P < 0.001$), between the baseline and follow-up periods. Mean lengths of IP stay decreased in both cohorts, and these decreases were significant among patients with BD-I for all-cause ($P = 0.011$) and mental health–related ($P = 0.007$) HCRU. The proportions of patients with an OP visit were similar between the baseline and follow-up periods for both disease cohorts.

CONCLUSIONS: This is the first real-world study to assess HCRU 6 months before and after OLZ/SAM initiation. Among patients with SZ or BD-I, OLZ/SAM initiation was associated with significant reductions in the proportions of patients with all-cause and mental health–related hospitalizations and ED visits. Findings indicate that OLZ/SAM may result in clinically meaningful reductions in patient and provider burden, as evidenced by changes in inpatient care.

SPONSORSHIP: Alkermes, Inc.

F19 Early adjunctive brexpiprazole initiation for major depressive disorder: Impact on health care resource utilization and cost—a US real-world analysis

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BACKGROUND: Brexpiprazole is an oral atypical antipsychotic indicated for adjunctive treatment of adults diagnosed with major depressive disorder (MDD). New real-world evidence focused on the economic impact related to use and timing of initiation of brexpiprazole in adults with MDD can support informed decision-making.

OBJECTIVE: To assess timing of brexpiprazole initiation, its impact on health care resource utilization (HCRU), and cost for adjunctive treatment of adults with MDD in real-world practice.

METHODS: This retrospective cohort study was conducted using deidentified MerativeTM MarketScan commercial claims data in the United States (January 2013 to December 2021). Adults (aged ≥18 years) with MDD were identified by using validated *International Classification of Diseases, Ninth Revision* and *International Classification of Diseases, Tenth Revision, Clinical Modification* codes with at least 1 inpatient or at least 2 outpatient visits. Adjunct brexpiprazole users were classified as late initiators if they were initiated 1 year or longer after antidepressant (ADT) following MDD diagnosis. Brexpiprazole initiation within 1 year after first ADT was further categorized into 2 groups (≤60 and >60 to 365 days) based on outpatient visit trends from a Poisson regression

model, using nonlinear splines. Overall and MDD-specific HCRU and adjusted cost, 1 year after brexpiprazole initiation (index date), was used as the outcome of this study. A negative binomial regression was used to model HCRU; a generalized linear model with γ distribution and log link was used to calculate adjusted annualized cost related to HCRU. $\alpha < 0.05$ was considered statistically significant.

RESULTS: Overall, 1,226 adults with MDD and adjunct brexpiprazole users were identified. Median age was 47 years (IQR = 36-55). No statistically significant differences were observed across 3 categories of brexpiprazole users and baseline covariates except sex. In a multivariable adjusted model, compared with those with brexpiprazole initiation 60 days or less after first ADT, late initiators were strongly associated with MDD-specific outpatient visits (adjusted incident rate ratio = 1.32, 95% CI = 1.08-1.62, P = 0.006). From an adjusted generalized linear model for 1-year cost following the index date, late initiators had significantly higher annualized total cost ($12,785) compared with those initiating brexpiprazole within 60 days ($8,036), P = 0.0009.

CONCLUSIONS: In this analysis of more than 1,000 adults, late initiation of brexpiprazole beyond 1 year after first ADT was associated with significantly higher outpatient health care utilization and cost in real-world practice. Early intervention with adjunct brexpiprazole may reduce HCRU burden and cost among adults with MDD.

SPONSORSHIP: Otsuka Pharmaceutical Development & Commercialization, Inc.

F20 Treatment patterns for newly diagnosed depression among commercially insured adolescents and adults in the United States

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BACKGROUND: Although the American Psychological Association guidelines recommend multimodal treatment (combination of medication and psychotherapy) for depression, little is known about the prevalence of such treatment among US adolescents and adult populations.

OBJECTIVE: To investigate correlates of multimodal treatment among a large sample of commercially insured US adolescents and adults newly diagnosed with depression.

METHODS: Commercially insured members aged 12 to 64 years newly diagnosed with depression between January 2018 and June 2022 were included. Patients diagnosed with postpartum depression, pregnancy, or schizophrenia, schizotypal, or nonmood psychotic disorders were excluded. Patients had continuous eligibility 1 year before index diagnosis and 6 months after. Multimodal treatment was defined as the use of both antidepressants and psychotherapy within 6 months following the index diagnosis. Bivariate and multivariate analyses were used to assess correlates of multimodal treatment by age groups (12-17 and 18-64).

RESULTS: Of 104,963 newly diagnosed patients, 9.4% were adolescents and 90.6% were adults. Patients in both age cohorts were predominately female and White, lived in urban areas, and had mild depression. Only 37.8% of adolescents and 18.4% of adults received multimodal treatment for their depression. For both groups, factors associated with a lower odds of receiving the multimodal treatment included being Hispanic or non-Hispanic Black and living in areas with higher social needs. Among those who filled any antidepressants, most adolescents (80%) received first-line selective-serotonin reuptake inhibitors and adults (80.3%) received first-line medications (selective-serotonin reuptake inhibitors, selective serotonin and norepinephrine reuptake inhibitors, and norepinephrine/dopamine reuptake inhibitors).

CONCLUSIONS: Despite American Psychological Association recommendations, the prevalence of receiving medication-psychotherapy treatment was low for both adolescents and adults. Furthermore, 16.7% of adolescents and 16.7% of adults received no treatment for depression. The study also highlighted important socioeconomic barriers to multimodal treatment for patients with newly diagnosed depression.

SPONSORSHIP: None.

F21 REAL-DMC: Review of Effect After Lithium Drug Manufacturer Change

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BACKGROUND: Lithium is a mood stabilizer used to treat bipolar disorders and other conditions. Toxic concentrations of lithium are close to the upper limit of the therapeutic range. Concern for lithium toxicity is usually associated with lithium levels equal to or greater than 1.3 mEq/L. Limited evidence exists regarding the clinical importance of obtaining a level after a drug manufacturer change. Under protocol, Kaiser Permanente Washington pharmacists ordered levels with each drug manufacturer change.

OBJECTIVE: To review lithium levels prior to and following a drug manufacturer change for immediate- and extended-release lithium formulations to observe laboratory changes and risk for potential toxicity.

METHODS: This is a retrospective, descriptive cohort analysis completed as part of quality improvement. Pharmacy benefit claims from June 2020 to August 2023 were collected to determine the impact of 6 known drug manufacturer

changes within the organization. Corresponding laboratory results preceding and at least 5 days following the change were analyzed. Claims were excluded if laboratory results were not available for all the following: calcium, creatinine, lithium, sodium, and thyroid-stimulating hormone (TSH) levels. The first coprimary endpoint explored whether there was a lithium level changed by more than 0.2 mEq/L, whereas the second coprimary endpoint evaluated the number of patients with a post–drug manufacturer level equal to or greater than 1.3 mEq/L.

RESULTS: A total of 299 claims were included in the analysis. Across the 6 known drug manufacturer changes, 43.5% (130 of 299) met the first coprimary endpoint, whereas 1.3% (4 of 299) met the second coprimary endpoint. Exploratory analysis on the 4 patients with postlithium level equal to or greater than 1.3 mEq/L revealed changes in serum calcium (–0.8 to –0.3 mg/dL), creatinine (–0.31 to 0.28 mg/dL), sodium (–4 to 2 mEq/L), TSH (–1.24 to 0.16 uIU/mL) prior to and following the drug manufacturer changes. Overall, serum creatinine, sodium, and TSH levels were within reference ranges prior to and following a drug manufacturer change. Serum calcium was elevated for 2 patients following a drug manufacturer change.

CONCLUSIONS: Differences in lithium levels occurred after a drug manufacturer change; however, levels above what is considered toxic (level equal to or greater than 1.3 mEq/L) were infrequently observed within the cohort. Further investigation is needed to understand whether obtaining lithium levels after a drug manufacturer change is required.

SPONSORSHIP: None.

F22 Economic burden among patients with major depressive disorder (MDD): A systematic review and analysis of variance in cost by severity and demography

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BACKGROUND: Major depressive disorder (MDD) remains among the most burdensome disorders worldwide, severely affecting individuals' daily functioning and quality of life and contributing substantially to global disability. The economic burden of major depressive disorder (MDD) in the United States has increased from $US236 billion in 2010 to $US384 billion in 2023.

OBJECTIVE: To highlight the rise in economic burden of MDD in the United States. In addition, the study will focus on highlighting significant costs differences by disease severity to aid health care providers in making informed decisions aimed at improving the lives of patients with MDD.

METHODS: Incident patients with MDD were selected in the study period 2019-2020 using *International Classification of Diseases, Tenth Revision* diagnosis codes from the Optum Market clarity database. Patients with 2 confirmed outpatient diagnoses (30 days apart) or 1 confirmed inpatient diagnosis of MDD were included in the study. Index event was the confirmed diagnosis of MDD. 12 months pre- and post-index medical and pharmacy eligibility was ensured. Mention of Patient Health Questionnaire-9 (PHQ-9) questionnaire along with composite score was ensured in these patients. Analysis of variance, ratio of mean, bivariate analysis, and statistical tests was performed to measure the level of significance among various variables.

RESULTS: Out of the total 209,000 patients, PHQ-9 with score was observed in 2% and 6% in structured and unstructured data, respectively. There was a significant ($P < 0.05$) increasing trend in average cost and visits per patient by severity. Cost and visits increased by 38% and 30%, respectively, from minimal depression to severe. Demographic features and severity score were proved as a driving force behind increasing treatment cost. Analysis of variance showed that younger adults (aged 18-40 years) were increasingly affected by MDD compared with other groups. The study showed women being affected with depression at roughly twice the rate as men. Average medical cost was highest for Black patients, whereas a higher number of patients were identified in the younger age group.

CONCLUSIONS: Patients with a severe depression score in PHQ-9 had higher overall medical costs and higher health care resource utilization compared with patients with minimal depression. The study can be used to identify the patients in need of psychotherapy, behavioral therapy, social support, or pharmacological management based on the disease severity.

SPONSORSHIP: Optum.

F23 Economic and humanistic burden associated with major depressive disorder with prominent anhedonia in the United States

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BACKGROUND: Anhedonia, a key symptom and diagnostic criterion of major depressive disorder (MDD), is associated with severity of MDD, functional impairment, and worse

prognosis. Despite the high prevalence of MDD in the United States, the burden of anhedonia in MDD is poorly understood.

OBJECTIVE: To examine the economic and humanistic burden of MDD with prominent anhedonia (MDD-ANH) compared with MDD with no/low anhedonia (other-MDD) and no MDD.

METHODS: Using the 2016-2019 waves of the nationally representative Medical Expenditure Panel Survey, we identified adults (aged ≥18 years) with and without MDD. We assessed the presence and degree of anhedonia using the first item of the Patient Health Questionnaire-2. Inverse probability weighting was used to balance characteristics between the 3 groups. Use and costs of pharmacologic and nonpharmacologic treatments, indirect (lost productivity) costs, and health-related quality of life (HRQoL) as assessed by the SF-12 Physical and Mental Component Summary scores (PCS and MCS) are presented.

RESULTS: We identified 5,838 (7.2%) and 75,502 (92.8%) individuals with and without MDD; 19.0% and 81.0% of those with MDD were classified as having MDD-ANH and other-MDD, respectively. Proportionately more individuals with MDD-ANH reported taking medications (90.2%) than those with other-MDD (85.7%) or without MDD (60.9%). A larger proportion of individuals with MDD-ANH had office/outpatient visits (87.3%) than those with other-MDD (81.4%) or without MDD (58.4%). A higher proportion of individuals with MDD-ANH had an emergency department visit (20.1%) than those with other-MDD (16.1%) or without MDD (11.2%). Individuals with MDD-ANH incurred higher medical costs ($7,534) than those with other-MDD ($5,437) or without MDD ($3,980). Costs associated with all prescription ($2,819) and psychotropic ($920) drugs were also higher for those with MDD-ANH than for those with other-MDD ($2,052 and $514) or without MDD ($1,400 and $45). Indirect costs were higher for those with MDD-ANH ($1,494) than for those with other-MDD ($874) and those without MDD ($578). HRQoL was lowest for individuals with MDD-ANH (PCS 46.2, MCS 30.9), followed by those with other-MDD (PCS 50.3, MCS 47.1) and those without MDD (PCS 50.9, MCS 53.6).

CONCLUSIONS: Prominent anhedonia in patients with MDD was associated with higher direct and indirect costs and lower HRQoL. These findings highlight the burden of prominent anhedonia in MDD and the need for targeted and effective treatments that improve patient outcomes and reduce cost to society.

SPONSORSHIP: Janssen Scientific Affairs, LLC.

F24 Identification and description of patients with anhedonia using Patient Voice available from a digital patient health community platform

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BACKGROUND: Anhedonia, or the loss of interest in formerly pleasurable activities, is one of 2 key symptoms of major depressive disorder (MDD). It is associated with more severe disease and worsened response to standard treatment. Patient (pt) identification in claims databases via *International Classification of Diseases, Tenth Revision* (ICD-10) codes for anhedonia is limited as its use in clinical practice is underutilized.

OBJECTIVE: To use unsupervised machine learning and natural language processing to identify anhedonia in posted conversations of an online community of pts with depression-anxiety and describe health care resource utilization (HCRU) and treatment choices for pts with anhedonia.

METHODS: Pts with various conditions join Inspire's digital health community and contribute their experience through online posts. Pts with anhedonia were identified using topic modeling of user online posts via latent Dirichlet allocation, followed by clinician annotation of anhedonic topics and finally selection of pts whose posts carried anhedonic topics. Pts were classified as "noted anhedonia" if their posts' anhedonia topic strength was within the top 20% of anhedonia topic strength across all posts. A subset of pts have linked electronic health records and medical and pharmacy claims. Baseline pt characteristics and HCRU were evaluated and compared between pts with and without noted anhedonia. Descriptive statistics were reported.

RESULTS: A total 2,885 (24%) members were categorized as noted anhedonia through clinician-informed topic analysis of online posts in Inspire's community of pts with depression-anxiety (N = 11,943). 854 of the 2,885 members with noted anhedonia and 2,484 of the 9,058 without anhedonia had linked electronic health records and medical and pharmacy claims. Both cohorts were 66% female, and 70% and 53% of patients with and without anhedonia, respectively, had at least 1 ICD-10 code for mental, behavioral and neurodevelopmental disorders. The median number of psychotherapy visits per pt was 15 for the anhedonia cohort and 12 for nonanhedonia cohort. The median number of hospitalizations per pt was 1 and 2 for the patients with and without anhedonia, respectively. Top psychiatric medications were the same between both cohorts.

CONCLUSIONS: Pt voice from digital online health platforms is an emerging source of data to help identify pts with anhedonia, as the diagnosis code is significantly underutilized in clinical practices. Describing early and frequent symptoms of anhedonia may help facilitate clinical diagnosis, awareness promotion, and treatment/therapy planning.

SPONSORSHIP: None.

F28 The effect of Ozempic vs Wegovy vs Mounjaro on the incidence of alcohol and substance use disorder in patients with obesity

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BACKGROUND: Newly approved antiobesity medications (AOMs), such as semaglutide (Ozempic and Wegovy) and tirzepatide (Mounjaro), are proven to be effective for alleviating obesity. However, there is limited research focusing on their effect on obesity-related comorbidities such as alcohol use disorder (AUD) and substance use disorder (SUD).

OBJECTIVE: To determine and compare the impact of Ozempic, Wegovy, and Mounjaro use on the incidence of AUD and SUD in US patients with obesity.

METHODS: We conducted a retrospective cohort study using Kythera Medicaid data from January 2020 to August 2022. Three cohorts of patients with obesity were identified: those taking Ozempic, those taking Wegovy, and those taking Mounjaro. Patients in each group had at least 1 pharmacy claim for Ozempic, Wegovy, or Mounjaro during the identification period (January 1, 2021, to August 31, 2022). The index date was the date of the first prescription claim for the medication. Patients were excluded from the study if they were prescribed any obesity medications during baseline, had AUD or SUD prior to the index date, had more than 1 claim of an obesity medication in the same index date, and were aged 99 years and older. We also compared findings by AOM vs non-AOM users. The presence of SUD and AUD was determined using diagnosis codes at outpatient and inpatient visits. Sociodemographic and clinical variables, SUD/AUD-specific comorbidities, and SUD/AUD event rates were analyzed. Propensity score matching was used for risk adjustment.

RESULTS: Mounjaro users had the lowest incidence of SUD (2.50% vs 8.37% for Wegovy vs 9.85% for Ozempic, $P = 0.2353$), AUD (0% vs 2.09% vs 0.89%, $P = 0.1688$), and any SUD or AUD (2.50% vs 9.62% vs 10.34%, $P = 0.2560$) compared with Wegovy and Ozempic users. However, differences in these rates were not statistically significant. Our study found that Wegovy users have more comorbidities, most commonly anxiety (30% for Mounjaro vs 40.17% for Wegovy vs 30.34% for Ozempic, $P = 0.0081$). Individuals in low-socioeconomic-status regions are more likely to use Mounjaro (40% vs 23.01% for Wegovy vs 32.91% for Ozempic; $P = 0.0045$).

CONCLUSIONS: The absence of statistically significant differences in the rates of SUD/AUD between those treated with Ozempic vs Wegovy vs Mounjaro demonstrates that patients are no more likely to experience an AUD/SUD event while on one medication vs the others. Nonetheless, when we compared patients with obesity on AOM vs no AOM, SUD/AUD rates were significantly lower in the AOM group (9.89% vs 14.24%, $P = 0.0015$).

SPONSORSHIP: None.

F29 Economic evaluation of DYANAVEL XR for the treatment of attention-deficit/hyperactivity disorder in US motor vehicle drivers

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BACKGROUND: Attention-deficit/hyperactivity disorder (ADHD) affects approximately 4.4% of adults in the United States. ADHD is associated with high-risk driving behavior and costly motor vehicle accidents. In 2019, the US societal costs of motor vehicle crashes were $340 billion. DYANAVEL XR (DXR) (Tris Pharma, Inc.) is a once-daily fast-acting amphetamine developed for the treatment of ADHD. A randomized controlled trial with driving performance endpoints showed that DXR patients were 43% less likely to crash during a driving simulation compared with individuals taking placebo. Study outcomes suggest a DXR crash rate similar to that of a driver without ADHD, whereas patients treated with the current standard of care (SOC) have a 52% higher crash risk than drivers without ADHD.

OBJECTIVE: To evaluate the economic benefits attributable to improved driving abilities and avoided crashes in DXR patients compared with patients treated with the SOC or who are untreated.

METHODS: A cost-impact model was built to estimate 1-year crash-related cost outcomes for DXR-treated patients compared with SOC-treated patients with ADHD and untreated individuals. SOC was assumed to consist of a combination of short-, intermediate-, and long-acting ADHD stimulant and nonstimulant medications. The primary model endpoints were crash severity, crash probability, and cost savings. DXR crash risk was assumed to be equivalent to the non-ADHD population risk, as supported by trial data. Crash risk for untreated and SOC-treated patients with ADHD were assumed to be 99% and 52% higher than the general

US population, respectively, according to recent literature. Model outcomes included the cost impact (medication costs and crash-related costs) and the number of crashes, injuries, and fatalities avoided for each arm.

RESULTS: Treatment with DXR would avoid 0.82 crashes, 0.016 injuries, and 0.036 fatalities per year compared with untreated patients and 0.036 crashes, 0.007 injuries, and 0.0001 fatalities per year compared with SOC-treated patients. When compared with an ADHD population of 25% SOC-treated patients and 75% untreated patients, DXR patients would save an average of $4,581 per person per year across all age groups when priced at $80 per month and $4,265 when priced at $120 per month. When the value of quality-of-life improvement is considered, savings increase more than 7-fold.

CONCLUSIONS: The economic model shows that DXR is cost-saving compared with untreated patients and SOC-treated patients by reducing the number of motor vehicle crashes in the ADHD population.

SPONSORSHIP: This study was sponsored by Tris Pharma, Inc.

F30 ADHD medication trends among middle market self-funded employer groups: 2019-2023

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BACKGROUND: Although there have not been many recently approved medications for attention-deficit/hyperactivity disorder (ADHD), the prevalence of this condition has grown. Mental health and environmental challenges during the pandemic may have contributed to its growth, including symptoms such as lack of focus and poor memory function. These symptoms, combined with easier access to telehealth services, may have led to a surge in new ADHD diagnoses.

OBJECTIVE: To identify drivers contributing to increased ADHD medication use within commercial employer groups over the past 5 years.

METHODS: Pharmacy claims data were evaluated for 112 employer groups (<3,000 lives each) from Q1 2019 to Q2 2023. Data were adjusted to account for an increase in membership by measuring percentage of total claims. ADHD claims were identified using GPI 61*, and non-ADHD indicated products were removed. A total of 164,895 ADHD claims were aggregated by quarter for the following: member age/sex, drug brand/generic status, and drug class (stimulant/nonstimulant).

RESULTS: Total ADHD claims increased from 3.08% to 3.89% from Q1 2019 to Q2 2023, with the largest growth occurring between Q4 2020 and Q1 2021. Claim growth was driven by a larger percentage of use among female individuals starting in Q2 2020 and continuing through Q2 2023. The percentage of ADHD claims for ages 0-19 decreased from 38.5% to 29.0%, whereas ages 20-89 increased from 61.5% to 71.0%. Data also showed ADHD claims for ages 10-19 consistently dropped across each year in Q2 and Q3, compared with claims for Q1 and Q4. This trend was not seen among adults. Nonstimulant products accounted for the most growth during the study period (Q4 2022), increasing from 13.03% of ADHD claims to 15.27%. Brand ADHD claims rose from 20.07% (Q2 2022) to 26.03% (Q2 2023).

CONCLUSIONS: ADHD claims increased in the past 5 years and appear to be influenced by the COVID-19 pandemic. Claims increases mirror the rise in diagnosis of ADHD, especially among female individuals. Claims among school-age children were lower during remote learning periods and higher during this same time in adults, many of whom moved to remote offices. Claims for school-age children also indicate preference for medication holidays. With the increase in diagnosis of ADHD, shortages became prevalent, driving use of nonstimulants and brands. To ensure access, formulary preferences should include generic ADHD medications and offer flexibility during medication shortages.

SPONSORSHIP: None.

G00-G99 Diseases of the Nervous System

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

G4 Health care resource utilization of oral edaravone–treated patients with amyotrophic lateral sclerosis enrolled in a US-based administrative claims database

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BACKGROUND: Intravenous (IV) edaravone (Radicava) was approved by the US Food and Drug Administration (FDA) in 2017 for the treatment of amyotrophic lateral sclerosis (ALS) and was shown in clinical trials to slow the rate of physical functional decline. Oral edaravone (Radicava ORS) was FDA approved for use in patients with ALS in May 2022.

OBJECTIVE: To describe demographics, characteristics, and preliminary data on health care resource utilization (HCRU) of oral edaravone–treated patients with ALS in this real-world, observational, US-based administrative claims analysis

METHODS: Patients with ALS who were continuously enrolled in Optum's deidentified Clinformatics Data Mart from June 15, 2022, through December 31, 2022, were included and divided into 2 groups: Group 1 initially received IV edaravone and switched to oral edaravone, and Group 2 received oral edaravone and was previously edaravone naive. The index date was the first dosing date of oral edaravone. HCRU was evaluated by group and by Medicare vs commercial insurance coverage.

RESULTS: Oral edaravone–treated patients with ALS (n = 231) comprised 59 patients in Group 1 and 172 patients in Group 2. Groups 1 and 2 were predominantly male (59.3% and 58.7%) and White (72.9% and 77.3%), with a mean ± SD age of 61.3 ± 11.8 and 63.9 ± 10.1 years, respectively. The mean ± SD treatment duration was 22.4 ± 15.7 months for Group 1 and 2.6 ± 1.9 months for Group 2. The percentage of patients in Groups 1 and 2, respectively, who reached the following pre-index progression milestones are listed: use of canes/walkers/wheelchairs (37.3% and 22.1%), artificial nutrition (27.1% and 16.9%), noninvasive ventilation (37.3% and 23.3%), invasive ventilation (1.7% and 2.3%), hospitalization (37.3% and 27.9%), and gastrostomy tube placement (15.3% and 11.0%). A higher percentage of patients were covered by Medicare in Group 1 (67.8%) vs Group 2 (59.3%) than commercial insurance. For patients covered by Medicare or commercial insurance, respectively, the overall mean ± SD was 6.6 ± 23.6 and 4.3 ± 10.8 pre-index inpatient admissions and 48.3 ± 83.1 and 43.5 ± 67.9 pre-index outpatient visits. For patients covered by Medicare or commercial insurance, respectively, the overall mean ± SD was 1.4 ± 6.3 and 1.2 ± 4.5 post-index inpatient admissions and 6.1 ± 12.0 and 4.5 ± 10.6 post-index outpatient visits.

CONCLUSIONS: These real-world data may help clinicians and payers better understand the demographics, clinical characteristics, and HCRU of oral edaravone–treated patients with ALS.

SPONSORSHIP: Sponsored by Mitsubishi Tanabe Pharma America, Inc.

G5 Impact of Zolgensma in health care utilization in patients with spinal muscular atrophy in the United States: A retrospective claims and electronic health records analysis

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BACKGROUND: Spinal muscular atrophy (SMA) is a rare genetic disease, which affects 1 in 10,000 live births in the United States. SMA is a motor neuron disease and has several subtypes based on the onset of age and severity. SMA type I is the most severe, requiring numerous hospitalizations and having a 95% fatality rate. Infants with SMA do not live beyond their second year. Zolgensma was first gene therapy approved by the US Food and Drug Administration in May 2019 for treatment in patients with SMA aged younger than 2 years.

OBJECTIVE: To evaluate health care utilization in patients with SMA after Zolgensma therapy.

METHODS: Using the Optum deidentified data from Market Clarity, a retrospective analysis was conducted from June 1, 2020, to June 30, 2022. A cohort was created using *International Classification of Diseases, Tenth Revision* codes (G12.0, G12.1, G12.8, G12.9) for patients with SMA. The index event was defined as the first claim for SMA diagnosis. Selection criteria included patients who had at least 2 SMA-related claims 30 days apart and had received Zolgensma. Patients with other motor neuron diseases (G12.2) were excluded from this study. Index date was defined as the date of Zolgensma administration. A 12-month period is used as the pre-and post-index period to evaluate health care utilization before and after Zolgensma treatment in patients with SMA.

RESULTS: Of the 716 patients identified with SMA during our study period, a substantial majority (n = 615) patients were administered Zolgensma. Our observations revealed a significant reduction in health care utilization following the administration of Zolgensma. Specifically, the average length of hospital stay notably decreased from 9.67 days to 5.58 days, indicating the potential effectiveness of the treatment. To further enhance our understanding of Zolgensma's impact on health care utilization, we plan to evaluate more comprehensive parameters. These include the frequency of inpatient admissions, visits to the emergency department, and the necessity for intensive care unit admissions, with or without the need for ventilator support

CONCLUSIONS: Zolgensma, a pioneering gene therapy for SMA, has demonstrated encouraging outcomes. There has been a noteworthy reduction in the average length of hospital stay for patients with SMA following the administration of

Zolgensma, underscoring the treatment's potential effectiveness.

SPONSORSHIP: Optum.

G10 All-cause mortality among users of anticoagulant and antiplatelet therapies in patients with mild cognitive impairment or Alzheimer dementia

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BACKGROUND: None.

OBJECTIVE: To examine the risk of all-cause mortality among new users of anticoagulants as compared with antiplatelet therapy in patients with mild cognitive impairment (MCI) or Alzheimer dementia (AD).

METHODS: Patients aged 65 years and older with MCI or AD were identified from US Medicare claims database (2008-18) and evaluated for use of anticoagulant/antiplatelet therapy over 2016-17. A random sample of therapy users (n = 42,735) was selected. Baseline clinical characteristics were defined during the 12 months prior to therapy initiation using components of the Charlson Comorbidity Index. A control group was selected from the MCI/AD cohort who did not receive the therapies and matched 1:1 to the therapy users by year of therapy initiation, age, and sex. All-cause mortality was compared between anticoagulant and antiplatelet users against the matched control groups and compared between MCI and AD using a Poisson regression.

RESULTS: A cohort of patients (N = 5,379,863) with MCI or AD was identified, of whom 487,745 were on anticoagulants, 373,096 were on antiplatelets, and 26,354 were on both. Over the period of 2016-17, greater than 96% therapy users were on a stable treatment regimen. Mean age was 83.3 years, with 60% women, 83.3% White, 9.3% Black, 3.7% Hispanic, 1.6% Asian, 0.3% Native American, and 1.7% Other/Unknown. Kaplan-Meier curves were nearly identical between the anticoagulant and antiplatelet user groups. Survival was the highest among patients with MCI with no therapy use and lowest among patients with AD with therapy use ($P < 0.001$). After statistical adjustments, we found increased death rates over 3 years with AD (40%) compared with MCI (26%) (rate ratio = 1.4, $P < 0.05$) and either therapy (43%) compared with nontherapy (29%) (rate ratio = 1.3, $P < 0.05$). The highest death rates were observed in patients with AD with either therapy (46%), and the lowest rates were observed in patients with MCI without therapy (21.7%). Mortality rates in patients with MCI were 31.2% with anticoagulant and 30.3% with antiplatelet use and 21.7% in patients with MCI without therapy. Mortality rates were similar between therapies of anticoagulants (43.2%) and antiplatelets (42.4%) but higher than that in the nontherapy group (29.4%). Mortality was no different between the White (36.7%) and Black (36.7) groups.

CONCLUSIONS: Relative to MCI, patients with AD had an increased risk for all-cause mortality. Use of anticoagulant or antiplatelet therapy was associated with an increased risk of deaths regardless of AD treatment in naturalistic clinical practice, potentially related to the conditions for which the therapies were prescribed or associated comorbidities.

SPONSORSHIP: Eisai.

G11 Usage patterns of antiplatelet therapy in patients with mild cognitive impairment or Alzheimer dementia

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BACKGROUND: None.

OBJECTIVE: To describe patterns and risk factors associated with antiplatelet therapy use in patients with mild cognitive impairment (MCI) or Alzheimer dementia (AD).

METHODS: Patients aged 65 years and older with MCI or AD were identified from the US Medicare claims database (2008-18) and evaluated for antiplatelet therapy use including prescription aspirin over 2016-17. A random sample of new therapy users (n = 18,346) was selected. Baseline clinical characteristics were constructed during the 12 months prior to therapy initiation using the components of the Charlson Comorbidity Index. Stable therapy was defined as continued use of at least 4 weeks. A nested case-control design was used with a control group selected from the MCI/AD cohort that did not receive therapy and matched to the therapy users by year of therapy initiation, age, and sex. A mixed-effects model was used to evaluate the likelihood of stable antiplatelet therapy with US census regions as a random effect.

RESULTS: A cohort of patients (N = 5,379,863) with MCI/AD was identified, of whom 373,096 were on antiplatelets with 98% stable use. Mean age of the sample was 82.9 years, with 58% women, 79.7% White, 10.1% Black, 5.3% Hispanic, 2.2% Asian, 0.3% Native American, and 2.1% Other/Unknown. The 3 most frequently observed comorbidities included 89.7% hypertension, 78.7% hyperlipidemia, and 46.3% mental disorder in the therapy user sample and 74.4%, 59.9%, and 44.8%, respectively, in the matched control sample. The analysis found that antiplatelet therapy was more likely observed in patients with coronary artery disease (odds

ratio [OR] = 3.18, $P < 0.05$), cerebrovascular disease (OR = 2.59, $P < 0.05$), congestive heart failure (OR = 1.69, $P < 0.05$), hypertension (OR = 1.6, $P < 0.05$), atherosclerosis (OR = 1.45, $P < 0.05$), depression (OR = 1.4, $P < 0.05$), chronic obstructive pulmonary disease (OR = 1.12, $P < 0.05$), and composite indications for therapy such as coronary artery bypass graft/percutaneous coronary intervention, atrial fibrillation, and others (OR = 1.88, $P < 0.05$), and in women vs men (OR = 1.27, $P < 0.05$), but less likely in patients with multiple sclerosis (OR = 0.48, $P < 0.05$). Therapy use increased after 2012 compared with before ($P < 0.05$). Hispanic patients had the highest rate of therapy use among all racial and ethnic groups (OR = 4.1 vs White [$P < 0.05$], OR = 1.52 vs Black [$P < 0.05$], OR = 1.26 vs Asian [$P < 0.05$], and OR = 1.34 vs Native American [$P = 0.5$]).

CONCLUSIONS: No difference was observed in the use of antiplatelet therapy between the groups of patients with MCI and AD. The higher use of therapy in Hispanic compared with other racial and ethnic groups is likely due to unobserved comorbidities unadjusted in the study.

SPONSORSHIP: Eisai.

G17 Promoting generic multiple sclerosis drug utilization and drug cost savings with a managed care pharmacist outreach program

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BACKGROUND: Generic multiple sclerosis (MS) medications have recently become widely available, including fingolimod, teriflunomide, dimethyl fumarate, glatiramer, and dalfampridine. Use of these generic MS drugs is supported by the American Academy of Neurology. Managed care pharmacists (MCPs) can aid in transitioning to generic therapy, reducing total MS drug spend and member cost.

OBJECTIVE: To assess the outcomes and financial impact of an MCP program targeting MS therapies using a web application facilitating MCP-to-provider or MCP-to-pharmacist outreach.

METHODS: Six months of pharmacy claims history was used to identify members across 14 million commercially insured lives who most recently used a branded MS drug for which a generic product exists. Estimated savings for the recommended change in therapy was calculated using claims data for the member's current brand drug and the median unit cost of the generic alternative. Identified cases were made available to MCP through a web application where outreaches and case details were documented. Cases were classified as successful, unsuccessful, not reviewed, or reviewed and no opportunity. Savings were documented in successful cases, defined as a paid claim for the generic drug following MCP outreach, and calculated using cost per day claim data from the member's most recent brand and generic drug claims annualized over 1 year. For unsuccessful cases, a reason for intervention failure was documented. Cases categorized as no opportunity were reviewed by an MCP and determined that outreach was not appropriate.

RESULTS: From September 2022 through August 2023, 125 of 778 cases (16%) resulted in a successful transition to a generic product, with total validated annualized savings of $9,080,622 and an average of $72,645 per case. There were an additional 159 cases in progress with estimated potential annualized savings of $11,035,972. 141 cases with outreach were unsuccessful in converting to generic: 72 were the provider rejecting the recommendation (51%), 18 did not have a response from the provider (13%), and for 51, another reason was cited (36%). 494 cases were classified by MCP as no opportunity.

CONCLUSIONS: An automated analytic rule process using claims data and providing MCP with actionable information successfully converted 16% of MS brand to generic therapy cases, resulting in $9 million validated savings, with an additional $11 million savings potential among in-progress cases. Using a web application to facilitate MCP outreach can aid in transitioning to generic therapy, reducing total MS drug spend and member cost.

SPONSORSHIP: Prime Therapeutics, LLC.

G18 Treatment journey and health outcomes of patients with multiple sclerosis and varying social needs being treated with ozanimod

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BACKGROUND: Multiple sclerosis (MS)–related health outcomes are affected by social determinants of health (SDOH), which describe the nonmedical factors that influence health and disease. Limited real-world evidence is available on ozanimod in diverse populations with MS.

OBJECTIVE: To describe treatment patterns and clinical outcomes of ozanimod in patients with MS (PwMS) with various levels of social needs, as defined by an SDOH index.

METHODS: PwMS initiating ozanimod (first ozanimod claim = ozanimod start) during the study period (April 2020 to April 2022) were included in this retrospective claims analysis of the Evernorth Health Services database. All patients were required to have minimum continuous enrollment of 12 months before and 6 months after

ozanimod start. An SDOH index was calculated as a weighted score (range, 0-100) of a series of characteristics derived from census tracts and mapped into 6 domains: economy, education, infrastructure, health, language/culture, and food access. A higher SDOH index score represents a higher level of social needs. Patients were categorized as low (L), medium (M), high (H), and very high (VH) need, based on a quantile distribution. The use of disease-modifying treatments (DMTs), number of patients with relapses, number of relapses per patient per month (PPPM), and infections were ascertained before and after ozanimod start. Treatment persistence was measured after ozanimod start. All results were stratified by SDOH category.

RESULTS: 137 patients (>78% female) were included in the analysis. The number (%) of patients in each SDOH category was L: 39 (28), M: 42 (31), H: 33 (24), and VH: 19 (14); there were 4 (3) uncategorized patients. No evidence of prior DMT (n [%]) use was observed for L: 14 (36), M: 20 (48), H: 15 (46), and VH: 3 (16); average days from diagnosis to ozanimod start was L: 247, M: 236, H: 269, and VH: 213. The average follow-up in days (SD) was L: 158 (57), M: 173 (34), H: 157 (57), and VH: 171 (38). Patients with relapses and relapses PPPM before ozanimod were L: 10 and 0.035, M: 8 and 0.028, H: 11 and 0.041, and VH: 3 and 0.030. After ozanimod start, these were L: 5 and 0.025, M: 3 and 0.013, H: 2 and 0.018, and VH: 1 and 0.009. There was no difference in number of infections before and after ozanimod start. The number of patients (%) who subsequently switched to another DMT was L: 3 (8), M: 0 (0), H: 3 (9), and VH: 1 (5).

CONCLUSIONS: This study provided evidence of ozanimod's benefit across all SDOH categories. Patients had fewer relapses after starting ozanimod, and most remained on therapy during follow-up.

SPONSORSHIP: Bristol Myers Squibb.

G19 Real-world evidence on the time from diagnosis to Medicare coverage for people with SOD1-ALS

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BACKGROUND: Superoxide dismutase 1 amyotrophic lateral sclerosis (SOD1-ALS) is a rare disease that represents ~2% of all ALS. In April 2023, tofersen received accelerated approval from the US Food and Drug Administration for treatment of ALS in adults who have a mutation in the SOD1 gene. Median survival for people with SOD1-ALS (pwSOD1-ALS) is 28 months. Given the impact of ALS on survival, federal law allows expedited approval for Medicare (MCR) regardless of age or time on disability. Real-world evidence on time to MCR coverage are not available.

OBJECTIVE: To quantify time from diagnosis (Dx) to first MCR claim for pwSOD1-ALS in a multipayer claims database.

METHODS: pwSOD1-ALS were deidentified in Invitae-Komodo Healthcare Map linked claims database from 1/2015 to 7/2023, linked to patient-level mortality data and SOD1 genetic testing results. Cohort entry required at least 2 medical claims for ALS and at least a 1-year claims history prior to their first claim for an ALS encounter or medication (Dx/Index Date). Counts, rates, and timing were evaluated for each pwSOD1-ALS on the first MCR claim relative to their first ALS claim, as well as the distribution of claims by payer before and after first MCR claim.

RESULTS: Study cohort included 115 pwSOD1-ALS (mean age = 52.3, 53% female), with 35% (n = 40) having MCR claims prior to ALS Dx. Of the 75 without MCR claims prior to Dx, 44% (n = 33) had no MCR claims during follow-up, and 15% (n = 11) died having no MCR claims. The observed lack of MCR transition did not appear related to limited follow-up time, as 45% (n = 5) who died and 76% (n = 25) who survived to end of follow-up had done so more than 180 days prior to death or last claim, respectively. Of the 41% (n = 31) with a first MCR claim during follow-up, 26% (n = 8) were less than or equal to 90 days, 74% (n = 23) more than 90 days, and 23% (n = 7) more than 1 year from ALS Dx. For these individuals, 97% of claims prior to MCR were from commercial payers. After their first MCR claim, commercial claims represented 28%, MCR 57%, and Medicaid 12%. With no MCR claims, the distribution was 84% commercial and 12% Medicaid.

CONCLUSIONS: Despite expedited eligibility, and treatment urgency for pw SOD1-ALS, delays in time to MCR coverage accounted for a large percentage of survival time from Dx, and many individuals died prior to MCR coverage. Evaluation of genetic-linked claims data offers a unique and important opportunity to understand patient journey insights related to payer coverage in ALS. These data highlight the potential need for targeted education to support earlier enrollment into federal benefits accessible to pwALS, which may improve the overall ALS care journey.

SPONSORSHIP: Biogen.

G21 Reduction in medical and pharmaceutical costs in US patients treated with eptinezumab for migraine prevention: A retrospective cohort study

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BACKGROUND: Eptinezumab (anti–calcitonin gene–related peptide [anti-CGRP] monoclonal antibody preventive migraine treatment) has demonstrated safety and efficacy in clinical trials. No studies have assessed its effect on health care resource utilization in patients with migraine.

OBJECTIVE: To estimate the real-world impact of eptinezumab on medical and pharmaceutical costs and medication use in patients with migraine.

METHODS: This retrospective study used IQVIA PharMetrics data to analyze adults with migraine and at least 2 eptinezumab claims between February 1, 2020 (US Food and Drug Administration approval date), and June 30, 2021. The index date was the first eptinezumab infusion. Patients had at least 12 months of continuous enrollment pre- and post-index and pre-index treatment with acute or preventive migraine medications. Medical cost included emergency, outpatient, inpatient, and urgent care visits. Pharmaceutical cost/use included preventive and acute headache treatment. Changes in continuous variables from pre-index to post-index were estimated using paired t-tests. Results were stratified by the number of eptinezumab infusions received (2, 3, or 4 or more), prior anti-CGRP or onabotulinumtoxinA use (yes/no), migraine type (episodic/chronic migraine [CM]), pre-index opioid use (yes/no), and depression-related claims.

RESULTS: The cohort included 556 patients (87% female; mean age = 45 years; 84% diagnosed with CM). Total cost reduction (sum of medical and migraine-specific pharmaceutical costs, excluding eptinezumab drug cost) in the cohort was –$4,411 (95% CI = –$6,652 to –$2,170) in the post-index compared with the pre-index period, which was primarily driven by inpatient and migraine-specific pharmaceutical costs. Total cost reduction was –$5,185 (95% CI = –$7,788 to –$2,583) in patients with at least 4 infusions, –$4,631 (–$7,139 to –$2,122) in those with CM, and –$9141 (–$13,295, –$4987) in those with pre-index opioid use. Mean triptan days/month decreased from 10.1 (SE 0.6) pre-index to 8.7 (0.6) post-index in the total cohort, a reduction of –1.4 (95% CI –2.2, –0.6) days. Mean change in days/month of triptan use was –1.7 (95% CI –2.7, –0.6) in patients with ≥4 infusions and –1.7 (–2.6, –0.8) in patients with CM. The proportion of patients with depression-related claims decreased by 5% in the total population (from 36% to 31%) and by 9% in those with pre-index opioid use (from 43% to 34%).

CONCLUSIONS: Eptinezumab treatment significantly reduced total medical and pharmaceutical costs; reductions were greatest in patients with pre-index opioid use. Patients treated with eptinezumab experienced notable reductions in triptan use.

SPONSORSHIP: Lundbeck LLC (Deerfield, IL).

G22 Real-world use and associated health care resource utilization among patients with epilepsy receiving rescue midazolam nasal spray

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BACKGROUND: Seizure clusters (SCs) are associated with high health care resource utilization (HCRU); however, there are limited published data.

OBJECTIVE: To assess characteristics, HCRU, and costs in patients with epilepsy (PwE) newly prescribed midazolam nasal spray (MDZ-NS).

METHODS: This was a retrospective analysis of deidentified data from Merative MarketScan (index date = date of MDZ-NS prescription in the identification period [12/01/2019 to 01/31/2023]). PwE (aged ≥12 years) newly prescribed MDZ-NS for SCs (based on secondary use) were identified. Epilepsy-related HCRU and costs (2023 USD) were captured 12 months before (baseline) and 6 months after (follow-up) MDZ-NS initiation and stratified according to 1 or 2 or more MDZ-NS prescription fills during follow-up.

RESULTS: 8,364 patients (mean age = 21.9 years; 54.0% male) were included; 4,157 and 2,107 received 1 and 2 or more MDZ-NS fills, respectively. Baseline characteristics were similar between 1 and 2-or-more fill groups, except a lower percentage of 1 vs 2-or-more fill groups had at least 2 prior/concomitant antiseizure medications (ASMs; 59.8%/50.6% vs 75.8%/69.0%) and had received on-/off-label use of rescue medication (3.5%/5.6% vs 6.7%/13.1%). During baseline, mean total epilepsy-related cost was $23,954 (inpatient [IP] 38%; outpatient [OP] 25%; pharmacy 37%); the highest epilepsy-related IP (6.6% of patients) and OP HCRU (71.2%) and mean epilepsy-related IP ($1479) and OP costs

($1044) occurred in the month before the index date. Within 1 month post-index, a lower proportion of 1 vs 2-or-more fill groups had epilepsy-related IP (2.4% vs 6.0%) and OP HCRU (49.5% vs 61.1%) and lower mean total epilepsy-related costs ($2,819 vs $5,451), respectively, mainly due to pharmacy. From month 1 to 2 post-index, epilepsy-related HCRU decreased by 23.2% and 7.0% in the 1 and 2-or-more fill groups, respectively, and mean total epilepsy-related costs decreased by 40.9% ($2,819 to $1,664) and 36.7% ($5,451 to $3,450); these reductions were sustained through month 6 post-index. Mean MDZ-NS costs accounted for 36.4% and 38.3% of the mean pharmacy costs in the 1 and 2-or-more fill groups, respectively, within 1 month post-index, and 6.5% and 4.8% in months 2 and 6 post-index, respectively, for the 2-or-more fill group.

CONCLUSIONS: Increased epilepsy-related HCRU in the month before MDZ-NS use suggests a precipitating event preceding the need for MDZ-NS. Compared with PwE who received 1 MDZ-NS, those who received 2 or more MDZ-NS fills may have had more severe epilepsy, as shown by a greater likelihood of having more than 2 prior/concomitant ASMs and higher epilepsy-related HCRU and costs. Overall, MDZ-NS was a minor contributor to pharmacy costs.

SPONSORSHIP: UCB Pharma.

H00-H95 Diseases of the Eye and Adnexa

(eg, macular degeneration)

H3 Incidence and prevalence of primary open-angle glaucoma and comorbid dry eye disease in Medicare FFS beneficiaries 2018-2021

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BACKGROUND: Glaucoma is a leading cause of blindness in the United States, and as the population ages, the prevalence of primary open-angle glaucoma (POAG) is predicted to increase. However, little has been published on this in the past 10 years.

OBJECTIVE: To report recent trends in the diagnosed prevalence and incidence of POAG, use of glaucoma medications, and prevalence of co-occurring dry eye disease (DED).

METHODS: A retrospective cohort analysis of Medicare fee-for-service (FFS) beneficiaries with Parts A, B, and D (2018-2021) was conducted to identify annual POAG prevalence, incidence, use of glaucoma medications, and prevalence of comorbid DED. Eligible individuals were aged 65 years and older and had 24 months of continuous enrollment. Prevalent POAG was identified if any of the following criteria was met: at least 2 medical claims with a diagnosis of POAG at least 30 days apart; at least 1 medical claim with POAG and at least 1 medical claim with ocular hypertension at least 30 days apart; at least 1 medical claim with POAG and at least 1 medical claim for a POAG-related procedure; or at least 1 medical claim with POAG and at least 1 pharmacy claim for POAG treatment. Beneficiaries without POAG in the prior 12 months were categorized as incident. Medication use in the 6 months after the POAG diagnosis was identified from pharmacy claims and reported by class.

RESULTS: Eligibility criteria identified 978,574 (6.2%), 983,429 (6.1%), 888,790 (5.5%), and 932,435 (5.9%) enrollees with prevalent POAG in 2018, 2019, 2020, and 2021, respectively. Prevalence decreased from 2019 to 2020 (6.1%-5.5%) but increased from 2020 to 2021 (5.5%-5.9%). Although Black Americans represented 5.4%-6.8% of beneficiaries, they constituted 11.0%-12.8% of the POAG prevalent population. Approximately 1.1%, 1.1%, 0.9%, and 1.3% of beneficiaries had incident POAG in 2018, 2019, 2020, and 2021, respectively. Most (81.3%) POAG beneficiaries filled at least 1 glaucoma medication, and the majority of those (56.2%-69.3%) were a prostaglandin. Nearly 30% of prevalent POAG beneficiaries had a concurrent diagnosis of dry eye.

CONCLUSIONS: A large proportion of Medicare FFS beneficiaries had POAG. As previously observed, POAG was more prevalent in Black beneficiaries. The COVID-19 pandemic decreased use of routine health care, which likely resulted in artificially lower POAG prevalence and incidence in 2020 and correspondingly higher incidence in 2021. A sizable proportion of POAG beneficiaries had comorbid DED. DED is a leading cause of ocular surface diseases, and individuals with POAG should be screened and treated for both disorders to optimize outcomes, where appropriate.

SPONSORSHIP: Bausch & Lomb Americas Inc.

H4 Real-world study of an FDA-approved binocular, dual-acting therapy for amblyopia: Vision and compliance outcomes from the treatment registry

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BACKGROUND: Amblyopia is a common neuro-visual condition in which visual acuity in one eye, the amblyopic eye (AE), is reduced because of neurologic suppression of signals from that eye. Luminopia is a binocular, digital, dual-acting treatment shown in phase 1, 2, and 3 trials to improve AE best corrected visual acuity (BCVA). Luminopia the first US Food and Drug Administration–approved therapy for treating vision in patients with amblyopia aged 4-7. The first real world study of Luminopia has been initiated via the creation of an observational registry, planned to enroll up to 2,000 patients, following for up to 3 years.

OBJECTIVE: To understand the real-world effect of Luminopia on patients with amblyopia, including change in vision and prescribing and use patterns.

METHODS: For the registry, demographic and vision data are collected per visit per patient. Treatment adherence is objectively tracked via software. Outcomes evaluated include demographics, prescribing and use patterns, and change in AE BCVA. Conversion rate (patients initiating treatment/patients prescribed Luminopia) was evaluated for registry sites.

RESULTS: The first analysis included 58 patients with a minimum of one visit post prescription. The median age was 8 years (IQR = 6-10). A total of 86% patients had received previous amblyopia treatment, including patching or blurring with atropine of the non-AE. Median duration of previous treatment was 36 months (IQR = 24-48). Average BCVA of patients at the time of prescription was approximately 20/50, with one-third of patients at 20/40 or better. Patients had been on Luminopia treatment for an average of 4.7 ± 2.3 months and improved by a statistically significant 1 line of vision on average (0.10 ± 0.13 logMAR, $P < 0.001$). Median adherence to treatment time was 67% (IQR = 39%-90%) of prescribed hours. Across registry sites, the mean treatment conversion rate was 62%, (range 53%-84%).

CONCLUSIONS: These registry data reflect real world amblyopia outcomes, including a large population of patients with residual amblyopia, treated for multiple years prior to starting Luminopia. Patients engaged in nearly two-thirds of their prescribed treatment, a marked improvement from the adherence for other treatments (ie, patching with only 44% adherence in clinical trials). AE BCVA improved in this registry analysis, in line with prior randomized controlled trial results. As registry enrollment grows, the precision of outcome estimates for subgroups of interest will grow and help guide individualized treatment recommendations.

SPONSORSHIP: Luminopia, Inc.

H5 Retinitis pigmentosa associated lifetime medical and nonmedical costs attributable to disability due to vision loss

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BACKGROUND: Retinitis pigmentosa (RP) is a rare, progressive genetic eye disease that causes vision loss. The direct and indirect costs associated with blindness and subsequent disability in this population is unknown.

OBJECTIVE: To examine disability-associated lifetime costs because of blindness in RP by quantifying the cost burden to patients, employers, payers, and government.

METHODS: We estimated direct and indirect costs associated with RP using an actuarial model of years of survival and lifetime excess costs incurred in years following legal blindness for a 35-year-old patient with RP, earning $56,000, under the following 2 scenarios: (1) becoming disabled at age 35 and (2) not being disabled, employed, and retiring at age 67. Indirect excess costs, including employer- and government-funded disability, lost income opportunity, government assistance programs, and years of life lost, were estimated using standard actuarial disability and mortality tables. Direct excess medical costs (medical, pharmacy, long-term care, and transportation) were calculated using administrative claims data. Direct nonmedical excess costs (paratransit benefits, guide dogs, and informal care costs) were estimated using published reports and literature.

RESULTS: Aggregate lifetime costs for a patient with RP who becomes visually impaired and disabled from age 35 are $2,314,495, compared with $584,800 for those without disability. Indirect excess costs associated with disability because of vision loss included $742,660 in disability benefits and $581,892 in lost income and government programs; direct nonmedical excess costs were $273,678. Survival after age 35 was estimated at 28.0 and 45.6 years for RP with and without disability, respectively. Lifetime medical costs for RP were estimated to be $613,890 with disability, compared with $563,125 without disability. On average, indirect and directs costs per year were $82,807 and $12,821 for RP with and without disability, respectively.

CONCLUSIONS: Excess mortality associated with disability because of vision loss is estimated to reduce life expectancy from age 35 by 17.7 years. Average per year indirect and direct costs for disabled patients with RP in our model is significantly higher than those without disability. Disability is attributed to 296% incremental costs in patients with RP. Delaying the progression of RP can minimize excess disability costs by avoiding or significantly delaying progression to blindness.

SPONSORSHIP: Janssen Scientific Affairs, LLC.

I00-I99 Diseases of the Circulatory System

(eg, atrial fibrillation, pulmonary hypertension)

11 Analysis of out-of-pocket cost in patients with heart failure: Post–Inflation Reduction Act implications for Medicare beneficiaries with coexisting health conditions

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BACKGROUND: The increasing costs associated with managing heart failure, particularly those tied to high-end medications, namely, angiotensin receptor-neprilysin inhibitors and sodium-glucose cotransporter 2 inhibitors, have led to substantial out-of-pocket (OOP) expenses for patients. Recognizing these challenges, the Inflation Reduction Act (IRA) implemented measures such as the selection of high-cost drugs for price negotiation and the introduction of an annual patient OOP cap of $2,000. These measures aim to reshape the financial dynamics for Medicare Part D beneficiaries.

OBJECTIVES: To assess the differential financial implications of the IRA for patients with heart failure with and without associated comorbidities, namely, diabetes mellitus, chronic obstructive pulmonary disease, and renal insufficiency, and to investigate the racial disparities evident in these financial outcomes.

METHODS: The study derived its data from 100% Medicare Part D Event claims for 2021-2022. Around 1.3 million unique beneficiaries with chronic heart failure diagnosis and continuously eligible for coverage for at least 12 months were selected for the analysis. Demographic information (age, race, low-income subsidy status, etc.) was obtained from the Master Beneficiary Summary Files. A multifaceted financial model incorporated IRA provisions, standard deductibles, varying low-income subsidy categories, and individual medication expenditures.

RESULTS: The annual average OOP costs for heart failure medications increased from $383 in 2021 to $456 in 2022. Among beneficiaries solely on heart failure medications in 2022 (n = 29,677, approximately 3% of chronic heart failure beneficiaries), 14% incurred OOP costs more than $2,000. Individuals with common heart failure comorbidities faced higher OOP costs, averaging $1,341 in 2022. In this group (n = 136,045), 22% exceeded $2,000 in OOP costs. Delving further, among those without prescriptions for major comorbidity drugs and with OOP costs exceeding $2,000, 8% of the beneficiaries were Black and 80% were White. However, for beneficiaries who are also taking drugs for comorbidities, the percentage of those with more than $2,000 OOP cost raised to 16% for Black patients.

CONCLUSIONS: The IRA has provisions that could provide some relief from health care expenses for individuals with heart failure. This may have implications for Black beneficiaries under Medicare who often face a variety of health and economic challenges. Initial assessments indicate IRA may have a role in moderating financial barriers to necessary health care for some of the more affected populations.

SPONSORSHIP: None.

12 Impact of a population-based hypertension outreach program with pharmacist consultation on clinical inertia and blood pressure control

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BACKGROUND: Improving hypertension control on a population level is a long-standing challenge, especially in the context of limited health care resources. Clinical inertia, which in this context refers to the failure to intensify therapy in the setting of uncontrolled blood pressure (BP), is a significant factor contributing to this problem.

OBJECTIVE: To evaluate the impact of a population health collaborative intervention of centralized patient-outreach navigators and clinic-based pharmacists to reduce clinical inertia and improve hypertension control in a primary care setting.

METHODS: This retrospective cohort study compares clinical and process outcomes in an intervention cohort vs a parallel comparator cohort of patients with hypertension. Centralized outreach coordinators ran weekly reports to identify patients whose most recent and the average of their last 3 systolic BPs was greater than 150 mmHg, called the patient, and scheduled a hypertension-focused primary

care visit, then forwarded a message to the clinical pharmacist practicing in that clinic. The pharmacist reviewed the patient record and documented clinical recommendations for hypertension control prior to the patient visit, including an option for the provider to refer the patient for pharmacist follow-up and management after the visit.

RESULTS: Outreach was performed for 426 intervention patients and outcomes were compared with 587 similar patients in nonparticipating clinics. The intervention patients were more likely to attend a clinic visit with a BP measurement (57.3% vs 38.8%, adjusted $P < 0.001$), have their hypertensive therapy addressed at that visit in the setting of BP greater than 140/90 (63.3% vs 44.2%, adjusted $P = 0.010$), and achieve a BP less than 140/90 mmHg (27.9% vs 16.9%, adjusted $P < 0.001$) within 6 months of outreach. The intervention execution was incomplete, with only 59% of outreach notes forwarded to the pharmacist, who documented a hypertension-focused consultation for 75% of these prior to the patient visit. Less than half of patients in either group with BP greater than 140/90 at their visit had a subsequent follow-up visit within the 6-month observation period (45% and 39% respectively, adjusted $P = 0.328$).

CONCLUSIONS: A hypertension-focused population health approach reduced clinical inertia and improved BP control in primary care practices within an academic medical center. Opportunities identified at different stages of this care process will be used to guide further improvement of this care model.

SPONSORSHIP: None.

13 The association of type 2 diabetes with 90-day episode of care spending following heart failure hospitalization among Medicare beneficiaries

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BACKGROUND: Heart failure (HF) is the most common admission diagnosis of Medicare beneficiaries, and estimates suggest up to a third of patients with HF also have type 2 diabetes mellitus (T2DM).

OBJECTIVE: To better characterize patterns of use and spending for patients with HF with and without T2DM.

METHODS: Using the 100% Medicare fee-for-service administrative claims data from 2016 to 2019, hospitalizations for HF (HHF) were identified as those with a primary discharge diagnosis code (*International Classification of Diseases, Tenth Revision, Clinical Modification* codes) of (1) systolic HF, (2) diastolic HF, (3) hypertensive heart disease (HHD) and HF with chronic kidney disease (CKD), and (4) HHD and HF without CKD. Hospitalizations were stratified into those with and without a diagnosis of T2DM. A total of 90-day episode of care payments (median and IQR) and temporal trends of coding patterns for above subgroups were analyzed.

RESULTS: In total, there were 1,187,259 unique HHF and more than half of those hospitalizations also had a diagnosis of T2DM (T2DM: 53.2%, no T2DM: 46.8%). The 90-day spending stratified by the presence of T2DM as a comorbidity was all HF codes combined (T2DM: median $21,764 [IQR = $12,484-$37,758] vs no T2DM: $20,355 [$11,894-$35,100]), systolic HF (T2DM: $23,022 [$13,080-$40,181] vs no T2DM: $20,030 [$11,391-$35,084]), diastolic HF (T2DM: $22,176 [$12,477-$38,641] vs no T2DM: $20,225 [$11,695-$34,892]), HHD with HF (T2DM: $18,425 [$10,950-$34,123] vs no T2DM: $17,713 [$10,685-$32,000]), and HHD with HF and CKD (T2DM: $25,386 [$14,741-$43,142] vs no T2DM: $22,980 [$13,587-$37,809]). Post–acute care, defined as health care resource utilization following HHF discharge, accounted for just more than half of total median 90-day spending in patients with HF both with and without T2DM, with spending at the skilled nursing facilities and other nonacute inpatient facilities comprising the majority of total post–acute care spending (T2DM: 61%, no T2DM: 60%). For all HF codes combined during the entire study period, the rate of 90-day readmissions among HHF with T2DM and without T2DM were 38.6% and 33.0%, respectively.

CONCLUSIONS: Understanding the drivers of 90-day spending can help guide opportunities to improve value in HF care. These findings have important implications for patients, providers, payers, and policymakers.

SPONSORSHIP: Boehringer Ingelheim.

16 Predictive accuracy of AI model for myocardial infarction hospitalization burden using multiyear HCUP data

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BACKGROUND: Myocardial infarction (MI) or heart attack is caused by ischemia or decreased/ceased blood flow to the heart muscles that may lead to sudden cardiac deaths. Annually, approximately 805,000 people in the Unites States have an MI, of which 605,000 are primary and 200,000 are

secondary MIs. MI is associated with substantial mortality and health care resource utilization burden. The Healthcare Cost Utilization Project (HCUP) database is a nationwide sample of 20% of all US hospitalizations and is perfectly suited for studying hospitalization burden of MI.

OBJECTIVE: To use AI predictive modeling technique to forecast hospitalization burden of MI using HCUP dataset.

METHODS: Hospitalizations with a primary diagnosis code for MI (*International Classification of Diseases, Tenth Revision* = I21*) were selected from the 2016-2018 HCUP dataset. An Extreme Gradient Boosting model was built with 2016-2018 as training data and validated in 2019 HCUP data. Predictive variables, like age, race, sex, hospital region, median household income, payer, number of hospital beds, hospital teaching status, and hospital National Immunization Survey number, were selected for the model based on their significance. Training data were grouped together using significant variables to determine the MI Hospitalization burden (number of hospitalizations in 2019).

RESULTS: HCUP data from 2016, 2017, and 2018 comprising 21 MM records were analyzed to yield 392,209 MI hospitalizations. MI hospitalizations were characterized by 62.13% male patients with a mean (SD) age of 66.95 (13.43) years. The average number of hospitals within the HCUP dataset each year was 3,300, with an average of 83.33 MI hospitalizations with length of stay of 4.43 (5.34) days and mean total charges of $95,253 ($118,624). Given the parameters in the training dataset, the predictive EGM model was able to successfully predict the number of MI hospitalizations for 2019. The model converged on the 50th iteration (root mean squared error of 0.359602 in EGM model iteration 1 was reduced to 0.000001 by the 50th iteration). Validation results predicted 132,403 hospitalizations in 2019 in line with observed HCUP data.

CONCLUSIONS: Using the Extreme Gradient Boosting model with 3-year HCUP data training resulted in a feasible AI model for predicting 2019 MI hospitalizations at the total level. Further validation tests and research are necessary to refine and generalize the model.

SPONSORSHIP: APPERTURE Health.

18 Budget impact of bempedoic acid for prevention of major cardiovascular events (MACEs) in patients at high risk for or with established atherosclerotic cardiovascular disease (ASCVD) in the United States

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BACKGROUND: A substantial number of patients with or at high risk for atherosclerotic cardiovascular disease (ASCVD) remain above recommended low-density lipoprotein cholesterol (LDL-C) goals despite treatment with statins. The CLEAR Outcomes trial demonstrated bempedoic acid (BA), a nonstatin lipid-lowering therapy (LLT), significantly reduced the risk of major adverse cardiovascular event (MACE)-4 in patients with high cardiovascular (CV) risk when used alone or in combination with background LLT that could include very low doses of statins.

OBJECTIVE: To estimate the budget impact of adding BA as a treatment option for MACE prevention in patients with high CV risk from a US payer perspective.

METHODS: An Excel model was developed to evaluate drug and MACE-related costs for a hypothetical 1-million-member health plan over a 3-year period. Inputs included age distribution, prevalence of ASCVD risk factors, frequency of statin use/history, LDL-C goal attainment, forecasted market shares of nonstatin LLT, wholesale acquisition costs, and avoidance of MACE and associated costs. BA MACE avoidance was obtained from the CLEAR Outcomes trial and extrapolated to all patients eligible for BA.

RESULTS: Overall, 5.7% (n = 56,504) were patients with high CV risk with statin history and not at LDL-C goal. Based on real-world data, in the scenario without BA, the majority (94%) were not receiving nonstatin LLT; ezetimibe (4%) and proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors (2%) comprised the nonstatin LLT market. In the scenario with BA, the model assumed that BA increased to 1%, 1.2%, and 1.4% at years 1, 2, and 3, respectively, coming equally from patients switching from PCSK9 inhibitors and patients entering the nonstatin LLT market (new to therapy). When incorporated into a 3-year time frame, the plan could be expected to pay an incremental $695,788 to $748,568 per year in total costs ($0.06 per member per month [PMPM]); drug costs account for the majority of costs, with 19%-27% cost-offset from MACE avoidance associated with reduced CV risk from BA. The total budget impact varies depending on the size of the population treated with nonstatin LLT. In a scenario assuming 2% annual increase of this population, the total net budget impact is cost saving ($0.08, $0.10, and

$0.24 PMPM for years 1, 2, and 3, respectively), driven by more patients initiating therapy with BA vs PCSK9 inhibitors and the lower wholesale acquisition costs of BA.

CONCLUSIONS: Adding BA for the prevention of MACE in high-risk patients resulted in incremental additional spending with improved clinical outcomes, which decreases with greater relative use of BA vs PCSK9 inhibitors.

SPONSORSHIP: Esperion Therapeutics, Inc.

I18 PCSK9i and statin use in reducing atherosclerotic cardiovascular diseases

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BACKGROUND: Clinical guidelines recommend Proprotein Convertase Subtilisin/Kexin Type 9 inhibitors (PCSK9i) use in patients with atherosclerotic cardiovascular disease (ASCVD) or familial hypercholesterolemia. PCSK9i are particularly useful for patients with maximally tolerated statin or who do not tolerate appropriate doses of statins and have high low-density lipoprotein. This study examines whether discontinuation of statin is associated with ASCVD events.

OBJECTIVE: To evaluate the relationship between discontinuation of statin use post-PCSK9i initiation and ASCVD events.

METHODS: Data came from the Komodo Healthcare Map—a nationally representative US pharmacy/medical claims database for more than 150 million patients. This retrospective study compared ASCVD events of adult patients (aged 18+) with an index claim of a PCSK9i, and at least 2 claims of ASCVD and statin from January 1, 2019, to April 30, 2021. Patients had 12 months of continuous pharmacy/medical insurance coverage prior to index (baseline) and 24 months post-index (follow-up). Proportion of post-index ASCVD events for patients remaining on statins after PCSK9i initiation (statin group) were compared with those who discontinued statins (no-statin group). Propensity score weighting was used to balance patient baseline characteristics between the 2 groups, including age, sex, region, Charlson comorbidity index (CCI), race and ethnicity, hypertension, statin intensity, and the social determinant of health index. Multivariate logistic regression was used to assess the odds of ASCVD between the 2 groups, while controlling for baseline use.

RESULTS: A total of 420 and 208 patients were in the statin and nonstatin groups, respectively. Unweighted results showed that compared with the nonstatin group, the statin group was more likely to be on high-intensity statin (32% vs 19%), have hypertension (95% vs 90%), have 3+ CCI (61% vs 51%), and have higher number of adjusted 30-day fills for any medication (85 vs 66) in the baseline. Both groups had an ASCVD baseline prevalence of 24%. In the follow-up period, both had a statistically significant reduction in ASCVD prevalence (statin vs nonstatin: 11% and 9%; $P<0.0001$), but the reduction between the 2 groups was not statistically significant. The odds of having any ASCVD post-index was not significantly different between the 2 groups (odds ratio = 0.88; $P = 0.52$).

CONCLUSIONS: Initiation of PCSK9i was associated with a reduction in ASCVD prevalence in the follow-up period, although the reduction between the 2 groups was statistically insignificant.

SPONSORSHIP: None.

J00-J99 Diseases of the Respiratory System

(eg, asthma, COPD, rhinitis)

J2 Budget impact of introducing live attenuated influenza vaccine for intranasal self- or caregiver administration in the United States

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BACKGROUND: A supplemental Biologics License Application for live attenuated influenza vaccine (LAIV; FluMist Quadrivalent [Influenza Vaccine Live, Intranasal] Intranasal spray) self or caregiver administration for individuals aged 18–49 and 2–17 years, respectively, has been accepted for review by the US Food and Drug Administration; a regulatory decision is anticipated in 2024.

OBJECTIVE: To estimate the impact of introducing self-/caregiver-administered LAIV in the United States.

METHODS: A budget impact model modeling the impact of introducing self-/caregiver-administered LAIV over a 5-year time horizon in populations aged 2–4, 5–17, and 18–49 years in a hypothetical 1-million-member plan was developed in Microsoft Excel. Comparators varied by age group and included influenza vaccination in the traditional health care setting with LAIV and injectable influenza vaccine. Direct costs (vaccine, physician/pharmacy visit) and indirect costs (productivity losses [daycare/school/work, parent accompanying child]) related to vaccine administration in the health care setting were sourced from the published literature and inflated to 2023 US dollars

using the Consumer Price Index. Time away from daycare/school/work for vaccination was assumed at 3 hours per child/adult. Productivity losses for a parent taking a child for vaccination were only applied to families in which both parents were employed (assumed at 65%).

RESULTS: Over a 5-year time horizon, the estimated mean budget impact of introducing self-/caregiver-administered LAIV was -$274,986 (-2.4%), -$988,754 (-3.0%), and -$1,558,249 (-2.1%) in individuals aged 2-4, 5-17, and 18-49 years, respectively. The total cost of vaccination increased across all populations with the availability of self-/caregiver-administered LAIV, with an average increase of 11.6% in individuals aged 2-4 and 5-17 years, and 8.8% in those aged 18-49 years over 5 years. However, these costs were offset by lower productivity losses because of fewer absences from daycare/school/work for vaccination and lower administration cost. In a threshold analysis, the introduction of self-/caregiver-administered LAIV remained cost-neutral when time away from work for adults was reduced to 0.5 hours and time away from school (5-17 years) or daycare (2-4 years) was reduced to 0.0 and 0.6 hours, respectively.

CONCLUSIONS: Preliminary results suggest that, if approved, the introduction of the first influenza vaccine for self/caregiver administration would not impact the overall budget in the United States and would provide an additional accessible option for influenza vaccination.

SPONSORSHIP: AstraZeneca.

J3 Incidence of COVID-19, associated health care resource utilization (HCRU), and costs in patients on immunosuppressive treatments (ISTs) in a commercially insured/Medicare Advantage population

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BACKGROUND: Patients receiving immunosuppressive treatments (ISTs) may have an increased risk for severe illness because of COVID-19, which may be partially due to suboptimal protection from vaccination.

OBJECTIVE: To estimate the real-world incidence rate of COVID-19 and associated health care utilization and costs among patients receiving ISTs in a commercially insured or Medicare Advantage population.

METHODS: A retrospective observational cohort study was conducted among US patients in the Healthcare Integrated Research Database from April 1, 2018, to April 30, 2023. A cohort of patients with at least 2 claims for ISTs (overall and by drug-specific subgroups) and the complete Healthcare Integrated Research Database Source Population (HSP) were identified. Continuous enrollment of at least 12 months was required in both cohorts. The index date was defined as day 366 of continuous enrollment in the study period for the HSP and as the first IST fill date or April 1, 2020 (whichever came last), for the IST cohort. Patients were followed until disenrollment in the health plan, study end date, or death, whichever came first. COVID-19 was identified through outpatient laboratory results and diagnosis codes on medical claims.

RESULTS: A total of 325,665 patients on ISTs (1.6%) were identified among the 20,140,907 in the HSP. COVID-19 prevalence was 19.3% in the IST cohort and 12.3% in the HSP over a mean follow-up of 1.7 years. Overall/severe COVID-19 Irs were 119.7/7.9 (IST) and 74.8/1.8 (HSP) per 1,000 patient years. A greater proportion of the IST cohort (13.5%) vs HSP (4.6%) were hospitalized for the first COVID-19 diagnosis. The mean all-cause hospitalization costs (2022 USD) for the first COVID-19 diagnosis for severe cases were $57,719 for the IST cohort and $53,171 for the HSP. Within the IST cohort, mean all-cause hospitalization costs among patients with severe COVID-19 were highest in the mycophenolate mofetil and B-cell-depleting therapies subgroups at $94,052 and $62,616, respectively. Total mean costs (medical + pharmacy; health plan + patient paid) among all IST users with COVID-19 increased from $10,309 to $17,815 in the 30 days pre-/post-infection, predominantly driven by increased inpatient costs post-SARS-CoV-2 infection. The greatest cost increases in this time frame were seen in the mycophenolate mofetil ($9,481 to $32,340), B-cell-depleting therapies ($13,518 to $37,265), and calcineurin inhibitors ($9,139 to $33,249) subgroups.

CONCLUSIONS: Members receiving ISTs continue to have a higher clinical and economic burden because of COVID-19 than the general population. Providers and payors should focus on optimal preventive and treatment strategies in this population.

SPONSORSHIP: AstraZeneca.

J4 Health care resource utilization, costs, and steroid use among patients with chronic rhinosinusitis with nasal polyps treated with mepolizumab: A real-world claims analysis

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BACKGROUND: Patients with chronic rhinosinusitis with nasal polyps (CRSwNP) have higher health care resource utilization (HRU) than patients without CRSwNP/with CRS without NP. Treatments include sinus surgery, corticosteroids (CS), and biologics, such as mepolizumab.

OBJECTIVE: To compare HRU, costs, and oral CS (OCS) use pre-/post-mepolizumab initiation in patients with CRSwNP.

METHODS: Komodo Research database data covering more than 320 million insured US patients were analyzed. The study included adults with CRSwNP without severe asthma who initiated mepolizumab 100 mg on/after July 29, 2021 (US mepolizumab approval date for CRSwNP; index date: first dispensing/administration). Patients had at least 2 mepolizumab dispensings/administrations less than or equal to 6 months from index, 12 months continuous health care enrollment pre-/greater than or equal to 6 months post-index, and no use of reslizumab/benralizumab/tezepelumab during study period. All-cause/NP-related HRU, costs (2023 US$), and OCS use per patient-year (PPY) were compared pre- and post-index. Outpatient visits associated with mepolizumab administration/pharmacy costs were excluded from the main analysis.

RESULTS: Of 240 patients included, 73.8% had comorbid mild/moderate asthma. Most were commercially (69.2%) or Medicaid (22.5%) insured and prescribed mepolizumab by allergists (32.1%) or otolaryngologists (27.9%). Mean (SD) number of NP-related outpatient visits PPY decreased from 4.8 (3.8) pre- to 3.5 (4.8) post-index (rate ratio [RR] [95% CI] = 0.69 [0.57-0.84], $P < 0.001$); rate of NP-related otolaryngologist visits PPY decreased 48% (RR [95% CI] = 0.52 [0.43-0.63], $P < 0.001$). Mean (SD) total NP-related costs (medical/pharmacy) PPY decreased from $9,167 (24,536) pre- to $2,294 (5,249) post-index (cost difference [CD] [95% CI] = $-6,275 [-9,575, to -3,412], $P < 0.001$), including significant reduction in NP-related respiratory specialist (allergist/otolaryngologist) visit costs post-index (CD [95% CI] = $-1,731 [-2,595, to -1,023], $P < 0.001$). Costs of NP-related otolaryngologist visits were still significantly reduced post-index with cost of mepolizumab administration included ($1,299 [2,545] pre- vs 521 [1,072] post-index (CD $-719 [-1,076, to -386], $P < 0.001$). Mean number of NP-related OCS dispensings and OCS bursts PPY decreased by 60% and 63% (RR [95% CI] = 0.40 [0.31-0.52] and 0.37 [0.28-0.50], all $P < 0.001$), respectively. Similar trends were observed for all-cause HRU, costs and OCS use.

CONCLUSIONS: Patients with CRSwNP had significantly less clinical and economic burden after mepolizumab initiation.

SPONSORSHIP: GSK 218957.

J7 Real-world treatment patterns associated with tezepelumab use among patients with severe asthma in the United States: An early view claims data study

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BACKGROUND: Tezepelumab was approved by the US Food and Drug Administration in late 2021 as an add-on maintenance treatment of adult and pediatric patients (aged 12 years and older) with severe asthma. A prior real-world study described patient characteristics of early recipients of tezepelumab; however, there was insufficient follow-up to assess treatment persistence and adherence.

OBJECTIVE: To assess the real-world treatment patterns associated with tezepelumab use for the treatment of severe asthma in early recipients in the United States.

METHODS: This retrospective study used the IQVIA open-source pharmacy and medical claims databases. Patients with at least 2 pharmacy/medical claim for tezepelumab between December 17, 2021, and June 30, 2023, were identified (first tezepelumab claim date = index date). Eligible patients were aged 12 years or older, had at least 12 months of pre-index and at least 6 months of post-index continuous data available. Proportion of days covered (PDC), persistence, and switching were assessed at 6- and 12-months post-index for patients with sufficient follow-up. PDC was calculated by summing the days supply divided by 180 or 360 days, capped at 1.0. Persistence was assessed as the proportion of patients that did not discontinue treatment, reported as the number of days from the start of treatment to discontinuation. Discontinuation was defined as a greater than or equal to 90-day gap in supply of tezepelumab.

RESULTS: Overall 1,734 patients were eligible for the study (mean age: 58.8 years; 72.1% female). At 6 months, patients had a mean of 5.3 claims of tezepelumab; and the mean

PDC was 0.77 (0.22). By 6 months, 83.9% of patients were on treatment (persistent patients plus patients who had temporarily stopped and then restarted tezepelumab). On average, patients received 5.4 months of treatment. The proportion of patients switching to a new biologic was 2.7%. In total, 775 (44.7%) had at least 12 months follow-up. At 12 months, patients had a mean of 8.9 claims of tezepelumab; and the mean PDC was 0.68 (0.27). By 12 months, 65.3% of patients were on treatment (persistent patients plus patients who had temporarily stopped and then restarted tezepelumab). On average, patients received 9.3 months of treatment. The proportion of patients switching to a new biologic was 7.9%.

CONCLUSIONS: The persistence and adherence rates at 6 and 12 months and low switching rates demonstrate that many patients who started tezepelumab treatment remained on therapy. These results suggest that tezepelumab treatment is a durable treatment option for the long-term management of severe asthma.

SPONSORSHIP: Amgen Inc. and AstraZeneca.

J8 Real-world trends in chronic obstructive pulmonary disease diagnoses from 2008 to 2022

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BACKGROUND: The World Health Organization estimates that chronic obstructive pulmonary disease (COPD) is the third leading cause of death globally, and in 2020 it was the sixth leading cause of death in the United States. Health care delivery and financing organizations are keenly interested in COPD trends for prevention and treatment planning.

OBJECTIVE: To estimate trends of COPD from 2008 to 2022 among adults aged 40 or older by age, sex, and race using real world data.

METHODS: We conducted a retrospective analysis of administrative data of research-eligible members aged 40 and older from January 1, 2008, to December 31, 2022. *International Classification of Diseases, Ninth Revision* (ICD-9) and ICD-10 diagnosis codes were used to identify patients with COPD: ICD-9: 490 (Bronchitis, not specified as acute or chronic), 491 (chronic bronchitis), 492 (emphysema), 496 (chronic airway obstruction, not elsewhere classified); ICD-10: J40 (bronchitis, not specified as acute or chronic), J41 (simple and mucopurulent chronic bronchitis), J42 (unspecified chronic bronchitis), J43 (emphysema), J44 (other COPD). Unique COPD counts and annual enrollment were used to calculate annual prevalence of COPD diagnoses for the population overall and by subgroups based on age group (40-59, 60-69, 70-79, 80+ years), sex (Male/Female/Unknown), and race and ethnicity category (American Indian/Alaskan Native, Asian, Black American, Hispanic, Other, Pacific Islander, White, and multiracial).

RESULTS: During the study period, the mean annual enrollment for the research-eligible population aged 40 years and older from 2008 to 2022 was 3,576,358 individuals. The prevalence rate across the total population (40 and older) varied over the time frame with no consistent trend. Prevalence rates were higher among women compared with men across all years we examined. White adults were the predominant race among the COPD diagnosed population. Across the age groups, we observed that adults aged 40-59 represented greater than 45% of COPD cases from 2008 to 2018, and then decreased to 22% in 2022. Conversely, adults aged 60-79 represented less than 45% of COPD cases from 2008 to 2016 and subsequently represented most cases including 64% in 2022.

CONCLUSIONS: We found that the age group with highest rates of COPD varied over time and shifted from a younger population (40-59) to an older population (60-79) around 2018. COPD remains a major public health concern, and continuous surveillance is needed to monitor epidemiological trends to inform care. Additional research is needed to better understand this shift in disease burden.

SPONSORSHIP: None.

J15 Disparity in treatment patterns of patients with lung diseases in the United States

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BACKGROUND: The health outcomes in lung disease are deeply affected by the prevailing health inequalities across ethnicities and races and sex, which impede the availability of care and appropriate treatment

OBJECTIVE: To gain insights into sex and racial and ethnic disparities in resource use and clinical outcomes of patients with 3 lung diseases—pneumonia, chronic obstructive lung disease (COPD), and lung cancer—in the United States.

METHODS: A retrospective study using the Optum deidentified Market Clarity Dataset (linked claims and electronic health records [EHRs] of patients) was done among adult (≥18 years) patients with 2 or more claims and/or EHRs with *International Classification of Diseases, Tenth Revision* (ICD-10) diagnosis code for pneumonia at least 48 hours apart or ICD-10 diagnosis code for COPD or lung cancer at least 30 days apart during January 1, 2018, to

December 31, 2021. Index date was defined as the first claim or EHR with pneumonia/COPD/lung cancer diagnosis. Only patients with no pneumonia/COPD/lung cancer diagnosis in claims or EHR during preceding 12 months from index date were included. All patients were followed-up for 12 months from index date to examine the sex and racial and ethnic disparities in disease-specific resource use (pneumococcal or influenza vaccines/smoking cessation counseling, antibiotics within 2 days of pneumonia or COPD diagnosis, anticancer treatment within 60 days of lung cancer diagnosis).

RESULTS: In the pneumonia cohort (n = 239,800), significantly fewer male patients and Black patients received the pneumococcal or influenza vaccine during the follow-up period. In the COPD cohort (n = 167,775), significantly fewer female patients and White patients received smoking cessation counseling in the 12 months follow-up, whereas greater number of female patients and White patients received the pneumococcal or influenza vaccine during the follow-up period. In the lung cancer cohort (n = 5,957), significantly fewer male patients and Black patients received the pneumococcal or influenza vaccine during the follow-up period, whereas a greater number of male patients and White patients received anticancer treatment within 60 days of diagnosis. Significantly higher use of inpatient services was observed in black patients and male patients for all 3 cohort. Further, we will analyze vaccination status, intensive care unit care, mechanical ventilation use, and clinical outcomes (complications like sepsis, septic shock, acute respiratory failure, acute respiratory distress syndrome, pulmonary embolism, etc.; readmission rate, patients with lung cancer that required palliative care) across race, sex, and insurance type.

CONCLUSIONS: There are varied sex and racial and ethnic disparities in resource use of acute and chronic lung diseases.

SPONSORSHIP: Optum.

K00-K93 Diseases of the Digestive System

(eg, Crohn disease, ulcerative colitis)

K4 Comparing the real-world inflammatory bowel disease (IBD) surgeries and related expenditures between infliximab dose–optimized patients using therapeutic drug monitoring (TDM) vs no TDM control group, in a community-based gastroenterology practice

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BACKGROUND: Inflammatory bowel disease (IBD) includes Crohn disease and ulcerative colitis and involves chronic gastrointestinal inflammation, which can lead to permanent bowel damage. Infliximab (IFX) is an anti–tumor necrosis factor (TNF) for moderate to severe IBD to achieve remission and avoid poor outcomes, such as surgery. Therapeutic drug monitoring (TDM), the measurement of drug and antibody levels, may assist IFX dose optimization to avoid loss of response. TDM is cited by guidelines and recommended by expert consensus, but some payers restrict TDM as "investigational."

OBJECTIVE: To compare real-world IBD surgery rates and related expenditures in patients in whom IFX was optimized using Anser TDM as part of ongoing care compared with no TDM control, in a community gastrointestinal (GI) practice.

METHODS: Deidentified charts from a US-community GI practice were analyzed (aged 8-89) for patients with IBD treated with IFX (2016-2022). Matching records to Prometheus Laboratories Anser test results were tokenized. Two cohorts were structured, TDM as part of ongoing IBD care and no TDM. Groups were matched by propensity score, baseline disease, demographics, and comorbidities. Real-world outcomes for 12- and 24-months were accessible via Lynx.MD as IBD-related surgeries (IBD-SGY), mean IBD surgery expenditures ($SGY), and mean biologic expenditures ($B). Analysis was conducted, stratifying patients as all IFX, anti-TNF naive (TNF-N), and by select payers. IBD surgeries were recorded in patient charts as colectomies, surgeries for fistula, bowel perforations, drainage of abscesses, adhesiolysis, and other surgical GI procedures. Statistical analysis was completed by Lynx.MD.

RESULTS: The TDM (n = 35-337) and no TDM (n = 223-321) cohorts varied depending on the analysis criteria. Crohn disease was 2/3 and median age 36 to 39. For 12-months all IFX patients, IBD-SGY was 1% for TDM vs 7% for no TDM

(5.4%, P = 0.001) ($SGY $161.3 and $B $35.2K and $SGY $939.6 and $B $32.6K, respectively). For TNF-N, IBD-SGY was 1% and 7%, respectively (6%, P = 0.001) ($SGY $131.6 and $B $31.4K and $SGY $989.6 and $B $33.1K, respectively). For 24-months all patients, IBD-SGY was 4% for TDM vs 10% for no TDM (4%, P = 0.016) ($SGY $583.4 & $B $70.8K and $SGY $1,575.7 & $B $76.5K, respectively). For TNF-N, IBD-SGY was 4% vs 9%, respectively (5%, P = 0.06) ($SGY $597 & $B $67K and $SGY $1,523.9 & $B $70K, respectively).

CONCLUSIONS: Real-world outcomes for 12- and 24-months demonstrate that Anser IFX TDM had significantly lower rates of IBD surgeries and related mean expenditures for all patients, suggesting a value proposition for TDM supported by real-world data.

SPONSORSHIP: Prometheus Laboratories & Lynx.MD.

K13 Evaluating the cost of care and disease progression among patients with nonalcoholic steatohepatitis (NASH): A US cohort study

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BACKGROUND: Nonalcoholic steatohepatitis (NASH), also known as metabolic dysfunction-associated steatohepatitis, is characterized by buildup of fat in the liver with inflammation, hepatocellular damage, and fibrosis. Those with more advanced diseases are more likely to progress to cirrhosis. Although costs of care in NASH in the United States are substantial and higher among severe disease, how costs differ by NASH progression status is unclear.

OBJECTIVE: To describe the difference in annual health care costs among patients with NASH according to the occurrence, type, and timing of disease progression.

METHODS: Optum's deidentified Clinformatics Data Mart was used to identify adult patients without baseline cirrhosis, assessed 6 months before and 30 days following the first diagnosis for NASH within the study period (October 2015 to December 2022). All patients were followed until death, loss to follow-up, or study end. Progression was defined by the presence of cirrhosis, decompensated cirrhosis (DCC), liver transplant, or hepatocellular carcinoma over the follow-up. Total annual costs per person (2022 USD) were compared between those with vs without progression using Student's t-test and generalized linear models adjusting for baseline covariates. Among those with progression, effects of timing and type of progression were estimated. Adjusted longitudinal changes were also estimated.

RESULTS: A total of 19,419 patients without cirrhosis (mean [SD] age = 59.8 [13.4]) were followed for 3.2 (1.5) years. During this, 4,235 patients progressed, with most being DCC events and occurring at least 1 year into follow-up. Annual costs were greater per person with progression ($58,128 [102,626]) than without (n = 15,184, $20,031 [39,740]; P < 0.01) and remained significant when adjusted (relative risk=2.3 [95% CI = 2.2-2.4]). Although costs largely varied with timing of progression, highest costs were generally observed among those with hepatocellular carcinoma, followed by liver transplant, DCC, and cirrhosis. Relative to year 1, adjusted annual costs per person significantly increased from 6% to 49% from year 2 to 6 among those with progression; and among those without, only significant increases in years 5 (14%) and 6 (19%) were observed.

CONCLUSIONS: These data show that the burden of care for NASH is substantial, and compared with those without progression, the annual costs per person with progression are at least 2-fold higher, with the gap increasing over time. Therapies that slow progression may help alleviate the financial burden of managing NASH.

SPONSORSHIP: Madrigal Pharmaceuticals.

K14 Examining racial and socioeconomic disparities in clinical outcomes and health care resource utilization in patients with hepatocellular carcinoma: A real-world data study

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BACKGROUND: Hepatocellular carcinoma (HCC) is rapidly increasing in the United States, yet there is a lack of comprehensive real-world data on disparities in clinical outcomes and health care resource utilization (HCRU) based on race and ethnicity and socioeconomic status (SES) in the HCC space.

OBJECTIVE: To assess the relative impact of race and ethnicity and SES on clinical outcomes and HCRU in patients with HCC.

METHODS: A retrospective study was conducted using the Optum deidentified Market Clarity Dataset, which includes linked claims and electronic health records (EHR) of patients. The study included patients aged 40 years or older with an *International Classification of Diseases, Tenth Revision* C22x of HCC. The study period ranged from January 1, 2016, to March 31, 2023. Patients identified between January 1, 2017, and March 31, 2022, were considered, and the first HCC diagnosis was considered the index date. Only patients with 12-month pre- and post-index continuous medical and pharmacy eligibility or continuous clinical activity, no HCC diagnosis in the preceding 12 months from the index date,

and Alpha Fetoprotein (AFP) lab results in both baseline and follow-up period were included. The study evaluated changes in AFP levels as a surrogate for clinical outcome and all-cause HCRU over a 12-month follow-up period. The outcomes among different race and SES groups were compared using a post-hoc test for Kruskal-Wallis.

RESULTS: A total of 1,405 patients with HCC were included in the study, with a median age of 64 years and 72% male composition. The distribution of race and ethnicity was as follows: 11% Black, 11% Hispanic, 66% White, 6% Asian, and 6% unknown. White patients had relatively lower AFP lab values than Black patients at baseline (mean 75.34 vs 104.18; $P = 0.0004$). Additionally, higher AFP values were observed in Black patients even after 12 months of follow-up (mean 52.11 vs 123.27; $P < 0.0001$). The mean (SD) HCRU visits between White patients and Black patients were as follows: emergency department visits (1.68 [3.98] vs 3.03 [6.72]; $P = 0.01$), IP visits (7.94 [20.51] vs 8.23 [19.25]; $P = 0.9339$), outpatient visits (20.55 [34.84] vs 20.56 [33.77]; $P = 1$), and office/clinics visits (17.99 [26.26] vs 18.23 [44.81]; $P = 0.7366$). Outcomes among different SES groups are yet to be analyzed.

CONCLUSIONS: This real-world data study highlights the existence of racial disparities in clinical outcomes and HCRU between Black and White patients with HCC. Implementing tailored health care interventions can significantly reduce these racial imbalances.

SPONSORSHIP: Optum.

K15 Real-world adherence to obeticholic acid therapy for primary biliary cholangitis

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BACKGROUND: Adherence to therapy can be challenging, especially for patients with chronic conditions. Medication adherence rates for chronic therapies are usually around 50% and may vary depending on the disease state and certain patient and medication factors. Obeticholic acid (OCA), a selective, potent, farnesoid X receptor agonist, is indicated as second-line treatment for patients with primary biliary cholangitis (PBC) who do not respond to or who cannot tolerate ursodeoxycholic acid.

OBJECTIVE: To assess adherence to OCA therapy among patients with PBC in a large, real-world dataset.

METHODS: This retrospective, observational study was conducted using data from the Komodo Healthcare Map (TM) database from 2015 to 2023. Patients aged 18 years or older with a diagnosis of PBC (≥1 inpatient claim or ≥2 outpatient claims on separate days), who filled at least 2 consecutive prescriptions for OCA (index date = date of first claim for OCA) and were continuously enrolled in a medical and pharmacy health plan for 12 months pre- and post-index date, were included in the study. A subgroup of patients aligned with the current US Prescribing Information (USPI) was also analyzed. Adherence to OCA therapy was measured as the proportion of days covered (PDC) over a 1-year period following the index date. Mean PDC and PDC greater than or equal to 80% were assessed in the overall and USPI populations.

RESULTS: A total of 1,412 patients met the study criteria. In the overall population, the mean age (SD) was 55.1 (±10.4) years. Most patients were female (n = 1,284, 90.9%), and approximately half were enrolled in commercial insurance (n = 745, 52.8%). The mean PDC (SD) in the overall population was 77.1% (±28.6%), and 62.2% (n = 878) of patients had PDC greater than or equal to 80%. The USPI population (n = 411) had similar demographic characteristics to the overall population. The mean PDC (SD) in the USPI population was 78.1% (±28.3%), and 63.7% (n = 262) of patients had PDC greater than or equal to 80%.

CONCLUSIONS: In this study population with PBC on OCA therapy, more than 60% of patients had PDC greater than or equal to 80% over the 12 months following OCA initiation. This is consistent with other estimates of medication adherence for chronic diseases and other independent OCA studies. As OCA use has been associated with improved long-term clinical outcomes, management of patients on OCA to support medication adherence and persistence is important.

SPONSORSHIP: Intercept Pharmaceuticals.

K16 Liver fibrosis is associated with economic burden related to cardiovascular disease in patients with nonalcoholic steatohepatitis: The unCoVer-NASH longitudinal cohort study

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BACKGROUND: There is a knowledge gap relating to economic burden of cardiovascular (CV) disease (CVD) in patients with nonalcoholic steatohepatitis (NASH).

OBJECTIVE: To assess the burden of CVD in patients with NASH stratified by Fibrosis-4 Index (FIB-4), using real-world US health care data (TriNetX).

METHODS: Patients (aged ≥18 years) were identified using the *International Classification of Diseases, Tenth Revision, Clinical Modification* code for NASH (October 2015 to June 2022) and required at least 1 FIB-4 measurement(s) calculated from data obtained 180 days prior to, or 30 days after, NASH diagnosis (index date); at least 12 months of data prior to index date (baseline period); and no evidence of cirrhosis during baseline or at index date. FIB-4 categories were low (<1.30), intermediate (1.30-2.67), and high (>2.67). Economic burden during follow-up (index date to end of enrollment, death, or study end) was analyzed for patients with at least 6 months of follow-up data available and was estimated as health care cost (total, medical, and pharmacy costs from claims data) and resource use (number of visits by type and length of inpatient stay) associated with CVD-related diagnosis or procedure records. Cost and hospitalization distribution was also analyzed for liver-related and other causes. Statistical difference for high vs low FIB-4 was assessed after adjusting for CV risk factors and events in baseline.

RESULTS: Of 579 patients, 78 had high, 166 had intermediate, and 335 had low FIB-4. Mean age was 60, 56, and 44 years, respectively, and most were female (54%-74%). CV-related resource use increased with FIB-4 score (length of stay: 12.7, 2.5, and 1.5 days; inpatient visits: 1.0, 0.5, and 0.3 per person per year [PPPY] for high, intermediate, and low FIB-4, respectively). Economic burden was significantly higher for high vs low FIB-4 after adjustment. CVD-related health care and medical costs were higher for high vs low FIB-4: $7,775 vs $1,828 ($P<0.0001$) and $7,228 vs $1,661 ($P<0.0001$) PPPY, respectively. Economic burden of CV-related medical costs and hospitalizations were observed in addition to increased liver-related burden, when the distribution by CV, liver, and other cause based on primary diagnosis was assessed. CV- and liver-related costs and hospitalizations increased with FIB-4 score.

CONCLUSIONS: Economic burden of CVD in patients with NASH was higher in those with higher baseline FIB-4 score, indicating a direct relationship between CV-related burden and hepatic fibrosis. Further assessment of the intermediate FIB-4 group is warranted to assess burden in this group.

SPONSORSHIP: Novo Nordisk A/S.

K17 A real-world observational study on the health care resource utilization of patients with primary biliary cholangitis with and without cirrhosis in the United States

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BACKGROUND: Estimates of the health care resource utilization (HCRU) of patients diagnosed with primary biliary cholangitis (PBC), a chronic, progressive autoimmune liver disease, in the United States are limited.

OBJECTIVE: To assess HCRU of patients diagnosed with PBC in the United States using a large real-world database.

METHODS: Adults with at least 1 inpatient claim or at least 2 outpatient claims indicating a PBC diagnosis (January 1, 2015-January 2, 2023; index date: date of first claim) were selected from the Komodo Healthcare Map (TM) administrative claims database. Patients were required to be enrolled in a medical and pharmacy plan for 12 months pre-index with at least 1 day post-index. The study population was stratified based on presence of pre-index cirrhosis. During the follow-up period, all-cause, liver-related (alcoholic-associated liver disease, toxic/inflammatory liver disease, chronic/viral hepatitis, hepatic failure, fibrosis, cirrhosis, hepatic decompensation, liver neoplasms, liver infections, liver complications, liver injury, other liver diseases), and PBC-related (pancreatobiliary disorders) hospitalizations and emergency department (ED) visits not leading to

inpatient visits were measured. Disease-specific HCRU was flagged based on *International Classification of Diseases, Ninth/Tenth Revision* codes in the first position.

RESULTS: Of 29,758 patients diagnosed with PBC (mean age: 59.2 years; 80.3% female; 48.6% with ursodeoxycholic acid treatment), 21.6% (mean age: 59.3 years; 68.3% female) had cirrhosis. Liver-related comorbidities were more prevalent among those with cirrhosis than among those without cirrhosis (nonalcoholic steatohepatitis: 17.9% vs 7.2%; chronic hepatitis: 7.8% vs 5.5%; viral hepatitis: 17.2% vs 4.9%; alcohol-associated liver disease: 24.1% vs 2.1%). In the overall population (mean ± SD follow-up: 34.3 ± 26.9 months), annualized rates of at least 1 all-cause, liver-related, and PBC-related hospitalization were 20.8%, 10.1%, and 3.7%, respectively; among those with cirrhosis, rates were 41.6%, 28.6%, and 9.0%, respectively; and among those without cirrhosis, rates were 15.1%, 4.9%, and 2.2%, respectively. Among patients with all-cause, liver-related, and PBC-related hospitalizations (annualized), 60.2%, 60.1%, and 48.5%, respectively, had additional hospitalization(s) with higher rates observed among those with cirrhosis (69.3%, 65.5%, and 51.2%, respectively). Similar trends were observed for ED visits.

CONCLUSIONS: In this large sample of patients (approximately 30,000) diagnosed with PBC, annual HCRU was high, with patients having multiple hospitalizations, particularly among those with cirrhosis, underscoring an unmet need for preventing PBC progression.

SPONSORSHIP: Intercept Pharmaceuticals.

K18 Economic burden of patients with primary biliary cholangitis by line of therapy in the United States

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BACKGROUND: Primary biliary cholangitis (PBC) is a chronic cholestatic liver disease associated with adverse health outcomes, including cirrhosis and end-stage liver disease. There are limited data on economic burden of PBC in the United States.

OBJECTIVE: To describe economic burden among patients (pts) with PBC in the United States by line of therapy.

METHODS: This retrospective study used IQVIA PharMetrics Plus data (2016-2022). Three nonmutually exclusive cohorts were created: (1) pts with newly diagnosed PBC without any PBC treatment (Tx) during entire follow-up (newly diagnosed), (2) pts who initiated first-line Tx (1L), and (3) pts who initiated second-line or more Tx (2L+). Index date was defined as initial PBC diagnosis, 1L Tx initiation, and 2L Tx initiation, respectively. For each cohort, baseline (12-month pre-index) characteristics were described; per patient per year (PPPY) health care resource utilization and PPPY health care costs post-index (index to next-line Tx initiation [1L cohort only], death, end of continuous enrollment, or end of data, whichever the earliest) were summarized.

RESULTS: A total of 609, 1,659, and 181 pts were included in the newly diagnosed, 1L, and 2L+ cohorts, respectively. Across cohorts, the mean age at index was 54 years, more than 77% pts were female, and the mean Charlson Comorbidity Index was 1.4, 2.1, and 2.5, respectively. Median post-index duration was 15.0, 18.5, and 15.2 months, respectively. Baseline PPPY total health care costs were $15,687, $14,470, and $14,288 for the newly diagnosed, 1L and 2L+ cohorts, respectively. Health care costs post-index were higher than pre-index ($54,226, $18,460, and $71,356, respectively). In the newly diagnosed cohort, the largest component was inpatient (IP) cost: mean PPPY IP, outpatient (OP), and emergency department costs were $37,974 , $14,298, and $1,855, respectively; 25% of pts had at least 1 IP visit. For the 1L cohort, the main driver was OP cost: mean PPPY IP, OP, emergency department, and PBC Tx costs were $5,854, $9,377, $887, and $2,251, respectively; 12% of pts had at least 1 IP visit. For the 2L+ cohort, the largest cost component was PBC Tx cost: mean PPPY IP, OP, ED, and PBC Tx costs were $6,898, $9,613, $1,052, and $53,698, respectively; 16% had at least 1 IP visit.

CONCLUSIONS: Substantial economic burden was observed in pts with PBC across lines of therapy. Pts left untreated after diagnosis had high IP costs; those receiving 1L and 2L+ Txs had lower IP costs but higher Tx costs. These findings highlight an unmet need for more cost-effective therapies in this pt population.

SPONSORSHIP: Ipsen.

K19 Treatment patterns, barriers, and associated costs reported by patients with chronic idiopathic constipation in the United States: Analysis from a cross-sectional observational study

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BACKGROUND: Chronic idiopathic constipation (CIC) is a common disorder characterized by reduced stool frequency, hard stools, and/or difficult defecation. Data on patients' real-world experiences of CIC management in the United States are limited.

OBJECTIVE: To provide a better understanding of patients' experiences regarding access to medications for CIC and their associated costs.

METHODS: This was a cross-sectional, observational study conducted in the United States (October 2022 to June 2023) in adult patients with CIC. Board-certified gastroenterologists, advanced practice providers, and primary care physicians recruited up to 8 patients each (aged ≥18 years). Patients completed a survey on their demographics, treatment patterns, important attributes of treatments, and associated barriers and costs.

RESULTS: Overall, 230 patients completed the survey. The mean (SD) age of patients was 49.7 (16.2) years; most patients were female (64.3%) and White (68.3%). Of those who responded (n = 198), the most common over-the-counter (OTC) medications currently taken by patients were polyethylene glycol (49.5%; n = 98), psyllium (31.8%; n = 63), bisacodyl (19.2%; n = 38), and senna (18.2%; n = 36). Of those who responded (n = 153), the most common prescription medications currently taken by patients were linaclotide (47.7%; n = 73), plecanatide (19.0%; n = 29), lubiprostone (16.3%; n = 25), and prucalopride (9.2%; n = 14). Patients considered symptom relief and treatment affordability the most important attributes when choosing a treatment, with 83.8% (192/229) and 80.7% (184/228) of patients, respectively, considering these as "very" or "extremely" important. Of those who responded (n = 135), the most common barriers to treatment reported by patients were "having trouble getting a health care professional (HCP) appointment" (36.3%; n = 49), "not aware that prescription medications were available for CIC" (34.8%; n = 47), and "CIC prescription medication was not covered by insurance" (25.9%; n = 35). The greatest expenses to patients (30-day average costs in US$ [SD]) were costs of seeing an HCP ($30.3 [49.4]), costs of copayment for prescription medications ($28.4 [40.0]), and costs of OTC medications ($24.3 [20.3]).

CONCLUSIONS: A substantial proportion of patients reported a lack of awareness of prescription medications for CIC and no insurance coverage of those medications. The highest out-of-pocket costs for patients were related to seeing an HCP and those associated with OTC and prescription medications. These factors may affect patient access to therapies for CIC.

SPONSORSHIP: Takeda Pharmaceuticals USA, Inc.

L00-L99 Diseases of the Skin and Subcutaneous Tissue

(eg, eczema, psoriasis)

L4 Does ruxolitinib cream reduce corticosteroid and biologic use in patients with a history of moderate to severe atopic dermatitis?

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BACKGROUND: In phase 3 studies of adults/adolescents with atopic dermatitis (AD; TRuE-AD1/TRuE-AD2), ruxolitinib cream was well tolerated and demonstrated superior efficacy compared with vehicle regardless of previous use of topical or systemic therapy.

OBJECTIVE: To examine treatment patterns after initiating ruxolitinib cream among patients with a history of moderate to severe AD based on previous use of very potent topical corticosteroids, systemic therapies, or phototherapy.

METHODS: This analysis used data from the Healthcare Integrated Research Database to identify patients with AD who received ruxolitinib cream between October 2021 and July 2022. Patients with moderate to severe AD were categorized as receiving systemic therapies, very potent topical corticosteroids, or phototherapy at baseline. The baseline and follow-up periods were the 6 months before and the 6 months after the index date, respectively.

RESULTS: A total of 749 patients (aged ≥12 years) with AD and at least 1 claim for ruxolitinib cream were included: mean (SD) age was 41.5 (17.01) years, 63.1% were female, and 59.8% were White. During the follow-up period, the mean (SD) number of ruxolitinib cream fills was 1.7 (1.11); 73.6% did not receive new classes of AD treatment other than ruxolitinib cream. Compared with baseline, there was a decrease in the use of topical corticosteroid (66.6% vs 33.1%), topical

calcineurin inhibitor (17.8% vs 7.6%), and topical phosphodiesterase-4 inhibitor (4.9% vs 2.3%) during the follow-up period. Oral corticosteroid use decreased from 44.1% to 20.7%; the mean cumulative prednisone-equivalent dose decreased by 49.4%, from 163.0 mg to 82.5 mg. Among 298 patients with claims for biologics within a 6-month period before ruxolitinib cream initiation, 17.4% did not receive biologics at follow-up; of 451 biologic-naive patients, 88.5% continued to not receive biologics during follow-up.

CONCLUSIONS: Within the first 6 months of initiation of ruxolitinib cream, claims analyses revealed reductions in other topical therapies and overall corticosteroid burden. Furthermore, most biologic-naive patients did not escalate to biologics; more than 1 in 6 patients with biologics at baseline did not receive a subsequent biologic therapy. The short-term use of ruxolitinib cream may reduce the need for typical therapies for patients with a history of moderate to severe AD.

SPONSORSHIP: Incyte Corporation.

L5 The impact of seborrheic dermatitis on quality of life: A Dermatology Life Quality Index benchmarking analysis

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BACKGROUND: Seborrheic dermatitis (SD) is a chronic, recurrent dermatologic disease characterized by scaling patches and persistent itch. Although there are data to support the quality of life (QOL) impacts of other dermatologic conditions, there is no published evidence for SD in US patients. To address this gap, STRATUM, a phase 3 clinical trial, assessed QOL data in moderate to severe SD using the Dermatology Life Quality Index (DLQI). The DLQI is a patient-reported questionnaire used to assess the impact of skin conditions on QOL in which higher scores indicate greater impact.

OBJECTIVE: To quantify the impact of SD on QOL and assess its impact relative to other dermatologic conditions using published DLQI data.

METHODS: A targeted literature review was conducted in PubMed to identify studies with DLQI data for plaque psoriasis (PsO) and atopic dermatitis (AD). Mean baseline DLQI scores were extracted from included studies and evaluated by condition and disease severity using descriptive statistics. The mean baseline DLQI score from the STRATUM trial was qualitatively benchmarked against DLQI scores identified in the targeted literature review.

RESULTS: A total of 23 studies were included in data extraction (15 for PsO; 8 for AD). Baseline patient characteristics were similar across studies, with disease severity measures differing by study population. Mean baseline DLQI scores for PsO ranged from 6.7 to 15.1, and mean baseline DLQI scores for AD ranged from 7.8 to 17.7. Studies evaluating patients with mild-to-moderate disease reported DLQI scores of 6.7 to 9.8 for PsO and 7.8 for AD. DLQI scores for moderate to severe PsO and AD were generally higher (PsO = 7.7 to 15.1; AD = 12.4 to 17.7). The mean baseline DLQI score for patients with SD in the STRATUM trial was 5.4 [standard deviation = 4.19], aligning with a moderate impact on QOL.

CONCLUSIONS: The results of our review suggest that relative to PsO and AD, QOL impacts associated with moderate to severe SD are generally comparable with those with mild to moderate PsO and AD, a patient population typically managed with topical therapy. Our findings provide new insights into the significant patient impacts of SD relative to other dermatologic conditions.

SPONSORSHIP: Arcutis Biotherapeutics, Inc.

L6 Impact of roflumilast foam 0.3% on patient-reported quality of life in seborrheic dermatitis: An analysis of STRATUM data for patients unresponsive or intolerant to topical corticosteroids

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BACKGROUND: Roflumilast foam 0.3% (roflumilast) has demonstrated efficacy and tolerability in the phase 3 clinical trial of patients with moderate to severe seborrheic dermatitis (SD) (STRATUM).

OBJECTIVE: To assess the quality of life impact of roflumilast vs vehicle in patients who reported an inadequate response, intolerance, or contraindication to topical corticosteroids (TCS).

METHODS: Baseline and follow-up Dermatology Life Quality Index (DLQI) data from the STRATUM trial were collected for patients aged 17 years and older with moderate to severe SD who had an inadequate response, intolerance, or contraindication to TCS. PRO endpoints included percentage change from baseline in DLQI score and achievement of a minimal important difference (defined as at least a 4-point reduction in baseline DLQI score) for roflumilast vs vehicle at weeks 2, 4, and 8. Differences in change from baseline

DLQI scores were assessed using the Kruskal-Wallis rank sum test. The Cochran–Mantel–Haenzel test was used to assess differences in the proportion of patients achieving binary endpoints between treatment arms in each subgroup.

RESULTS: A total of 166 patients at baseline (113 roflumilast, 53 vehicle) were included in the subgroup analysis. At each time point, percentage change from baseline in DLQI score was significantly larger for roflumilast-treated patients relative to vehicle (week 2: −45.65% [95% CI = −54.44% to −35.46%] vs −13.62% [95% CI = −28.82% to 0.64%]; $P < 0.001$; week 4: −55.35% [95% CI = −64.88% to −42.38%] vs −25.08% [95% CI = −37.25% to −12.21%]; $P < 0.001$; week 8: −61.93% [95% CI = −71.38% to −49.96%] vs −37.06% [95% CI = −53.10% to −21.30%]; $P = 0.001$). Treatment with roflumilast significantly increased the odds of achieving a minimal important difference in DLQI from baseline to weeks 2, 4, or 8 (common odds ratio = 6.97; 95% CI = 3.97-12.24; $P < 0.001$).

CONCLUSIONS: These results suggest that roflumilast foam 0.3% provides significant and meaningful quality-of-life benefits for patients with moderate to severe SD with an inadequate response, intolerance, or contraindication to TCS.

SPONSORSHIP: Arcutis Biotherapeutics, Inc.

L7 Effect of roflumilast foam 0.3% on quality of life in patients with seborrheic dermatitis: Patient-reported outcomes from the STRATUM phase 3 trial

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BACKGROUND: STRATUM is a phase 3 clinical trial that evaluated the safety and efficacy of roflumilast foam 0.3% in patients with moderate to severe seborrheic dermatitis (SD). Patient-reported outcomes included the Dermatology Life Quality Index (DLQI), a validated measure used to assess quality of life (QOL) in patients with skin disease. Meaningful reductions in DLQI score are associated with a higher QOL, with a score of 0 or 1 indicating no effect on QOL.

OBJECTIVE: To evaluate the effects of roflumilast foam 0.3% on patient-reported QOL in patients with SD.

METHODS: This analysis evaluated DLQI data collected from STRATUM patients aged 17 years or older with moderate to severe SD. Patients received roflumilast foam 0.3% or vehicle foam once daily for 8 weeks. Patient-reported outcome endpoints included percentage change from baseline in DLQI score, achievement of a minimal important difference (defined as at least a 4-point reduction in baseline DLQI score), and achievement of a DLQI score of 0 or 1, for roflumilast vs vehicle at weeks 2, 4, and 8. The Cochran–Mantel–Haenzel test was used to assess differences in the proportion of patients achieving binary endpoints between treatment arms. Differences in change from baseline DLQI scores were assessed using analysis of covariance.

RESULTS: A total of 430 patients were included in the analysis (290 for roflumilast; 140 for vehicle). At each time point, percentage change from baseline DLQI score was significantly larger for roflumilast-treated patients relative to vehicle (week 2: −48.81 [8.24] vs −17.23 [8.94]; $P < 0.0001$; week 4: 52.86 [6.64] vs 33.81 [7.24]; $P = 0.0011$; week 8: −61.74 [7.23] vs −45.20 [7.82]; $P = 0.0065$). Compared with vehicle, treatment with roflumilast significantly increased the odds of achieving a minimal important difference in DLQI score from baseline at weeks 2, 4, or 8 (odds ratio = 3.18; 95% CI = 2.19-4.62; $P < 0.0001$). Roflumilast significantly increased the odds of achieving a DLQI score of 0 or 1 compared with vehicle at weeks 2, 4, or 8 (odds ratio = 2.07; 95% CI = 1.56-2.75; $P < 0.0001$).

CONCLUSIONS: As early as week 2, treatment with roflumilast demonstrated a significantly larger reduction (improvement) in DLQI scores compared with vehicle, with improvements maintained through week 8. Relative to vehicle, the roflumilast group had a higher likelihood of achieving meaningful improvement in QOL and reduction of DLQI scores to levels that reflect no patient impact. The results suggest that roflumilast foam 0.3% has a meaningful impact on the QOL burden associated with SD.

SPONSORSHIP: Arcutis Biotherapeutics, Inc.

L8 Rapid and early onset of itch relief with tapinarof cream 1% once daily in two pivotal phase 3 trials in adults and children down to age 2 years with atopic dermatitis

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BACKGROUND: Itch is the most bothersome symptom for patients with atopic dermatitis (AD) and has a significant negative impact on health-related quality of life. Rapid onset of pruritus relief with sustained efficacy is a key outcome for AD therapies. In ADORING 1 and 2, 2 identical phase 3, double-blind, vehicle-controlled trials, tapinarof cream 1% (VTAMA, Dermavant Sciences, Inc.) once daily (QD) demonstrated efficacy and was well tolerated in adults and children aged 2 years or older with AD.

OBJECTIVE: To evaluate time to onset of itch relief in the pivotal phase 3 trials.

METHODS: In ADORING 1 and 2, patients with a Validated Investigator Global Assessment for Atopic DermatitisTM score of 3 or more, an Eczema Area and Severity Index score of 6 or more, and body surface area involvement of 5%–35% were randomized 2:1 to tapinarof cream or vehicle QD for 8 weeks. Itch relief was assessed by changes in Peak Pruritus Numerical Rating Scale (PP-NRS) score, daily and by visit, from baseline through week 8. PP-NRS considers itch over the past 24 hours; lower scores indicate less pruritus.

RESULTS: A total of 407 and 406 patients were randomized in ADORING 1 and 2, respectively. At baseline, mean PP-NRS scores were 6.7 and 6.8 in both trials, respectively. For daily evaluations of itch from baseline, greater reductions in mean PP-NRS scores for tapinarof vs vehicle were observed as early as day 1, 24 hours after initial application in ADORING 1 (–1.2 vs –0.9), and day 2 in ADORING 2 (–1.6 vs –1.4). Daily itch improvements continued through week 8 in both trials. Statistically significant reductions in mean weekly PP-NRS scores occurred as early as week 1 (earliest assessment) with tapinarof vs vehicle (–2.0 vs –1.2 [$P < 0.0001$]) and (–2.0 vs –1.3 [$P = 0.0010$]) in ADORING 1 and 2, respectively. Significantly greater reductions in mean PP-NRS scores with tapinarof vs vehicle were seen for all visits through week 8 (–4.1 vs –2.6 and –4.1 vs –2.4 [both $P < 0.0001$]).

CONCLUSIONS: Tapinarof cream 1% QD demonstrated rapid, significant, and clinically meaningful pruritus relief from 24 hours after initial application, with improvements increasing through week 8 in both trials in adults and children aged 2 years or older with AD.

SPONSORSHIP: Dermavant Sciences, Inc.

L9 Tapinarof cream 1% once daily is efficacious for the treatment of atopic dermatitis in patients with skin of color down to age 2 years in 2 pivotal phase 3 trials

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BACKGROUND: Patients with atopic dermatitis (AD) and skin of color can have heterogeneous presentations and treatment responses. In the pivotal phase 3 ADORING 1 and 2 trials, tapinarof cream 1% once daily (QD) was significantly efficacious and well tolerated vs vehicle in adults and children aged 2 years or older with AD.

OBJECTIVE: To report efficacy of tapinarof cream vs vehicle in the phase 3 ADORING 1 and 2 trials among adults and children by self-identified race.

METHODS: In ADORING 1 and 2, patients with a Validated Investigator Global Assessment for Atopic DermatitisTM (vIGA-ADTM) score of 3 or more, an Eczema Area and Severity Index (EASI75) score of 6 or more, and body surface area involvement of 5%–35% were randomized 2:1 to tapinarof cream or vehicle QD for 8 weeks. The primary efficacy endpoint was a vIGA-ADTM score of 0 (clear) or 1 (almost clear) and an at least 2-grade improvement from baseline at week 8. Secondary endpoints included proportion of patients with a 75% or more improvement in EASI75.

RESULTS: Of 407 and 406 randomized patients, 8.8%–15.3% were Asian, 26.5%–35.0% were Black, 44.8%–56.8% were White, and 2.7%–5.2% were Other groups (including

American Indian or Alaska Native, Native Hawaiian or Pacific Islander, or multiple races) across trials. Patients with Fitzpatrick skin types IV, V, and VI represented 23.8% to 25.1%, 20.6% to 22.2%, and 7.6% to 8.9%, respectively, of patients (>50% in both trials). Across trials, vIGA-ADTM responses (ranges) for tapinarof vs vehicle were Asian (39.5%-48.9% vs 3.7%-18.5%), Black (43.1%-47.0% vs 17.5%-24.1%), White (49.4%-52.1% vs 12.2%-14.5%), and Other (26.0%-44.8% vs 0.0%-40.2%). EASI75 responses for tapinarof vs vehicle were Asian (47.6%-76.6% vs 17.7%-20.2%), Black (48.9%-55.3% vs 25.7%-30.0%), White (61.4%-67.8% vs 19.6%-20.7%), and Other (38.3%-63.3% vs 0.0%-40.6%).

CONCLUSIONS: Tapinarof cream 1% QD was consistently efficacious among all racial groups, including patients with skin of color, who were highly represented in these trials.

SPONSORSHIP: Dermavant Sciences, Inc.

L10 Impact of a multiyear initiative for managed care payer professionals to increase their understanding of atopic dermatitis (AD)

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BACKGROUND: Atopic dermatitis (AD) can present serious medical complications and difficulties and is often a complex condition for patients to navigate clinically, economically, and from a humanistic perspective. Managed care professionals need to have a comprehensive understanding of AD treatments and consequences to ensure cost-effectiveness, improve health care quality, and facilitate access to effective treatments for individuals dealing with AD.

OBJECTIVE: To describe the impact of a multi-year (2021-2023) and multi-pronged educational initiative to address the knowledge gaps that may impede access to high quality care for those living with AD by educating managed care and payer professionals.

METHODS: Impact Education, LLC, and the National Eczema Association held 3 national webcast series, 2 PayerTalkCE series, and a compendium of case studies. These educational initiatives were created based on the guidance and best practices developed from previously held roundtable discussions with payers, providers, and community advocates.

RESULTS: Overall, 882 managed care professionals participated in 2 webinars series, with 628 completing for CE credit. In the 2021-2022 webcast series, there was a 60 percentage-point increase in learners' ability to identify the most burdensome symptoms of AD (20% pre-event, 80% post-event). In the 2022-2023 webcast series, learners increased their knowledge of the clinical and lived experience heterogeneity of AD. There was an increase in 42 percentage points between a pre- and post-survey question ($P < 0.01$) on how AD affects the pediatric population. A 15 percentage-point increase was also seen in a second knowledge-based outcomes question related to moderate to severe AD. Series participants estimated more than a quarter of a million (>250,000) patients are expected to benefit from program learnings.

CONCLUSIONS: A multi-year educational initiative, developed through collaboration among various stakeholders, successfully educates managed care payer professionals on the complexities of AD, thereby enhancing their capacity to implement best practices effectively.

SPONSORSHIP: This program was supported by independent educational grants from Incyte Corporation, Pfizer Inc., Sanofi Genzyme, and Regeneron Pharmaceuticals, Inc.

L18 A matching-adjusted indirect comparison of the efficacy of bimekizumab (IL17A/F inhibitor) and ustekinumab (IL-12/23 inhibitor) at 52 weeks for the treatment of psoriatic arthritis

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BACKGROUND: A matching-adjusted indirect comparison (MAIC) was conducted to assess the relative efficacy of bimekizumab (BKZ) (160 mg Q4W) and ustekinumab (UST) (45 mg or 90 mg Q12W) in patients (pts) with psoriatic arthritis (PsA) who were biologic disease-modifying anti-rheumatic drug-naive (bio-n) or tumor necrosis factor inhibitor-experienced (TNFi-exp) at 52 weeks (Wk52).

OBJECTIVE: To assess the comparative efficacy of BKZ 160 mg Q4W vs UST 45 mg or 90 mg Q12W in bio-n or TNFi-exp pts with PsA at Wk52.

METHODS: Relevant trials were systematically identified. Individual pt data from BE OPTIMAL (NCT03895203; n = 431) and BE COMPLETE (NCT03896581; n = 260) were matched with summary data of bio-n pts from PSUMMIT 1 (NCT01009086; 45 mg, n = 205; 90 mg; n = 204) and a subset of TNFi-exp pts from PSUMMIT 2 (NCT01077362; 45 mg, n = 60; 90 mg; n = 58), respectively. UST dose (ie, 45 mg vs 90 mg) is based on pt weight. Pts from BKZ trials were reweighted using a logistic regression based on sex, age, methotrexate use, Health Assessment Questionnaire-Disability Index, percentage with psoriasis affecting at least 3% body surface area, swollen and tender joint counts, and disease duration to match baseline characteristics of UST trial pts. Adjustment variables were selected based on expert consensus (n = 5) and adherence to established MAIC guidelines. Nonplacebo-adjusted comparisons of recalculated BKZ and UST Wk52 outcomes for American College of Rheumatology (ACR) 20/50/70 index nonresponder imputation outcomes were reported as odds ratios. Significance was determined by the exclusion of 1 in 95% CIs.

RESULTS: In bio-n pts, BKZ (45 mg, effective sample size [ESS] = 147; 90 mg, ESS = 153) had a significantly greater likelihood of response at Wk52 than UST 45/90 mg for ACR20 (45 mg: odds ratio [95% CI]: 2.14 [1.35-3.40], $P = 0.001$; 90 mg: 1.98 [1.24-3.16], $P = 0.004$), ACR50 (45 mg: 2.74 [1.75-4.29], $P < 0.001$; 90 mg: 2.29 [1.48-3.55], $P < 0.001$), and ACR70 (45 mg: 3.33 [2.04-5.46], $P < 0.001$; 90 mg: 3.05 [1.89-4.91], $P < 0.001$). In TNFi-exp pts, BKZ (45 mg, ESS = 102; 90 mg, ESS = 71) had a significantly greater likelihood of response at Wk52 than UST 45/90 mg for ACR20 (45 mg: 4.17 [2.13-8.16], $P < 0.001$; 90 mg: 4.19 [2.07-8.49], $P < 0.001$), ACR50 (45 mg: 5.00 [2.26-11.05]; $P < 0.001$; 90 mg: 3.86 [1.70-8.79]; $P < 0.001$), and ACR70 (45 mg: 9.85 [2.79-34.79], $P < 0.001$; 90 mg: 6.29 [1.98-20.04]; $P = 0.002$).

CONCLUSIONS: Using MAIC, BKZ showed greater likelihood of efficacy than UST in achieving ACR response in bio-n pts and TNFi-exp pts with PsA at Wk52. These data provide provisional evidence to support therapeutic choices in the absence of head-to-head comparative trials.

SPONSORSHIP: UCB Pharma.

L19 A matching-adjusted indirect comparison of the efficacy of bimekizumab (IL17A/F inhibitor) and risankizumab (IL-23 inhibitor) at 52 weeks for the treatment of psoriatic arthritis

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BACKGROUND: Bimekizumab (BKZ), a selective inhibitor of interleukin (IL)-17F in addition to IL-17A, has demonstrated efficacy and safety in patients (pts) with active psoriatic arthritis (PsA) in phase 3 trials BE OPTIMAL (NCT03895203) and BE COMPLETE (NCT03896581). Risankizumab (RIS) is an IL-23 inhibitor approved for treatment of active PsA. The relative efficacy of BKZ (160 mg Q4W) and RIS (150mg Q12W) in pts with PsA who were biologic disease-modifying antirheumatic drug-naive (bio-n) or tumor necrosis factor inhibitor-experienced (TNFi-exp) was assessed at 52 weeks (Wk52) using a matching-adjusted indirect comparison (MAIC).

OBJECTIVE: To assess the comparative efficacy of BKZ 160 mg Q4W vs RIS 150 mg Q12W in bio-n or TNFi-exp pts with PsA at Wk52.

METHODS: Relevant trials were systematically identified. For bio-n pts, individual patient data from BE OPTIMAL (n = 431) were matched with summary data from KEEPsAKE 1 (NCT03675308; n = 483). For TNFi-exp pts, individual patient data from BE COMPLETE (n = 260) were matched with TNFi-exp subgroup summary data from KEEPsAKE 2 (NCT03671148; n = 105). To adjust for cross-trial differences, pts from the BKZ trials were reweighted to match baseline characteristics of the RIS trial pts. Weights were determined using a logistic regression based on sex, age, methotrexate use, Health Assessment Questionnaire-Disability Index, percentage with psoriasis affecting at least 3% body surface area, swollen and tender joint counts, and disease duration. The adjustment variables were selected based on expert consensus (n = 5) and adherence to established MAIC

guidelines. Recalculated BKZ Wk52 outcomes for American College of Rheumatology (ACR)20/50/70 and minimal disease activity (MDA) index (nonresponder imputation) were compared with RIS outcomes via nonplacebo-adjusted comparisons and were reported as odds ratios. Significance was determined by the exclusion of value 1 from the 95% CIs.

RESULTS: In bio-n pts, BKZ (effective sample size = 231) had a significantly greater likelihood of response at Wk52 than RIS for ACR50 (odds ratio [95% CI] = 1.52 [1.11-2.09]; P = 0.009) and ACR70 (1.80 [1.29-2.51]; P < 0.001). In TNFi-exp pts, BKZ (effective sample size = 162) had a significantly greater likelihood of response at Wk52 than RIS for ACR20 (1.78 [1.08-2.96]; P = 0.025), ACR50 (3.05 [1.74-5.32]; P < 0.001), ACR70 (3.69 [1.82-7.46]; P < 0.001), and MDA (2.43 [1.37-4.32]; P = 0.003).

CONCLUSIONS: Using MAIC, BKZ demonstrated greater likelihood of efficacy in most ACR and MDA outcomes than RIS in bio-n pts and TNFi-exp pts with PsA at Wk52. These data provide provisional evidence to support therapeutic choices in the absence of head-to-head comparative trials.

SPONSORSHIP: UCB Pharma.

L25 Tapinarof cream 1% once daily: Significant efficacy in atopic dermatitis in two phase 3 trials in adults and children down to age 2 years

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BACKGROUND: ADORING 1 and 2 were 2 identical phase 3, randomized, double-blind, vehicle-controlled trials of tapinarof cream 1% (VTAMA, Dermavant Sciences, Inc.) once daily (QD) in adults and children aged 2 years or older with atopic dermatitis (AD).

OBJECTIVE: To report pivotal phase 3 efficacy and safety from ADORING 1 and 2.

METHODS: Patients with a Validated Investigator Global Assessment for Atopic DermatitisTM (vIGA-ADTM) score of at least 3, Eczema Area and Severity Index (EASI) score of at least 6, and body surface area involvement of 5%-35% were randomized to tapinarof cream or vehicle QD for 8 weeks. The primary efficacy endpoint was vIGA-ADTM response (score of clear [0] or almost clear [1] and ≥2-grade improvement from baseline at week 8). Secondary efficacy endpoints included at least 75% improvement in EASI score (EASI75) and proportion of patients (aged ≥12 years) with baseline Peak Pruritus Numerical Rating Scale score of at least 4 achieving at least 4-point reduction at week 8. Safety assessments included the incidence of adverse events (AEs).

RESULTS: A total of 407 and 406 patients were randomized in ADORING 1 and 2, respectively. At baseline, 84.%-89.9% of patients had a vIGA-ADTM score of 3 (moderate), mean EASI score of 12.5-13.3, and mean body surface area affected of 16.7%-16.9% across trials. At week 8, primary and secondary efficacy endpoints were met with statistical significance with tapinarof vs vehicle: vIGA-ADTM response (45.4% vs 13.9% and 46.4% vs 18.0% [both P < 0.0001]), EASI75 response (55.8% vs 22.9% and 59.1% vs 21.2% [both P < 0.0001]), and at least 4-point reduction in Peak Pruritus Numerical Rating Scale (55.8% vs 34.2% [P = 0.0366] and 52.8% vs 24.1% [P = 0.0015]), in ADORING 1 and 2, respectively. AEs were mostly mild or moderate; the most frequent (≥5% any group) were folliculitis, headache, and nasopharyngitis. Trial discontinuation rates because of AEs were lower with tapinarof vs vehicle (ADORING 1: 1.9% vs 3.6%; ADORING 2: 1.5% vs 3.0%, respectively).

CONCLUSIONS: Tapinarof cream 1% QD demonstrated statistically significant efficacy vs vehicle for both primary and secondary endpoints in adults and children aged 2 years or older with AD. Tapinarof was well tolerated, with no new safety signals. AEs were mostly mild to moderate and led to low rates of trial discontinuation, demonstrating the predictable safety profile of tapinarof cream 1% QD.

SPONSORSHIP: Dermavant Sciences, Inc.

L26 Tapinarof cream 1% once daily: Interim analysis of ADORING 3 phase 3 long-term extension trial in adults and children down to age 2 years with atopic dermatitis

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BACKGROUND: Tapinarof cream 1% once daily (QD) demonstrated significant efficacy vs vehicle and was well tolerated in adults and children aged 2 years or older with atopic dermatitis (AD) in 2 pivotal phase 3 trials (ADORING 1 and 2).

OBJECTIVE: To present baseline characteristics and outcomes from the prespecified interim analysis of ADORING 3, the long-term extension trial assessing safety and efficacy of up to 48-weeks' open-label tapinarof cream 1% QD for adults and children with AD.

METHODS: Patients completing the 8-week ADORING 1 and 2 trials, 4-week maximal usage pharmacokinetics trial, and direct-enrollers were eligible for 48-weeks' open-label treatment with tapinarof cream 1% QD.

RESULTS: A total of 728 patients enrolled in ADORING 3, representing a large, diverse AD population comprising a high proportion (91%) of eligible patients from the pivotal ADORING trials, 28 patients from a 4-week maximal usage pharmacokinetics trial, and an additional 76 tapinarof-naive patients aged 2-17 years with various disease severities (mild; or moderate or worse with body surface area ≥40%), who were ineligible for preceding trials. The majority of patients in ADORING 3 were pediatric; 26.6% were aged 2–6 years, 27.1% 7-11 years, 29.3% 12-17 years, and 17.0% were adults. Overall, 46.6% were male, 52.6% White, 11.1% Asian, 30.1% Black/African American, and 4.4% other race categories.

CONCLUSIONS: Patients with AD present with different phenotypes and treatment responses. A high proportion of primarily pediatric patients elected to rollover from previous trials, and the diverse population enrolled in ADORING 3 is representative across the broad spectrum of disease severity, body surface area affected (up to 95%), and demographics. No new safety signals were reported with long-term treatment in this interim analysis. The full analysis in 2024 will report further safety and efficacy data with tapinarof cream 1% QD.

SPONSORSHIP: Dermavant Sciences, Inc.

M00-M99 Diseases of the Musculoskeletal System and Connective Tissue

(eg, osteoarthritis, osteoporosis, rheumatoid arthritis)

M1 Adalimumab-bwwd, a biosimilar of adalimumab, has the potential for substantial cost savings when prescribed

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BACKGROUND: Biologics are the single most costly category of therapeutics to the US payer. The availability of biosimilars represent a pivotal opportunity to reduce costs to both payers and patients, if used.

OBJECTIVE: To project the budgetary impact and cost-savings associated with formulary changes from reference adalimumab to biosimilar adalimumab-bwwd across a range of indicated diseases in a hypothetical health plan.

METHODS: A budget impact model was constructed that incorporates drug acquisition costs. Other treatment or management costs were excluded because they are assumed to be identical between the biosimilar and originator therapy (in line with US Food and Drug Administration [FDA] approvals). The model accounts for uptake rates and allows for the adjustment of all parameters (including patient population) to analyze different scenarios. Sensitivity analyses to identify the key drivers of the model and to test alternate payer perspectives are also allowed. The model displays results as total or incremental cost change by patient or member between 1 and 5 years. The base case analysis uses publicly available data on price and published epidemiological data to generate a hypothetical cohort.

RESULTS: For a hypothetical plan population of one million members, 1-year drug acquisition costs were $25,277,471 lower when 2% of adalimumab patients were switched to adalimumab-bwwd. This is the equivalent of a $2.11 per member per month savings. The impact of price and/or market share exhibited the largest magnitude change on

the results but not the direction. In all scenarios tested, cost savings were achieved.

CONCLUSIONS: In a scenario based on publicly available pricing, substantial cost savings were generated from switching patients to adalimumab-bwwd. As confirmed by real-world experience of other biosimilar adoption in the United States, the magnitude of these savings is difficult to predict because of invisible rebate structures but adoption of biosimilars would inevitably realize substantial savings to plans.

SPONSORSHIP: This analysis was designed and performed by Bluepath, and sponsored by Organon, who have an FDA-approved adalimumab biosimilar.

M2 Assessment of prior authorization rejections and social determinants of health in immunology

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BACKGROUND: In recent years, prior authorization (PA) requirements have continued to grow at a significant rate. Pharmacy prescription rejections for PA can result in the delay of therapeutic treatment, which may disproportionately impact different patient populations when looking at select social determinants of health.

OBJECTIVE: To assess the impact of PA rejections on patients with pharmacy claims submitted for select immunology products during a specified 52-week study period.

METHODS: Patients included in this analysis were limited to those with Commercial insurance and had at least 1 pharmacy claim submitted for a product of interest. Upon claim submission, patient activity was tracked at the claim transaction level for 28 days. With regard to the initial payer, both the initial and final disposition of the claim were recorded. Patients were stratified on product, diagnosis, source of business, race and ethnicity, sex, age group, prescribers' specialty, geographic location, and patient out-of-pocket to assess the impact of PA rejections. In addition, measures of health care resource utilization including all-cause (ie, hospitalizations, emergency department visits, etc.) were explored. Plan control rates were compared across patient characteristics using chi-square tests. Time to overcome and patient out-of-pocket were compared using analysis of variance.

RESULTS: A total of 263,475 patients with 861,428 claims were analyzed as part of this study. All endpoints mentioned had *P* values of less than 0.0001 and therefore are statistically significant. Males were more likely to experience an initial rejection for PA (22.3% vs 21.6%). Patients younger than 18 were more likely to experience a PA (27.3% vs 21.9% avg) and more likely to overcome (10.3% vs 8.6% avg), whereas patients 50+ were less likely to experience a PA (21.2%) and less likely to overcome (8.3%). Black/African American patients were more likely to experience a PA (25.1% vs 21.9% avg). Geographic location impacts the number of initial rejections as well as rejections for PAs. Of the claims with timestamps that overcame initial PA rejection, the mean time to overcome the rejection was 11.8 days and the median was 9.0 days, with ranges from 0 to 73 days. There was a significant difference within race and ethnicity and geographic location.

CONCLUSIONS: When considering various social determinants of health, PAs disproportionately impact different populations in the immunology therapeutic area.

SPONSORSHIP: Symphony Health, an ICON plc.

M10 Health system specialty pharmacy: Ensuring continuity of care during provider transitions

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BACKGROUND: Patients with rheumatologic conditions are a vulnerable population, as changes in their health care can negatively influence the course of their condition. Transitional periods, such as a change in health care provider, introduce risks, including therapy gaps, medication noncompliance, or disease progression. Health system specialty pharmacy (HSSP) teams, embedded within clinics, play a pivotal role in maintaining continuity of care during transitional periods. In these times, HSSP teams remain a mainstay in clinic in which they proactively identify and address concerns that may otherwise exacerbate these conditions. Studies describing how HSSP provides continuity of care during transitional periods in rheumatology clinics are limited.

OBJECTIVE: To describe the role of HSSP during a provider transition.

METHODS: This was a retrospective, descriptive study from June 2023 to September 2023. Patients were included if they were enrolled into HSSP services, diagnosed with a rheumatologic condition, prescribed a specialty medication, and impacted by a provider transition. Services offered by HSSP, including obtaining additional refill prescriptions, were evaluated. RAPID3 scores were collected at the start of the provider transition and 3 months thereafter to assess changes in disease activity severity. Lastly, a 5-item

questionnaire was conducted to understand patient journey and satisfaction during this time.

RESULTS: Forty-six patients were included in this study. The average age was 55 years, and most patients were female (85%). Adalimumab (26%) was the most commonly prescribed therapy, followed by etanercept (20%) and upadacitinib (15%). Throughout the transitional period, no patients had a change in RAPID3 severity category. HSSP secured a total of 106 additional refill prescriptions, to avoid therapy gaps, for 83% of patients. Because of these efforts, only 3 patients (6.5 %) experienced an interruption in therapy during the transitional period. The questionnaire revealed that more than 40% of patients never received a referral to a new rheumatology clinic during the transitional period. Those who did reported an average driving distance of 74 miles to the new clinic. Nearly 92% of patients stated that they were most satisfied with the care they received from HSSP team.

CONCLUSIONS: HSSP teams successfully provided continuity of care during a transitional period for patients with rheumatologic conditions. Because of their high-touch care, patients were not lost to follow-up and did not report increased symptoms during this period.

SPONSORSHIP: None.

M14 Agreement and accuracy of ambulatory definitions in Duchenne muscular dystrophy (DMD): A cross-sectional analysis using the Cooperative International Neuromuscular Research Group (CINRG) registry

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BACKGROUND: Loss of ambulation (LOA), a critical milestone in the progression of Duchenne muscular dystrophy (DMD), is often defined in a heterogeneous manner, including patient/caregiver-reported continuous wheelchair use or physician-verified functional tests (10-meter walk/run [10MWR], 6-minute walk test [6MWT]). Furthermore, although some ambulatory measures used in clinical research may be useful for assessing treatment efficacy, they may not be practical in the clinic. Therefore, different definitions of ambulation are used by stakeholders across a variety of settings. Payers often restrict access to approved therapies based on ambulatory status, making it important to evaluate if discrepancies in defining ambulation impact patient access to treatment.

OBJECTIVE: To evaluate the agreement and accuracy of various definitions used to categorize ambulation in patients with DMD.

METHODS: This observational, cross-sectional study included patients with DMD (≥7 years of age with available results for both 10MWR and 6MWT on the same visit) enrolled from 2006 to 2016 in the Cooperative International Neuromuscular Research Group (CINRG) registry. Study objectives were to assess the agreement and accuracy of 10MWR/6MWT thresholds compared with the CINRG ambulatory definition (full-time wheelchair use), the accuracy of the 6MWT compared with the 10MWR, and the time gap between first LOA 10MWR/6MWT results and first report of LOA by the CINRG definition.

RESULTS: A total of 121 patients with DMD were included in this analysis (median age 9.3 years [range 7-22 years]); 90.1% were ambulant per the CINRG definition (mean LOA age 10.3 years). Compared with the CINRG definition, the 10MWR (30 seconds) showed strong agreement (k = 0.80) and correctly identified 95% of the same ambulant patients with DMD. The 6MWT (300 m) showed weak agreement (k = 0.30) and lower sensitivity (68%). Using the 10MWR (30 seconds) as the reference test, the 6MWT (300 m) correctly identified 71% of the same ambulant patients and may result in up to one-third of ambulant patients being incorrectly categorized as nonambulant. Exploratory analysis showed that 6MWT (180, 200, 250, 300 m) thresholds could classify more than 50% of patients with DMD as nonambulant at least 2 years before the CINRG definition would.

CONCLUSIONS: This study provides real-world evidence on the impact of using various definitions and thresholds to identify ambulatory patients with DMD and highlights the need for standard criteria to ensure all patients who may benefit from therapy have access.

SPONSORSHIP: Sarepta Therapeutics, Inc.

M17 The impact of safety labeling changes on parathyroid hormone analog utilization and persistence

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BACKGROUND: Parathyroid hormone (PTH) analog use was historically limited to 2 years of lifetime exposure based on black-box warnings in package inserts (PIs) for osteosarcoma risk. In 2020 and 2021, black-box level warnings were removed on teriparatide and abaloparatide. Extended teriparatide may be considered in those at high fracture risk. Published studies indicate 47% of patients with osteoporosis meet the American Association of Clinical Endocrinology criteria for very high fracture risk, and 30% have risk factors for bisphosphonate

intolerance or contraindications. Thus, PI updates may influence PTH analog use for a large subset of patients.

OBJECTIVE: To evaluate whether PI changes alter PTH analog use and observe the impact of specialty management on PTH analog duration and persistence.

METHODS: A large commercially insured pharmacy claims database was retrospectively analyzed for continuously eligible patients with index fill of PTH analog, with no use in prior 6 months, and at least 30 months follow-up. Two cohorts were compared based on index fill relative to September 2020 PI update. Cohort 1 started at least 25 months before PI change, and cohort 2 started within 24 months of PI change.

RESULTS: There were 3,571 patients in cohort 1 and 2,480 in cohort 2. First and second cohorts had average age of 69.3 (11.3) and 66.0 (11.5) ($P < 0.01$), were 85.1% and 82.3% female ($P < 0.01$), and used specialty management 48.6% and 42.3% ($P < 0.01$), respectively. In cohort 1, 2.9% continued PTH analog more than 24 months compared with 4.5% in cohort 2 ($P < 0.01$). Specialty-managed patients in cohort 1 were less likely to exceed 24 months use (1.9% vs 4.5%, $P < 0.01$); in cohort 2, 4.5% of both specialty and other channel patients exceeded 24 months. After PI change, 24-month persistence increased 1.6% ($P < 0.01$) and was better overall for specialty by 10.3%, controlling for age, sex, and channel ($P < 0.01$). Incidence of repeat PTH analog course did not differ between cohorts 1 and 2 (16.7% and 15.1%, $P = 0.09$).

CONCLUSIONS: PTH analog PI changes were associated with increased use of more than 24 months but not with incidence of a second PTH analog course. Specialty-managed patients were less likely to exceed 2-year use limits before PI changes but matched other channels' rate of extended use afterward. After PI changes, fewer specialty-managed patients stopped therapy early, demonstrating better persistence at 24 months compared with other patients. Specialty management of PTH analogs reflects labeled use over time and balances treatment persistence with use limits.

SPONSORSHIP: Evernorth Health Services.

M18 A digital behavioral therapy for fibromyalgia progressively improves clinical outcomes: Results of the PROSPER-FM randomized clinical trial

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BACKGROUND: Acceptance and Commitment Therapy (ACT), a form of guideline-recommended cognitive behavioral therapy, has been empirically supported as a nondrug treatment for fibromyalgia (FM). However, clinical adoption is difficult due to limited number of qualified providers. A smartphone-based, Class II prescription digital therapy (FM-ACT) addresses the access barrier by providing self-guided ACT for management of FM symptoms. This report presents the results from PROSPER-FM, a pivotal randomized controlled trial.

OBJECTIVE: To investigate the effectiveness of FM-ACT on improving FM outcomes.

METHODS: Individuals meeting 2016 FM diagnostic criteria were randomized to receive 12 weeks of FM-ACT or an active comparator (Symptom Tracker [ST]) while remaining stable on ongoing FM treatment(s). Through FM-ACT, patients learn and practice core ACT skills related to processes of acceptance, values, present moment awareness, cognitive defusion, self as context, and committed action to build psychological flexibility. The ST application is a daily symptom tracker/monitor with access to FM and health education materials. The primary endpoint was Patient Global Impression of Change at week 12. Secondary endpoints (collected weekly) included the Revised Fibromyalgia Impact Questionnaire (FIQ-R), Pain Intensity, Pain Interference, and Sleep Interference. Exploratory endpoints were PROMIS Fatigue and Sleep Disturbance, Beck Depression Inventory II, Psychological Inflexibility in Pain Scale, and Committed Action Questionnaire.

RESULTS: A total of 275 participants were randomized (FM-ACT = 140; ST = 135). At week 12, 70.6% of the FM-ACT participants improved on Patient Global Impression of Change (vs 22.2% in the ST control, $P < 0.001$). Significantly greater improvement on FIQ-R was observed compared with the ST control ($P < 0.001$, effect size = 0.65). Superiority of FM-ACT emerged at week 3 on FIQ-R total with the between-arm difference continuing to increase through week 12. Similar early emergence of superiority (ranged between weeks 2 and 7) was also observed on additional secondary endpoints, including FIQ-R domains, Pain Intensity, and Pain Interference. FM-ACT was superior to ST control on virtually all study measures at week 12. No treatment related adverse events were observed.

CONCLUSIONS: Results from the pivotal randomized controlled trial demonstrated that FM-ACT offers clinical benefits in improving wellbeing, lowering FM severity, and reducing common symptoms associated with FM. Positive clinical effects were seen after just a few weeks of digital therapy and tended to increase over the course of therapy.

SPONSORSHIP: Swing Therapeutics.

N00-N99 Diseases of the Genitourinary System

(eg, chronic kidney disease)

N2 Clinical and economic outcomes of delaying initiation of empagliflozin in chronic kidney disease (CKD) management in the United States

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BACKGROUND: In the EMPA-KIDNEY trial, empagliflozin (EMPA) significantly reduced chronic kidney disease (CKD) progression or death from cardiovascular causes, on top of standard of care (SoC). The CKD Progression Model (CKD-PM) showed that EMPA+SoC is a cost-effective option for CKD vs SoC alone from US commercial and Medicare payer perspectives.

OBJECTIVE: To evaluate the impact of delaying treatment initiation with EMPA.

METHODS: The CKD-PM, a Markov microsimulation model, used health states based on Kidney Disease Improving Global Outcomes categories. The model projected CKD progression defined by decline of estimated glomerular filtration rate, increase in urine albumin-creatinine ratio, and other complications over a lifetime horizon. Patient baseline characteristics and all treatment effects came from EMPA-KIDNEY. Drug, complication management, and adverse events costs and utilities/disutilities came from literature. A 3.0% discount rate/year was applied. Costs were compared vs SoC and clinical outcomes between 4 scenarios of EMPA treatment initiation: no delay in treatment (base case) vs 1-, 3-, and 5-years delay.

RESULTS: Initiating EMPA on top of SoC without delay resulted in incremental gains of 1.08 life-years (LYs) and 1.03 quality-adjusted LYs (QALYs) primarily because of a lower incidence of renal replacement therapy (RRT) in the EMPA group vs the SoC group (54.2% vs 65.5%; [relative risk (RR) = 0.83]) and longer time to (TT) RRT (9.01 years vs 6.40 years; difference = 2.61 years; $P < 0.001$). Cost difference per patient was -$16,364 for commercial and $53,541 for Medicare vs SoC. Delaying EMPA initiation by 1 year reduced the benefits gains to 0.87 LYs, 0.83 QALYs, 0.85 RRT RR, 2.12 years TT RRT difference, and cost difference per patient of -$15,528 in commercial and $41,807 in Medicare. With a 3-year delay, the benefits gains decreased to 0.51 LYs, 0.48 QALYs, 0.92 RRT RR, 1.20 years TT RRT difference, and cost difference of -$6,012 in commercial and $26,054 in Medicare. With 5 years delay, EMPA benefits vs SoC became marginal: 0.23 LYs, 0.37 QALYs, 0.96 RRT RR, a TT RRT difference of 0.60 years, and cost difference per patient of -$6,184 in commercial and $10,245 in Medicare. EMPA was the dominant alternative for commercial payer and cost-effective for Medicare in the base case and all delay scenarios at a willingness-to-pay threshold of $150,000/QALYs.

CONCLUSIONS: Early initiation of EMPA increased clinical benefits in terms of gains in LYs and slower disease progression without significant economic impact, compared with delayed initiation of treatment.

SPONSORSHIP: Boehringer Ingelheim Pharmaceuticals, Inc.

N3 Cost-effectiveness analysis of a prognostic risk assessment for patients with early-stage 1-3b diabetic kidney disease in a US Medicare population

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BACKGROUND: Diabetic kidney disease (DKD) accounts for 44% of new chronic kidney disease cases and is associated with significant morbidity and mortality. Despite evidence

that agents such as sodium-glucose cotransporter-2 inhibitors (SGLT2i) can reduce cardiorenal outcomes, current DKD staging typically relying on estimated glomerular filtration rate and albuminuria (GAC) leaves SGLT2i underused in clinical practice. Recently, a new biomarker-enriched, machine-learned risk score (KidneyIntelXTM; Renalytix, Inc.) was developed to predict a rapid, progressive decline in kidney function in patients with early-stage DKD. KidneyIntelX categorizes patients as low, intermediate, or high risk for disease progression, which can guide resource use, prescribing of drugs such as SGLT2i, and improvements in efficiency of care. A KidneyIntelX validation study demonstrated 69% accuracy in identifying high-risk patients compared with 40% with GAC, whereas only 10% of those scored as low risk by KidneyIntelX experienced progression.

OBJECTIVE: To estimate the cost-effectiveness of stratification with KidneyIntelX compared with GAC by generating an incremental cost-effectiveness ratio (ICER).

METHODS: The model adopted a US Medicare perspective and consisted of patients with DKD in stages G1-3b using either KidneyIntelX or GAC. A 10-state Markov state transition structure was employed over a lifetime horizon, which includes DKD stages 1-5, dialysis, kidney transplant, cardiovascular (CV) death, and non-CV death. Transition probabilities and risk group distributions for KidneyIntelX and GAC were sourced from a KidneyIntelX validation study. Evaluation resulting from KidneyIntelX or GAC informed SGLT2i use in the model. Cost inputs included testing, medications, and office visit costs, as well as annual costs for each DKD stage, dialysis, and kidney transplant. Quality of life for each disease state was captured as use values informed by literature.

RESULTS: KidneyIntelX use led to a reduction in kidney progression and CV events, as well as dialysis starts, dialysis crashes, and kidney transplants, compared with GAC. KidneyIntelX led to added diagnostic and treatment costs of approximately $762 per patient and quality-adjusted life-year (QALY) gains of 0.044, resulting in an ICER of $17,163 per QALY.

CONCLUSIONS: Wide deployment of KidneyIntelX in Medicare patients with DKD G1-3b is expected to be cost-effective compared with GAC from the Medicare perspective, with an ICER well below the accepted willingness-to-pay threshold in the United States of $100,000.

SPONSORSHIP: Renalytix.

N10 Clinical characteristics and treatment patterns of women diagnosed with uterine fibroids (UF), heavy menstrual bleeding (HMB), and anemia in a large US claims dataset

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BACKGROUND: Leiomyomas (UF) are common, benign uterine tumors affecting nearly 70% of women of reproductive age. Heavy menstrual bleeding (HBD) is the most common symptom and can often be associated with anemia. Limited data exists on the presence of anemia in women with UF-HMB.

OBJECTIVE: To describe the prevalence of anemia, the sequence of diagnostic recognition, and the impact on treatment patterns in women with UF-HMB.

METHODS: A retrospective observational study using PharMetrics Plus, a US administrative claims database (2013-2022), identified women (18-55 years) with UF (index = first diagnosis) and HMB (at any time) with and without anemia. Medical and pharmacy coverage for 24 months pre- and post-index were required. Treatment patterns, including hormonal therapy and surgeries, were investigated. Surgeries of interest included hysterectomy, myomectomy, ablation, or abdominal laparoscopy. To assess health care research utilization (HCRU), procedure claims in which at least one of the diagnosis codes included UF, HMB, or anemia were analyzed.

RESULTS: Women with UF and HMB (109, 175) were identified with a mean age of 44.5 years. The majority (76,959 [70%]) were diagnosed with HMB prior to the UF diagnosis. Overall, 25,202 (23.1%) had anemia and HMB during the study period. Of those women, the diagnosis of anemia preceded the documentation of UF in 13,389 (53.1%) and the diagnosis of HMB in 9,741 (38.7%). Post-index, 30,346 (28%) received pharmacologic therapy, whereas 56,241 (51.5%) underwent a surgical procedure. Specifically, 41,764 (38.3%) had a hysterectomy, 9,751 (49.5%) of those with anemia, compared with 32,013 (35.8%) without. A chi square tests showed the distributions were significantly different from expected with P value less than 0.05. HCRU was greater in patients diagnosed with anemia post-index (19,709). Although 22,461 (20.6%) were hospitalized with 7,734 (39.2%) of those diagnosed with anemia compared with 14,727 (16.5%) without, only 6,695 (6.1%) had an emergency department visit, with 2,848 (14.5%) of those diagnosed with anemia compared with 3,847 (4.3%) without. The mean post-index cost (pharmacologic therapy + surgery) was 1.5 times more for patients with anemia post-index ($4,712.77) compared with a patient without ($3,208.46).

CONCLUSIONS: UF-HMB that is associated with anemia increases HCRU and costs and drives surgical interventions including definitive therapy with a hysterectomy. Timely diagnosis and effective management of anemia in women with UF-HMB should be considered to reduce HCRU in these patients.

SPONSORSHIP: Myovant Sciences, Inc now known as Sumitomo Pharma America, Inc Pfizer.

N11 Sociodemographic disparities in treatment discontinuation among women newly diagnosed with vasomotor symptoms

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BACKGROUND: Most women experience vasomotor symptoms (VMSs), commonly presenting as hot flashes and night sweats, during menopause. However, evidence suggests that symptom reporting and health care–seeking behaviors differ across sociodemographic factors, such as race, ethnicity, and income. To our knowledge, no analysis of health care claims data has examined the sociodemographic correlates of VMS-related treatment behaviors among women of menopausal age.

OBJECTIVE: To assess potential sociodemographic differences in the duration and risk of discontinuation of VMS-related treatments among women newly diagnosed with VMSs in a large claims database.

METHODS: In this retrospective study, data from IQVIA's PharMetrics Plus claims database were linked to data from IQVIA's Consumer Attributes (Cx) database (study period: October 1, 2015, to December 31, 2021; selection period: April 1, 2016, to December 31, 2020). Women newly diagnosed with VMSs aged 40-64 years with linked PharMetrics Plus/IQVIA's Consumer Attributes data were included. Continuous health plan enrollment was required for at least 6 months before and 12 months after the index date (date of first VMS diagnosis). Discontinuation of VMS-related treatment was assessed for treatment initiated on the index date or during the 12 months immediately after, and duration of treatment was assessed from the index date to the first day of a treatment gap of at least 90 days. A Cox proportional hazards model was used to determine factors associated with risk of discontinuation of VMS-related treatments.

RESULTS: Among women newly diagnosed with VMSs, median treatment duration was 297 days. Women aged 61-64 years had the highest risk of discontinuing VMS-related treatments (hazard ratio [95% CI] = 1.22 [1.16-1.29]; $P < 0.0001$). Further, women of non-Hispanic Black race (1.18 [1.14-1.23]; $P < 0.0001$), non-Hispanic Asian race (1.22 [1.14-1.30]; $P < 0.0001$), and Hispanic ethnicity (1.26 [1.21-1.31]; $P < 0.0001$) had higher risk of discontinuing VMS-related treatment (reference: non-Hispanic White race). The risk of discontinuation of VMS-related treatments was similar across most income levels; however, the risk of discontinuing VMS-related treatments was significantly lower among women in the highest income subgroup (eg, ≥$250,000 (0.94 [0.90-0.99]; $P = 0.019$; reference ≤$34,999).

CONCLUSIONS: Our data show a higher risk of discontinuation of VMS-related treatment among racial and ethnic minorities and among women with lower income, highlighting an unmet need among vulnerable populations that warrants further investigation.

SPONSORSHIP: Astellas Pharma, Inc.

N12 Women with endometriosis: Patient treatment journey using real-world evidence (RWE)

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BACKGROUND: Endometriosis (EM), a systemic condition characterized by endometrial tissue outside the uterine cavity, affects approximately 10% of reproductive-aged women. Surgery (laparoscopy, ablation, hysterectomy), though commonly performed, is not always curative. Several pharmacological therapies, including hormonal and analgesic, are used to treat EM-related pain. Recently, 2 medications, GnRH antagonists, indicated to treat EM-associated pain were approved.

OBJECTIVE: To provide insight into the treatment journey of women with EM-associated pain, a retrospective, longitudinal study using RWE was conducted.

METHODS: The Merative MarketScan Research Database, a large, US representative, patient-level claims dataset with more than 273 million individuals, was used. The study period was January 1, 2016, to December 31, 2021, with first EM claim as the index date. Study participants were followed for 24 months pre- and post-index.

RESULTS: The analysis included 6,612 patients with an EM diagnosis, with a mean age of 37.1 (SD 9.0). Post-index surgery (ablation, hysterectomy, and laparoscopy) was the most common (n = 3,594, 54%) first-line therapy (1L). The second most common (23%) 1L treatment was "no pharmacologic

or surgical treatment" (patients did not receive any EM treatment at diagnosis or within the following 6 months). Less frequently used 1L therapies were oral contraceptives (6%) with an additional group continuing on contraceptives started pre-index (7%), progestins (4%), and GnRH agonists/antagonists (3%). The average duration of GnRH agonist/antagonists use was less than 7 months. For those having 1L surgery, approximately 30% were treated with second line (2L) hormonal therapy. In the 12 months post-index (regardless of line of therapy), 27% of EM patients received a hysterectomy. The most common 2L treatment for patients with 1L hormonal therapy was no hormonal treatment; the next most common 2L treatment was surgery. More than one-half of patients in all pharmacologic treatment groups received more than 1 pain medication in conjunction with 1L treatment.

CONCLUSIONS: Hysterectomy was used early and often. Hormonal medication was used infrequently; however, concomitant analgesic medication was frequently used. Newer hormonal medications indicated for the reduction of EM-associated pain may decrease use of concurrent analgesics and potential morbidity associated with chronic use. GnRH antagonists should be considered in the treatment algorithm for EM-associated pain more frequently, earlier, and for durations up to 24 months.

SPONSORSHIP: Sumitomo Pharma, America.

O1 Socioeconomic status and postpartum depression among commercial health insurance enrollees

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BACKGROUND: Postpartum depression (PPD) is a prevalent psychological condition. Although the effect of obstetrical and maternal complications on PPD are well described, the impact of socioeconomic status (SES) on PPD is relatively unexplored.

OBJECTIVE: To investigate the effect of SES on PPD among commercial health insurance enrollees.

METHODS: In a retrospective cohort study, we constructed a summary measure of SES for each US zip code using data on income, education, and occupation from the 5-year estimates for 2021 US Census data and linked the data to national commercial claims for the years 2017-2023. PPD status was determined using diagnosis codes at outpatient and inpatient visits as well as prescription drug use during the 3-, 6-, 9-, and 12-month postpartum period. Multivariate analysis was used to control for age, comorbidity index, obstetrical and maternal complications, and lifestyle risk factors.

RESULTS: The prevalence of PPD in national commercial claims was 11.48%. Among the patients with PPD during the 12-month period after childbirth, 45% of the PPD events were in the first 3 months. Patients with PPD had a higher rate of obstetrical (odds ratio [OR] = 1.56; $P < 0.0001$) and maternal complications (OR = 1.14; $P < 0.0001$) and more lifestyle risk factors, including vitamin deficiencies, sleep disorders, and smoking (OR = 1.11; $P < 0.0001$). Overall, patients with PPD were also sicker. SES score was significantly lower in patients with PPD than those without (4.87 vs 5.23, $P < 0.0001$). After controlling for age and clinical factors, we found that living in a disadvantaged neighborhood is associated with an increased incidence of PPD among commercially insured patients (OR = 1.14, $P < 0.001$).

CONCLUSIONS: The inverse and significant effect of area-based high SES on PPD rates demonstrates that effective efforts for preventing PPD may require interventions that focus on both the patient and the lived environment.

SPONSORSHIP: None.

P1 Fetal and neonatal alloimmune thrombocytopenia: a systematic literature review and meta-analysis of adverse pregnancy-related outcomes to support the development of a novel prophylactic therapeutic

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BACKGROUND: Fetal/neonatal alloimmune thrombocytopenia (FNAIT) results from maternal alloimmunization against fetal human platelet antigens (HPAs). It is a rare and potentially devastating condition that can cause intracranial hemorrhage in the fetus/neonate and subsequent death or lifelong disability. Prenatal screening does not usually include FNAIT; no therapy is available to prevent alloimmunization. Mother–fetus mismatch on antigen HPA-1a accounts for 75%-80% of FNAIT cases; alloimmunization is approximately 25-fold more frequent in women also positive for the allele HLA-DRB3*01:01. RLYB212 is in development to prevent HPA-1a–related FNAIT and its consequences. Clinical development of RLYB212 requires real-world evidence on the size of the at-risk population and frequency of pregnancy/neonatal outcomes from FNAIT under standard care. This literature review was conducted to fill this knowledge gap.

OBJECTIVE: To quantify the frequency of HPA-1a–negative, HLA-DRB3*01:01–positive pregnant women, those who were newly alloimmunized (in the current pregnancy or parturition) and carrying an HPA-1a positive fetus, and associated pregnancy/neonatal outcomes.

METHODS: PubMed and Embase were searched for articles published in 2008-2021; earlier studies were identified from existing reviews. Two reviewers independently applied prespecified criteria to determine inclusion. Article quality was assessed. Results of meta-analysis using random-effects models are presented (PROSPERO registration: CRD42022309672).

RESULTS: Searches identified 501 unique records; 12 observational cohort studies from Europe, Canada, and Egypt published from 1985 through 2018 were selected. Article quality was generally adequate. Of 198,062 screened pregnant women, 2.2% (95% CI = 2.0%-2.5%) were HPA-1a negative; 32.3% (28.6%-36.1%) of HPA-1a–negative women were HLA-DRB3*01:01 positive (at higher risk for alloimmunization). Articles did not report on newly alloimmunized women who carried HPA-1a positive fetuses. Approximately 10% of HPA-1a–negative women were alloimmunized to HPA-1a. The prevalence of intracranial hemorrhage was 2.2% (0.7%-4.4%) among newborns of HPA-1a–negative women with unknown HLA-DRB3 status and an HPA-1a–positive/genotype unknown partner/fetus.

CONCLUSIONS: Published research did not report on new alloimmunization, which is needed to inform RLYB212 clinical development, but confirmed frequency of FNAIT risk factors and outcomes. A natural history study to fill this knowledge gap, along with the planned trial to assess RLYB212's efficacy, is needed to characterize the potential value of RLYB212 in standard care.

SPONSORSHIP: Rallybio Inc

T1 Real-world health care resource utilization (HCRU) and economic burden of opioid overdose (OOD) in patients with and without naloxone prescription in the United States

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BACKGROUND: The number of opioid overdoses (OODs) has increased in recent years because of the availability of opioids as prescription medication for chronic pain management. Many highly potent synthetic opioids are also available in illicit drug markets. OOD is accountable for more than half of the deaths from substance uses in the United States. Opioid prescription guidelines recommend coprescription of Naloxone as an antidote to OOD. Naloxone is a medication that rapidly reverses the effect of OOD if administered at the right time and hence, can be assumed to lower the health care resource utilization (HCRU) and cost associated with OOD.

OBJECTIVE: To understand the impact of Naloxone prescription on HCRU and cost among all patients who had OOD, including those who are on prescription opioid (PO) or had OOD because of opioid misuse (OM).

METHODS: Optum De-Identified Normative Health Information Research Database was used to identify patients who had ODD from January 1, 2016, to December 31, 2019. Patients with both medical and pharmacy coverage and continuous eligibility through 12 months pre- and post-index were included in the analysis. OOD event was considered as the index event and patients with OOD in the pre-index period was excluded from the study. All patients who had OOD during the analysis period were classified into PO and OM group. Demographic factors and clinical comorbidities were analyzed for each group. Number of patients who received Naloxone at the index event within each group was determined along with their HCRU (inpatient, emergency department, and intensive care unit [ICU] admission rate) and overall cost of managing OOD.

RESULTS: A total of 28,984 patients had OOD diagnosis during the study period (60% in PO, 28% in OM). Demographic analysis showed that mean age of PO was much higher (54±16 years) than other groups, more female patients (61%) were prescribed opioid, and more male (60%) had OM. Patients receiving Naloxone at index event were found to be 9% and 11% for OP and OM, respectively. Number of patients who required inpatient and ICU care were much lesser when given Naloxone at index across all groups (Naloxone vs w/o Naloxone: inpatient: 29% vs 53% for OP and 21% vs 30% for OM; ICU: 13% vs 29% for OP and 6% vs 15% for OM). The average cost of managing OOD was much less in patients receiving Naloxone at index for all groups (Naloxone vs w/o Naloxone: $5,129 vs $11,959 for OP and $1,940 vs $4,862 for OM).

CONCLUSIONS: Benefit of Naloxone administration has been observed across all categories of patients who had OOD. Analysis of Naloxone prescription in pre- and post-index on HCRU and cost can be performed for a holistic view.

SPONSORSHIP: Optum.

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 Early implementation of PIE for specific drug categories

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BACKGROUND: With an increasing trend of drug approvals with high cost and for rare conditions, payers may be monitoring these drugs more closely and conducting preliminary assessments of impact prior to approval. Regulations and legislation support preapproval information exchange (PIE) between payers and manufacturers.

OBJECTIVE: To identify the types of drugs that payers desire earlier with PIE, outline the types of information they need, and define optimal timing for delivery.

METHODS: A double-blinded, web-based survey was fielded with advisors from Cencora's Managed Care Network from June 5 to 27, 2023.

RESULTS: A total of 45 advisors responded to the survey and represented health plans (51%), integrated delivery networks (24%), and pharmacy benefit managers (24%), representing pharmacy directors (62%), medical directors (31%), etc. Although most payers generally prefer to receive preapproval information within 6 months of anticipated US Food and Drug Administration (FDA) approval, a portion (24%) prefer up to 1 year prior. For all, the leading factors driving preference for earlier PIE are high cost of therapy and high patient use, and the top categories are cell and gene therapy, oncology, and rare disease. Specifically for cell and gene therapies, 16% of payers prefer to engage as early as greater than 1 year prior to approval, and 44% prefer greater than 6 months prior to approval; for biosimilar drugs, 13% prefer greater than 1 year prior to approval, and 31% prefer greater than 6 months. The most desired preapproval information in the early stages is target indication, FDA approval timeline, product pricing information, and patient use projections. Additionally, even prior to the availability of phase 3 data, payers still find preapproval information valuable on the following topics: indication (73%), unmet need with current treatment options (69%), trial information (67%), and FDA regulatory timeline (67%).

CONCLUSIONS: The following key factors were identified by payers who prefer to receive preapproval information earlier than usual: drugs with an anticipated high cost and/or high use, such as cell and gene therapies, oncology, and rare disease. The data suggest that, for particular drugs, there may be an opportunity to receive fundamental preapproval information from the manufacturer in 2 stages: one very early, sometimes as early as prior to phase 3 data, and another one closer to approval with more robust preapproval information. Manufacturers need to begin the development process of PIE materials at least 6-12 months prior to payers' preferred timeline for receipt (ie, 12-18 months prior to approval).

SPONSORSHIP: Cencora.

U2 The crucial role of pharmaceutical services in addressing drug-drug interactions for patients on multiple medications in managed care

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BACKGROUND: Pharmaceutical services are essential in managing drug-drug interactions (DDIs), especially as medication regimens grow more complex, notably within the Medicare Advantage population. Comprehensive Medication Reviews by clinical pharmacists become vital in identifying and mitigating DDIs, thereby safeguarding patients on multiple drugs.

OBJECTIVE: To evaluate the effectiveness of these interventions and the consequent provider responses.

METHODS: Using a retrospective observational design, this study analyzed medication recommendation responses to DDIs within a regional managed health care plan. Participants, managing multiple drugs for chronic conditions, underwent comprehensive medication reviews leveraging claims data and a specialized history platform. Inclusion was limited to patients with complete response records from 2021 to 2023. Analytical focus was on categorized responses to DDI recommendations, ranging from clarifications to medication discontinuations. Ethical considerations ensured all data was anonymized, maintaining patient confidentiality in line with regulatory guidelines.

RESULTS: A comprehensive total of 16,968 reports were incorporated into the scope of this analysis. Among these, 3,810 reports were specifically associated with DDIs. Remarkably, in merely 20 instances (constituting 0.52% of the total), the recommendations provided by clinical pharmacists were embraced, resulting in medication modifications. In a total of

421 occurrences (accounting for 11% of the cases), the recommendations underwent thorough review by relevant parties, but ultimately, no changes were implemented. Among the recommendations assessed, 84 instances stood out, as they were evaluated and acknowledged as helpful, even though no actual changes were implemented. Conversely, 62 recommendations were deemed "not helpful." Notably, a significant majority of the recommendations (3,202 cases, 84%) failed to prompt any form of response or action.

CONCLUSIONS: Overall, these findings underscore the intricate interplay between clinical recommendations, response dynamics, and the eventual implementation of changes in medication management, revealing opportunities to optimize the impact of pharmaceutical care in mitigating DDIs and enhancing patient outcomes.

SPONSORSHIP: None.

U3 Navigating medication challenges: Insights from a comprehensive medication review in managed health care (2021-2023)

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BACKGROUND: Pharmaceutical care services, essential for patient safety and improved health outcomes, focus on medication adherence, effectiveness, safety, and indication. Through Comprehensive Medication Reviews, potential issues are proactively addressed, enhancing patient safety and refining pharmaceutical care standards. These insights are pivotal for bettering managed care protocols.

OBJECTIVE: To analyze and present insights derived from a Comprehensive Medication Review conducted within a managed health care plan from 2021 to 2023.

METHODS: In this retrospective descriptive study within a managed health care plan, medication recommendation responses were analyzed with a focus on safety, adherence, effectiveness, and indication. Participants with chronic conditions were assessed using claims data and a specialized history platform from 2021 to 2023. The study identified adherence factors, like dosage discrepancies, inappropriate forms, safety issues, such as drug-disease precautions, DDIs, and side effects, indication elements, like duplicate therapies, therapy gaps, and effectiveness aspects, emphasizing better alternatives and administration techniques. Data integrity and confidentiality were maintained through anonymization.

RESULTS: Safety concerns predominantly arose from drug-age precautions (7,672 cases) and drug-drug interactions (4,325 cases). Adherence discrepancies were mainly due to missing fills (578 cases) and dosage discrepancies (260 cases). Indication-related issues were primarily caused by gaps in therapy (1,100 cases) and duplicate therapies (226 cases). Effectiveness was largely impacted by low dose alerts (19 cases) and incorrect storage (9 cases). Sex-wise, female patients reported 7,614 safety issues, 1,149 adherence challenges, 702 indication discrepancies, and 28 effectiveness concerns. Correspondingly, male patients presented 6,038 safety, 1,057 adherence, 762 indication, and 37 effectiveness problems.

CONCLUSIONS: The study emphasizes the criticality of pharmaceutical care in managing medication outcomes. Predominant issues, like drug age precautions and missing fills, highlight areas for intervention. Sex disparities in reported concerns suggest a need for tailored care strategies. These findings are instrumental for refining pharmaceutical care practices, emphasizing patient safety and effective therapeutic outcomes within managed health care settings.

SPONSORSHIP: None.

U10 Contemporary insights into patient and provider perceptions of and barriers to biosimilar use from the Biosim.care Web App

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BACKGROUND: As the number of US Food and Drug Administration–approved biosimilars is rapidly expanding, there is a critical need to identify and address patient and provider barriers to their evidence-based use. Tethered web apps provide a digital platform to gain contemporary insights and support patient and provider learning.

OBJECTIVE: To evaluate patient and provider perceptions and challenges regarding biosimilars, we developed and evaluated companion patient-provider web apps in partnership with the Academy of Managed Care Pharmacy Foundation and the Biosimilars Council.

METHODS: Upon accessing their respective web portals at www.biosim.care, patients and providers select from a menu including information on biosimilars, clinical data, shared decision-making, and navigating prior authorizations. Opt-in surveys assess perceptions and actions.

RESULTS: Between August and October 2023, the web apps were accessed by 1,639 providers and 290 patients. Surveys were completed by 526 providers (43% rheumatology, 32% gastroenterology, 25% oncology) and 153 patients (43% rheumatology, 38% gastroenterology, 19% oncology). Only 15% of patients had been prescribed a biosimilar. Few patients reported a high or very high understanding of biosimilars (22%), and only 28% would be confident switching from a biologic to a biosimilar. The top barriers to biosimilars reported by providers were patient resistance to switching (41%) and insurance coverage (41%). Before engaging in the web app, only 38% of providers reported that they often or always counsel patients on the safety and efficacy of switching to biosimilars, which increased to 53% after using the web app. Only one-quarter (26%) of patients reported that their health plan always provides the information they need, and only 21% reported that their clinical care team provides a high level of support navigating insurance. Prior to accessing the web app, 22% of providers had high/very high confidence in navigating the insurance approval process for biosimilars, which increased to 37% after using the web app. After completing the web app, 41% of providers planned to become more familiar with the biosimilar agents available in their area of practice.

CONCLUSIONS: These findings highlight persistent gaps in patients' familiarity/confidence with biosimilars and provider-led counseling about biosimilar switching. Both patients and providers require significant support in navigating insurance approval processes. Managed care organizations can play key roles in addressing these gaps to improve evidence-based access to biosimilars.

SPONSORSHIP: Coherus BioSciences, Inc.; Fresenius Kabi USA, LLC; Biocon; Organon LLC; Pfizer, Inc.

U11 Pipeline forecasting as a drug utilization management tool in an academic medical center

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BACKGROUND: Health plans use pipeline forecasting to predict financial and patient care impacts for drugs still in development. Academic medical centers can also use pipeline forecasting as a drug use–management strategy.

OBJECTIVE: To describe the Stanford Healthcare (SHC) and SHC Tri-Valley Drug Utilization Management process for selection and evaluation of pipeline drugs of interest and engagement of internal stakeholders in an inaugural pipeline forecasting forum.

METHODS: In May 2023, Drug Utilization Management selected pipeline drugs in late-stage development and assessed the potential financial, clinical, and operational implications at SHC and SHC Tri-Valley. Drug selection criteria included the following: US Food and Drug Administration (FDA) fast track designation, FDA breakthrough designation, FDA priority review, biobetter, inpatient use, specialty drug, or treatment for a rare disease. For each drug, the team researched and collected the following information: (1) description of the product (active ingredient, strength, dosage form, route of administration, and indication being sought), (2) potential advantages and disadvantages over existing therapy, including comparison of key endpoints from clinical trials for the pipeline drug vs currently available therapies, (3) potential use based on historic use of comparable medications and/or prevalence of relevant electronic health record diagnoses, (4) business sectors affected (eg, infusion center vs patient self-administration), and (5) site of care changes for pipeline drug vs currently available drugs. Administrators and specialists were invited to a virtual inaugural forecasting forum to review and discuss projected use and financial impact, as well as pharmacy budget mitigation strategies, for the pipeline drugs.

RESULTS: In August 2023, 22 physician leaders spanning 6 specialties (neurology, gastroenterology, hematology, oncology, infectious disease, radiology) attended the virtual pipeline forecasting forum and engaged in strategic planning for the selected pipeline drugs. Strategies included developing care pathways for conditions with high market growth (eg, ulcerative colitis), establishing subcommittees to build strategies for ultra-high-cost therapies (eg, gene and cell therapies), and determining eligibility criteria and processes to ensure equitable access to high-demand therapies (eg, Alzheimer disease treatments). Feedback on the forum was positive.

CONCLUSIONS: Academic medical centers can use pipeline forecasting forums to develop strategies for ensuring cost-effective, evidence-based, equitable access to new medications.

SPONSORSHIP: None.

U12 Medically integrated dispensing of oral oncolytics: Real-world cost-of-care comparison with traditional dispensing

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BACKGROUND: Medically integrated dispensing, consisting of multidisciplinary care teams dispensing drugs within clinics, has been associated with better outcomes, lower waste, and better patient care experiences for members receiving oral oncolytics (OOs). Recognizing this value, payers have developed integrated dispensing networks to supplement traditional dispensing sites; however, little information is available comparing total cost of care (TCC) between these channels.

OBJECTIVE: To compare 6-month pre/post cost of care between integrated and nonintegrated dispensing channels among commercially insured members initiating OO therapy.

METHODS: The 16 million commercially insured Prime Therapeutics integrated pharmacy and medical claims database was used to identify members newly initiating an OO drug of interest (index date) between January 1, 2019, and December 1, 2022. For study inclusion, members were required to be continuously enrolled 6 months before and after index, had a cancer diagnosis, and had at least some medical spending. Dispensing channel Integrated Health System Specialty Pharmacy (Int-HSSP), Integrated Physician Office (Int-Phys), Non-Integrated (Non-Int) was assigned using index OO fill. The primary outcome was change in all-cause TCC, obtained by summing medical (Med) and pharmacy benefit cost paid amounts. Difference-in-difference regression analysis was used to compare change in spending across channels, adjusting for demographics, health status, and cancer type.

RESULTS: A total of 31,594 (Int-HSSP: n = 5,666; Int-Phys: n = 2,589; Non-Int: n = 23,339) commercially insured members met all study criteria. Mean age ranged from 54.1 (Int-HSSP) to 56.0 years (Non-Int). Compared with Non-Int (TCC [Pre: $67,466, Post: $114,472]; Med [Pre: $59,006, Post: $70,515]), significant cost savings were observed in Int-Phys for TCC (Pre: $73,774, Post: $115,002; adj. diff -$4,329 [-$8,522 to -$136; P = 0.04]) and Med cost (Pre: $65,538, Post: $67,024; adj. diff -$4,800 [-$8,727 to -$873; P = 0.02]). No significant cost savings were observed in Int-HSSP (TCC [Pre: $83,831, Post: $131,180]; Med [Pre: $74,321, Post: $83,168]; pharmacy benefit cost [Pre: $9,510, Post: $48,012]) when compared with Non-Int.

CONCLUSIONS: Int-Phys dispensing channel for OO drugs was associated with 7.2% lower medical cost and 3.8% lower TCC compared with the Non-Int dispensing channel. These Int-Phys channel cost offsets supplement previously published clinical care and member experience benefits, supporting innovative network designs that increase member access to this dispensing channel.

SPONSORSHIP: Prime Therapeutics, LLC.

U13 Factors driving biosimilar access among US health plans

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BACKGROUND: Despite their lower cost, biosimilars have seen slow uptake in the United States.

OBJECTIVE: To understand the factors associated with access restrictions on biosimilars, and which therapeutic areas are poised for increased biosimilar uptake.

METHODS: A survey was conducted with health plan stakeholders recruited from a proprietary database of market-access decision-makers in October 2023. Twenty-five individuals responded.

RESULTS: A majority preferred a low-WAC, low-rebate strategy (84%) to a high-WAC, high-rebate strategy (16%) for new biosimilar contracting. When asked which types of indication are most likely to lead to greater access restrictions on a biosimilar compared with its reference product, most respondents selected rare cancer indications (32%) and pediatric indications (32%). Biosimilars for noncancer rare diseases (20%) and nonrare cancers (16%) were less likely to face restrictions. A pharmacy benefit manager contract for the reference product was most likely to lead to restrictions on the biosimilar (36% of respondents) when considering market factors. Existing restrictions on the reference product was next (32%), followed by availability of 2 or more biosimilars (24%) and availability of 1 biosimilar competitor (8%). More respondents were likely to restrict a biosimilar covered under the pharmacy benefit (64%) than the medical benefit (36%). The most common operational barrier was the need for pharmacies to contact prescribers for a biosimilar prescription (44%). Pharmacy stocking of multiple biosimilars was a barrier for 40%, and 20% agreed that switching prior authorizations from the reference product was a barrier. However, 96% were confident in their ability to facilitate a switch to a biosimilar. Reference products retain strong claim volume across 8 therapeutic areas. The advantage is strongest in rare disease, with reference products retaining 69% of volume (expected to drop to 60% next

year). Multiple sclerosis, pulmonary, and ophthalmology follow with 67% each (expected to drop to 53%, 54%, and 53% next year, respectively). Reference products retain the lowest volume in oncolytic therapy (49%). Respondents expect reference product share to shrink across all therapeutic areas in the next year, with the largest decline expected for inflammatory conditions (64% to 46%).

CONCLUSIONS: Although pharmacy benefit manager contracting and rare cancer indications continue to be the biggest influences on biosimilar access, the anticipated decline of reference product share across the board may indicate that these factors will weaken in the future.

SPONSORSHIP: Precision Value & Health.

U14 Real-world costs and site-of-care patterns of fixed-dose subcutaneous vs intravenous formulations of pertuzumab and trastuzumab

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BACKGROUND: The introduction of fixed dose subcutaneous (SC) formulation of pertuzumab and trastuzumab (PH) offers patients and health care providers a convenient and efficient route of administration, contrasting the time-intensive intravenous, which could last for hours. However, it remains uncertain whether the SC formulation is associated with lower health care costs and has led to a shift in the site of care from high cost to lower cost settings.

OBJECTIVE: To describe real-world cost of care and site of care patterns associated with maintenance cycles of SC vs intravenous formulations of PH among patients with positive human epidermal growth factor receptor 2 breast cancer.

METHODS: We retrospectively identified adult women with human epidermal growth factor receptor 2–positive breast cancer between January 1, 2021, and December 31, 2022, from the IQVIA PharMetrics Plus database. Patients were required to have claims for PH on the same day and at least 3 months of continuous enrollment prior to the first administration of PH to identify and exclude loading cycles of PH. The total costs incurred on the day of administering PH were categorized into the PH drug, administration, chemotherapy, and remaining costs (costs in 2022 USD). Results were presented using the following 3 groups: PH biosimilar (PHS) when a trastuzumab biosimilar was used, PH brand (PHB) when trastuzumab Brand (Herceptin) was used, and PHSC (Phesgo; subcutaneous). Furthermore, results were stratified by chemotherapy coadministration status, health plan type, site of care, and patient region.

RESULTS: A total of 24,699 PH claims were included in the study, comprising 78% for PHS, 12% for PHB, and 10% for PHSC. The majority of PH claims were paid by non–health maintenance organization health plans, ranging from 80% to 85%. Chemotherapy was coadministered with half of PHS and PHB cycles compared with 33% of PHSC cycles. The proportion of PH administered in an outpatient hospital setting was 71% for PHB, 57% for PHS, and 55% for PHSC. The total cost of care on the day of PH administration was $25,958 for PHB, $19,151 for PHS, and $16,083 for PHSC. The combined cost of PH and administration was $21,468 for PHB, $15,474 for PHS, and $12,823 for PHSC. Shifting care from outpatient hospital settings to office settings resulted in average per-cycle savings of PH drug and administration costs of $7,296 for PHS, $9,737 for PHB, and $5,681 for PHSC.

CONCLUSIONS: PHSC is associated with lower total costs of care compared with PHS and PHB, primarily driven by a combination of lower costs of drug, cost of administration, and slight shift of care from outpatient hospital to lower cost site of care.

SPONSORSHIP: Genentech, a subsidiary of F. Hoffmann-La Roche Ltd.

U15 Changes in US payer biosimilar coverage policies of granulocyte colony-stimulating factor products

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BACKGROUND: The biosimilar pathway to US drug approval was established by the US Food and Drug Administration (FDA) in 2009 with the Biologics Price Competition and Innovation Act. Although this allowed the FDA to approve its first biosimilar, Zarxio, the United States still lags behind Europe in biosimilar approvals. Lack of biosimilar uptake by US payers has dampened potential benefits of biosimilars.

OBJECTIVE: To provide a descriptive analysis of US payer commercial coverage policies on biosimilars over time with focus on granulocyte colony stimulating factors.

METHODS: Payer biosimilar coverage policies from the top 50 US payers (based on number of covered lives) were reviewed for historical changes from publicly available information found on each payer's website. Payer websites were analyzed for availability of policies and robustness of historical policy record. Payer policies were then reviewed to extract filgrastim and pegfilgrastim biosimilar coverage status and payer choice of the preferred product. Data were

analyzed for preferred/nonpreferred status, and policy updates were compared with FDA approval date.

RESULTS: From the 50 payers analyzed, 38 (76%) payers had policies available for filgrastim and 42 (84%) had policies available for pegfilgrastim. For filgrastim biosimilars, 84% of payers preferred Zarxio, whereas Neupogen, Nivestym, and Releuko were most commonly nonpreferred. Nivestym was the second most preferred with 37% of payers preferring this agent. On average, filgrastim biosimilars were added to a policy 4.7 months after FDA approval. Of the 14 filgrastim policies with historical record, 36% have undergone changes to their preferred products. For pegfilgrastim biosimilars, 62% of payers preferred Ziextenzo, 60% preferred Neulasta, and 55% preferred Fulphila, whereas Nyvepria, Fylnetra, and Stimufend were most commonly nonpreferred. Preference for Udenyca was split, with 45% of payers preferring this agent and 45% of payers listing it as nonpreferred. On average, pegfilgrastim biosimilars were added to a policy 4.1 months after FDA approval. Of the 18 pegfilgrastim policies with historical record, 66% have undergone changes to their preferred products.

CONCLUSIONS: Payer policies for granulocyte colony stimulating factor biosimilars indicated that Neulasta has retained much of its preferred status, whereas Neupogen is often nonpreferred. In both cases, average time to policy addition was about 4 months after FDA approval. Further, pegfilgrastim policies had more updates to the preferred product status than filgrastim policies, possibly because of more pegfilgrastim biosimilars being approved and marketed.

SPONSORSHIP: Cencora, Inc.

U16 Payer perspectives of cell therapy and gene therapy treatment paradigms for an inherited retinal disorder

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BACKGROUND: Serious challenges persist around coverage and reimbursement for cell and gene therapies (CGTs) in the United States. Market research often groups cell therapies (CTs) and gene therapies (GTs) as a single entity despite their mechanistic differences. Gaps in the literature remain for detecting the similarities and differences on payer perception of CT vs GT.

OBJECTIVE: To understand how US payer perspectives differ between emerging CTs and GTs.

METHODS: A double-blinded, web-based survey was fielded in September 2023 to payers from health plans and integrated delivery networks. The survey used a hypothetical narrative to describe CT and GT paradigms for treating retinitis pigmentosa. Payer perceptions were assessed through an identical set of questions posed independently for CTs and GTs.

RESULTS: A total of 32 payers (75% health plan, 25% integrated delivery network) comprising Pharmacy Directors (59%), Medical Directors (22%), Chief Medical/Pharmacy Officers (16%), and Clinical Pharmacists (3%) completed the survey. Disease Overview (GT = 31%, CT = 31%) was the most important information to respondents during preapproval information exchange, and Study Design & Results (GT = 25%, CT = 28%) was most important to payers following approval. Cost of Therapy was the primary concern of payers for each treatment (GT = 97%, CT = 97%), and Durability of Therapy (GT = 41%, CT = 34%) was ranked as the most important factor when evaluating for coverage determination. In both situations, payers may exclude a new therapy from formulary after 2 therapies have been added (GT = 50%, CT = 53%). In the combined question set, 47% of payers cover the full cost of genetic testing and none (0%) considered this a patient responsibility. Most payers (56%) felt travel assistance to Centers of Excellence should be provided by the manufacturer. Finally, if asked to choose one agent to add to formulary, 75% of payers would add a GT to formulary over a CT, and 78% view GT as the more attractive treatment approach.

CONCLUSIONS: Payer perceptions of CTs and GTs were highly similar, despite most respondents selecting GT as the optimal treatment paradigm. Payers are most concerned with cost and durability of therapies. As CGTs continue to enter the market for treatment of rare to prevalent diseases, this survey highlights key considerations, including cost sharing, durability of response, and the potential coverage challenges of third-in-class or later CGTs. Future research should focus on understanding which specific qualities of GTs make them a more desirable treatment approach.

SPONSORSHIP: Cencora, Inc.

U18 Impact of route of administration on access and reimbursement of cell and gene therapies: A survey of US payers

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BACKGROUND: Cell and gene therapies (CGTs) have the potential to provide curative treatments for certain diseases. However, there has been limited research on factors impacting access to CGTs, and particularly how route of administration (ROA) impacts payers' perspectives.

OBJECTIVE: To understand the role that ROA plays in shaping payers' perspectives when evaluating CGTs for formulary coverage.

METHODS: A blinded online survey was fielded in September 2023 to payers from Cencora's Managed Care Network. A screener survey was used to identify qualified respondents based on predetermined inclusion and exclusion criteria.

RESULTS: A total of 32 payers (75% health plans, 25% integrated delivery networks) completed the survey, including pharmacy directors (59%), medical directors (22%), chief medical/pharmacy officers (16%), and clinical pharmacists (3%). Based on the complexity of establishing reimbursement policies, 69% of respondents identified cell transplantation/implantation as the most complex ROA, whereas 63% viewed topical application as the simplest ROA. More than half (53%) of respondents require manufacturers to implement safety and efficacy monitoring programs before a CGT product is added to formulary, and ROA plays a significant role in shaping these programs. When determining the necessity of monitoring programs based on ROA, 76% of respondents ranked cell transplantation/implantation as most necessary, whereas 94% ranked topical application as least necessary. Respondents showed a higher willingness to participate in innovative contracts for curative therapies compared with multi-dose therapies, whereas the ROA played a minor role in their willingness to participate. Based on their experience, respondents reported familiarity with manufacturer-sponsored patient support programs for intravenous (66%) and cell/transplantation/implantation (34%) CGTs, but none for other ROAs.

CONCLUSIONS: ROA impacts reimbursement policies for CGTs. The majority of payers find cell transplantation/implantation the most complex and topical application the simplest to establish reimbursement policies for CGTs. Monitoring programs and willingness to participate in innovative contracts are also influenced by ROA. Further research should be considered to explore the influence of ROA on payers' formulary decisions for CGTs.

SPONSORSHIP: Cencora, Inc.

U19 Sourcing value: Understanding payer perceptions of value assessment information for formulary decision-making

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BACKGROUND: In recent years, US payers have increasingly used value assessment information (VAI) to help evaluate interventions, informing pricing negotiations and formulary decisions. Because of the potential impact of these decisions on patients, it is important to understand the sources of VAI that payers currently use.

OBJECTIVE: To identify which sources of VAI payers find the most useful and relevant for formulary decision-making.

METHODS: Double-blinded, web-based survey of US health care payers was fielded through Cencora's research panel, the Managed Care Network, in July 2023.

RESULTS: A total of 48 advisors from health plans (n = 27), integrated delivery networks (n = 9), and pharmacy benefit managers (n = 12) participated in the survey. Although advisors reported various roles that were responsible for reviewing VAI, pharmacy directors (83%), medical directors (56%), and clinical pharmacists (50%) were most often cited. Most organizations indicated that training resources for reviewers of VAI were developed internally (52%), with 38% externally sourced training resources from the Institute for Clinical and Economic Review (ICER) and 31% from the National Comprehensive Cancer Network (NCCN). When assessing the usefulness of various sources of VAI, most payers reported that specialty society guidelines (60%), NCCN Evidence Blocks (56%), and ICER Evidence Reports (50%) were very/extremely useful for informing coverage and formulary decisions. In the past 24 months, 40% of payers indicated that most (at least 60%) coverage and formulary decisions were informed by specialty society guidelines, 34% said most were informed by NCCN Evidence Blocks, 31% said most were informed by ICER Evidence Reports, and 28% said most were informed by Academy of Managed Care Pharmacy dossiers (28%). Sources that payers reported using less often included the Patient-Centered Outcomes Research Institute comparative-effectiveness research, international health technology assessment sources, and Evidence Street reviews.

CONCLUSIONS: More than half of payer respondents report developing internal resources for reviewing VAI sources and cite multiple roles that are responsible for reviewing VAI, indicating broad organizational interest in VAI and its application. Payers use various sources of VAI to inform payer decision-making, but the relevance and usefulness

of VAI sources vary substantially, with specialty society guidelines, NCCN, ICER, and Academy of Managed Care Pharmacy being the most useful.

SPONSORSHIP: Cencora.

U20 Mind the "preapproval" gap: Payer preapproval information needs and how manufacturers can better meet them

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BACKGROUND: In 2018, US Food and Drug Administration (FDA) guidance for preapproval information exchange (PIE) provided a pathway for manufacturers to communicate with payers before approval of a new product or new indication. In 2022, the Consolidated Appropriations Act, 2023 (sometimes referred to as PIE legislation) was passed and codified a permanent safe harbor for manufacturers to proactively engage in PIE.

OBJECTIVE: To understand whether payers are receiving from manufacturers the preapproval information needed to support formulary decision-making and to identify what types of information are of most value.

METHODS: A double-blinded, web-based survey was fielded with advisors from Cencora's Managed Care Network from June 5, to 27, 2023.

RESULTS: A total of 45 advisors responded to the survey representing health plans (51%), IDNs (24%), and pharmacy benefit managers (24%), with roles as pharmacy directors (62%) and medical directors (31%), among others. Of the payer respondents, 47% perceived a gap in preapproval information needed for their organization vs what was available in literature and/or supplied by the manufacturer. Pricing information (90%), place in therapy (67%), and patient use projections (48%) were identified as the most common types of preapproval information needed by payers but not provided by manufacturers. This was consistent with what payers perceived as the most impactful; product pricing information (71%), place in therapy (69%), and factual presentation of study results (69%) were extremely or very impactful in formulary decision-making. In the absence of product price prior to FDA approval, alternate pricing information desired included an estimated product price (31%), comparative information relative to similar therapy (22%), estimated price range (20%), etc. From a delivery perspective, 46% of payers indicated that they rarely or never receive preapproval dossiers without formally requesting them. For payers who perceived a gap in preapproval information needed vs available, 100% cited that their formulary decision-making ability would be at least somewhat improved if they were to receive the preapproval information needed.

CONCLUSIONS: Payers perceive a gap in preapproval information needed vs what is provided by manufacturers, such as pricing information, place in therapy, and patient use projections. Further, although PIE legislation permits the proactive dissemination of preapproval information, payers do not consistently receive preapproval dossiers, representing a missed opportunity by manufacturers to help inform payer formulary and budget planning for preapproval products or indications.

SPONSORSHIP: Cencora.

U21 Payer insights on value perception and satisfaction of information sources

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BACKGROUND: Payers use many sources of information to assist in the evaluation of new products, prioritizing existing treatment options and conducting drug and clinical reviews to make coverage decisions. Understanding payers' preferred sources and the rationale for their perception would help to prioritize resources used to develop information sources.

OBJECTIVE: To understand sources of information most valued by payers for making decisions and conducting drug and clinical reviews.

METHODS: US payers with the responsibility of making coverage decisions, preparing for and/or conducting drug/clinical reviews independently, or as part of their organization's pharmacy and therapeutics committee participated in a 3-phased double-blind study. The first phase consisted of interviews to inform survey design, followed by a 30-minute online survey, and then follow-up interviews to collect rationale for survey responses. In addition to types and sources of information used, rank ordering the information sources and satisfaction rating were collected.

RESULTS: The survey was completed by 44 payers (pharmacy directors [59%], medical directors [23%], clinical pharmacists [18%]) from health plans (64%), integrated delivery networks (23%), and pharmacy benefit managers (14%). The most frequently used information was published literature (89%), clinical trial (84%), and cost data (75%). The sources of data most frequently ranked to have the highest value are medical information (36%), Institute for Clinical and Economic Review (ICER) (18%), and third-party platforms (14%). ICER was ranked the highest by more pharmacy directors (27%) than medical directors (0%) and more national payers (31%) than regional payers (11%). A total of 73% of payers

rated very/extremely satisfied with medical information sources, followed by 61% for ICER, and 55% with third-party platforms. The most frequently stated reasons for high satisfaction were relevant information being provided and unbiased information. Academy of Managed Care Pharmacy sources were rated high by 48%-52% of responders, and yet, only up to 11% found it valuable, most influenced by medical directors stating relevance and access as the most frequently stated reasons.

CONCLUSIONS: Payers value information sources that deliver relevant and unbiased information. Information relevance is different for medical vs pharmacy directors, as indicated by their value perception of some information sources. Customization and prioritization of information sources presented to payers would optimize the evaluation process.

SPONSORSHIP: Pfizer Medical Affairs.

U22 Accumulator and maximizer impact on medication adherence and health services usage

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BACKGROUND: In the last 5 years, pharmacy benefit managers, employers, and insurers' use of copay adjustment programs has increased. In general, these programs, referred to as copay accumulators and maximizers, prohibit the application of copayment assistance programs dollars to count toward the patient's out-of-pocket deductibles or out-of-pocket maximum. Research suggests that the use of these programs may negatively impact a patient continuing to take their medication (ie, greater medication discontinuation, lower adherence to medications). Potentially compounding the effect of these programs is research suggesting that exposure to these programs is more likely among historically marginalized populations.

OBJECTIVE: To compare medication persistence and health care utilization of patients exposed to copayment accumulator and copay maximizer to those on standard (not on maximizer or accumulator).

METHODS: This study was a pooled, cross-sectional study data obtained from IQVIA's Longitudinal Access and Adjudication Data linked to Experian consumer data between January 1, 2019, and December 31, 2021. Inclusion was limited to unique patients who were covered by commercial insurance or health exchanges, had at least 1 pharmacy claim for immunology, multiple sclerosis or oncology, and had continuous eligibility throughout the study period. Patients were excluded if they had a secondary payer and prescription claims throughout the study period. Patients were categorized into 1 of the following 3 copay cohorts: (1) maximizers, (2) accumulators, and (3) standard–patients identified as being on standard coinsurance or copay plans. Medication persistence was defined as percentage of days covered in the 365 days following the first medication in the study period.

RESULTS: Of the 41,790 who met the selection criteria, 5,511 were categorized as accumulators, 2,544 were maximizers, and 33,735 were standard patients. Accumulator patients have a lower proportion of nonpersistent patients compared with the standard cohort, 54% and 61%, respectively. Among the 9,278 patients who had medical data available and whose pharmacy spending reached the deductible cap, accumulator patients had much higher rates of emergency department visits per 100 compared with the standard patient cohort, 31.4 and 22.2, respectively, but similar rates of inpatient and office visits.

CONCLUSIONS: The analysis indicates that medication persistence among patients experiencing copayment accumulators was lower compared with patients with a standard benefit design. Additionally, the accumulator cohort had higher emergency department visits.

SPONSORSHIP: None.

U23 Prescription digital therapeutics (PDTs): Timeline and turning point for wider acceptance and reimbursement

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BACKGROUND: Prescription digital therapeutics (PDTs) are software-based treatments designed to focus on behavioral elements related to specific conditions and diseases. These applications are studied in clinical trials for safety and efficacy before US Food and Drug Administration (FDA) authorization. Because of their standardized delivery, PDTs can help address health care equity issues, are scalable, and offer patient convenience. PDTs also provide advantages, such as absence of drug interactions and increased treatment plan adherence.

OBJECTIVE: To collate a historical timeline behind development, application, and approvals of PDTs to understand and gather insights of adoption patterns by regulators and payers.

METHODS: Review literature on the areas impacted and reported economics, study the Senate bill related to Centers for Medicare & Medicaid Services acceptance and reimbursement, and consider FDA actions related to the subject.

RESULTS: With 6 years of activity since the first FDA PDT approval, the last 2 years have seen an increasing number of events from the FDA, regulators, and payers recognizing the importance and value of PDTs. In 2017, the FDA approved the first PDT, named reSET, for treatment of substance use disorder. In 2018, the first demonstrated real-world economic savings was associated with use of reSET. Reductions were seen in in-hospital encounters, ED visits, and inpatient stays, reducing 6-month costs by approximately $3,600. In 2021, 40% of payers were estimated to offer any PDT coverage. In 2022, access to Prescription Digital Therapeutics Act of 2022 was introduced. Included PDT definition with requirements for application of coverage, opened the door for approved PDTs to be incorporated into Centers for Medicare & Medicaid Services treatment programs and be reimbursed. In 2022, Healthcare Common Procedure Coding System Level II code K1028 was established for specific PDT application. In 2022, the first large commercial insurer created a coverage policy stating FDA-approved PDTs were medically necessary. In 2023, 29 marketed and 154 PDTs were under development, with 19 in late development. Therapeutic areas include central nervous system, cardiometabolic, gastrointestinal, oncology, and women's health. In 2023, access to Prescription Digital Therapeutics Act was reintroduced. In 2023, the FDA began accepting applications to fill a 9-member Digital Health Advisory Committee.

CONCLUSIONS: 2022-2023 actions build on previous activity and are the likely tipping point for increased acceptance and reimbursement of PDTs. Patients with a variety of conditions could benefit from improved access to PDTs, addressing a variety of health care equity concerns and patient compliance issues.

SPONSORSHIP: ICON plc.

U24 Differences in opioid utilization metrics among beneficiaries enrolled in Mississippi Medicaid using claims-linked PMP data versus claims data only

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BACKGROUND: Monitoring opioid prescribing trends is a critical drug utilization review activity for Medicaid programs. Mississippi Medicaid has traditionally used administrative claims data alone to assess these trends in high-risk opioid prescribing. A recent study incorporating MS Prescription Monitoring Program (PMP) claims data with MS Medicaid claims found that 42% of opioid claims for individuals enrolled in MS Medicaid were paid for by a source other than Medicaid. Using Medicaid claims data alone to assess opioid prescribing trends provides only a partial picture of an individual's true opioid use.

OBJECTIVE: To examine trends in opioid prescribing using 2 methodologies (MS Medicaid claims data only and MS Medicaid claims linked with PMP data) and compare differences in trends between the 2 methods.

METHODS: A retrospective analysis from July 2019 to June 2022 was conducted using MS Medicaid fee-for-service and coordinated care organization administrative claims data and MS PMP claims data for Medicaid-enrolled beneficiaries. monthly trends in opioid prescribing (number of beneficiaries with opioid claims, number of opioid claims, the days' supply of opioid claims, number of beneficiaries with high morphine milligram equivalent claims, and the rate of concomitant prescribing with benzodiazepines) were calculated using the 2 following data sources: MS Medicaid claims only and MS Medicaid claims linked with MS PMP data. Differences in monthly trends in opioid prescribing between the 2 data sources were assessed using paired t-tests.

RESULTS: Between July 2019 and June 2022, 132,591 beneficiaries were identified as having opioid claims when using MS Medicaid claims data only, whereas 157,776 beneficiaries were identified when combining MS Medicaid claims linked with PMP data. On average during the study period, the number of monthly opioid prescriptions (14,008 vs 12,336; $P < 0.001$), the monthly number of beneficiaries with opioid prescriptions (12,339 vs 10,972; $P < 0.001$), the monthly number of beneficiaries with morphine milligram equivalent greater than 90 mg (138.7 vs 118.1; $P < 0.001$), and the monthly rate of concomitant prescribing with benzodiazepines per 1,000 beneficiaries (48.3 vs 38.2; $P < 0.001$) were all found to be significantly higher when estimated using MS Medicaid claims linked with PMP data vs MS Medicaid claims data only.

CONCLUSIONS: This study demonstrated that incorporating PMP claims data into Medicaid prescription claims data significantly impacted the metrics Medicaid used to identify high-risk opioid prescribing.

SPONSORSHIP: Mississippi Division of Medicaid.

U25 Trends in pharmaceutical expenditure and characteristics of very high-cost prescription drug users in the United States, 2018-2022

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BACKGROUND: A small portion of patients accounts for a highly disproportionate amount of pharmaceutical expenditure, termed very high-cost users. Prior studies found that 2.3% of the population accounted for the top 50% of the national retail prescription spend.

OBJECTIVE: To examine the demographic and clinical characteristics of very high-cost users and the medications and drug classes that accounted for high prescription expenditure among these users.

METHODS: This large, retrospective, cross-sectional study included data on 65,739,791 US adults aged 18 years or older from a national pharmacy benefits manager from January 1, 2018, to December 31, 2022. In each year, members were required to have continuous pharmacy benefit and to be enrolled in a commercial, exchange, Medicare, or Medicaid health plan. Patients were categorized as very-high-cost users if their total pharmacy expenditure was equal to or greater than the 99th percentile each year. Pharmacy expenditures included spending by both patients and health plans. Descriptive statistics were used to present trends in pharmaceutical expenditure among very-high-cost users. Logistics regression was used to assess characteristics associated with being very-high-cost users.

RESULTS: From 2018 to 2022, very-high-cost users made up 1% of the study sample, but they accounted for most of pharmaceutical expenditure (38.7% in 2018, 45.5% in 2022), with an average expenditure of $78,279/user in 2018 and $84,207/user in 2022. Among very-high-cost users, a large share of expenditure was concentrated among drug classes used for treatment of inflammatory conditions (38.5% in 2022), oncology (24.5%), and multiple sclerosis (7.1%). Adalimumab accounted for the largest share of expenditure in 2021 (14.1%), followed by ustekinumab (7.1%). Compared with other users, very-high-cost users were more likely to be aged 45-64 years, to be male, to be non-Hispanic Black, to live in areas with low social needs, and to be enrolled in an exchange health plan.

CONCLUSIONS: Although very-high-cost users account for a trivial portion of the population, their share of pharmaceutical expenditure has been growing considerably between 2018 and 2022. This study highlighted unique characteristics of this population, as well as specific drugs that drove their high pharmaceutical expenditure. Findings from this study may help understand rising pharmacy costs in the United States. They may also help identify issues and solutions of specific cost drivers within our health care system.

SPONSORSHIP: None.

U26 Insights to payer perspectives on the Inflation Reduction Act: A survey of US payers

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BACKGROUND: The Inflation Reduction Act of 2022 (IRA) represents a landmark shift in federal policy governing the Centers for Medicare and Medicaid Services' approach to prescription drug pricing and reimbursement. IRA provisions aim to improve accessibility and affordability of health care by lowering prescription drug costs for patients, addressing rising drug prices, and reducing federal drug spending.

OBJECTIVE: To assess how payers may be considering new strategies related to formulary decisions, benefit design, cost control measures, and contracting negotiations in response to the IRA.

METHODS: Medical or pharmacy directors from regional or national health plans and pharmacy benefit managers were recruited to participate in an online survey. Survey questions focused on expected payer reactions to Medicare Drug Price Negotiation Program (DPNP), Medicare Part B and D Inflation penalties, and Medicare Part D Redesign. Descriptive statistics were reported.

RESULTS: Representatives from 30 payers, including 5 national health plans, 18 regional health plans, and 7 pharmacy benefit managers, representing over 290 million lives, completed the survey. The majority of respondents believe the IRA DPNP will result in Medicare Part B prices lower than current negotiated rates (66%), whereas current Medicare Part D negotiated prices are believed to be already lower than what will be negotiated (51%). A total of 70% of respondents indicated net price is their main determinant in coverage decisions for drugs not subject to negotiation. A total of 53% expect price negotiation to affect their use of use management tools. Approximately 83% of respondents believe IRA-inflation policies will result in increased launch prices. In response to Part D redesign, 90% expect manufacturers to increase launch prices as a result of Part D benefit redesign, 77% decreasing flexibility to negotiate

rebates for commercial plans, and 59% increasing the use of outcomes based contracting agreements.

CONCLUSIONS: Survey results suggest payers foresee IRA's Medicare DPNP having the largest impact, followed by Medicare Part D redesign. Payers are also anticipating increasing management of higher-cost drugs, as well as employing greater control measures and narrowing formularies in response to the IRA. However, payers are anticipating that the net price of the drugs will remain the primary driver in making coverage determinations and establishing formulary preferences, regardless of the IRA.

SPONSORSHIP: Magnolia Market Access.

U27 Impact of 90-day supply fill incentive on antidiabetic therapies to non–dual-eligible Medicare-covered beneficiaries in New York City

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BACKGROUND: Health plans are in a unique position to shape the member experience of pharmacy benefits. Studies have found that increased day supply (DS) fills can lead to increased adherence rates and overall improved health outcomes. The purpose of this study was to determine the impact of a 90DS fill incentive–allowing members to access a 90DS for the copay of a 30DS–for antidiabetic drugs on the health cost outcomes of nondual-eligible Medicare-covered beneficiaries.

OBJECTIVE: To evaluate the effectiveness of providing financial incentives on 90-day fills for antidiabetic therapy and its impact on clinical outcomes.

METHODS: A retrospective cohort claims-based analysis was performed to include members who filled at least one 30DS prescription (Rx) of an antidiabetic medication between January 1, 2021, and March 30, 2023. *International Classification of Diseases, Tenth Revision* codes were used to identify those who had diabetes-related medical claims and/or hospitalizations. Members were placed into these DS conversion category groups: nonconversion 30DS (NC30), nonconversion 90DS (NC90), conversion from 30DS to 90DS (C90), and mixed conversions (MCs).

RESULTS: All 16,526 unique cohort members (UCMs) were confirmed to have a diabetes indicator in their medical claims. A total of 206,830 Rxs were filled. A total of 11% (n = 1,784) of UCMs were in the NC30 group and had $1,580/member Rx spend. A total of 38% (n = 667) of NC30 had a medical claim with $4,361/member spend, and 3% (n = 45) of NC30 group had a hospitalization. A total of 51% (n = 8,503) of UCMs were in the NC90 group and had $1417/member Rx spend. 51% (n = 4,330) of NC90 had a medical claim with $2,148/member spend, and 1% (n = 102) of NC90 group had a hospitalization. Approximately 22% (n = 3,667) of UCMs were in the C90 group and had a $5,809/member Rx spend. A total of 65% (n = 2,389) of C90 had a medical claim with $7,039/member spend, and 3% (n = 102) of C90 group had a hospitalization. A total of 16% (n = 2,572) of UCMs were in the MC group and had a $4,588/member Rx spend. A total of 56% (n = 1,437) of MC had a medical claim with $4,748/member spend, and 3% (n = 78) of MC group had a hospitalization.

CONCLUSIONS: Members in the NC90 group who consistently used 90DS had the lowest overall cost of care in each spend category. The C90 group had the highest cost of care in each spend category. The MC group had a higher cost of care than those who did not switch DS. Additional analyses, including year-over-year spend metrics and adherence rates, will be conducted to validate the long-term impacts of this pharmacy benefit change on members.

SPONSORSHIP: N/A.

Z00-Z99 Factors Influencing Health Status and Contact With Health Services

Z1 Practice efficiencies to health care institutions associated with use of epcoritamab vs other novel therapies in patients with relapsed or refractory follicular lymphoma

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BACKGROUND: Follicular lymphoma (FL) is the most common type of clinically indolent non-Hodgkin lymphoma, accounting for approximately 20% of all lymphomas. The recent emergence of novel therapy options for relapsed or refractory FL include chimeric antigen receptor T-cell (CAR-T) therapy and bispecific antibodies. Epcoritamab (subcutaneous [SC]) is a CD3xCD20 bispecific antibody with demonstrated efficacy and safety in treating relapsed or refractory FL after 2 or more lines of therapy and is the first in the class to be offered as a SC treatment.

OBJECTIVE: To understand the efficiencies for institutions while treating patients with epcoritamab vs other novel treatments.

METHODS: A microcosting analysis was developed to compare epcoritamab vs mosunetuzumab and axicabtagene ciloleucel (axi-cel). Practice efficiencies were estimated over various time horizons (6 months, 1 year, median

treatment cycle) based on time for health care personnel (pharmacy technician, pharmacist, and nurse) and in-chair treatment time throughout treatment stages, as well as time spent in the hospital for post-treatment adverse event monitoring. Dosing and time inputs were based on prescribing information, published studies/databases, and clinical expert opinion.

RESULTS: Over the 1-year time horizon, epcoritamab was associated with shorter health care personnel time and in-chair treatment time per patient relative to mosunetuzumab and CAR-T (axi-cel). Treatment with epcoritamab demonstrated a 31% reduction in hospital personnel time (29 vs 42 hours) and 48% reduction in chair time (22 vs 52 hours) relative to mosunetuzumab per one treated patient. Compared with axi-cel, there was a substantial savings in personnel time associated with epcoritamab (29 vs 58 hours), but slightly longer chair time (22 vs 20 hours), largely because of the one-time administration of CAR-Ts. The trends are consistent when looking at shorter time horizons, including 6 months and median number of treatment cycles.

CONCLUSIONS: With its unique SC administration, epcoritamab may improve institutional practice efficiency from a chair time and hospital personnel time perspective. These efficiencies may alleviate capacity constraints at infusion centers and redirect health care resources to other needs, improving the availability and quality of health care services.

SPONSORSHIP: Genmab A/S AbbVie.

Z5 Medication nonadherence social determinants of health risk score: Development and use

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BACKGROUND: Social determinants of health (SDOH), defined as the conditions in persons' environments that affect health, functioning, and quality of life outcomes and risks, contribute as much as 80% of variation in health outcomes. Planned Medicare SDOH initiatives, such as the health equity index reward, start collecting data in 2024 and will impact Quality Bonus Payments.

OBJECTIVE: To support SDOH-related care management efforts by developing a prioritization score of Medicare members at risk of SDOH-related medication nonadherence.

METHODS: Data to create the medication nonadherence SDOH score came from pharmacy claims for adherence measure-eligible members enrolled in 65 Medicare Advantage and Part D contracts during 2022. The 3 Star Ratings program adherence measures were used for this analysis. Potential SDOH factors for the analysis were identified through literature review and assessment of stakeholder priorities. The final set of factors were selected based on data accuracy, feasibility, licensing, and availability, as well as collinearity with other factors and the strength and clarity of the relationship to nonadherence. Factor weights were derived from a linear model with adherence, dichotomized as proportion of days covered less than 0.8 vs greater than or equal to 0.8, as the dependent variable and SDOH factors as key independent variables. SDOH factor model coefficients were multiplied by 100 to create factor-specific weights, and these weights were summed at the member level to create a single score representing the member's percentage point likelihood of SDOH-related medication nonadherence.

RESULTS: The final model included 1,035,005 Medicare enrollees, and SDOH factors consisted of SDOH-related Z-codes, social vulnerability index, low-income subsidy status, disability status, Medicaid enrollment status, age, sex, and rural-urban status. The distribution of SDOH scores appeared skewed and multimodal, with large clusters of members close to 0, close to 1.25, and around 4.25. The mean score was 1.6 with a median of 1.1 and a max of 11.6. The most influential factors were SDOH-related Z-codes and aged younger than 60 with factor weights of 3.6 and 4.1, respectively.

CONCLUSIONS: This managed care pharmacy SDOH health risk score used historical data to estimate likelihood of future medication nonadherence and can support Medicare Advantage and Part D plan sponsors' efforts in response to Medicare's SDOH-related initiatives. These findings demonstrate the feasibility of combining different types of SDOH-related data into a single score to be used by pharmacists' and pharmacies' care management services.

SPONSORSHIP: Prime Therapeutics, LLC.

Z11 What will be the impact on minority groups in 2026 when Medicare Part D price cuts take effect?

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BACKGROUND: Negotiation for selected Medicare Part D drugs is a key component of the Inflation Reduction Act (IRA), which aims to improve affordability of prescription drugs for Medicare enrollees. The US Department of Health and Human Services (HHS) has highlighted Asian, Black, and Latino enrollees as 3 specific ethnic groups that are poised to benefit from the IRA.

OBJECTIVE: To assess the use of the first 10 drugs selected for Part D price negotiations by 3 highlighted ethnic groups and how Medicare Part D enrollees will benefit from the projected impact of price negotiations.

METHODS: Analyzing information is available from Centers for Medicare & Medicaid Services, HHS, Kaiser Family Foundation, and Centers for Disease Control and Prevention.

RESULTS: The 10 drugs selected for price negotiations represented approximately 20% of Medicare Part D drug spend, or $50.5 billion, for the year ending May 31, 2023. Medicare enrollees paid $3.4 billion in out-of-pocket (OOP) costs for these drugs in 2022, up to $6,497 per enrollee for those without additional financial assistance. All 3 groups have higher use than Medicare enrollees overall, for use of selected diabetes drugs, Farxiga (dapagliflozin), Januvia (sitagliptin), and Jardiance (empagliflozin). Black and Latino enrollees also index higher for use of Novolog/Fiasp (insulin aspart). Approximately 2.1 million Medicare enrollees are Asian. The life expectancy for Asian people is 83.5 years—the highest of any group and higher than the overall population. Asian people's index is lower for 7 of the 10 drugs selected for negotiation. Approximately 5.8 million Medicare enrollees are Black. The life expectancy for Black patients is 70.8 years, down from 75.3 years in 2014. Black people's index is high on 5 of the 10 selected drugs. Approximately 5.3 million Medicare enrollees are Latino. The life expectancy for Latino people is 77.7 years, which is 1.3 years longer than White people. Latino people's index high for use of Enbrel (etanercept). Latino people's index is high on 5 of the 10 selected drugs. Negotiations are expected to lower costs to Medicare. Medicare Part D plans are required to include the selected drugs in their formularies. There is no requirement to give selected drugs preferred formulary status or offer reduced copayments to patients.

CONCLUSIONS: Unlike the IRA's $35 insulin cap, elimination of OOP costs on adult vaccines and expansion of the Low-Income Subsidy Program, Part D Price Negotiation will not lower OOP costs for enrollees including the ethnic groups highlighted by HHS. Ways to make selected drugs more affordable to disadvantaged populations should be considered.

SPONSORSHIP: ICON PLC.

Student Poster Titles and Presenters

B11 Adherence rates of single-tablet regimens vs multitablet regimens in HIV-positive patients in commercially insured health plans

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B12 Evaluating prescribing patterns and member utilization of preexposure prophylaxis for self-insured employers

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B18 Effect of nirmatrelvir/ritonavir and molnupiravir on emergency department visits, hospitalizations, and health care costs in patients with COVID-19

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B19 Pharmacist-driven tele-antimicrobial/antibiotic stewardship program

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B20 Utilizing the Collaboration to Harmonize Antimicrobial Registry Measures (CHARM) data to assess prescribing trends for amoxicillin during a shortage

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C9 Prevalence of lung cancer screening in a commercially insured population: A retrospective analysis of claims data

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C13 Impact of a site of care (SOC) program on members' accessibility to infusible oncology medications

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C16 Management of phosphoinositide 3-kinase inhibitor–induced hyperglycemia: A targeted literature review

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C17 Cost-effectiveness of adjuvant radiation therapy vs breast-conserving surgery and tamoxifen alone in older adult women with early-stage breast cancer: Base-case analysis

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C19 A systematic review: Evaluating patient-reported outcomes used in ADC clinical trials in oncology

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C38 Real-world assessment of chimeric antigen receptor therapy response rate and direct costs as observed by a regional health plan

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C39 Toxicities of advanced asparaginase products compared with pegaspargase in the treatment of pediatric acute lymphoblastic leukemia: A systematic literature review

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D12 An evaluation of the impact of disease-modifying agents for sickle cell disease on the utilization of health care services including hospitalizations and emergency department visits in a Medicaid population

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E1 Real-world treatment patterns and patient characteristics in drug-naive type 2 diabetes population: An analysis of initial combination therapy vs step therapy

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E15 An evaluation of hospitalizations and health care costs in Medicaid patients with insulin-dependent type 2 diabetes mellitus monitored with continuous glucose monitoring devices vs capillary blood glucose monitoring

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E16 Evaluation of an adherence intervention on patient compliance rates for Medicare Part D members in a large health plan

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E17 Evaluating Lantidra vs standard of care during 5 years using clinical trial data in patients with type 1 diabetes in the United States: A cost-offset model

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E18 Clinical impact of a pharmacist-led diabetes management program integrated in an accountable care organization

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E19 Increase in follow-on biologic insulin glargine utilization in a real-world database

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E20 Impact of cardiovascular and mental health comorbidities on all-cause health care utilization among older patients with type 2 diabetes

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E21 The impact of ADA guideline changes and utilization management on the use of first-line antidiabetic medication classes for the treatment of type 2 diabetes mellitus in a commercial population

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E22 Hemoglobin A1c control of continuous glucose monitoring compared with self–monitoring of blood glucose in type 2 diabetes

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E23 Real-world evaluation of GLP-1 RA formulary management on type 2 diabetes outcomes

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E24 Predictors of nonadherence and nonpersistence to self-injectable antidiabetic agents in Medicare patients with type 2 diabetes

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E25 Retrospective analysis of continuous glucose monitoring device utilization before and after pharmacy benefit coverage expansion

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E26 Comorbid mental health conditions do not affect the COVID-19 vaccine rate among patients with diabetes

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E28 Impact of insulin copay cap legislation on savings, adherence, and utilization among health plan Medicare beneficiaries

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E29 Impact of a unique management strategy on GLP-1 utilization in a mid-sized, self-funded employer group

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E30 Effect of the initial combination therapy approach vs step therapy on trajectories of adherence in drug-naive patients with type 2 diabetes

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E31 Real-world utilization of SGT2 inhibitors and GLP-1 agonists after metformin monotherapy

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E32 Comparative analysis of continuous glucose monitoring devices and traditional blood glucose self-monitoring methods in reducing diabetes-related health care costs for Medicaid patients under CareFirst BlueCross BlueShield Community Health Plan in DC

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E33 Redefining patient care: Payer pharmacist partnership with primary care clinics to support diabetes management

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E35 Impact of GLP-1 utilization for nondiabetic indications on plan management for a Medicare Advantage Part D plan

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E36 Utilization patterns and formulary impact of GLP-1s in multiple state Medicaid programs with and without expanded weight-loss drug coverage

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E37 An automated approach to diagnosis verification: Effects on utilization of glucagon-like peptide-1 agonists (GLP-1as)

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E38 A comparison of health care resource utilization and health care costs in new users of SGLT2 inhibitors vs GLP-1 agonists

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E39 Among privately insured US adults with cardiodiabesity, evaluating the association between social determinants of health and adherence to sodium-glucose cotransporter 2 inhibitors and glucagon-like peptide 1 receptor agonists and total cost of care

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E40 Evaluating the usage of sodium glucose cotransporter-2 inhibitors and glucagon-like peptide-1 receptor agonists in patients with type 2 diabetes mellitus or chronic kidney disease: A retrospective analysis of pharmacy and medical claims data

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E51 Glucagon-like peptide 1 receptor agonists in obesity: A study of weight management, medication utilization, and health care resource utilization

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E52 Obesity with preexisting cardiovascular disease without diabetes: Current glucagon-like peptide-1 (GLP-1) agonist treatment prevalence among 16 million commercially insured members

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E53 Comparative economic assessment of clinical trial data of weight loss therapies: Indirect descriptive comparison of tirzepatide vs semaglutide

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E54 Impact of glucagon-like peptide-1 agonist (GLP-1a) utilization on total cost of care when used for obesity management in Medicaid members

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E55 Real-world evaluation of glucagon-like peptide 1 receptor agonists vs phentermine with or without topiramate for weight loss

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E56 A cost analysis on the impact of adding antiobesity medication coverage: A comparison by industry

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F2 Repurposing antihypertensive medications to reduce the risk of Alzheimer disease and related dementias: A machine learning approach for causal estimates

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F3 Causal effect of antihypertensive medications on economic burdens using an artificial intelligence approach: Repurposing pharmacological therapies for patients with Alzheimer disease and related dementias

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F5 Improving behavioral health quality metrics with a pharmacist-led clinical program

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F18 The prevalence of behavioral health conditions among Medicare patients eligible for CMS Star Rating measures for medication adherence with diabetes, hypertension, and/or hyperlipidemia

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F25 Comparing efficacy and safety of Symbyax (olanzapine-fluoxetine), Seroquel XR (quetiapine XR), and Spravato (intranasal esketamine) for treatment-resistant depression: A literature review

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F26 Retrospective analysis of antidepressant utilization in a commercial health plan population

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F31 Impact of the 2022-2023 prescription stimulant drug shortage on cost of care and utilization in a commercial health plan: A retrospective analysis

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F32 Characteristics and patterns of care of Medicaid pediatric populations with anxiety and depression

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G2 Real-world clinical and economic outcomes of an adalimumab biosimilar switch program

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G7 Racial and ethnic differences in survival among patients with amyotrophic lateral sclerosis in Texas

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G25 Adherence outcomes from a pharmacist-led treatment goal intervention for specialty pharmacy patients with narcolepsy

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G26 Clinical characteristics and social determinants of health (SDoH) of patients with migraine (PwM) using Optum's deidentified Clinformatics Data Mart Database

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G27 Assessment of antimigraine pharmacotherapy prescribing requirements on therapy selection and utilization of care in the community (CITC) resources within the Veterans Integrated Service Network (VISN) 17

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G28 Health care resource utilization associated with use of calcitonin gene-related peptide (CGRP) antagonists and onabotulinumtoxinA (Botox) for migraine prophylaxis

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G29 Evaluating multiple sclerosis medication adherence factors in a commercially insured population

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G30 Clinical assessment to lower migraines: Implementing population health management for patients with migraine in a health system specialty pharmacy setting

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G31 Real-world-outcomes of CGRP agents and onabotulinumtoxinA as combination therapy for the treatment of migraine in adults

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I4 Analysis of the impact of the Inflation Reduction Act on cardiovascular medication cost, access, and development

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I5 Patient portal outreach with pharmacist support to address medication nonadherence in Medicare Advantage enrollees

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I7 Assessing treatment gaps in clinical atherosclerotic cardiovascular disease: A descriptive analysis

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I16 A managed care perspective about the cost and affordability of congestive heart failure management: A systematic review

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I17 A descriptive study of factors related to anticoagulant treatment in newly diagnosed nonvalvular atrial fibrillation

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I19 Medicare beneficiaries' generic dabigatran adoption: The impact of one Medicare advantage plan's promotion of dabigatran within an integrated delivery network

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I20 Proportion of GLP1-RA users at elevated risk of cardiovascular disease in real-world database

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J1 Impact of educational intervention for corticosteroid use treating acute respiratory tract infections in an urgent care setting

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J13 Evaluating the impact of the 2019 Global Initiative for Asthma guideline update on asthma prescribing patterns, clinical outcomes, and costs in a commercially insured population

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J14 Utilization trends of medications used as single maintenance and reliever therapy for chronic and acute asthma

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J16 Impact of adding asthma biologics to standard therapy on rates of asthma exacerbations

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J20 Leveraging albuterol's anti-inflammatory properties to address immune activation induced by inhalation of microplastics and nanoplastics

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J21 Cost-benefit analysis of a pharmacist's contribution in decreasing asthma-related economic and health burden with a focus on the Hispanic population

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J22 A cost-benefit analysis of pediatric respiratory syncytial virus treatment and prophylaxis

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K5 Evaluating the safety and effectiveness of switching from reference product adalimumab to biosimilar adalimumab-atto in patients with inflammatory bowel disease in an integrated health care system

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K20 An economic analysis of patients with metastatic colorectal cancer and their treatment journey in the United States

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L11 Systematic review of the effectiveness of tumor necrosis factor α inhibitors vs nonbiologic orals and topicals in treating moderate to severe plaque psoriasis

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L12 Evaluating the efficacy of probiotic products in the treatment of dermatological disorders such as atopic dermatitis and psoriasis: A literature review

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L13 Evaluating prescriber acceptance rates for pharmacist interventions in health system specialty pharmacy (HSSP) patients

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L20 Comparative effectiveness of home- vs office-based phototherapy for the treatment of psoriasis: The Light Treatment Effectiveness (LITE) study

Bishop B[1], *Howard L*[2], *Harris J*[2], *Fielding E*[3], *Flowers R*[4], *Fox J*[5], *Kalb R*[6], *Mangold A*[7], *Shin D*[3], *Callis-Duffin K*[8], *Gelfand J*[3]; *brooke.bishop@pennmedicine.upenn.edu*
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L24 Evaluation of the efficacy of JAK inhibitors for the treatment of alopecia areata

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M3 Predictors of cardiovascular care gaps in patients with rheumatoid arthritis

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M4 Adherence of first- vs second-line biologics for the management of immune-mediated inflammatory diseases

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M5 The landscape of real-world research of treatment patterns and clinical outcomes in patients treated with adalimumab: A scoping review

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M15 Analysis of current and future therapies for treatment of Duchenne muscular dystrophy

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M16 Health care costs among patients with myasthenia gravis in the United States

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N4 Evaluating the prevalence of polypharmacy in VIVA MEDICARE patients with a diagnosis of chronic kidney disease stage 3 and above that could benefit from deprescribing

Basetty V[1], *Saab H*[1], *Carr J*[1], *Collins K*[1], *Parker M*[1]; *vbasetty1997@gmail.com*
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R1 Fluoroquinolone antibiotic use in outpatient settings in Michigan

Starmer S[1], *Torney N*[2], *Dahal K*[1], *Klepser M*[3], *Pontefract B*[3], *Sohn M*[1]; *starmes@ferris.edu*; *MinjiSohn@ferris.edu*
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T2 High-risk anticholinergic medication use in older adults: A descriptive retrospective analysis

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T3 Medication regimen changes after nonfatal overdose among Massachusetts Medicaid enrollees

Finke W[1], *Alcusky M*[1], *Salsabili M*[1], *Heidari E*[1]; *william.finke@umassmed.edu*
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T4 The impact of lead exposure and toxicity in the Medicaid population and an exploration of utilizing pharmacists to improve related outcomes

Lang E[1], *Dickey K*[1], *Enghauser A*[1], *Hatton J*[1], *Medina E*[2], *Steele S*[1]; *edwin.lang@caresource.com*
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U28 An assessment of care in the community prescribing practices and clinical pharmacy medication management opportunities at the West Texas Veterans Affairs Healthcare System

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U29 Health system specialty pharmacist interventions related to patient-reported outcome measures

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U30 US payer perceptions on formulary evaluation and management of cell and gene therapies

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U31 Enhancing adherence quality measures through innovative outreach strategies in the New York Medicare population

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U32 Impact of prescription savings program on member outcomes

Um M[1], *Wu K*[2], *Yokoyama K*[2], *Kao D*[2], *Nguyen N*[2], *Cronin A*[2], *Wong H*[2], *Ma S*[2]; *michelle.um@blueshieldca.com*
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U33 Descriptive analysis of specialty infusion therapies by place of treatment

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U34 Pharmacist-led adherence interventions explored in a systematic review for future cost-benefit insight

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U35 Addressing barriers to prescription pickup among Medicare Advantage patients taking chronic medications

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U36 Utility and perspectives on the Academy of Managed Care Pharmacy (AMCP) Pharmacy & Therapeutics (P&T) competition

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U37 The impact of enhanced 2-way text services and digital services on adherence in the rare disease population

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U38 Assessment of the implementation of collaborative pharmacy practice agreements in an integrated health system specialty pharmacy

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U39 Identifying electronic prescribing trends in the pharmacy hub space

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U40 Evaluating low-touch vs high-touch low-cost alternative program outcomes

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U41 Enhancing medication safety in managed care: Approaches to improve patient readability of medication labels

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U42 Beyond value assessment reports: A review of payer perspectives on ICER's initiatives and tools

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U43 Factors associated with prescription abandonment and nonpersistence within 6 months of initiating oral first-in-class rare disease medications

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U44 Impact to adherence STARs measures from ongoing collaboration between a regional Medicare Advantage plan and local pharmacies

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U45 Exploring the impact of gene therapy on the budget management of a managed care model health plan

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U46 Impact of a pharmacist-led specialty drug care management program involving member outreach at a regional health plan

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U47 A health system specialty pharmacy initiative to identify and address social determinants of health

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U48 Understanding payer expectations of manufacturer-sponsored real-world evidence and health economics outcomes research data

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U49 Leveraging pharmacometrics for rare disease treatment: A comprehensive review

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U50 Ripple effects of virtual care on managed care health plans

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U51 Artificial intelligence and the future of managed care pharmacy

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U52 Budget impact analysis of pediatric integrative medicine practices for the management of chronic pain

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U53 Retrospective claims analysis of opioid-prescribing patterns: Single and combination agents for acute pain and subsequent conversion to chronic opioid usage among commercial patients

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U54 Descriptive analysis of market penetration for rituximab biosimilar

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U55 Improving P&T process efficiency and committee member satisfaction

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Z4 Retrospective study assessing the effectiveness of an interactive instant messaging program on Medicare Star adherence measures: Preliminary data

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Z6 Literature review of the economic and patient-centered effects of over-the-counter naloxone

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Z7 Evaluation and impact of a human papillomavirus (HPV) vaccination clinical program in a commercially insured population

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Z8 Systems-thinking approach to improving health literacy: An educational training intervention

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Z9 Implementing an in-house pharmacy in a free clinic: A preliminary assessment

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Z10 Cost analysis: Insurance prescription benefit vs prescription discount programs

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Z12 Integrating social determinants of health (SDOH) into clinical trials: Feasibility assessment and early results

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Encore Poster Titles and Presenters

B15 Experience and burden of post-transplant cytomegalovirus infection and treatment from the patient's perspective

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B16 The value of the influenza cell–based vaccine in the pediatric population: A dynamic transmission modeling approach in the United States

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B17 The impact of influenza vaccines on hospitalization costs for older adults in the United States: A real-world economic assessment of adjuvanted trivalent influenza vaccine compared with quadrivalent standard influenza vaccine for the 2018-19 and 2019-20 influenza seasons

Mould-Quevedo J[1], *Levin M*[2], *Postoma M*[3], *Pelton S*[4], *Divino V*[5], *DeKoven M*[5], *Zhou S*[5]; *joaquin.Mould-Quevedo@seqirus.com*; *Myron.levin@cuanschutz.edu*
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C24 Clinical and patient factors associated with treatment intensification for metastatic hormone-sensitive prostate cancer

Kalayeh B[1], *Williams T*[2], *Appukkuttan S*[1], *Jhaveri J*[3], *Campbell D*[2], *Kong S*[1], *Ramsey S*[2]; *bashir.kalayeh@bayer.com*; *Troy.Williams@curtahealth.com*
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C27 Avelumab first-line maintenance (1LM) therapy for locally advanced/metastatic urothelial carcinoma (la/mUC): Results from the real-world US PATRIOT-II study

Grivas P[1], *Barata P*[2], *Moon H*[3], *Gupta S*[4], *Hutson T*[5], *Sternberg C*[6], *Brown J*[2], *Dave V*[7], *Downey C*[7], *Shillington A*[8], *Katzenstein H*[9], *Kirker M*[10], *Hanson S*[10], *Liu F*[9], *Morris V*[9], *Bhanegaonkar A*[11], *Sonpavde G*[12]; *pgrivas@uw.edu*; *abhijeet.bhanegaonkar@emdserono.com*
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C28 Health care costs associated with first-line (1L) treatment of patients with locally advanced or metastatic urothelial carcinoma (la/mUC) in the United States

Ike C[1], *Kongnakorn T*[2], *Tichy E*[2], *Benedict A*[2], *Sanchez Alvarez J*[2], *Kearney M*[3]; *chiemeka.ike@emdserono.com*
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C36 Estimation of patients with relapsed/refractory follicular lymphoma on therapy in the United States

Johnston K[1], *Bennett M*[1], *Bains Chawla S*[2], *Yang S*[2], *Wang A*[3], *Yu J*[3], *Jun M*[2]; *kjohnston@broadstreetheor.com*; *sbs@genmab.com*
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C37 Similar ibrutinib (ibru) efficacy across ALPINE and ELEVATE-RR trials in relapsed/refractory chronic lymphocytic leukemia (R/R CLL): Matching-adjusted indirect comparison (MAIC)

Shadman M[1], Tedeschi A[2], Mohseninejad L[3], Yang K[4], Lamanna N[5], Xu S[6], Cohen A[4], Challagulla S[4], Xue M[4], Williams R[4], O'Brien S[7], Brown J[8], Tam C[9]; mshadman@fredhutch.org; keri.yang@beigene.com
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D1 Improvement of patient-reported outcomes in the IMerge phase 3 trial of imetelstat vs placebo in heavily pretreated patients with lower-risk myelodysplastic syndromes and high transfusion burden

Sekeres M[1], Díez-Campelo M[2], Zeidan A[3], Platzbecker U[4], Regnault A[5], Creel K[5], Sengupta N[6], Wan Y[6], Sun L[6], Xia Q[6], Berry T[6], Dougherty S[6], Shah S[6], Navada S[6], Santini V[7], Valcárcel D[8]; msekeres@med.miami.edu
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D2 Association between durable transfusion independence (TI) and improved survival in patients (Pts) with lower-risk myelodysplastic syndrome (LR-MDS): A US population-level analysis from the Optum Claims Database

Komrokji R[1], Sengupta N[2], Supina D[2], Navada S[2], Potluri R[3], Tyagi R[3], Werwath T[3], Xie Z[1], Padron E[1], Sallman D[1]; Rami.Komrokji@moffitt.org
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D8 Long-term ravulizumab treatment in complement inhibitor–experienced patients with PNH provides durable control of intravascular hemolysis with low incidence of major adverse vascular events and death

Kulasekararaj A[1], Brodsky R[2], Griffin M[3], Röth A[4], Piatek C[5], Ogawa M[6], Yu J[6], Patel Y[6], GONZALEZ F[7], Nishimura J[8], Peffault de Latour R[9], Szer J[10], Lee J[11]; austin.kulasekararaj@nhs.net; Yogesh.Patel@alexion.com
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D9 Thromboembolic (TE) events in cold agglutinin disease (CAD): Post hoc analysis PRE- and ON-sutimlimab treatment in the phase 3 CARDINAL and CADENZA studies

Röth A[1], Ueda Y[2], McCrae K[3], Khan U[4], Kralova K[5], Wardecki M[6], Shafer F[7], Yoo R[8], Broome C[9]; alexander.roeth@uk-essen.de
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D10 Hemolytic markers, mortality, and thromboembolic events in CAD: Risk assessment by time period since diagnosis

Hill Q[1], *Barcellini W*[2], *Röth A*[3], *Karaouni A*[4], *Afonso M*[5], *Yoo R*[6], *Tanniou J*[7], *Rubio J*[7], *Broome C*[8]; *quentinhill@nhs.net*
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D11 Inhibition of complement C1s with sutimlimab in patients with cold agglutinin disease (CAD): Results following 9-week off-treatment period (washout) in the phase 3 Cadenza study

Röth A[1], *Berentsen S*[2], *Barcellini W*[3], *D'Sa S*[4], *Jilma B*[5], *Michel M*[6], *Weitz I*[7], *Yamaguchi M*[8], *Nishimura J*[9], *Vos J*[10], *Cid J*[11], *Storek M*[12], *Wong N*[12], *Yoo R*[13], *Jayawardene D*[12], *Kralova K*[14], *Wardecki M*[15], *Shafer F*[16], *Lee M*[17], *Broome C*[18]; *alexander.roeth@uk-essen.de*
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D13 Ravulizumab effectiveness in the real world: Evidence from the International PNH Registry

Patel A[1], *Röth A*[2], *Patriquin C*[3], *Szer J*[4], *Terriou L*[5], *Gustovic P*[6], *Nishimura J*[7], *Brodsky R*[8]; *Ami.Patel@alexion.com*
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D15 Evaluation of health care resource utilization and cost among first-line patients receiving ibrutinib vs acalabrutinib for chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL): A commercial claims database analysis

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D18 Revumenib monotherapy in patients (pts) with relapsed/refractory (R/R) KMT2A-rearranged (KMT2Ar) acute leukemia: Efficacy and safety results from the AUGMENT-101 phase (Ph) 1/2 study

Aldoss I[1], *Issa G*[2], *Thirman M*[3], *DiPersio J*[4], *Arellano M*[5], *Blachly J*[6], *Mannis G*[7], *Perl A*[8], *Dickens D*[9], *McMahon C*[10], *Traer E*[11], *Zwaan C*[12], *Grove C*[13], *Stone R*[14], *Shami P*[15], *Mantzaris I*[16], *Greenwood M*[17], *Shukla N*[18], *Cuglievan B*[2], *Gu Y*[19], *Bagley R*[19], *Madigan K*[19], *Sunkaraneni S*[19], *Nguyen H*[19], *McNeer N*[19], *Stein E*[18]; *ialdoss@coh.org*
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E14 Health care utilization and cost associated with empagliflozin in older adults with type 2 diabetes: Results from the EMPRISE study

Htoo P[1], *Tesfaye H*[1], *Schneeweiss S*[1], *Wexler D*[1], *Glynn R*[1], *Schmedt N*[2], *Déraux-Luyet A*[2], *Koeneman L*[3], *Paik J*[1], *Patorno E*[1]; *phtoo@bwh.harvard.edu*
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E48 Work loss among privately insured employees with overweight and obesity in the United States

Shepherd M[1], *Shinde S*[1], *Jerry M*[2], *Tran A*[2], *Lee C*[1]; *shepherd_michael_e@lilly.com*; *shinde_shraddha@lilly.com*
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E49 Tirzepatide reduces the predicted risk of developing type 2 diabetes: SURMOUNT-1 post hoc analysis by prediabetes status

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E50 Modeling outcomes of tirzepatide vs lifestyle modification for overweight and obesity

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E57 Effect size analysis of cipaglucosidase alfa plus miglustat vs alglucosidase alfa in enzyme replacement therapy–experienced adults with late-onset Pompe disease in PROPEL

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F15 Treatment and economic challenges when managing patients with agitation associated with schizophrenia or bipolar disorder in the emergency department (ED)

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F16 Long-acting injectable antipsychotic treatment: Calculating cost offsets from real-world data

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F27 Assessing the incremental health care burden of postpartum depression

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G3 Indirect treatment comparison of valbenazine with deutetrabenazine for improvement in total maximal chorea score in Huntington disease

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G6 MOXIe clinical trial overview of omaveloxolone for patients with Friedreich ataxia

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G8 Persistence, health care resource utilization, and costs among onabotulinumtoxinA-treated patients with cervical dystonia in the United States

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G9 Estimates of productivity loss due to neurological diseases in the United States

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G12 The clinical and humanistic value of "good on-time" among patients with advanced Parkinson disease: A real-world study from 7 countries

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G13 Geographic disparities and access to device-aided therapy services for Medicare beneficiaries with advanced Parkinson disease

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G14 Estimating mild cognitive impairment and mild dementia due to Alzheimer disease in the United States

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G15 Physician attitudes toward the diagnosis and management of early Alzheimer disease in the United States

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G16 Community-based diagnostic and treatment patterns in early Alzheimer disease in the United States

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G20 Economic burden of patients with idiopathic hypersomnia and narcolepsy: A US claims-based analysis

Saad R[1], *Lillaney P*[1], *Profant D*[1], *Fuller D*[1], *Poole E*[1], *Alvord T*[2], *Prince P*[2], *Desai S*[2], *Whalen M*[1], *Macfadden W*[1], *Ni W*[1], *Black J*[3]; *ragysaad@gmail.com*; *Wayne.Macfadden@jazzpharma.com*
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G23 Access barriers to antiseizure medications and neurologists: Effects on epilepsy stakeholder experiences

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G24 Higher health care resource utilization and costs among patients with idiopathic hypersomnia compared with matched controls

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H2 Efficacy of cyclosporine ophthalmic solution 0.09% in patients with dry eye disease uncontrolled on cyclosporine ophthalmic emulsion 0.05%

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I9 High rates of major adverse cardiovascular events persist at 1 year after myocardial infarction in patients with multivessel disease: A systematic literature review

Bahit M[1], *Korjian S*[2], *Daaboul Y*[2], *Chi G*[3], *Jiang G*[2], *Libby P*[4], *Bhatt D*[5], *Reynolds M*[2], *Mehran R*[5], *Ridker P*[4], *Baron S*[6], *Sacks F*[7], *Gabriel S*[8], *Nara P*[8], *Shaunik A*[8], *Gibson C*[2]; *ceciliabahit@gmail.com*; *alka.shaunik@cslbehring.com*
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I10 Pharmacological interventional trials for the treatment or prevention of coronary artery disease: Analysis of ClinicalTrials.gov listings from 2008 to 2022

Chi G[1], *Bahit M*[2], *Korjian S*[3], *Allaham L*[3], *Nara P*[4], *Shaunik A*[4], *Gibson C*[3]; *cchi@bidmc.harvard.edu*; *paul.nara@cslbehring.com*
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I11 Patient-reported burden of disease in the first year after acute myocardial infarction: Findings from an online US questionnaire

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I12 Trends and characteristics of cardiovascular trials over the last 15 years: Analysis of ClinicalTrials.gov listings from 2008 to 2022

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I13 Elevation in neutrophil-to-lymphocyte ratio induced by acute myocardial infarction is reduced by CSL112 (apolipoprotein A-I [human])

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J5 Baseline corticosteroid use and surgery history among patients with CRSwNP in the global AROMA registry

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J6 Coexisting allergic rhinitis in patients with moderate to severe asthma initiating dupilumab in real-world clinical practice: The RAPID registry study

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J9 Pooled safety results over 24 weeks from the ENHANCE program with ensifentrine, a novel dual phosphodiesterase (PDE) 3 and 4 inhibitor

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J10 Real-world disease burden and mortality associated with bronchiectasis

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J11 Improved lung function is associated with better asthma control in children aged 6 to 11 years with moderate to severe type 2 asthma: A post hoc analysis of VOYAGE

Bacharier L[1], Dell S[2], de Mir I[3], Piacentini G[4], Hamelmann E[5], Msihid J[6], Gall R[7], Ledanois O[6], Wang J[7], Cheng W[6], Sacks H[7], Jacob-Nara J[6], Rowe P[6], Deniz Y[7]; leonard.bacharier@vumc.org; Rebecca.Gall@Regeneron.com
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J12 Inhaled ensifentrine, decreased health care resource utilization, and reduced moderate exacerbation rate and risk in COPD over 24 weeks

Watz H[1], *Rheault T*[2], *Bengtsson T*[3], *Rickard K*[2], *Lamprey C*[2]; *h.watz@pulmoresearch.de*; *claudia.lamprey@veronapharma.com*
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J17 Nocebo effect of nintedanib on gastrointestinal (GI) adverse events (AEs) in patients with interstitial lung diseases (ILDs)

Distler O[1], *Highland K*[2], *Azuma A*[3], *Kulkarni T*[4], *Wuyts W*[5], *Miede C*[6], *Alves M*[7], *Sfikakis P*[8]; *Oliver.Distler@usz.ch*
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J18 Meta-analysis of the effect of nintedanib on mortality in subjects with idiopathic pulmonary fibrosis (IPF) and other forms of progressive pulmonary fibrosis (PPF)

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J19 Additive effect of BI 1015550 and nintedanib in patients with idiopathic pulmonary fibrosis (IPF)

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K1 Treatment goals and satisfaction among patients with chronic erosive esophagitis: Results from the Study of Acid-Related Disorders (SOARD)

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K2 Patient burden and treatment goals in the management of erosive esophagitis in the United States: Results from the Study of Acid-Related Disorders (SOARD)

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K3 Disease burden and treatment patterns among patients with ulcerative colitis with isolated proctitis in the United States: A real-world study

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K6 Treatment persistence and augmentation differences across second-line treatment strategies among tumor necrosis factor inhibitor (TNFi)–experienced patients with ulcerative colitis: TNFi cyclers vs MOA switchers

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K7 Real-world rate and magnitude of dose escalation with biologics in patients with Crohn disease

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K8 Cost per remission for mirikizumab vs ustekinumab in the maintenance phase for moderately to severely active ulcerative colitis treatment from the US commercial payer perspective

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K9 Budget impact of mirikizumab-mrkz in the treatment of adult patients with moderately to severely active ulcerative colitis in the United States

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K10 Real-world rate and magnitude of dose escalation with biologics in patients with ulcerative colitis

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K11 Cost-effectiveness analysis of mirikizumab vs ustekinumab in advanced therapy–experienced patients with moderately to severely active ulcerative colitis in the United States

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L1 Survey of health care providers to understand the diagnosis and treatment patterns for patients with seborrheic dermatitis

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L2 A novel efficacy index for measuring outcome durability in long-term therapy expressed by EASI 75 and IGA (0,1) response in atopic dermatitis

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L3 Variability in patient-reported impacts of seborrheic dermatitis: Disease severity measures may not tell the whole story

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L14 Health care resource utilization among patients with generalized pustular psoriasis with and without documented flares

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L15 Efficacy and safety of tildrakizumab for the treatment of moderate to severe plaque psoriasis of the scalp: Week 52 results from a phase 3b, randomized, double-blind, placebo-controlled trial

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L16 A US claims database analysis estimating risk of all-cause mortality in patients with generalized pustular psoriasis

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L17 Health care resource utilization and costs among patients with generalized pustular psoriasis: A US claims analysis

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L21 Efficacy of the oral JAK1/JAK2 inhibitor deuruxolitinib in adult patients with moderate to severe alopecia areata: Pooled results from the multinational double-blind, placebo-controlled THRIVE-AA1 and THRIVE-AA2 phase 3 trials

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L22 Pooled safety assessments from the multinational phase 3 THRIVE-AA1 and THRIVE-AA2 trials of deuruxolitinib in adult patients with moderate to severe alopecia areata

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L23 Pooled patient-reported outcomes from the phase 3 THRIVE-AA1 and THRIVE-AA2 trials of deuruxolitinib in adult patients with moderate to severe alopecia areata

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M6 Pooled safety analysis from the VOLTAIRE trials in patients with rheumatoid arthritis, Crohn disease, and chronic plaque psoriasis

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M7 Patient experiences with chronic refractory gout (CRG) and its impact on health-related quality of life (HRQoL)

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M11 Clinical and economic burden of polymyalgia rheumatica in patients with an inadequate response to glucocorticoids in a real-world setting

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M12 Decreased health care resource utilization with lidocaine topical system 1.8% compared with lidocaine 5% patch: A retrospective claims analysis

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M13 The potential impact of delandistrogene moxeparvovec on work opportunity in individuals with Duchenne muscular dystrophy in the United States

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M19 Hospitalizations and health outcomes impacting quality of life in spinal muscular atrophy type 1 following onasemnogene abeparvovec (OA) gene replacement therapy

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M20 Assessing risdiplam utilization, adherence, and associated health care costs in patients with spinal muscular atrophy: Analysis of a US retrospective claims database

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N1 Modeling long-term outcomes for patients with immunoglobulin A nephropathy from short-term proteinuria data

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N5 Anticholinergic burden in patients with overactive bladder and association with health outcomes: A retrospective database claims analysis

Nesheim J[1], Richter H[2], Chastek B[3], Carrera A[1], Landis C[3], Snyder D[1], Abedinzadeh L[1], Bancroft T[3], Dmochowski R[4], Hijaz A[5], Frankel J[6]; jeffrey.nesheim@us.sumitomo-pharma.com
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N6 The effect of prior docetaxel (DOC) treatment on efficacy and safety of apalutamide (APA) plus androgen deprivation therapy (ADT) in patients (pts) with metastatic castration-sensitive prostate cancer (mCSPC) from TITAN

Chi K[1], Merseburger A[2], Ozguroglu M[3], Chowdhury S[4], Bjartell A[5], Chung B[6], Gomes A[7], Given R[8], Juárez A[9], Uemura H[10], Ye D[11], Karsh L[12], Gartrell B[13], Brookman-May S[14], Mundle S[15], McCarthy S[16], Lefresne F[15], Rooney O[17], Bhaumik A[18], Agarwal N[19]; kchi@bccancer.bc.ca

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N7 Impact of a rash management guide on incidence and severity of rash with apalutamide: Experience from the Apa-RP study in high-risk localized prostate cancer

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N8 Efficacy of niraparib and abiraterone acetate plus prednisone (NIRA+AAP) in homologous recombination repair gene-altered (HRR+) metastatic castration-resistant prostate cancer (mCRPC) by tissue and/or plasma assays in the MAGNITUDE trial

Attard G[1], Sandhu S[2], Rathkopf D[3], Castro E[4], Saad M[5], Smith M[6], Small E[7], Olmos D[4], Gomes A[8], Roubaud G[9], Zurawski B[10], Efstathiou E[11], Wu D[12], Diorio B[13], Urtishak K[14], Singh U[15], Xu Y[15], Lopez-Gitlitz A[12], Del Corral A[16], Chi K[17]; g.attard@ucl.ac.uk

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N9 Presence of somatic/germline homologous recombination repair (HRR) mutations and outcomes in patients (pts) with metastatic castration-resistant prostate cancer (mCRPC) receiving first-line (1L) treatment stratified by BRCA status

Olmos D[1], Lorente D[2], Alameda D[3], Cattrini C[4], Romero-Laorden N[5], Lozano R[6], Lopez-Casas P[7], Capone C[8], Vanden Broecke A[9], Trevisan M[10], Van Sanden S[11], Jürgens A[12], Herrera-Imbroda B[3], Castro E[1]; dolmos.imas12@h12o.es
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Q1 Efficacy and safety of maralixibat in patients with progressive familial intrahepatic cholestasis (MARCH): A randomized placebo-controlled phase 3 study

Miethke A[1], Moukarzel A[2], Porta G[3], Czubkowski P[4], Aqul A[5], Sokal E[6], D'Agostino D[7], Baumann U[8], D'Antiga L[9], Kasi N[10], Laborde N[11], Lin C[12], Gilmour S[13], Mittal N[14], Chiou F[15], Horslen S[16], Van Leerberghe A[17], Weber Ronn S[17], Nunes T[17], LaRow A[17], Mogul D[17], Garner W[17], Vig P[17], Hupertz V[18], Gonzalez-Peralta R[19], Thompson R[20]; Alexander.Miethke@cchmc.org; april.larow@mirumpharma.com
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U4 Real-world experience of needle length use based on body mass index for IgPro20 administration

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U5 Impact of clinical dashboards for data capture and reporting across health system specialty pharmacies

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U6 Maximizing cost savings: The impact of specialty pharmacist interventions at a community oncology center

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U7 Assessing the value of home courier service for sterile compounded medications

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U8 Effect of empagliflozin on all-cause hospitalization in EMPA-KIDNEY

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U9 Chronic kidney disease progression model: Development and validation

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