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SUPPLEMENT

Poster Abstracts

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ABSTRACT REVIEW PROCESS

Thirty-two reviewers and 4 *JMCP* editors completed the review process for NEXUS 2023. 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
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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 NEXUS 2023 were as follows:

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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.

Nicholas J. Friedlander, PharmD; et al. [E26] Identification and management of duplicate therapy involving incretin-targeting therapies for diabetes and weight loss

Caitlin Sheetz, MPH; et al. [U11] Evaluating the impact of the Inflation Reduction Act $2,000 out-of-pocket spending cap on Medicare Part D beneficiaries

Jane Y. Ha, PharmD, MS; et al. [U12] Making the cut: A review of evidence trends in the Institute for Clinical and Economic Review's Unsupported Price Increase reports

Rochelle Henderson, PhD; et al. [Z3] Specialty drug use varies by race and wage among employees with employer-sponsored health insurance

Ibrahim Khilfeh, PharmD; et al. [C25] Time-to-next treatment and overall survival among White and Black patients with homologous recombination repair–positive metastatic castration-resistant prostate cancer who initiated first-line therapy

Stephen J. Kogut, PhD, MBA, RPh; et al. [C31] Biosimilar filgrastim utilization in Medicare Part D 2016-2020

Djeneba Djibo, PhD; et al. [D15] Describing medication switching patterns in adults with rheumatoid arthritis from 2016-2022: A real-world data study

Laura Wilson, PharmD; et al. [E2] A retrospective cohort study comparing health care resource utilization, length of stay and 30-day readmissions in users and non-users of a digital diabetes health intervention for patients with type 2 diabetes mellitus

Bimal V. Patel, PharmD, MS; et al. [E12] Predicting the impact of switching from multiple daily injections to a hybrid closed-loop system on rates of high-cost adverse events for patients with type 1 diabetes

Gerhardt M. Pohl, PhD; et al. [E23] Obesity-related comorbidities with the highest annual cost for medical services per beneficiary by weight class and age

Courtney E. Flynn, MPH; et al. [F4] Health care utilization and costs associated with management of opioid use disorder within residential treatment programs and office-based opioid treatment programs

Foster Carr, MD; et al. [F5] Remote medication monitoring for patients with opioid use disorder treated with methadone: Economic evaluation of the potential implications for the health care system

Divya D'Souza, MD; et al. [H7] The safety of avacincaptad pegol in combination with anti–vascular endothelial growth factor treatment in patients with wet age-related macular degeneration

Medal-Winning Abstracts

Terry Richardson, PharmD, BCACP; et al. [K1] Sequential continuing education programs for managed care and payer professionals increase knowledge of breakthrough therapies for the management of eosinophilic esophagitis treatments

Chelsea P. Renfro, PharmD; et al. [K4] Ustekinumab infusion to subcutaneous transition: Coordinating care and identifying potential gaps

Brett Stephenson, PharmD; et al. [L9] The impact of seborrheic dermatitis on quality of life: A Dermatology Life Quality Index benchmarking analysis

Daniel Enright, MS; et al. [U16] How do US commercial health plans cite health technology assessments in their specialty drug coverage policies?

Khanh Duong, BPharm, MSc; et al. [B6] Summarizing the economic value of rapid start antiretroviral therapy in patients with HIV infections: A systematic literature review

Divyan Chopra, PhD; et al. [C9] Real-world treatment patterns, health care costs, and health care utilization in US patients with non–small cell lung cancer receiving sotorasib

Ibrahim Khilfeh, PharmD; et al. [C26] Real-world economic burden associated with progression from metastatic castration-sensitive to metastatic castration-resistant prostate cancer

Bingcao Wu, n/a; et al. [C36] Impact of treatment-emergent peripheral neuropathy in patients with multiple myeloma

Anthony Wheeler, PhD; et al. [F1] The diagnostic journey of patients with mild cognitive impairment or Alzheimer disease dementia, and challenges associated with timely diagnosis: Results from a real-world survey in the United States

Ann Childress, MD; et al. [F23] Health care resource utilization and costs associated with psychiatric comorbidities in pediatric patients with attention-deficit/hyperactivity disorder

Jenny Park, PharmD, MS; et al. [G2] Treatment patterns among patients with neuromyelitis optica spectrum disorder initiating off-label biologics

Richard B. Lipton, MD; et al. [G43] Real-world effectiveness, treatment satisfaction, and treatment optimization of ubrogepant for acute treatment of migraine when used with anti-calcitonin gene–related peptide monoclonal antibody and onabotulinumtoxinA preventives: COURAGE results

Satabdi Chatterjee, PhD; et al. [N2] Health care costs associated with development of cardio-renal-metabolic conditions in patients before and after incidence of chronic kidney disease

Satabdi Chatterjee, PhD; et al. [N3] Cost-effectiveness analysis of empagliflozin vs standard of care in patients with chronic kidney disease in the United States

Jeffrey J. Ellis, PharmD, MS; et al. [N4] Risk factors for treatment failure among US female outpatients with uncomplicated urinary tract infection treated with empirically prescribed oral antibiotics

Benjamin Ham, PharmD; et al. [U3] Real-world impact of proactive formulary management on drug costs in the multiple sclerosis drug class

Molly T. Beinfeld, MPH; et al. [U17] Trends in US commercial health plan coverage of biosimilars

Medal-Winning Abstracts

Ami R. Buikema, MPH; et al. [A1] Factors associated with recurrent *Clostridioides difficile* among Commercial and Medicare Advantage–insured patients

Brandon Cash, PharmD; et al. [B4] Cost-effectiveness of ibalizumab vs routine clinical care in heavily treatment-experienced people with HIV in the United States

Li Tao, MD; et al. [B5] Impact of the United States Preventive Services Task Force guidelines on pre-exposure prophylaxis claims and HIV-1 infection incidence: An interrupted time series with segmented regression analysis

Devin Abrahami, PhD; et al. [C6] Real-world analysis of biomarker test-level characteristics in metastatic colorectal cancer in the United States

Takako Kiener, PharmD, MS; et al. [C17] Impact of CDK4/6 inhibitors on health-related quality of life outcomes in patients with metastatic breast cancer: A systematic review and meta-analysis

James Motyka, PharmD; et al. [C20] Oncology drug development: A drug-level analysis of subsequent indications

Andrew Delgado, PhD, PharmD; et al. [C27] Long-term temporal trends of health care cost associated with nivolumab plus ipilimumab and pembrolizumab plus axitinib as first-line treatment in advanced or metastatic renal cell carcinoma in a real-world setting

Neil Milloy, BA Hons; et al. [C41] Real-world clinical characteristics and treatment patterns in fast-progressing patients with follicular lymphoma in the United States

Adriana Boateng-Kuffour, MS,MPH; et al. [E10] Health care resource utilization and costs in patients with type 1 diabetes with severe hypoglycemic events across different age cohorts in the United States: A descriptive cohort claims analysis

Jennifer Ward, RN, BSN; et al. [E27] Impact of tirzepatide and other antiobesity medications on productivity in adults with obesity or overweight from a US employer perspective

Oralee J. Varnado, PhD; et al. [G40] Health care resource utilization and costs incurred over 24 months after initiating galcanezumab or standard-of-care preventive migraine treatments

Kimberly Westrich, MA; et al. [U4] Payer reactions to the implementation of the Inflation Reduction Act: Forecasting future changes to Part D plans

Denise A. Garner, PharmD; et al. [Z6] Abortion medications online in the post–*Roe v. Wade* era

Platinum Award-Winning Abstracts

E26 Identification and management of duplicate therapy involving incretin-targeting therapies for diabetes and weight loss

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BACKGROUND: Diabetes management commonly involves use of multiple drugs and when mechanistically similar may result in duplicate therapy and increased costs. Of concern is combination glucagon-like peptide-1 agonist (GLP-1) and dipeptidyl peptidase-4 inhibitor (DPP-IV) drug use despite historical recommendations advising against this combination due to overlapping mechanisms of action. Providing pharmacists with identified GLP-1–DPP-IV duplicate therapy utilizers can aid in diabetes drug therapy optimization.

OBJECTIVE: To manage duplicate therapy and reduce associated expense, we developed and integrated duplicate therapy detection logic targeting GLP-1–DPP-IV combination therapy into a pharmacist-facing tool designed to facilitate pharmacist-to-provider or pharmacist-to-pharmacist outreach.

METHODS: Six months of pharmacy claims history was used to identify members utilizing GLP-1 and DPP-IV in combination. Claims data provided case-specific unique overlap episodes and duration of combination therapy, and identified cases were made available to pharmacists through a web application. After confirming ongoing duplicate therapy, pharmacists contacted prescribers, pharmacists, and/or other health professionals involved in member care to discuss appropriateness of ongoing duplication of therapy. Notes regarding case review and outreach were documented. Total savings were calculated for each successful case, defined by discontinuation of either the GLP-1 or DPP-IV drug, based on the cost per day of the duplicate therapy regimen compared with the adjusted therapeutic regimen.

RESULTS: Of 16 million commercially insured members, we identified 7,471 unique members with pharmacy claims history indicating GLP-1–DPP-IV duplication from July 2022 through April 2023; 6,773 cases were loaded to the web application for pharmacist review. Of those cases, 196 were successful at the time of abstract submission, resulting in validated annualized program savings of $1,142,462. An additional 283 cases were currently in progress with estimated potential annual savings of $1,375,619. 180 interventions were unsuccessful, most commonly due to not receiving a response from the provider.

CONCLUSIONS: Due to rising high-cost incretin drug utilization for the treatment of diabetes and obesity, novel payer management strategies are important for controlling costs. Duplicate therapy involving use of GLP-1 and DPP-IV drugs in combination is identifiable through pharmacy claims data, and pharmacist-to-provider outreach is an effective strategy for managing duplicative use of these drugs.

SPONSORSHIP: Prime Therapeutics LLC.

U11 Evaluating the impact of the Inflation Reduction Act $2,000 out-of-pocket spending cap on Medicare Part D beneficiaries

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BACKGROUND: The Inflation Reduction Act (IRA) includes several provisions that will impact the price of prescription drugs and Medicare Part D enrollee liability. Beginning in 2025, the Part D benefit redesign will take effect with a $2,000 out-of-pocket (OOP) maximum for beneficiaries combined with increased plan and manufacturer liability throughout the benefit.

OBJECTIVE: To determine (1) which patient demographics may be impacted by the new Part D design, (2) which month, in the year, patients surpass the $2,000 threshold, and (3) how high-cost drugs may be driving people over the $2,000 threshold.

METHODS: The 100% Part D Event (PDE) files from 2017-2022 were assessed. Patient liability (patient OOP, low-income subsidy payments, and other payers) was summed for each beneficiary across all drugs within the year. Demographic information was attributed from the Master Beneficiary Summary File.

RESULTS: Throughout the years of analysis, approximately 12% of beneficiaries with Part D coverage were above the $2,000 OOP threshold. In 2022, low-income subsidy (LIS) beneficiaries make up more than 70% of people above the $2,000 OOP threshold. Black beneficiaries are 11% of Part D beneficiaries, but they make up a disproportionately high percentage of beneficiaries above the threshold (16%). Additionally, Black beneficiaries also averaged the highest amount of liability above the $2,000 threshold in both LIS and non-LIS. When above the $2,000 OOP threshold, LIS beneficiaries average $1,496 in additional spending, whereas non-LIS beneficiaries average $4,421. For LIS beneficiaries, half will reach the threshold in June, whereas for non-LIS beneficiaries, half will reach the threshold by August. For both LIS and non-LIS beneficiaries, the main driver pushing people over the limit was not variety of prescribed drugs, but rather the volume of scripts over the course of the year.

CONCLUSIONS: Although the Inflation Reduction Act will impact Medicare Part D through drug price negotiations, inflationary rebates, and other mechanisms, the most immediate result that beneficiaries may feel is the $2,000 OOP spending cap taking effect in 2025. Black Part D beneficiaries will be more affected by the OOP cap, as they spend more than any other racial group and are disproportionally represented among beneficiaries reaching the $2,000 OOP threshold. Beneficiaries with more than 6 prescriptions per month will also reach the threshold 1-2 months faster than beneficiaries filling fewer scripts per month.

SPONSORSHIP: None.

U12 Making the cut: A review of evidence trends in the Institute for Clinical and Economic Review's Unsupported Price Increase reports

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BACKGROUND: In its Unsupported Price Increase (UPI) reports, the Institute for Clinical and Economic Review (ICER) aims to identify drugs with substantial price increases that lack new evidence to justify the increases.

OBJECTIVE: To evaluate how ICER appraises evidence submitted by manufacturers and identify trends in manufacturer submissions and ICER's rejection and acceptance decisions.

METHODS: We reviewed evidence submitted by manufacturers for the 4 national UPI reports published from 2019 to 2022. A codebook was developed to compile and categorize types of evidence and ICER's reasons for rejecting or accepting evidence. We identified trends regarding the quantity and quality of evidence, as well as study characteristics for evidence accepted in support of a price increase.

RESULTS: Manufacturers submitted evidence for 34 of the 44 drugs reviewed across the 4 reports, totaling 1,145 pieces of evidence and averaging 34 pieces per drug. This average declined over time (n = 67 in 2019, n = 28 in 2020 and 2021, n = 17 in 2022). Overall, 97% of evidence submissions were rejected by ICER, with a slight downward trend (99% in 2019, 97% in 2020, 93% in 2021, 94% in 2022). Across the 4 reports, 64% of rejected evidence submissions were rejected for not meeting UPI criteria and 36% for not meeting the criteria for new moderate- to high-quality evidence. Trends in ICER's rejection reasons shifted toward the latter (19% in 2019, 38% in 2020, 52% in 2021, 61% in 2022). Only 38 pieces of evidence, representing 18 distinct randomized controlled trials (RCTs), were accepted as high-quality evidence in support of a price increase. All evidence was from RCTs in phase 3 (n = 17) or phase 4 (n = 1), with a majority double-blinded (n = 13). In 2019, ICER described the impact of accepted evidence using a single category: longer-term data with improved outcomes (n = 5). In subsequent years, ICER moved to more descriptive categories, including evidence that supported US Food and Drug Administration (FDA) label expansion for a new (n = 5) or existing (n = 4) indication, supported accelerated approval (n = 2), extended the evidence base to new populations excluded in previous trials (n = 1), and strengthened the existing guideline recommendations (n = 1).

CONCLUSIONS: Our findings demonstrate that ICER rejects the vast majority of UPI evidence submissions (97%). Accepted evidence was typically from phase 3, double-blinded RCTs that demonstrated new information on improved outcomes or supported FDA label expansion. Manufacturers appeared to become increasingly selective over time with evidence they submitted to ICER's UPI reports.

SPONSORSHIP: Xcenda/AmerisourceBergen.

Z3 Specialty drug use varies by race and wage among employees with employer-sponsored health insurance

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BACKGROUND: The relationship between wage, race/ethnicity and specialty medication (SpRx) use among employees with autoimmune conditions is poorly understood.

Insight into demographic variations in SpRx use can inform health equity improvement efforts.

OBJECTIVE: To assess the association of race, ethnicity and wage status on SpRx use and adherence patterns among employees with autoimmune conditions (AICs) enrolled in employer-sponsored health insurance.

METHODS: This was an observational, retrospective cohort study for the year 2018 among full-time, benefits-enrolled employees. Data were obtained from the IBM Watson MarketScan database for calendar year 2018. Employees were separated into race/ethnicity subgroups based on employer-provided data. Midyear employee wage data were used to allocate employees into annual income quartiles: $47,000 or less, $47,001-$71,000, $71,001-$106,000, and $106,001 or more. The lowest quartile was further divided into 2 groups ($35,000 or less, $35,001-$47,000) to better evaluate subgroup differences. Outcomes included monthly days' SpRx-AIC supply, proportion of days covered (PDC), and medication discontinuation rates. Generalized linear regressions were used to assess differences while adjusting for patient and other characteristics.

RESULTS: From a sample of more than 2 million enrollees, race/ethnicity data were available for 617,117 (29.8%). Of those, 47,839 (7.8%) were identified as having an AIC of interest, with prevalence rates of AICs differing by race within wage categories. Among those with AICs, 5,358 (11.2%) had filled at least 1 SpRx-AIC prescription. Following adjustment, except for the highest wage category, prevalence of SpRx-AIC use was significantly less among Black and Hispanic subpopulations. Black patients had significantly lower SpRx-AIC utilization rates than White patients (≤$35K: 4.9% vs 9.4%, >$35K-$47K: 5.5% vs 10.6%, >$47K-$71K: 8.5% vs 11.1%, and >$71K-$106K: 9.1% vs 12.7%; $P < 0.001$ for all). For Hispanic patients, prevalence rates were significantly lower than those for White patients in 3 different wage categories (≤$35K: 4.5% vs 9.4%, >$35K-$47K: 6.1% vs 10.6%, and >$71K-$106K: 8.6% vs 12.7%; $P < 0.001$). PDC and 90-day discontinuation rates did not differ among race/ethnicity groups within the respective wage bands.

CONCLUSIONS: Race/ethnicity and wage-related disparities in SpRx use for treatment of autoimmune conditions likely contribute to inequities in health care outcomes among non-White and low-income populations with employer-sponsored insurance.

SPONSORSHIP: National Pharmaceutical Council.

Professional Reviewed Abstracts

A00-B99 Certain Infectious and Parasitic Diseases

(eg, hepatitis C, HIV)

A1 Factors associated with recurrent *Clostridioides difficile* among commercial and Medicare Advantage–insured patients

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BACKGROUND: *Clostridioides difficile* infection (CDI) is the leading cause of hospital-acquired infection in the United States and contributes to significant health care burden and costs to payers. Among patients initially treated for CDI, approximately 25% experience a CDI recurrence, and rates of recurrence are higher in patients aged 65 years and older. Recurrent CDI (rCDI) is difficult to treat and associated with excess health care utilization and costs. Identifying patients at highest risk for rCDI and targeting these patients for potential treatments to prevent rCDI could have significant benefits.

OBJECTIVE: To describe risk factors of rCDI among patients with commercial or Medicare Advantage with Part D (MAPD) insurance, using a large US administrative claims database.

METHODS: Patients aged 18 years and older surviving an initial CDI episode (inpatient or outpatient setting), and with 12 months' baseline continuous enrollment before the start of the initial episode, were identified between January 1, 2017, and December 31, 2019, in the Optum Research Database. CDI episodes were defined by *International Classification of Diseases, Tenth Revision* diagnoses and included CDI-related visits, hospitalizations, testing, or treatment until a greater than or equal to 14-day gap. Multivariable logistic regression was used to identify risk factors associated with rCDI in the 12 weeks following the initial CDI episode, overall and stratified by insurance type. Risk factors assessed included demographics; baseline comorbidities, treatments, and other CDI risk factors; and characteristics of the initial CDI episode.

RESULTS: In total, 5,058 commercial and 15,304 MAPD patients surviving an initial CDI episode were identified; 19.5% and 25.4% had at least 1 rCDI episode within 12 weeks following the end of the initial episode, respectively. Female patients made up 59.3% of commercial and 63.5% of MAPD patients, with a mean age of 52 ± 16 and 75 ± 10 years, respectively. Overall, the strongest predictors for rCDI included residence in a long-term care facility, age of 65 years and older, and treatment with vancomycin or fidaxomicin during the initial episode. Additional factors associated with rCDI in both populations included female sex, baseline chronic gastrointestinal or electrolyte disorders, and other characteristics of the initial episode (longer duration, emergency department site of care). Outpatient site of care for the initial episode was a risk factor only in the commercial population, whereas inpatient site of care, Hispanic ethnicity, and baseline skin disorders were associated with rCDI only in the MAPD population.

CONCLUSIONS: The strongest predictors for rCDI included residence in a long-term care facility, older age, and treatment with vancomycin or fidaxomicin. Risk factors were similar among commercial and MAPD-insured patients, and more research is needed to understand the differences in risk factors by payer type. Identifying patients more likely to have rCDI using real-world data may help payers and providers to better understand the risk of rCDI and inform treatment decision-making, patient management, and recurrence prevention efforts.

SPONSORSHIP: None.

B1 Interventions for improving herpes zoster vaccination: A literature review

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BACKGROUND: Herpes zoster (HZ) is characterized by a painful dermatomal rash and is associated with increased health care costs and decreased quality of life. In 2018, the Advisory Committee on Immunization Practices recommended recombinant zoster vaccine (RZV) for HZ prevention in immunocompetent adults aged 50 years and older. In 2022, the Advisory Committee on Immunization Practices recommendations were extended to immunodeficient/immunosuppressed adults aged 19 years and older. In the United States, HZ vaccination coverage remains suboptimal, and a summary of approaches that have been examined to improve HZ vaccination is lacking.

OBJECTIVE: To identify and summarize the scientific evidence on interventions aimed at improving HZ vaccination outcomes in the United States.

METHODS: A protocol-based targeted literature review was conducted. Searches were run in Embase and MEDLINE from January 2012 to November 2022. Searches were supplemented by searches of proceedings from 2020 to 2022 from key conferences. Eligible US studies included those describing interventions related to HZ vaccination uptake or RZV series completion. All potentially relevant publications were screened by a single reviewer against prespecified criteria, with a sample check from a second reviewer.

RESULTS: Overall, 422 publications were identified. Following screening, 24 unique studies were included in the targeted literature review. Two-thirds of studies described interventions implemented in the community pharmacy setting (15 of 24). Study design, sample size, and outcomes varied across publications. Most studies were related to HZ vaccination uptake, and 2 were related to RZV series completion. Two studies described HZ vaccination outcomes among immunocompromised populations (solid organ transplant candidates and older people living with HIV). Interventions included no-cost vaccination, immunization screening, patient outreach, provider and patient education, training, motivational interviewing, vaccine registries, and decision support and point-of-care tools and were implemented alone and in combination. The impact of interventions on HZ vaccination uptake varied considerably. The 2 studies related to RZV series completion were conducted in large retail pharmacy chains and showed small but significant increases.

CONCLUSIONS: A range of interventions were identified, with several showing modest but important increases in HZ vaccination outcomes. Evidence on interventions related to RZV series completion was limited. Further studies are needed to assess optimal interventions using large sample sizes and robust study designs.

SPONSORSHIP: GlaxoSmithKline Biologicals SA (VEO-00388).

B2 Value and real-world utilization of preventive services for the management of older adults in the United States

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BACKGROUND: The Affordable Care Act placed a high value on improving access to preventive services recommended by the Advisory Committee on Immunization Practices and United States Preventive Services Task Force. However, previous reviews evaluating the value and use of preventive services lacked evidence summarizing newly available preventive measures, such as the recombinant zoster vaccine (RZV).

OBJECTIVE: To summarize the evidence on real-world utilization and clinical, and economic value of preventive services recommended for US adults aged ≥50 years compared to RZV.

METHODS: This protocol-based, targeted literature review describes the published evidence of prevalent preventive services recommended for older US adults (aged ≥50 years). The chosen services (RZV, influenza, Tdap, and pneumococcal vaccination and colorectal cancer screening) were determined collaboratively by evaluating preventive measures recommended for adults aged older than 50 years. Following selection, the study team sourced eligible information and studies from government websites (e.g., Advisory Committee on Immunization Practices, United States Preventive Services Task Force, Medicare, Agency for Healthcare Research and Quality) and through searching Embase, Emcare, and MEDLINE to identify real-world utilization, economic, clinical, and humanistic value data from 2012 to 2022.

RESULTS: The review included data from 72 published manuscripts and publicly available reports on preventive services for older adults, 14 of which included or focused solely on RZV. Compared with other vaccines recommended for US adults aged 50 years and older, RZV coverage estimates (2 doses) were generally lower (0.7%-12.4%), particularly compared with influenza (26.4%-68.8%) and pneumococcal (58%-86%) vaccination; coverage was also considerably lower when compared with colorectal cancer screening (42.8%-74.2%). However, RZV utilization trends by demographics (eg, age, race, sex) were similar to other recommended vaccinations. Compared with other vaccines, the influenza vaccine prevents a significantly higher number of cases of disease (vs no vaccination); however, RZV appears to prevent a higher number of cases of disease compared with both Tdap and pneumococcal vaccination and when controlling for the number of patients vaccinated. Additionally, the cost-effectiveness estimates for RZV were favorable (ie, <$100,000 per quality-adjusted life-year) and lower than Tdap ($477,000), pneumococcal ($112,000 to $2.3 million), and hepatitis B ($371,606-$541,461) vaccination.

CONCLUSIONS: Although the cost-effectiveness of RZV vaccination has been demonstrated, uptake of the vaccine remains low compared with other preventive services recommended for US adults aged 50 years and older.

SPONSORSHIP: GlaxoSmithKline Biologicals SA (VEO-00354).

B4 Cost-effectiveness of ibalizumab vs routine clinical care in heavily treatment-experienced people with HIV in the United States

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BACKGROUND: Ibalizumab is a monoclonal antibody approved in the United States for heavily treatment-experienced (HTE) people with HIV with ongoing viremia. Clinical evidence demonstrates that ibalizumab is effective in reducing and managing viral load (vL) in HTE people with HIV, which may have an economic benefit to US payers.

OBJECTIVE: To estimate the cost-effectiveness of the addition of ibalizumab to routine clinical care (e.g., optimized background regimens [OBR]) from a US payer perspective.

METHODS: A Markov model estimated the cost per quality-adjusted life-year (QALY) gained following the addition of ibalizumab to OBR from a US payer perspective. The model considered HTE people with HIV as per ibalizumab's pivotal trials (TMB-201 and TMB-301/311). Model health states were as follows: virally undetectable (vL < 50 copies/mL), virally suppressed (50 ≤ vL ≤ 200 copies/mL), and virally unsuppressed (vL > 200 copies/mL). Estimates of comparative effectiveness were derived through a standardized mortality rate–weighting analysis of TMB-201 and TMB-301/311 data to non-IBA-containing regimens in routine clinical care from the OPERA cohort. Costs were derived from appropriate US sources and included treatment acquisition and administration, monitoring, adverse events, opportunistic infections, and terminal care. Mortality assumptions and health-state utility values were based on disease-specific published literature and clinical trial data. Costs and outcomes were discounted at 3% per annum.

RESULTS: Over a lifetime horizon, the addition of ibalizumab to OBR increased the time patients spent virally undetectable or suppressed and extended a patient's QALYs compared with OBR alone. A base-case incremental cost-effectiveness ratio vs OBR of $169,103 was calculated. Deterministic and probabilistic scenario analyses indicated that the result was robust to changes to structural and parameter uncertainty.

CONCLUSIONS: The addition of ibalizumab to OBR resulted in increased costs and QALYs. The incremental cost-effectiveness ratio fell within an acceptable cost-effectiveness range and demonstrates that the addition of ibalizumab to routine clinical care may provide payers with a cost-effective treatment option that can substantially improve outcomes for HTE people with HIV.

SPONSORSHIP: Theratechnologies, Inc.

B5 Impact of the United States Preventive Services Task Force guidelines on pre-exposure prophylaxis claims and HIV-1 infection incidence: An interrupted time series with segmented regression analysis

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BACKGROUND: The US Preventive Services Task Force (USPSTF) guidelines recommend pre-exposure prophylaxis (PrEP) for people who may acquire HIV. Due to a wide range of barriers, including social inequities, lack of awareness, out-of-pocket costs, and prior authorization requirements, only 25% of the 1.2 million people in the United States who could benefit are accessing PrEP. USPSTF guidelines aim to overcome barriers related to the out-of-pocket cost of PrEP and ancillary services.

OBJECTIVE: To assess the impact of USPSTF guidelines, we examined trends in compliant PrEP claims and new HIV-1 infections before and after guideline milestones (first recommendation [June 2019]; plans must cover PrEP without copay [June 2020]; FAQ release clarifying implementation [July 2021]).

METHODS: Compliance with USPSTF guidelines, defined as zero copay, was assessed as monthly percentage of all PrEP prescriptions with zero copay (private insurance claims for FTC/TDF, gFTC/TDF, FTC/TAF or injectable cabotegravir; January 1, 2019, to February 28, 2023). Monthly HIV incidence was calculated as new diagnosis or treatment initiations/total number of enrolled individuals in the 12 months following initial PrEP prescription. Time series analysis with segmented regression compared changes in zero-copay claims and HIV incidence pre- vs post-milestone timepoints.

RESULTS: Overall, 537,715 HIV-1 negative individuals with 3,706,170 oral or injectable PrEP claims were included. Following USPSTF guidelines, there was an increase in all PrEP zero copay claims (monthly average): prior to guidelines (January to June 2019), 45.5%; after first statement (July 2019 to June 2020), 51.8%; after zero copay compliance deadline (July 2020 to June 2021), 60.0%; after FAQ release (July 2021 to February 2023), 64.0%. Although the rate of monthly zero copay adoption initially showed consistent growth, it gradually flattened over time. In the same time frames, new HIV infections (per 100 person months) consistently decreased over time: 0.31, 0.22, 0.17, and 0.13, respectively, over the segmented periods. Impact on copay was more marked on FTC/TDF than gFTC/TDF. The percentage of individuals with zero out-of-pocket expenses for FTC/TAF remained relatively constant (~56%-57%).

CONCLUSIONS: This analysis showed greater compliance to implementing USPSTF guidelines over time, with an increased proportion of PrEP claims with zero copay, and a corresponding decline in HIV incidence. However, implementation of zero copay is incomplete, rates are slowing over time, and one-third of the market continues to bear financial barriers to PrEP access. To improve access and uptake of PrEP, insurers and regulators should actively ensure that all plans are fully compliant with USPSTF guidelines.

SPONSORSHIP: Gilead Sciences, Inc.

B6 Summarizing the economic value of rapid start antiretroviral therapy in patients with HIV infections: A systematic literature review

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BACKGROUND: HIV guidelines now recommend that antiretroviral therapy (ART) be initiated as quickly as possible in appropriate patients. We hypothesized that rapid ART initiation will decrease health care spending and resource utilization.

OBJECTIVE: To comprehensively synthesize the evidence on economic outcomes comparing rapid vs nonrapid ART initiation.

METHODS: We performed a systematic literature search in PubMed, Embase, Web of Science, and ProQuest from January 2017 to January 2023. The search supplemented a previous literature review (Ford N, et al. AIDS 2018;32(1):7-23). Hand-searching from reference lists was also conducted. The eligibility criteria comprised any studies that reported economic outcomes, either cost-analysis or economic-evaluation (cost-effectiveness analysis [CEA]) studies, for both rapid and nonrapid ART. The definition of rapid ART was not restricted. We performed a qualitative synthesis of included studies. The Economic Evaluation Bias and Larg and Moss checklists were used to assess the quality of CEA and cost-analysis studies, respectively.

RESULTS: A total of 11 studies were included. Nine studies were CEA studies, using mathematical dynamic modeling (4 studies), Markov models (4 studies), and a microsimulation model (1 study); none were modeled in the United States. The remaining 2 studies were cost analyses of US claim databases (Medicaid and MarketScan). Of the 9 CEA studies, quality-adjusted life-years (QALYs) and averted HIV transmission were outcomes reported in 5 and 7 studies, respectively. Regarding base-case results, 4 studies (44%) reported cost savings and all 9 (100%) reported cost-effectiveness when compared with nonrapid ART. Reported incremental cost-effectiveness ratio values ranged from US$495/QALY (India, 2021) to US$36,903/QALY (Spain, 2021). Averted HIV transmissions with rapid ART were estimated from 2% to 81% more than with nonrapid ART. Incremental QALYs ranged from 0.039 to 0.79 with rapid ART vs nonrapid ART. In the 2 cost-analysis studies, the reported per-patient per-month costs across the first 36 months of treatment were US$651 and US$3,040 for rapid ART, vs US$1,196 and US$3,246 for nonrapid ART, respectively. In both studies, the lower costs from rapid ART were due to decreased health care visits and other services.

CONCLUSIONS: Rapid initiation of ART was consistently shown to be cost-effective and was associated with lower real-world health care costs when compared with nonrapid ART. Clinicians and policymakers may consider these results to facilitate rapid initiation of ART in patients with HIV infection.

SPONSORSHIP: Gilead Sciences, Inc.

C00-D49 Neoplasms

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

C1 Real-world treatment patterns and outcomes for patients with neoadjuvant treatment for gastric or gastroesophageal junction cancer in the US community setting

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BACKGROUND: Despite mounting evidence and recent therapy approvals, treatment options remain limited and prognosis remains poor for patients with locally advanced gastric or gastroesophageal junction cancer (GC/GEJC).

OBJECTIVE: To examine patient characteristics, treatment patterns, and outcomes in the US community oncology setting.

METHODS: This retrospective observational cohort study used electronic health records. Patients with stage II-IVA GC/GEJC adenocarcinoma who initiated neoadjuvant therapy (index date) within The US Oncology Network between January 1, 2011, and December 31, 2018, were identified and followed through June 30, 2022, last record, or death, whichever came first. Descriptive analyses were run to evaluate patient and treatment characteristics. Kaplan-Meier was used to assess overall survival (OS) and event-free survival (EFS) in months from index.

RESULTS: The final sample comprised 261 patients. Median age at index was 65.5 years; 65.1% were male and 63.2% White. Stage IIB, III, and II(not otherwise specified)/IIA were the most common (36.0%, 33.0%, and 31.0%, respectively). Most patients had an Eastern Cooperative Oncology Group performance status of 0-1 (75.5%). Median follow-up was 20.2 months. The most common neoadjuvant systemic regimens were triplets (40.6%), platinum-based doublets (27.6%), CROSS (14.6%), and FLOT (13.8%). A total of 71.3% (n = 186) patients underwent surgery; 55 received adjuvant therapy afterward. A total of 89 patients progressed to receive first-line therapy (38 with prior adjuvant, 51 without). More than half of all patients (52.9%) died before the end of follow-up. Patients with surgery had longer median (95% CI) OS and EFS vs without: 41.7 (28.5-76.7) vs 10.3 (7.8-19.1) and 19.8 (15.8-24.7) vs 4.5 (3.8-5.4) (log rank *P* value < 0.0001). Patients receiving doublets directionally had the longest median (95% CI) OS, followed by FLOT, triplet and CROSS: 39.6 (19.6 to not reached), 29.7 (19.2 to not reached), 27.9 (19.2-40.2), and 23.5 (13.6-35.6). FLOT directionally had the longest median (95% CI) EFS (16.5 [9.0-26.3]), followed by doublets (15.8 [13.2-20.7]), CROSS (13.2 [7.1-18.1]), and triplets (13.1 [9.5-19.9]).

CONCLUSIONS: Treatment and outcome patterns in this study highlight an unmet need. Most patients progressed or died within 2 years. Those who had surgery had a better prognosis than those without. Various neoadjuvant treatment regimens were used, with no apparent consensus on a standard. As the treatment landscape continues to change over time, new targeted agents are needed in this setting.

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

C2 Real-world treatment patterns of patients treated with regorafenib or trifluridine/tipiracil for metastatic colorectal cancer in the US community oncology setting

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BACKGROUND: Regorafenib (REGO) and trifluridine/tipiracil (FTD/TPI) extend overall survival in patients with metastatic colorectal cancer (mCRC) previously treated with fluoropyrimidine-based chemotherapies. However, there are limited real-world data in the community setting regarding treatment sequencing among patients undergoing treatment with these drugs.

OBJECTIVE: To evaluate—in a real-world study—patients who initiated REGO and/or FTD/TPI in any line of treatment (LOT) from a community oncology setting.

METHODS: A retrospective analysis using electronic medical record data from The US Oncology Network examined adult patients with mCRC who initiated REGO or FTD/TPI between September 1, 2015, and March 31, 2022 (index date), with follow-up until September 30, 2022. Baseline demographic, clinical characteristics, and treatment characteristics were reported descriptively.

RESULTS: In total, 2,142 patients with mCRC initiating REGO or FTD/TPI (REGO only, 634 pts; FTD/TPI only, 813 pts; both, 695 pts) in any LOT during the observation period were identified. The median (range) time from initial diagnosis to index date was 37.7 (30.8) months, 1,180 (55.1%) patients were male, 1,530 (71.4%) patients were White, and 1,597 (74.6%) patients had colon cancer as the initial diagnosis. The median ages were 62, 63, and 62 years and the median follow-up periods were 4.5, 5.1, and 10.7 months, respectively, in patients with REGO only, FTD/TPI only, and both. Patients most frequently initiated REGO in 4L (n = 336, 15.7%) or 3L (n = 325,15.2%) and patients initiated FTD/TPI in 4L (n = 387, 18.1%) or 3L (n = 329,15.4%). Approximately 12% of patients initiated REGO or FTD/TPI in 5L. Among the 695 patients that received both, 366 (52.7%) initiated REGO prior to FTD/TPI and 306 (44.0%) initiated FTD/TPI prior to REGO; 23 (3.3%) were concurrent users. Doublet therapy (FOLFOX and FOLFIRI-based) represented 26.8% of 3L and 20.6% of 4L therapies. The most common prior systemic therapies used were chemo ± bevacizumab (n = 1,672, 78.1%) followed by FOLFIRI-based regimens (n = 1,314, 61.3%) and FOLFOX-based regimens (n = 1,007, 47.0%).

CONCLUSIONS: The baseline characteristics of the cohorts were similar. In the real world, REGO and FTD/TPI are initiated predominantly as third line and beyond. This is consistent with guideline recommendations suggesting these agents for patients progressed on all standard therapies. However, moderate use of doublet therapy in the 3L and 4L setting suggests chemo-recycling in the community oncology setting, which may push initiation of REGO and FTD/TPI to later LOTs. Further research on the efficacy and clinical outcomes of these patients is necessary.

SPONSORSHIP: Bayer Healthcare Pharmaceuticals.

C3 Cost-effectiveness of nivolumab + platinum doublet chemotherapy as neoadjuvant treatment for resectable non–small cell lung cancer in the United States

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BACKGROUND: In March 2022, based on outcomes of the CHECKMATE-816 (CM-816) trial, the US Food and Drug Administration (FDA) approved nivolumab for the treatment of adult patients with resectable (tumors ≥4 cm or node positive) non–small cell lung cancer (rNSCLC) in the neoadjuvant setting in combination with platinum doublet chemotherapy (PDC)—the first FDA-approved chemoimmunotherapy in this setting.

OBJECTIVE: To estimate the cost-effectiveness of neoadjuvant nivolumab + PDC (N+PDC) vs current treatments for rNSCLC in the United States.

METHODS: A 4-state, semi-Markov cohort model was developed based on rNSCLC treatment guidelines, existing early-stage oncology health technology assessment submissions, and clinician input. Patients entered the model event free and could develop locoregional recurrence (LR) or distant metastasis (DM); those with LR could develop DM. Patients could die at any time. All-state transition probabilities were time varying and based on standard parametric or spline models using CM-816 data, except for progression from LR to DM (assumed constant and informed by published data). Based on CM-816, time to progression was specific to the rNSCLC treatment received and mortality was rNSCLC treatment agnostic and linked to health state. As evidence and clinical opinion suggests tumor resection can be curative in rNSCLC, it was assumed that 95% of patients who did not progress or die within the first 5 years are considered "cured" and experience no disease-specific mortality, only age and sex-adjusted US general population mortality. Comparators of interest were neoadjuvant PDC, neoadjuvant chemoradiotherapy (neoCRT), adjuvant PDC (adjPDC), and surgery only (surg). Indirect treatment comparison informed transition probabilities for neoCRT, adjPDC, and surg. Utilities were derived from EQ-5D data collected in CM-816, capped at US population norms. Costs included drug wholesale acquisition, administration, adverse event management, medical resource use, and surgical resection costs; published US-based sources informed all costs. US sources informed treatment patterns in LR and DM.

RESULTS: Over a lifetime with a 3% discount rate applied to costs and quality-adjusted life years (QALYs), N+PDC provides 1.04, 0.84, and 1.34 more QALYs at an additional cost of $28,794, $4,605, and $29,374 vs neoadjuvant PDC, adjPDC and surgery only, resulting in incremental cost-effectiveness ratios of $27,742, $5,502, and $21,974 per QALY, respectively. N+PDC dominated neoCRT, providing 0.4 more QALYs and saving $2,279.

CONCLUSIONS: N+PDC is a cost-effective treatment option for rNSCLC, with model incremental cost-effectiveness ratios well within the range commonly considered cost-effective in the US.

SPONSORSHIP: Bristol Myers Squibb

C4 Impact of next-generation sequencing vs polymerase chain reaction testing on costs and clinical outcomes throughout the treatment journey of patients with metastatic non–small cell lung cancer

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BACKGROUND: Among patients with metastatic non–small cell lung cancer (mNSCLC), next-generation sequencing (NGS) biomarker testing has been associated with shorter time to appropriate targeted therapy and lower costs relative to polymerase chain reaction (PCR) testing. However, the impact of NGS vs PCR testing on costs and clinical outcomes over patients' treatment journey is not well understood.

OBJECTIVE: To assess costs and clinical outcomes of NGS vs PCR biomarker testing among patients with mNSCLC from a US payers' perspective.

METHODS: A Markov model from the start of testing up to 3 years after assessed costs and clinical outcomes of NGS vs PCR testing. Patients entered the model after receiving test results, at which point they initiated first-line (1L) targeted or non-targeted therapy (chemotherapy [CTX] and/or immunotherapy [IO]), depending on the detection of actionable mutations; a proportion of patients with an actionable mutation were not detected by PCR and inappropriately initiated 1L CTX/IO. At each 1-month cycle, patients could remain treated with 1L, progress to second line or later, or die. Literature-based inputs included rates of progression-free survival (PFS) and overall survival (OS), costs for targeted and non-targeted therapy, total costs of testing, and medical costs of 1L, second line or later, and death. Per patient average PFS and OS, as well as cumulative costs, were reported for NGS and PCR testing.

RESULTS: In a modeled cohort of 100 patients (75% commercial, 25% Medicare), 45.9% of NGS and 40.0% of PCR patients tested positive for an actionable mutation and initiated 1L

targeted therapy. Relative to PCR, NGS had cost savings of $7,386 per patient (NGS = $326,154; PCR = $333,540) at 1 year, driven by lower costs associated with testing, including estimated costs of delayed care and CTX/IO initiated prior to receiving test results (NGS = $8,866; PCR = $16,373). Treatment costs were similar (NGS = $305,644; PCR = $305,283). In PCR patients, costs of inappropriate 1L treatment with CTX/IO were $6,455 per patient. Relative to PCR testing, NGS was associated with cost savings of $4,060 at 2 years and $1,092 at 3 years. Relative to PCR patients inappropriately initiating 1L CTX/IO, those initiating 1L targeted therapy had an additional 0.448, 0.732, and 0.864 years of PFS and an additional 0.113, 0.300, and 0.447, years of OS at 1, 2, and 3 years. respectively.

CONCLUSIONS: Over 3 years following biomarker testing, patients with mNSCLC undergoing NGS testing are projected to have cost savings, as well as longer average PFS and OS relative to those tested with PCR strategies.

SPONSORSHIP: Janssen Scientific Affairs, LLC.

C5 Mutation profile, resistance mechanisms, and outcomes in epidermal growth factor receptor-mutated non–small cell lung cancer: A systematic literature review

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BACKGROUND: Treatment resistance can occur as a result of concurrent or posttreatment development of gene alterations that interfere with drug effectiveness or tolerability. Treatment resistance remains a clinical challenge for patients with epidermal growth factor receptor (EGFR)–mutated advanced or metastatic non–small cell lung cancer (NSCLC).

OBJECTIVE: To describe the resistance mutation profile and the impact of resistance mutations on clinical outcomes in adults with EGFR-mutated advanced or metastatic NSCLC in the United States.

METHODS: A systematic literature review was performed following Cochrane and PRISMA guidelines. MEDLINE and Embase were searched from 2018 to August 2022, supplemented by a review of conference abstracts and bibliographies. Clinical trials and observational studies of acquired resistance mechanisms or their impact on clinical outcomes were included.

RESULTS: Among 2,972 records, a total of 45 studies were included. Osimertinib was the most commonly reported treatment (osimertinib alone: 15 studies, osimertinib combinations: 19 studies), followed by other tyrosine kinase inhibitors (5 studies). Treatment type was unspecified for 6 studies. With use of first-line (1L) or second-line (2L) osimertinib, 15 EGFR-dependent mechanisms of acquired resistance were identified; most frequently occurring mechanisms were T790M loss (1L: 15.4%-47%; 2L: 20.5%-49%), C797S mutation (1L: 2.9%-22%; 2L: 13.7%), and C797X (1L: 8%-12.5%; 2L: 13.9%-17.5%). In addition, 29 EGFR-independent resistance mechanisms were identified with MET amplification (1L: 0.6%-66%; 2L: 7.2%-19%), TP53 mutation (1L: 20%-29.2%), and CCNE1 amplification (1L: 7.9%; 2L: 10.3%) being most frequently occurring. Patients receiving osimertinib, EGFR T790M mutation loss, EGFR amplification, MET amplification, HER2 amplification, RET fusion, and PIK3CA mutation were associated with worse progression-free survival.

CONCLUSIONS: Resistance mechanisms resulting from NSCLC treatments are heterogeneous and complex. Findings from this systematic literature review highlight the need for new therapies with broad antitumor activity capable of addressing common EGFR-dependent and EGFR-independent resistance mutations, to improve clinical outcomes for patients with EGFR-mutated advanced NSCLC.

SPONSORSHIP: Janssen Scientific Affairs, LLC.

C6 Real-world analysis of biomarker test-level characteristics in metastatic colorectal cancer in the United States

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BACKGROUND: Molecular testing is recommended in National Comprehensive Cancer Network guidelines for all patients with metastatic colorectal cancer (mCRC). This includes testing for BRAF, MSI/MMR, KRAS, and NRAS mutations, and most recently for HER2. Despite clinical guideline recommendations, contemporary real-world biomarker testing patterns in mCRC are not fully known.

OBJECTIVE: To investigate real-world use of biomarker (BRAF, MSI/MMR, KRAS, and NRAS) testing in the United States.

METHODS: This was a retrospective cohort study of patients with mCRC in the Flatiron Health Database from 2013 to 2022. Adults aged 18 years or older newly diagnosed with mCRC (index date: first mCRC diagnosis) with at least 2 months of follow-up and receipt of a biomarker test of interest were included. Patients were excluded if they had no activity within 90 days after mCRC diagnosis or if both biomarker result date and specimen received date were missing. Test type (next-generation sequencing [NGS], multiple [distinct

tests within 7 days], or single [no other distinct tests within 7 days]) was explored in the cohort. Sample type (proportion of distinct biomarker tests using blood, tissue, or other, out of the total number of tests for each biomarker), dual positivity (proportion of distinct patients with dual positive [BRAF/MSI-H, KRAS/MSI-H, NRAS/MSI-H] results out of the total number of patients with known results for both tests of interest), and test positivity (proportion of patients with positive result out of the total number of patients with a test for each biomarker per year) were explored at the level of each biomarker.

RESULTS: 26,120 patients were included, generating 21,134 BRAF, 33,981 MSI/MMR, 26,904 KRAS, and 19,957 NRAS tests from 2013 to 2022. The proportion of NGS tests increased from 2013 to 2022 (7.6% to 80.7%), whereas the proportion of multiple and single tests decreased over time. Tissue was the most common sample type for all biomarkers (BRAF = 87.0%, MSI/MMR = 93.4%, KRAS = 89.2%, NRAS = 86.5%). 2.7% of patients tested for BRAF and MSI/MMR had dual positivity compared with 1.6% for KRAS and MSI/MMR and 0.2% for NRAS and MSI/MMR. Test positivity decreased over time in BRAF (13.6% to 8.0%), and MSI/MMR (6.3% to 4.8%), was stable for KRAS (43.0% to 44.3%), and slightly increased for NRAS (3.1% to 5.4%).

CONCLUSIONS: This study provides the latest real-world biomarker testing characteristics in mCRC, highlighting increased NGS testing, which may lead to earlier diagnosis and management of patients with mCRC with BRAF, MSI/MMR, KRAS, or NRAS mutations. Tissue continues to be most common sample type.

SPONSORSHIP: Pfizer.

C8 Real-world treatment patterns and characteristics of patients treated with amivantamab after platinum-based chemotherapy for advanced or metastatic non–small cell lung cancer with epidermal growth factor receptor exon 20 insertion mutations

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BACKGROUND: Amivantamab (AMI) is indicated for the treatment of patients with epidermal growth factor receptor (EGFR) exon 20 insertion mutations (ex20ins) in locally advanced or metastatic non–small cell lung cancer (NSCLC) who have progressed on or after platinum-based chemotherapy—a population with historically unmet medical need and poor prognosis. The median progression-free survival (PFS) observed with AMI in this population was 8.3 months in the CHRYSALIS trial.

OBJECTIVE: To describe patient characteristics and treatment patterns in patients with advanced or metastatic NSCLC with EGFR ex20ins treated with AMI monotherapy after platinum-based chemotherapy.

METHODS: This retrospective cohort study of pooled electronic health record data from the Flatiron NSCLC Core Registry (January 1, 2011, to August 31, 2022) and the Ontada database (January 1, 2013, to January 31, 2023) included patients with advanced or metastatic NSCLC; AMI treatment on or after May 1, 2021; documentation of ex20ins; prior platinum-based chemotherapy; no initiation of first-line therapy more than 14 days prior to first observed diagnosis; and aged 20 years or older at index. The index date was defined as the date of AMI initiation. Time to next treatment (TTNT) and time to treatment discontinuation (TTD) were assessed using Kaplan-Meier analysis. In the assessment of TTNT, patients without an event were censored at the earliest of their last activity date if they were last to follow up or the last date of data availability. Treatment discontinuation was confirmed by a clinical visit 150 days post regimen end date, death, or next line of therapy; otherwise, the patient was censored.

RESULTS: A total of 36 patients with AMI were included in the study. Median age was 64 years; 47% of patients were male and the proportions of patients with and without smoking history were similar among those with smoking status information. Median follow-up time was 4.7 months. AMI was used as second-line therapy in 58% of patients with the remaining patients receiving AMI in third line or later. Median TTNT was 9.2 months and median TTD was 8.6 months.

CONCLUSIONS: This is one of the first real-world studies to describe patient characteristics and treatment patterns among patients with EGFR ex20ins treated with AMI. Results of TTNT from this real-world population were consistent with the median PFS observed with AMI in the CHRYSALIS trial (8.3 months) in patients with ex20ins with prior platinum-based chemotherapy. TTNT and TTD may serve as real-world indicators of tolerability and PFS in this patient population and continue to be monitored in future analyses.

SPONSORSHIP: Janssen Scientific Affairs, LLC.

C9 Real-world treatment patterns, health care costs and health care utilization in US patients with non–small cell lung cancer receiving sotorasib

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

OBJECTIVE: To describe real-world treatment patterns, health care costs (HCC), and health care resource utilization (HCRU) for US patients with advanced NSCLC treated with sotorasib.

METHODS: Patients aged 18 years or older using sotorasib with a prior diagnosis of lung cancer were identified using Optum Clinformatics claims database (until June 2022) containing commercially insured and Medicare advantage patients in the United States. Index date was defined as the date of first sotorasib prescription. Patients were continuously enrolled from 6-months prior to first diagnosis of lung cancer until at least 30-days post-index date and received no medications for small cell lung cancer. Key outcomes assessed over the sotorasib treatment (Tx) period included proportion of days covered, time to next treatment (TTNT), HCC, and HCRU. HCC and HCRU were reported on a per-patient-per-month (PPPM) basis. HCC and HCRU were also assessed over the baseline-period (6 months prior to index date).

RESULTS: Among 168 patients with lung cancer receiving sotorasib, 99 met all inclusion criteria. 84 of the 99 (85%) patients used sotorasib as second line or more (2L+) Tx. Among patients with 2L+ sotorasib Tx, the mean age was 71 years, 67% were females and 55% received prior Tx with platinum-based chemotherapy plus immune checkpoint inhibitors. Mean (SD) proportion of days covered associated with sotorasib use was 96% (8.1) and median TTNT was 4.4 (range: 3.7-5.9) months. During the sotorasib Tx period, total (medical, pharmacy) and medical (inpatient, outpatient, emergency) HCC PPPM were $23,209 ($20,632) and $7,507 ($19,088), respectively. Outpatient HCC ($4,097 PPPM) represented the majority of medical costs. In terms of HCRU visits PPPM, patients on average had 3.8 (4.0) outpatient, 0.11 (0.51) acute inpatient, and 0.12 (0.57) emergency visits. Baseline total and medical HCC PPPM were $24,748 ($19,252) and $23,643 ($18,504), respectively.

CONCLUSIONS: This study provides initial evidence on characteristics and outcomes of patients with NSCLC receiving sotorasib as 2L+ in US clinical practice. These findings suggest patients using sotorasib as targeted therapy show high adherence, TTNT similar to progression-free survival observed in clinical trials of sotorasib, and total HCC and HCRU similar to pre-index treatment.

SPONSORSHIP: Amgen Inc.

C10 Health care resource utilization and cost associated with disease recurrence in patients with stage IIB-C melanoma following complete resection: An analysis of Surveillance, Epidemiology, and End Results–Medicare linked database

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BACKGROUND: Real-world evidence on incremental health care resource utilization (HRU) and costs due to disease recurrence in patients with early-stage melanoma is limited.

OBJECTIVE: To evaluate HRU and costs associated with recurrence among patients with stage 2B/2C melanoma following complete resection.

METHODS: Patients were identified from the Surveillance, Epidemiology, and End Results (SEER)–Medicare database (2013-2019) and grouped into recurrent vs nonrecurrent cohorts. Recurrence was classified as distant or locoregional based on claims after resection. Patients with and without recurrence were 1:1 propensity score matched on demographics, melanoma diagnosis date, and resection date. Index date was defined as the recurrence date in the recurrent cohort and a random distribution-matched date in the non-recurrent cohort. HRU and costs on a per patient per month (PPPM) basis were measured over 12 months post-index. Unadjusted and multivariable regressions compared all-cause and melanoma-related incidence rates (IRs) and mean costs (in 2020 US dollars) for recurrent vs non-recurrent and distant vs locoregional recurrent cohorts.

RESULTS: The analysis included 359 pairs of recurrent and non-recurrent patients. Of the recurrent patients, 158 had distant and 201 had locoregional recurrence. Patient and disease characteristics were similar between cohorts. Recurrent patients had higher all-cause PPPM inpatient (IP) visits (IR ratio [IRR], 95% CI = 2.48 [1.89-3.24]) and days hospitalized (IRR: 2.74 [1.78-4.24]) vs non-recurrent patients. Distant recurrence was associated with more PPPM IP visits (IRR: 4.87 [3.46-6.85]) and days hospitalized (IRR: 3.57

[2.06-6.19]) than locoregional recurrence. Recurrence was also associated with a higher all-cause PPPM total health care cost (Cost difference [CD], 95% CI = 4,583 (3,576-5,610); $P < 0.001$), primarily attributable to medical cost (CD: 4,395 [3,429-5,327]; $P < 0.001$), which was mainly due to IP (CD: 2,227 [1,485-2,964]; $P < 0.001$) and outpatient (CD: 1,125 [719-1,517]; $P < 0.001$) costs. Similarly, distant vs locoregional recurrence was associated with higher PPPM all-cause total health care costs (CD: 6,654 [4,836-8,498]; $P < 0.001$), primarily attributable to IP costs (CD: 3,874 [2,557-5,218]; $P < 0.001$). Multivariable adjusted results were largely consistent with the unadjusted results. Similar trends were observed for melanoma-related HRU and costs.

CONCLUSIONS: Recurrence in patients with resected stage 2B/2C melanoma is associated with greater HRU and costs, highlighting the need to consider treatment for patients with early-stage melanoma to decrease recurrence risk.

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

C13 A retrospective claims database analysis of health care resource utilization and costs of managing HR+/HER2– metastatic breast cancer through multiple lines of therapy in the United States

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BACKGROUND: HR+/HER2– breast cancer (BC) is the most common BC subtype. Endocrine therapy (ET) plus cyclin-dependent kinase 4 and 6 inhibitors (CDK4/6i) are standard care, but ET resistance typically develops. Until recently, the main treatments (txs) for ET resistant disease included traditional chemotherapy (CT). With the recent addition of antibody-drug conjugates to the tx landscape, there is a need to understand health care resource utilization (HCRU) and costs to contextualize value of novel therapies.

OBJECTIVE: To evaluate HCRU and costs for patients with HR+/HER2– metastatic BC (mBC) previously treated with ET and at least 2 lines of CT in the metastatic setting.

METHODS: This retrospective study identified adult female patients with HR+/HER2– mBC using the Optum Research Database to examine all-cause and BC-specific HCRU and costs. This allowed data capture after clinical practice incorporation of CDK4/6i. Patients had at least 1 prior ET and completed at least 2 CTs with their 3 or more CTs being initiated in the metastatic setting between January 2016 and March 2022 and used as the start (index) date for HCRU and cost calculations (CDK4/6i was an optional choice). HCRU included ambulatory visits, emergency department visits, inpatient (IP) stays, and pharmacy claims. Costs included medical and pharmacy costs (ambulatory [physician office and hospital outpatient] costs), emergency service costs, IP costs, and other costs (laboratory and ancillary costs) adjusted to 2022 US dollars. HCRU and costs were reported as per patient per month (PPPM) during the third to sixth or greater CT (CT3, CT4, CT5, CT6+).

RESULTS: A total of 769 patients were included. Mean age was 64 years (SD = 13.1 years). Most had a baseline National Cancer Institute comorbidity score of 0 (44%) or 1-2 (39%), and 51% of patients were covered by commercial insurance. Median days (interquartile range) of CT tx duration decreased with increasing prior CTs (CT3 118 [63-190]; CT4 91 [56-170]; CT5 95 [59-164]; CT6+ 88 [59-136]). The likelihood of emergency department visits and IP stays increased across CT length of therapy (LOT). Median all-cause PPPM medical costs increased across CT LOT (CT3 $7,267; CT4 $8,423; CT5 $9,043; CT6+ $9,667). Median all-cause PPPM pharmacy costs decreased (CT3 $309, CT4 $237, CT5 $176, CT6+ $189); this may be due to decreased use of oral CT (pharmacy cost) and increased use of infusion CT (medical cost) across CT LOT, but the overall cost increased.

CONCLUSIONS: In this retrospective real-world study, significant economic burden was associated with increasing CT LOT. As the treatment landscape for HR+/HER– mBC evolves, these findings provide an economic benchmark and highlight the importance of novel therapies for improving efficacy and associated HCRU and costs.

SPONSORSHIP: Gilead Sciences, Inc.

C15 Health care resource utilization and cost comparison among palbociclib, abemaciclib, and ribociclib in US patients with HR+/HER2– metastatic breast cancer

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BACKGROUND: Breast cancer is the most common cancer in women, accounting for considerable health care expenditure.

OBJECTIVE: To evaluate economic outcomes in patients with hormone receptor positive/human epidermal growth factor receptor 2–negative metastatic breast cancer treated with first- or second-line cyclin-dependent kinase 4/6 inhibitors (CDK4/6i): palbociclib (palbo), abemaciclib (abema)

or ribociclib (ribo). Other similar studies in this population had short follow-up, with many patients receiving CDK4/6is off-label.

METHODS: A retrospective analysis was conducted on 3,617 patients (aged ≥18 years) using Optum's Clinformatics DataMart dataset from January 1, 2014, to September 30, 2021. Patients were included if they had at least 1 pharmacy claim for palbo, abeam, or ribo in first- or second-line and had at least 6 months of continuous health plan enrollment in the pre-index (date of first CDK4/6i claim) and follow-up periods. All-cause per patient per month (PPPM) medical (inpatient, emergency department, and outpatient) health care resource use (HCRU) and costs, and outpatient pharmacy prescriptions costs, were compared between CDK4/6is by adjusting for differences in patients' baseline characteristics using inverse probability of treatment weighting. Subgroup analyses evaluated Medicare patients aged 65 years or older.

RESULTS: We identified 3,182 palbo, 286 abema, and 149 ribo patients with a median follow-up of 20.8, 16.6, and 19.9 months, respectively. Median age ranged between 69 and 71 years. After inverse probability of treatment weighting adjustment, palbo was associated with a lower risk of inpatient admissions (35.8% vs 41.6%; odds ratio = 1.31; P = 0.034) vs abema. No other differences were seen for HCRU. Compared with abema, PPPM outpatient costs were lower with palbo by $754 (P = 0.05). PPPM inpatient ($2,252 vs $6,286), medical ($6,948 vs $11,717), and total ($19,370 vs $23,639) costs were lower with palbo vs abema, although not statistically significant. PPPM HCRU were not different with palbo vs ribo, whereas PPPM inpatient ($2,252 vs $4,362), medical ($6,948 vs $8407), and total ($19,370 vs $20,951) costs were lower with palbo, but not statistically significant. In Medicare patients, PPPM medical costs were lower with palbo vs abema by $1,608 [P = 0.04], whereas other costs were not different. No differences in costs were seen with palbo vs ribo.

CONCLUSIONS: All-cause HCRU and costs were generally similar between the CDK4/6is but trended in favor of palbo for inpatient and medical costs vs abema. Alongside efficacy and safety, HCRU and costs should be considered when selecting CDK4/6is to understand the economic impact of treatment.

SPONSORSHIP: Pfizer, Inc.

C16 Health care resource utilization in patients with metastatic triple-negative breast cancer after initiating second line therapy: A real-world claims database analysis

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BACKGROUND: Metastatic triple-negative breast cancer (mTNBC) is aggressive and difficult to treat. Patients with mTNBC have poor prognosis and high economic burden.[1] Updated real-world data are needed to understand disease progression and health care resource utilization among patients with mTNBC after failure on first line of therapy in the current treatment landscape.

OBJECTIVE: To examine disease progression and hospitalization rates among patients with mTNBC after initiation of second-line therapy (2L).

METHODS: Adult female (age 18+ years) patients newly diagnosed with metastatic BC (mBC) (and without any other primary tumors) between January 1, 2015, and June 30, 2022, from the Merative MarketScan Commercial and Medicare databases were initially identified. Patients were required to initiate a 2L systemic treatment regimen following mBC diagnosis (index date). Patients were followed until database disenrollment or study end, and a minimum of 30 days follow-up post index was required. Patients who received hormonal therapy or targeted agents specific for treating HER2+, HR+, or ER+ mBC at any point during follow-up were excluded (to limit inclusion of patients without TNBC in the study). Disease progression was defined as receiving third line (3L) treatment and hospitalization rates were measured prior to and following progression.

RESULTS: A total of 1,228 patients with mTNBC who received 2L therapy were included for analysis with mean (SD) age 54.8 (10.7) years, mean National Cancer Institute adapted comorbidity score 0.31 (0.43), and a median (interquartile range) of 7.8 months (3.7-16.0) of follow-up. Of all patients, 39.4% (n = 484) and 17.5% (n = 215) progressed to 3L and 4L, respectively. During the progression-free period after 2L initiation, 37.7% of the 1,228 patients had at least 1 hospitalization, the number of admissions per patient per month was 0.14 (0.28), and with a mean length of stay per admission of 5.4 (5.2) days. Following progression to 3L (among those who progressed; n = 484), 55.2% had at least 1 hospitalization, the number of admissions per patient per month was 0.19 (0.03), and with a mean length of stay per admission of 5.3 (3.5) days.

CONCLUSIONS: More than one-third of patients with mTNBC experienced treatment progression within a year of 2L therapy initiation. Hospitalization rates were higher after progression, highlighting the importance of using treatment options shown to delay progression rates. 1. Aly A, 2019. Future Oncol. doi: 10.2217/fon-2018-0407

SPONSORSHIP: Gilead Sciences, Inc.

C17 Impact of CDK4/6 inhibitors on health-related quality of life outcomes in patients with metastatic breast cancer: A systematic review and meta-analysis

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BACKGROUND: The use of cyclin-dependent kinases 4 and 6 (CDK4/6) inhibitors and endocrine therapy in treatment of hormone receptor-positive (HR+)/HER2-negative metastatic breast cancer (MBC) has been shown to be effective in prolonged progression-free survival and manageable safety profiles. However, clinical trials of CDK4/6 inhibitors assessing health-related quality of life (HRQoL) outcomes showed non-uniform results thus far.

OBJECTIVE: To perform a systematic review and meta-analysis to comprehensively assess the impact of CDK 4/6 inhibitors on HRQoL outcomes in patients with MBC.

METHODS: A literature search on PubMed, Embase, and Clinicaltrials.gov databases was performed through February 2023 to identify randomized controlled trials reporting HRQoL outcomes of CDK4/6 inhibitors in treatment of MBC. CDK4/6 inhibitors included in this study are palbociclib, abemaciclib, and ribociclib. Heterogeneity among studies was evaluated by the I^2 statistics.

RESULTS: Fifteen randomized controlled trials involving 4,660 participants, were included. Treatment durations ranged from 6 to 65 months. HRQoL outcomes measured with the general European Organisation for Research and Treatment of Cancer Quality-of-Life Questionnaire (EORTC QLQ-C30) and breast-cancer specific (EORTC QLQ-BC23) were the most widely used (13/15, 87%), followed by the EuroQol- 5 Dimension (7/15, 47%). CDK4/6 inhibitors were associated with worsen HRQoL outcomes measured appetite loss and diarrhea, as well as systemic side effects and upset by hair loss. The differences of the mean changes from baseline for the EORTC QLQ-C30 appetite loss, EORTC QLQ-C30 diarrhea, EORTC QLQ-BR23 systemic side effects, and EORTC QLQ-BR23 upset by hair loss were 2.51 (95% CI = 0.85-4.17, $P = 0.003$, $I^2 = 45\%$), 11.50 (95% CI = 3.07-19.93, $P = 0.007$, $I^2 = 99\%$), 2.82 (95% CI = 0.40-5.24, $P = 0.02$, $I^2 = 86\%$), and 10.24 (95% CI = 8.88-11.59, $P < 0.001$, $I^2 = 45\%$), respectively. The values of EORTC QLQ-C30 diarrhea and EORTC BR-23 alopecia were greater than the published minimum clinically important difference values.

CONCLUSIONS: Treatment with CDK4/6 inhibitors was generally not worsening overall HRQoL outcomes in patients with MBC except for specific symptom-related to diarrhea and alopecia in patient-reported measures.

SPONSORSHIP: None.

C20 Oncology drug development: A drug-level analysis of subsequent indications

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BACKGROUND: Post-approval indications of oncology drugs expand treatment options in new cancer types, stages, lines, or combinations. New drugs are often first studied in patients with advanced diseases who have exhausted available treatment options and later receive indications for earlier lines of treatment. The Inflation Reduction Act deems small molecule and biologic drugs to be eligible for price setting 7 or 11 years, respectively, after initial US Food and Drug Administration (FDA) approval, which may impact research and development toward new oncology indications.

OBJECTIVE: To describe indication trajectories for new cancers, stages, lines, and combinations in a cohort of recently approved oncology drugs with at least 1 subsequent indication.

METHODS: We examined oncology drugs first approved by the FDA from 2008 to 2018 as a new molecular entity drug or original biologic with at least 1 subsequent indication. For each drug, we recorded the cancer (including mutation, gene or protein expression, and histology, if applicable), stage, and line of each indication, as well as whether it was approved in combination or as monotherapy. We then conducted a drug-level analysis, describing the number and proportion of drugs with subsequent indications of each type.

RESULTS: Overall, the 56 included new oncology drugs (70% small molecule) were approved for a median of two subsequent indications. Most novel oncology drugs were later approved in an additional cancer type (59%). Nearly half of the drugs (47%) received subsequent indications for new lines for the same cancer and stage. A quarter (26%) gained expanded indications for patients with the same cancer but different mutations, gene or protein expression, or histology than the initial approval. A similar proportion (27%) of drugs were later approved for a new stage of a previously indicated cancer. Development for new lines and stages were

nearly always from later to early line and most often from more to less advanced stages. Several drugs launched additional indications for new combination therapies, including an indication for combination therapy following a prior approval as monotherapy for the same cancer and stage (29%) or an indication for a different combination than an earlier approval (27%).

CONCLUSIONS: In a cohort of new oncology drugs, trajectories of FDA approval for subsequent indications demonstrate that drugs often launch in additional cancer types, new lines of therapy, and combinations. The Inflation Reduction Act will disincentivize the launch of additional drug indications in new cancers and lines of therapy, leading to fewer treatment options for patients with life-threatening diseases.

SPONSORSHIP: None.

C21 Budget impact of dostarlimab plus carboplatin-paclitaxel for primary advanced (stage 3 or 4) or first recurrent endometrial cancer from a US payer perspective

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BACKGROUND: In RUBY (NCT03981796), a phase 3 trial, dostarlimab plus carboplatin-paclitaxel (D+CP) significantly increased progression-free survival vs CP alone in patients (pts) with primary advanced or first recurrent endometrial cancer (pA/rEC) (Mirza MR, et al. N Engl J Med. 2023).

OBJECTIVE: To estimate the per-member per-month (PMPM) costs of introducing D+CP as a treatment alternative for pts with pA/rEC from the perspective of a third-party payer in the United States.

METHODS: A budget impact model was developed to estimate the costs of introducing D+CP into commercial and Medicare health plans over a 3-year time horizon (2023-2025). The base case modeled an incident pA/rEC population and considered scenarios before and after approval of D+CP. Epidemiology data, clinical inputs, treatment costs, and market share estimates were used to calculate the total costs for each scenario. Clinical inputs were sourced from primary clinical trials for each respective treatment (ie, D+CP, CP, bevacizumab + CP, and pembrolizumab [PEM] + CP; PEM and PEM + lenvatinib were also included to reflect the current real-world treatment landscape). Current and future market shares were predicted using analyses in which D+CP was expected to reduce the market share of CP only. Cost inputs were sourced from relevant literature and US-specific databases. Analyses were performed in deficient mismatch mutation repair/microsatellite instability-high (dMMR/MSI-H) and overall (all-comers) pA/rEC populations. A US 2023 cost year was used.

RESULTS: For a commercial plan, 7 pts with dMMR/MSI-H and 21 all-comers per 1,000,000 members were expected to be treated with D+CP over 3 years. The average annual budget impact per patient treated was $117,315, resulting in an average budget impact of $9,776 per patient treated per month (PPPM) and $0.02 PMPM in the dMMR/MSI-H population. In the all-comers population, the average annual budget impact per patient treated was $122,480, resulting in an average budget impact of $10,207 PPPM and $0.06 PMPM. For a Medicare plan, 23 pts with dMMR/MSI-H and 73 all-comers per 1,000,000 members were expected to be treated with D+CP over 3 years. The average annual budget impact per patient treated and PPPM was the same as for the commercial plan in both the dMMR/MSI-H and all-comers populations; budget impact PMPM was $0.07 in the dMMR/MSI-H population and $0.23 in the all-comers population.

CONCLUSIONS: Introducing D+CP as a first-line treatment alternative for pts with pA/rEC results in minimal budget impact from the perspective of a third-party US payer. This, together with efficacy and safety results, supports D+CP as a potential treatment option.

SPONSORSHIP: GSK.

C22 Real-world use of niraparib in patients with homologous recombination–deficient breast cancer gene wild-type and homologous recombination–proficient cancer in the United States

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BACKGROUND: Based on the PRIMA trial (NCT02655016) niraparib, a poly (ADP-ribose) polymerase inhibitor, received US Food and Drug approval in 2020 for first-line maintenance (1Lm) in patients (pts) with advanced ovarian cancer (AOC) regardless of biomarker status. This approval enabled newly diagnosed pts with homologous recombination-deficient (HRd)/breast cancer gene wild-type (BRCAwt) and HR-proficient (HRp) AOC to be treated with polymerase-inhibitor maintenance for the first time.

OBJECTIVE: To describe pt characteristics and real-world treatment (tx) patterns for pts with HRd/BRCAwt or HRp AOC who received 1Lm niraparib.

METHODS: This retrospective cohort study used the US nationwide Flatiron Health deidentified electronic health record–derived database. Eligible pts had diagnosed AOC-initiated 1Lm niraparib in January 2020 or later with documented HRd/BRCAwt or HRp status. Pts were followed

until end of clinical activity/end of study (May 2022). Pt characteristics and tx patterns were described for the HRd/BRCAwt and HRp groups.

RESULTS: In total, 114 pts (36% of eligible pts ever tested for HR deficiency status during study) were included; 57 pts had HRd/BRCAwt and 57 pts had HRp disease. Median age was 64 and 67 years; 28% and 26% of pts were non-White, respectively. Majority of pts had stage 3 disease (HRd/BRCAwt = 74% and HR = 72%) and approximately 20% of pts were treated in an academic setting; 47% of HRd/BRCAwt and 42% of HRp pts had primary debulking surgery. Approximately half of pts had no residual disease (HRd/BRCAwt = 51% and HRp = 54%) and up to 20% of pts had unknown residual disease status after surgery. Median follow-up for HRd/BRCAwt and HRp pts was 13.4 (IQR = 6.0-18.1) and 11.2 (IQR = 6.4-15.1) months, respectively. Bevacizumab + chemotherapy in 1L, prior to niraparib maintenance tx, was received by 16% and 25% of HRd/BRCAwt and HRp pts, respectively. Overall, 56% of HRd/BRCAwt and 54% of HRp pts discontinued tx during the study period; 14% of HRd/BRCAwt and 12% of HRp pts discontinued without receiving a second-line tx. Of the pts who received a second-line tx (42% in both pt groups), approximately 60% had received bevacizumab + chemotherapy in both groups.

CONCLUSIONS: This study describes the characteristics and tx sequences of real-world pts with HRd/BRCAwt and HRp AOC who received 1Lm niraparib monotherapy. HR deficiency status was not available for all pts in the data source, resulting in small pt numbers; however, because of the unmet need in these biomarker populations, additional real-world studies should be conducted. Sponsorship: GSK 217730. Editorial support was provided by Fishawack Health, funded by GSK.

SPONSORSHIP: GSK.

C23 Cardiovascular events among patients with prostate cancer treated with abiraterone and enzalutamide in Veterans Affairs

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BACKGROUND: Abiraterone acetate (AA), an androgen biosynthesis inhibitor, and enzalutamide (ENZ), an androgen receptor signaling inhibitor, are novel hormonal therapies for treating prostate cancer. There is growing concern of the adverse metabolic and cardiovascular effects of these medications because of the higher risk of cardiovascular disease among the population that receive the therapy.

OBJECTIVE: To analyze the risk of developing cardiovascular adverse events when treated with AA and ENZ among the Veterans' prostate cancer population.

METHODS: Using Veterans' Administration Data from January 2019 to October 2022, we identified patients with prostate cancer (*International Classification of Diseases, Tenth Revision* C61, Z85.46,) and divided it into 2 cohorts: patients treated with AA (National Drug Code 71921-0178) and ENZ (National Drug Code 0469-0625). Index date was defined by greater than 1 pharmacy claims for AA and ENZ during January 2020 to December 2021. We then defined cardiovascular event presentation as the presence of hypertension, ischemic heart disease, myocardial infarction, heart failure, ventricular arrhythmias, cerebrovascular accidents, peripheral artery disease, pulmonary heart diseases, atrial fibrillation, paroxysmal tachycardia, cardiomyopathy, pulmonary embolism, and aortic aneurysm. Descriptive and multivariate analysis were conducted using SAS. Propensity Matching technique was used for risk adjustment.

RESULTS: We analyzed 972 and 3,537 patients in the AA and ENZ cohorts, respectively. Across these cohorts, the mean ages were 73 and 75; more than 40 percent resided in the Southern region of the United States, with Charlson comorbidity scores 2.62 and 2.54. After controlling for age, regional and comorbidity differences, propensity score matching yield 956 matched patient. Follow up cardiovascular events—hypertension (46.03% vs 45.40%), ischemic heart disease (16.84% vs 17.26%), myocardial infarction (1.88% vs 2.30%), heart failure (10.77% vs 9.62%), ventricular arrhythmias (5.02% vs 5.33%), cerebral infarction (2.09% vs 2.51%), peripheral vascular diseases (3.77% vs 4.08%), pulmonary heart diseases (0.94% vs 1.36%), atrial fibrillation (13.18% vs 11.92%), paroxysmal tachycardia (1.88% vs 1.67%), cardiomyopathy (2.62% vs 3.14%), pulmonary embolism (2.51% vs 1.78%), and aortic aneurysm (2.41% vs 2.20%)—were similar between AA users and ENZ users.

CONCLUSIONS: Once the baseline comorbidities and sociodemographic factors are adjusted, the likelihood of getting any cardiovascular event is not different among the AA and ENZ users.

SPONSORSHIP: None.

C25 Time to next treatment and overall survival among White and Black patients with homologous recombination repair–positive metastatic castration-resistant prostate cancer who initiated first-line therapy

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BACKGROUND: Among patients with metastatic castration-resistant prostate cancer (mCRPC) with homologous recombination repair positive (HRR+) alterations, clinical outcomes may differ by race. Real-world data on outcomes among Black patients with HRR+ mCRPC are limited.

OBJECTIVE: To describe time to next treatment (TTNT) and overall survival (OS) among White and Black patients with HRR+ who initiated first-line mCRPC therapy.

METHODS: Deidentified clinical data from community oncology and academic centers included in the US-based Flatiron Health–Foundation Medicine, Inc., Metastatic Prostate Cancer Clinico-Genomic Database (January 1, 2011, to June 30, 2022) were used to identify patients with mCRPC positive for 1 or more HRR alterations (ie, ATM, BRCA1, BRCA2, BRIP1, CDK12, CHEK2, FANCA, PALB2) prior to or on the date of first-line therapy initiation (index date). TTNT and OS were assessed from index to the start of second-line treatment (TTNT), or death (OS) using Kaplan-Meier curves, respectively. Flatiron Health, Inc., did not participate in analyses.

RESULTS: A total of 219 White (mean age: 70 years) and 37 Black (mean age: 68 years) patients with HRR+ were identified. At first prostate cancer (PC) diagnosis, 44.3% of White and 40.5% of Black patients were diagnosed in the metastatic setting. Baseline PC treatment use was higher in White relative to Black patients, including androgen signaling inhibitors (34.2% vs 16.2%) and chemotherapy (12.3% vs 5.4%). Distribution of alteration types varied between cohorts (White patients: 25.1% somatic, 26.5% germline; Black patients: 56.8% somatic, 2.7% germline). BRCA2, CDK12, and ATM were the most common alterations in both cohorts, with numerically higher prevalence in Black patients (35.1%, 29.7%, and 27.0%, respectively) relative to White patients (28.8%, 26.9%, and 26.0%, respectively). Median TTNT was 6.6 months in both cohorts, but White patients had numerically longer median OS (23.7 months) relative to Black patients (21.4 months).

CONCLUSIONS: Despite similar TTNT and OS observed in White and Black patients with HRR+ with mCRPC, results of this study suggest disparities may exist in access to appropriate therapies in Black as compared to White men with mCRPC. This study also found that when tested, a higher proportion of Black men tested positive for BRCA2 and therefore may benefit from BRCA-specific therapies. This finding is important in light of earlier studies that showed Black men with PC were less likely than White men to receive biomarker testing, and therefore less likely to receive targeted therapy.

SPONSORSHIP: Janssen Scientific Affairs, LLC.

C26 Real-world economic burden associated with progression from metastatic castration-sensitive to metastatic castration-resistant prostate cancer

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BACKGROUND: Patients with prostate cancer (PC) may progress to metastatic disease, which has a poor prognosis and has been associated with higher incremental health care costs. These trends continue to be important to monitor as changes in the treatment landscape may impact clinical and economic outcomes in PC.

OBJECTIVE: To describe health care costs of patients with metastatic castration-sensitive PC (mCSPC) before and after progression to metastatic castration-resistant PC (mCRPC).

METHODS: Data from Flatiron Metastatic PC Core Registry linked to Komodo Health Solutions were evaluated. Patients who progressed directly from mCSPC to mCRPC and who initiated a first line mCRPC regimen on or after January 1, 2017, were included in the study. Patients were excluded if they had less than 12 months of insurance history prior to date of progression to castration resistance (CR; index date), had less than 3 months from mCSPC to mCRPC, received a clinical trial therapy as first post-index treatment, or claims for the Flatiron defined therapy were missing in Komodo. PC-related total costs (medical and pharmacy) per patient per month (PPPM) were described from a payer's perspective for up to 12 months before index and after index until the earliest between the end of continuous eligibility, end of data availability, or death (post-CR period). Flatiron Health, Inc., did not participate in data analyses.

RESULTS: A total of 296 patients with mCSPC who progressed to mCRPC (mean age 69 years, and 61% White) were identified. Androgen deprivation therapy was observed in 95% of patients before index. The average (median) duration of the mCSPC pre-index period was 10.2 months, during

which mean (median) PC-related total costs PPPM were $2,859 ($900), PC-related medical costs PPPM were $1,626 ($490), and PC-related pharmacy costs PPPM were $1,233 ($3). The average duration of the post-CR period was 10.3 months, during which mean PC-related total costs PPPM were $8,012 ($6,873), PC-related medical costs PPPM were $3,285 ($851), and PC-related pharmacy costs PPPM were $4,727 ($3,651).

CONCLUSIONS: In this descriptive study, mean PC-related total costs increased more than 2-fold during the post-CR relative to pre-CR period. Incremental costs following progression to CR were driven in part by an increase of more than 3-fold in mean PC-related pharmacy costs and more than 2-fold mean PC-related medical costs relative to the pre-CR period. Clinical interventions aiming to delay costly progression in patients with advanced PC are warranted.

SPONSORSHIP: Janssen Scientific Affairs, LLC.

C27 Long-term temporal trends of health care cost associated with nivolumab plus ipilimumab and pembrolizumab plus axitinib as first-line treatment in advanced or metastatic renal cell carcinoma in a real-world setting

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BACKGROUND: As immuno-oncology combination therapies become the new standard of care for treatment-naive advanced or metastatic renal cell carcinoma (aRCC), cost of care for patients receiving these regimens remains uncertain.

OBJECTIVE: To evaluate the long-term temporal trends of health care costs associated with nivolumab plus ipilimumab (N+I) and pembrolizumab plus axitinib (P+A) as first-line (1L) aRCC treatments.

METHODS: The Merative Marketscan Commercial and Medicare Supplemental Databases (January 1, 2014, to September 30, 2021) were used. Adult patients who received 1L N+I or P+A (index date) after aRCC diagnosis were included. Patients were required to have at least 6 months (mos) of continuous insurance coverage before and after index date. Monthly all-cause and RCC-related health care costs, including medical and drug costs, were evaluated at 6-mo intervals up to 24 mos. Adjusted cost differences between the two treatments were estimated using a generalized estimating equation method with a Tweedie distribution. The multivariable model's covariates included key baseline characteristics (ie, age, sex, geographic region, insurance, index year, metastatic sites, Charlson comorbidity index, and time from aRCC diagnosis to index date).

RESULTS: The number of patients included in the analysis was 219, 210, 119 and 81 for N+I and 106, 103, 48 and 25 for P+A during mos 0-6, 7-12, 13-18 and 19-24, respectively. Median ages of patients receiving N+I and P+A were 58 and 60 years, respectively; other baseline characteristics were similar between the cohorts. After adjustment, for all-cause costs, N+I was associated with $5,324 (95% CI = $959-$9,739) higher monthly costs than P+A during mos 0-6, and $4,129 (–$79 to $8,278) lower monthly costs during mos 7-12, $4,678 (–$868 to $10,418) lower monthly costs during mos 13-18, and $10,914 ($1,091-$21,436) lower monthly costs during mos 19-24. The difference in total costs between N+I and P+A was mainly driven by the difference in drug costs: $1,137 ($–2,947 to $5261), –$5,555 (–$9,527 to –$1,600), –$7,217 (–$13,005 to –$1709), and –$16,682 (–$29,022 to –$5055) during the 4 time periods. RCC-related costs showed similar patterns as all-cause costs.

CONCLUSIONS: Despite numerically higher monthly health care costs for N+I compared with P+A in the first 6 mos of treatment, N+I was associated with directionally lower monthly costs from 7 to 24 mos in patients with previously untreated aRCC. The cost savings in later mos were mainly driven by the difference in drug costs. This suggests that N+I may offer a more cost-efficient option vs P+A over an extended period. Future research with a larger sample size and longer follow-up is warranted.

SPONSORSHIP: Bristol Myers Squibb.

C28 Real-world treatment patterns and characteristics of Medicare patients with locally advanced or metastatic urothelial carcinoma receiving enfortumab vedotin-ejfv

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BACKGROUND: Enfortumab vedotin-ejfv (EV) is approved by the US Food and Drug Administration for adults with locally advanced or metastatic urothelial carcinoma (la/mUC) as monotherapy in the second line setting or later; in April 2023, it received accelerated approval in combination with pembrolizumab for patients who are ineligible for cisplatin.

OBJECTIVE: To describe real-world treatment patterns and characteristics of US patients with la/mUC prior to treatment with EV.

METHODS: This retrospective analysis used claims from the US Centers for Medicare & Medicaid Services 100% Fee-for-Service Medicare database (2015-2020). Patients who received EV after la/mUC diagnosis were included; the EV initiation date was the index date. The baseline period was a minimum of 12 months prior to the index date. All-cause health care resource utilization and costs (2020 US dollars) were measured 12 months prior to index date. Patient characteristics and treatment patterns were measured prior to index date with a minimum of 12 months of available data. All endpoints were summarized descriptively.

RESULTS: In total, 529 patients were included (mean age, 76.5 years; men, 77.1%; White, 88.1%). The most common comorbidity was hypertension (85.1%). During the 12 months before EV initiation, most (54.8%) patients had at least 1 inpatient visit (mean among those with ≥1 visit: 2.6), emergency department visit (51.4%; mean: 2.2), and outpatient visit (85.6%; mean: 38.8). Mean total health care cost ($106,258/patient) was driven by outpatient costs (inclusive of office visit and/or outpatient procedure; $74,560). Most (73.3%) patients received 2 lines of systemic therapy before EV initiation, most commonly platinum-based chemotherapy (43.9%) or a PD-1/L1 inhibitor (21.4%). The most common therapy observed in the line immediately before EV initiation was a PD-1/L1 inhibitor (61.4%) or platinum-based chemotherapy (19.5%). Median EV treatment duration was 4.1 months.

CONCLUSIONS: Based on this study, most systemic treatment for US patients with la/mUC prior to EV was platinum-based chemotherapy or a PD-1/L1 inhibitor. Health care resource utilization and cost were not inconsequential in the year prior to receiving EV, indicating that burden is substantial among this population. This study was conducted prior to the April 2023 accelerated approval of EV plus pembrolizumab in la/mUC for the first-line setting; additional research should be conducted when sufficient data are available.

SPONSORSHIP: Astellas Pharma, Inc., and Seagen Inc.

C29 Overall health care cost savings with Gleolan-guided surgery compared with conventional white light surgery for high-grade glioma

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BACKGROUND: Gleolan (aminolevulinic acid HCl) oral solution (also known as 5-ALA) is the only US Food and Drug Administration (FDA)–approved optical imaging agent indicated in patients with glioma (WHO suspected grades 3 and 4 on preoperative imaging) as an adjunct for the visualization of malignant tissue during surgery. Gleolan-guided surgery in conjunction with blue light has been associated with improved imaging complete resection and progression-free survival vs conventional white light surgery.

OBJECTIVE: To understand overall health care cost differences with Gleolan-guided surgery compared with conventional white light surgery for patients with high-grade glioma.

METHODS: The rate of follow-up operations for additional resection with Gleolan-guided surgery vs conventional white light surgery was retrieved from the Gleolan FDA briefing package. Ex-factory cost per vial of Gleolan at $2,998 per vial was taken from First Data Bank as of September 2022. Two vials were used in the analysis, which accounts for patients with a body mass of up to 150 kg (331 lbs). EncoderPro was used as a resource to reference the "base" payment rate and to calculate the "average adjusted total" payment rate for 30 facilities that represent 80% of all Gleolan use in the United States (actual payment made to hospitals as of September 2022). Overall health care costs were calculated by multiplying payment rates by the rate of follow-up operations with Gleolan-guided surgery vs conventional white light surgery.

RESULTS: A 23% reduction in 1 follow-up operation was observed with Gleolan-guided surgery vs conventional white light surgery. Overall health care costs were 7% lower with Gleolan-guided surgery vs conventional white light surgery ($1,067,666 vs $998,209) when using the base payment rate. Similarly, overall health care costs were 13% lower ($1,752,033 vs $1,522,368) with Gleolan-guided surgery compared with conventional white light surgery when using the average adjusted total payment rate for 30 of the largest hospital users of Gleolan.

CONCLUSIONS: Gleolan-guided surgery decreased overall health care costs vs conventional white light surgery in patients with high-grade glioma because of fewer follow-up operations and is associated with improved imaging complete resection and progression-free survival. In the study, if reflected in real-world evidence a 23% reduction in reoperations would result in associated cost savings of approximately $229,000 per 100 patients.

SPONSORSHIP: Medexus Pharma, Inc.

C30 Health care resource utilization among Medicare beneficiaries with non–small cell lung and thyroid cancers

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BACKGROUND: Metastatic cancer is linked to high health care resource utilization (HCRU). The mean cost per hospitalization for cancer is $22,100 at a cost per day of $3,400 (Agency for Healthcare Research and Quality [AHRQ], Healthcare Cost and Utilization Project [HCUP], National Inpatient Sample [NIS], 2017). Targeted therapies, such as tyrosine receptor kinase inhibitors, have shown superior efficacy vs standard of care in indirect comparisons which may lead to reductions in HCRU.

OBJECTIVE: To compare inpatient admissions and length of stay (LOS) for patients diagnosed with locally advanced or metastatic non–small cell lung cancer (NSCLC) and differentiated thyroid cancer (DTC) from the larotrectinib clinical trial (NAVIGATE) to patients with stage 3 or 4 NSCLC and DTC from SEER-Medicare with similar baseline characteristics except for neurotrophic tyrosine receptor kinase gene fusion status as a proxy for a standard of care cohort.

METHODS: This is a retrospective study using the SEER-Medicare linked database, which has SEER cancer diagnoses available through 2017 and linked Medicare claims and mortality data through 2019. The study period is January 1, 2007, through December 31, 2019. Patient characteristics, treatment patterns, and HCRU were described for patients with NSCLC and DTC. A subgroup of SEER-Medicare patients with NSCLC (n = 12,533) and DTC (n = 90) was developed based on select NAVIGATE trial inclusion/exclusion criteria and compared with patients with NSCLC and DTC from larotrectinib clinical trial.

RESULTS: For patients with NSCLC, incidence of hospitalizations per patient per month (PPPM) from NAVIGATE (0.039, 95% CI = 0.024-0.059) was approximately half that observed in the SEER-Medicare subgroup (0.093, 95% CI = 0.091-0.095). Average LOS PPPM for patients with an admission during NAVIGATE (0.9 days) was approximately half the LOS PPPM in the SEER-Medicare subgroup (2.1 days). In patients with DTC, incidence of PPPM hospitalizations in NAVIGATE (0.032, 95% CI = 0.021-0.046) was approximately half that observed in the SEER-Medicare subgroup (0.062, 95% CI = 0.044-0.081). Average LOS PPPM for patients with an admission from NAVIGATE (0.8 days) was approximately half of the LOS PPPM observed in the SEER-Medicare subgroup (1.7 days).

CONCLUSIONS: Patients with NSCLC and DTC from larotrectinib NAVIGATE trial had approximately half the PPPM hospitalizations and LOS compared with SEER-Medicare patients. The SEER-Medicare cohort was not balanced to the trial sample on characteristics such as age, sex, race, or stage distribution. Further analysis is warranted to understand the drivers of the differences in HCRU.

SPONSORSHIP: Analysis Funded by Bayer.

C31 Biosimilar filgrastim use in Medicare Part D 2016-2020

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BACKGROUND: The first biosimilar filgrastim was approved by the US Food and Drug Administration in 2015, and two additional biosimilars have since entered the market. There is a lack of data regarding the use of biosimilar filgrastim in the Medicare Part D population over time.

OBJECTIVE: To determine the uptake of biosimilar filgrastim during 2016-2020 in Medicare Part D and assess US regional differences in the use of biosimilar filgrastim in 2020.

METHODS: We analyzed the publicly available Medicare Part D Prescribers by Provider and Drug Dataset for the years 2016-2020. The proportion of filgrastim claims that were for biosimilars (TBO-filgrastim, filgrastim-AAFI, and filgrastim-SNDZ) was determined for 2016-2020 for the US overall, and for each census region, including 99% CIs. We also determined the average claim cost for brand and biosimilar filgrastim paid by Part D plans, and estimated the savings yielded from the use of biosimilars over the 5-year period, adjusted to 2020 dollars.

RESULTS: The proportion of biosimilar filgrastim claims grew substantially in Medicare Part D, increasing from 23.1% (99% CI = 22.3%-23.9%) of 28,058 reported Part D filgrastim claims in 2016 to 74.2% (99% CI = 73.5%-74.9%) of 32,922 Part D claims in 2020. Use of biosimilar filgrastim increased most substantially in the US Southwest region (73.9% of claims in 2020, 99% CI = 71%-76.6%), with comparatively lesser use in the US Southeast region (65.4% of claims in 2020, 99% CI = 63.4%-67.4%). The average cost per filgrastim claim in 2020 was $2,823 for brand filgrastim and $2,175 for biosimilars. Overall, the use of biosimilar filgrastim yielded an estimated $40,144,805 in total US savings for Part D plans over the 5-year period spanning 2016-2020.

CONCLUSIONS: During 2016-2020, the use of biosimilar filgrastim increased substantially in the Medicare Part D population, whereas the extent of biosimilar use varied by US region, suggesting potential unrealized savings. These findings may inform trajectories of biosimilar uptake in Medicare Part D for other drug classes.

SPONSORSHIP: None.

C32 Budget impact of shifting the treatment setting of unresectable liver metastases associated with primary colorectal cancer using Yttrium-90 resin microspheres from the outpatient hospital to the office-based laboratory

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BACKGROUND: Metastatic disease to the liver is the most common form of hepatic malignancy. Surgical interventions provide potentially curative options for selected patients, but the majority have unresectable tumors and are not eligible for surgery. Yttrium-90 resin microspheres are indicated for the treatment of unresectable metastatic liver tumors from primary colorectal cancer (CRC) in patients refractory to, or intolerant of, chemotherapy.

OBJECTIVE: To assess the difference in health plan reimbursement costs for the treatment of unresectable liver metastases associated with CRC in an outpatient hospital setting (HOPPS) vs an office-based laboratory (OBL).

METHODS: The size of the eligible patient population was estimated using an incidence-based approach. Modeled costs were based on 2023 published Medicare reimbursement rates, and included treatment costs associated with imaging, product administration, staff time, and materials acquisition. Budget impact scenarios were estimated as the differences in annual total cost of treatment per patient and per health plan by shifting the treatment of varying percentages of patients (25%, 50%, and 100%) from the HOPPS setting to the OBL setting for a hypothetical health plan with one million covered lives. Per-member-per-month (PMPM) budget impacts were also calculated.

RESULTS: Annually, 29 patients per year were estimated to have metastatic CRC and unresectable liver metastases in a hypothetical health plan of 1 million members. The average cost of Yttrium-90 resin microspheres treatment per each eligible patient is estimated to be $55,505 per patient in the HOPPS setting vs $39,229 in the OBL setting; an average cost savings of $16,276 to the health plan for each patient who switches from HOPPS to OBL. Annual cost savings for the health plan would thus range from $117,783 if 25% of eligible patients switched treatment settings (a $0.12 PMPM cost benefit) to $471,134 if 100% of eligible patients switched treatment settings from HOPPS to OBL (a $0.47 PMPM cost benefit).

CONCLUSIONS: Shifting the treatment of unresectable liver metastases with Yttrium-90 resin microspheres to an OBL setting from a HOPPS setting would result in overall cost savings for US health plans.

SPONSORSHIP: Sirtex Medical Holdings Ltd.

C33 Economic burden of adverse events and hospitalizations associated with treatments for the third-line-or-later setting of relapsed or refractory diffuse large B-cell lymphoma: A systematic literature review

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BACKGROUND: Diffuse large B-cell lymphoma is the most common lymphoma type in the United States, with several novel therapies recently approved. It is important to estimate the cost and health care resource use (HCRU) burden associated with adverse events (AEs) and hospitalizations related to currently available therapies.

OBJECTIVE: To identify evidence for AE- and hospital-related costs and HCRU associated with therapies used for third-line-or-later relapsed or refractory diffuse large B-cell lymphoma based on a systematic literature review. AEs of interest included cytokine release syndrome (CRS) and neurological events (NEs).

METHODS: The systematic literature review included English-language publications, conference abstracts, and health technology assessments reporting costs and HCRU in the target population, identified between 2017 and 2022 using Embase, MEDLINE, EconLit, conference searches (n = 9), and health technology assessment agency websites (n = 7).

RESULTS: We identified 27 cost and HCRU studies (23 retrospective observational studies, 3 micro-costing analyses, and 1 cross-sectional registry study). Most studies evaluated CD19 chimeric antigen receptor T-cell (CAR T-cell) therapies (n = 19) and mixed therapies (n = 8; including CAR T-cell therapies [n = 4]). Reported outcomes were heterogeneous given different objectives, study designs, treatments, and definitions. A high average cost related to AEs was

identified for CAR T-cell therapies, cytotoxic, and targeted agents (n = 8). Studies evaluating primarily CAR T-cell therapies (n = 5) focused on CRS and NE for AE cost and HCRU reporting. The cost per grade 3/4 CRS event was US$20,375 (n = 1), most of which was attributed to admissions to the intensive care unit (US$16,528). In the 3 months after CAR T-cell infusion, mean total costs were higher for patients with severe CRS (US$476,000-$711,615) compared with those with any-grade CRS (US$344,486-$577,000) (n = 2). Similar trends were observed for NEs, and patients who experienced CRS and NEs concurrently had higher costs than those who had either event alone (n = 1). Hospitalizations were associated with high burden in terms of HCRU (n = 23) and costs (n = 8), especially for CAR T-cell therapies, which reported over 3 months after CAR T-cell infusion a mean hospital length of stay of 17-22 days (n = 2) and inpatient costs of $236,135-$486,533 (n = 2).

CONCLUSIONS: AEs and hospitalizations related to third-line-or-later treatments, primarily CAR T-cell therapies, for relapsed or refractory diffuse large B-cell lymphoma are associated with a high cost and HCRU burden that rises with increased AE severity, which should be accounted for in economic evaluations.

SPONSORSHIP: Regeneron Pharmaceuticals Inc.

C34 Health care resource utilization and costs among patients receiving systemic treatment for peripheral T-cell lymphoma: A retrospective database study

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BACKGROUND: Health care resource utilization (HRU) among patients with peripheral T-cell lymphoma (PTCL) imposes a significant cost and clinical burden. However, data on HRU and associated costs for patients with PTCL by lines of therapy are limited.

OBJECTIVE: To describe HRU and costs by lines of therapy (LOTs) among treated patients with PTCL in the United States.

METHODS: IQVIA PharMetrics Plus claims data were retrospectively analyzed (April 2011 to November 2021) to identify patients (aged ≥18 years) with at least 1 inpatient or at least 2 outpatient (≥30 days apart) *International Classification of Diseases* diagnoses of PTCL. Patients with evidence of at least 1 systemic treatment for PTCL (excluding steroid monotherapy) were identified; the date of first PTCL treatment claim was the index date. Patients had continuous enrollment for 6 months before and at least 1 month after the index date. Using a regimen-based algorithm, the total number of LOTs observed during follow-up were defined and 3 mutually exclusive cohorts were created: 1LOT, 2LOT, and ≥3LOT. All-cause and PTCL-related HRU and associated costs per patient per month (PPPM) were reported for the LOT cohorts. PTCL-related HRU was defined as any service/claim with at least 1 PTCL diagnosis code in any position; PTCL-related pharmacy included medications indicated for PTCL.

RESULTS: A total of 189 (21.0%) patients with PTCL had systemic treatment: 117 (61.9%) patients had 1LOT, 41 (21.7%) had 2LOT, and 31 (16.4%) had ≥3LOT. Most patients were male (62.4%), aged 55 years and older (59.3%), and commercially insured (65.6%). Hypertension (40.2%, 29.3%, and 32.3%), chronic pulmonary disease, (20.5%, 9.8%, and 16.1%), and mild to moderate diabetes (16.2%, 14.6% and 12.9%) were the most prevalent comorbidities. Among all treated patients, 59.3% had at least 1 hospitalization, 48.1% had at least 1 emergency department visit, and the mean prescriptions PPPM was 8.0 (SD = 6.4), suggesting substantial HRU. Hospitalizations, emergency department visits, and the number of prescriptions PPPM increased with increasing LOTs. Similar trends were observed for PTCL-related HRU. Total all-cause costs PPPM was highest for the 2LOT cohort ($28,591) and lowest for the 1LOT cohort ($23,366), driven by hospitalizations and prescription drug costs. PTCL-related costs accounted for 69.8%, 69.3%, and 67.2% of total all-cause costs of the 1LOT, 2LOT and ≥3LOT cohorts, respectively.

CONCLUSIONS: High all-cause and PTCL-related HRU and costs were observed among patients with PTCL treated with systemic therapy, with PTCL-related costs accounting for nearly 70% of total costs. Hospitalizations and prescription drug use were the major cost drivers.

SPONSORSHIP: Daiichi Sankyo, Inc.

C35 Impact of patient support program participation on treatment access among patients prescribed ibrutinib

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BACKGROUND: Administration of oral oncolytics, such as ibrutinib, can be associated with challenges in treatment uptake. Imbruvica By Your Side (BYS), a patient support program that offers financial assistance and education, has been shown to improve ibrutinib treatment persistency. However,

the effect of the BYS program on initial treatment access is unknown.

OBJECTIVE: To describe patient characteristics and compare the initial treatment access of BYS program enrollees vs nonenrollees.

METHODS: BYS data and linked Symphony Health all-payer open-source administrative claims data (January 15, 2021, to February 28, 2023) were used to identify commercially insured adults with at least 1 ibrutinib pharmacy claim. At least 3 months of follow-up data after claim submission were required. Baseline demographics and clinical characteristics, ibrutinib prescription approval date, dispense rate, first fill adherence, and time to dispense were extracted. Treatment access was compared between BYS enrollees and nonenrollees using a multivariable model, with or without adjustment for age, sex, income, race, region, Charlson Comorbidity Index, and indication with starting dosage.

RESULTS: Among 2,223 eligible patients, baseline demographics were generally similar between BYS enrollees (n = 523) vs nonenrollees (n = 1,700) (men, 64% vs 59%, $P = 0.07$; White race, 66% vs 66%, $P = 0.34$). Some key differences in age (mean age [SD], 66 [9] vs 70 [7] years, $P < 0.01$) and Charlson Comorbidity Index score (58% vs 53% with score of 2; $P < 0.01$) were observed in enrollees vs nonenrollees. Approximately half of enrollees and nonenrollees reported no baseline prescription medications (86% vs 88%; $P = 0.10$). In multivariable analysis, BYS enrollees had a significantly higher prescription approval rate (unadjusted hazard ratio [HR] = 2.88, $P < 0.01$), dispense rate (HR = 2.49, $P < 0.01$), first fill adherence rate (HR = 1.92, $P < 0.01$), and shorter time to dispense (–5.8 days, $P < 0.01$). In patients stratified by race or ethnicity, the rates were numerically higher for enrollees vs nonenrollees, but small sample sizes precluded statistical analysis.

CONCLUSIONS: These data suggest that BYS enrollment is associated with improved initial access to ibrutinib, which is consistent with previous findings of better persistence among BYS participants. Further analyses with larger sample sizes, especially in low-income and non-White patients, are warranted. This study's limitations are inherent to those based on claims data.

SPONSORSHIP: This study has been funded by AbbVie Inc.

C36 Impact of treatment-emergent peripheral neuropathy in patients with multiple myeloma

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BACKGROUND: Treatment (tx)-emergent peripheral neuropathy (TEPN) is seen with some commonly used multiple myeloma (MM) txs. Literature shows the health care burden of TEPN, but current evidence is dated and bears methodology limitations.

OBJECTIVE: To examine the clinical and economic impact of TEPN in US patients (pts) with MM.

METHODS: This matched cohort study used the Optum claims database to identify pts with MM who had at least 1 line of therapy (LOT; claims-based algorithm) between January 1, 2018, and March 31, 2022, and continuous health plan enrollment for at least 12 months (mo) before and at least 3 mo after the index LOT (earliest LOT from January 1, 2018). Pts with TEPN had a claim for TEPN during the index LOT but had no such claim in the prior 12 mo. Pts without TEPN (controls) were selected 2:1 with exact matching on index year (y), LOT number, index LOT regimen, and propensity score matching on baseline characteristics. Index date for pts with TEPN was defined as the date of earliest TEPN claim within index LOT. A pseudo index date was assigned to controls as index LOT start date plus time to TEPN of matched pts with TEPN. Cox, logit, and generalized linear models were used to assess tx discontinuation, health care resource use, and cost outcomes, respectively.

RESULTS: Of 6,508 eligible pts, 1,137 (17%) experienced TEPN; of these, 1,086 (96%) had it in their first LOT. 834 pts with TEPN and 1,668 controls were matched. Baseline characteristics were balanced in the matched cohorts (mean age = 71 y, 48% female, mean Quan-Charlson Comorbidity Index = 3.5, 77% covered by Medicare Advantage plan, mean follow-up = 18 mo for both groups). Mean time from start of index LOT to TEPN was 3.4 (±2.0) mo. Pts with TEPN discontinued index LOT significantly earlier than controls (median 7.8 vs 9.3 mo, hazard ratio = 1.16, $P = 0.014$) and incurred significantly higher hospitalization cost during the remainder of index LOT ($5,763 vs $3,714 per pt per mo [PPPM], $P < 0.0001$) owing to significantly higher rates of hospitalization (54% vs 44%, odds ratio = 1.48, $P < 0.0001$), higher mean number of hospitalizations (0.20 vs 0.15 PPPM, $P = 0.0118$), and longer hospital stays (1.43 vs 0.96 days PPPM, $P < 0.0001$).

CONCLUSIONS: Pts with MM experience TEPN primarily during their first LOT, resulting in earlier tx discontinuation and significant clinical and economic burden. This highlights the importance of considering effective MM therapies with minimal risk of TEPN that may allow pts to stay on treatment longer, especially in earlier LOTs.

SPONSORSHIP: Janssen Scientific Affairs, LLC.

C37 Number needed to benefit with momelotinib to prevent grade 3/4 anemia and reduce transfusion dependence in patients with myelofibrosis

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BACKGROUND: Anemia is a key manifestation of myelofibrosis (MF) and is known to negatively impact survival. Severe anemia reduces median overall survival in patients with MF by as much as 5.8 years. Nearly all patients with MF become anemic over time, and approximately half require red blood cell (RBC) transfusions within 1 year of diagnosis. The increased use of RBC transfusions can result in substantial health care resource utilization. The number needed to benefit (NNTB) offers a measurement of the impact of a medicine or therapy by estimating the number of patients who need to be treated to have an impact on 1 person.

OBJECTIVE: Momelotinib (MMB), a Janus kinase (JAK) 1/JAK2 and activin A receptor type 1 inhibitor, has shown consistent benefits in terms of spleen response, symptom response, and transfusion independence (TI) rates across three phase 3 trials (SIMPLIFY-1 [S1], SIMPLIFY-2 [S2], and MOMENTUM). This analysis quantified the number of patients needed to benefit to prevent 1 more incidence of severe anemia and promote 1 more conversion to TI.

METHODS: The analysis included data from two phase 3 trials—S1 (MMB vs ruxolitinib in JAK inhibitor [JAKi]–naive patients) and S2 (MMB vs best available therapy [BAT] in JAKi-experienced patients). The study evaluated the incidence of grade 3/4 anemia and the achievement of TI at week 24. The NNTB was calculated from the absolute risk reduction of these outcomes for MMB vs comparators (NNTB = 1/absolute risk reduction). Severe anemia was defined as grade 3 or 4, while TI conversion was assessed in a subset of patients who were TD at baseline (hemoglobin levels < 8 g/dL with ≤4 RBC transfusions in the 8-week period prior to randomization) and were TI at week 24.

RESULTS: In comparison with ruxolitinib in S1, treating 4 patients with MMB resulted in the prevention of 1 additional grade 3/4 anemia event over 24 weeks. Treating 8 patients with MMB led to 1 additional patient transitioning from TD at baseline to TI at week 24. In comparison with best available therapy in S2, treating 7 patients was sufficient to prevent the occurrence of 1 additional grade 3/4 anemia event over 24 weeks, and 4 patients needed to be treated to achieve 1 more conversion of transfusion status from TD to TI.

CONCLUSIONS: In either JAKi-naive or JAKi-experienced patients with MF, MMB led to fewer severe anemia events and improved transfusion status, contributing to potentially reduced treatment costs.

SPONSORSHIP: GSK plc.

C38 Patient characteristics, treatment patterns, and survival of older patients in the United States with relapsed or refractory follicular lymphoma: Surveillance, Epidemiology, and End Results: Medicare 2012-2019

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BACKGROUND: Early relapsed follicular lymphoma (FL) POD24 is defined as progression of disease 24 months or less after initial treatment (tx) with a CD20 antibody and alkylator 6 months or less from initial FL diagnosis and is associated with poor prognosis and survival outcomes. Currently, there remains limited evidence on the tx patterns and clinical outcomes among patients (pts) with FL POD24.

OBJECTIVE: To describe demographic and clinical characteristics, tx patterns, and survival outcomes of older pts with FL POD24 in the real-world setting.

METHODS: This was a retrospective cohort study using data from SEER-Medicare between January 1, 2012, and December 31, 2019. Eligible pts were aged 66 years and older with FL POD24. Demographic and clinical characteristics were identified during the 6 months before FL diagnosis. The outcomes assessed were tx patterns by line (L), overall survival (OS), and survival by line of therapy. Right-censored Kaplan-Meier methods were used to describe time to initiation (TTI), time to tx discontinuation (TTD), and time to next tx (TTNT).

RESULTS: Among 589 pts with FL POD24, mean age was 75.7 years, 53.1% were female, and 92.4% were White. More than 40% of pts were diagnosed at stage III or greater, the majority (53.1%) did not have B symptoms, including unexplained fever, night sweats, and weight loss, and more than 30% had an National Cancer Institute comorbidity index greater than or equal to 3. Rituximab (R) monotherapy was the most commonly received regimen for 1L (45.8%), 2L at point of FL POD24 identification (37.9%), 3L (51.8%), and 4L (67.1%). Bendamustine + R in 1L (18.8%), radiation + R in 2L (13.1%), and

radiation alone in 3L (12.7%) and 4L (5.3%) were the second most commonly received regimens. Median TTI in 1L was 52 days. Median TTD was 102, 178, 116, and 76 days, and median TTNT was 154, 400, 203, and 140 days in 1L, 2L, 3L, and 4L, respectively. Five-year OS was 73.1%, 35.8%, and 63.4% for pts in 2L, 3L, and 4L, respectively. Median survival was 49.3% in 3L. Five-year OS was only 67.5% among all pts with FL POD24.

CONCLUSIONS: In Medicare pts, the use of anti-CD20 monotherapy remained high across all tx lines, and there was a decreasing trend for more complex regimens. The TTNT was noticeably short in the 1L, 3L, and 4L settings, indicating a quick time to progression and potentially suboptimal responses to recycled txs. With the large proportion of deaths after 3L and poor 5-year OS, these findings demonstrate a substantial unmet need for txs that increase OS for older pts with FL POD24.

SPONSORSHIP: BMS.

C40 Treatment patterns, health care resource utilization, and cost among commercially insured patients with relapsed/refractory follicular lymphoma in the United States: MarketScan 2015-2021

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BACKGROUND: Follicular lymphoma (FL) POD24, defined as disease progression 24 months or less after initial treatment (tx) with a CD20 antibody and alkylator 6 months or less from initial diagnosis, is associated with poor survival outcomes. Evidence is needed to develop novel therapeutic approaches to improve outcomes.

OBJECTIVE: To describe patient (pt) characteristics, tx patterns, health care resource utilization (HCRU), and costs across tx lines (L) among US adults with FL POD24.

METHODS: Merative MarketScan claims were retrospectively analyzed (January 2015 to June 2021) for commercially insured pts aged 18 years and older, diagnosed with FL POD24. Pts were followed 6 months or more from initiating 2L tx to end of tx line, death, or end of study period. For selected tx patterns, descriptive analysis was conducted by line of therapy (LOT). Right-censored Kaplan-Meier methods were used to describe time to initiation (TTI), time to tx discontinuation (TTD), and time to next tx (TTNT). Descriptive analyses for all-cause and FL-related HCRU and costs were stratified by health care setting. Computed sums for each pt as frequencies and costs were divided by each pt's follow-up time (per person per month [PPPM]). Cost data were adjusted for inflation to 2022 US dollars and outcomes were assessed by LOT.

RESULTS: Among 1,043 pts identified with FL POD24, mean age was 60.2 years, 51.1% were male, 60.5% were primarily diagnosed in 2015, and 17% had a Charlson Comorbidity Index score greater than or equal to 2. Rituximab (R) alone was the most used regimen (56.1% for 1L, 46.6% for 2L at point of FL POD24 identification, and 62.7% for 3L). Median (IQR) length of follow-up was 29.8 months (20.8-42.1), and median (IQR) 1L TTI was 30 days (7-66). Median (IQR) TTD in 1L, 2L, and 3L, respectively, was 2.7 months (2.0-5.4), 4.4 months (3.8-5.2), and 2.7 months (2.4-3.1). Median (IQR) TTNT from 1L to 2L was 4.2 months (2.8-4.6). Mean outpatient visits for all-cause HCRU in 1L, 2L, and 3L, respectively, were 1.89, 1.59, and 1.89 PPPM. Total mean all-cause cost was $17,193, $11,972, and $12,872 PPPM for 1L, 2L, and 3L, respectively. FL-related costs accounted for 58% of all-cause total medical costs. Outpatient cost was the primary cost driver, ranging from 46% to 55% of total PPPM cost across tx lines.

CONCLUSIONS: Commercially insured pts with FL POD24 were treated primarily with recycled tx such as R with high FL recurrence rate and short remission between tx lines. Also, costs accrued across LOTs with the highest cost in the 1L setting. These findings highlight the need for novel txs to lower the economic and public health burden of FL POD24.

SPONSORSHIP: BMS.

C41 Real-world clinical characteristics and treatment patterns in fast-progressing patients with follicular lymphoma in the United States

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BACKGROUND: Patients (pts) with follicular lymphoma (FL) have significant disease (dx) and treatment (tx) burden. Pts with progressive disease (PD) after 24 months or less of first-line (1L) tx (POD24) are known to have worse survival outcomes.

OBJECTIVE: To assess dx characteristics and tx patterns for POD24 vs non-POD24 pts.

METHODS: Data were from the Adelphi FL Disease Specific Programme, a cross-sectional survey of hematologists, heme-oncologists, medical oncologists, and their pts conducted in the United States from June 2021 to January 2022. Historic and current tx data were assessed. All pts were alive at time of data collection. Bivariate analyses and Kaplan-Meier curves were conducted.

RESULTS: Analyses included 171 pts (116 POD24; 55 non-POD24). A total of 74 pts were on 2L, 45 pts on 3L, and 52 pts on 4L at time of data collection. Relative to pts with

non-POD24, pts with POD24 were younger (67 vs 71 years; $P = 0.0057$), had a shorter time since FL diagnosis (3.2 vs 6.4 years ago; $P < 0.0001$), and were more likely to have commercial insurance (41% vs 24%; $P = 0.0366$) vs Medicare (53% vs 71%; $P = 0.0366$). POD24 was more likely to be grade 3A/B (44% vs 14%) FL ($P < 0.0001$) at diagnosis. At 1L, R-CHOP was used to treat 49% POD24 vs 33% non-POD24 cases, and rituximab-bendamustine 49% non-POD24 vs 20% POD24 cases ($P = 0.0066$). Throughout all lines, pts with POD24 were more likely to choose induction tx based on health insurance copay (1L, 26% vs 4%; $P = 0.0003$; 2L, 32% vs 7%; $P = 0.0002$; 3L, 29% vs 9%; $P = 0.0381$). Time to relapse was shorter in pts with POD24 than non-POD24 for 1L induction (13.4 vs 44.8 months; $P = 0.0000$), 1L maintenance (11.1 vs 38.1 months; $P = 0.0000$), and 2L induction (4.9 vs 9.0 months; $P = 0.0107$). Complete response and partial response, respectively, were achieved in only 53% and 28% of pts with POD24 at 1L (non-POD24, 84% and 16%; $P = 0.0003$). For pts with POD24 at 1L, 48% stopped tx early because of PD (2% non-POD24; $P < 0.0001$); this trend continued in 2L (62% vs 39%; $P = 0.0488$). Overall, 62% of pts had responses to tx; 14% of pts with POD24 had PD (4% non-POD24). The next physician choice in line of tx were chimeric antigen receptor T-cell tx or a different drug was 37% for pts with POD24 (45% non-POD24).

CONCLUSIONS: Pts with POD24 were younger and more likely to have private insurance, which potentially influenced their tx choices. Pts with POD24 and non-POD24 were treated differently in 1L; POD24 was less responsive to tx. 2L and 3L tx did not differ significantly. Pts with POD24 were more likely to relapse sooner from tx at both 1L and 2L and have PD at data collection. Further research is needed to review rationale for poor outcomes in pts with POD24.

SPONSORSHIP: BMS.

C42 Real-world outcomes following chimeric-antigen receptor T-cell therapy for large B-cell lymphoma

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BACKGROUND: Clinical trials have demonstrated chimeric antigen receptor T-cell (CAR-T) therapy efficacy for relapsed/refractory (RR) large B-cell lymphoma (LBCL). Currently, these therapies are reserved for pretreated patients with few treatment options. Limited real-world CAR-T treatment outcomes are available.

OBJECTIVE: To identify, using claims data, LBCL treatment with CAR-T therapy and describe clinical outcomes following CAR-T therapy administration.

METHODS: Integrated pharmacy and medical claims data were queried among 16.5 million commercially insured members per month from January 2021 to December 2022 to identify members with 2 or more diagnoses for LBCL on different dates of service and a CAR-T drug claim (Healthcare Common Procedure Coding System, National Drug Code, revenue code). Members were required to be aged younger than 65 years at CART-T administration claim date (index date) and continuously enrolled 1 month prior to the index date and 6 months following or until the earliest claim indicating initiation of subsequent treatment, death at discharge, or hospice care, whichever occurred first. Post–CAR-T clinical outcomes were identified using National Drug Code, Healthcare Common Procedure Coding System, *International Classification of Diseases, Tenth Revision, Clinical Modification* codes, summarized descriptively, and assessed using time-to-event analyses: subsequent systemic therapy, death or hospice, immune effector cell–associated neurotoxicity syndrome, and cytokine release syndrome.

RESULTS: A total of 85 members received CAR-T therapy for LBCL during the 2-year study period. 65 members met final study inclusion criteria (40% female, mean age 53.6 years). A total of 29 members (44.6%) had 1 or more claims for any-grade cytokine release syndrome (n = 27) or any-grade immune effector cell–associated neurotoxicity syndrome (n = 4) during follow up. 24 (36.9%) members initiated subsequent treatment prior to disenrollment or end of follow-up; chemotherapy was most frequently initiated (n = 17, 26.2%) followed by radiation (n = 7, 10.8%). Among members initiating subsequent treatment, average time to chemotherapy and radiation was 72.4 days (SD = 38.4) and 59.6 days (SD = 36.8), respectively. Median time to next treatment or death was not reached (95% CI = 120 days to not reached; events = 27, censored = 38). Six (9.2%) members died within 6 months of follow-up.

CONCLUSIONS: These data reflect recent CAR-T LBCL real-world outcomes. Real-world clinical outcomes associated with CAR-T therapies are fundamental for value assessments and supporting value-based contracting with pharmaceutical manufacturers.

SPONSORSHIP: Prime Therapeutics, LLC.

C43 Real-world use of chimeric antigen receptor T-cell therapy vs standard of care for relapsed/refractory follicular lymphoma at third-line treatment or higher: Analysis of treatment patterns, health care resource utilization, and costs in the United States

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BACKGROUND: Relapsed/refractory (R/R) follicular lymphoma (FL) often requires multiple lines of standard-of-care (SC) therapy. Chimeric antigen receptor T-cell (CAR T) therapy was recently approved as a treatment for FL following the failure of at least 2 lines of therapy (LOTs) (3L+).

OBJECTIVE: To assess real-world treatment patterns, health care resource utilization (HRU), and costs in patients (pts) with 3L+ FL who received SC therapy or CAR T.

METHODS: Two cohorts of adult pts with R/R 3L+ FL were selected from Medicare and commercial insurance claims. The SC cohort included pts who did not receive CAR T (January 2016 to December 2022); the CAR T cohort included pts treated with CAR T (March 2021 to December 2022). Pts were continuously enrolled in their health plans and not enrolled in clinical trials. The index date: SC cohort – 3L initiation; CAR T cohort – CAR T infusion. Outcomes included duration of therapy (DOT), HRU, and costs. HRU and costs were reported by LOT and per-patient-per-month (PPPM) values. Costs were stratified by payer type.

RESULTS: 4,367 SC and 305 CAR T pts were included. Compared with SC pts, CAR T pts were more often commercially insured (31% vs 16%; $P<0.01$), younger (median 68 vs 75; $P<0.01$), male (56% vs 50%; $P=0.04$), and greater mean Charlson Comorbidity score (5.4 vs 4.8; $P<0.01$). Median follow-up after index was 472 (SC) and 219 (CAR T) days. The proportion of SC pts requiring additional therapies increased with LOT (33% after 3L to 53% after 8L). Mean SC DOT decreased with LOT from 137 days (3L) to 29 days (9L). Only 9% of CAR T pts required additional LOTs, with DOT of 54 days for 1L post. All-cause inpatient, emergency department, and outpatient visits for SC 3L+ were 49%, 43%, and 90% vs 24%, 15%, and 67% for post-CAR T, respectively. Mean Medicare (commercial; standardized to Medicare rates) PPPM costs for SC increased from $8,860 ($6,297) to $10,060 ($8,612) from 3L to 6L. Medicare (commercial) PPPM costs post-CAR T were $7,513 ($5,169). Compared with the pre-CAR T period, PPPM costs post-CAR T episode were 21% (–$2,020) and 43% (–$3,826) lower for Medicare and commercial, respectively. Risk-adjusted comparisons and time to next treatment will be presented with longer follow-up data.

CONCLUSIONS: SC was associated with a higher proportion of additional LOTs and decreasing DOTs, suggestive of earlier progression as pts cycle through SC therapies. HRU and standardized costs were higher for SC vs post-CAR T episode periods. Earlier CAR T use may mitigate the need for successive and costlier SC LOTs, which are less effective, potentially reducing HRU and financial burden for pts with R/R FL and the health care system.

SPONSORSHIP: Kite.

C44 Real-world use of chimeric antigen receptor T-cell vs. standard therapy for relapsed/refractory mantle cell lymphoma: Analysis of treatment patterns, health care resource utilization, and costs

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BACKGROUND: Current standard of care (SOC) for relapsed/refractory mantle cell lymphoma (RR MCL) is chemoimmunotherapy and targeted therapies (eg, Bruton tyrosine kinase inhibitors [BTKi]). The approval of chimeric antigen receptor T-cell (CAR T) therapy expanded the therapeutic landscape.

OBJECTIVE: To characterize real-world treatment patterns, health care resource utilization (HRU), and costs for patients (pts) with RR MCL treated with CAR T vs SOC.

METHODS: Adult pts with RR MCL from Medicare (MC) and commercial (CM) (2016-2022) claims sources were categorized: (1) SOC cohort: 2 or more lines (2L) of non-CAR T therapies; (2) CAR T cohort: CAR T therapy (2020-2022). Both cohorts were continuously enrolled with medical and pharmacy benefits and excluded clinical trial pts. Index dates for SOC and CAR T cohorts were at 2L and CAR T initiation, respectively. Outcomes included treatment regimens, duration of therapy (DOT), HRU, and costs. HRU and costs were reported by line of therapy (L) and per-patient-per-month (PPPM) values.

RESULTS: 2,819 SOC and 113 CAR T pts were included. CAR T pts were younger (median 70 vs 74 years; $P<0.01$), less MC-insured (77% vs 84%; $P<0.07$), and more often male (75% vs 65%; $P<0.02$) and had more comorbidities (mean Charlson score: 5.4 vs 4.9; $P=0.10$). Median follow-up post-index was 406 and 173 days for SOC and CAR T, respectively. 36% of SOC pts required 3L or more. Mean SOC DOT sequentially

decreased from 201 (2L) to 68 days (6L). Among CAR T pts, 15% had additional L after CAR T; DOT for 1L after CAR T was 33 days. Use of targeted therapies in SOC increased sequentially by L (2L: 76%; 6L: 93%; BTKi 2L: 27%; BTKi 6L: 35%). Following CAR T, 11% of pts received targeted therapy, predominantly lenalidomide-based. All-cause HRU was measured as percentage of pts with inpatient, outpatient, and emergency department visits post-index. For SOC, rates were 52%, 90%, and 43%, respectively; for CAR T, 25%, 59%, and 15%. All-cause PPPM costs for SOC increased by L (MC 2L: $10,181, 6L: $21,062; CM 2L: $7,908, 6L: $56,709), whereas all-cause PPPM costs post-CAR T decreased by 24% (before vs after CAR T: $11,955 vs $9,096) and 70% (before vs after CAR T: $15,910 vs $4,822) for MC and CM, respectively.

CONCLUSIONS: 36% of SOC pts post-index required therapy beyond 2L, with decreasing DOT and increasing costs and HRU at each L. By contrast, CAR T pts showed significant reductions in HRU and cost post-index, with only 15% having post-CAR T L. This suggests that earlier adoption of CAR T may reduce cycling through increasingly more expensive and less effective SOC L, potentially reducing the HRU and financial burdens on the health system.

SPONSORSHIP: Kite.

C45 Understanding real-world treatment patterns and economic burden of relapsed/refractory multiple myeloma in the era of new treatments: A retrospective, observational study

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BACKGROUND: Although survival rates have increased, multiple myeloma (MM) remains incurable, and many patients (pts) will relapse. As treatments evolve, understanding treatment patterns and costs for pts with relapsed/refractory (RR) MM is crucial.

OBJECTIVE: To assess treatment patterns, costs, and health care resource utilization (HCRU) for pts with RRMM receiving MM-related treatment.

METHODS: The OPTUM Clinformatics Data Mart database was used to identify pts with MM, first diagnosed (index) between January 1, 2011, and December 31, 2022, aged 18 years and older at index, with continuous enrollment for 180 days pre- and 90 days post-index, and without prior cancers. RRMM was defined as receipt of at least 3 lines of therapy (LOTs). Total costs (TC; medical + pharmaceutical) per pt per month (PPPM) and HCRU were assessed across LOTs among the pts with RRMM. Generalized linear mixed effects models (GLM) were used to determine the impact of progression on costs. Last LOT is followed until the earliest of last day of therapy, data cutoff, or last active date.

RESULTS: Of 1,320 pts with RRMM, 54% were male, median age was 68 years, and 58% were covered by Medicare Advantage. Median follow-up time was 49.1 months, with 454 and 151 pts progressing to fourth (4L) and fifth plus (5L+) LOTs, respectively. Immunomodulatory drug (IMID) + proteasome inhibitor use, with/without steroids, decreased from early LOT (ie, 1-2L, 27.3%) with progression (3L, 10.2%; 4L, 6.6%; 5L+, 8.0%). Conversely, use of IMID + monoclonal antibodies with/without steroids increased (1-2L, 3.7%) as pts progressed (3L, 13.9%; 4L, 16.1%; 5L+, 14.7%). The mean (interquartile range) TC PPPM increased from $17,187 (7,925-22,849) 1-2L to $28,289 (12,546-39,053) in 3L, $39,391 (12,383-41,890) in 4L, and $26,702 (8,275-37,151) in 5L+. The proportion of medical costs (MC) out of TC increased from 1-2L with later LOTs. GLM on 454 pts with at least 4 LOTs showed TC and MC increased significantly with progression. Patients with RRMM with prior triple-class exposure incurred significantly more pharmacy costs and TC than those without triple-class exposure. Compared with 1-2L, the mean number of ED visits (1-2L, 0.2; 3L, 0.5; 4L, 0.8; 5L+, 0.5), inpatient admissions (1-2L, 1.3; 3L, 3.6; 4L, 6.0; 5L+, 5.1), and inpatient stay length (1-2L, 2.1; 3L, 3.0; 4L, 4.6; 5L+, 4.5) per 100 days generally increased with progression.

CONCLUSIONS: HCRU, as well as TC and MC, increased with RRMM and LOT, and pts with prior TCE incurred significantly more TC and pharmacy costs. There was a decrease in trend in costs and HCRU for pts progressing to 5L+, this may reflect a move to end-of-life care. HCRU data were consistent with prior findings.

SPONSORSHIP: AbbVie, Genentech.

D2 Cancer incidence among the Medicaid population: A retrospective analysis of a national all-payer claims database

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BACKGROUND: Cancer disparities have been documented in Medicaid patients. The 2014 Medicaid expansion sought to narrow disparities in care. However, there is limited real-world evidence of cancer burden in the Medicaid population in the post-expansion period.

OBJECTIVE: To fill the gap using a nationwide claims database to describe the cancer burden in the Medicaid population.

METHODS: This is a retrospective study using RWD Insights, a US national all payers' claims database that covers ~87% of the insured population. Medicaid-insured patients (aged ≥18 years) with at least 1 inpatient claim or at least 2 outpatient claims (≥30 days apart) with ICD-CM cancer diagnosis codes were identified from January 1, 2015, to December 31, 2020. The index date was the first date of cancer diagnosis. All patients had medical benefits 12 months pre- (baseline) and post-index date (follow-up). Incidence, cancer treatment, health care cost, and mortality by metastatic status were assessed.

RESULTS: A total of 279,749 patients with incident cancer were identified; 12.2% of patients had metastases at diagnosis. The average annual cancer incidence rate was 460/100,000 from 2015 to 2019 (compared with 425/100,000 in the general population [Surveillance, Epidemiology, and End Results]), with a steep drop in 2020 to 243/100,000. The 10 states with the highest cancer incidence rates all adopted Medicaid expansion. A higher proportion of patients were diagnosed with metastases in states without Medicaid expansion than those with Medicaid expansion (14.1% vs 12.0%). More than half of the patients with cancer were aged 50-64 years, with cancer incidence increasing with age. Compared with patients with nonmetastatic cancer, those with metastatic cancer were more likely to be older (55.5 vs 53.1), male (42.1% vs 39.3%), Black (16.9% vs. 15.4%), and smokers (33.2% vs 28.0%) and to have at least 1 comorbidity (41.1% vs 39.2%) (all $P < 0.0001$). In the 12-month follow-up, more patients with metastases received multiple anticancer treatments compared with patients without metastases (46.3% vs 19.5%, $P < 0.0001$); they also had significantly higher total cost and higher 12-month mortality than patients without metastases ($93,640 (SD = $245,767) vs $44,011 (SD = $163,708), 17.4% vs. 0.01%, respectively; all $P < 0.0001$).

CONCLUSIONS: The increased cancer burden in the Medicaid-insured population vs the general population indicates that disparities in cancer care still exist in the Medicaid population. The disease burden associated with metastatic cancer highlights the call for increased focus on early cancer detection in the Medicaid population.

SPONSORSHIP: GRAIL, LLC.

D4 Health care resource utilization from OPERA: A real-world study of pegcetacoplan treatment in US adults with paroxysmal nocturnal hemoglobinuria

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BACKGROUND: Paroxysmal nocturnal hemoglobinuria (PNH) is an ultra-rare (1-1.5 cases per million), acquired, life-threatening disease characterized by complement-mediated hemolysis and thrombosis. PNH symptoms can lead to transfusion dependence, and hospital/emergency department (ED) visits, increasing health care resource utilization (HCRU). Although clinical trials have assessed pegcetacoplan (PEG) efficacy, there is limited information on the use of PEG in a real-world setting.

OBJECTIVE: To report trends in HCRU, in the form of transfusions, all-cause ED visits and hospitalizations, hemoglobin (Hb) levels, and treatment compliance for patients in OPERA, an ongoing, observational real-world study on PEG treatment for US adults with PNH, after approval.

METHODS: Since January 2022, OPERA, a centrally recruited, nationally representative study (institutional review board approved), enrolled US patients with PNH, aged 18 years and older, who were prescribed PEG by a licensed medical professional. OPERA collected data from routine medical encounters, not directing any interventions. Patients provided baseline (BL) HCRU through online questionnaires, BL Hb level was reported by the site (health care provider verified). Follow-up Hb and HCRU data were reported during monthly calls (when available). Hemoglobin analysis only included patients with no reported transfusions during PEG treatment, who reported both a BL and at least 1 follow-up Hb value. Given disease rarity, a small sample size was expected.

RESULTS: Over 16 months, OPERA enrolled 54 patients with PNH, mean (SD) age of 45.5 (17.1) years, 53.7% female. At BL, 20.4% of patients were previously treated with eculizumab, 59.3% with ravulizumab, and 14.8% with both. Of 39 patients with available BL data, 76.9% reported ever receiving transfusions, 30.8% reported more than 4 in the 12 months prior to enrollment, and 66.7% reported spending at least 3 hours at centers for transfusion care. For 49 patients completing at least 1 monthly call, the incidence rate per person-year was 0.8 (95% CI = 0.6-0.9) for transfusions, 0.4 (95% CI = 0.3-0.6) for ED visits, and 0.2 (95% CI = 0.1-0.4) for hospitalizations, after initiating PEG. For 43 patients with available data, over 320.5 person-months, mean (range) PEG treatment compliance was 97% (69%-100%) since enrollment. Of 35 patients meeting Hb analysis criteria, mean (SD) BL Hb level was

8.9 (1.8) g/dL and latest reported Hb level was 12.3 (1.7) g/dL, with a median (interquartile range) follow-up period of 8.0 (5.5) months.

CONCLUSIONS: This ongoing real-world study of US adults with PNH receiving PEG indicates low HCRU, high treatment compliance, and positive trends in Hb levels, with PEG.

SPONSORSHIP: Apellis Pharmaceuticals Inc.

D5 Cost outcomes of noninhibitor patients with hemophilia A switching from prophylaxis with factor VIII to emicizumab: A meta-analysis of real-world evidence studies in the United States

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BACKGROUND: Individuals with hemophilia A (HA) may be prophylactically treated with factor VIII (FVIII) or nonfactor therapies (eg, emicizumab) to prevent or reduce the frequency of bleeding episodes.

OBJECTIVE: To assess—using a meta-analysis (MA) on the real-world evidence—total cost of care (TCC) in the United States among noninhibitor patients with HA switching from prophylaxis with FVIII to emicizumab.

METHODS: Publications related to real-world studies reporting TCC outcomes in noninhibitor patients with HA who switched from prophylaxis with FVIII therapies to emicizumab were systematically reviewed in the PubMed, Embase, Cochrane Library, and EconLit databases. Only publications about studies conducted in the United States were eligible. No date limitations were applied. Identified publications were evaluated for inclusion in the MA, which was then performed for TCC outcomes. A sensitivity analysis was also conducted to restrict patient populations from overlapping between studies due to the similar databases used by some studies to obtain patient records. All effect sizes for all endpoints were calculated using standardized mean change (SMC). The consistency of data was examined using the I^2 value and the *P* value of the chi-square test.

RESULTS: Of the 89 screened publications, 4 unique studies with a TCC endpoint were identified. Three observational studies using data from US health care claims databases were sufficiently comparable for inclusion in the primary MA and sensitivity analysis. The post-switch TCC for emicizumab was statistically significantly greater than the pre-switch TCC for FVIII for all studies in the MA (overall pooled SMC: 0.431; 95% CI = 0.307–0.554; $P < 0.001$) and for all studies in the sensitivity analysis (overall pooled SMC: 0.467; 95% CI = 0.331–0.603; $P < 0.001$). There was no statistically significant evidence to suggest heterogeneity across the included studies for the primary or sensitivity analyses ($I^2 = 0\%$).

CONCLUSIONS: MA indicated that the TCC post-switch for emicizumab in noninhibitor patients with HA was statistically significantly greater than the TCC pre-switch for FVIII for both the primary and sensitivity analyses. In addition to the previously proven efficacy of FVIII prophylaxis in noninhibitor patients with HA, the results of this comparison using real-world evidence suggest that FVIII prophylaxis is also less costly. The post-switch higher TCC with emicizumab is an important consideration for payers when determining an optimal resource allocation strategy alongside patient outcomes.

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

D6 Cost-effectiveness of efanesoctocog alfa vs extended half-life factor VIII therapies and dosing of extended half-life therapies to elevated trough levels in adolescent and adult patients with hemophilia A without inhibitors in the United States

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BACKGROUND: Standard of care for hemophilia A is prophylaxis, which may include extended half-life (EHL) factor VIII (FVIII) replacement products. Recurrent joint bleeds lead to hemophilic arthropathy, which can cause chronic pain and reduced quality of life. Efanesoctocog alfa (ALTUVIIIO) is a first-in-class FVIII replacement therapy designed to provide high sustained FVIII activity levels and extend bleed protection with once-weekly dosing in people with hemophilia A.

OBJECTIVE: To evaluate the cost-effectiveness of efanesoctocog alfa compared with EHL therapies and dosing of EHL therapies to elevated trough levels, from the US perspective.

METHODS: A lifetime (maximum 100 years) Markov cost-effectiveness model with 6-month cycles was developed to compare efanesoctocog alfa prophylaxis with the class of EHL FVIII therapies (base-case) and the elevated dosing of an EHL targeting FVIII trough levels of 8%–12%. The model used clinical data from an indirect treatment comparison of phase 3 studies, US medical cost data from the literature, and US wholesale acquisition drug costs. Patients aged 12 years and older with hemophilia A without inhibitors entered the model and received prophylaxis with efanesoctocog alfa or a comparator. Bleed rates determined transition across Pettersson scores, a measure of joint health, with subsequent consequences in patient utility and health care resource utilization. Outcomes included number of joint and nonjoint

bleeds, quality-adjusted life years (QALYs), total US direct medical and drug costs, and the incremental cost-effectiveness ratio. One-way and probabilistic sensitivity analyses were conducted.

RESULTS: The model showed that efanesoctocog alfa is dominant vs EHL therapies and is associated with a lower average lifetime number of joint (14.82 vs 61.31) and nonjoint (5.81 vs 24.41) bleeds, slightly higher QALYs (21.32 vs 20.74), and lower lifetime costs ($30,710,778 vs $32,933,710). Efanesoctocog alfa is also dominant when compared with elevated dosing of EHLs (target trough levels of 8%-12%): lower average number of joint (14.82 vs 29.06) and nonjoint (5.81 vs 8.43) bleeds, slightly higher QALYs (21.32 vs 21.15), and lower costs ($30,710,778 vs $42,940,716). Efanesoctocog alfa is cost-effective vs dosing of EHL therapies to elevated trough levels at a price 40.7% higher than the current list price. In sensitivity analyses, the model was most sensitive to the costs per IU of each comparator and dosing.

CONCLUSIONS: Efanesoctocog alfa is dominant vs EHLs and dosing of EHL therapies to elevated trough levels, with a lower number of bleeds, lower costs, and higher QALYs.

SPONSORSHIP: Sanofi.

D7 Evaluating the impact of a comprehensive hemophilia management program on utilization and clinical outcomes

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BACKGROUND: Hemophilia is a rare, inherited bleeding disorder caused by missing or defective clotting factors. Treatment options include factor products, both standard half-life (SHL) and extended half-life (EHL), bypassing agents, emicizumab, and, most recently, gene therapy. Annualized bleed rate (ABR) is one way to assess clinical benefit of treatment. Decreased ABR can lead to long-term health benefits and reduction in total cost of care by preventing negative effects from uncontrolled bleeding. Comprehensive hemophilia care and managed care strategies may play a key role in optimizing clinical outcomes and overall cost reduction.

OBJECTIVE: To analyze ABR, utilization, and cost trends before and after implementation of a hemophilia program.

METHODS: This retrospective analysis of a comprehensive hemophilia program reviewed prior authorization and medical claims data from August 15, 2019, to August 15, 2020, for a single health plan with more than 2.6 million covered lives. Patients in scope of the program using factor VIII, factor IX, bypassing agents, or emicizumab were included (n = 59). Excluded patients were aged 12 years and younger, termed during the study period, or were identified as outliers (defined as ≥200% difference in pre-and post-program costs). Overall utilization, ABR, and cost trends associated with program implementation were analyzed. ABR was calculated for members with pre- and post-program implementation bleed history available (n = 29) using the following formula: ABR = [Reported bleeds(n) : months of authorization(n)] × 12.

RESULTS: During the study period, the program reduced overall utilization of high-cost hemophilia agents. For all products, utilization decreased by 596,345 total units after program implementation. Through utilization management, the hemophilia program facilitated overall cost avoidance. After standardizing the cost of treatment based on unit cost, the program resulted in savings of $3,709,950.79 compared to anticipated costs from unmanaged utilization. ABR pre-program was 2.55 compared to 3.41 post-program. Despite this increase, bleed rates decreased from an average of 0.55 to 0.24 bleeds per patient from quarter one to quarter three of 2020. Bleed data was collected for 59 patients post-program versus 29 patients pre-program.

CONCLUSIONS: Implementation of the hemophilia program resulted in a 12.5% decrease in utilization of hemophilia products, prevented unnecessary spend, improved quarterly post-program bleed rates, and enhanced documentation and outcomes reporting. Additional follow-up and outcomes data may help to elucidate the long-term benefits of comprehensive hemophilia management.

SPONSORSHIP: None.

D8 Long-term impact of the gene therapy etranacogene dezaparvovec for the treatment of hemophilia B in the United States

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BACKGROUND: Etranacogene dezaparvovec (EDZ) is a gene therapy recently approved for use in people with hemophilia B (PwHB). EDZ increases FIX activity levels, reduces the risk of breakthrough bleeding episodes, and eliminates the need for routine, FIX prophylaxis replacement therapy.

OBJECTIVE: To estimate long-term clinical impact and cost of EDZ in the United States.

METHODS: A decision-analytic model was developed to evaluate the long-term impact of introducing EDZ to treat PwHB in the United States over a 20-year time horizon. FIX

prophylaxis comparator was a composite weighted average of different FIX prophylaxis regimens based on US market share data. We compared a scenario in which EDZ is introduced in the United States vs a scenario without EDZ. Clinical inputs (annualized FIX-treated bleed rate; adverse event rates) were obtained from the HOPE B phase 3 trial. EDZ durability input was sourced from a published analysis of long-term prediction of FIX activity with EDZ. EDZ has a one-time price of $3.5 million. Other medical costs (in 2022 USD), including FIX prophylaxis, disease monitoring, bleeding episode management, and adverse events, were sourced from published literature. The model estimated annual and cumulative costs, treated bleeds, and joint procedures for the PwHB population over 20 years from EDZ market introduction.

RESULTS: Assuming approximately 600 PwHB were eligible for EDZ in the United States, EDZ uptake was estimated to avert 11,579 bleeds and 66 joint procedures over 20 years. With the adoption of EDZ, although there was an annual incremental cost in years 1-5 (mean: $53 million annually, total $265 million), annual cost savings were achieved beginning in year 6 (mean: $177 million annually; total $2.66 billion in years 6-20). The total cumulative 20-year cost savings was $2.39 billion, with incremental cumulative cost in the first 7 years but cumulative cost savings achieved beginning in year 8.

CONCLUSIONS: Introducing EDZ to treat PwHB is expected to result in cost savings and patient benefit over 20 years. Initiating PwHB on EDZ sooner can produce greater and earlier savings and additional bleeds avoided. These results may be considered a conservative estimate of the full value delivery of EDZ to the health care system, as PwHB would continue to accrue savings from FIX prophylaxis use and bleeding episodes averted beyond 20 years.

SPONSORSHIP: CSL Behring.

D13 Assessing parenteral treatment burden in hereditary angioedema therapies and patient preferences for on-demand treatment

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BACKGROUND: Current on-demand treatments for hereditary angioedema (HAE) are limited to parenteral therapies, which can be associated with significant burden and adherence challenges.

OBJECTIVE: To assess the patient-reported burden of parenteral HAE therapies and on-demand treatment preferences.

METHODS: We used a mixed-methods approach to assess parenteral HAE treatment burden and therapy preference. Targeted literature reviews were conducted in PubMed and Google Scholar to identify literature in HAE and analogous disease states. Peer-reviewed articles and conference proceedings in English from January 1, 2017, to April 1, 2023, were prioritized, but older articles were considered, if relevant. A qualitative study was also conducted in 2022 with 20 adolescents and adults with HAE types 1/2 in the United States, recruited through the US HAE Association, to assess satisfaction with current on-demand treatments and route of administration preferences.

RESULTS: Our targeted literature reviews yielded 17 studies: 9 on HAE therapy injection burden and 8 on oral therapy preference. Injection site reactions were experienced in as many as 98% of patients. In one study, 71% of patients starting prophylactic treatment in the past 6 months reported ongoing anxiety about their HAE medication. In another, 62% of respondents who used a peripheral vein for treatment had difficulty finding a usable vein or getting infusions to work properly at least some of the time. HAE medications with an oral route of administration were strongly preferred, mainly due to ease of administration. One study reported 98% of patients receiving prophylaxis and 100% of patients not receiving prophylaxis would try an oral on-demand treatment option, if available. In analogue chronic diseases, oral therapies had higher patient adherence rates vs parenteral (67% vs 59%). In our qualitative study, all 20 interviewees chose oral over injectable-HAE treatment when presented with hypothetical on-demand treatments with similar efficacy and safety profiles. When profiles were varied, most participants (adolescents: 90%, adults: 80%) preferred injection treatment only when it offered "substantially better" efficacy vs oral treatment within the same time frame.

CONCLUSIONS: Study findings revealed that current parenteral HAE therapies are burdensome to patients and there is a strong preference for an oral on-demand treatment option. Future research in larger cohorts can further characterize preferences for on-demand treatments that could help address unmet patient needs and improve adherence and outcomes.

SPONSORSHIP: KalVista Pharmaceuticals, Inc.

D14 Characteristics of patients with hereditary angioedema on long-term prophylaxis with lanadelumab who did and did not down-titrate lanadelumab during 18 months of treatment persistence

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BACKGROUND: Hereditary angioedema (HAE) is a rare genetic disorder characterized by painful and functionally debilitating swelling attacks. Current treatment includes long-term prophylaxis (LTP) that decrease the risk of serious HAE attacks and the need for costly on-demand therapy. Lanadelumab is the only LTP for HAE with a labeled indication for reduced dosing frequency ("down-titration"), if the patient is well controlled (eg, attack free) for more than 6 months. Understanding the characteristics of patients who down-titrate may help better understand the population of patients with HAE.

OBJECTIVE: To describe the demographic and clinical characteristics of patients with HAE who did and did not down-titrate lanadelumab during 18 months or longer of persistent treatment.

METHODS: A retrospective, observational study used data between July 1, 2017, and June 30, 2022, including patients with HAE persistent on lanadelumab for 18 months or longer derived from health care insurance claims databases: Merative MarketScan Commercial, Medicare, and Early View Research Databases. Persistence was defined as lanadelumab treatment without a gap of at least 60 days during the 18-month follow-up period. Down-titration was defined as a decrease of 25% or more in lanadelumab costs during months 7-12 or 13-18 compared with 0-6 from lanadelumab initiation.

RESULTS: Of 265 identified patients with at least 1 claim for lanadelumab, 54 had evidence of persistence and were included in this analysis. Among the included patients, 25 (46%) had evidence of down-titration (15 during months 7-12, 10 during months 13-18). Patients who down-titrated (vs no down-titration) were younger on average (mean 40.9 vs 43.0), were more likely to be male (44% vs 38%), and had a lower baseline comorbidity burden (Deyo Charlson Comorbidity Index 0.5 vs 0.8). During the 6-month baseline before lanadelumab initiation, down-titrators were less likely to experience HAE triggers/symptoms and had lower use of acute rescue or short-term prophylaxis medication (4.7 vs 7.1 claims), a lower proportion receiving prior LTP (20% vs 28%), fewer HAE-related emergency department visits (2.0 vs 11.7), and lower overall HAE treatment costs ($139,520 vs $233,814). In months 0-6 after lanadelumab initiation, down-titrators remained less likely to have had experienced HAE triggers/symptoms. However, HAE-related health care resource utilization in months 0-6 after lanadelumab was similar between groups.

CONCLUSIONS: Patients with HAE who have a lower comorbidity burden and exhibit lower disease activity prior to or within 6 months of treatment initiation may be more likely to down-titrate lanadelumab during 18 months of persistence.

SPONSORSHIP: Takeda Pharmaceuticals USA, Inc.

D15 Describing medication switching patterns in adults with rheumatoid arthritis from 2016 to 2022: A real-world data study

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BACKGROUND: Managing patients with rheumatoid arthritis (RA) is challenging; many require several attempts at therapy to identify an effective regimen. Although switching between or adding medications is common, these patterns have not been characterized in a large cohort of commercially insured patients.

OBJECTIVE: To examine treatment patterns for targeted immunomodulators (biologics, Janus kinase inhibitors [JAKs], and disease-modifying antirheumatic drugs [DMARDs]) used in RA treatment.

METHODS: We conducted a retrospective analysis of administrative claims for Aetna enrollees aged 18 years and older from January 1, 2016, to December 31, 2022. Included members had an RA diagnosis with at least 183 days of medical and pharmacy coverage prior to initiating a medication of interest during the study period. RA medications were identified using Healthcare Common Procedure Coding System codes and National Drug Codes. Patients were followed from incident use through end of enrollment, end of study period, disenrollment (including death), or medication discontinuation. RA medication initiation and switching (ie, events where patients added a medication or switched to a new medication) were described for incident users.

RESULTS: A total of 11,945 individuals were identified, of whom 87.4% (n=10,442) initiated a DMARD and 11.5% (n=1,373) started a biologic. Only 1.1% (n=130) indexed on JAK inhibitors. Incident DMARD users were slightly older, with a mean age of 63.6 years (SD=13.7), whereas mean

ages of biologic and JAK incident users were similar at 59.5 (SD = 15.0) and 58.2 (SD = 12.2) years, respectively. Fewer JAK incident users were male (19.2%) compared with biologic (26.5%) and DMARD (25.4%) users. The most common co-occurring disorders across incident RA medication users were psoriatic arthritis (n = 348, 2.9%), ankylosing spondylitis (n = 346, 2.9%), and psoriasis (n = 325, 2.7%). Switching was most common for JAK incident users, with 27.7% (n = 36) switching to at least 1 other medication. Switching was less common in biologic and DMARD incident users, with 17.5% (n = 241) and 9.5% (n = 1,018), respectively, experiencing post-initiation switching.

CONCLUSIONS: Individuals initiating traditional DMARDs as first-line RA treatment tended to be older than those indexing on JAKs and biologics. Incident JAK users were more likely to switch medications than those on biologics and DMARDs. Additional research is required to explore switching and adherence within these medication classes and identify optimal treatment scenarios.

SPONSORSHIP: Biologics and Biosimilars Collective Intelligence Consortium.

D17 A cost model comparing long-term prophylaxis options for hereditary angioedema: Lanadelumab and berotralstat

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BACKGROUND: Hereditary angioedema (HAE) is a rare genetic disorder characterized by attacks of tissue swelling that can require acute clinical management. Besides on-demand treatment for acute attacks, current therapy includes long-term prophylactic (LTP) medications, such as lanadelumab and berotralstat, that reduce the risk of HAE attacks.

OBJECTIVE: To compare the expected costs per patient (pp) of 2 LTP therapies (lanadelumab and berotralstat) among patients with HAE in the United States.

METHODS: A Microsoft Excel–based model was constructed to examine the annual pp treatment costs for lanadelumab or berotralstat from a US third-party commercial payer perspective. Model inputs included LTP costs, efficacy inputs (reduction of breakthrough attacks from an indirect treatment comparison), and direct medical costs (acute attack treatments, emergency department [ED] visits, hospitalizations, adverse events) in 2023 USD. The model also included the percentage of lanadelumab patients who were maintained on every-4-week vs 2-week dosing. Percentages from real-world evidence were used to test the impact on the model (19.0%, 27.8%, 46.3%). The patient population comprised adults aged 18 years and older with a confirmed HAE diagnosis and a history of at least 1 attack per 4-week period. LTP treatment costs were incurred continuously throughout the 12-month period. Acute treatment costs were only incurred when breakthrough attacks occurred; costs were dependent on attack severity. One-way and probabilistic sensitivity analyses were performed to validate the robustness of the model's assumptions and specific parameter estimates.

RESULTS: Total annual HAE-related pp costs were lower for lanadelumab in all 3 down-titration percentages ($634,119; $611,417; $563,877) than for berotralstat ($757,137), resulting in an estimated annual cost savings from $123,017 to $193,260 pp with lanadelumab. Total annual LTP cost savings ranged from $42,641 to –$43,141 and acute attack cost savings ranged from $150,398 to $166,158 for lanadelumab compared with berotralstat. Cost savings were driven by lower acute attack drug acquisitions, drug administration, hospitalizations, and ED visits. Total costs/annum were most sensitive to lanadelumab and berotralstat package costs, lanadelumab dosage proportion, and the attack rate ratios used to determine the number of attacks/month. However, lanadelumab remained less costly than berotralstat in 99.9% of 1,000 simulations performed.

CONCLUSIONS: This model found lanadelumab was cost saving compared with berotralstat for LTP treatment of adults with HAE.

SPONSORSHIP: Takeda Pharmaceuticals USA, Inc.

D18 A real-world comparison of health care resource utilization and health care costs among patients with activated PI3K-delta syndrome vs a control cohort of patients without activated PI3K-delta syndrome in the United States

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BACKGROUND: Despite the known morbidity associated with activated PI3K-delta syndrome (APDS), little is understood about health care resource utilization (HRU) and economic burden attributable to this condition.

OBJECTIVE: To compare all-cause HRU and associated health care costs among patients with APDS vs a control cohort of patients without APDS.

METHODS: Patients were identified via the Symphony Health IDV database (October 1, 2015, to March 31, 2022). HRU rates (hospitalization and emergency department [ED], outpatient [OP], and other visits) per person-year and health care costs were evaluated during the observation period, which spanned from the start of clinical activity to the earliest of 3 years later, end of clinical activity, or end of data availability. Controls without APDS, primary immunodeficiency, or malignancy were matched demographically to patients with APDS using a 10:1 ratio (controls: patients with APDS). HRU rates were compared between cohorts using rate ratios (RRs) estimated from Poisson regression models. Health care costs were compared using cost ratios (CRs) estimated from γ regression models.

RESULTS: Forty-two patients with APDS and 420 controls were identified, with mean ages of 16.0 and 16.9 years, respectively. Compared with controls, patients with APDS had significantly higher rates of hospitalization (RR = 4.31 [95% CI = 1.83-8.03]; $P < 0.001$) and OP visits (RR = 1.77 [95% CI = 1.24-2.61]; $P < 0.001$). OP visits were driven by significantly higher rates of OP hospital visits (RR = 5.32 [95% CI = 3.30-8.29]; $P < 0.001$). No HRU differences in patients with APDS vs controls were higher, but not significantly, in ED, OP office/clinic, and other visits. Patients with APDS also had significantly higher health care costs overall (CR = 10.54 [95% CI = 4.56-20.67]; $P < 0.001$), which were driven by higher medical costs (CR = 12.39 [95% CI = 5.04-25.82]; $P < 0.001$). As with HRU, significantly higher health care costs were observed for hospitalizations, OP visits, and OP hospital visits among patients with APDS vs controls. Significant differences were also observed for ED, OP office/clinic, and other visit costs.

CONCLUSIONS: The economic burden of patients with APDS is high compared with that of patients without APDS. Our study highlights the morbidity associated with APDS as seen in the differences in HRU and costs. Although treatment options for APDS have historically been limited, new targeted therapies may have the potential to reduce the economic burden incurred by these patients.

SPONSORSHIP: Pharming Healthcare, Inc.

D19 Reporting of administration site reactions with parenteral drugs for the on-demand treatment of hereditary angioedema attacks: Analysis of the FAERS database 2009 to 2022

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BACKGROUND: Hereditary angioedema (HAE) is characterized by recurrent and unpredictable episodes of subcutaneous or submucosal swelling.

OBJECTIVE: This study examined administration site adverse drug reactions (AS-ADRs) associated with approved on-demand HAE therapies using real-world data provided by the US Food and Drug Administration's (FDA) Adverse Event Reporting System (FAERS).

METHODS: We searched the FAERS database (October 1, 2009, to March 31, 2022) for reports of all FDA-approved on-demand therapies for HAE attacks (human C1-inhibitor, ecallantide, icatibant, and recombinant C1-inhibitor). The number of ADRs for which the drug was listed as the "primary suspect" was recorded. ADR preferred terms were grouped into 15 ADR domains, and each drug's reports were calculated per year from their approval through March 2022. Descriptive results are presented. In addition, the preferred terms associated with AS-ADRs denoted on US package inserts were examined. For each drug-ADR pair, the reporting odds ratio (ROR) [two-sided 95% CI] and the empirical Bayesian geometric mean (EBGM) [one-sided 95% lower bound] were calculated to detect pairs with higher-than-expected rates compared with other non-HAE parental drugs. Significance was declared when both lower 95% CI bounds were greater than 1 (Bate and Evans, 2009).

RESULTS: The 3 most frequently reported AS-ADR domains were injection site pain, site swelling, and site erythema. Icatibant had highest reported rates overall and human C1-inhibitor had the highest rate of incorrect route of product administration and showed statistically a significant elevated risk of injection site reactions (ROR = 3.59 [2.36-5.46]; EBGM = 1.97 [1.39]). A trend toward increased

risk of administration site reactions was found for icatibant (ROR = 1.15 [1.01-1.30]; EBGM = 1.00 [0.90]) and recombinant C1-inhibitor (ROR = 2.85 [1.82-4.48]; EBGM = 1.32 [0.90]).

CONCLUSIONS: FAERS real-world data suggest that currently approved parenteral, on-demand therapies for HAE attacks are associated with AS-ADRs. These real-world descriptive results suggest that patients reported a significant treatment burden associated with FDA-approved parenteral on-demand therapies for HAE attacks.

SPONSORSHIP: KalVista Pharmaceuticals.

E00-E90 Endocrine, Nutritional, and Metabolic Diseases

(eg, diabetes, growth hormone, lipids)

E1 Clinical and economic burden of postsurgical chronic hypoparathyroidism: A US Medicare retrospective analysis

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BACKGROUND: Hypoparathyroidism is a rare endocrine disease characterized by insufficient parathyroid hormone (PTH) production and is associated with substantial burden of illness. Individuals with hypoparathyroidism often report physical, emotional, and cognitive symptoms indicating impaired health-related quality of life (HRQoL).

OBJECTIVE: To describe demographics, clinical characteristics, health care resource utilization (HCRU), and costs among individuals with postsurgical chronic hypoparathyroidism compared with individuals without hypoparathyroidism in Medicare Fee-for-Service.

METHODS: Adults with newly diagnosed postsurgical chronic hypoparathyroidism were identified from the Medicare 100% Limited Data Set between July 1, 2017, and March 31, 2020. All had a confirmed diagnosis within 6-12 months after index diagnosis. Individuals were required to be continuously enrolled for at least 6 months pre- and at least 12 months post-index for baseline and follow-up assessments. Those with a prior hypoparathyroidism diagnosis in the baseline period were excluded. A random sample of enrollees without hypoparathyroidism was synthetically assigned an index date of diagnosis to ensure similar baseline and follow-up periods as individuals with postsurgical chronic hypoparathyroidism. Baseline demographics and comorbidities were compared descriptively. All-cause HCRU and costs during baseline and follow-up were evaluated. All costs were inflated to 2021 US dollars.

RESULTS: Individuals with postsurgical chronic hypoparathyroidism (N = 1,166) were older than those without hypoparathyroidism (N = 11,258) (median age of 69 vs 64 years) and more were female (76% vs 57%); they also had higher Charlson Comorbidity Index scores at baseline (3.24 vs 0.73) and a higher prevalence of moderate or severe renal disease (28.8% vs 5.6%), nephrolithiasis (8.3% vs 1.0%), urinary tract infections (9.9% vs 2.2%), hospitalizations for infections (11.9% vs 2.5%), and congestive heart failure (13.1% vs 3.0%), among others. Over a median follow-up of 30 months, mean [SD] all-cause medical costs per patient per year (PPPY) were significantly higher among individuals with postsurgical chronic hypoparathyroidism ($199,297 [$443,294] vs $61,897 [$210,825]). This difference was largely attributable to higher all-cause medical utilization among individuals with postsurgical chronic hypoparathyroidism (22.0 vs 11.6 inpatient days PPPY; 15.3 vs 5.8 outpatient visits PPPY). Individuals with postsurgical chronic hypoparathyroidism also had higher mortality than those without hypoparathyroidism (hazard ratio = 2.75 (95% CI = 2.15-3.51).

CONCLUSIONS: The clinical and economic burden of individuals with postsurgical chronic hypoparathyroidism in Medicare Fee-for-Service is substantial, highlighting the need for innovative treatment options to replace the missing PTH hormone.

SPONSORSHIP: Study funded by Ascendis Pharma Inc., USA.

E2 A retrospective cohort study comparing health care resource utilization, length of stay, and 30-day readmissions in users and nonusers of a digital diabetes health intervention for patients with type 2 diabetes mellitus

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BACKGROUND: The Dario Diabetes Solution (DDS) is a nonprescriptive mobile app linked to a blood glucose (BG) meter that tracks physiological parameters to facilitate personalized diabetes management. Evidence for health care resource utilization (HCRU) among DDS users is limited.

OBJECTIVE: To assess HCRU, length of stay (LOS), and 30-day readmissions in DDS users vs nonusers.

METHODS: In this retrospective cohort study, adults (aged >18 years) receiving therapy for type 2 diabetes who used

DDS from January 1, 2017, to April 30, 2021, were identified; index date was defined as the date of first DDS registration. Anonymized DDS user data were linked to patient-level claims data within the Symphony Health Integrated Dataverse. The DDS cohort was matched 1:3 using exact and propensity score matching to a nonuser cohort from the Symphony Health Integrated Dataverse with medical claims for type 2 diabetes mellitus during the study period. For nonusers, the index date was the first medical claim date in the matched quarter. All patients were required to have 12 months' post-index follow-up and to have at least 2 outpatient claims (>30 days apart) or at least 1 inpatient claim within this period. This analysis compared all-cause HCRU rates (inpatient + emergency department), LOS, and 30-day readmission rates in DDS users and nonusers. Negative binomial generalized linear models adjusting for baseline rates were used to generate incidence rates (per person-year) and incidence rate ratios (IRRs) and corresponding 95% CIs for all-cause HCRU and 30-day readmission rates. LOS was compared between groups using a two-sample t-test.

RESULTS: DDS users (n = 2,445) and nonusers (n = 7,334) were well matched (mean + SD age: 58.2 + 10.6 vs 58.3 + 12.5 years; sex, 53.3% female for both). At follow-up, the all-cause HCRU rate was 0.47 (95% CI = 0.44-0.52) in DDS users and 0.52 (95% CI = 0.50-0.55) in nonusers (IRR = 0.91; 95% CI = 0.83-1.00; P = 0.041). The mean all-cause inpatient event rate was 0.17 (95% CI = 0.15-0.19) in DDS users and 0.22 (95% CI = 0.20-0.23) in nonusers (IRR = 0.77; 95% CI = 0.67-0.87; P < 0.0001); there was no significant difference in emergency department visits. DDS users with an inpatient event (users, n = 327; nonusers, n = 1,196) had a shorter LOS (7.2 vs 8.8 days; P = 0.017) and lower 30-day readmission rate (IRR = 0.64; 95% CI = 0.45-0.92; P = 0.014) vs nonusers.

CONCLUSIONS: In this real-world analysis, all-cause HCRU, inpatient, and 30-day readmission rates were significantly lower among DDS users vs nonusers (9%, 23%, and 36%, respectively), and LOS was significantly shorter (1.6 days).

SPONSORSHIP: Sanofi.

E3 Association between more frequent engagement with the Dario Diabetes Solution, a digital health technology, and a reduction in HbA1c in adults with type 2 diabetes mellitus

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BACKGROUND: Meaningful engagement is crucial to the success of interventions using digital health technologies, but little is known about this relationship in the context of type 2 diabetes mellitus (T2DM). The Dario Diabetes Solution (DDS) combines remote self-monitoring of blood glucose (BG), data visualization, and disease education to facilitate behavior change. In a retrospective cohort study, adults with uncontrolled T2DM who used DDS had better outcomes at 180 days, with more significant hemoglobin A1c reductions, than matched nonusers who received usual care.

OBJECTIVE: To further analyze the impact of engagement frequency on changes in A1c in DDS users.

METHODS: This analysis included DDS users receiving at least 1 diabetes medication, with A1c ≥7.0%, and not using a continuous glucose monitor between January 1, 2017, and October 31, 2021. Baseline (BL) was 1 year before the index date (first registration for DDS), with follow-up of 180 days from the index date. Engagement activities were collected via the DDS app. Engagement activity was measured in active days (ie, number of days when a user performed any engagement activity). Ten DDS engagement activities were evaluated, including measuring BG, tagging (timing of BG measurement or meal type), food logging, and sharing logbook. Associations between overall DDS engagement and change in A1c were analyzed over 180 days using a linear regression method, and associations were evaluated at 60-day intervals over those 180 days. Individual components of engagement were also analyzed.

RESULTS: 568 DDS users were included. At BL, their mean age was 57.3 years (SD ±11.3) and mean A1c was 9.14 ± 1.78%. Median engagement activity was 65 active days of 180. Each day with any DDS engagement activity was associated with a 0.01% change in A1c (P < 0.0001). Users in the most engaged quartile had 5× greater reduction in A1c than the least engaged quartile. Individual engagement activities with significant associations with reduced A1c were BG measurement, tagging (meal type), and inputting insulin dose.

Engagement was highest in the first 60 days of follow-up and fell in both subsequent 60-day periods.

CONCLUSIONS: Higher DDS engagement was associated with a significantly greater reduction in A1c in adults with T2DM. The highest engagement was in the first 2 months of follow-up and correlated with the greatest reductions in HbA1c. Engagement decreased over time during follow-up. Further research is needed to assess additional interventions that may sustain engagement over time.

SPONSORSHIP: Sanofi.

E4 Budget impact analysis of faricimab (VABYSMO) in the treatment of diabetic macular edema: A US payer's perspective

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BACKGROUND: Diabetic macular edema (DME) affects approximately 756,000 people aged 40 years and older in the United States, with an estimated societal cost of $3 billion. The first line of treatment for DME includes vascular endothelial growth factor (VEGF) inhibitors such as bevacizumab, ranibizumab, aflibercept, and faricimab. Studies of the recently launched faricimab showed robust vision gains and improved best-corrected visual acuity at reduced injection compared with other anti-VEGFs. However, no study in the United States has evaluated the cost impact of adding faricimab to the health plan.

OBJECTIVE: To estimate the budgetary impact of faricimab at 5%,10%, and 15% market share for treating DME from a US commercial payer's perspective.

METHODS: A 1-year budget impact model was developed using Microsoft Excel from a private payer perspective with 1 million hypothetical enrollees in the health plan. Patients with DME receiving anti-VEGFs were identified using 2023 US census data (aged ≥18 years) and the prevalence of DME in patients with diagnosed diabetes mellitus. The model included drug wholesale acquisition cost, administration cost, monitoring, and physician visit costs for each therapy. The drug dosing, monitoring frequency, and physician visits were determined based on manufacturers' recommendations from the US Food and Drug Administration label. Anti-VEGF market share data for treating DME before and after the faricimab launch was calculated using electronic medical records and registry data from published real-world studies. The budget impact of adding faricimab to the health plan was estimated at 5%, 10%, and 15% market share. One-way deterministic sensitivity analysis was performed on key model inputs.

RESULTS: 1,750 enrollees were eligible for anti-VEGF treatment in the health plan. After introduction of faricimab, the budget impact increased, resulting in the excessive expenditure of $579,825 ($0.048 PMPM), 1,159,651 ($0.097 PMPM), and $1,739,476 ($0.145 PMPM) at 5%, 10%, and 15% market share, respectively. Sensitivity analysis showed that varying the wholesale acquisition cost of faricimab by 10% had the highest impact on the base-case model, followed by eligible patients with DME taking anti-VEGFs, and the prevalence of DME.

CONCLUSIONS: The inclusion of faricimab in the health plan resulted in a significant increase in the annual budget of the commercial payer. Assessing the budget impact of different treatment guidelines for anti-VEGFs and providers' preferences for those guidelines is further warranted.

SPONSORSHIP: None.

E5 Health care utilization and costs associated with chronic kidney disease progression in patients with type 2 diabetes

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BACKGROUND: Type 2 diabetes (T2D) is a leading cause of chronic kidney disease (CKD). The health care resource utilization (HCRU) and costs associated with the progression of CKD among patients with T2D, along with the impact of T2D on overall health care costs, require further elucidation.

OBJECTIVE: To examine—in a real-world, retrospective, cohort study—HCRU and costs in patients with CKD and T2D.

METHODS: Data were obtained from the Merative MarketScan Explorys Claims-Electronic Health Record Database (January 1, 2016, to June 30, 2021). Patients were aged 18 years and older and had at least 2 estimated glomerular filtration rate (eGFR) values between 15 and 89 mL/min, indicating the same CKD stage within a 90-day period. The first eGFR value qualifying for inclusion was the index date, and patients were continuously enrolled for 6 months pre-index and 12 months post-index. Patients had diagnoses of CKD and T2D in the pre-index period. HCRU and cost outcomes were calculated based on administrative claims records according to CKD stages 2-4.

RESULTS: A total of 7,261 patients were included (mean ± SD age, 72.4 ± 10.6 years; 56.4% male). Patients had CKD stage 2 (28.0%), 3a (27.4%), 3b (29.5%), or 4 (15.1%). Comorbidity burden was high, with mean Charlson Comorbidity Index score ranging from 4.9 to 5.7 across CKD stages. For annual all-cause HCRU post-index, the proportion of patients with at least 1

inpatient admission increased across CKD stages. Mean ± SD total all-cause and T2D-related costs (2021 US$) during the 12-month post-index period were $50,923 ± $74,388 and $11,520 ± $16,217, respectively. Mean total CKD-related cost was $6,681 ± $23,649. Overall, T2D-related costs were similar across CKD stages ($11,402 ± $16,588 for patients with stage 2 to $12,969 ± $18,616 for patients with stage 4) and accounted for ~20%-25% of total all-cause costs, regardless of CKD stage. In contrast, CKD-related costs increased with disease progression, from $2,728 ± $8,717 for patients with stage 2 to $16,667 ± $47,759 for patients with stage 4. CKD-related costs accounted for 5.1%, 10.0%, 15.0%, and 29.6% of total all-cause costs for patients with CKD stage 2, 3a, 3b, and 4, respectively.

CONCLUSIONS: Comorbidities, including CKD severity, increased all-cause costs for patients with CKD and T2D. CKD-related costs increased with disease progression, and T2D-related costs, despite making up one-quarter of total all-cause costs, remained static. Management of T2D through glycemic control may save costs by preventing/delaying CKD progression and other complications.

SPONSORSHIP: Novo Nordisk Inc.

E6 Impact of a real time prescription benefit program on adherence and utilization of low-cost prescription alternatives for patients new to diabetes treatment

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BACKGROUND: Chronic diseases such as diabetes are a major detriment to the US health care system. Improved medication adherence helps treat diabetes by improving health outcomes and reducing cost. Cost of medications can contribute to nonadherence. Use of a formulary decision support system with e-prescribing may be associated with greater use of generic medications, leading to lower costs and better adherence. A Real Time Prescription Benefit (RTPB) solution provides patient-specific drug pricing, benefit information, and therapeutic options to choose the most cost-effective and clinically appropriate treatment.

OBJECTIVE: To determine whether RTPB is associated with increased adherence measured by proportion of days covered (PDC), higher utilization of generics, and generic fill rate and whether RTPB is associated with lower plan and patient out-of-pocket (OOP) costs per utilizer per month (PUPM) costs.

METHODS: This study used a retrospective, matched intervention-control analysis of members using a large pharmacy benefits manager. Members were eligible for inclusion if they initiated therapy between January and August 2021. Members were excluded if they were not continuously eligible coverage over the study period. Members that initiated diabetes therapy with a prescriber using RTPB (intervention) were compared with those new to therapy with a prescriber not utilizing RTPB (control). Index date for both samples was the first medication prescription in the index period. Members were matched on demographics. The evaluation period lasted 12 months after the index date. Multivariable regression models were used to assess the impact of RTPB program on adherence and plan and OOP patient costs controlling for demographics and other covariates.

RESULTS: 1,302 matched pairs were included in the analysis. Findings show PDC was 68.7% for control and 71.4% for RTPB members ($P < 0.05$). Average number of generic Rxs for control and RTPB samples were 4.06 and 5.66, respectively ($P < 0.05$), and the generic fill rates were 44.9% and 60.1%, respectively ($P < 0.05$). Average PUPM plan cost for control and RTPB samples were $334.50 (SD $322.05) and $252.81 (SD $318.64), respectively ($P < 0.0001$). RTPB contributed to lower average patient OOP costs vs the control group ($10.94 [SD $22.03] and $20.65 [SD $47.86], respectively, $P < 0.0001$).

CONCLUSIONS: Access to RTPB provides prescribers with formulary benefit and therapeutic options that allow them to provide the lowest cost clinical treatment, thus improving adherence, increasing use of generic medications, and lowering plan and patient OOP costs.

SPONSORSHIP: Evernorth, UPMC.

E7 Insulin pen needle fill rates among insured adults with type 1 and type 2 diabetes in the United States, 2019-2021: A retrospective claims analysis

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BACKGROUND: Insulin pen needles (PNs) are intended for a single subcutaneous (SQ) injection; however, patients with diabetes often reuse PNs, a practice that can cause PN tip deformity, breakage, and contamination, and that has been significantly associated with lipohypertrophy and injection pain.

OBJECTIVE: To compare the actual annual fill rate of insulin PNs with the expected fill rate (with single use) based on insulin regimen.

METHODS: This retrospective study drew on US claims data (October 1, 2018, to December 31, 2022) from the Aetna fully

insured Commercial and Medicare Advantage (MA) databases. Eligible patients were aged 18 years and older with type 1 or type 2 diabetes mellitus (T1D or T2D); had at least 1 claim for SQ insulin via PNs from January 1, 2019, to December 31, 2021 (index claim), with continuous medical/pharmacy eligibility for 3 months before index and 1 year after (follow-up); and, during follow-up, had at least 2 claims for their insulin regimen. We excluded patients receiving hospice or palliative care or using mail order prescriptions. The "expected" injections/day by insulin regimen were 4 for T1D basal+prandial insulin and, for T2D, 1 for basal long-acting insulin, 2-4 for basal+prandial, and 2 for premixed. Whether the annual median actual-to-expected ratio (A:E) for number of PNs equaled 1 was evaluated using t-tests with 2-sided *P* values.

RESULTS: In the Aetna fully insured Commercial database (N = 10,854), mean age was 53 years; 55% men; 10% T1D; mean social vulnerability index (SVI) was 0.46 (possible range 0 to 1 = most vulnerable). The A:E medians ranged from 0.41 (T1D basal+prandial cohort) to 0.82 (T2D basal cohort; all $P < 0.001$). For T2D basal+prandial, A:E medians were 0.68 and 0.34 for 2 and 4 expected injections/day, respectively. Mean numbers of 100-count boxes/patient in 1-year follow-up were 4.8 overall, and 5.5 vs 4.0 with SVI of less than 0.25 vs greater than or equal to 0.75, respectively. In the MA database (N = 32,495; mean age of 70; 47% men; 2% T1D; mean SVI 0.49), the A:E medians ranged from 0.55 (T1D basal+prandial) to 1.10 (T2D basal and basal+prandial), with A:E median of 0.55 for 4 expected T2D basal+prandial injections/day (all $P < 0.001$). Mean boxes/patient in 1-year follow-up were 5.5 overall, and 5.7 vs. 5.2 with SVI of less than 0.25 vs greater than or equal to 0.75, respectively.

CONCLUSIONS: The actual number of PNs dispensed was fewer than the expected number by insulin regimen for most cohorts, suggesting the need for educational support to ensure an adequate supply of PNs with prescribed insulin regimens, particularly for more vulnerable communities, where fewer PNs per patient were dispensed.

SPONSORSHIP: embecta.

E8 Persistence and adherence of oral semaglutide vs liraglutide in patients with type 2 diabetes in a US real-world setting

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BACKGROUND: Oral semaglutide is a glucagon-like peptide-1 receptor agonist (GLP-1RA) approved for use in patients with type 2 diabetes (T2D). It is unique within the GLP-1RA class as it offers a once-daily oral route of administration, unlike other GLP-1RAs (eg, liraglutide) that require daily injections. Real-world data comparing persistence and adherence with oral semaglutide vs other once-daily GLP-1RAs in patients with T2D are needed.

OBJECTIVE: To assess—in a real-world retrospective cohort study—persistence and adherence in patients with T2D initiating once-daily oral semaglutide and compare outcomes with a cohort of patients initiating once-daily liraglutide.

METHODS: Data were obtained from the Merative MarketScan Commercial and Medicare databases (April 1, 2019, to March 31, 2022). Patients were new users of oral semaglutide or liraglutide; patients who used GLP-1RAs in the pre-index period were excluded. Adherence was defined as the proportion of days covered (PDC) ≥ 0.80 over the 12 months following first medication fill (index date). Persistence was defined as the number of days until discontinuation (defined as a ≥45-day gap in therapy), using greater than or equal to 6- and greater than or equal to 9-month cutoffs. Inverse probability of treatment weighting was used to adjust for differences in baseline characteristics between the 2 cohorts.

RESULTS: Following propensity score weighting, there were 5,485 and 5,326 patients in the oral semaglutide and liraglutide cohorts, respectively. Patient demographics, clinical characteristics, and monthly out-of-pocket index drug costs were well balanced between oral semaglutide and liraglutide (mean age, 52.7 and 52.6 years; mean Deyo-Charlson Comorbidity Index, 1.8 and 1.8, and mean costs [US$], $103 and $105, respectively). Adherence was significantly higher with oral semaglutide vs liraglutide (mean PDC, 0.59 vs 0.52, and PDC ≥0.80 in 41.6% vs 28.6% of patients, respectively; both $P < 0.001$). Persistence was significantly higher with oral semaglutide vs liraglutide (mean duration of persistence, 213 vs 182 days, respectively; $P < 0.001$). A significantly greater proportion of patients in the oral semaglutide vs liraglutide group were persistent for at least 6 and at least 9 months (53.0% vs 42.9% and 45.0% vs 33.3%, respectively; both $P < 0.001$).

CONCLUSIONS: Treatment persistence and adherence were significantly higher in patients initiating oral semaglutide than in patients initiating liraglutide for T2D. Oral semaglutide is an additional option for the management of T2D that may be associated with improved adherence over other GLP-1RAs.

SPONSORSHIP: Novo Nordisk Inc.

E9 The impact of a digital health technology on health care quality measures and clinical outcomes in adults with type 2 diabetes mellitus

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BACKGROUND: Health quality outcomes data are crucial to the decision-making of providers of health insurance and health care in the United States. The US National Committee for Quality Assurance Healthcare Effectiveness Data and Information Set (HEDIS) is one of the most widely used performance evaluation tools. These tools allow assessments of quality outcomes in disease states, including type 2 diabetes mellitus (T2DM). HEDIS defines a target for hemoglobin A1c control of less than 8% and poor control as greater than 9%.

OBJECTIVE: To determine the effectiveness of the Dario Diabetes Solution (DDS). DDS is a digital health technology that combines remote self-monitoring of blood glucose, data visualization, and disease education to facilitate behavior change.

METHODS: Cohorts of 568 DDS users and 1,699 nonusers were compared. Inclusion criteria were as follows: adults with a diagnosis of T2DM, receiving at least 1 diabetes medication, A1c greater than or equal to 7.0%, and not using a continuous glucose monitor between January 1, 2017, and October 31, 2021. The primary endpoint was a change in A1c from baseline (BL) during a 180-day follow-up period, with subgroup analyses of people with BL A1c greater than 7.5%, greater than 8%, and greater than 9%. Exploratory analyses were conducted to evaluate whether DDS use could facilitate a lowering of BL A1c from greater than or equal to 8% to less than 8% and from greater than 9% to less than 9% in adults with T2DM. Secondary endpoints included severe hypoglycemia (event requiring medical intervention) rates for all included DDS users and nonusers and for those with BL A1c greater than or equal to 8% who achieved a predefined target A1c of less than 8%.

RESULTS: Overall, DDS user and nonuser cohorts were well matched , including by payer type (70% commercial and 18% Medicare for both groups). Among 387 DDS users with BL A1c greater than or equal to 8%, 174 (45%) had A1c less than 8% during follow-up, compared with 393 (36%) of 1,089 nonusers ($P = 0.0021$). In a subgroup analysis of people with BL A1c greater than 9%, among 237 DDS users, 86 (36%) had follow-up A1c greater than 9%, compared with 347 (49%) of 713 nonusers ($P = 0.0009$). There was no increase in rates of severe hypoglycemia comparing groups ($P > 0.4$).

CONCLUSIONS: In this retrospective study, in adults with T2DM, a greater proportion of DDS users with BL A1c greater than or equal to 8% achieved A1c less than 8% and a smaller proportion with BL A1c greater than 9% remained greater than 9%, compared with a matched cohort of nonusers, without increasing the risk of severe hypoglycemia. DDS offers improved quality outcomes based on HEDIS A1c criteria.

SPONSORSHIP: Sanofi.

E10 Health care resource utilization and costs in patients with type 1 diabetes with severe hypoglycemic events across different age cohorts in the United States: A descriptive cohort claims analysis

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BACKGROUND: Severe hypoglycemic events (SHEs) in patients (pts) with type 1 diabetes (T1D) may increase health care resource utilization (HCRU) and costs.

OBJECTIVE: To evaluate the HCRU and costs in pts with T1D and SHEs treated in the hospital setting (hsSHEs) and an age group stratification.

METHODS: We used IQVIA's PharMetrics Plus (2015-2022) database to identify pts with T1D in the United States: at least 1 claim with a T1D diagnosis code (first claim was the "index date"), aged 18 years and older, continuously enrolled for at least 6 months in the pre-index period, a ratio of T1D to type 2 diabetes diagnosis codes greater than 0.5, and no pre-index prescription for a noninsulin antidiabetic drug (general T1D population, cohort 1). Among these, pts who had at least 1 claim of hypoglycemia and inpatient (IP) or emergency department (ED) visit on the same day as the hypoglycemia diagnosis during the variable post-index period were designated as hsSHE (cohort 2). Demographic characteristics were assessed at index date. HCRU and costs (2022 USD) were analyzed per patient per month in the post-index period. Costs were presented as annualized means. Subgroup analyses were conducted by age group (18-25, 26-34, 35-44, 45-54, 55-64, ≥65 years.).

RESULTS: We identified 96,946 pts with T1D and 4,662 with hsSHE. Pt demographics were similar across cohorts 1 and 2: mean age = 40.5 years (SD = 13.8) vs 41.4 (SD = 14), payer type: commercial (67.1% vs 62.4%), Medicaid (4.9% vs 4.3%),

Medicare Advantage (1.4% vs 2.6%), other (26.5% vs 30.8%)—a distribution reflective of the database. All-cause HCRU were lower in cohort 1 vs 2: pts with at least 1 IP stay (12.4% vs 45.2%) and pts with at least 1 ED visit (32.6% vs 85.6%). Total all-cause costs were lower in cohort 1 vs 2: $25,905 vs $52,068. In cohort 2, HCRU across age groups were greater in the 65 years and older group: pts with at least 1 IP stay (range: 41.2%-62.3%), mean annualized length of stay (range: 4.8-7.2), and pts with at least 1 ED visit (range: 87.6%-92.5%). In cohort 2, higher all-cause costs were observed per age increment but decreased in the 65 years and older group (range: $34,992-$57,588)—a $12,648 cost decrement between the 55-64 years and 65 years and older groups.

CONCLUSIONS: Costs were twice as high in pts with hsSHE than the general T1D population. Within the hsSHE cohort, costs were highest in the 55-64 years group and HCRU were highest in the 65 years and older group. However, the 65 years and older group may not reflect a generalized age group, but rather the database used. A causal relationship should not be assumed owing to limitations inherent in using claims data and the inability to control for duration of T1D, which could be a confounding factor.

SPONSORSHIP: Vertex Pharmaceuticals.

E11 Impact of Medicare Part D Senior Savings Model on treatment persistence and associated outcomes in people with type 2 diabetes treated with iGlarLixi: A retrospective cohort study based on real-world data

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BACKGROUND: More than 3.3 million Medicare beneficiaries rely on insulin, but high costs are a barrier to access. The Part D Senior Savings Model (SSM) was introduced to cap the 1-month insulin cost at $35 and increase affordability. iGlarLixi 100/33 is a fixed-ratio combination of insulin glargine and the glucagon-like peptide-1 receptor agonist lixisenatide and is covered by SSM.

OBJECTIVE: To assess—using a retrospective analysis of the US Optum Clinformatics database—the impact of SSM cover (according to copays of ≤$35 vs >$35/month) on outcomes in people with type 2 diabetes (T2D) who newly initiated iGlarLixi in the calendar year 2021.

METHODS: The primary endpoint was persistence with iGlarLixi (no gap >45 days) after 6 months of follow-up (SSM disenrollment or last available data, whichever first). Secondary endpoints were iGlarLixi adherence (≥80% proportion of days covered), health care resource utilization (hospitalizations; emergency room [ED] visits, per 100 person-years), and costs (per person per year, US$). Statistical analysis was performed for the primary endpoint only.

RESULTS: 644 SSM participants and 644 propensity score–matched non-SSM counterparts were included. Mean age was 70 years. Persistence with iGlarLixi was significantly higher for SSM vs non-SSM participants (63.5% vs 38.7%; adjusted odds ratio [95% CI] = 0.58 [0.49-0.68]; $P < 0.0001$) and adherence was higher (52.3% vs 31.8%: 2.48 [1.96-3.14]). Hospitalizations (all-cause: 24.9 vs 40.3; diabetes-related (22.7 vs 33.7) and ED visits (all-cause: 85.3 vs 100.7; diabetes-related: 13.7 vs 19.3) were lower for SSM vs non-SSM participants. Incremental cost increases (cost ratio [95% CI]) were observed in non-SSM participants for total claims (all cause: $4,567: 0.85 [0.75-0.96]; diabetes-related: $3,044: 0.81 [0.72-0.92]), hospitalization (all-cause: $4,507: 0.81 [0.49-1.32]; diabetes-related: $3,456: 0.79 [0.49-1.28]), ED visits (all-cause: $121: 0.69 [0.58-0.83]: diabetes-related: $35: 0.72 [0.52-1.01]), and medical claims (all-cause: $6,748: 0.71 [0.61-0.84]; diabetes-related: $4,321: 0.67 [0.55-0.81]), but pharmacy costs were higher for SSM vs non-SSM participants (all-cause: +$2,181: 1.26 [1.16-1.37]; diabetes-related: +$1,277: 1.21 [1.12-1.30]).

CONCLUSIONS: This observational study in people with T2D prescribed iGlarLixi showed that those enrolled in SSM had significantly higher persistence with iGlarLixi, higher adherence, lower health care resource utilization, and lower costs vs those who were not, except for pharmacy costs, which were higher and possibly related to improved treatment persistence.

SPONSORSHIP: Sanofi US.

E12 Predicting the impact of switching from multiple daily injections to a hybrid closed-loop system on rates of high-cost adverse events for patients with type 1 diabetes

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BACKGROUND: Patients with type 1 diabetes (PwT1D) must manage their glucose levels to reduce the risks of hyperglycemia, hypoglycemia, and long-term diabetes-related complications. Hybrid closed-loop systems (HCLS), which include continuous glucose monitoring, insulin pump, and algorithms that predict blood sugar and automate insulin delivery, can independently improve outcomes for PwT1D. Switching from multiple daily injections (MDI) with or

without continuous glucose monitoring to an HCLS has been shown to improve hemoglobin A1c and time-in-range. These effects reduce downstream complications and thus may offset costs.

OBJECTIVE: To estimate the change in rates of costly complications in PwT1D switching from MDI to HCLS.

METHODS: This study used the IQVIA Core Diabetes Model (CDM) to simulate MDI and HCLS patient health over 5 years using 1,000-patient cohorts. The CDM is a validated model of T1D progression based on baseline patient characteristics, risk factors, and A1c that can be used to predict complication rates. The costliest complications are stroke ($55,298), congestive heart failure ($31,192), ulcer ($7,283), and neuropathy ($2,420) based on 1-year cost, inflated to 2022USD, from literature. Three patient cohorts were simulated: all, high-risk (starting A1c ≥9%), and Medicare-eligible patients. Baseline ages were 34 years, 31 years, and 62 years, with A1c of 8.31%, 10.62%, and 8.01%, respectively. Each cohort had a mean of 17 years since T1D diagnosis. Using HCLS reduced A1c by 1.02%, 3.06%, and 0.86% and for all cohorts decreased hyperglycemia 3.2× and hypoglycemia 2.7×, based on evidence from PwT1D using t:slim X2 with Control-IQ technology, an HCLS.

RESULTS: In the full cohort, the number of stroke, congestive heart failure, ulcer, and neuropathy events for the MDI comparator group were 0.10, 0.12, 0.13, and 12.94, over 5 years. Switching to HCLS reduced these by 0.01 (10%), 0.03 (25%), 0.02 (15%), and 5.72 (44%). Complication numbers in the high-risk cohort for the MDI group were 0.13, 0.16, 0.17, and 43.68, which decreased by 0.06 (46%), 0.08 (50%), 0.06 (35%), and 35.20 (81%) with the use of HCLS. Within the Medicare population, events were 1.13, 1.58, 0.39, and 10.64 and were reduced using HCLS by 0.21 (19%), 0.30 (19%), 0.04 (10%), and 4.13 (39%).

CONCLUSIONS: Improving A1c by switching from MDI to HCLS for PwT1D reduces rates of costly complications in all populations evaluated. Specific reductions directly correlate with baseline characteristics such as age and A1c, with more benefits for older patients and those with higher A1c.

SPONSORSHIP: Tandem Diabetes Care.

E19 Real-world burden of disease, treatment, and health care resource utilization in acromegaly

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BACKGROUND: Acromegaly is a chronic rare endocrine disease caused by excessive secretion of growth hormone (GH) due to a pituitary adenoma. Patients who are ineligible for or have an inadequate response to surgery and/or radiotherapy often require pharmacotherapy such as monthly somatostatin analog depot injections (SSA-DI).

OBJECTIVE: To understand disease/treatment burden and health care resource utilization (HCRU) of patients with acromegaly.

METHODS: A quantitative study was conducted among symptomatic patients with acromegaly (aged 18-75 years, US, Canada, and UK residents) receiving medical therapy, including monthly SSA-DI, for acromegaly. A web-based survey captured demographics and the 3-month experience of the disease including the presence and severity of acromegaly-associated symptoms, treatment experience, HCRU, and impact on the ability to work (Work Productivity and Impairment Questionnaire [WPAI]).

RESULTS: Results relate to the prior 3-month period, except for the WPAI (prior 7 days). 58 patients completed the survey, of whom 79% reported at least 6 acromegaly symptoms, with 67% having at least 1 symptom with a severity of 8 or more on a scale of 0-10. 36 patients (62%) received an SSA-DI, either as monotherapy (MT) (18 [50%]) or in combination with other agents. 13 patients (22%) reported high interference in their daily lives due to acromegaly (28% of SSA-DI vs 14% of non-SSA-DI users). Of the 18 patients on monthly SSA-DI MT, 12 (67%) reported at least 1 breakthrough acromegaly symptom prior to the next injection. HCRU reported due to acromegaly treatment included the following: 83% of patients had at least 1 doctor visit (89% of SSA-DI MT users), an overall mean of 2.6 doctor visits (3.1 visits for SSA-DI MT users), 14% had at least 1 emergency department visit (22% of SSA-DI MT users), and 10% had at least 1 overnight hospitalization (17% of SSA-DI MT users). WPAI scores were highest for daily activity impairment (51%), impairment while working (38%), overall work impairment (34%), and work time missed (6%). 78% of patients reported receiving caregiver support to manage their acromegaly. When asked about treatment preferences, 60% of patients preferred oral vs injectable therapy and 81% preferred a therapy that can be taken at home.

CONCLUSIONS: Despite current pharmacotherapies, patients reported significant burden due to acromegaly and its treatment that extends beyond clinical manifestations to impact activities, productivity, and HCRU. The use of SSA-DI resulted in a numerically higher treatment-related burden on patients and cost burden on the health care system compared with non-SSA-DI utilization.

SPONSORSHIP: Crinetics Pharmaceuticals.

E20 Economic burden of patients with chronic hypoparathyroidism in the United States: A claims data analysis

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BACKGROUND: Hypoparathyroidism (HP) is a rare endocrine disorder characterized by insufficient production or function of parathyroid hormone (PTH). The health care burden of chronic HP (cHP) can be significant owing to the chronic nature of the condition and its impact on multiple organ systems.

OBJECTIVE: To better understand the health care resource utilization patterns and associated costs for patients with cHP, using a cohort of patients with transient HP (tHP) as a reference.

METHODS: We conducted an analysis of a US healthcare claims database from October 2014 to December 2019. Patients were defined as having cHP if they had an HP diagnosis claim at least 6 months following a specified neck surgery (parathyroidectomy, thyroidectomy, or neck dissection). Patients were classified as having tHP if they had neck surgery and at least 1 HP diagnosis claim, but no HP claims more than 6 months following surgery. Data were extracted 1 year before the surgery and up to 2 years after their qualifying HP claim for surgical patients. Data were descriptively analyzed. All patients were included in the cost analyses, regardless of whether costs were reported or incurred.

RESULTS: Included in the analyses were 773 patients with tHP and 1,184 patients with cHP. Both groups had an average age of approximately 53 years and more than 80% were female. In the year post-index, 32.7% of patients with cHP and 29.1% of patients with tHP had an emergency department visit. Both groups also had similar proportions of patients with hospitalizations (25.6% cHP, 25.1% tHP) and clinic visits (96.2% cHP, 96.8% tHP). However, during this period, compared with the tHP cohort, the cHP cohort saw a higher variety of providers: endocrinology (36% cHP, 31% tHP); cardiology (21% cHP, 16% tHP); neuropsychiatry (11% cHP, 10% tHP); and nephrology (7% cHP, 5% tHP). The mean unadjusted total all-cause costs in the first-year post-index were nearly 5 times greater for the cHP cohort than the tHP cohort ($15,545 [SD = $27,902], $2,731 [SD = $27,677], respectively). These costs remained higher for the cHP cohort compared with the tHP between years 1 and 2 post-index ($12,153 [SD = $22,341], $305 [SD = $1,585], respectively).

CONCLUSIONS: This study suggests that the economic burden of cHP is significant for individuals and health care systems and these costs could continue to accumulate over a person's lifetime. Continued efforts in research, clinical trials, education, and advocacy are crucial to improving the diagnosis, treatment, and overall care for individuals with hypoparathyroidism and helping to reduce the economic impact of the condition.

SPONSORSHIP: Amolyt Pharma.

E21 A budget impact analysis of SKYTROFA (lonapegsomatropin-tcgd) for the treatment of pediatric patients with growth hormone deficiency in a US health plan

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BACKGROUND: Daily growth hormones (GHs) can be a burden for pediatric patients with growth hormone deficiency (GHD) and their families, and poor adherence has been associated with suboptimal growth outcomes. SKYTROFA (lonapegsomatropin-tcgd), a prodrug with sustained release of somatropin, is the first US Food and Drug Administration–approved once-weekly treatment for pediatric GHD that may improve patient adherence and growth outcomes.

OBJECTIVE: To estimate the financial significance of introducing SKYTROFA to a market with daily GH and to identify potential averted costs associated with SKYTROFA use.

METHODS: This budget impact analysis compares 2 hypothetical scenarios: one with only current daily GHs available and another where SKYTROFA is introduced to the market of daily GHs. The analysis is from a US health plan perspective with 1 million members, has a time horizon of 5 years, and assumes no price discounts. SKYTROFA was introduced to a market with Norditropin, Genotropin, and Nutropin.

RESULTS: An estimated 21 patients in the first year, increasing to 27 in the fifth year, will be treated with GHs based on pediatric GHD incidence rate. With introduction of SKYTROFA, the total GH use is estimated to be decreased by 3,292 mg (122 mg per patient), primarily due to a reduction

in Norditropin use, which is administered at one-third above its recommended dosage in the real world based on the results from the ANSWER registry. The total plan budget is estimated to increase by $474,584 over 5 years, which equals $0.04 per member per month. This includes an investment of $3,351,596 for adopting SKYTROFA and a cost offset of $2,877,012 due to the reduction in use of daily GHs.

CONCLUSIONS: Adding SKYTROFA to the formulary for the treatment of pediatric patients with GHD has a minimal budget impact from a US payers' perspective while maintaining or improving growth outcomes.

SPONSORSHIP: Study funded by Ascendis Pharma Inc., USA.

E22 Impact of tirzepatide vs other antiobesity medications on annual medical costs in adults with overweight or obesity in the United States

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BACKGROUND: Reductions in weight are associated with reductions in health complications and medical costs. Tirzepatide, a novel glucose-dependent insulinotropic polypeptide (GIP) and glucagon-like peptide-1 (GLP-1) receptor agonist (RA), approved for type 2 diabetes (T2D) and in development for chronic weight management, has demonstrated mean weight reductions of 16%-22.5% in clinical trial participants with a body mass index (BMI) greater than or equal to 30 kg/m^2 or 27-29.9 kg/m^2 with at least 1 weight-related complication.

OBJECTIVE: To model the annual all-cause and disease-specific medical cost offsets for tirzepatide vs other antiobesity medications (AOMs) in adults with obesity or overweight in the United States.

METHODS: A budget impact model, including medical cost offsets, was developed from the perspective of a US health care payer for people with overweight/obesity without T2D. Mean weight loss data were sourced from SURMOUNT-1, STEP 1, SCALE, CONQUER, and COR-I clinical trials. Follow-up data ranged from 56 to 72 weeks, and for the purpose of the model it was assumed that efficacy during 52 weeks was equal to clinical trial follow-up. Total all-cause medical costs were sourced from a published study using data from the Medical Expenditure Panel Survey to estimate the causal impact of changes in BMI on medical care expenditure. Disease-specific medical costs were estimated by linking the odds ratio of developing comorbidities (ie, asthma, cancer, ischemic heart disease, osteoarthritis, sleep apnea, and T2D), base-case event rates, and weight loss achieved for tirzepatide (5, 10, and 15 mg) and comparators. Costs were inflated to 2022 values using the Bureau of Labor Statistics Consumer Price Index.

RESULTS: Based on mean weight loss and associated treatment effect on BMI, estimated mean all-cause annual medical costs per patient were estimated to be lower for tirzepatide 5 mg ($3,977), 10 mg ($3,459), and 15 mg ($3,315) compared with no treatment ($6,374), semaglutide 2.4 mg ($3,989), liraglutide 3 mg ($4,961), phentermine/topiramate 7.5 mg/46 mg ($4,989) and 15 mg/92 mg ($4,703), and bupropion/naltrexone 32 mg/360 mg ($5,246). Disease-specific total annual medical costs per patient were lower for tirzepatide (range, $1,818-$2,265) than those for the comparator AOMs (range, $2,273-$3,145) and untreated patients ($3,891).

CONCLUSIONS: In this model, tirzepatide is estimated to result in lower mean all-cause and disease-specific medical costs compared with other AOMs or no treatment.

SPONSORSHIP: This study was supported by funding from Eli Lilly and Company, Indianapolis, IN, USA.

E23 Obesity-related comorbidities with the highest annual cost for medical services per beneficiary by weight class and age

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BACKGROUND: More than 40% of the adult population of the United States has overweight or obesity. Excess weight is a risk factor for a wide variety of diseases and a substantial driver of medical services costs.

OBJECTIVE: To determine which obesity-related comorbidities (ORCs) are associated with the greatest per-beneficiary medical services costs and how these costs change with age and weight class.

METHODS: We examined 2019 annual service costs associated with 17 ORCs from Optum's de-identified Market Clarity Data, linked electronic health records, and insurance claims: heart failure (HF), atrial fibrillation (AF), cerebrovascular disease (CVD), coronary artery disease (CAD), peripheral artery disease (PAD), hypertension (HTN), dyslipidemia, asthma, depression/anxiety, osteoarthritis (OA), gout, chronic kidney disease (CKD), obstructive sleep apnea (OSA), nonalcoholic steatohepatitis (NASH), lower back pain (LBP), type 2 diabetes (T2D), and reproductive diseases. Costs were associated to individual ORCs based on the primary *International Classification of Diseases, Tenth Revision diagnosis* code in medical service claim. BMI categories were derived from the beneficiary's median BMI in

the electronic health records between January 1, 2019, and December 31, 2019: Overweight was taken as BMI 25 to less than 30 kg/m^2 or 23 to less than 25 kg/m^2 for Asian people; class 1 obesity, 30 to less than 35 kg/m^2 or 25 to less than 27.5 kg/m^2; class 2 obesity, 35 to less than 40 kg/m^2 or 27.5 to less than 40 kg/m^2; and class 3 obesity, greater than or equal to 40 kg/m^2.

RESULTS: All-cause medical services costs increased by age group and by obesity category within each age group. In ages 19-40, mean annual per beneficiary cost was $5,443, $5,848, $6,353, and $7,728; in ages 41-65, $8,394, $9,101, $10,060, and $11,738; and in ages older than 65 years, $11,463, $12,450, $13,965, and $15,539, respectively, for overweight, class 1, class 2, and class 3 obesity. The ORCs with highest contribution to medical service cost changed with age. Depression/anxiety and to a lesser extent LBP predominated in ages 19-40. In ages 41-65, cost of depression/anxiety diminished, and cost of OA predominated. The costs of AF , CAD, HTN, CKD, OSA, and T2D increased while the cost of LBP held near levels seen in ages 19-40. In ages older than 65 years, OA was the largest contributor. Costs for HF, AF , CAD, PAD, HTN, CKD, and T2D increased while OSA and LBP held at levels seen in ages 41-65.

CONCLUSIONS: The interaction of age and weight class on medical services costs is complex, increasing with age and with weight class within age group. Early treatment for overweight and obesity may help to alleviate increased costs. More research is needed to elucidate the opportunities to efficiently manage the population with overweight and obesity.

SPONSORSHIP: Eli Lilly & Company.

E26 Identification and management of duplicate therapy involving incretin-targeting therapies for diabetes and weight loss

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BACKGROUND: Diabetes management commonly involves use of multiple drugs and when mechanistically similar may result in duplicate therapy and increased costs. Of concern is combination glucagon-like peptide-1 agonist (GLP-1) and dipeptidyl peptidase-4 inhibitor (DPP-IV) drug use despite historical recommendations advising against this combination due to overlapping mechanisms of action. Providing pharmacists with identified GLP-1–DPP-IV duplicate therapy utilizers can aid in diabetes drug therapy optimization.

OBJECTIVE: To manage duplicate therapy and reduce associated expense, we developed and integrated duplicate therapy detection logic targeting GLP-1–DPP-IV combination therapy into a pharmacist-facing tool designed to facilitate pharmacist-to-provider or pharmacist-to-pharmacist outreach.

METHODS: Six months of pharmacy claims history was used to identify members using GLP-1 and DPP-IV in combination. Claims data provided case-specific unique overlap episodes and duration of combination therapy, and identified cases were made available to pharmacists through a web application. After confirming ongoing duplicate therapy, pharmacists contacted prescribers, pharmacists, and/or other health professionals involved in member care to discuss appropriateness of ongoing duplication of therapy. Notes regarding case review and outreach were documented. Total savings were calculated for each successful case, defined by discontinuation of either the GLP-1 or DPP-IV drug, based on the cost per day of the duplicate therapy regimen compared with the adjusted therapeutic regimen.

RESULTS: Of 16 million commercially insured members, we identified 7,471 unique members with pharmacy claims history indicating GLP-1–DPP-IV duplication from July 2022 through April 2023; 6,773 cases were loaded to the web application for pharmacist review. Of those cases, 196 were successful at the time of abstract submission, resulting in validated annualized program savings of $1,142,462. An additional 283 cases were currently in progress with estimated potential annual savings of $1,375,619. 180 interventions were unsuccessful, most commonly due to not receiving a response from the provider.

CONCLUSIONS: Due to rising high-cost incretin drug utilization for the treatment of diabetes and obesity, novel payer management strategies are important for controlling costs. Duplicate therapy involving use of GLP-1 and DPP-IV drugs in combination is identifiable through pharmacy claims data, and pharmacist-to-provider outreach is an effective strategy for managing duplicative use of these drugs.

SPONSORSHIP: Prime Therapeutics LLC.

E27 Impact of tirzepatide and other antiobesity medications on productivity in adults with obesity or overweight from a US employer perspective

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BACKGROUND: Estimated nationwide productivity costs of obesity-related absenteeism range from $3.4 to $6.4 billion annually. Tirzepatide, a novel glucose-dependent insulinotropic polypeptide (GIP) and glucagon-like peptide-1 (GLP-1) receptor agonist (RA), approved for type 2 diabetes and in development for chronic weight management, has demonstrated mean weight reductions of 16%-22.5% in SURMOUNT-1 clinical trial participants with a body mass index (BMI) greater than or equal to 30 kg/m^2 or 27-29.9 kg/m^2 with at least 1 weight-related comorbidity. The potential impact of tirzepatide and other antiobesity medications (AOMs) on productivity is important for employer-sponsored health care plans.

OBJECTIVE: To model the annual impact on productivity for tirzepatide and other AOMs in adults with obesity or overweight from a US employer perspective.

METHODS: A budget impact model, with an employer perspective, was developed to measure the impact of productivity loss. Mean weight loss data were sourced from SURMOUNT-1, STEP 1, SCALE, CONQUER, and COR-I clinical trials. Applying the mean BMI following treatment with tirzepatide and other AOMs, the impact on productivity was estimated compared with no treatment. Productivity data were taken from a study that assessed absenteeism (sick days), short-term disability days, and workers' compensation (defined as days of lost productivity due to claiming workers' compensation) as a function of BMI to estimate days of lost productivity due to treatment with AOMs and no treatment. Presenteeism data were taken from a study of self-reported productivity measures of 10,026 employees in the United States. Figures were digitized to create a dataset of days lost by BMI score. The total number of days lost per year were multiplied by average daily earnings of $217 (US Bureau of Labor Statistics, 2022) to estimate the annual cost of productivity loss.

RESULTS: Based on mean BMI following treatment, the mean total number of lost days and associated cost of lost work per year were estimated to be lower for tirzepatide 5 mg (17.84; $3,872), 10 mg (16.96; $3,680), and 15 mg (16.69; $3,622) compared with no treatment (20.60; $4,470), semaglutide 2.4 mg (17.86; $3,876), liraglutide 3 mg (19.18; $4,162), phentermine/topiramate 7.5 mg/46 mg (19.22; $4,170) and 15 mg/92 mg (18.84; $4,087), and bupropion/naltrexone 32 mg/360 mg (19.54; $4,240).

CONCLUSIONS: Based on this model, tirzepatide is estimated to result in lower annual productivity loss compared with other AOMs.

SPONSORSHIP: This study was supported by funding from Eli Lilly and Company, Indianapolis, IN, USA.

E30 A multiphase initiative to disseminate payer best practices in the development of coverage policy and benefit design for cystic fibrosis

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BACKGROUND: The management of cystic fibrosis (CF) requires multiple therapies, devices, and multidisciplinary care provided by Cystic Fibrosis Foundation (CFF)–accredited care centers. Several hours of daily treatments and the rigors of navigating the health care system further contribute to the psychological, financial, and time burden of managing the disease. Managed care professionals play a vital role in affecting access to care for the CF community.

OBJECTIVE: To enlist the input of key payer stakeholders, health care providers, and members of the CF patient/family community to identify barriers to appropriate access to care and develop best practices for coverage policy and benefit design.

METHODS: CFF and educational partner, Impact Education, LLC (IMPACT), conducted a virtual working group meeting in April 2022 to elicit the input of 5 payer/purchaser stakeholders, 4 health care providers, and 2 patient/caregiver representatives on the access, coverage, and provision of high-quality care for CF. To further develop innovative collaboration between payers and providers and identify best practices in coverage policy and benefit design, 2 state-specific roundtable meetings were convened in October 2022 following the initial working group meeting. These meetings were attended by 6 payer/purchaser representatives and 6 health care providers from Texas and Michigan. Specific topics discussed at the meetings included barriers to care, administrative burden on people with CF, care teams, and payers, financial burden, and opportunities for payers and providers to collaborate.

RESULTS: Throughout the multiphase initiative, the barriers members of the CF community and their providers encounter while navigating health insurance coverage were elucidated. Common themes that emerged included difficulty navigating care in multiple health systems and geographic areas and the complexities of the prior authorization (PA) process. Ongoing communication and collaboration between payer

and provider stakeholders—facilitated by CFF—was recommended going forward, in addition to several PA-directed best practices. The most prominent among these were extending the duration of authorizations, bundling multiple CF-specific therapies and supplements under a single PA, and exploring opportunities to enhance adoption of electronic PAs.

CONCLUSIONS: The recommendations developed as part of this multiphase initiative are intended to improve patient access to care and enhance clinical outcomes in a manner that is cost-effective and ultimately benefits all involved stakeholders. Findings on payer best practices will be disseminated in the form of a white paper and related initiatives are proposed for the future.

SPONSORSHIP: Cystic Fibrosis Foundation.

E31 Clinical and economic burden of patients with and without AL amyloidosis: A matched control analysis of insurance claims

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BACKGROUND: Real-world estimates of health care resource utilization (HCRU) and costs among patients with AL amyloidosis are limited, and many studies relied on nonspecific *International Classification of Diseases, Ninth Revision* diagnosis codes to identify patients.

OBJECTIVE: To compare HCRU and costs in patients with and without AL amyloidosis, identified using *International Classification of Diseases, Tenth Revision* codes.

METHODS: This retrospective analysis used 2018-2020 data from the Merative MarketScan Commercial and Medicare Supplemental and the IQVIA Pharmetrics Plus databases to identify adult patients (existing or newly diagnosed) with at least 1 inpatient or at least 2 outpatient claims for AL amyloidosis (*International Classification of Diseases, Tenth Revision, Clinical Modification* code E85.81) in any diagnosis field during each calendar year of the study period (January 1, 2018, December 31, 2020) in the United States. In order to compare the clinical and economic burden between patients with AL amyloidosis (cases) and those without, controls were derived from a general population without AL amyloidosis. Controls were matched 2:1 to cases based on age, sex, region, and type of insurance. Continuous enrollment in a health plan in each calendar year was required for both cases and controls. Study outcomes included demographic and clinical characteristics, and all-cause HCRU and costs (adjusted to 2020 dollars) during each calendar year.

RESULTS: We identified 574 cases and 1,148 matched controls (2018), 588 cases and 1,176 matched controls (2019), and 667 cases and 1,334 matched controls (2020). Cases had higher comorbidity burden than matched controls—mean (SD) Charlson Comorbidity Index score: 4.1 (2.8) vs 1.0 (1.7). Cases had more frequent hospitalizations and emergency department visits than matched controls: 39.0% and 33.0% vs. 7.3% and 14.3% (2020). Mean total health care costs were significantly greater among cases compared with matched controls: $142,456 vs $9,135 (2020). Results for 2018 and 2019 were consistent with 2020 ($P < 0.001$ for all).

CONCLUSIONS: Patients with AL amyloidosis had greater HCRU and costs than patients without AL amyloidosis. These results indicate that there is an ongoing need for improvement in areas that impact disease prognosis and may decrease costs, such as additional treatment options, more disease awareness, and earlier diagnosis.

SPONSORSHIP: Prothena Biosciences Limited.

F00-F99 Mental and Behavioral Disorders

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

F1 The diagnostic journey of patients with mild cognitive impairment or Alzheimer disease dementia, and challenges associated with timely diagnosis: Results from a real-world survey in the United States

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BACKGROUND: Alzheimer disease (AD) is a progressive neurodegenerative disorder associated with cognitive, functional, and behavioral impairment and characterized by the accumulation of amyloid plaques and tau neurofibrillary tangles in the brain. AD progresses in a continuum, from cognitively unimpaired with evidence of AD pathology to AD with mild cognitive impairment (MCI) to dementia caused by AD. A timely diagnosis is important for future access to treatment given the successful results of recent amyloid-targeting therapy clinical trials.

OBJECTIVE: To understand the diagnostic journey of patients with MCI/AD in the real world and to assess physician perceptions of the challenges in making a timely diagnosis.

METHODS: Data were drawn from the Adelphi Real World AD Disease Specific Programme, a cross-sectional survey of primary care physicians (PCPs) and specialists (neurologists/geriatricians/psychiatrists), and their consulting patients with MCI/AD conducted in the United States between December 2022 and May 2023. Descriptive analyses were performed; sample sizes varied between variables, and missing data were not imputed. Data are summarized as percentages or median (interquartile range).

RESULTS: Overall, 82 PCPs and 100 specialists reported data on 1,246 patients (452 with MCI and 794 with AD dementia). Patients first consulted a PCP in 74% of cases; 53% of these patients were diagnosed by a PCP and 37% by a neurologist. Overall, 47% of patients were diagnosed at their first consultation, likely based upon clinical impression; the median time to diagnosis for the remaining patients was 12 (5-26) weeks. Diagnosis was aided by feedback provided by the patient/patient's family for 87% of patients and cognitive/behavioral assessments for 90% of patients. Few patients underwent biomarker testing (cerebrospinal fluid [7%], amyloid positron emission tomography [PET] scan [4%], and tau PET scan [1%]) despite 74% of specialists reporting biomarker testing will be "important"/"extremely important" for identifying AD in patients with MCI in the future. Specialists reported that key diagnostic barriers for the early identification of patients with MCI include patients delaying seeking help because of a lack of awareness/perceived stigma (60%), a wide variation in how patients typically first present (38%), and a lack of understanding about normal ageing (37%).

CONCLUSIONS: It is crucial to increase patient and physician awareness of AD and access to biomarker testing to allow timely diagnosis and early disease management.

SPONSORSHIP: The analysis described here used data from the Adelphi Real World Alzheimer's Disease DSP. The DSP is a wholly owned Adelphi Real World product. Eli Lilly & Company is one of multiple subscribers to the DSP.

F4 Health care utilization and costs associated with management of opioid use disorder within residential treatment programs and office-based opioid treatment programs

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BACKGROUND: The economic burden of opioid abuse is high, and costs associated with different opioid treatment programs have not been extensively studied.

OBJECTIVE: To compare characteristics, health care utilization, and costs of patients enrolled in residential treatment programs (RTPs) and office-based opioid treatment programs (OBOTs).

METHODS: A retrospective longitudinal study using IQVIA's PharMetrics Plus claims data was performed. Adult patients enrolled in an RTP or OBOT between March 1, 2018, and December 31, 2020 (enrollment date=index date), with evidence of medication for opioid use disorder (OUD) were identified. RTPs and OBOTs were defined using place of service and Healthcare Common Procedure Coding System and revenue codes, and Magellan and Evernorth billing guidelines were referenced to replicate payor guidance. Baseline characteristics were evaluated during the 12-month pre-index period, and opioid-related health care resource utilization and costs were evaluated during the 12-month post-index period.

RESULTS: A total of 472 patients enrolled in RTPs, and 4,990 patients enrolled in OBOTs were included. Compared with OBOT patients, RTP patients were younger (mean: 36.7 vs 42.2 years; $P<0.0001$) and had a higher prevalence of other substance use disorders (52.3% vs 36.0%; $P<0.0001$), depression (36.7% vs 28.9%; $P=0.0004$), anxiety disorder (44.7% vs 39.4%; $P=0.0234$), alcohol use disorder (21.4% vs 11.5%; $P<0.0001$), and prior opioid overdose (4.0% vs 1.6%; $P=0.0002$) at baseline. During the post-index period, the rate of opioid overdose and opioid-related hospitalizations, emergency department visits, and outpatient nonphysician office visits unrelated to opioid treatment programs were similar between the 2 cohorts. More OBOT patients had telehealth visits (10.8% vs 3.6%; $P<0.0001$) and physician office visits (27.3% vs 15.0%; $P<0.0001$) compared with RTP patients. Mean opioid-related total costs were notably higher for RTP patients compared with OBOT patients ($21,038 vs $6,522; $P<0.0001$).

CONCLUSIONS: Differences exist between patients with OUD managed in RTPs and OBOTs. Although some outcomes were similar in both cohorts, cost was significantly lower in the OBOT setting. Further study related to the

value of care provided through RTP and OBOT treatment settings is warranted.

SPONSORSHIP: Indivior.

F5 Remote medication monitoring for patients with opioid use disorder treated with methadone: Economic evaluation of the potential implications for the health care system

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BACKGROUND: Each year about 40% of the approximately 637,000 patients treated with methadone receive subtherapeutic doses, leading to persistent cravings, withdrawal symptoms, and high treatment dropout. Remote medication monitoring (RMM) has the potential to improve therapeutic drug levels and may lead to improved retention in treatment and improved outcomes. The potential economic impact of RMM has not been evaluated.

OBJECTIVE: To assess the potential economic implications associated with RMM in patients with opioid use disorder treated with methadone.

METHODS: We used one-year decision analytic and budget impact analyses from the payer perspective evaluating target population and quality-adjusted life year (QALY) impact of a clinical pathway incorporating RMM vs treatment as usual (TAU) for methadone-treated patients in a 1 million covered lives population. The cost of RMM was set at $5,000 per patient per year, improvement in treatment retention set at 15% vs TAU (which has a retention rate of 57% in the first 6 months and 67% in subsequent 6 months reported in the literature), and it was assumed that 25% of patients treated with methadone would receive RMM. Six-month health care costs and health utility impact of retained vs nonretained patients were obtained from the literature (retained: $7,774 and 0.574 vs nonretained: $22,438 and 0.809). Sensitivity analyses were conducted by varying model inputs by ±10%.

RESULTS: Over 1 year, 613 patients would be treated with RMM per million population per year. The base case scenario showed a QALY gain of 0.042 and cost reductions of $250 per patient (cost/QALY of –$5,936). Per member per month (PMPM) savings increased by approximately $0.026 for every 10% increase in RMM-treated patients and ranged from –$0.1 (RMM cost of $80/week [$4,160 annually]) to $0.07 (RMM cost of $160/week [$8,320 annually]). Sensitivity analyses showed that the cost of nonretained patients was the strongest driver of the cost/QALY changes, followed by efficacy improvement over TAU, and 6-month utility impact in retained patients.

CONCLUSIONS: In this economic evaluation, the modeled base case RMM clinical pathway was economically dominant (more efficacious and less costly) compared wth the TAU approach and exhibited a low PMPM impact in scenarios with higher RMM cost. These results indicate that RMM has the potential to improve health-related quality of life while reducing costs associated with low retention in treatment, especially in populations in which the health care costs of untreated patients are high. Additional economic evaluations should be conducted as additional clinical data emerge.

SPONSORSHIP: CARI Health.

F8 Budget impact analysis of TV-46000 a long-acting subcutaneous antipsychotic formulation of risperidone in adults with schizophrenia in the United States

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BACKGROUND: Antipsychotics are considered first-line treatment for patients with schizophrenia. Despite clinical benefits, adherence rates are relatively poor because of concerns about adverse events and the symptoms associated with schizophrenia. Long-acting injectable antipsychotics (LAIs) have been shown to have better adherence rates compared with daily oral antipsychotics. TV-46000 is a long-acting subcutaneous antipsychotic (LASCA) that combines risperidone and an innovative, copolymer-based drug delivery technology that was recently approved for once-monthly (q1m) and once-every-2-months (q2m) treatment of adults with schizophrenia.

OBJECTIVE: To estimate the incremental budget impact of TV-46000 for the treatment of adults with schizophrenia from a US health care–insured population.

METHODS: An illustrative budget impact model (BIM) using a base-case (overall US population) payer population of 1,000,000 covered adult lives, 0.6% prevalence of schizophrenia, 95% treatment and eligibility rate over a 5-year horizon, no change in utilization mix for oral antipsychotics, and increased utilization mix for TV-46000 arising only from replacing other LAIs. The BIM used inputs about the population, relapse rates, and costs associated with medication and relapse to estimate total costs of treatment with LAIs, as well as hospitalizations and emergency department (ED) visits associated with relapse. Relapse rates were

estimated from US Food and Drug Administration prescribing information and clinical study reports. Costs associated with hospitalizations and ED visits were estimated using the National Inpatient Sample. Additional payer archetypes (eg, Medicaid or Medicare) were developed per data availability.

RESULTS: In the base-case payer scenario of patients treated for schizophrenia (n = 4,207), an increase in utilization mix for TV-46000 from 0.12% (0.09% q1m, 0.03% q2m) in year 1 to 1.17% (0.88% q1m, 0.29% q2m) in year 5 was estimated to reduce relapses by 0.9 in year 1 and by 8.2 in year 5. Hospitalizations were predicted to decrease by 0.6 in year 1 and 5.7 in year 5, and ED visits by 0.8 in year 1 and 7.8 in year 5. The net budget impact, calculated as a difference in total budgets of scenarios with TV-46000 and without TV-46000, was estimated to be –$71,903 (–$0.006 per member per month) in year 1 and –$318,077 (–$0.026) in year 5.

CONCLUSIONS: These findings demonstrate the potential economic benefits of TV-46000 from a US payer perspective, stemming from a reduction in the number of relapses and associated hospitalizations and ED visits.

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

F9 Burden of bipolar I disorder on clinical, economic, and humanistic outcomes: Matched analysis of US National Health and Wellness Survey data

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BACKGROUND: Bipolar I disorder (BD-I) is associated with a risk of obesity and related cardiometabolic sequelae, but real-world impacts accompanying obesity in this population are not well understood.

OBJECTIVE: To evaluate clinical, humanistic, and economic outcomes in adults with and those without BD-I across body mass index (BMI) categories.

METHODS: Respondents with a self-reported physician's diagnosis of BD-I from the 2016/2020 National Health and Wellness Survey were matched to controls without BD-I (1:2 greedy propensity score matching on demographic/health characteristics). Outcomes were compared among cohorts and BMI categories.

RESULTS: Results from 5,418 respondents were analyzed (BD-I, n = 1,806; controls, n = 3,612). Most were female (64.5%), White (62.8%), and unemployed (54.2%); the average age was 38.7 years. BD-I was associated with increased risks for insomnia (odds ratio [OR] = 4.23), asthma (OR = 1.86), sleep apnea (OR = 1.84), hypertension (OR = 1.57), and high cholesterol (OR = 1.44), among other comorbidities. BD-I was associated with lower health-related quality-of-life scores vs controls and higher productivity losses (presenteeism: 57.5% vs 49.6%; total work productivity loss: 66.7% vs 57.4%). Mean health care resource utilization was higher vs controls (hospitalizations: 0.8 vs 0.5; emergency room visits: 1.7 vs 1.0; outpatient visits: 11.9 vs 5.9). Indirect and direct costs among those with BD-I were higher than controls. Further, respondents with BD-I reported worse outcomes than controls across BMI categories.

CONCLUSIONS: People living with BD-I may be at increased risk for comorbidities, lower quality of life, and higher indirect/direct costs. These risks and their associated burdens appear to increase as BMI rises, worsening patient outcomes in this vulnerable patient population.

SPONSORSHIP: Alkermes, Inc.

F10 Oral antipsychotic medication switching for patients with schizophrenia: Reasons, treatment patterns and costs

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BACKGROUND: Antipsychotic medications for patients with schizophrenia are often changed over the course of a patient's illness. However, research regarding the reasons for switching and economic consequences of switching is limited and at times contradictory.

OBJECTIVE: To describe (1) switching patterns among patients with schizophrenia who initiate oral antipsychotic medication (OAM) monotherapy, (2) health care costs and resource utilization among patients who switch OAMs matched with those who do not, (3) reasons for switching, and (4) costs and resource utilization associated with different reasons for switching.

METHODS: Adults with at least 2 claims with a diagnosis code for schizophrenia and initiating OAM monotherapy between January 1, 2015, and June 30, 2021, were identified in the Optum Research Database. An algorithm based on the timing of therapies and treatment gaps identified lines of therapy, including medication changes. Claims were observed for up to 6 years and 9 months. A control cohort of nonswitchers was matched to the switchers to compare resource utilization and costs 3 months after and up to 3 months before the first switch. For a subgroup of switchers, medical charts were abstracted 4 months prior through 2 months after the switch for the reason of the switch.

RESULTS: A total of 6,425 patients who initiated OAM monotherapy were identified. The mean age was 53 years, 53%

were male, and 90% initiated a second generation OAM. Of those patients, 1,505 (23%) had at least 1 switch to a different OAM monotherapy, with a mean time to first switch of 209 days (SD = 333 days; median = 67 days), a rate of 0.65 switches per person-year of follow-up among switchers, and 56% of first switches occurring within 3 months of initiation. The most frequent switching sequence was from quetiapine fumarate to risperidone (8% of switchers). Switchers used statistically more schizophrenia-related resources (outpatient visits, emergency room visits , hospitalizations, pharmacy fills) compared with nonswitchers. Mean total schizophrenia-related costs per patient per month were $1,252 (SD = $2,602; median = $190) for switchers compared with $402 (SD = $2,027; median = $52) for nonswitchers ($P < 0.001$). The most common reasons for switching were lack of efficacy and tolerability issues.

CONCLUSIONS: Nearly a quarter of patients switched OAMs, more than half within the first 3 months of therapy, with higher costs for switchers compared with nonswitchers. These findings suggest the importance of patients' initiating an OAM that does not result in medication switching to optimize clinical outcomes and costs.

SPONSORSHIP: Cerevel Therapeutics.

F11 Safety and efficacy of KarXT in schizophrenia in the randomized, double-blind, placebo-controlled, phase 3 EMERGENT-3 trial

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BACKGROUND: KarXT combines the dual M1/M4 preferring muscarinic receptor agonist xanomeline and the peripherally restricted muscarinic receptor antagonist trospium chloride. KarXT is designed to preserve the beneficial central nervous system effects of xanomeline while ameliorating side effects due to peripheral muscarinic receptor activation. In the EMERGENT-1 and EMERGENT-2 trials in people with schizophrenia with acute psychosis, KarXT met the primary endpoint and secondary outcomes measures and was generally well tolerated.

OBJECTIVE: To assess the safety and efficacy of KarXT in adults with schizophrenia.

METHODS: EMERGENT-3 (NCT04738123) was a 5-week, randomized, double-blind, placebo-controlled, phase 3 trial of KarXT in people with schizophrenia with acute psychosis. Key inclusion criteria were recent worsening of positive symptoms warranting hospitalization, Positive and Negative Syndrome Scale (PANSS) total score greater than or equal to 80, and Clinical Global Impression–Severity (CGI-S) score greater than or equal to 4. Participants were randomized 1:1 to KarXT or placebo. KarXT dosing (mg xanomeline/mg trospium) started at 50 mg/20 mg twice daily and increased to a maximum of 125 mg/30 mg twice daily. The primary endpoint was change from baseline to week 5 in PANSS total score. Secondary outcomes measures were change from baseline to week 5 in PANSS positive subscale, PANSS negative subscale, PANSS Marder negative factor, and CGI-S scores, and the proportion of people with greater than or equal to 30% reduction from baseline to week 5 in PANSS total score.

RESULTS: A total of 256 people were enrolled. KarXT significantly reduced PANSS total score compared with placebo (KarXT: –20.6; placebo: –12.2 [least squares mean difference = –8.4; 95% CI = –12.4 to –4.3; $P < 0.0001$; Cohen's d effect size = 0.60]). Results for secondary outcomes measures significantly favored KarXT at week 5, except PANSS negative subscale and PANSS Marder negative factor scores, which achieved statistical significance only at week 4. Discontinuation due to treatment-emergent adverse events (TEAEs) was similar between KarXT and placebo groups (6.4% vs 5.5%). The most common TEAEs in the KarXT group were nausea (19.2%), dyspepsia (16.0%), vomiting (16.0%), and constipation (12.8%); these TEAEs were mild or moderate and transient in nature. Measures of extrapyramidal motor symptoms/akathisia, weight gain, and somnolence were similar between treatment groups.

CONCLUSIONS: KarXT has the potential to be the first in a new class of antipsychotic medication based on muscarinic receptor agonism and a well-tolerated alternative to currently approved treatments.

SPONSORSHIP: Karuna Therapeutics.

F14 Impact of formulary-related pharmacy claim rejections on health care resource utilization and treatment patterns among Medicaid patients using cariprazine for bipolar I disorder

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BACKGROUND: Cariprazine is an atypical antipsychotic (AA) approved to treat manic, mixed, and depressive episodes of bipolar I disorder (BP-I). However, little is known about the consequences of formulary restrictions on cariprazine for Medicaid patients with BP-I.

OBJECTIVE: To evaluate the impact of formulary-related rejections on health care resource utilization (HRU) and

treatment patterns among Medicaid patients with BP-I and an initial cariprazine claim.

METHODS: The Symphony Health Integrated Dataverse (March 1, 2015, to October 31, 2020) was used to identify adults with BP-I and Medicaid insurance. Patients with their first cariprazine claim rejected for a formulary-related reason (formulary noncoverage, prior authorization, or step therapy) were matched (1:1) to patients with their first 2 cariprazine claims approved (initial claim = index) using propensity scores. HRU outcomes included all-cause and mental health (MH)–related hospitalizations, emergency department (ED) visits, and outpatient visits, reported per patient-year (PPY). HRU was compared between cohorts using rate ratios (RRs) with 95% CIs and P values calculated via nonparametric bootstrap procedures. Treatment patterns were analyzed using descriptive statistics.

RESULTS: Matched rejected and approved cohorts comprised 2,216 patients each, with an average follow-up of 0.8 years for both cohorts. Rates of all-cause and MH-related hospitalizations PPY were significantly higher in the rejected cohort vs in the approved cohort (all-cause: RR [95% CI] = 1.37 [1.13-1.68], $P < 0.001$; MH-related: 1.45 [1.19-1.79], $P < 0.001$). All-cause and MH-related ED and outpatient visit rates were similar between cohorts. Only 20% of patients in the rejected cohort subsequently received cariprazine (110 days after initial rejection on average). Patients in the rejected cohort received 0.67 different AAs (excluding cariprazine) during follow-up, whereas patients in the approved cohort received 0.47 different AAs. Of patients in the rejected cohort, approximately 40% never received any AA following an initial rejection.

CONCLUSIONS: Medicaid patients with BP-I whose initial cariprazine claim was rejected for a formulary-related reason had significantly more hospitalizations than patients with 2 approved initial claims. Similar results were observed in a prior study of commercially insured patients. Additionally, many patients whose initial cariprazine claim was rejected never received any AAs during follow-up, suggesting that formulary restrictions on cariprazine may have unintended consequences.

SPONSORSHIP: AbbVie

F15 Impact of formulary-related pharmacy claim rejections on health care resource utilization and treatment patterns among patients using cariprazine as adjunctive treatment for major depressive disorder

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BACKGROUND: Cariprazine was recently approved as an adjunct to antidepressant therapy (ADT) for the treatment of major depressive disorder (MDD); however, formulary restrictions may limit access to cariprazine for some patients with MDD.

OBJECTIVE: To evaluate the impact of formulary restrictions on health care resource utilization (HRU) among patients with a cariprazine claim for the adjunctive treatment of MDD.

METHODS: The Symphony Health Integrated Dataverse (March 1, 2015, to October 31, 2020) was used to identify commercially insured adults with MDD, at least 1 cariprazine claim (first claim = index), and at least 2 dispensed ADTs with at least 14 days of overlap with cariprazine. Two cohorts were defined as patients whose initial cariprazine claim was approved or rejected for a formulary-related reason. Patients in both cohorts were required to have an approved atypical antipsychotic (AA) dispensing on index or at some point post-index. Rejected and approved claim cohorts were matched (1:2) using propensity scores based on patient characteristics. Outcomes evaluated post-index included all-cause and mental health (MH)–related HRU (hospitalizations, emergency department [ED] visits, and outpatient visits) and treatment patterns. HRU was reported per patient-year (PPY) and compared between cohorts using rate ratios (RRs), with 95% CIs and P values calculated via nonparametric bootstrap procedures. Treatment patterns were analyzed using descriptive statistics.

RESULTS: The rejected cariprazine claim cohort included 566 patients, with 1,132 matched patients in the approved claim cohort. The mean follow-up time was 1.8 years, mean age was 42 years, and 71%-73% of patients were female. Relative to the approved cohort, the rejected cohort had significantly higher rates of hospitalizations PPY (all-cause: RR [95% CI] = 1.61 [1.15-2.32], $P = 0.012$; MH-related: 1.89 [1.18-2.89], $P = 0.016$). Rates of ED and outpatient visits were numerically higher among the rejected cohort. Most patients in the rejected cohort never received cariprazine

(68.4%), and those who did received it an average of 6 months after initial rejection. During follow-up, patients in the rejected cohort received 1.20 different types of AAs (excluding cariprazine) on average whereas patients in the approved cohort received 0.66.

CONCLUSIONS: Among patients with MDD, those with an initial formulary-related rejection of adjunctive cariprazine had significantly more hospitalizations than those with an initially approved claim, suggesting that formulary restrictions on cariprazine are associated with negative downstream effects.

SPONSORSHIP: AbbVie.

F16 Impact of social determinants of health on esketamine initiation among patients with treatment-resistant depression in the United States

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BACKGROUND: Esketamine (ESK) nasal spray is an innovative therapy approved for treatment-resistant depression (TRD) in the United States on March 5, 2019. It is administered under the direct supervision of a health care provider (HCP).

OBJECTIVE: To evaluate education and household (HH) income as factors associated with ESK initiation among insured patients with TRD.

METHODS: Commercially and Medicare Advantage–insured adults with evidence of TRD were selected from Optum's de-identified Clinformatics Data Mart Database (January 2016-June 2022). The baseline period spanned 12 months before the index date (latter of evidence of TRD or US ESK approval date); the follow-up period spanned the index date until the end of health plan eligibility/data availability. Cox proportional hazard models evaluated the association of education and HH income, among other factors, with ESK initiation; patients who did not initiate ESK were censored at the end of follow-up.

RESULTS: A total of 201,937 patients with evidence of TRD were selected (mean age: 62.3 years, 75.0% female, 80.9% White, 82.8% with less than a bachelor's degree [BA], 60.3% with HH income <$75,000, and 64.0% Medicare Advantage insured). Patients with an education of less than a BA and an HH income less than $75,000 had a 36% lower chance of initiating ESK relative to patients with education of at least a BA and an HH income of at least $75,000 (hazard ratio [HR] = 0.64, $P < 0.001$) in a model adjusted for other demographics, index year, baseline comorbidities, treatments, and health care resource use. Either education less than a BA alone (HR = 0.85; $P = 0.174$) or HH income less than $75,000 alone (HR = 1.09; $P = 0.681$) did not significantly impact chances of initiating ESK relative to patients with an education of at least a BA and an HH income of at least $75,000. Also, in this model, being aged at least 65 years reduced chances of ESK initiation by 64% (HR = 0.36, $P < 0.001$), being female by 38% (HR = 0.62, $P < 0.001$), and having Medicare Advantage plan by 29% (HR = 0.71, $P = 0.033$). Racial or ethnic minority patients had chances of ESK initiation similar to White patients (HR = 1.23; $P = 0.102$).

CONCLUSIONS: Lower education and income reduced chances of ESK initiation in otherwise comparable commercially or Medicare Advantage–insured US adults with TRD. This analysis highlights a potential health equity gap among adults with TRD based on disadvantaged socioeconomic status. Trends observed may be related to the availability of health care services locally, transportation, caregiver time, motivation, and other conditions necessary for ESK treatment. Collaboration between drug manufacturers, HCPs, and payers is warranted to enhance access to ESK treatment.

SPONSORSHIP: Janssen Scientific Affairs, LLC.

F17 Medication burden in patients with major depressive disorder aged 65 years or older who are treated with antidepressants with or without the top 5 prevalent comorbidities

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BACKGROUND: Major depressive disorder (MDD) affects at least 5% of older adult US patients (aged ≥65 years). MDD and older age are independently associated with a greater prevalence and severity of comorbidities. Limited evidence exists on the most commonly occurring comorbidities in older patients with MDD and their associated medication burden.

OBJECTIVE: To evaluate the medication burden in older adult patients with MDD treated with antidepressant treatments (ADTs), with or without the top 5 comorbidities of interest.

METHODS: The study used claims data from Komodo's Healthcare Map to identify patients (aged ≥65 years) diagnosed with MDD. MDD was defined as at least 1 MDD medical claim in an inpatient/emergency room setting, at least 2 MDD claims in an outpatient setting, or at least 1 MDD claim and at least 1 depression claim in an outpatient

setting during the baseline period or within 30 days after the index date (first ADT claim during the identification period January 1, 2017-September 30, 2021) and receiving at least 1 ADT claim. The baseline and follow-up periods were 24 and 12 months preceding and following the index date, respectively. All-cause and comorbidity-specific medication burden (prescription claims per person per month [PPPM]) for the top 5 comorbidities of interest were calculated over the baseline and follow-up periods.

RESULTS: Among 430,353 older adults with MDD (mean age: 73.2 years; female: 72.4%) treated with ADTs, 94.2% had at least 1 of the top 5 comorbidities identified during the baseline period: hypertension (77.9%), hyperlipidemia (73.2%), diabetes (type 1 and 2: 52.7%), anxiety (37.9%), and chronic obstructive pulmonary disease (COPD; 18.9%). The all-cause PPPM medication burden during baseline and follow-up was 3.8 and 4.5, respectively, for patients with at least 1 top 5 comorbidity and 1.9 and 2.5, respectively, for those without a top comorbidity. The comorbidity-specific baseline and follow-up PPPM medication burden for those with at least 1 top 5 comorbidity was 0.6 and 0.7, respectively, for hypertension; 0.4 and 0.4, respectively, for hyperlipidemia; 0.5 and 0.6, respectively, for diabetes; 0.6 and 0.7, respectively, for anxiety; and 0.3 and 0.4, respectively, for COPD. Among psychiatric medications, benzodiazepines were the most commonly used products by those with and without at least 1 top 5 comorbidity (benzodiazepines: 29.1% vs 21.1%; sedative hypnotics: 6.8% vs 7.3%; antipsychotics: 5.8% vs 5.6%, respectively).

CONCLUSIONS: This study highlights the prevalence of comorbidities in ADT-treated older adult patients with MDD. Comorbidity-specific PPPM costs increased for 4 of the top 5 comorbidities during the study's follow-up period.

SPONSORSHIP: Sage Therapeutics Inc. and Biogen Inc.

F18 Young adults with major depressive disorder in the United States: Economic burden and antidepressant treatment patterns

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BACKGROUND: Major depressive disorder (MDD) disproportionately impacts young adults aged 18-25 years, with prevalence rates almost twice as large as those in patients aged 26-49 years. This impact may be even greater among college students, with survey data from 2020-2021 reporting that 39% of college-aged students met the Patient Health Questionnaire-9 screening criteria for depression.

OBJECTIVE: To compare all-cause health care resource utilization (HCRU) and all-cause total cost of care (TCC; medical + pharmacy) between young adults (aged 18-25 years) with an MDD diagnosis and matched young adults without MDD and explore treatment patterns among patients with MDD initiating antidepressant pharmacotherapy.

METHODS: This was a retrospective, observational analysis of IBM MarketScan US commercial claims data. Adults aged 18-25 years with continuous enrollment 12 or more months before and after the patient's first MDD diagnosis from 2017 to 2018 were included in the analysis. HCRU and all-cause TCC were compared among young adults with MDD and a 1:1 exact matched cohort of young adults without MDD during the same period. Treatment patterns (persistence, discontinuation, switch, combination, and augmentation) were analyzed for young adults with MDD starting first-line antidepressant monotherapy for up to 12 months following their antidepressant index date.

RESULTS: A total of 98,344 young adults with MDD were matched 1:1 to a cohort of young adults without MDD. Mean all-cause TCC per year was $6,000 (SD = $123; $P < 0.0001$) higher among young adults with MDD than among patients without MDD ($9,640 vs $3,641, respectively). Young adults with MDD also had statistically significant greater all-cause HCRU. There were 11,682 young adults with MDD who received antidepressant monotherapy as their first-line MDD treatment whose treatment patterns were examined. Among the first patterns observed following initiation, 14.3% of patients persisted with their first-line therapy, 59.0% discontinued antidepressant therapy, and 26.8% experienced a treatment change during the 12-month follow-up period. The median days until first treatment change were 64 days for those discontinuing and 46 days for those switching antidepressants.

CONCLUSIONS: Health care costs accrued for young adults with MDD are significantly greater than those for young adults without MDD. The antidepressant utilization patterns observed in this population may be indicative of considerable challenges with treatment options for patients with MDD and highlight the urgency of addressing mental health in young adult populations.

SPONSORSHIP: Sage Therapeutics Inc. and Biogen Inc.

F20 Efficacy of MDMA-assisted therapy, pharmacological treatments, and psychotherapies for chronic, posttraumatic stress disorder: A systematic literature review

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BACKGROUND: 3,4-methylenedioxymethamphetamine-assisted therapy (MDMA-AT) is being investigated as a potential treatment option for patients with posttraumatic stress disorder (PTSD).

OBJECTIVE: To provide a comprehensive efficacy overview of investigational MDMA-AT and current treatments for PTSD.

METHODS: A PubMed and Embase search for randomized controlled trials published in English was conducted on February 24, 2023, using predefined Population, Intervention, Comparison, Outcomes, and Study criteria. Populations included adults with chronic, treatment-resistant, moderate-extreme PTSD. Interventions were MDMA-AT and comparators based on PTSD guidelines. Outcomes of interest were the Clinician-Administered PTSD Scale (CAPS) and loss of diagnosis (LOD). Two reviewers screened the publications; a third reviewer resolved any disagreements. The quality of trials was assessed with the National Institute for Health and Excellence appraisal checklist.

RESULTS: Of 4,323 identified publications, 69 studies were deemed appropriate for analysis. Phase 2/3 trials consistently reported significantly greater CAPS improvement with MDMA-AT vs placebo with therapy or low-dose MDMA-AT controls after 2-3 experimental sessions. Durability was observed in a long-term follow-up trial (mean duration = 45.4 months) with a 0.9-point CAPS decrease from posttreatment. US Food and Drug Administration–approved medications and those used off-label for PTSD treatment did not demonstrate a consistently greater CAPS decrease vs control arms across trials. Significant CAPS improvement was observed in venlafaxine ER, olanzapine, propranolol, nefazodone, and nabilone placebo-controlled trials. Most psychotherapy (PT) trials lacked between-group statistical assessments. Significant CAPS decrease compared with the waitlist was reported for cognitive, cognitive behavioral (CBT), cognitive processing (CPT), prolonged exposure (PE), and group cognitive-exposure therapies. Persistence of CAPS improvement was shown for CPT and PE in long-term follow up (mean duration = 6.2 years). The percentage of participants with LOD after 2-3 active-dose MDMA-AT sessions ranged from 41.7% to 83.3%. For PTs, LOD ranged from 36.0% to 88.3% in CBT modalities, 28.2% to 53.0% for CPT, and 21.0% to 53.0% in PE. Among medications, LOD was reported only for fluoxetine (73.0%). D-cycloserine with virtual reality exposure reported 21.4% LOD.

CONCLUSIONS: This systematic review suggests that current treatments for PTSD are associated with heterogeneous evidence; the majority did not demonstrate sustained effects. Results from investigational MDMA-AT studies showed consistent improvements in CAPS and LOD.

SPONSORSHIP: MAPS Public Benefit Corporation.

F21 Characterizing patients with Rett syndrome in the United States: A real-world analysis of the Rett Syndrome Natural History Study database

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BACKGROUND: Rett syndrome (RTT) is a rare neurodevelopmental disorder that almost exclusively affects females.

OBJECTIVE: To provide an overview of the characteristics of individuals with RTT and its clinical manifestations in the United States.

METHODS: This retrospective cohort study used registry data from the 5,211 RTT Natural History Study, a multicenter study of individuals with RTT that spanned from November 2015 to July 2021. Female participants with classic or atypical RTT, no brain trauma (current/history), and at least 1 follow-up visit were evaluated. Demographics and clinical characteristics at first visit were described; mortality was evaluated over subsequent visits. Results were described overall, by classic and atypical RTT, and for pediatric and adult participants.

RESULTS: The study included 455 female participants, of whom 90.5% had classic RTT and 9.5% had atypical RTT; 79.8% were pediatric participants. Mean (SD) age was 11.8 (9.5) years and mean (SD) age at onset of motor and communication regression was 2.3 (0.8) years. Most subjects had an MECP2 mutation (98.2%). Common clinical manifestations of RTT included loss of language (95.8%), hand stereotypies (92.3%), respiratory dysfunction (75.8%), sleep disturbances (75.6%), and constipation (74.5%). Those with

atypical RTT had fewer clinical manifestations than those with classic RTT (loss of language: 60.5% vs 99.5%; hand stereotypies: 72.1% vs 94.4%; sleep disturbances: 60.5% vs 77.2%; and respiratory dysfunction: 44.2% vs 79.1%). Relative to pediatric participants, adults had a higher prevalence of scoliosis (73.9% vs 45.7%), constipation (83.7% vs 72.2%), and epilepsy (56.5% vs 43.5%). The ability to sit, stand, or walk independently was less prevalent among those with classic RTT (classic: 47.3%-74.0%; atypical: 58.1%-79.1%). Mortality was rare (0.7%) in the overall population.

CONCLUSIONS: People with RTT have substantial disease burden across age and RTT subtype. These findings underscore the need for effective therapies for this population.

SPONSORSHIP: This study was sponsored by Acadia Pharmaceuticals Inc.

F22 Prevalence of gastrointestinal comorbidities by age group among patients with Rett Syndrome: An analysis of coded electronic health record and pharmacy data and clinical notes

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BACKGROUND: Rett Syndrome (RTT) is a neurodevelopmental disorder that mostly affects females. Gastrointestinal (GI) comorbidities are common in RTT. As patients with RTT often report multiple issues during a clinic visit, GI symptoms may sometimes not be coded in the medical record. Clinician progress notes are rich with details that might complement well the coded data, which are often the focus in a traditional analysis of electronic health record (EHR) data.

OBJECTIVE: To utilize clinical progress notes to supplement coded data from the EHR to calculate prevalence and types of GI comorbidities among individuals with RTT.

METHODS: Study data were EHR coded fields and clinical progress notes from Vanderbilt University Medical Center's (VUMC) Nashville Biosciences. Eligible individuals had more than 1 encounter with an RTT diagnosis (*International Classification of Diseases, Tenth Revision* [ICD-10]: F84.2) and were younger than 30 years at the time of index (first RTT diagnosis). GI diagnosis (based on presence of ICD-10 diagnosis, medications indicated for GI diagnoses, or reference to GI symptoms in the clinical note) and utilization were measured during the 6-month pre-index through the 12-month follow-up period. Cases were grouped based on the age at index: 0-2 years; older than 2-10 years; and older than 10 years. Chi-square tests were used to test statistical differences for the categorical variables.

RESULTS: Of the 112 RTT cases, 79 were eligible for the 6-month pre-index and 12-month post-index periods and met the age criteria. Most were female (83.5%), with a mean age (SD) of 10.2 ± 7.4 years (median = 7.8 years). GI comorbidities were present for 61 (77.2%) cases (34 with a diagnosis code in the EHR, 21 with no GI diagnosis code but with GI symptom described in the clinical note, and 6 with neither a GI diagnosis nor a GI-related note but GI-related medications). The most prevalent GI comorbidities were constipation (41.8%) followed by dysphagia (36.7%) and gastroesophageal reflux disease (27.8%). More of the age 0-2 years group (100%) had at least 1 GI comorbidity compared with the older 2 groups (86.0% and 48.3%, respectively) ($P < .05$). Dysphagia (85.7%) and constipation (46.5%) were the most prevalent GI comorbidities among those aged 0-2 years and the older than 2-10 years groups, whereas constipation (34.5%) and gastroesophageal reflux disease (34.5%) were the most prevalent among the oldest age group.

CONCLUSIONS: The total prevalence of GI-related comorbidities emerged only when data from coded EHR fields were combined with clinical notes and pharmacy data. GI comorbidities are prevalent among all age groups of patients with RTT; however, the most prevalent comorbidities differ according to age group.

SPONSORSHIP: Acadia Pharmaceuticals Inc.

F23 Health care resource utilization and costs associated with psychiatric comorbidities in pediatric patients with attention-deficit/hyperactivity disorder

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BACKGROUND: Attention-deficit/hyperactivity disorder (ADHD) is associated with high rates of psychiatric comorbidities. Although ADHD has been shown to pose considerable clinical and economic burden, research quantifying the added burden attributable to psychiatric comorbidities in pediatric ADHD is scarce.

OBJECTIVE: To assess the impact of psychiatric comorbidities, specifically anxiety and depression, on health care resource utilization (HRU) and health care costs in pediatric patients with ADHD in the United States.

METHODS: Pediatric patients with ADHD aged 6-17 years were identified in the IQVIA PharMetrics Plus database (October 1, 2015-September 30, 2021). The index date was

defined as the date of initiation of a randomly selected ADHD treatment. Eligible patients had continuous health plan enrollment for at least 6 months pre-index (baseline period) and at least 12 months post-index (study period). Patients with at least 1 diagnosis for anxiety and/or depression during both the baseline and study periods were classified in the ADHD+anxiety/depression cohort, and those without diagnoses for anxiety or depression during both periods were classified in the ADHD-only cohort. Entropy balancing was used to create reweighted cohorts with similar baseline characteristics. All-cause HRU and health care costs during the study period were compared between cohorts using regression analyses.

RESULTS: The ADHD+anxiety/depression cohort (n=66,231) and ADHD-only cohort (n=204,723) had similar characteristics after reweighting: the mean patient age was 11.9 years, the majority were male (72.8%), and they had the combined ADHD type (56.2%). Patients in the ADHD+anxiety/depression cohort had higher HRU than those in the ADHD-only cohort (incidence rate ratios for inpatient admissions: 10.3; emergency room visits: 1.6; outpatient visits: 2.3; specialist visits: 5.3; and psychotherapy visits: 6.1; all $P<0.01$). The higher HRU translated to greater all-cause health care costs, with the mean per-patient-per-year (PPPY) costs being $8,682 vs $3,988 in the ADHD-only cohort ($P<0.01$). All-cause health care costs were highest when both comorbidities were present; among patients with ADHD who had only anxiety, only depression, and both anxiety and depression, the mean all-cause health care costs were $7,309, $9,901, and $13,785 PPPY, respectively (all $P<0.01$).

CONCLUSIONS: Comorbid anxiety and depression was associated with increased HRU and health care costs among pediatric patients with ADHD. Strategies to co-manage ADHD and psychiatric comorbidities may help mitigate the burden borne by patients and the health care system.

SPONSORSHIP: Otsuka Pharmaceutical Development & Commercialization, Inc.

G00-G99 Diseases of the Nervous System

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

G1 Potential medication wastage and impact on cost due to switching treatment among people with multiple sclerosis on oral or self-injectable disease-modifying therapy

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BACKGROUND: Unused medications have come under scrutiny because of their impact on patient health outcomes, health care resource use, and environmental safety. Medication wastage contributes to the overall reported wastage of 30% of annual health care expenditures (approximately $700 billion). A single-center study reported $6.3 million dollars (average wholesale price) wasted in 2018 due to switching or discontinuation of multiple sclerosis (MS) disease-modifying therapies (DMTs) within a calendar year.

OBJECTIVE: To estimate the cost of unused medication as potential medication wastage (PMW) associated with switching among people with MS (pwMS) receiving oral or self-injectable US Food and Drug Administration–approved MS DMTs in the United States.

METHODS: This retrospective cohort study by year included all adult pwMS using PharMetrics Plus claims data from 2017 to 2021 with an index date of January 1 of each year. All pwMS were required to have 12 months of continuous eligibility for the entire year and have a claim for at least 2 different DMTs during the same calendar year. Two cohorts were identified based on whether a person had an aggregate overlap in days supply across DMT switches within the year. The cost of PMW (US dollars 2021) because of overlap was calculated only at the point of switch to the new DMT and was defined as the cost of the remaining days supply of the prior DMT. People in the non-PMW cohort did not have an aggregate overlap in medication supplies across the switches.

RESULTS: In 2021, of the 1,782 pwMS who met the inclusion criteria, 447 (25%) contributed to PMW, representing the study cohort. In the cohort with PMW, approximately 34% of the total cost of the prior DMTs was attributable to wastage. The total cost of PMW paid by the insurer and pwMS was $1,325,067. Although the majority of the total cost was paid by the insurer ($1,250,489), $74,578 was still owed by pwMS. In the entire cohort of people with switches (PMW

and non-PMW) in 2012, the per-person per-year cost paid by the insurer and pwMS was $744. Similar findings were observed in each of the years.

CONCLUSIONS: The mean cost attributable to PMW due to switching from an oral or injectable DMTs can be an area of potential savings for insurers. The majority of the cost was paid by the insurer; however, a significant amount was still owed by pwMS. Because this sample was limited to pwMS who switched from an oral or injectable DMT, results may not be generalizable to all pwMS. The contribution of infused therapies to PMW remains unclear but may be lower than that of oral or self-injectable treatments.

SPONSORSHIP: Sponsored by F. Hoffmann-La Roche Ltd.

G2 Treatment patterns among patients with neuromyelitis optica spectrum disorder initiating off-label biologics

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BACKGROUND: Neuromyelitis optica spectrum disorder (NMOSD) is a rare, autoimmune, inflammatory disorder of the central nervous system characterized by recurrent attacks of optic neuritis and/or transverse myelitis. NMOSD treatment mainly comprised off-label immunosuppressive or immunomodulatory medications until biologics were recently approved for NMOSD.

OBJECTIVE: To examine treatment persistence, discontinuation, switching, and stacking associated with off-label biologics among patients with NMOSD.

METHODS: Adult patients with NMOSD initiating an off-label biologic between 2016 and 2021 were identified in the Veradigm electronic health record–Komodo claims database and followed for 12 months from treatment initiation. Off-label biologics included rituximab, ocrelizumab, and tocilizumab. Treatment persistence was defined as use without a 60-day treatment gap following the product-specific expected duration of clinical benefit per use. Switches were defined as initiation of a new nonindex biologic, including approved biologics (eculizumab, inebilizumab, satralizumab).

RESULTS: A total of 2,111 eligible patients were identified in the study, with a mean age of 46 years (SD = 14) and 79% were female. Rituximab was the most prevalent index therapy (78%), followed by ocrelizumab (22%) and tocilizumab (0.6%). 60% of patients (n = 1,275) were nonpersistent to index therapy during follow-up. Of the nonpersistent patients, 97% (n = 1,239) discontinued therapy and 3% (n = 38) switched treatments. Discontinuation and switching occurred, on average, 169 days (SD = 84) and 209 days (SD = 94) following treatment initiation, respectively. Among those who discontinued treatment, 49% (n = 611) restarted their index therapy, on average, 185 days (SD = 78) after discontinuation. Among patients who switched treatments, the majority (57%) did so after a 60-day gap in their initial therapy and 42% switched prior to the end of the prior therapy's expected duration of clinical benefit; only 20 patients switched from off-label to an approved biologic. Stacking with nonsteroidal immunosuppressants was observed in 10% (n = 212) of patients. The most commonly used nonsteroidal immunosuppressants in conjunction with index treatment were mycophenolate mofetil (58%), azathioprine (31%), and methotrexate (10%).

CONCLUSIONS: In this real-world study, persistence with off-label biologics was poor, and many patients experienced gaps in their therapy for several months. Switching to approved biologic therapies was uncommon. Future studies should examine the impact of off-label biologic therapies on overall health care resources and outcomes among patients with NMOSD.

SPONSORSHIP: Horizon Therapeutics.

G5 Real-world adherence patterns for a nusinersen-treated spinal muscular atrophy population by race and ethnicity

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BACKGROUND: Nusinersen (NUS), an antisense oligonucleotide approved for treatment of spinal muscular atrophy across all ages, is administered intrathecally at a dose of 12 mg via 4 loading doses (intervals of 14, 14, and 30 days) and maintenance doses every 4 months thereafter. Limited evidence exists on real-world adherence for NUS by race and ethnicity.

OBJECTIVE: To evaluate real-world adherence patterns for NUS-treated patients by race and ethnicity using a large US claims database.

METHODS: Patients on NUS were identified using anonymized claims from Komodo's Healthcare MapTM January 1, 2017, to September 30, 2022. Those likely to have complete information on date of NUS initiation and continuous enrollment 12 months prior to index were included. Using number of doses on time and distribution of interdose intervals, adherence was measured for loading and maintenance periods among those with at least 2 doses. Percentage of doses on time was determined using grace periods of 7 days for loading and 30 days for maintenance doses. Adherence was evaluated in the overall spinal muscular atrophy

population and by race and ethnicity: White, Asian/Pacific Islander (API), Black/African American (B/A), Hispanic/Latinx (H/L), other and unknown. Because patient-reported race and ethnicity is optional, missingness is a limitation for this analysis.

RESULTS: Overall, 428 individuals receiving NUS were identified, with a median age of 16 years and 52% female; 53% were pediatric (age range: 0-17), and 47% were adult (range: 18-67). Payor mix included Medicaid (49%), Commercial (42%), and Medicare (9%). The distribution of race and ethnicity was as follows: 38% White, 15% H/L, 7% B/A, 3% API, 4% Other, and 32% Unknown. The majority of NUS doses were received on-time (%): Overall (86), White (85), H/L (85), B/A (85), API (85), Other (88), and Unknown (87). Similar results were seen for loading and maintenance phases separately. Calculated interdose intervals aligned with the expected dosing schedule of NUS, such as median (quartile 1, quartile 3) days from the previous dose for the maintenance phase, were as follows: Overall (125 [118, 133]), White (125 [119, 133]), H/L (126 [119, 133]), B/A (126 [120, 138]), API (122 [113, 131), Other (122 [113, 133]), and Unknown (123 [114, 129]). Overall mean doses per patient were 3.8 and 5.7 for the loading and maintenance phases. These mean per-patient doses were similar by race and ethnicity.

CONCLUSIONS: This study demonstrates that NUS adherence was similar regardless of race or H/L ethnicity among this patient population.

SPONSORSHIP: Biogen.

G6 Understanding health care resource utilization in patients with amyotrophic lateral sclerosis with and without intravenous edaravone treatment: A retrospective administrative claims analysis

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BACKGROUND: Amyotrophic lateral sclerosis (ALS) is an incurable and progressive neurodegenerative disease. Although relatively rare, ALS requires considerable health care resource utilization (HCRU). However, little is known about how HCRU may vary by intravenous (IV) edaravone use.

OBJECTIVE: To understand the ALS-related HCRU in the United States among IV edaravone users compared to non–IV edaravone users in a real-world setting.

METHODS: This retrospective, observational study used a US administrative claims database to identify patients with ALS with and without IV edaravone treatment between August 8, 2017, (first date of US market availability) and March 31, 2022 (end of study period). This study described per patient per month (PPPM) ALS-related HCRU before and after index (treatment initiation for IV-edaravone users; August 8, 2017, for non–IV edaravone users). We employed a 6-month baseline period and a variable follow-up period (treatment initiation until death, health plan disenrollment, end of study period, IV edaravone discontinuation, or incident riluzole use—whichever came first).

RESULTS: This study identified 208 IV-edaravone users and 1,021 non–IV edaravone users. Compared with non–IV edaravone users, IV-edaravone users had more PPPM riluzole fills (IV edaravone = 0.3, non-IV edaravone = 0.1; $P < 0.001$) and PPPM outpatient visits (2.6, 1.7; $P = 0.005$) over the baseline period. Non–IV edaravone and IV-edaravone users had similar PPPM inpatient (0.02, 0.02; $P = 0.39$) and PPPM emergency department (ED) use (0.01, 0.02, P=0.27) over the baseline period. As seen during the baseline period, IV-edaravone users had more PPPM riluzole fills (0.7, 0.2; $P = 0.006$) and PPPM outpatient visits (10.8, 2.3; $P < 0.001$) compared with non–IV edaravone users over the follow-up period. In contrast to the baseline period, IV-edaravone users had more PPPM inpatient (0.07, 0.04; $P = 0.025$) and PPPM ED use (0.06, 0.01; $P = 0.015$) compared with non–IV edaravone users over the follow-up period.

CONCLUSIONS: IV-edaravone users' higher ALS-related outpatient use and riluzole use suggest that IV-edaravone users may be more proactive about their ALS care. We recommend future research to explore the hypothesis that the increased use of inpatient and ED resources among IV-edaravone users over the follow-up period is associated with an underlying difference in disease progression between these populations.

SPONSORSHIP: Mitsubishi Tanabe Pharma America, Inc.

G10 Health care resource utilization and direct health care spending among Medicare patients with essential tremor

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BACKGROUND: Essential tremor (ET) is one of the most common movement disorders with prevalence over 6% among US adults aged 65 years or older. Few studies have examined real-world patient treatment patterns and the associated economic burden of ET.

OBJECTIVE: To characterize health care resource utilization (HCRU) and health care spending for Medicare patients with incident ET across successive treatment regimens—given as

the disease progresses (ie, lines of treatment [LOT]) compared with matched non-ET individuals.

METHODS: This retrospective observational study was conducted using health care claims from the Medicare 100% sample. Age-qualified (≥65 years) Medicare patients with an ET diagnosis on 2 claims (*International Classification of Diseases, Tenth Revision, Clinical Modification*: G250) during the study period (January 1, 2005, to December 31, 2020) were compared with age- and sex-matched non-ET individuals. The earliest claim with ET diagnosis was identified as index date. Health care resource utilization and spending (2020 USD) were compared between ET and non-ET cohorts by LOT using linear regression adjusted for differences in baseline characteristics using propensity score weighting.

RESULTS: There were 74,607 patients with ET; mean age was 75 years (SD = 6.8) and 57% were female. Median months of treatment duration were 5.5 for LOT1, 3.9 for LOT2, 4.4 for LOT3, and 3.0 for LOT4 or later (LOT4+). Propranolol, primidone, and gabapentin were the most used agents across all LOTs. The use of multiple therapies increased from 5.1% in LOT1 to 20.8% in LOT2, 26.9% in LOT3, and 38.3% in LOT4+. Patients with ET had higher annualized incremental health care spending, including direct all-cause medical and pharmacy, with increases in later LOTs (LOT1 ET = $28,933 vs non-ET = $17,113; LOT2 ET = $35,448 vs non-ET = $17,287; LOT3 ET = $35,317 vs non-ET = $18,032; LOT4+ ET = $38,320 vs non-ET = $18,487; all $P < 0.001$). Across LOTs, patients with ET had higher counts of annualized inpatient, outpatient, skilled nursing facility, and emergency department claim days vs matched non-ET individuals ($P < 0.001$). Inpatient, Medicare Part B, and outpatient facility spending were the largest contributors to incremental spending.

CONCLUSIONS: These findings indicate that among Medicare beneficiaries, the extra economic burden of ET is considerable. Although treatment duration decreased with LOT progression, incremental health care spending vs non-ET control individuals increased with LOT progression, ranging from approximately $12,000 in LOT1 to nearly $20,000 in LOT4+. This substantial economic burden highlights the need for novel treatments that can improve outcomes for patients with ET.

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

G11 Long-term treatment switch and cost impact for cladribine tablets vs other disease-modifying therapies in multiple sclerosis

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BACKGROUND: Multiple sclerosis (MS) is a chronic neuroinflammatory disease associated with significant disability, reduced quality of life, and considerable economic burden. A growing array of disease modifying therapies (DMTs) are available to improve relapse outcomes and delay disease progression; however, there is limited evidence around the long-term treatment pattern and cost impact of these treatments.

OBJECTIVE: To compare the long-term treatment switch and cost impact of patients treated with cladribine tablets vs other DMTs in MS from the US payer perspective.

METHODS: An economic model with a 10-year time horizon was developed to compare the treatment switch and cost impact of cladribine tablets and ublituximab, ofatumumab, natalizumab, ocrelizumab, siponimod, ponesimod, ozanimod, fingolimod, teriflunomide, diroximel fumarate, and dimethyl fumarate from a US payer perspective. Treatment switch rates were sourced from the phase 4 CLASSIC-MS study (median follow-up of 10.9 years) for cladribine tablets and were proxied by annual discontinuation rates derived from published clinical trial data for other DMTs because of lack of data. Total treatment costs in 2022 US dollars included DMT acquisition and administration costs. Acquisition and administration costs of subsequent treatments were applied to patients who started on cladribine tablets and switched to another DMT. As several DMTs have generic drugs available, the model assumed the market share of the generic drugs in 2022.

RESULTS: The cumulative proportion of patients switching or discontinuing treatment was lowest for cladribine tablets over 10 years (absolute difference 0.4%-43.0% lower). Total treatment costs were lowest for dimethyl fumarate ($223,233), followed by alemtuzumab ($316,715) and cladribine tablets ($375,500) over 10 years. The low treatment costs of dimethyl fumarate were driven by the high usage of generic dimethyl fumarate. Total treatment costs for the other DMTs surpassed the costs of cladribine tablets by years 2-5.

CONCLUSIONS: The model projected that patients on cladribine tablets would have the lowest proportion of patients switching or discontinuing treatment and the third lowest treatment cost when evaluated over 10 years,

demonstrating the favorable clinical and economic impact of cladribine tablets over the long term.

SPONSORSHIP: EMD Serono.

G12 Rising prevalence of multiple sclerosis in the Veterans Affairs population

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BACKGROUND: Current and reliable estimates of the prevalence of multiple sclerosis (MS) in the Veterans Affairs (VA) population are essential in order to improve clinical support, health care services, and quality of life among patients with MS.

OBJECTIVE: To assess the prevalence of MS in the VA population overall and by age, race, and sex.

METHODS: Data for this retrospective study were derived from the VA Informatics and Computing Infrastructure. Veterans who had at least 1 health care encounter in the VA health system in a given year were included in the study. A claims-based validated algorithm was used to identify the cases of MS (≥2 inpatient claims with MS diagnoses or ≥3 outpatient claims with MS diagnoses or ≥1 disease-modifying therapy claims within 1 year). The yearly prevalence of MS was assessed from 2013 to 2022 for the VA population, as well as among age, race, and sex subgroups.

RESULTS: The prevalence of MS in the VA population increased steadily over the past 10 years, from 203 per 100,000 in 2013 to 225 per 100,000 in 2022. This corresponded to an average annual increase in the prevalence of MS of 1.1% over 10 years. MS prevalence was highest among those aged 35-44 and 45-54 (320 and 318 per 100,000 patients, respectively), followed by those aged 55-64 (236 per 100,000), 65-74 (177 per 100,000), 18-34 (127 per 100,000), and 75 or older (109 per 100,000) in 2022. Black patients had higher prevalence of MS in 2022 (278 per 100,000) compared with White patients (243 per 100,000). The prevalence of MS was 2.98 times higher among females vs males in 2022 (567 vs 190 per 100,000, respectively). The prevalence of MS increased over time for all age, race, and sex subgroups in the VA. People aged 65 years or older had a greater increase in the prevalence of MS in the VA over the last 10 years compared with the other age groups. Black patients had a greater increase in the prevalence of MS in the VA over the past 10 years, with the prevalence of MS in Black patients surpassing the prevalence of MS in White patients in 2016.

CONCLUSIONS: The prevalence of MS increased steadily in the VA population over the past 10 years. MS prevalence varied substantially by age, race, and sex. Black patients may have similar or higher risk of developing MS compared with White patients in the VA. The study suggested an increase in the prevalence of MS specifically in the older population, which needs to be confirmed in future studies.

SPONSORSHIP: EMD Serono.

G14 Impact of agitation symptoms in Alzheimer disease and related dementia on caregiver outcomes

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BACKGROUND: Health care costs for informal caregivers in the same household as patients with Alzheimer disease are, on average, $4,766 more per year than for noncaregivers.

OBJECTIVE: To examine whether caregiver burden, such as self-reported out-of-pocket costs, hospital length of stay, and well-being, is further amplified by agitation symptoms in patients with Alzheimer and related dementia (ADRD).

METHODS: The Health and Retirement Study (HRS) data, which include a survey component from patients and caregivers, collecting data on employment status, self-reported emotional state, and medical history, were linked with the Aging, Demographics, and Memory Study (ADAMS). The ADAMS data are a supplement that, from 2002 to 2008, provided additional information on the presentation of agitation, which was defined using the Neuropsychiatric Inventory agitation domain. To predict the presence of agitation symptoms as a dichotomous variable past 2008, we trained a predictive model on linked HRS and ADAMS data from 2002 to 2008 respondents (at 78% accuracy), which was subsequently used to predict agitation symptoms in patients with ADRD from 2018 to 2020. Caregivers of agitated vs nonagitated patients with ADRD were propensity score–matched on basic demographic features, including age, sex, and retirement status. Identified caregivers' outcomes for each of the 2 groups were compared using either a chi-square or Welch's two-sample t-test.

RESULTS: A total of 630 caregivers (n=315 in each cohort of nonagitated and agitated) were eligible and matched. Examining outcomes from the predicted agitated vs nonagitated groups identified significant differences in health care resource utilization; self-reported evaluations, ie, life satisfaction, emotional/psychiatric problems, and

overall health; and demographic and employment factors between their respective caregiver populations. All measured outcomes were worse for the caregivers of agitated patients, the largest disparities being (1) the $1,172 vs $2,145 out-of-pocket cost difference over 2 years for nonagitated and agitated populations, respectively; (2) the 18% higher number of caregivers of nonagitated patients with ADRD reported very/completely satisfied life vs the agitated population; and (3) the 42.7% higher number of caregivers of agitated patients with ADRD who reported having emotional/psychiatric problems.

CONCLUSIONS: Our findings reinforce the impact of agitation in ADRD on caregiver health and well-being and suggest that informal caregivers of patients with ADRD with agitation live with increased pressure and stress to accommodate the additional needs of their patients with ADRD.

SPONSORSHIP: Otsuka Pharmaceutical.

G15 Predicting risk of emergency department visits in patients with colorectal cancer: A machine learning approach

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BACKGROUND: Colorectal cancer (CRC) diagnosis is often delayed because of vague symptoms, leading to frequent emergency department (ED) visits. Therefore, predictive modeling for ED visits is critical for patients with CRC, particularly in disease prevention and symptom mitigation. The integration of artificial intelligence techniques, such as machine learning models, has the potential to improve the accuracy of the predictive models. However, there is still no predictive model based on machine learning to predict ED visits in patients with CRC.

OBJECTIVE: To use artificial intelligence techniques, specifically machine learning models, to predict ED visits using real-world big data.

METHODS: We conducted a retrospective cohort study to predict ED visits. The data was obtained from the 2012 to 2020 IBM MarketScan Explorys Claims-EMR Data Set. Patients with incident CRC were identified using *International Classification of Diseases, Ninth* and *Tenth Revision* codes. ED visits were identified using revenue codes. A total of 47 predictors were included in this study to predict ED visits. The dataset was divided into training and testing subsets for model training and evaluation, respectively. Seven machine learning algorithms, including Logistic Regression, K-Nearest Neighbors, Support Vector Machine, Random Forest, Gradient Boosting Machine, LightGBM, and XGBoost, were constructed to predict ED visits. The primary metric used to evaluate the performance of the algorithms was the area under the receiver operating characteristic (AUROC). Other metrics included accuracy, sensitivity, and specificity. Feature importance analysis was conducted using SHapley Additive exPlanations (SHAP) values.

RESULTS: Among the 7 machine learning algorithms, XGBoost achieved the highest AUROC value of 0.747, followed closely by LightGBM with an AUROC of 0.745. Regarding accuracy, XGBoost achieved the highest accuracy of 0.681, followed by LightGBM (0.680) and Random Forest (0.673). In terms of sensitivity, XGBoost achieved the highest value of 0.678, closely followed by LightGBM (0.601) and Random Forest (0.597). Regarding specificity, K-Nearest Neighbors (0.858) demonstrated the highest. Overall, using XGBoost demonstrated the best performance across multiple metrics, and the top 3 most important predictors were radiation therapy (SHAP = 0.311), ED visits before the diagnosis of CRC (SHAP = 0.223), and inpatient visits after the diagnosis of CRC (SHAP = 0.200).

CONCLUSIONS: The effective XGBoost model can be implemented in clinical settings to identify high-risk patients with CRC for ED visits. This top-performing machine learning algorithm has identified that radiation therapy, pre-CRC ED visits, and postdiagnosis inpatient visits are the most important features to predict ED visits. Identified patients should receive specialized treatment plans, including monitoring and regular follow-ups, to prevent emergencies. Tailored support and education can mitigate symptoms leading to ED visits.

SPONSORSHIP: None.

G19 A longitudinal analysis of multiple sclerosis phenotype transitions using medical charts in the United States

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BACKGROUND: Multiple sclerosis (MS) phenotype transitions and associated predictors have been inadequately characterized in terms of patient characteristics, disease course, or therapeutic interventions that may impact the transition from relapsing-remitting MS (RRMS) to secondary progressive MS (SPMS).

OBJECTIVE: To investigate transitions between MS phenotypes over time and explore predictors of these transitions.

METHODS: A multicenter, retrospective medical chart review of adult patients with MS (PwMS) was conducted across various clinical sites in the United States. Enrolled PwMS were required to have at least 10 years of data for descriptive and predictive analysis (follow-up cut-off date: November 18, 2021). PwMS were classified by phenotype: RRMS, primary-progressive MS (PPMS), SPMS including active secondary progressive MS (aSPMS; experiencing relapses during a 2-year period) and nonrelapsing secondary progressive MS (nrSPMS; not experiencing relapses during a 2-year period). Demographics and disability scores (Expanded Disability Status Scale [EDSS]) were abstracted. The time to transition was calculated and predictors of transition from RRMS to nrSPMS were identified using logistic regression models.

RESULTS: A total of 215 medical charts of PwMS were included in this study (RRMS = 192 and PPMS = 23 at baseline). Of the 192 patients diagnosed with RRMS , 181 (94.3%) transitioned to SPMS (mean disease duration = 13 years). At study end, 159 of 181 (87.8%) had nrSPMS (mean disease duration = 18.7 ± 5.8 years), and the remaining 22 (12.2%) had aSPMS (mean disease duration = 14.1 ± 3.8 years). At initial SPMS transition, patients with nrSPMS were older (≥40 years), had longer disease duration (mean = 13.6 ± 5.0 vs 10.8 ± 7.2 years), and had lower EDSS (mean = 3.4 vs 4.5 years) than patients with aSPMS. Older age at SPMS transition (≥40 years vs <40 years) (odds ratio [OR] [95% CI] = 4.17 [1.47-12.50]; $P = 0.007$), fewer relapses in 2 years following MS onset (OR [95% CI] = 3.57 [1.85-7.14]; $P < 0.001$), and fewer relapses in 2 years before SPMS transition (OR [95% CI] = 5.00 [1.96-12.50]; $P < 0.001$) were associated with the time to the first ever nrSPMS transition (all $P \leq 0.007$).

CONCLUSIONS: Of the 94.3% of patients with RRMS who transitioned to SPMS during the follow-up period, a majority (87.8%) transitioned without relapses (nrSPMS). Patients who were older at their initial SPMS transition with fewer relapses following MS diagnosis as well as before their transition were more likely to transition to nrSPMS. These data support the emerging view that smoldering inflammatory processes drive disability accumulation independent of relapse activity across the spectrum of MS.

SPONSORSHIP: Sanofi.

G20 Adherence rates of sphingosine-1-phosphate modulators in patients with multiple sclerosis

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BACKGROUND: Multiple sclerosis (MS) is a chronic, autoimmune, inflammatory disease of the central nervous system. Although there is no cure for MS, oral disease-modifying therapies (DMTs) such as sphingosine-1-phosphate receptor modulators (S1PRMs) offer a practical route of administration, higher efficacy, and better tolerability. As new DMTs are developed, adherence comparisons of these new therapies are warranted.

OBJECTIVE: To assess whether patients prescribed S1PRMs demonstrate higher adherence rates than patients prescribed other oral therapies (OOTs).

METHODS: This is a retrospective cohort study of commercial fully insured and Medicare patients from a large national health care payor in the United States. Adult patients with MS prescribed S1PRMs or OOTs from April 15, 2021, to April 15, 2023, were included. Patients were excluded if they switched between medication classes, were prescribed cladribine, or had fewer than 6 months of eligibility. Medication adherence was calculated using the proportion of days covered (PDC). PDC was defined as the sum of days covered by medication/number of eligible days in a period; optimal adherence was defined as a PDC of at least 0.8. We conducted a secondary analysis of only newly initiated patients, who were identified as having no prescription claims in the 6 months before their initial medication fill in the study period. We used Student's t-tests and chi-square tests to assess for differences between groups; P values less than 0.05 were significant.

RESULTS: 1,420 patients were included; 528 (37.2%) were prescribed an S1PRM. The average (SD) age of the cohort was 47.9 (11.0) years; 74% (1,053) identified as female. There were no significant differences in age or sex between those prescribed S1PRMs vs OOTs (both $P > 0.05$). Patients prescribed OOTs were more likely to be newly started on the medication (21.5% vs 15%; $P = 0.003$) compared with those prescribed S1PRMs. There were no significant differences in PDC (98.8% vs 98.6%; $P = 0.284$) and adherence (88.3% vs 86.4%; $P = 0.363$) between patients prescribed S1PRMs and OOTs. In the secondary analysis of newly initiated patients, the results were similar to the primary analysis. PDCs (98.5% vs 99.2%; $P = 0.808$) and adherence (91.1% vs. 87.5%; $P = 0.519$) were not significantly different between S1PRM and OOT cohorts.

CONCLUSIONS: In this study, there were no differences in PDC and adherence between patients prescribed S1PRMs and OOTs, with both groups reporting high percentages. Findings were consistent in newly initiated patients.

SPONSORSHIP: CVS Health.

G21 Challenges in access to care for patients with metachromatic leukodystrophy: Results from a US claims data analysis

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BACKGROUND: Metachromatic leukodystrophy (MLD) is an ultra-rare neurodegenerative genetic disease caused by deficiency of the lysosomal enzyme arylsulfatase A (ARSA). Prevalence is estimated at 1 in 100,000, although discrepancies between observed prevalence and predicted ARSA mutation carriage rate suggest that MLD is underdiagnosed. Diagnosis upon suspicion of disease involves imaging, biochemical testing, and genetic analysis. Timely diagnosis is challenging, especially absent a family history of MLD, as diagnosis is often delayed or missed. However, early diagnosis and referral is crucial to effective treatment and access to novel therapies. An understanding of the geographic burden of initial diagnosis and subsequent access to MLD care is of interest to managed care organizations.

OBJECTIVE: To understand, from real-world data, the geographic distribution of care sites for patients with early-onset MLD and the location-related burden of access to care for this population.

METHODS: De-identified medical claims for patients with MLD (*International Classification of Diseases, Tenth Revision* code E75.25) were obtained for a large US-based managed care population using Symphony PatientSource data from July 2013 to August 2022. Patient location (at ZIP2+state granularity) was cross-referenced against physician location, and centroid distance was computed for each encounter. Days with encounters outside of a patient's home location were tabulated along with the associated distance travelled. Provider specialty and affiliation data were used to identify centers of care. Census data were used to compute patient density at the ZIP2/state level.

RESULTS: Medical claims for 224 patients with early-onset MLD, with a mean (SD) age of diagnosis 3.0 (±1.6) years, was cross-referenced against location data for 3,911 treating and 783 diagnosing physicians. Diagnosing physicians with 3 or more patients with MLD are clustered in just 7 treatment centers. The patient cohort is dispersed across 43 states, with density per million residents ranging from 0.2 to 6.9. In the 187 patients who travelled outside their home area for treatment, the proportion of travel to treatment days increases from 33.4% in the 2 years immediately preceding MLD diagnosis to 40.1% immediately after, and the mean annual encounter days increase from 8.4 to 24.7. The mean travel distance postdiagnosis is weakly correlated with distance from the nearest major treatment center ($R^2 = 0.32$).

CONCLUSIONS: Patients with MLD incur significant travel burden to access care concentrated in a handful of specialized treatment centers. This burden is highest upon and immediately after diagnosis.

SPONSORSHIP: Orchard Therapeutics.

G22 Patient-reported disability progression outcomes: Findings from a multiple sclerosis value-based agreement

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BACKGROUND: Value-based contracts (VBCs) aim to measure and demonstrate the value of prescription medications based on predefined clinical indicators in real-world patient populations. Such contracts are established between payers and manufacturers where payment for medications is directly tied to patient outcomes, creating shared risk between the 2 entities. VBCs have gained popularity as the health care industry shifts away from volume-based payment models to value-based systems that support affordable, high-quality care for patients. Despite the increased use of VBCs, a lack of transparency around contract elements and limited reporting of findings have made it difficult to evaluate their impact on the health care system. Therefore, we aim to report findings from a multiple sclerosis (MS) VBC based on a patient-reported outcome (PRO) measure of disability. MS PROs provide important insights into the patient's health and are valuable ways to monitor treatment efficacy.

OBJECTIVE: To report the findings of a VBC that was executed in a large regional health system for patients with MS who were prescribed interferon β-1a/dimethyl fumarate.

METHODS: In this prospective real-world analysis, commercial or health insurance exchange members were included based on the VBC parameters. Disability progression was assessed using a PRO, Patient-Determined Disease Steps (PDDS), as the measurement tool for the contract. In the VBC, members aged at least 18 years with an MS diagnosis were included in the contract. A baseline score was collected for eligible members, with follow-up scores occurring

between 90 and 180 days after the baseline score. If a follow-up score was greater than the baseline score, a subsequent PDDS score was collected between 90 and 120 days to determine if the PDDS score remained elevated, indicating that the member had disability progression.

RESULTS: During the contract period, there were 410 patients eligible for PDDS collection (241 dimethyl fumarate and 169 interferon β-1a patients). There were 162 patients who were lost to follow-up and 64 patients who were ineligible per the contract. Of the remaining 184 eligible patients (107 dimethyl fumarate and 77 interferon β-1a patients), 21 (11%) patients had confirmed disability progression (6 dimethyl fumarate patients [5.6%] and 15 interferon β-1a patients [19.5%]), which was lower than expected as compared with randomized clinical trial findings.

CONCLUSIONS: Our findings suggest that meaningful PROs can be operationalized in an innovative VBC; however, positive impacts are limited by the high dropout rate.

SPONSORSHIP: UPMC.

G23 Real-world use of diroximel fumarate among fumarate-naïve patients for the treatment of multiple sclerosis in the United States

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BACKGROUND: Diroximel fumarate (DRF) is a disease-modifying therapy (DMT) in the fumarate class for the treatment of relapsing forms of multiple sclerosis (MS).

OBJECTIVE: To assess treatment outcomes including relapse and health care resource use (HCRU) and medical costs among fumarate-naïve patients initiating DRF for the treatment of MS.

METHODS: A retrospective observational study was conducted using Komodo Health Sentinel Claims Database (October 2019-May 2022) among adult patients with MS without prior fumarate exposure and continuous enrolment 12 months before (baseline) and 12 months following DRF initiation (follow-up). *P* values were calculated using Wilcoxon signed-rank tests and McNemar tests. Costs were reported in US dollars.

RESULTS: 504 fumarate-naïve DRF patients were eligible; the average (SD) age was 45.8 (11.5) years and the majority were female (80.6%) and commercially insured (69.2%). The baseline average (SD) Charlson Comorbidity Index score was 0.6 (1.1). The majority had 0 prior DMTs (56.3%) or 1 prior DMT (40.7%) during baseline. The mean (SD) proportion of days covered (PDC) during follow-up was 91.8 (13.8), and 85.5% patients were adherent to DRF (PDC ≥ 80%). The claim-based annualized relapse rate (ARR) decreased significantly from 0.44 (95% confidence interval = 0.38-0.50) during baseline to 0.33 (0.27-0.39) during the follow-up on-treatment period (mean [SD] = 8.5 [4.1] months), resulting in a 25.4% ARR reduction ($P = 0.009$). Significant reductions in the proportions of patients seeking medical care were observed across all settings, resulting in significant per patient per year cost reductions in the average total all-cause medical expenditure (baseline to follow-up: $16,154 vs $13,639; $P < 0.001$) as well as the average total MS-related medical expenditure ($9,617 vs. $6,949, $P < 0.001$), primary driven by reductions in outpatient and inpatient costs.

CONCLUSIONS: DRF initiation was associated with significant reductions in claim-based ARR, as well as all-cause and MS-related HCRU and medical costs among fumarate-naïve patients, demonstrating the clinical and economic benefits of DRF for patients with MS and payers.

SPONSORSHIP: Biogen.

G24 Understanding multiple sclerosis phenotype-specific treatment satisfaction and unmet needs in the United States and Europe: A patient survey study

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BACKGROUND: Multiple sclerosis (MS) is a leading cause of disability worldwide. Disease-modifying therapies (DMTs) aim to potentially delay disease progression in patients with MS (PwMS). Although numerous DMTs are available, with varied efficacy and safety profiles, the satisfaction and experience with current treatments and unmet needs among PwMS across all subtypes in real-world settings remain unexplored.

OBJECTIVE: To understand—through a survey of PwMS—satisfaction and unmet needs with their MS treatments in the United States and Europe by MS phenotype.

METHODS: A mixed-method research approach including targeted literature review, qualitative focus group interviews (n = 57), and a quantitative patient survey (n = 501) was undertaken. Descriptive statistics assessed experience and satisfaction with current treatments among adult PwMS by phenotypes: relapsing-remitting MS (RRMS), secondary progressive MS (SPMS), and primary progressive MS (PPMS).

RESULTS: Among all PwMS, less than 50% of patients were "very satisfied" with their most recent DMTs (47% RRMS, 38% PPMS, and 22% SPMS). DMT switches in the past 12 months were more common in patients with PPMS (mean age: 42 ± 8.8

years) and SPMS (44±10.3 years) than in those with RRMS (43±8.9 years) (PPMS: 38%; SPMS: 32%; RRMS: 18%). Among the most recent DMTs not meeting expectations, the inability to fully control MS symptoms was the top treatment attribute, followed by a lack of long-term safety information in patients with RRMS and disease progression in patients with SPMS and PPMS. Convenience of treatment (34%-40% of patients with RRMS and SPMS) and treatment enabling patients to maintain daily activities and functioning (35% of patients with PPMS) were attributes ranking highest in the "very satisfying" category, whereas safety (3% of patients with RRMS) and quality of life (6%-9% of patients with SPMS and PPMS) ranked highest as "very dissatisfying." The majority of patients (51% RRMS and 63% SPMS and PPMS) were likely to consider switching to a new daily oral DMT that would not deplete immune cells and improve physical function and physical symptoms. Among MS symptoms, mobility, ability to think clearly, and memory difficulties/ability to process new information were the most important to improve across all PwMS.

CONCLUSIONS: Although many PwMS were satisfied with their current DMTs, there remains an unmet need for more effective treatments that fully control MS symptoms, especially for patients with SPMS and PPMS. Despite the multitude of DMTs available (especially in RRMS), those that improve mobility and cognitive functions would best address the treatment needs across PwMS.

SPONSORSHIP: Sanofi.

G30 Demographic, clinical, and treatment characteristics of patients diagnosed with migraines and treated with preventive therapy within an academic health care setting

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BACKGROUND: Migraines affect 10% of people worldwide, and in the United States, 20% of women and 11% of men experienced a migraine during the past 3 months. The annual economic impact of migraines has been estimated at $22 billion in the United States.

OBJECTIVE: To evaluate the demographic, clinical, and treatment characteristics of patients diagnosed with migraine and treated with preventive therapy within an academic health care setting.

METHODS: A retrospective cohort study was conducted using electronic medical record data from the University of Utah Health System for adolescents and adults (aged ≥12 years) with an *International Classification of Diseases, Tenth Revision* code (G43.x) suggestive of migraines between January 1, 2016, and December 31, 2022, who received preventive medication therapy. Patients were stratified into the headache clinic (HAC) or non–headache clinic (NHAC) cohort based on a single visit to the headache clinic. Descriptive statistical analyses were performed to compare patient characteristics between cohorts where appropriate.

RESULTS: During the study time frame, 809,274 patients visited a UHealth clinic, of whom 5,101 were included in this analysis. The HAC cohort included 3,696 (72%) patients, whereas 1,405 (28%) made up the NHAC cohort. The median age was 45 and 43 years for the HAC and NHAC cohorts, respectively ($P<0.005$). White/Caucasian patients were more likely to be treated in the HAC (74%) compared with Black (66%) and Asian/Pacific Islander patients (57%; $P<0.005$). Likewise, more non-Hispanic patients (73%) were treated at the HAC compared with Hispanic patients (65%; $P<0.005$). Of patients diagnosed with migraines by the Family & Preventative Medicine department (n=1,960, 38%), 925 (18%) were later treated in the HAC. Most HAC patients (n=2,024, 55%) were diagnosed within the HAC. Compared with the NHAC cohort, the HAC cohort had a significantly higher proportion ($P<0.005$) of patients with major depressive disorder (64% vs 57%), sleep disorder (58% vs 40%), hypertensive disease (39% vs 30%), and cerebrovascular disease (17% vs 3%). Across all patients with migraine, anticonvulsants (n=1,960, 38%) were the most frequently used first-line preventive treatment. The HAC cohort used more onabotulinumtoxinA (39% vs 2%, $P<0.005$) and calcitonin gene–related peptide inhibitors (31% vs 4%, $P<0.005$) compared with the NHAC cohort for migraine prevention.

CONCLUSIONS: Demographic and clinical characteristics influence a patient's access to migraine care. Patients seen in the HAC are older, are more often White, and have more comorbidities. More specialized treatments (such as calcitonin gene–related peptide inhibitors and onabotulinumtoxinA) were more commonly prescribed by clinicians in the HAC.

SPONSORSHIP: Aruene Corporation.

G31 Effects of insurance coverage and antiseizure medication formulary policies on the experiences of patients with epilepsy and health care professionals: A qualitative study

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BACKGROUND: Scant information is available regarding the challenges experienced by patients with epilepsy (PWE) and

health care professionals (HCPs) to access epilepsy care and treatment.

OBJECTIVE: To understand the impact of insurance coverage and antiseizure medication (ASM) formulary policies on stakeholder experiences related to disease management and ASM initiation, access, affordability, and adherence.

METHODS: Qualitative interviews with HCPs and non-HCPs were conducted from January 13, 2023, to February 17, 2023. Interview transcripts were analyzed for key themes and insights.

RESULTS: 40 HCPs (15 primary care physicians [PCPs], 10 neurologists, 5 epileptologists, 10 pharmacists) and 25 non-HCPs (13 PWE, 6 caregivers, 6 patient advocates) were included. Limited specialist access results in PCPs playing an outsized role in ASM refills/ongoing management of PWE. Specialists most often treat complex cases and prescribe initial ASM but are associated with shortages, long wait times, and low Medicaid acceptance. Pharmacists play a small role in epilepsy management that is limited to notifying HCPs of insurance requirements. Advocacy organizations help patients with transport and, in limited instances, with copay assistance for ASMs (via bridge programs, pharma companies, or charitable organizations). Most patients are adherent with ASMs and have positive HCP relationships; nonadherent patients tend to be those who are older or those with psychiatric disorders. Some patients encounter barriers to specialist care (long wait times, travel distance, insurance type [local practices may accept little/no Medicaid patients], limited telehealth visits). PCPs typically use first/second-generation ASMs and avoid third-generation ASMs, whereas specialists use third-generation ASMs more often and are willing to appeal insurance denials. Appeals are time consuming and can delay treatment by up to 6 weeks. Challenges faced by Medicaid/Medicare- vs commercially insured patients include access to fewer specialists; delays in ASM prescription, treatment initiation, and specialist-led treatment changes; fewer treatment options (access to newer/branded ASMs); and higher out-of-pocket costs.

CONCLUSIONS: This study identified challenges and insights among PWE and HCPs in managing epilepsy treatment. Findings suggest PCPs would benefit from education/support to manage more complex cases with newer ASMs and navigate the insurance approval process. Improved access to specialists is needed. Medicaid patients would benefit from programs that connect them with specialists, patient advocacy programs, and financial assistance to help address barriers to epilepsy care.

SPONSORSHIP: UCB Pharma.

G33 Characteristics, health care resource utilization, and costs among patients with multifocal motor neuropathy: A US claims database cohort study

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BACKGROUND: Multifocal motor neuropathy (MMN) is a rare disease that is often misdiagnosed. Real-world evidence describing the burden of MMN is needed.

OBJECTIVE: To assess the characteristics and economic burden associated with MMN.

METHODS: This retrospective study included de-identified patients (all ages) from the US Optum Research Database (October 2015 to December 2021) with at least 1 claim, an MMN *International Classification of Diseases, Tenth Revision, Clinical Modification* (ICD-10-CM) code (first diagnosis date = index date), and continuous enrollment 12 months pre- and post-index. Patients were classified into MMN (≥2 claims with MMN ICD-10-CM codes ≥30 days apart and no amyotrophic lateral sclerosis diagnosis during the minimum post-index period) and MMN-mimic (excluded from MMN) cohorts. Health care resource utilization (HCRU) and costs were MMN related if claims had an MMN diagnosis code or had a medication/procedure for MMN.

RESULTS: Of 904 patients with a claim for MMN, 336 (37%) met the study definition of MMN; all others were classified into the MMN-mimic cohort (63%). Patients with MMN were younger in age (mean: 64.9 vs 66.8 years; $P = 0.047$) and had longer follow-up (mean: 31.8 vs 27.2 months; $P < 0.001$) than patients with MMN-mimics. More than half (~54%) of patients in both cohorts were men. For all-cause HCRU during the pre-index period, the proportion of patients in the MMN cohort (vs MMN-mimic cohort) with inpatient stays was significantly lower (21% vs 31%; $P = 0.001$), whereas ambulatory visits, emergency visits, and pharmacy use were comparable. Post-index, all-cause HCRU categories were comparable between cohorts. Health care costs were higher for the MMN vs the MMN-mimic cohort during both pre-index and post-index periods for all-cause total costs (mean: pre-index $58,974 vs $48,132 [$P = 0.100$] and post-index $74,187 vs $50,652 [$P = 0.002$]) and MMN-related total costs (mean: pre-index $23,625 vs $12,890 [$P = 0.011$] and post-index $39,521 vs $11,938 [$P < 0.001$]). In the MMN cohort, MMN-related ambulatory visits increased post-index (mean: 1.9 visits pre-index vs 7.7 visits post-index).

CONCLUSIONS: All-cause and MMN-related costs were greater for patients with MMN relative to patients with mimic conditions. Increased costs may be attributable to disease complexity and the burden associated with MMN.

SPONSORSHIP: Takeda Pharmaceuticals USA, Inc.

G34 Infusion-related costs for HyQvia compared with Hizentra in chronic inflammatory demyelinating polyradiculoneuropathy

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BACKGROUND: Chronic inflammatory demyelinating polyradiculoneuropathy (CIDP) is a rare autoimmune disease that affects the peripheral nervous system resulting in symmetric weakness and impaired sensory function in the arms and legs. Individuals with CIDP typically receive standard of care, including corticosteroids, plasma exchange, or intravenous immunoglobulin therapy, but additional treatments are needed to improve adherence, convenience, and tolerability. HyQvia (immune globulin infusion 10% [human] with recombinant human hyaluronidase) subcutaneous immunoglobulin (IG + HY), a facilitated subcutaneous immunoglobulin therapy, is being evaluated for maintenance treatment for most individuals with CIDP and allows for less-frequent injections (every 4 weeks) compared with weekly administered Hizentra (immune globulin subcutaneous [human], 20% liquid; SCIG 20%).

OBJECTIVE: To model infusion-related costs over 1 year for US adults with CIDP receiving maintenance therapy with IG + HY vs SCIG 20%.

METHODS: Using a US commercial payers' perspective over a 1-year time horizon, an economic model evaluated infusion-related costs per person for adults receiving maintenance therapy with IG + HY or SCIG 20%. Parameter and infusion-related cost data were identified through a CIDP literature review and ad hoc searches. Similar resource-use estimates were used for both treatment groups, but with differences captured in dosing frequency, frequency of at-home vs infusion center administration, and frequency of nursing visits for assistance with at-home administration.

RESULTS: All annual infusion-related costs were lower for IG + HY compared with SCIG 20%. Total infusion-related costs were $4,808 for IG + HY and $6,484 for SCIG 20%. Annual infusion center visits contributed most to costs, at $3,345 for IG + HY and $4,295 for SCIG 20%. Additional annual infusion-related costs included self-infusion pump and materials (IG + HY: $1,017; SCIG 20%: $1,017), nurse hours (IG + HY: $446; SCIG 20%: $1,128), and manual push infusion and materials (IG + HY: $0; SCIG 20%: $44). Additionally, a scenario analysis demonstrated that IG + HY was cost saving if more than 53% of individuals received IG + HY at home.

CONCLUSIONS: This analysis compared infusion-related costs for individuals with CIDP treated with IG + HY vs SCIG 20% over a 1-year time horizon. From a US payer perspective, IG + HY resulted in total annual savings of $1,676 per person with CIDP. Savings are attributed to less-frequent administration, resulting in fewer per-person infusion costs and nursing hours.

SPONSORSHIP: Takeda Pharmaceuticals USA, Inc.

G38 Epidemiology and treatment patterns in essential tremor: A systematic literature review

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BACKGROUND: Essential tremor is a serious, progressive, and chronically debilitating neurological disorder that can profoundly affect physical and psychosocial functioning. Although it is among the most common movement disorders, limited data describe the epidemiology and treatment patterns of essential tremor.

OBJECTIVE: To summarize the epidemiology and treatment patterns in patients with essential tremor through a systematic literature review.

METHODS: Electronic databases (Embase, MEDLINE, EBM Reviews, EconLit), reference lists, conference proceedings, and handpicked databases and websites were searched to identify real-world publications from 2000 to 2022. Reported prevalence, proportions of patients receiving treatment for essential tremor, most common treatments, adherence, persistence, and discontinuation were summarized.

RESULTS: Prevalence of essential tremor was reported in 35 studies (0.041%-13.04%). Three studies reported incidence; 2 reported the incidence per 100,000 person-years (18.2-636) and 1 reported incidence as a percentage (3.4%). Despite heterogeneous sample sizes across studies, prevalence and incidence of essential tremor increased with age, with no consistent sex-specific differences observed. Twelve studies reported the proportion of patients receiving medication for essential tremor (adult [n = 11], median 72%; pediatric [n = 1], 33.7%-38.1%). Most prescribed drug classes were beta-blockers (adult, 61%-64%; pediatric, 55%-57%) and anticonvulsants (adult, 53%-61%; pediatric, 36%-44%). Propranolol and primidone were the most common medications used to treat essential tremor. One study

found mean adherence was similar for propranolol (79%) and primidone (80%), and median persistence was 32 months for propranolol and 27 months for primidone. Discontinuation for primidone (10.4%-63.7%) and propranolol (16.4%-54.6%) reportedly occurred because of adverse events and lack of efficacy.

CONCLUSIONS: Studies on the epidemiology and treatment patterns of essential tremor shared large interstudy heterogeneity driven by differences in study design, population selection, and diagnostic criteria. Prevalence and incidence of essential tremor increased with age; however, there is a paucity of data on incidence. Given the significant disease burden of essential tremor, future research on prevalence, incidence, and treatment patterns among patients with essential tremor is needed.

SPONSORSHIP: Jazz Pharmaceuticals.

G39 Health care resource utilization and costs incurred over 12 months by patients with migraine initiating calcitonin gene–related peptide monoclonal antibodies: A US real-world study

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BACKGROUND: Calcitonin gene–related peptide monoclonal antibodies (CGRP mAbs) are newer agents approved for migraine prevention. Limited information is available comparing the health care resource utilization (HCRU) and costs associated with initiating different CGRP mAbs.

OBJECTIVE: To compare all-cause and migraine-related HCRU and direct costs in patients with migraine initiating the self-injectable CGRP mAbs galcanezumab (GMB), fremanezumab, and erenumab.

METHODS: This retrospective cohort study used data from Merative Marketscan Commercial and Medicare Databases. Adults with at least 1 claim (first claim = index) for the above CGRP mAbs between May 2018 and September 2020 (index period), with continuous enrollment for 12 months pre- (baseline [BL]) and post-index (follow-up), were included. Patients with a claim for index drug during BL were excluded. Mean HCRU and mean total costs (inpatient, outpatient, and outpatient pharmacy costs) were evaluated over 12 months post-index. Propensity score matching was used to balance the GMB vs fremanezumab (2:1) and GMB vs erenumab (1:1) cohorts. *P* values <0.05 were considered statistically significant. BL vs 6 months post-index results were also compared (results not shown here).

RESULTS: After matching, patient demographics and clinical characteristics were similar between GMB vs fremanezumab (n = 2,674 pairs) and GMB vs erenumab (n = 3,503 pairs) cohorts. Relative to BL, numerically lower all-cause and migraine-related HCRU (inpatient and outpatient visits) was observed in both cohorts over the follow-up period, whereas outpatient pharmacy HCRU was numerically higher. All-cause and migraine-related total costs (mean) were higher over the follow-up period in both cohorts (all $P < 0.05$). Mean all-cause and migraine-related cost increases were numerically similar for GMB vs fremanezumab ($503 vs $518 and $467 vs $468) and for GMB vs erenumab ($504 vs $499 and $462 vs $443). Outpatient pharmacy costs contributed greatly to migraine-related costs, whereas all-cause costs were greatly driven by outpatient costs.

CONCLUSIONS: HCRU and direct cost differences observed at 12 months following initiation of self-injectable CGRP mAbs for migraine prevention were numerically similar across cohorts. Although overall results demonstrate parity between GMB vs fremanezumab and erenumab as related to HCRU and direct costs, other outcomes associated with treatment utilization may indicate favorable results with one self-injectable CGRP mAb over others.

SPONSORSHIP: Eli Lilly and Company.

G40 Health care resource utilization and costs incurred over 24 months after initiating galcanezumab or standard-of-care preventive migraine treatments

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BACKGROUND: Studies have shown reductions in health care resource utilization (HCRU) and direct costs 6 to 12 months (mo) following initiation of galcanezumab (GMB) and standard-of-care (SOC) preventive migraine treatment. A gap in knowledge exists in understanding longer-term HCRU and costs.

OBJECTIVE: To describe all-cause and migraine-related HCRU and direct costs in patients (pts) with migraine initiating GMB or SOC preventive migraine treatment (anticonvulsants, beta-blockers, antidepressants, or onabotulinumtoxinA) over a 24-mo follow-up.

METHODS: This retrospective study used Optum de-identified Market Clarity Data. Adults diagnosed with migraine, newly initiating GMB or an SOC preventive migraine therapy from September 2018 to March 2020 and continuous enrollment for 12 mo before (baseline [BL]) and 24 mo after (follow-up) the index date (date of first GMB or SOC claim)

were included. Patient demographics and clinical characteristics were summarized descriptively. All-cause and migraine-related HCRU and direct costs for GMB vs SOC cohorts were reported as mean [SD] change per pt per month (PPPM) from BL to 24-mo follow-up and compared using a two-sample t-test. Costs were inflated to 2022 US$.

RESULTS: A total of 2,363 (mean [SD] age: 44.4 [12.0] years; 87.1% females) and 61,576 (mean [SD] age: 43.3 [13.9] years; 81.9% females) pts were identified for the GMB and SOC cohorts, respectively. During BL or on the index date, 44.8% and 20.1% of pts had chronic migraine in the GMB and SOC cohorts, respectively. Relative to BL, all-cause mean [SD] count of PPPM office visits decreased for GMB while it did not change for SOC (0.09 [1.3] vs 0.0 [1.3], $P = 0.001$) at follow-up; emergency department (ED) visits decreased in both GMB and SOC cohorts (–0.02 [0.3] vs –0.03 [0.2], $P = 0.008$). Migraine-related office visits decreased for GMB and increased for SOC (0.04 [0.3] vs 0.03 [0.2], $P < 0.001$), and reduction in ED visits was similar between cohorts. Relative to BL, mean [SD] all-cause PPPM costs of office visits decreased for GMB and increased for SOC (–$3.7 [473.3] vs. $24.5 [571.0], $P = 0.005$). Migraine-related PPPM office visit costs increased in both cohorts and was higher for SOC ($2.8 [143.9] vs. $25.8 [129.8], $P < 0.001$).

CONCLUSIONS: Following GMB or SOC initiation, some all-cause and migraine-related HCRU and direct cost reductions were observed. Analyses accounting for differences in pts demographic, clinical, and treatment characteristics are necessary to fully evaluate and compare HCRU and direct costs between GMB and SOC initiators.

SPONSORSHIP: Eli Lilly and Company.

G41 Health care resource utilization before and after initiation of cannabidiol, among Medicaid patients with Dravet syndrome, Lennox-Gastaut syndrome, tuberous sclerosis complex, and other refractory epilepsies

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BACKGROUND: The effects of cannabidiol (CBD) on health care resource utilization (HCRU) are unclear.

OBJECTIVE: To assess changes in HCRU before and after initiation of CBD, among Medicaid patients with Dravet syndrome (DS), Lennox-Gastaut syndrome (LGS), tuberous sclerosis complex (TSC), and other refractory epilepsies.

METHODS: This is a retrospective pre-post study using the US MarketScan administrative claims database. Patients were included if they had LGS, DS, TSC, or other refractory epilepsies and initiated CBD (EPIDIOLEX) between June 2019 and December 2021, with 180 days of continuous Medicaid enrollment before and after initiation. HCRU includes epilepsy-related (primary diagnosis) and all-cause physician office visits, hospital outpatient visits, emergency department (ED) visits, home health, inpatient admissions, and intensive care unit admissions. The number of events for each type of HCRU per patient per month was assessed in the 6 months of pre- and post-CBD initiation. Segmented regression-based interrupted time-series (ITS) analyses were applied to investigate trends of HCRU use. Regression coefficients from the ITS analyses were used to compute the annualized changes in HCRU after CBD initiation.

RESULTS: A total of 1,663 patients were included, with a mean age of 16 ± 11 years, and 44% were female. LGS accounted for 973 patients, DS for 70, TSC for 72, and other refractory epilepsies for 568. Intellectual disorder was the most frequent comorbidity (71%), followed by autism (21%), anxiety (11%), and learning disabilities (11%). Approximately 53% of patients had Charlson Comorbidity Index scores greater than 3. Increasing trends before CBD and decreasing/flat trends after CBD initiation were observed for the HCRU. For epilepsy-related HCRU, trends for physician office visits, hospital outpatient visits, and ED visits were statistically significant ($P < 0.05$) but underpowered for hospital/intensive care unit admissions. For all-cause HCRU, all trends were statistically significant except for hospital admission (underpowered). Annualized estimation suggests that CBD initiation is associated with a reduction of approximately 4 epilepsy-related and 5 all-cause physician office visits, 1 epilepsy-related and 4 all-cause hospital outpatient visits, and 1 epilepsy-related and all-cause ED visit per patient per year.

CONCLUSIONS: Post-CBD initiation among Medicaid patients was associated with significantly lower epilepsy-related physician office, hospital outpatient, and ED visits, as well as lower all-cause HCRU except for inpatient admissions (underpowered). Progressively decreasing trends of HCRU were associated with CBD use.

SPONSORSHIP: Jazz Pharmaceuticals, Inc.

G42 Productivity loss and indirect costs associated with galcanezumab compared with standard-of-care treatment in adults with migraine

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BACKGROUND: Little knowledge exists regarding the productivity loss and indirect costs for patients with migraine

initiating calcitonin gene–related peptide monoclonal antibodies and standard-of-care (SoC) preventive medications.

OBJECTIVE: To describe the productivity loss and indirect costs among adult patients with migraine initiating galcanezumab (GMB) or SoC (anticonvulsants, beta-blockers, tricyclic antidepressants, calcium channel blockers, angiotensin II receptor antagonists, or onabotulinumtoxinA) using an administrative claims database.

METHODS: This retrospective study used de-identified claims data from MerativeTM MarketScan Health and Productivity Management Database. Adults diagnosed with migraine, newly initiating GMB or an SoC preventive migraine therapy from May 2018 to June 2021 (first claim = index date) and continuous enrollment for 12 months before (baseline) and 12 months after (follow-up) index, were included. Changes in hours of absence (absenteeism); days of short-term disability (STD) and long-term disability (LTD); and costs (USD/month) associated with absenteeism, STD, and LTD from baseline to follow-up were examined in the GMB and SOC cohorts.

RESULTS: A total of 6,933 and 34,563 patients qualified for the GMB and SoC cohorts, respectively. Patients in the GMB cohort were older (42.6 ± 11.1 vs 41.9 ± 11.9) and were more often female (87.4% vs 83.2%) compared with the SoC cohort (all $P < 0.001$). Changes in productivity outcomes from baseline to follow-up were examined for subsets of patients with available data (absenteeism: 699 SoC and 111 GMB; STD: 6,436 SoC and 1,313 GMB; LTD: 6,425 SoC and 1,309 GMB). Following initiation of GMB, patients with an absence or LTD claim had a numerically lower number of absence hours (–0.3 hour/month) or LTD days (–1.2 days/month) along with numerically lower absenteeism-related (–$8/month) or LTD-related (–$141/month) costs. Conversely, the SoC cohort demonstrated slight numeric increases in absenteeism (0.3 hour/month; $8/month) and LTD outcomes (0.3 day/month; $30/month) among patients with at least 1 claim. The SoC cohort demonstrated significant increases in STD outcomes (0.6 day/month; $88/month, all $P < 0.001$); STD outcomes were slightly higher for the GMB cohort (0.2 day/month; $33/month) but did not reach the level of statistical significance.

CONCLUSIONS: Patients initiating GMB showed a numerically reduced absenteeism and LTD days and costs compared with numerical increases seen with those initiating SOC. Numerically lower increases in STD outcomes were seen for GMB vs SOC, with SOC significantly increasing from baseline.

SPONSORSHIP: Eli Lilly and Company.

G43 Real-world effectiveness, treatment satisfaction, and treatment optimization of ubrogepant for acute treatment of migraine when used with anti–calcitonin gene–related peptide monoclonal antibody and onabotulinumtoxinA preventives: COURAGE results

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BACKGROUND: Ubrogepant is an oral calcitonin gene–related peptide (CGRP) receptor antagonist approved for acute treatment of migraine in people on or off preventive treatments.

OBJECTIVE: To evaluate the real-world effectiveness, treatment satisfaction, and treatment optimization of ubrogepant for acute treatment of migraine when used in combination with an anti-CGRP monoclonal antibody (mAb) and onabotulinumtoxinA for preventive treatment.

METHODS: COURAGE was a prospective observational study using data collected via the Migraine Buddy application from adults who had at least 3 migraine attacks in the last 30 days, treated at least 3 prior attacks with ubrogepant, and were concurrently taking an anti-CGRP mAb, onabotulinumtoxinA, or both. This analysis was conducted among participants who reported at least 1 treated attack after enrollment and were taking both an anti-CGRP mAb and onabotulinumtoxinA concurrently with ubrogepant. Self-assessments included meaningful pain relief (MPR) and return to normal function (RNF) at 2 and 4 hours after dosing and patient satisfaction (using a 7-point rating scale) and acute treatment optimization (assessed via the Migraine Treatment Optimization Questionnaire-4) after 30 days of real-world treatment. This analysis used generalized linear models to account for correlation of repeated attacks.

RESULTS: The analysis population included 69 participants (mean age 43.8 years, 89.9% female, 84.4% White) who reported a total of 354 attacks. During the first treated attack, 63.8% (95% CI = 52-74) and 39.1% (95% CI = 28-51) of participants achieved MPR and RNF, respectively, at 2 hours after the dose; at 4 hours, these percentages increased to 84.1% (95% CI = 73-91) and 55.1% (95% CI = 43-66). Across up to 10 ubrogepant-treated attacks, MPR and RNF were achieved in 49.6% (95% CI = 44-55) and 30.8% (95% CI = 26-36) of attacks, respectively, at 2 hours after the dose and 66.6% (95% CI = 62, 72) and 48.4% (95% CI = 43-54), respectively, at 4 hours. Most participants reported satisfaction with ubrogepant used in combination with their current preventives (59.4%); 78.1%

of participants achieved acute treatment optimization (Migraine Treatment Optimization Questionnaire-4 score ≥4).

CONCLUSIONS: Real-world use of ubrogepant in combination with an anti-CGRP mAb and onabotulinumtoxinA was effective across repeated migraine attacks and was associated with treatment satisfaction; additionally, the majority of participants achieved acute treatment optimization.

SPONSORSHIP: Allergan (prior to its acquisition by AbbVie).

H00-H95 Diseases of the Eye and Adnexa

(eg, macular degeneration)

H2 Evaluation of treatment and switching patterns for dry eye disease medications using linked electronic health record and claims data

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BACKGROUND: Dry eye disease (DED) manifests as loss of homeostasis of the tear film and damage to the ocular surface.

OBJECTIVE: To understand the characteristics and treatment patterns of patients with DED with ocular drops.

METHODS: This retrospective cohort study used the American Academy of Ophthalmology's Intelligent Research in Sight Registry linked with Komodo Health claims data (January 2017 to June 2022). Patients aged 18 years or older without a claim for a DED agent in the prior 12 months were followed for at least 1 year. The first pharmacy claim between January 2018 and June 2021 for Restasis, Xiidra, or Cequa defined the index date and agent. Discontinuation was defined as a 60-day or more gap between the expected days supply and next refill and switch as a claim for a different DED therapy prior to discontinuing the index agent. Time on index therapy was time between the index claim and date of switch, or date of discontinuation if no switch occurred, or end of days supply for the final claim for the index therapy if no switch or discontinuation occurred.

RESULTS: Overall, 73,309 patients with DED with a mean age 59.9 years, 81% female met the inclusion criteria; 47,819 received Restasis, 23,699 Xiidra, and 1,791 Cequa. 62% were White and 6.6% Black, but race was unknown for 23.1% of patients. 10.9% were Hispanic, but ethnicity was missing for 29.8% of patients. Mean time on therapy was higher for Restasis (185.6.1±130.5 days) and Xiidra (200.3±134.8 days) compared with Cequa (140.7±123.8 days). Only a small proportion, 2.8% of Restasis, 6.5% of Xiidra, and 7.8% of Cequa patients, switched therapy. More than 90% of patients discontinued treatment within the first year. Importantly, 57.1% of Restasis, 53.2% of Xiidra, and 70.0% of Cequa patients discontinued after their first script, and 85.7% of Restasis, 86.3% Xiidra, and 91.8% Cequa patients discontinued within 180 days.

CONCLUSIONS: A significant proportion (>90%) of patients prescribed medication for DED discontinued their treatment within a year. Moreover, the majority (57%-70%) discontinued prior to their first refill. Only a small proportion of patients switched to another prescription treatment. Reason for discontinuation was not available; however, perceived lack of clinical effectiveness, tolerability, or medication cost may lead to lack of adherence to these prescribed therapies for chronic DED. Some patients may switch to over-the-counter products; however, their use was not captured in this dataset.

SPONSORSHIP: Bausch & Lomb.

H4 Advances in payer and provider collaboration to facilitate optimal outcomes for the management of retinal diseases and identify health plan best practice recommendations

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BACKGROUND: Although the choice of treatment for retinal diseases is largely based on the experience and preference of the treating retinal specialist and patient preferences, payers are key stakeholders in impacting treatment selection through formulary placement, step therapy, and site-of-care policies, which can affect member access.

OBJECTIVE: To enlist the input of key payer stakeholders and retinal specialists to identify barriers to appropriate access to retinal care and develop best practices for coverage policy and benefit design.

METHODS: The multiphase approach began with Impact Education, LLC, conducting a series of 5 expert interviews and 2 virtual working group meetings in 2022. Retina specialists (n=14) and payer experts (n=21) participated in the 2 working group meetings. Payers represented more than 170 million covered lives, including approximately 2 million Medicare lives. Feedback from the working group meetings validated the original needs assessment and informed the content development for national continuing education activities that followed.

RESULTS: As a result of the expert interviews and working group meetings, key educational messages were identified specific to the management of retinal diseases, including age-related macular degeneration, diabetic retinopathy/diabetic macular edema, and retinal vein occlusion. These included the following: treat early and often to salvage vision, use US Food and Drug Administration–approved vascular endothelial growth factor treatments to ensure quality, safety, and efficacy, remove administrative barriers to timely treatment, and develop evidence-based and disease-specific coverage policies. Based on these results, content was developed for continuing education programs for payers, including a multitrack live webcast series attended by 610 payer professionals, representing 226 organizations, and with an estimated impact on more than 268,500 covered lives being managed for retinal diseases. Evaluation data showed 74% of webcast series participants plan to implement changes or had their current practice and/or administrative routine reinforced. There was a 19% increase (pre- to post-activity data) in participants' confidence to implement medical and pharmacy benefit design strategies that facilitate patient access to evidence-based treatment options for retinal diseases.

CONCLUSIONS: A multiphase payer and provider collaboration is an effective strategy to identify and address payer practice gaps and educational needs for appropriate access to retinal disease therapies and related plan strategies for improving the overall management of retinal diseases.

SPONSORSHIP: Regeneron Pharmaceuticals, Inc.

H5 Geographic atrophy disease progression among patients enrolled in Medicare Advantage

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BACKGROUND: Geographic atrophy (GA) is the dry form of advanced age-related macular degeneration (AMD) that leads to visual impairment. Until recently, there was no approved treatment. Published studies estimate one million people in the United States have GA in at least one eye. There is a lack of real-world evidence from a US payer perspective on clinical outcomes like GA disease progression among Medicare Advantage enrollees.

OBJECTIVE: To examine disease state progression from GA without subfoveal involvement (SFI) to GA with SFI and to blindness among Medicare Advantage enrollees.

METHODS: The study was conducted using Humana's Medicare Advantage plan claims for individuals aged 65 years or older. Enrollees with incident GA diagnosis during July 2018 through June 2021 were identified (cases) and propensity score matched to enrollees without GA diagnosis (controls) using baseline demographic and clinical characteristics. For cases, index date was date of first GA diagnosis. For controls, index date was randomly assigned based on distribution of index dates among cases. A 12-month pre-index and at least 12 months post-index enrollment was required. Disease state progression was evaluated using *International Classification of Diseases, 10th Revision, Clinical Modification* codes.

RESULTS: A total of 9,511 GA cases were matched 1:1 to controls. Mean follow-up time was 2.3 years. Among cases, 4,781 (50.3%) patients had GA without SFI and 4,697 (49.4%) had GA with SFI at index. Among cases without SFI at index, 479 (10.2%) progressed to GA with SFI and 173 (3.6%) developed blindness during follow-up. Of cases with SFI, 312 (6.6%) developed blindness as well as 51 (0.5%) controls. At the end of follow-up, survival probabilities for blindness among cohorts were 99.3% (controls), 94.4% (GA without SFI), and 90.4% (GA with SFI, Kaplan-Meier: Log-Rank test $P<0.001$). Significant predictors of progression to GA with SFI were wet AMD at baseline (hazard ratio [HR] = 5.70; $P<0.001$), and Elixhauser comorbidity score of 4-5 (HR = 1.46; $P=0.006$), and greater than 5 (HR = 1.40; $P=0.035$), and residence in suburban location (HR = 0.77; $P=0.023$). Diagnosis of GA without SFI (HR = 6.77; $P<0.001$) and GA with SFI (HR = 12.59; $P<0.001$) were strongly associated with increased risk of developing blindness.

CONCLUSIONS: GA was associated with development of blindness, and the rate of progression may depend upon the stage of GA. Among patients with GA, GA with SFI indicated faster progression to blindness. The strongest predictor of progression to GA with SFI was cooccurring wet AMD.

SPONSORSHIP: Apellis Pharmaceuticals, Inc.

H6 Impact of visual impairment on health care resource utilization and associated costs for real-world patients with geographic atrophy

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BACKGROUND: Geographic atrophy (GA) is an advanced form of age-related macular degeneration that can lead to irreversible vision loss and greatly impact patients' quality of life.

OBJECTIVE: To gain a better understanding—by using real-world databases—of the clinical characteristics, disease

progression, health care resource utilization (HCRU), and associated costs in patients with GA.

METHODS: This study is a retrospective cohort study using the American Academy of Ophthalmology Intelligent Research in Sight (IRIS) Registry in patients diagnosed with GA (based on *International Classification of Diseases, 10th Revision, Clinical Modification* code) between April 1, 2016, and December 31, 2021. Patients aged 50 years and older with at least 1 valid visual acuity (VA) measurement at the index date and at least 1 at 1 year from the index date were included. Evidence was generated to describe demographic and clinical characteristics, as well as visual outcomes. HCRU and associated costs will be assessed for a subcohort with available claims data. This subcohort will be assessed using the IRIS Registry linked to the Komodo Health Research Dataset, which is an insurance claims dataset.

RESULTS: Interim results identified 156,698 patients with GA with 21,912 (14%) followed for 5 years. The average age of the cohort was 80.74 (SD = 7.95) and 65% were female. Known patient insurers include 68% Medicare fee-for-service, 12% commercial, and 11% Medicare Advantage. 46% of patients had bilateral GA. At baseline, 45% of patients had neovascular age-related macular degeneration, 34% had cataracts, and 21% had glaucoma or ocular hypertension. VA at baseline averaged 56 (SD, 26) converted Early Treatment of Diabetic Retinopathy Study letters and 47 (SD = 29) at year 5. Annual VA change was assessed and showed that 43%-48.5% of patients have stable VA (<5 letters lost or gained), 18%-20% have mild (5< 15 letters) VA decline, and 14%-16% have significant (≥15 letters) decline. Annual HCRU will be characterized for a subcohort of patients with GA and further stratified by disease progression based on VA. Overall care, ophthalmic care, and other categories of care will be described in all settings.

CONCLUSIONS: This retrospective cohort study uses the IRIS Registry, which is the largest electronic health record based comprehensive eye disease and condition registry in the United States. By leveraging real-world data from the IRIS Registry, this study will provide a better understanding of the clinical characteristics of patients with GA, as well as their HCRU and associated costs.

SPONSORSHIP: Iveric Bio.

H7 The safety of avacincaptad pegol in combination with anti-vascular endothelial growth factor treatment in patients with wet age-related macular degeneration

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BACKGROUND: The advanced stages of age-related macular degeneration (AMD), wet AMD, and geographic atrophy (GA) are leading causes of vision loss in individuals aged 50 years and older. Several anti-vascular endothelial growth factor (VEGF) agents have been approved for wet AMD. Complement inhibition has been shown to reduce GA growth in phase 3 studies, with one complement inhibitor recently approved for GA, and another, avacincaptad pegol (ACP), currently under US Food and Drug Administration review.

OBJECTIVE: GA development is common in patients with wet AMD 5 years after initiating anti-VEGF treatment. Here we present the safety data from phase 1 and 2 studies evaluating ACP in combination with an anti-VEGF in patients with wet AMD.

METHODS: The phase 1 OPH2000 study had a 2-part design; an ascending dose of ACP (0.03, 0.3, 1 mg) + ranibizumab 0.5 mg (weeks 0, 4, 8, 12, 16, 20) and a parallel group whereby patients with wet AMD received either ACP 0.3, 1 or 2 mg + ranibizumab 0.5 mg (weeks 0, 4, 8, 12, 16, 20). OPH2007 was a phase 2a study in treatment-naive patients with wet AMD who were enrolled in 1 of 4 cohorts: (1) monthly ranibizumab 0.5 mg day 0 + ACP 4 mg day 2 for 5 months; (2) monthly ranibizumab 0.5 mg + ACP 2 mg on the same day for 5 months; (3) ranibizumab 0.5 mg + ACP 2 mg on the same day and ACP 2 mg day 14 for month 1 and 2 followed by ranibizumab 0.5 mg + ACP 2 mg on the same day for months 3-5; and (4) ranibizumab 0.5 mg + ACP 2 mg on the same day and ACP 2 mg day 14 for month 1 and 2 followed by ACP 2 mg day 0 and ranibizumab 0.5 mg + ACP 2 mg on day 2 for months 3-5. Safety, including loss of visual acuity (VA), was evaluated.

RESULTS: The most common adverse events with ACP in combination with an anti-VEGF agent were related to the injection procedure. In the phase 1 study, no safety issues related to VA were observed, and VA improved in all treatment groups (0.3, 1, 2 mg) that received 6 injections of combined treatment (n = 43). At the week 24 follow-up, 46%, 47%, and 60% of patients who received 0.3, 1, and 2 mg + ranibizumab 0.5 mg, respectively, gained at least 15 letters. In the phase 2a study in treatment-naive patients (n = 64), no patient across the 4 cohorts experienced a meaningful loss of VA over 6 months. In cohort 2, 60% of patients who received monthly ranibizumab 0.5 mg + ACP 2 mg on the same day gained at least 15 letters.

CONCLUSIONS: The phase 1 and 2a studies demonstrate ACP 2 mg in combination with anti-VEGF agent was well tolerated in patients with wet AMD.

SPONSORSHIP: Iveric Bio.

I00-I99 Diseases of the Circulatory System

(eg, atrial fibrillation, pulmonary hypertension)

13 Acute kidney failure adds significant burden to in-hospital outcomes in patients with heart failure: A propensity matched sample analysis of Healthcare Cost and Utilization Project data

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BACKGROUND: Acute kidney failure (AKF) is a frequently observed complication among patients with heart failure (HF), leading to a significant escalation in morbidity, mortality, and associated health care costs. Estimating the financial implications stemming from increased mortality risk, hospital stays, and overall charges is essential for effective future cost management strategies.

OBJECTIVE: To evaluate the impact of AKF on various in-hospital outcomes among patients diagnosed with HF.

METHODS: Data from the Healthcare Cost and Utilization Project National Inpatient Sample, 2017 was used to identify patients with principal diagnosis of HF (*International Classification of Diseases, 10th Revision* [ICD-10] code: I50) and secondary diagnosis of AKF (ICD-10 code: N17). Propensity score matching was performed using socioeconomic and demographic, as well as hospital-specific, variables to control for severity and case mix. Outcome variables, including length of stay, total charges, and mortality, were compared between patients with HF with and without AKF.

RESULTS: Out of the initial 42,440 hospitalizations for HF, a subgroup of 9,345 patients (22.0%) were diagnosed with AKF. A matched cohort consisting of 8,564 patients with and without AKF was created, resulting in similar mean ages (70 years) and female patients accounted for (44%) of the 2 cohorts. Majority of patients were White (71%), whereas Hispanics represented only 7% of the cohorts. Medicare and Medicaid covered 70% and 12% of matched cohort population, respectively. The mean length of stay was 23.71% longer in patients with HF with AKF as compared with patients with HF without AKF (7.46 ± 10.08 days [mean ± SD] vs 6.03 ± 8.52 days; $P < 0.001$). The mean hospital charges were 33% higher in patients with HF with AKF ($83,441 ± 251,427.59) than those without AKF ($63,339 ± 178,785; $P < 0.001$). The paired t-test analysis revealed that patients with HF with AKF had a higher mortality rate (6.00%) compared with the patients with HF without AKF (4.99%), which was an increase of 20% relative risk ($P < 0.001$).

CONCLUSIONS: AKF presents a significant burden among patients diagnosed with HF, leading to increased morbidity, mortality, and health care costs. Our findings emphasize the importance of early detection, management, and targeted interventions for AKF in patients with HF to improve outcomes and optimize health care resource utilization.

SPONSORSHIP: None.

14 Association between oral anticoagulant type and costs of care following myocardial infarction with percutaneous coronary intervention in patients with nonvalvular atrial fibrillation

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BACKGROUND: Clinical trials have shown improved outcomes with direct-acting oral anticoagulant (DOAC) vs warfarin regimens in patients with nonvalvular atrial fibrillation (NVAF) with acute coronary syndrome and/or undergoing percutaneous coronary intervention (PCI). Although the economic burden of NVAF is known to be substantial, data on costs associated with NVAF after a myocardial infarction (MI) event are limited.

OBJECTIVE: To investigate the impact of anticoagulant type on real-world costs of care post-hospitalization in patients with NVAF following an MI managed with PCI.

METHODS: This retrospective, observational study used data from 2 large, nationally representative US claims databases: Optum Research and PharMetrics Plus. Patients with NVAF were included in the study if they were hospitalized for MI and underwent PCI between January 1, 2014, and December 31, 2020, and initiated treatment exclusively with a DOAC (dabigatran, rivaroxaban, apixaban, or edoxaban) or warfarin during the index hospitalization or within 365 days of discharge. Once identified, patients were followed for up to 12 months postdischarge. Per-patient-per-month (PPPM) total all-cause direct health care costs, stroke/systemic embolism–related costs, and major bleeding-related costs post-hospitalization were compared for patients treated with DOACs vs warfarin using 2-part regression analyses.

RESULTS: Among 2,647 patients (1,997 DOAC, 650 warfarin) from the Optum database, baseline patient characteristics were generally similar for DOAC and warfarin treatment groups. Among 2,056 patients (1,468 DOAC, 588 warfarin) from the PharMetrics database, some patient characteristics differed significantly between groups, suggesting that patients receiving warfarin had more comorbidities and a higher risk of stroke and major bleeds. Adjusted all-cause, stroke/ systemic embolism–related, and bleed-related costs post-hospitalization were numerically lower for DOACs vs warfarin in the Optum database (mean difference $473, $24, and $84 PPPM, respectively) and significantly lower for DOACs in the PharMetrics database (mean difference $1,065, $523, and $224 PPPM, respectively; $P < 0.05$).

CONCLUSIONS: In this study, real-world data demonstrated that post-hospitalization costs of care for patients with NVAF who were hospitalized for MI and underwent PCI were lower with DOAC treatments than with warfarin. Thus, DOACs may be associated with lower overall health care costs for this patient population. Further research is needed to validate this conclusion.

SPONSORSHIP: Bristol Myers Squibb and Pfizer Alliance.

15 Cost-effectiveness of sotagliflozin for the treatment of patients with diabetes and recent worsening heart failure

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BACKGROUND: Heart failure (HF) is among the leading causes of death in the United States. Sotagliflozin is an inhibitor of sodium-glucose cotransporter-2 and sodium-glucose cotransporter-1. In phase 3 clinical trials, sotagliflozin significantly reduced the composite of cardiovascular death and HF events in patients with HF.

OBJECTIVE: To quantify the cost-effectiveness of sotagliflozin compared with standard of care (SoC) from a US payer perspective.

METHODS: An economic model was created for patients hospitalized for HF reflective. The model used a Markov structure with a 30-year time horizon. Clinical outcomes of interest were hospital readmission, emergency department (ED) visits, and all-cause death after an HF hospitalization. Baseline event frequencies were derived from previously published observational studies; sotagliflozin's efficacy was derived from the SOLOIST-WHF trial. Patient health benefit was quantified using quality-adjusted life years (QALYs). Costs included pharmaceutical costs ($598 per 30-day supply), rehospitalization, ED visits, and adverse events. Economic value was measured using the incremental cost-effectiveness ratio statistic.

RESULTS: Sotagliflozin use decreased annualized rehospitalization rates over the study period by 34.5% (0.228 vs 0.348, difference: −0.120), decreased annualized ED visits by 40.0% (0.091 vs 0.153, difference: −0.061), and decreased annualized mortality by 18.0% (0.298 vs 0.363, difference: −0.065) relative to SoC, resulting in a net improvement in QALYs of 0.425 relative to SoC (2.305 vs 1.880). Use of sotagliflozin increased costs by $19,374 over the lifetime of the patient ($31,953 vs $12,579), driven largely by increased pharmaceutical cost. Estimated incremental cost-effectiveness ratio was $45,596 per QALY. Model results were most sensitive to sotagliflozin's efficacy and price.

CONCLUSIONS: Sotagliflozin is a cost-effective alternative for patients hospitalized with HF.

SPONSORSHIP: Lexicon Pharmaceuticals, Inc.

16 Differences in health care resource use and cost by treatment choice among patients with symptomatic obstructive hypertrophic cardiomyopathy: Real-world analysis of 2016-2021 claims data

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BACKGROUND: For symptomatic obstructive hypertrophic cardiomyopathy (soHCM), standard treatment traditionally consists of pharmacotherapy with beta-blockers (BB) or calcium channel blockers (CCB) as first-line; combination therapy (BB+CCB, disopyramide+BB, disopyramide+CCB, or disopyramide+BB+CCB) as second-line; and invasive procedures, such as septal reduction therapy (SRT), for patients refractory to pharmacotherapy. In addition, patients may require a pacemaker or implantable cardioverter-defibrillator (ICD).

OBJECTIVE: To determine whether health care resource use (HRU) and costs vary by initial treatment in soHCM, and whether combination therapy and invasive procedures are associated with higher HRU and costs than monotherapy with BB or CCB.

METHODS: We analyzed Symphony medical and pharmacy claims from 2016 to 2021 and associated *International Classification of Diseases, 10th Revision* codes to identify adult patients in the United States with soHCM. Patients included in the study cohort were required to be treatment-naive (≥12 months' activity before first treatment) and symptomatic (fatigue, chest pain, syncope, dyspnea, heart

failure, or palpitations within 3 months of index date). We grouped patients by first index treatment (BB, CCB, disopyramide, combination therapy, SRT, ICD, or pacemaker). We report HRU and charges (per person per year [PPPY], in US dollars) by initial treatment.

RESULTS: Among 9,490 patients with soHCM, the median age was 64 years and 55.9% were female. For initial therapy, patients received BB (50.9%), CCB (16.3%), disopyramide (0.9%), combination therapy (9.9%), SRT (8.7%), ICD (10.7%), or pacemaker (2.4%). Among patients treated with pharmacotherapy, 87.4% were prescribed monotherapy. Outpatient visits were the main driver of HRU (mean 11.5 PPPY) and varied by initial treatment (BB = 11.0, CCB = 10.5, disopyramide = 7.2, combination therapy = 12.1, SRT = 12.9, ICD = 12.0, pacemaker = 16.5). Urgent care visits were more frequent than inpatient visits (means: 5.19 and <1 PPPY, respectively). All-cause incurred charges were $51,835 PPPY overall and varied by treatment (BB = $45,995, CCB = $41,283, disopyramide = $27,015, combination therapy = $53,893, SRT = $48,778, ICD = $80,725, and pacemaker = $74,856).

CONCLUSIONS: In this large, US-based cohort of treatment-naive patients with soHCM, initial therapy was most commonly BB and CCB monotherapy, but a substantial minority received combination medical therapy or an invasive procedure. Unadjusted HRU and costs were high for most patients but greater for those treated initially with combination therapy and invasive procedures.

SPONSORSHIP: Cytokinetics, Incorporated.

17 Economic impact of sotagliflozin among patients with heart failure: Budget impact analysis from US payer perspective

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BACKGROUND: Sotagliflozin, an inhibitor of sodium-glucose contransporter-2 and sodium-glucose contransporter-1 is approved for use in heart failure (HF). Phase 3 clinical trials showed sotagliflozin significantly reduces the composite of cardiovascular death and HF events in patients with HF with type 2 diabetes, but sotagliflozin's budget impact is unclear.

OBJECTIVE: To quantify the payer budget impact of sotagliflozin following market entry.

METHODS: The budget impact was modeled as the change in medical and pharmacy cost from using sotagliflozin in addition to the standard of care (SoC) compared with the SoC alone among US patients hospitalized with HF. Costs included pharmacy, inpatient, emergency department visits, and other medical and adverse event costs. Sotagliflozin's impact on health care resource utilization was estimated from the SOLOIST-WHF clinical trial; baseline event rates under SoC were derived from published real-world data analyses. Sotagliflozin price was $598 for a 30-day supply. The model estimated pharmacy, medical, and total plan cost impact from a US payer perspective assuming a 1% and 5% uptake among hospitalized patients with HF in year 1 and 5 respectively. Budget impact was measured separately for commercial payer and all-payer scenarios.

RESULTS: Among a health plan with 1 million members, 2,000 commercial and 3,445 all-payer patients would have an index HF hospitalization treatable by sotagliflozin per year. For commercial payers, sotagliflozin use increased pharmacy cost ($7,276 per year) vs SoC. Because of reduced readmission rates and post-acute emergency department visits, annual medical costs fell by $4,729 (sotagliflozin: $9,825 vs SoC: $14,554) resulting in a change in total spending of $2,547 per year (sotagliflozin: $17,101 vs SoC: $14,554). A 1% (5%) sotagliflozin uptake in the first (fifth) year after entry would increase commercial health plan per member per month (PMPM) costs by $0.05 ($0.24). In the all-payer scenario, annual medical costs per patient fell by $2,367 (sotagliflozin: $4,920 vs SoC: $7,287) resulting in a change in total spending per patient of $4,909 per year (sotagliflozin: $12,196 vs SoC: $7,287). A 1% (5%) sotagliflozin market share across all payers in the first (fifth) year would increase increased PMPM costs by $0.17 ($0.83).

CONCLUSIONS: Health plans adopting sotagliflozin can expect to see an increase in pharmacy costs, but about a third of this cost was offset by lower medical cost. PMPM spending is expected to increase less for commercial payers, as HF is more prevalent among Medicare beneficiaries than the commercially insured.

SPONSORSHIP: Lexicon Pharmaceuticals, Inc.

18 Nonmedical switching or discontinuation patterns among patients with nonvalvular atrial fibrillation treated with direct oral anticoagulants in the United States

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BACKGROUND: Patients with nonvalvular atrial fibrillation (NVAF) may experience anticoagulation therapy switches/discontinuations (S/D) because of medical or nonmedical reasons (eg, changes in formulary or benefit plan).

OBJECTIVE: To describe S/D patterns in patients with NVAF in 2019 by quarter and evaluate socioeconomic risk factors of S/D.

METHODS: Adults with NVAF initiating stable (no gap >60 days) direct oral anticoagulant (DOAC; apixaban, dabigatran, edoxaban, rivaroxaban) treatment from July 2018 to December 2018 were selected from Symphony Health Solutions' Patient Transactional Datasets (April 1, 2017, to January 31, 2021). Switch to another DOAC/warfarin and discontinuation patterns were reported by quarter in patients who switched/discontinued in the first (Q1), second (Q2), and third (Q3) quarters of 2019, separately. Nonmedical switching or discontinuation was defined as the difference in S/D rate in 2019 Q1 and the mean rate across the other quarters of 2019. The effects of socioeconomic factors on switch/discontinuation rates were estimated using multivariable logistic models.

RESULTS: Overall, 46,793 patients (78.7% ≥65 years; 52.6% male; 7.7% Black) were included. 18.0% switched or discontinued in Q1 vs mean 8.8% (Q2 = 10.9%; Q3 = 8.7%; Q4 = 6.9%), corresponding to nonmedical switching or discontinuation of 9.2%. During the quarter following the S/D, more patients with S/D in Q1 remained untreated (Q1 = 77.0%; Q2 = 74.3%; Q3 = 71.2%) and fewer reinitiated index DOAC (Q1 = 17.6%; Q2 = 20.8%; Q3 = 24.0%). Factors associated with higher likelihood of switch/discontinuation in Q1 were race (Black vs White: odds ratio = 1.14; $P = 0.003$), age (18-44 vs ≥75 years: 1.90, $P < 0.001$; 45-54 vs ≥75: 1.47, $P < 0.001$), sex (male vs female: 1.07, $P = 0.004$), insurance type (noncommercial vs commercial: 1.06; $P = 0.036$), and household income (<$30,000 vs $100,000+: 1.13, $P = 0.003$; $30,000-$49,999 vs $100,000+: 1.11, $P = 0.023$). Results were similar for S/D evaluated during the entire year.

CONCLUSIONS: Patients with NVAF recently stabilized on DOACs tended to switch or discontinue more in Q1 2019 vs other quarters, potentially driven by formulary changes early in the year and benefit plan design elements. Patients with S/D in Q1 were more likely to remain untreated than those who did so later in the year, suggesting long-term impacts on discontinuation because of nonmedical reasons. Black, younger, and lower-income patients were more likely to experience S/D, highlighting potential socioeconomic discrepancies in treatment continuity.

SPONSORSHIP: Janssen Scientific Affairs

19 Prescription patterns of sodium-glucose cotransporter 2 inhibitors in patients with heart failure following recent guideline release: An interrupted time series analysis

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BACKGROUND: Subgroup analyses of cardiovascular safety trials first observed a potential clinical benefit of sodium-glucose cotransporter 2 inhibitors (SGLT2i) in patients with heart failure (HF) in 2015. Subsequently, in 2019 and 2020, randomized controlled trials of patients with HF and/or diabetes mellitus confirmed the ability of this pharmacologic class to reduce the composite, clinical outcome of cardiovascular mortality and HF hospitalizations. SGLT2i were formally acknowledged as an effective treatment of HF in the 2021 Update to the 2017 American College of Cardiology Expert Consensus Decision Pathway for Optimization of Heart Failure Treatment. On April 1, 2022, the American Heart Association/American College of Cardiology/Heart Failure Society of America Guideline for the Management of Heart Failure was released. These guidelines provided class 1a recommendations for SGLT2i to treat HF with reduced ejection fraction (HFrEF).

OBJECTIVE: To evaluate whether publication of the 2022 HF guideline was associated with a change in the use of SGLT2i in patients with HFrEF.

METHODS: A population based interrupted times series analysis was conducted to compare pre- and post-guideline SGLT2i prescription patterns among adult (≥18 years) patients with HFrEF. We used Inovalon data from 2016 to October 2022, covering nearly 200 million lives and containing professional and institutional medical claims from mostly Commercial and some Medicare Advantage and Medicaid payers. Individuals were classified as having a diagnosis of HFrEF based on the presence of at least 1 *International Classification of Diseases, 10th Revision* for HFrEF (ICD-10: I50.2x) during a 1-year lookback period. Primary outcome measure was SGLT2i prescription rate per 1,000 HFrEF patients/month. We also performed subgroup analyses by sex and age groups.

RESULTS: An average of 274,478 patients with HFrEF were observed each month. Mean SGLT2i prescription rates for patients with HFrEF before and after the guidelines change were 34.0 (SD = 13.9) and 77.6 (SD = 8.5) per 1,000 patients/month, respectively. There was a significant increase in the SGLT2i prescription rate immediately after guideline release (6.1 SGLT2i per 1,000 patients with HFrEF; $P < 0.008$),

and the change was sustained throughout the remainder of the study period. The SGLT2i prescription rates post-guideline changes increased relative to that of pre-guideline change on a trend of 1.8 patients per 1,000 patients/month ($P < 0.001$). Similar patterns were observed in subgroup analyses by sex and age groups.

CONCLUSIONS: The rate of SGLT2i prescriptions increased after publication of the 2022 HF guideline. Further research is needed to show if there is any difference in SGLT2i prescribing patterns based on other patient characteristics.

SPONSORSHIP: None.

I10 Strategies for advancing equitable, evidence-based care for patients with heart failure: A new survey of managed care professionals across Medicare Advantage plans

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BACKGROUND: Heart failure (HF) is a major cause of mortality and morbidity in the United States and also represents a significant economic burden. Evidence shows that guideline-directed medical therapy (GDMT) is underused in patients with HF, especially in minority, racial, and ethnic patient populations. Managed care professionals are uniquely positioned to inform initiatives that advance equitable, guideline-directed care in HF.

OBJECTIVE: To evaluate perceptions regarding the economic impact of worsening HF and health care disparities, implementation of GDMT, considerations for patient selection, and equitable, evidence-based use of new worsening HF therapies.

METHODS: Invitations to complete the online survey were emailed to payers from Medicare Advantage programs between January and February 2023.

RESULTS: Survey responses were received from 129 payers. The most common work settings were health plan administration (37%), health system administration (14%), and specialty pharmacy (12%). On average, payers reported managing 3,412 patients with HF monthly. Of surveyed payers, 66% estimated that less than 50% of patients with HF covered by their organization were on GDMT, and 30% estimated that less than 25% of patients with HF were on GDMT. The use of sacubitril/valsartan required preauthorization or stepped therapy in 31% of respondents' plans and was not included in the formulary in 5%. Similarly, the use of sodium-glucose cotransporter 2 inhibitors required preauthorization or stepped therapy in 28% of respondents' plans and was not included in the formulary in 9%. Top barriers identified for authorizing add-on therapies for HF were "fulfilling stepped care requirements" (36%), and "lack of documentation supporting patient eligibility" (32%). Proposed strategies for overcoming barriers to GDMT implementation included removing stepped therapy requirements, streamlining documentation and workflows, and removing provider education. When asked about racial/socioeconomic status disparities in HF treatment, 50% of respondents considered that race/socioeconomic status has "considerable" or a "great deal" of impact on access to treatments for HF. Proposed strategies for reducing disparities in HF care included increasing racial minority representation in clinical trials, educating providers on implicit bias, and expanding access to care in underserved populations.

CONCLUSIONS: Underuse of GDMT among Medicare Advantage patient populations with HF was common and formulary requirements were identified as barriers. The survey findings can inform strategies to improve equitable, guideline-directed care for patients with HF.

SPONSORSHIP: Cytokinetics, Inc.

I11 Comparative effectiveness and safety of apixaban and warfarin among patients with venous thromboembolism in an extended treatment setting

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BACKGROUND: Among patients with venous thromboembolism (VTE), extended anticoagulant (AC) treatment beyond the minimum standard duration of 3 months is recommended in those at high thrombotic risk to prevent recurrences of VTE.

OBJECTIVE: To evaluate the risk of recurrent VTE and major bleeding (MB) among VTE patients prescribed apixaban or warfarin (reference) beyond the initial 3 months of AC therapy.

METHODS: This retrospective study included patients aged 18 years or older diagnosed with VTE who initiated apixaban or warfarin within 30 days following the first VTE event using a large administrative claims database that represents

at greater than or equal to 140 million patients enrolled in various US health plans. Data from July 1, 2016, to April 30, 2022, were used. The AC treatment start date was defined as the AC initiation date. Patients were required to have at least 3 months of continuous enrollment and at least 3 months of continuous primary AC treatment following the AC initiation date. The end of 3 months of primary treatment was defined as the index date. The follow-up period was from the day after the index date until the earliest of disenrollment, discontinuation of index AC, switch to another AC, or end of study period. Inverse-probability treatment weighting was used to balance the treatment cohorts on relevant demographic and clinical characteristics. The recurrent VTE and MB outcomes were evaluated and compared in the follow-up period. Incidence rates (IRs) for the outcomes were calculated per 100 person-years. Cox proportional hazard models were used to evaluate the adjusted risk of recurrent VTE and MB reported as hazard ratios (HRs) along with a CI of 95%.

RESULTS: After selection criteria were applied, a total of 90,245 patients had extended apixaban and 17,088 had extended warfarin treatment beyond the initial 3 months of AC therapy. After inverse-probability treatment weighting, the treatment cohorts were balanced on selected baseline patient characteristics. In the follow-up period, IRs per 100 person-years and risk for MB events were lower for apixaban vs warfarin (IR = 3.21 vs 4.15, $P < 0.0001$; HR = 0.74, 95% CI = 0.67-0.82). IRs per 100 person-years and risk for recurrent VTE were similar for apixaban and warfarin (IR = 2.16 vs 2.24, $P = 0.5850$; HR = 0.91, 95% CI = 0.79-1.04).

CONCLUSIONS: In this observational cohort analysis of patients with VTE, extended AC treatment beyond 3 months with apixaban was associated with a lower risk of MB and a similar risk of recurrent VTE compared with extended warfarin treatment.

SPONSORSHIP: Bristol-Myers Squibb and Pfizer.

J00-J99 Diseases of the Respiratory System

(eg, asthma, COPD, rhinitis)

J2 Clinical and economic burden of hospitalized respiratory syncytial virus cases among adults aged 50 years and older with chronic conditions

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BACKGROUND: Despite underdiagnosis in routine care, respiratory syncytial virus (RSV) is a common cause of acute respiratory illness (ARI) in older adults and adults with chronic conditions who are at increased risk of severe outcomes of RSV.

OBJECTIVE: To describe the clinical and economic burden of hospitalized cases of diagnosed RSV in adults aged at least 50 years with chronic conditions.

METHODS: This retrospective cohort study identified patients aged at least 50 years in an administrative claims database including members with commercial insurance or Medicare Advantage with Part D. Among adults with chronic conditions, diagnosed RSV cases were identified from July 2016 to June 2020 using *International Classification of Diseases, Tenth Revision, Clinical Modification* diagnosis codes. Control patients (without RSV) were identified during this period and matched to RSV cases based on their clinical, demographic, and health care utilization characteristics. For RSV cases, matching characteristics were measured during the 12 months before their first ARI diagnosis within the RSV episode (the index date); for controls, characteristics were measured during a corresponding 12-month baseline period. Total costs and total cost differences for matched cohorts of RSV cases vs controls were assessed as well as hospital discharge status and 30-day mortality for hospitalized RSV cases.

RESULTS: The matched cohorts included 10,639 diagnosed RSV cases and 36,151 control patients. Patients with diagnosed RSV cases had a mean (SD) age of 75.6 (9.7) years and a mean (SD) Charlson Comorbidity Index score of 5.1 (4.0); baseline characteristics were similar in matched controls. Most diagnosed RSV cases (69.5%) were hospitalized. During the period of 7 days before to 30 days after the index date, mean (SD) total costs were $42,719 ($55,628) and $7,317 ($26,249) for diagnosed RSV cases with a hospitalization and matched controls, respectively, with a difference of $34,282 (paired t-test $P < 0.01$). For the subset of hospitalized

RSV cases in adults aged 50-59 years, this cost difference was $31,811. Among hospitalized RSV cases, 48.4% were discharged home, another 21.2% were discharged home with home health follow up, 4.8% were discharged to hospice, and 4.3% were discharged to a skilled nursing facility. All-cause 30-day mortality was 8.1% for hospitalized RSV cases.

CONCLUSIONS: Among adults with chronic conditions, hospitalized RSV episodes were associated with substantial clinical and economic burden, including risk of mortality. Although results were limited to patients with diagnosed RSV, findings show the importance of RSV prevention in these patients.

SPONSORSHIP: GlaxoSmithKline Biologicals SA (VEO-000322).

J3 Respiratory syncytial virus older adult vaccine implementation plans among health systems and pharmacies in the United States

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BACKGROUND: Respiratory syncytial virus (RSV) results in substantial burden each year among older adults and adults at increased risk of severe RSV. Although RSV vaccines were recently approved by the US Food and Drug Administration for use in adults aged 60 years or older, the impact of these vaccines in reducing RSV burden will depend on vaccine implementation efforts.

OBJECTIVE: To better understand adult vaccination policies in health systems and pharmacies and assess RSV awareness, vaccine implementation plans, and anticipated vaccination barriers/facilitators.

METHODS: Qualitative interviews and a cross-sectional, web-based survey of vaccine policymakers and immunization coordinators were conducted between April and May 2023 to better understand RSV vaccine implementation plans in health systems and pharmacies. Because of the relatively small number of individuals in these positions (and the large number of adults served by their organizations), the study included a limited sample. Responses were analyzed descriptively, with interviews providing additional insights.

RESULTS: Interviews (n = 10) and surveys (n = 50) were completed by an equal number of health system and pharmacy respondents. Most respondents consider it important to protect older adults from RSV (84%) and reported that it would be acceptable (90%) and feasible (88%) to recommend/administer RSV vaccines to older adults. Anticipated RSV vaccination coverage goals in the 2023-2024 season ranged from 15% to 100% (mean = 54%), with nearly all organizations (98%) likely to recommend or implement policies facilitating the coadministration of RSV and influenza vaccines. On average, respondents estimated that RSV awareness is lower among older adults (32%) vs health care providers (HCPs)/pharmacists (76%), with limited patient awareness of RSV expected to be the most challenging barrier to vaccination. However, to support RSV vaccination, respondents ranked RSV disease and vaccine education as being most important for pharmacists, followed by physicians, patients, and other HCPs. Most respondents (84%) plan to use awareness campaigns and educational materials at HCP settings to support RSV vaccination, with many also planning to use patient phone calls (38%), emails (34%), and text messages (30%).

CONCLUSIONS: This study provides insights on the acceptability of older adult RSV vaccines and implementation plans in health systems and pharmacies, including anticipated barriers to vaccination and strategies to overcome these barriers. Results can be used by population-based decision-makers to inform RSV vaccine implementation plans more broadly.

SPONSORSHIP: GlaxoSmithKline Biologicals SA (VEO-000524).

J5 Evaluation of a digital remote monitoring program on asthma rescue and controller medication utilization

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BACKGROUND: Asthma affects people of all ages, and previous findings show 1 in 12 Americans have been diagnosed. Adherence to asthma controller medications is key to preventing symptoms and reducing exacerbations. Yet, between 22% and 46% of patients fail to take medication as directed. To address challenges of nonadherence, a large health services organization tested a remote monitoring (RM) platform, which included electronic sensors capturing rescue and controller inhaler usage, and a mobile app that provided dose reminders and usage feedback to members. Virtual clinical pharmacists reviewed member data and performed outreach as needed.

OBJECTIVE: To determine if RM is associated with decreases in rescue inhaler use (based on pharmacy fill data). Does RM increase adherence, defined as percent days covered (PDC) of at least 80%, to controller medication?

METHODS: This study was conducted using a retrospective, pre-post, matched intervention-control analysis of members enrolled in a large pharmacy benefits manager eligible

for the RM program. Members were eligible for enrollment if they were nonadherent (PDC <80%) on their controller medication. Members in RM were compared with those who were targeted but did not enroll (control). The enrollment date for the intervention sample was the index date. The index date for controls was the first date of the index period, January 1, 2020. The pre-post periods were 12 months before and after the index date. All outcome variables were measured in both study periods. Multivariable linear and logistic regression models were used to assess the impact of the RM program on adherence and rescue inhaler use, controlling for demographics and preperiod PDC or utilization.

RESULTS: 564 matched pairs were included in the analysis, including those with rescue medications (n=186 pairs) and those with rescue and controller medications (n=378 pairs). Findings show 24.7% of control and 36.3% of intervention members who were nonadherent to controller medications in the preperiod became adherent in the postperiod ($P<0.001$). Controlling for demographics and preperiod PDC, nonadherent members in intervention were 73% ($P<0.001$) more likely to become adherent to controller medications in the postperiod compared with controls. Intervention members averaged 1.29 ($P<0.001$) fewer rescue fills compared with controls.

CONCLUSIONS: These results indicate that an RM solution, combined with education and clinical support, may decrease the need for rescue inhaler use and promote increased adherence to controller medications, potentially reducing exacerbations.

SPONSORSHIP: Evernorth, ResMed, Propeller Health.

J6 Evaluation of health care resource use among individuals with chronic obstructive pulmonary disease with and without α-1 antitrypsin deficiency in a US Medicare Advantage population

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BACKGROUND: Chronic obstructive pulmonary disease (COPD) contributes to a substantial health care burden. A-1-antitrypsin deficiency (AATD) accounts for 1%-2% of COPD cases, though sparse testing underrepresents its true prevalence. There is a gap in our understanding about health outcomes among patients with AATD in the rapidly growing Medicare population.

OBJECTIVE: To compare health care resource use (HCRU) and costs among people with COPD with and without evidence of AATD, enrolled in a US Medicare Advantage Prescription Drug (MAPD) plan.

METHODS: This retrospective, observational analysis of administrative claims data included people aged 18-89 years, enrolled in an MAPD plan, with a diagnosis of COPD with and without evidence of AATD between January 1, 2014, and March 31, 2021. We used a risk-set–matching approach to define the non-AATD group. Baseline characteristics and outcomes for 12 months following the index date (date of AATD diagnosis) were compared between groups.

RESULTS: We matched 742 individuals with AATD to 7,420 individuals without AATD based on age (mean = 68 ± 9 years), sex (55.0% female), and race (White: 97.2%, Black: 2.8%). We observed a higher proportion of COPD-related exacerbations (41.6% vs 30.4%; $P<0.001$) and exacerbation-related hospitalizations (6.3% vs 3.4%; $P<0.001$) in the AATD group vs the non-AATD group, respectively. Rates were higher in the AATD group compared with the non-AATD group, respectively, for all-cause inpatient admissions (31.7% vs 27.3%; $P=0.011$); COPD-specific and exacerbation-related inpatient admissions (7.4% vs 4.3%; $P<0.001$); and COPD-specific and exacerbation-related emergency department visits (19.5% vs 10.8%; $P<0.001$) but not all-cause ED visits (41.8% vs 40.6%; $P=0.521$). AATD was associated with higher median total all-cause costs (1.7-fold greater), with differences in COPD-specific medical costs (3.7-fold greater), with all-cause pharmacy costs (2.2-fold greater), and with all-cause medical costs (1.4-fold greater; $P<0.001$ for all comparisons) vs non-AATD COPD.

CONCLUSIONS: This real-world MAPD analysis shows that individuals with COPD and AATD have higher rates of COPD-related exacerbations, inpatient admissions, emergency department visits, and costs vs those without AATD. Increased AATD awareness, testing, and treatment may reduce the health care burden in a Medicare population. Further research is needed to assess the impact of improved AATD testing and treatment strategies on clinical outcomes, HCRU, and costs in those with COPD.

SPONSORSHIP: Takeda Pharmaceuticals USA, Inc.

J7 Health care resource utilization and associated costs among US patients diagnosed with noncystic fibrosis bronchiectasis over a 2-year follow-up period, stratified by payer type

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BACKGROUND: Bronchiectasis (BE) is a chronic respiratory condition characterized by permanent dilation of the airways, persistent cough, and frequent pulmonary exacerbations. BE is associated with increased burden of disease, health care costs, and mortality.

OBJECTIVE: To examine health care resource utilization (HCRU) and costs among patients diagnosed with BE in the United States, stratified by payer type.

METHODS: This retrospective study using Merative MarketScan Commercial Claims and Medicare Supplemental databases included adults with BE from October 1, 2016, to December 31, 2020 (≥2 outpatient claims with BE diagnosis code between 30 days and 1 year apart, ≥1 inpatient claim with BE as primary diagnosis, or 1 chest computerized tomography scan followed by ≥2 outpatient or inpatient claims). Patients had continuous enrollment at least 12 months pre-index and were followed for no more than 2 years postindex. Respiratory-specific (visits with primary diagnosis of respiratory-related conditions) HCRU and inflation-adjusted costs during follow-up were reported per patient per year (PPPY) to account for variable follow-up. Mean US dollar costs per visit during follow-up were also reported.

RESULTS: Among 18,046 patients identified with BE (mean [SD] age = 66.2 [14.4] years; 64.8% female), 9,278 (51.4%) were enrolled in Medicare (mean [SD] age = 77.3 [7.6] years), and 8,768 (48.6%) were enrolled in commercial plans (mean [SD] age = 54.4 [9.8] years). The most frequent baseline comorbidities were acute lower respiratory infections (46.8%), chronic obstructive pulmonary disease (43.3%), and asthma (32.8%). The number of health care encounters in commercial and Medicare patients, respectively (PPPY), were similar for hospitalizations (0.99 vs 0.96; $P = 0.984$), outpatient visits (8.94 vs 11.25; $P = 0.871$), emergency department visits (0.92 vs 0.97; $P = 0.967$), and number of inpatient days (7.59 vs 6.35; $P = 0.900$). The total cost of health care encounters PPPY was also similar for commercial vs Medicare patients, respectively: hospitalization ($35,530.8 vs $21,470.0; $P = 0.722$), outpatient visits ($4,688.1 vs $4,324.8; $P = 0.955$), and emergency department visits ($1,155.5 vs $1,429.5; $P = 0.880$). The average cost per hospitalization for commercial and Medicare patients was $36,041 and $22,397, respectively.

CONCLUSIONS: HCRU and economic burden were comparable in younger, commercially insured patients and older Medicare-insured patients with BE. Hospitalizations were the major cost drivers for both commercial and Medicare patients, indicating a need for novel treatment strategies to reduce hospitalizations and economic burden.

SPONSORSHIP: Insmed Incorporated.

J10 Alignment of COPD maintenance treatment patterns in community practice relative to GOLD 2023: Results of an HCP survey

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BACKGROUND: The GOLD strategy, used by health care providers (HCPs) to guide the management of patients with chronic obstructive pulmonary disease (COPD), was recently updated for 2023. The GOLD 2023 strategy no longer encourages the use of LABA/ICS (long-acting β-agonist/inhaled corticosteroid) as a COPD maintenance therapy.

OBJECTIVE: To determine the degree of alignment between HCP-reported prescribing practices in COPD and the recently updated GOLD 2023 strategy.

METHODS: In April 2023, US-based HCPs (including pulmonologists, primary care physicians [PCPs], and nurse practitioners [NPs] and physician assistants [PAs]) were invited to participate in a 45-minute online survey to assess the management of their COPD patients (treating ≥30 patients in the past month for PCPs and NP/PAs and 60 patients for pulmonologists). Descriptive analyses were conducted.

RESULTS: 75 pulmonologists, 46 PCPs, and 32 NPs/PAs completed the survey, with an average monthly volume of 121, 57, and 81 patients, respectively. Most patients were receiving maintenance therapy. PCPs reported the highest number of patients with mild disease, whereas pulmonologists reported the highest number of patients with severe/very severe COPD. Overall, HCPs reported prescribing dual therapy (LABA/ICS or LABA/long-acting muscarinic antagonist [LAMA]) most frequently in patients with moderate disease. LABA/ICS is still prescribed by all HCP types, with the least use by pulmonologists, reporting use in 13% of mild, 15% of moderate, 10% of severe, and 6% of patients with very severe COPD. PCPs report 17%, 20%, 20%, and 13% use, and NP/PAs report 18%, 22%, 17%, and 16% use in mild, moderate, severe, and very severe patients, respectively. HCPs were also asked how they would treat a hypothetical patient

population. They reported similar use of LABA/ICS. The HCPs also reported their level of agreement with the GOLD strategy. Only 54% of HCPs reported that they strongly agreed with the GOLD recommendation to use LAMA/LABA over ICS/LABA, with only 42% strongly agreeing that they always follow GOLD recommendations when making treatment decisions for their patients with COPD.

CONCLUSIONS: Misalignment exists between HCP-reported prescribing practices and the newly updated GOLD 2023 strategy, specifically around the use of LABA/ICS. A study limitation may be that HCPs did not have enough time to adopt the 2023 GOLD strategy, but HCPs still reported LABA/ICS use in a hypothetical patient population. Further education is needed to bridge the gap between HCP prescribing practice and global treatment recommendations.

SPONSORSHIP: Verona Pharma PLC.

J11 Overlap of interleukin 5–driven diseases and the associated health care resource use and cost among patients prescribed mepolizumab

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BACKGROUND: Patients with overlapping interleukin 5 (IL5)–driven diseases often have complex disease management needs, for which there are limited data on clinical presentation or health care system burden.

OBJECTIVE: To describe the clinical presentation, health care resource use (HRU), and associated costs for patients who have been prescribed mepolizumab for the treatment of an IL5-driven disease.

METHODS: This retrospective cohort study, using US claims databases (IBM MarketScan Commercial Claims and Encounters and Medicare supplemental databases), identified patients aged at least 18 years, with at least 1 IL5-driven disease (including severe asthma [SA], chronic rhinosinusitis with nasal polyps [CRSwNP], and eosinophilic granulomatosis with polyangiitis [EGPA]), and prescribed mepolizumab between January 1, 2018, and December 31, 2020 (index date). Outcomes were assessed during the baseline (12 months pre-index) and follow-up periods (12 months postindex); cohorts with a diagnosis of SA, CRSwNP, EGPA, and overlaps were identified in the 24-month baseline/follow-up period. Patient demographics, clinical characteristics, and HRU (including admissions and costs) at baseline were analyzed by disease cohort (where n>10).

RESULTS: In total, 1,683 patients were identified. Those patients had the following conditions: SA only (n=1,222; 73%), SA/CRSwNP (n=296; 18%), SA/EGPA (n=61; 4%), and SA/CRSwNP/EGPA (n=31; 2%). The mean (SD) ages were 53 (11) for SA only, 51 (11) for SA/CRSwNP, 51 (12) for SA/EGPA, and 46 (12) for SA/CRSwNP/EGPA. All cohorts had a greater proportion of female patients (55% [SA/CRSwNP/EGPA]–69% [SA]). Baseline comorbidities varied between the patient cohorts. Mean (SD) total medical costs were, in general, higher for patients with multiple IL5-driven diseases compared with patients with SA only (SA only: $25,410 [$37,870], SA/CRSwNP: $27,159 [$63,886], SA/EGPA: $36,171 [$59,607], and SA/CRSwNP/EGPA: $44,430 [$65,089]). HRU varied between cohorts: patients with SA/CRSwNP/EGPA had the highest mean number of inpatient and outpatient visits, whereas patients with SA only had the highest number of emergency department visits and pharmacy claims.

CONCLUSIONS: This study highlights the importance of understanding patients with multiple overlapping IL5-driven diseases who have complex disease management needs. Patients with SA/CRSwNP/EGPA have a particularly high disease burden, with each additional condition increasing costs compared with SA alone. Treatments such as mepolizumab, which can improve multiple conditions, could be of great value to patients and health care systems.

SPONSORSHIP: GSK (ID: 217608).

J12 Learnings on the definition of chronic obstructive pulmonary disease control: A perception study of pulmonologists

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BACKGROUND: Chronic obstructive pulmonary disease (COPD) is defined by progressive airflow obstruction and inflammation that causes significant social and economic burden for patients and society. Despite a multitude of treatment options available, patients may still experience continued symptoms and exacerbations. The definition of controlled or uncontrolled COPD has not yet been well-defined.

OBJECTIVE: To determine pulmonologists' perceptions of disease control in their COPD patient population.

METHODS: In April 2023, US-based pulmonologists were invited to participate in a 45-minute online-survey to assess their perceptions of disease severity and management of their patients with COPD. To participate, pulmonologists had to treat at least 60 patients with COPD in the past month, with at least 50% of the patients receiving maintenance therapy. Descriptive analyses were conducted.

RESULTS: 75 pulmonologists completed the survey, with an average monthly volume of 121 patients with COPD.

Most patients were receiving maintenance therapy (83%). Pulmonologists reported that 16% of their patients were considered mild, 35% moderate, 31% severe, and 19% very severe by GOLD spirometry criteria. Exacerbation frequency increased with patient severity, reporting 16%, 26%, 34%, and 37% of mild, moderate, severe, and very severe patients, respectively, experiencing 1-2 exacerbations in the past year. Pulmonologists reported that 5% of their mild, 10% of moderate, 18% of severe, and 27% of very severe patients experienced 3 or more exacerbations in the past year. Patients considered uncontrolled by the pulmonologist increased with disease severity, reporting 15%, 24%, 31%, and 37% of their mild, moderate, severe, and very severe patients, respectively, as uncontrolled. Pulmonologists were asked to rate factors that would contribute to classifying a patient as uncontrolled. The highest rated factors included hospitalization because of severity of exacerbations, symptom deterioration, deterioration in quality of life, need for add-on therapies, and increase in frequency of exacerbations.

CONCLUSIONS: Although there is no standard definition for COPD disease control, pulmonologists indicated that exacerbations, symptoms, quality of life, and the need for add-on therapies are important considerations. Despite 83% of this patient population receiving maintenance therapy, pulmonologists still classified a significant number of their patients as uncontrolled, indicating there is a continued need for additional therapies to achieve optimal COPD control.

SPONSORSHIP: Verona Pharma PLC.

J19 Treatment patterns and sequencing among patients with ROS1-positive advanced or metastatic non–small cell lung cancer in the United States

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BACKGROUND: Oncogenic ROS1 rearrangements occur in 1%-2% of patients with non–small cell lung cancer (NSCLC). Treatment guidelines recommend targeted therapy as the first-line (1L) treatment for such patients. Among these patients, little is known about real-world treatment patterns in the United States.

OBJECTIVE: To describe 1L treatment patterns, sequencing, and discontinuation in US patients with ROS1 positive (ROS1+) advanced or metastatic NSCLC.

METHODS: This retrospective cohort study evaluated newly diagnosed adult patients with ROS1+ NSCLC from the nationwide Flatiron Health electronic health record–derived de-identified database who received any systemic treatment in 1L from March 1, 2015, to June 30, 2022. 1L time-to-treatment discontinuation (TTD) was calculated as the time from the start of 1L treatment (index date) to the initiation of new therapy, death, or discontinuation, whichever occurred first. 1L time-to-next-treatment (TTNT) was calculated as the time from the index date to the initiation of a different therapy or death. TTD and TTNT were assessed among patients with and without baseline brain metastases. Kaplan-Meier statistics were calculated for TTD and TTNT.

RESULTS: 222 patients with ROS1+ NSCLC were included: the median age was 65 years, 63% were female, 68% were White, 19% had brain metastases, 47% had no history of smoking, 63% had an Eastern Cooperative Oncology Group score of 0/1, and 75% were in community practice. The 1L therapies initiated included crizotinib (n = 92), entrectinib (n = 29), ceritinib (n = 5), and other systemic treatments (n = 96). 54% of patients initiated second-line therapies, including crizotinib (n = 22), entrectinib (n = 13), lorlatinib (n = 20), ceritinib (n = 3), and other systemic treatments (n = 62). Overall, for the 1L therapies, the median TTD and TTNT were 6.4 months (95% CI = 5.2-8.1) and 7.6 months (95% CI = 6.4-9.6), respectively. For patients with brain metastases, 1L median TTD and TTNT were 5.5 months (95% CI = 2.8-11.4) and 5.5 months (95% CI = 4.0-13.2), respectively. For patients without brain metastases, 1L median TTD and TTNT were 6.4 months (95% CI = 5.1-8.5) and 7.8 months (95% CI = 6.5-11.2), respectively.

CONCLUSIONS: In this real-world, mostly community practice setting, 57% of patients with ROS1+ NSCLC received 1L targeted therapies; however, overall TTD and TTNT could be improved. This study highlights the unmet needs of patients with ROS1+ NSCLC with opportunities to improve clinical outcomes by treatment with the latest targeted therapies as per treatment guidelines. Future work should evaluate outcomes by treatment regimens and assess clinical response and survival outcomes.

SPONSORSHIP: Bristol Myers Squibb.

J20 Socioeconomic and clinical predictors of antifibrotic medication initiation in Medicare patients with idiopathic pulmonary fibrosis

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BACKGROUND: Idiopathic pulmonary fibrosis (IPF) is a life-threatening rare disease characterized by a decline in lung function caused by the progression of fibrosis in the lung

interstitium. Antifibrotics (AFs) have been shown to slow IPF progression in both clinical trials and real-world evidence.

OBJECTIVE: To assess the socioeconomic and clinical predictors of AF initiation among patients with IPF because the median survival of nontreated patients with IPF is 3 years from diagnosis.

METHODS: Patients with at least 1 inpatient or at least 2 outpatient claims for IPF were identified in 100% fee-for-service Medicare claims data from October 2013 to December 2019. Patients were aged at least 65 years at the time of their earliest AF claim (index date) and had at least 3 months of Part D coverage after the index date. AF incidence was calculated as AF initiation among patients with no prior AF use. A discrete-time proportional hazards model was estimated to assess the risk of AF initiation following a visit with an AF prescriber as a function of time-invariant factors (age, sex, race and ethnicity, and region) and time-varying factors (clinical characteristics, such as lung biopsy, high-resolution computed tomography scan, oxygen use, pulmonary rehabilitation, and ventilator use; overall health care use; and IPF-related care, such as pulmonology visit count and antifibrotic prescriber visit count).

RESULTS: The mean age was 78.4 years, and 45.4% were women in the overall IPF population. 11,522 (25.3%) of 45,458 patients with IPF initiated AF medications. Higher age (≥75 years vs <75; hazard ratio [HR] = 0.70; 95% CI = 0.67-0.73), women (HR = 0.66; 95% CI = 0.63-0.68), and race (Black vs non-Hispanic White; HR = 0.82; 95% CI = 0.72-0.93) were significantly associated with lower rates of AF initiation. Among the clinical characteristics, higher Gagne comorbidity index (1-point increase; HR = 0.92; 95% CI = 0.91-0.92), inpatient hospitalizations occurrence within the preceding month of AF start (HR = 0.59; 95% CI = 0.52-0.67), emergency department visit (within 1 month; HR = 0.72; 95% CI = 0.64-0.80), and ventilator use (within 1 month; HR = 0.48; 95% CI = 0.35-0.67) were associated with lower rates of AF initiation; whereas recent pulmonary visit (within 1 month; HR = 1.79; 95% CI = 1.39-2.31) and recent high-resolution computed tomography scan (within 1 month; HR = 1.91; 95% CI = 1.79-2.05) were associated with higher rates of AF initiation.

CONCLUSIONS: These results indicate that there are significant differences in the initiation of AF agents in patients with IPF by socioeconomic and clinical factors. IPF outcomes can be improved by increasing treatment rates in these populations.

SPONSORSHIP: P.P. and A.O. are employees of Boehringer Ingelheim and may own stock. D.N. and A.J.E. are employees of Medicus Economics, which was paid by Boehringer Ingelheim to participate in this research.

K00-K93 Diseases of the Digestive System

(eg, Crohn disease, ulcerative colitis)

K1 Sequential continuing education programs for managed care and payer professionals increase knowledge of breakthrough therapies for the management eosinophilic esophagitis treatments

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BACKGROUND: Bridging the communication gap between payer decision-makers and their affiliated network clinicians results in immediate opportunities for collaboration to streamline access to the right treatment, for the right patient, at the right time. The recent introduction of a high-investment therapy indicated for the treatment of eosinophilic esophagitis (EoE) challenges payers to find the appropriate balance between cost management and patient access to therapy in an environment of limited health care resources.

OBJECTIVE: To increase payers' confidence and knowledge about the clinical and economic benefits of EoE treatments.

METHODS: A series of 2 virtual roundtables were conducted to identify knowledge gaps with payers and providers recruited from a proprietary database of managed care decision-makers from November 7, 2022, to November 9, 2022. Participants were asked about collaborative opportunities between gastroenterology, allergy, and regional payer decision-makers. A best practice management infographic and 2 live webcasts were developed to highlight key takeaways from the roundtables. 4 educational cases were developed and hosted on an innovative learning management system that includes outcomes reporting.

RESULTS: Data were aggregated in April 2023 for the 3 programs; 255 learners completed activities for credit. Self-identified specialties included pharmacist (81%), nurse, (10%), and medical physician (7%). Preactivity, 22% of learners self-reported as very, moderately, or confident in their ability to characterize evidence-based treatment plans for patients with EoE compared with 59% of postactivity learners ($P < 0.01$). Preactivity, 46% of learners who had it within their scope of practice to recommend and/or apply

multidisciplinary collaborative care interventions for the management of patients with EoE self-reported as being very, moderately, confident, or somewhat confident in making these interventions compared with 68% of postactivity learners ($P < 0.01$).

CONCLUSIONS: Participants demonstrated increased knowledge and confidence after completing at least1activity. Education specifically for managed care professionals focused on appropriate treatment of rare diseases, such as EoE, is vital to manage diverse needs, access challenges, and resource utilization to improve patient outcomes. Educational gaps and potential objectives include the clinical and economic burden of EoE, the importance of early diagnosis of EoE, current and emerging treatment options for EoE, the importance of balancing patient access to novel therapies and payer benefit management strategies, and strategies to ensure referral to care teams which include the appropriate specialists to optimize EoE diagnosis and treatment outcomes.

SPONSORSHIP: Regeneron Pharmaceuticals, Inc. and Sanofi.

K2 Payer and provider challenges and opportunities to improve access to appropriate and timely treatment of eosinophilic esophagitis

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BACKGROUND: Bridging communication gaps between payers and providers results in improved collaboration and access to timely treatments for patients. The recent introduction of a high-investment treatments for eosinophilic esophagitis (EoE) challenges the balance between cost management and patient access in an environment of limited health care resources.

OBJECTIVE: To describe challenges and opportunities to improve access to appropriate and timely treatment of EoE through payer and provider collaborations.

METHODS: A series of virtual roundtables were conducted with payers and providers recruited from a proprietary database from November 7, 2022, to November 9, 2022. Participants were asked about collaborative opportunities between gastroenterologists, allergists, and payer decision-makers. Responses were analyzed to identify common themes.

RESULTS: Insights from payers and providers (n = 16) were evaluated following the roundtables. Participating payers represented more than 140 million covered lives and the providers had more than 200 years of cumulative experience within their respective specialties. Provider (n = 9) identified challenges were (1) payers lack of understanding on how early screening and monitoring of EoE can improve the quality of care and reduce costs, (2) payers lack of understanding of how atopic comorbidities impact treatment choice, (3) lack of coverage of dietary services, (4) prior authorizations, and (5) step therapy requiring use of a medication not approved by the US Food and Drug Administration. Payer (n = 7) identified challenges were (1) lack of understanding EoE symptoms and progression, (2) the rigor of available clinical data, (3) lack of up-to-date clinical treatment guidelines, and (4) fragmentation of care and insurance. The collaborative opportunity with the highest level of payer and provider support was for respected academic centers to create treatment recommendations that bridge the gap between current evidence and treatment guidelines, followed by use of provider attestations in coverage determinations, improved access to clinical peers for appeals, and use of grandfathering.

CONCLUSIONS: Payers and providers have opportunities to improve access to appropriate treatments of EoE through collaborations. As additional treatment options for EoE are approved, it will be important for all stakeholders to consider these challenges and to use these opportunities to support appropriate patient access to these treatments.

SPONSORSHIP: Regeneron Pharmaceuticals, Inc. and Sanofi.

K4 Ustekinumab infusion to subcutaneous transition: Coordinating care and identifying potential gaps

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BACKGROUND: Ustekinumab, approved for the treatment of moderate to severe Crohn disease (CD) and ulcerative colitis (UC), requires a clinic administered intravenous (IV) infusion at initiation followed by transition to self-administered, subcutaneous (SQ) injection for maintenance 8 weeks after the initial IV infusion. To avoid potential waste, SQ doses should be sent to the patient between 4 and 8 weeks after infusion to allow time to evaluate for safety and effectiveness of the infusion without delaying SQ initiation.

OBJECTIVE: To evaluate factors impacting the transition time from IV to SQ ustekinumab and potential delays or barriers in the patient journey.

METHODS: A single-center, retrospective cohort analysis of data collected from electronic medical records and specialty pharmacy management system was conducted. Patients prescribed ustekinumab for CD or UC by a Vanderbilt University Medical Centerprovider between November 1, 2021, and March 31, 2022, were included. Patients were excluded if they never received an infusion or received the SQ dose at an infusion center. Primary outcomes were time from decision to treat with ustekinumab to SQ shipment date and number of patients whose SQ ustekinumab shipments occurred between 4 and 8 weeks after infusion. Secondary outcomes were time between each step in the patient journey. A logistic regression model was used to test for associations between shipment of SQ ustekinumab within the appropriate window and age, insurance type (commercial vs not commercial) and whether the patient filled at Vanderbilt Specialty Pharmacy (VSP).

RESULTS: In the 70 included patients, median age was 36 (interquartile range [IQR] = 28-44) years. Patients were predominantly White (90%) and female sex (60%) with a CD diagnosis (66%). Most patients had commercial insurance (79%) and filled SQ doses outside of VSP (53%). Insurance denial was the biggest barrier to SQ access with 11% of initial SQ prior authorizations (PAs) denied. The average time from infusion to SQ medication shipment was 48 days (IQR = 27-54). Time from PA approval to medication shipment was 49 days (IQR = 34-73). Prescriptions filled with VSP had 2.5 times higher odds of being shipped in the appropriate window as compared with non-VSP prescriptions (95% CI = 0.8-7.8, $P = 0.126$).

CONCLUSIONS: Patients transitioning from ustekinumab IV infusion to SQ maintenance dosing may experience delays because of PA requirements. SQ prescriptions from the integrated health-system specialty pharmacy were more likely to ship in the appropriate time frame window after infusion.

SPONSORSHIP: None.

K5 Real-world dose escalation and associated costs of ustekinumab in the management of ulcerative colitis in the United States: A retrospective database study

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BACKGROUND: Dose escalation among patients treated with advanced therapies for ulcerative colitis (UC) results in high drug costs to payers and patients. Ustekinumab (UST) was approved by the US Food and Drug Administration (FDA) for adult patients with moderately to severely active UC in October 2019. However, UST dose escalation and associated incremental costs in patients with UC have not been investigated yet.

OBJECTIVE: To investigate the dose escalation patterns and incremental costs due to dose escalation in patients treated with UST for UC in the United States.

METHODS: The study used Merative MarketScan database in the United States to identify adult patients with at least 2 claims for UC and at least 2 subcutaneous injection (maintenance phase) claims for UST from April 2019 to December 2022. Patients were required to have continuous enrollment during baseline (6 months) and follow-up period (23 months). Patients were stratified by presence (bio-experienced) or absence (bio-naive) of other advanced therapy claims during baseline period. Key measures included magnitude of dose titration, time to first dose escalation, and incremental cost paid by payer and/or patients among those who had dose escalation. Descriptive statistics were used to summarize the nonmissing data. Frequencies and percentages were used for the categorical variables. Mean, SD, and median were used for the continuous variables.

RESULTS: Of 192 patients with UC identified initiating UST, 170 (bio-naive: 43 [25%], bio-experienced: 127 [75%]) were included in the analysis. Among 170 patients with dose escalation, average maintenance dose [SD] was 24.6% [48.2] higher than FDA-labeled maintenance dose (bio-naive: 11.8% [42.4] vs bio-experienced: 28.9% [49.4]). Overall, 34.7% of patients received a dose at least 20% compared with FDA-labeled maintenance dose (bio-naive 20.9% vs bio-experienced 39.4%). Among those who had dose escalation of at least 20%, average maintenance dose was 78.8% higher than FDA-labeled maintenance dose, median time to first dose escalation was 161 days (bio-naive 234 days vs bio-experienced 148 days) and estimated annual incremental cost per patient incurred due to dose escalation [SD] in US

dollars was $74,942 [$38,397] (bio-naive $70,609 [$41,057] vs bio-experienced $75,738 [$38,284]).

CONCLUSIONS: Dose escalation in UC was common with ustekinumab, especially in bio-experienced patients. This practice increased the cost of ustekinumab to payers and patients relative to that of its approved dose. Further research is needed to determine if other treatments or switching treatments earlier would be more cost-efficient.

SPONSORSHIP: Eli Lilly and Company.

K6 Implementation of a flowsheet to track patients with inflammatory bowel disease initiating a biologic with complex dosing regimens

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BACKGROUND: An increasing number of biologics used to treat inflammatory bowel disease (IBD) require induction infusions (IV) prior to subcutaneous (SQ) maintenance injections. Typically, IVs are billed under the patient's medical benefit and SQ medications are billed under the pharmacy benefit. Care coordination between medical and pharmacy teams is important as transitioning between induction and maintenance dosing could require additional health care resources if time sensitive milestones are not met.

OBJECTIVE: To implement a visible, streamlined process of managing patients with IBD receiving specialty medications that have complex dosing regimens with IV to SQ routes of administration.

METHODS: This single-center quality improvement project was implemented in the Vanderbilt IBD Clinic in July 2022. A flowsheet was designed in the electronic health record (EHR) to track patients initiating a biologic medication requiring IV doses prior to SQ maintenance therapy. Clinic-based infusion and specialty pharmacists documented in the flowsheet: referral date, infusion status and administration dates, maintenance injection approval, prescription sent date, and due date of the first injection. Alerts were sent to the specialty pharmacists in the EHR when designated milestones were met to ensure patients have access to maintenance medication at the appropriate time. Data was visible to clinic and pharmacy staff within the patient's medical record and used to populate a patient monitoring dashboard. A postimplementation survey was conducted to assess pharmacist satisfaction.

RESULTS: Through June 1, 2023, 230 patients were monitored from referral to SQ injection delivery. Patients were mostly White (88%), commercially insured (80%), with a median age of 43 years (interquartile range = 30-53). The individual patient journey was visible to clinic and pharmacy staff through a synopsis view in the EHR. Aggregate patient data was viewable using the patient monitoring dashboard. Specialty pharmacists reported high rates of satisfaction with the flowsheet. Clinic and specialty pharmacists (n = 5) agree or strongly agree that the flowsheet increased visibility into the patient's treatment status and streamlined coordination of care.

CONCLUSIONS: Implementation of a flowsheet within the EHR to manage patients with IBD treated with biologic medications requiring an induction IV dose prior to starting SQ maintenance injections provided a streamlined approach to patient management and care coordination between medical and specialty pharmacy staff.

SPONSORSHIP: None.

K8 Analysis of infliximab and adalimumab concentrations and antidrug antibody levels from therapeutic drug monitoring in patients with inflammatory bowel disease as indicator of status of current treatment regimen and disease activity from 3 national payers

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BACKGROUND: Inflammatory bowel disease (IBD) includes Crohn disease and ulcerative colitis (UC) and involves chronic inflammation that can lead to permanent bowel damage and surgery. Anti–tumor necrosis factors (TNFs) are standard of care in moderate to severe IBD, but still present challenges due to loss of response (LOR), potentially because of antibodies-to-drug (ATD) from subtherapeutic drug levels. Therapeutic drug monitoring (TDM) assists clinicians in adjusting anti-TNF dosing or the need to switch drug based on trough drug level targets and ATD status. Anser infliximab (IFX) and adalimumab (ADA) are drug tolerant homogenous mobility shift assays for TDM by Prometheus Laboratories, a Clinical Laboratory Improvement Amendments–certified laboratory. Previously, payer policies have restricted TDM as investigational despite literature, guidelines, and expert consensus statements that support the utility. Consequently, TDM may be sparingly used, ordered reactively with relapse symptoms, or clinicians may defer to empiric dose changes. With biosimilars, payers have an opportunity to maximize anti-TNFs as the lowest cost standard of care for moderate-severe IBD by ensuring therapeutic dosing to mitigate ATD and support treatment durability to improve outcomes.

OBJECTIVE: To describe for IFX and ADA, drug level and ATD results determined from TDM, as an indicator of potential LOR in patients with IBD based on billed tests to 3 national payers.

METHODS: Clinical Laboratory Improvement Amendments laboratory data analysis was conducted using 2022 de-identified results for IFX and ADA. Results for 3 national payers were analyzed to determine none/low, medium, or high risk status.

RESULTS: A total of 4,289 Anser IFX & ADA test results (64% IFX) billed to 3 national payers were analyzed to identify medium risk (potential LOR) or high risk (require drug switch) status. Demographics: 31/37 average age, 52%/51% male sex, and 69%/67% Crohn's disease for IFX and ADA, respectively. Most common dose for IFX was 5 mg/kg every 8 weeks and ADA 40mg every 2 weeks. At medium or high risk were 19% IFX/34% ADA and 7% IFX/4% ADA, respectively. In patients aged younger than 21 years, 15% IFX/18% ADA and 4% IFX/ADA were medium or high risk, respectively. Patients with low/no risk with sufficient drug conc. included 75% of IFX and 62% of ADA results (≥5 IFX or ≥7.5 ADA ug/mL) and undetectable/low ATD (<3.1 IFX or <1.7 ADA U/mL).

CONCLUSIONS: Total of 26% IFX and 38% ADA results indicate patients were not anti-TNF dose optimized, which is associated with increased risk of LOR or drug switch. If TDM was used routinely or proactively without barriers, ATDs may be mitigated by achieving appropriate trough targets, thereby supporting treatment persistence.

SPONSORSHIP: Prometheus Laboratories.

K10 Costs and patient characteristics associated with high vs low health care resource utilization in patients with inflammatory bowel disease: A real-world study in the United States

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BACKGROUND: Identifying factors that contribute to health care resource utilization (HCRU) in patients with Crohn disease (CD) or ulcerative colitis (UC) may enable tailoring of treatment plans.

OBJECTIVE: To identify differences in the HCRU-associated costs and characteristics of patients with UC or CD with high and low HCRU.

METHODS: RADAR-2 was a retrospective analysis of claims and/or electronic medical record (EMR) data from the Allegheny Health Network (AHN) and Highmark Inc. records between January 1, 2016, and February 28, 2020. AHN-attributed adults with Highmark Insurance and a diagnosis of UC or CD were included. The index date was the first date of a UC or CD diagnosis within the identification period. Patients had at least 2 years of medical and pharmacy data before the index date and at least 1 year of follow-up data after the index date. High or low HCRU were defined as the top and bottom quartiles of the total patient-driven payment model spend, respectively. Variables included all-cause and inflammatory bowel disease (IBD)–related costs and baseline characteristics. Factors associated with per-member per-month (PMPM) spend were determined using a generalized linear model.

RESULTS: Of 507 patients with CD or UC, 127 each were stratified into high and low HCRU groups. For both CD and UC, the median PMPM spend was 7- to 10-fold higher in the high HCRU group than the low HCRU group for patients with commercial insurance (CD: high = $2,225, low = $315; UC: high = $2,322, low = $330) and Medicare Advantage insurance (CD: high = $3,702, low = $372; UC: high = $3,114, low = $375). Mean Consumer Price Index–adjusted IBD-related annualized costs were 88.2% of all-cause costs in the low HCRU group ($4,427 of $5,017) but 29.9% of all-cause costs in the high HCRU group ($15,115 of $50,534). Patient demographics were similar between HCRU groups, except for median age (high = 72 years, low = 68 years; $P = 0.016$). The high HCRU group had longer mean hospital stays than the low HCRU group (6.0 vs 3.3 days). Higher Charlson Comorbidity Index scores and weight loss were significantly associated with higher PMPM spend ($P < 0.001$ and $P = 0.001$, respectively). Anemia or colon cancer predicted higher PMPM spend but did not reach statistical significance.

CONCLUSIONS: Using both claims and EMR data, we show that comorbidities, rather than IBD severity and treatment, are the main driver of HCRU costs in a subset of patients with IBD in the United States. Coordinated management of comorbidities may improve outcomes and reduce costs in IBD care.

SPONSORSHIP: Takeda Pharmaceuticals USA, Inc.

K13 Epidemiology of patients with short bowel syndrome with intestinal failure in the United States: Findings using real-world data

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BACKGROUND: Short bowel syndrome with intestinal failure (SBS-IF) is a severe organ failure condition defined as patients with SBS who have had surgical bowel resection or congenital abnormality and are dependent on life-long parenteral support (PS). SBS-IF is associated with increased mortality, morbidity, and reduced quality of life. Identifying the true prevalence of SBS-IF is challenging as there is no *International Classification of Diseases, Tenth Revision* code that specifically identifies the patients with PS-dependent SBS. This analysis was conducted to generate accurate and up-to-date prevalence data for SBS-IF in the United States.

OBJECTIVE: To enumerate and characterize the United States annual prevalence of the SBS-IF population in 2019, 2020, and 2021.

METHODS: Retrospective claims analysis was conducted using the Komodo Healthcare Map database, which comprises roughly 150 million patients with payer complete enrollment, to identify patients in the United States with1or more nutrition claims and having a continuously enrolled observation window in the previous 3 years. The SBS-IF population was estimated based on the following criteria: requiring chronic and continuous PS for at least 6 months, a confirmed diagnosis of malabsorption and history of intestinal resection or congenital abnormality of the intestine. Annual estimates and prevalence were calculated using sample diagnosis rates projected to the US population by age and sex.

RESULTS: Among 44 million patients in the Komodo database receiving nutritional support or with a gastrointestinal-related disease diagnosis, the estimated number of patients with SBS-IF in the United States in 2019-2021 was 9,500, 10,800, and 11,800, respectively. Patient estimates grew by 13% year-on-year in 2020 and 9% in 2021. The majority of patients were female (66%). The oldest age group (45+ years) was the single largest cohort (43%), followed by those aged 18-44 years (31%) and 3-17 years (26%). Gastrointestinal (GI) comorbidities between 2019 and 2021 included GI disorders (81%), abdominal pain (80%), and fluid/electrolyte disorders (72%) GI complications included colorectal cancers (5%) and bacterial infection (41%).

CONCLUSIONS: This study employed robust and stringent criteria for the identification of patients with SBS-IF to provide up-to-date and accurate prevalence estimates of SBS-IF in the United States. Additional analysis may be needed to better understand the growth rate observed in SBS-IF prevalence and identify factors contributing to this growth. Furthermore, detailed clinical characteristics of patients with SBS-IF are needed to inform clinicians' strategies for patient identification and disease management.

SPONSORSHIP: VectivBio.

K16 Characterizing the prevalence of nonalcoholic steatohepatitis in the United States using 2 independent real-world cohorts

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BACKGROUND: Nonalcoholic steatohepatitis (NASH) is characterized by a buildup of fat in the liver causing inflammation and hepatocellular damage that may lead to liver scarring. NASH affects approximately 3%-6% of adults; however, the exact prevalence is largely unknown.

OBJECTIVE: To characterize the prevalence and incidence of NASH among US adults.

METHODS: Optum's de-identified Clinformatics Data Mart (CDM) Database and Veradigm's electronic health record (EHR) linked to Komodo claims database (October 1, 2015, to December 31, 2022) were used for this study. Within CDM, NASH was defined as at least 1 inpatient claim for NASH (*International Classification of Diseases, Tenth Revision*, Clinical Modification K75.81) as the primary or secondary diagnosis, or at least 2 outpatient claims for NASH on different days. Within Veradigm's EHR, NASH was defined as at least 1 entry of the diagnosis. Individuals with at least 6 months of baseline data before first NASH diagnosis were defined as incident patients. In addition to demographics, total case counts, annual and period prevalence per 100,000 adults, and annual incidence per 100,000 adults was summarized. Prevalence estimates were scaled to approximate the impact in the 2022 US adult population.

RESULTS: Using CDM, 28,576 patients with NASH were identified. Estimated period prevalence was 179.0. Annual prevalence ranged from 29.4 to 138.2. Annual incidence ranged from 20.4 to 34.9. In comparison, 422,217 NASH patients were identified using Veradigm's EHR linked database.

Estimated period prevalence was 368.0. Annual prevalence ranged from 73.6 to 129.2. Annual incidence ranged from 57.1 to 64.0. Mean (SD) age in CDM was older compared with Veradigm: 62.2 (13.0) vs 57.5 (13.9) years. Both cohorts were predominantly female (61.0% vs 60.4%). The extrapolated 2022 US adult population with NASH was estimated to range from 254,249 (CDM) to 426,954 (Veradigm).

CONCLUSIONS: These data highlight the substantial and growing burden of NASH in the United States. A more specific definition of NASH was used within CDM, whereas a more sensitive definition was required within Veradigm, which offers a lower and higher bound estimate, respectively. These findings are reflective of the populations captured within each database and may not be generalizable to the entire US population. As the prevalence of NASH increases so will the demand for treatments that can reduce the overall burden of the disease.

SPONSORSHIP: Madrigal Pharma.

K18 A cohort study assessing diagnostic testing patterns, treatment, and progression in patients diagnosed with nonalcoholic steatohepatitis

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BACKGROUND: Nonalcoholic steatohepatitis (NASH), a progressive form of nonalcoholic fatty liver disease that can lead to cirrhosis, is estimated to affect 5% of US adults.

OBJECTIVE: To compare testing and treatment patterns before and after diagnosis and to assess postdiagnosis progression to complications in patients aged 18 years or older diagnosed with NASH.

METHODS: This observational study used longitudinal medical and pharmacy claims data from the Healthcare Integrated Research Database, which includes data for commercially insured and Medicare Advantage members from across the United States, to compare outcomes between patients with new and existing NASH diagnoses. Patients with a diagnosis of NASH (≥2 entries for *International Classification of Diseases, Tenth Revision, Clinical Modification* code K76.0) between October 1, 2016, and October 31, 2020, and at least 12 months of continuous enrollment before (baseline) and after diagnosis (follow-up) were included. Diagnostic testing and treatment patterns were determined by procedures and pharmacy claims. Progression was assessed by the proportion of patients developing cirrhosis with complications, hepatocellular carcinoma, need for liver transplant, major adverse cardiac events, and colorectal cancer.

RESULTS: The cohort included 10,205 patients with a new NASH diagnosis (n = 1,104 with cirrhosis) and 1,671 patients with an existing diagnosis (n = 277 with cirrhosis). Prediagnosis, 10.6% of patients had a liver biopsy, 41.2% had an ultrasound, and up to 4% had other imaging procedures. At baseline, 35.3%, 42.0%, and 60.2% of newly diagnosed patients chronically used glucose-lowering treatments, antihyperlipidemics, and antihypertensives, respectively. At follow-up, the proportion of newly diagnosed patients prescribed glucagon-like protein-1 receptor agonists (7.0% to 8.7%), sodium-glucose transport protein-2 inhibitors (5.5% to 7.0%), and statins (37.1% to 39.4%) increased ($P < 0.001$ for all). Among patients with cirrhosis at baseline, progression to cirrhosis with complications occurred in 86.6% of newly diagnosed patients, within a mean (SD) of 83 (161) days, and 92.1% of patients with an existing diagnosis, within a mean (SD) of 104 (200) days.

CONCLUSIONS: Biopsy and imaging procedures were performed in a minority of patients before NASH diagnosis. Prescriptions for glucose-lowering treatments and statins increased after NASH diagnosis. Among patients with new and existing NASH diagnoses with cirrhosis, progression to cirrhosis with complications is common, suggesting that many patients who are diagnosed with NASH present with advanced stages of liver disease.

SPONSORSHIP: This study was sponsored by Novo Nordisk Inc.

K19 Assessment of access barriers to rifaximin among patients with overt hepatic encephalopathy using adjudicated claims data

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BACKGROUND: Overt hepatic encephalopathy (OHE) is a serious complication of cirrhosis characterized by recurring episodes of deteriorating neurological function. Xifaxan 550mg (rifaximin) twice daily is indicated for reducing the risk of OHE recurrence in adults and continuous rifaximin treatment is associated with lower hospitalization rates.

The extent of access barriers to rifaximin and factors affecting treatment gaps are not well known.

OBJECTIVE: To assess barriers to rifaximin access and characterize treatment gaps and reasons for prescription claim rejections among commercially insured adult patients with OHE in the United States.

METHODS: IQVIA PharMetrics Plus database linked with Longitudinal Access and Adjudicated Data (LAAD; 2015-2022) was used to identify adults with OHE (aged 18-64 years) who had at least 1 paid rifaximin prescription fill. Rifaximin treatment gaps were assessed during a 12-month study period spanning from the first observed rifaximin attempt defined as a paid, reversed, or rejected prescription claim.

RESULTS: Of the 6,455 patients with OHE with at least 1 paid rifaximin prescription fill, 1,711 patients (26.6%) had continuous eligibility during the study period. Over the study period, patients attempted to access rifaximin 8.8 times on average, of which 6.4 were paid, 1.5 rejected, and 0.9 reversed. Almost all patients (97.0%) experienced a treatment gap of at least 1 day, with an average of 2.9 gaps per patient, for a total duration of 157.4 days without exposure to rifaximin (medication possession ratio: 56.9%). Treatment initiation delays in receiving rifaximin were experienced by 34.8% of patients with an average delay of 37.6 days from first attempt to first paid claim; 77.7% of initiation delays were because of rejected claims with most commonly reported reasons being: Prior Authorization Required (61.8%), Drug Not on Formulary (6.9%), and Product Not Covered (6.3%). Active treatment gaps following initial paid claim were experienced by 72.7% of patients with an average duration of 22.9 days; 18.1% of active treatment gaps were because of rejected claims with most commonly reported reasons being: Plan Limitations Exceeded (31.2%), Refill Too Soon (18.1%), and Prior Authorization Required (7.4%). At the end of the 12-month study period, 53.8% of patients were not actively receiving rifaximin (average gap duration of 181.0 days).

CONCLUSIONS: Prescription claim rejections frequently led to delays in rifaximin initiation and gaps in exposure during active treatment. Access barriers to rifaximin limit patients' access to critical treatment that may result in increased rates of OHE-related hospitalizations.

SPONSORSHIP: Bausch Health.

K20 The cost of care among patients with nonalcoholic steatohepatitis, with vs without cirrhosis: A US cohort study

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BACKGROUND: Nonalcoholic steatohepatitis (NASH) is characterized by buildup of fat in the liver with inflammation and, in a proportion of patients, fibrosis. By 2025, it is predicted that NASH will be the most common indication for liver transplant. Although the cost of care of NASH has been shown to be substantial, how costs differ among NASH patients with vs without cirrhosis is unclear.

OBJECTIVE: To compare annual costs among patients with NASH with vs without cirrhosis in the United States.

METHODS: Adults with NASH were identified from Optum's de-identified Clinformatics Data Mart Database (October 2015 to December 2021). Baseline cirrhosis status was defined as at least 1 code for cirrhosis, liver transplant, or hepatocellular carcinoma before the first NASH diagnosis. Patients were followed until death, loss to follow-up, or study end. Outcomes were compared by baseline cirrhosis status. Student's t-test was used to compare continuous outcomes. Generalized linear models with log-link gamma distributions were used to compare costs/person-year and changes in annual costs over time (with additional adjustment for within-patient effects and deaths). Analyses were performed within the Optum de-identified data workspace.

RESULTS: 2 cohorts were defined: patients with cirrhosis (mean [SD] age, 67.1 [10.8] years; n = 9,157) followed for 2.5 (1.6) years and patients without cirrhosis (59.8 [13.4] years; n = 19,419) followed for 3.2 (1.5) years. Annual costs among patients with cirrhosis were significantly greater (2022 US dollars: $110,403 [226,037] vs $28,340 [61,472]; $P < 0.01$) and remained significantly greater (risk ratio [95% CI] 2.0 [1.9-2.1]) when adjusted for demographics, and baseline comorbidities and costs. Compared with year 1, total annual costs/person increased by 2% (1.02 [0.99-1.05]) in year 2 and 21% (1.21 [1.08-1.36]) in year 6 among patients with cirrhosis and by 1% (1.01 [0.99-1.03]) and by 32% (1.32 1.24-1.40]) among patients without cirrhosis.

CONCLUSIONS: Adjusted costs/person-year among patients with NASH with cirrhosis was twice that of patients with NASH without cirrhosis. Although patients without cirrhosis had lower costs overall, they experienced greater increases in costs over time. These findings are reflective of the population captured within Optum's Clinformatics Data

Mart Database and may not be generalizable to the entire US population. Nevertheless, our data suggest the burden of care for NASH is substantial and significantly greater among patients with NASH with cirrhosis. Therapies that slow progression to cirrhosis may help alleviate the financial burden of managing NASH.

SPONSORSHIP: Madrigal Pharmaceuticals.

L00-L99 Diseases of the Skin and Subcutaneous Tissue

(eg, eczema, psoriasis)

L2 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 scores 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–Haenszel 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 (ANCOVA).

RESULTS: A total of 430 patients were included in the analysis (140 for vehicle; 290 for roflumilast). 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 scores 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 achieved significantly larger improvements 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 improvements in QOL and reaching DLQI scores indicative of no disease impact. The results suggest that roflumilast has a meaningful impact on the QOL burden associated with SD.

SPONSORSHIP: Arcutis Biotherapeutics, Inc.

L3 Disease control and physician satisfaction with ruxolitinib cream in US adults with mild-to-moderate atopic dermatitis

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BACKGROUND: The US Food and Drug Administration approved ruxolitinib (RUX) cream in 2021 as a topical short-term and noncontinuous chronic treatment of mild-to-moderate atopic dermatitis (AD) in nonimmunocompromised adult and pediatric patients aged 12 years or older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.

OBJECTIVE: To describe disease control and physician satisfaction among patients with mild-to-moderate AD receiving RUX cream.

METHODS: Adelphi AD Disease Specific Programme data, a cross-sectional survey of physicians and their patients, were used. Seventy-six US dermatologists, allergists, and primary care physicians recruited adults with AD (≥18 years) between October 2022 and March 2023. The study included patients with mild-to-moderate AD treated with RUX cream for at least 1 month.

RESULTS: Mean age of 149 adults treated with RUX cream was 36.9 years; most were female (66.4%) and White (67.1%). Mean AD duration was 7.9 years; median duration of treatment with RUX cream was 179 days; 22 (14.8%) received RUX

cream first line. Of those for whom previous therapy was known (n = 100), 41% were treated with a moderate-potency topical corticosteroid (TCS), 37% a high-potency TCS, 31% a topical calcineurin inhibitor, 14% a very-high-potency TCS, 14% crisaborole, and 10% dupilumab. RUX cream was used as monotherapy (39.6%), with advanced AD treatments (18.8%), or with other agents (41.6%). Most patients on advanced AD treatments were on dupilumab (67.9%). Before treatment, 84.6% had moderate AD as measured by Investigator's Global Assessment, 13.4% had mild AD, and 2.0% had almost clear skin. After treatment with RUX cream, 20.1% had clear skin, 28.2% almost clear skin, 29.5% mild AD, 21.5% moderate AD, and 0.7% (n = 1) severe AD. Similar disease control was observed in patients treated with RUX cream monotherapy (20.3% clear; 22.0% almost clear). 81.2% were not currently flaring. The foremost reasons for physicians to choose RUX cream included relieving itch (56.9%), improving lesion redness or thickness (46.7%), achieving clear or almost clear skin (46.0%) and long-term control (44.5%), and reducing and/or controlling flares (40.9%). Physicians were satisfied with disease control for 87.3% of patients using RUX cream.

CONCLUSIONS: Physicians reported high satisfaction with RUX cream for AD and good initial disease control with almost half of patients achieving clear or almost clear skin. Furthermore, when used as monotherapy, RUX cream provided disease control in a similar percentage of patients.

SPONSORSHIP: Incyte Corporation.

L7 Variability in patient-reported impacts of seborrheic dermatitis: Disease severity measures may not tell the whole story

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BACKGROUND: Although seborrheic dermatitis (SD) is a relatively common dermatologic condition, its clinical presentation and related impacts are underrepresented in the literature. Due in part to the limited development of new treatments for SD, there is a paucity of published evidence to describe the patient-reported effects of SD on health-related quality of life (QOL). In addition, physician-rated clinical measures may not fully capture important patient considerations.

OBJECTIVE: To describe patient-reported perceptions of the impact of SD on QOL, and to explore the relationship between physician- and patient-rated disease measures in patients with moderate-to-severe SD.

METHODS: These analyses were performed on patient- and physician-assessed endpoints from STRATUM, a phase 3 clinical trial evaluating the safety and efficacy of roflumilast foam 0.3% in patients with moderate-to-severe SD. Patient-rated measures included the Dermatology Life Quality Index (DLQI), a validated measure assessing QOL in patients with skin diseases. The DLQI comprises 10 items relating to patients' perceptions of QOL impact and has a score range of 0-30 with higher scores indicating greater QOL effects. Disease severity was assessed using a 5-point physician-rated Investigator Global Assessment (IGA). A Kruskal–Wallis rank sum test was performed to test for differences in DLQI scores at baseline by IGA severity groups. Box plots were produced to qualitatively compare the distribution of baseline DLQI scores across IGA severity groups.

RESULTS: 430 patients were included in the analysis. Mean baseline DLQI scores for patients with moderate IGA severity was 5.40 (95% CI = 4.99-5.80), compared with 5.96 (95% CI = 4.52-7.64) for patients categorized as severe SD ($P = 0.356$). The box plots indicated substantial variability in patient-reported impacts of SD; in particular, the DLQI baseline scores in the moderate severity group had a large variance with some patients reporting DLQI scores up to 24 (extremely large effect on QOL).

CONCLUSIONS: Patient-reported impacts of the effect of moderate-to-severe SD on QOL varied significantly and were not associated with physician-rated disease severity (IGA). In the STRATUM study, many patients with moderate severity by IGA had DLQI scores indicative of an extremely large effect on QOL. These results highlight the importance of patient-centered endpoints alongside standard clinical assessments as a necessary component of new drug evaluations.

SPONSORSHIP: Arcutis Biotherapeutics, Inc.

L8 Survey of health care providers to understand the diagnosis and treatment patterns for patients with seborrheic dermatitis

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BACKGROUND: Seborrheic dermatitis (SD) is a chronic inflammatory skin disease significantly impacting quality of life. Little is known about real-world patterns of diagnosis and treatment for SD.

OBJECTIVE: To conduct a survey of health care providers (HCPs), including MDs, NPs, and PAs, in the United States

to understand the diagnosis and treatment patterns of patients with SD.

METHODS: This survey was conducted via interviews over 4 weeks among dermatology HCPs (n = 111) throughout the United States. HCPs surveyed include Nurse Practitioners, Physicians Assistants, and Doctors of Medicine, and did not exclude HCPs based on years of experience.

RESULTS: Most HCPs (80.0%) estimated the annual prevalence of SD in the United States to be greater than or equal to 5 million. The majority (67%) determined that more than half of patients with SD have mixed morphologies, such as SD and psoriasis (sebopsoriasis), atopic dermatitis (AD), rosacea, and perioral dermatitis. HCPs reported that among patients with mixed morphologies, 40.6% have sebopsoriasis, 24.1% have SD and AD, 23.8% have SD and rosacea, and 15.1% have SD and perioral dermatitis. The most common therapies that HCPs chose for SD disease management overall were azoles (oral, topical; 86.0%), corticosteroids (72.9%), clobetasol solution specifically (54.2%), and other (biologic, phosphodiesterase-4 inhibitors, oral antihistamines, etc; 25.2%). For patients with mixed morphologies, the most common reported treatments were clobetasol solution (43.4%), Janus kinase inhibitors (oral or topical; 26.3%), topical calcineurin inhibitors (25.8%), dupilumab (24%), biologics (22%), apremilast (15%), and other treatments (10%). HCPs reported most frequently coding mixed morphology as L21.9 (SD, unspecified; 67.5%), L40.X (psoriasis; 35.6%), L20.9 (AD; 18.3%), and L30.9 (dermatitis, unspecified; 16%). Furthermore, HCPs noted that for almost half of patients with mixed morphology (48.0%), they would only include an *International Classification of Diseases* code for non-SD diagnosis (AD, psoriasis, etc), leaving out SD itself.

CONCLUSIONS: The presentation of SD is of a complex disease with mixed morphologies. The treatment choice of HCPs varies based on the presence of individual or mixed morphologies, in which systemic therapies are used more often. Nearly half of HCPs code for one of the patient's dermatoses and do not code for SD when mixed morphology is present. The introduction of an approved, targeted treatment for SD may aid in reduction in systemic therapies used to treat patients with SD.

SPONSORSHIP: Arcutis Biotherapeutics, Inc.

L9 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 = 7.7-15.1; AD = 12.4-17.7). The mean baseline DLQI score for patients with SD in the STRATUM trial was 5.4 [standard deviation = 0.19], 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, patient populations 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.

L15 Economic burden of orthopedic surgery among patients with psoriatic arthritis after second line biologics initiation: A retrospective study using claims data, 2000-2022 in the United States

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BACKGROUND: Patients (pts) with psoriatic arthritis (PsA) can be managed effectively with nonoperative treatment, but orthopedic surgery may be necessary when medications fail to prevent inflammation and joint deterioration. The economic burden of PsA was evaluated previously, but little is known about the additional burden of surgeries in these pts.

OBJECTIVE: To evaluate the health care resource utilization (HCRU) and costs associated with surgeries among pts with PsA after second line (L2) biologic therapy in the United States.

METHODS: Pts with PsA were identified in the IBM MarketScan Commercial Database from January 2000 to October 2020 as pts with at least 2 PsA diagnoses initiating (L2) after 2015. Cases were defined as pts with surgeries within two years of L2 initiation with the index date as the first surgery date. Index dates for pts without surgeries (controls) were randomly drawn from distribution between L2 initiation and first surgery among cases. All pts were required to have 24 months of continuous enrolment starting 1 year prior to index date. Controls were matched 3:1 to cases using propensity scores adjusted on demographics and clinical characteristics. HCRU and costs (expressed in 2022 USD) during 1 year of follow-up were compared between both groups.

RESULTS: 264 pts with PsA had a surgery within 2 years following L2 initiation vs 3,262 controls. Prior to matching, cases were on average slightly older than controls (aged 52 vs 48 years, respectively). Concurrent rheumatoid arthritis and osteoarthritis diagnoses were present in 23% and 67% of cases, respectively, and in 18% and 31% of controls. The proportion of pts with a Charlson Comorbidity Index greater than or equal to 2 was higher for cases (33%) than controls (21%). Cases were matched to 782 controls, and characteristics were balanced after matching. Mean annual all-cause health care costs were greater among cases vs controls ($128,990 vs $70,555; $P<0.0001$), because of significantly greater inpatient ($38,417 vs $2,346; $P<0.0001$) and outpatient medical costs ($35,158 vs $15,082; $P<0.0001$). Differences are explained by cases' significantly greater HCRU for hospital inpatient and outpatient services, physician office visits, radiology, laboratory, emergency department, and outpatient pharmacy services.

CONCLUSIONS: Results show that pts with PsA with surgeries after L2 initiation incurred significantly greater HCRU and costs than controls. Findings suggest that effective therapies that can prevent the need for orthopedic surgeries among pts with PsA may improve clinical outcomes and decrease HCRU and costs.

SPONSORSHIP: None.

L16 Economic burden of orthopedic surgery among patients with psoriatic arthritis after first line biologics initiation: A retrospective study using claims data, 2000-2022 in the United States

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BACKGROUND: Most patients (pts) with psoriatic arthritis (PsA) can be managed effectively with nonoperative treatments, but orthopedic surgery may be necessary when medications fail to prevent inflammation and joint deterioration. The economic burden of PsA was evaluated previously, but little is known about the additional burden of surgeries in these pts.

OBJECTIVE: To evaluate the health care resource utilization (HCRU) and costs associated with surgeries among pts with PsA after initiating first line (L1) biologic therapy in the United States.

METHODS: Pts with PsA were identified in the IBM MarketScan Commercial Database from January 2000 to October 2021 as pts with at least 2 PsA diagnoses initiating a L1 biologic therapy after 2015. Case pts were identified as those undergoing at least 1 orthopedic surgery procedure within 2 years of L1 therapy initiation with the index date as the first surgery date. Index dates for pts without surgeries (controls) were randomly drawn from distribution between L1 initiation and first surgery among cases. All pts were required to have 24 months of continuous enrolment starting 1 year prior to index date. Controls were matched 3:1 to cases using propensity scores adjusted on demographics and clinical characteristics. HCRU and costs (2022 USD) during 1 year of follow-up were compared between both groups.

RESULTS: 636 pts with PsA had a surgery within 2 years following L1 initiation vs 7,820 controls. Prior to matching, cases were on average slightly older than controls (52 vs 48 years, respectively). Concurrent rheumatoid arthritis and osteoarthritis diagnoses were found in 26% and 69% of cases, respectively, and in 19% and 31% of controls. The proportion of pts with a Charlson Comorbidity Index greater than or equal to 2 was higher for cases (33%) than controls (20%). Cases were matched to 1,894 controls, and baseline

characteristics were balanced after matching. Mean annual all-cause health care costs were greater among cases vs controls ($106,348 vs $62,329; P < 0.0001), because of significantly greater inpatient ($26,439 vs $2,070; P < 0.0001) and outpatient medical costs ($32,837 vs $12,454; P < 0.0001). Differences are explained by cases' significantly greater HCRU for hospital inpatient and outpatient services, physician office visits, radiology, laboratory, emergency department, and outpatient pharmacy services.

CONCLUSIONS: Pts with PsA with orthopedic surgeries after L1 initiation incurred significantly greater HCRU and costs than controls, suggesting that effective therapies that prevent the need for orthopedic surgeries among pts with PsA may improve clinical outcomes and decrease HCRU and costs.

SPONSORSHIP: None.

L19 Burden of moderate to severe acne vulgaris among commercially insured patients in the United States: A claims-based analysis

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BACKGROUND: Acne is a highly prevalent dermatologic condition affecting more than 8 million Americans, particularly adolescents and young adults. Understanding the burden of acne, including health care costs and treatment outcomes, is crucial for improving patient care and addressing unmet needs.

OBJECTIVE: To assess health care costs, treatment patterns, and symptom control associated with moderate-to-severe acne among commercially insured patients in the United States.

METHODS: Patients (9-64 years) treated for moderate-to-severe acne were identified in the Merative MarketScan database (October 1, 2015, to June 30, 2022). Treatments included isotretinoin, oral antibiotics, spironolactone, and topical combinations. The index date was defined as the date of treatment initiation, and the study period was defined as the 12 months following the index date. Health care costs, treatment patterns, and symptom control were measured during the study period. Patients who remained on index treatment with acne-related visits at least 6 months apart stepped down from index treatment, or discontinued all treatments with at least 1 acne-related follow-up visit were considered adequately controlled. Health care costs (medical + pharmacy) were described for patients with moderate-to-severe acne and those without acne stratified by age (9-25, 26-45, and 46+ years).

RESULTS: In total, 342,791 patients with moderate-to-severe acne and 321,430 patients without acne were included. Among patients with acne, mean age was 22.0 years (76.3% aged 9-25 years) and 66.2% were female. Across all age groups, patients with acne had higher unadjusted health care costs than those without acne (9-25: $5,352 vs $2,842; 26-45: $8,146 vs $4,930; 46+: $12,953 vs $8,730), driven in part by higher outpatient costs. The most common index treatments were topical combinations (39.5%), followed by oral antibiotics (37.8%), isotretinoin (12.8%), and spironolactone (9.9%). Treatment patterns were highly variable with nearly 4,000 unique treatment sequences observed. Although rates of symptom control varied by treatment type, acne was inadequately controlled in 62.1% of patients at 16 weeks and 39.3% of patients at 12 months.

CONCLUSIONS: Moderate-to-severe acne imposes a burden on commercially insured patients resulting in increased unadjusted health care costs, particularly in outpatient settings. The heterogeneity of treatment patterns and notable proportion of patients inadequately controlled with current therapies suggests a need for novel, more effective treatment options to improve patient care and alleviate the economic impact of acne on the health care system.

SPONSORSHIP: Bausch Health US, LLC.

L20 Vitiligo-associated autoimmune disorders in patients in the United States: A systematic review and meta-analysis

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BACKGROUND: Vitiligo is a chronic multifactorial pigmentary autoimmune disorder that negatively impacts patients' quality of life and well-being. Prevalence in the United States ranges from 0.1% to 1.5% of the general population. In 2022, the US Food and Drug Administration approved ruxolitinib cream 1.5% to treat nonsegmental vitiligo in patients aged 12 years and older.

OBJECTIVE: To further characterize and understand the association between vitiligo and other autoimmune disorders among the adult US patient population.

METHODS: A comprehensive search of the MEDLINE and Embase library databases from January 1, 2012, to November 30, 2022, was conducted. Key search terms included

vitiligo, autoimmune disease, and comorbidities. Of 3,104 studies initially identified, 226 full-text articles were assessed for eligibility. A total of 8 full-text manuscripts met the eligibility criteria (ie, study design, sample size, patients, comorbidities, characteristics, and outcomes). Two reviewers independently extracted data.

RESULTS: Among the 8 unique studies and 10,246 unique patients in the analysis, several autoimmune disorders were associated with vitiligo, including hypothyroidism (10.0%; 95% CI = 9.1-10.8), which was the most common autoimmune comorbidity, followed by psoriasis (5.1%; 95% CI = 2.3-7.9), rheumatoid arthritis (3.2%; 95% CI = 1.7-4.6), alopecia areata (2.7%; 95% CI = 2.3-3.1), hyperthyroidism (2.1%; 95% CI = 1.6-2.6), type 1 diabetes mellitus (1.8%; 95% CI = 0.9-2.8), inflammatory bowel disease (1.8%; 95% CI = 1.0-2.7), pernicious anemia (1.6%; 95% CI = 0.4-2.8), and chronic urticaria (1.6%; 95% CI = 0.7-2.5). Patients with vitiligo were 4.02 (95% CI = 3.29-4.88) times as likely to have hypothyroidism and 3.13 (95% CI = 1.08-9.10) times as likely to have alopecia areata compared with the general population.

CONCLUSIONS: There is significant evidence that vitiligo is associated with multiple autoimmune disorders in the US patient population, which in turn emphasizes the autoimmune-pathogenic nature of vitiligo. Given the economic burden of these autoimmune comorbidities, a deeper understanding of these correlations is crucial for more efficient management of the disease, for reducing associated costs, and also for minimizing the overall disease burden.

SPONSORSHIP: Incyte Corporation.

L23 Dupilumab improves mental health burden in patients with prurigo nodularis: Results from two pooled randomized phase 3 clinical trials

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BACKGROUND: Prurigo nodularis (PN) is a chronic inflammatory skin disease that severely impacts quality of life. This post hoc analysis evaluates the impact of dupilumab on anxiety and depression in patients with PN as measured by the patient-reported Hospital Anxiety and Depression Scale (HADS).

OBJECTIVE: To evaluate the impact of dupilumab in the mental health of patients with PN, including anxiety and depression, as measured by HADS questionnaire.

METHODS: LIBERTY-PN PRIME/PRIME2 (NCT04183335/NCT04202679) were multicenter, double-blind, 24-week (wk), phase 3 trials in adults with PN receiving 300 mg dupilumab (600 mg loading dose; n = 153) or placebo (n = 158) every 2 wks. HADS is a patient-reported 14-item questionnaire used to assess anxiety (HADS-A) and depression (HADS-D) scores. Scores for each range 0-21 (≤7 = normal, 8-10 = borderline (possible case), ≥11 = probable case of anxiety/depression). Data from the two studies were pooled and analyzed using CMH test (percentage of patients with HADS scores <11) and ANCOVA (change from baseline in HADS scores).

RESULTS: At baseline, 40% of patients reported a HADS-A or HADS-D score of at least 11. Among patients with a HADS-A score of at least 11 at baseline (37%), a significantly greater proportion receiving dupilumab reported HADS-A less than 11 by wk 24 vs placebo (71% vs 36%; $P = 0.0001$). Among patients with a HADS-D score of at least 11 at baseline (15%), a numerically greater proportion receiving dupilumab reported HADS-D less than 11 by wk 24 vs placebo (65% vs 29%; $P = 0.0577$). Among patients with a HADS-A or HADS-D score of at least 11 at baseline, a significantly greater proportion receiving dupilumab reported HADS-A or HADS-D less than 11 by wk 24 vs placebo (68% vs 31%; $P = 0.0002$). HADS-A scores in dupilumab-treated patients improved significantly by wk 24 vs placebo (LS mean change from baseline: −3.0 vs −1.6; $P = 0.0004$), as did HADS-D scores (−2.0 vs −0.8; $P = 0.0004$). Overall safety was consistent with the known safety profile of dupilumab.

CONCLUSIONS: At baseline, 4 out of 10 adult patients with PN reported HADS-A or HADS-D score at least 11. Dupilumab-treated patients experienced significant improvement in anxiety and depression compared with placebo over a 24-wk treatment period.

SPONSORSHIP: Research sponsored by Sanofi and Regeneron Pharmaceuticals Inc. ClinicalTrials.gov Identifiers: NCT04183335 and NCT04202679. Medical writing/editorial assistance was provided by Moataz Badawi, PhD, and Maria Coimbra-Dores, PhD, of Excerpta Medica, and was funded by Sanofi and Regeneron Pharmaceuticals, Inc., according to the Good Publication Practice guideline.

M00-M99 Diseases of the Musculoskeletal System and Connective Tissue

(eg, osteoarthritis, osteoporosis, rheumatoid arthritis)

M1 Exploring the influence of price and coverage differences on biosimilar utilization for rheumatoid arthritis

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BACKGROUND: Biologic therapies have improved rheumatoid arthritis (RA) treatment. However, their high costs may prevent adequate access for all patients who need treatment. Biosimilars offer cost-effective alternatives to biologics. This analysis aims to explore how payer coverage and pricing differences influence biosimilar therapy usage in RA.

OBJECTIVE: To understand the utilization of biosimilars for RA and analyze the influence of coverage, order of market entry, and price differences on new product uptake.

METHODS: We conducted a retrospective claims analysis using longitudinal patient claims data. First, we established a cohort of patients diagnosed with RA. Then we identified patients with RA who were prescribed biologics or biosimilars using the relevant J and NDC numbers. Our analysis examined switching patterns of patients transitioning from RA biologics to their respective biosimilars or other biologics. We compared the biologics and biosimilars' yearly therapy prices and access to explore the relationship between pricing, access, and use.

RESULTS: We evaluated 2 biologics: Remicade and Rituxan. For Remicade's biosimilars, being first to market appears to be more important than price; for Rutixan's biosimilars, preferable price and payer coverage may have improved market share. Remicade's first biosimilar to market—Inflectra—still has a higher price than its competitors but has managed to secure better market share than other infliximab biosimilars. In 2023, Inflectra captured 5% of patients who switched from Remicade and attracted 24% of new patients, indicating the impact of being a pioneering player in the market. Ruxience—the second Rituxan biosimilar—has achieved a comparable market position and better formulary coverage than Truxima, Rituxan's first biosimilar, likely owing to its lower price. In 2023, Ruxience captured 11% of patients transitioning from Rituxan and 18% of new patients while Truxima garnered 13% and 20%, respectively. Truxima market share is slowly decreasing as Ruxience is gaining new patients.

CONCLUSIONS: Biosimilars have gained market share, but established biologics remain dominant. Being the first biosimilar to launch may have a larger impact on utilization than price; however, when multiple biosimilars are present, price may be the driving factor for increased utilization.

SPONSORSHIP: Syneos Health Consulting.

M2 Timely use of biosimilars in rheumatoid arthritis: A cost-effectiveness model from the US payer perspective

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BACKGROUND: Rheumatoid arthritis (RA) is a chronic, progressive inflammatory disease affecting approximately 1.3 million adults in the United States. RA incurs significant economic burden to society, with annual direct health care costs estimated to be $19.3 billion. Biologic disease-modifying antirheumatic drugs (bDMARD) are a mainstay of therapy in RA. Given the growth of the US biosimilar market, we assessed the value of timely usage of bDMARD compared with prolonged conventional synthetic DMARDs therapies in RA.

OBJECTIVE: To evaluate if timely use of biosimilar adalimumab (bADA) plus methotrexate (MTX) is cost effective when compared with late introduction of biologics in patients with moderate-to-severe RA who inadequately responded to MTX.

METHODS: A Markov model was constructed simulating the management of patients with moderate to severe RA (diagnosed <2 years) aged at least 51 years over a 5-year time horizon from a US commercial payer perspective. Direct costs evaluated included drug acquisition and administration, treatment switching, disease management, therapeutic drug monitoring, prophylactic treatment, and adverse events. bADA annual cost was assumed to be $2,724.18. The treatment sequences compared were timely use of bADA as first-line followed by best supportive care (oral MTX+ corticosteroids) or continuing MTX as first-line followed by delayed bADA. The model provided estimates of total costs and quality-adjusted-life-years (QALYs) as a measure of effectiveness and of the costs associated with managing RA in the United States, both discounted at 3% annually.

RESULTS: Timely use of bADA was dominant when compared with continued use of MTX. For the bADA sequence, total treatment costs were $425,471.81 and QALYs were $2.54. For

the MTX sequence, total treatment costs were $431,630.23 and QALYs were $2.52. The difference in total costs was $6,158.42 and the difference in QALYs was 0.029 between the sequences.

CONCLUSIONS: Results from this cost-effectiveness model analysis indicate that timely biosimilar initiation in the treatment of moderate-to-severe RA after MTX failure is more cost effective than continuing MTX. The upcoming launches of multiple bADA products may potentially lower costs for payers and increase patient access. References 1. Xu Y, Wu Q. J Clin Med. 2021;10(15). 2. Birnbaum H, Pike C, Kaufman R, et al. Curr Med Res Opin. 2010;26(1):77-90.

SPONSORSHIP: This study was designed and conducted by Xcenda in collaboration with the sponsor, Sandoz Inc., who has a US Food and Drug Administration–approved adalimumab biosimilar.

M4 Real-world treatment patterns, adherence, and economic burden among patients with incident systemic lupus erythematosus in the United States: A retrospective analysis of a US claims database

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BACKGROUND: Systemic lupus erythematosus (SLE) is a complex autoimmune disease that can require a variety of medications to treat. However, there is limited research on how these medications are used in different stages of treatment and how they impact adherence, health care resource utilization (HCRU), and costs. Additionally, the use of oral corticosteroids for SLE is associated with side effects including the risk of contributing to chronic organ damage and infection.

OBJECTIVE: To evaluate the treatment patterns including corticosteroid use, adherence, HCRU, and associated costs up to 3 sequences-of-therapy (SOT), and SOT transition-related factors among adult with newly diagnosed SLE in the United States.

METHODS: This retrospective observational cohort study used Merative MarketScan Commercial and Medicare Supplemental Database (January 2011 to December 2019). We identified SLE patients using *International Classification of Diseases Ninth/Tenth Revision, Clinical Modification* codes and at least 24 months of continuous enrollment before and after index date (January 2013 to December 2017). SOT 1 start date was earliest SLE treatment prescription on/following index date. A new medication (added/switched) resulted in a new SOT. Medication use, adherence (medication possession ratio [MPR] ≥0.8), HCRU, and associated costs were evaluated for each SOT. Multivariable logistic regression was used to identify factors associated with SOT transition.

RESULTS: Among 2,476 patients initiating SLE treatment, 38.3% and 16.9% progressed to SOT 2 and 3, respectively. Antimalarials (85.7%) were most common in SOT 1, and immunosuppressants in SOT 2 (85.4%) and SOT 3 (77.5%); biologic use increased from SOT 1 (1.2%) to SOT 3 (31.1%). Of 1,085 oral corticosteroid users, 76%-84% had daily prednisone-equivalent doses of at least 7.5 mg, with 23%-32% receiving more than 20 mg/day. Adherence to biologics was highest (MPR = 0.71), followed by antimalarials (MPR = 0.65) and immunosuppressants (MPR = 0.56), regardless of SOT. HCRU and associated costs increased across SOT. Patients were twice as likely to transition to SOT 2 if taking immunosuppressants only (adjusted odds ratio = 2.10; $P \leq 0.001$), and if they had severe disease activity in SOT 2 (adjusted odds ratio = 2.13; $P = 0.001$).

CONCLUSIONS: A range of medications were prescribed to patients newly initiating treatment of SLE. Further, HCRU and associated costs increased across SOT and adherence was low across all SOTs. These findings underscore need for treatments with greater adherence that reduce HCRU, associated costs, and steroid utilization in SLE.

SPONSORSHIP: Amgen Inc.

M5 Chronic low back pain patients treated with Belbuca and buprenorphine transdermal patches: A retrospective US commercial claims health care cost analysis

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BACKGROUND: Chronic low back pain (cLBP) is one of the leading disability causes in the United States. Despite opioids being an effective cLBP treatment, buprenorphine has an increasing prescribing trend because of encouraging risk-benefit profile.

OBJECTIVE: To explore health care cost (HCC) changes in patients with cLBP treated with Belbuca or buprenorphine transdermal patches (BTPs) observed before and after the treatment initiation.

METHODS: The study was performed on Merative MarketScan commercial claims in the 2018-2021 period. The index date was the first date of Belbuca or BTP prescription. Patients

were observed over 6-month pre-index and 12-month post-index periods. The population consisted of adult cLBP patients treated with Belbuca or BTP. Gaps in insurance coverage, opioid use disorder, and switching between study treatments were not allowed during the observational period. Demographics were determined on index date, while clinical characteristics were assessed during pre-index period. Propensity-score matching was performed to minimize selection bias and ensure a homogeneous population pool. HCC trends were analyzed in each cohort between periods of equal duration, thus the 6-month pre- and post-index, ensuring a valid within-group comparison.

RESULTS: Out of 17,439 patients prescribed Belbuca or BTP, the final matched sample consisted of 1,416 patients (708 per cohort). Belbuca was associated with a trend of stable (insignificant change) any-cause and cLBP-related total HCCs. A significant benefit was observed in the cLBP-related emergency department (ED) costs after treatment introduction ($56 cost saving, $P = 0.025$). On the contrary, BTP led to a cost raise in any-cause ($3,989, $P < 0.001$) and cLBP-related total HCCs ($1,337, $P = 0.043$). The raise in expenditures after the BTP initiation was mostly driven by the increases in any-cause outpatient ($1,734, $P < 0.001$) and inpatient ($1,648, $P = 0.057$) HCCs. The pre-index health care expenditures were similar between the cohorts. The only significant difference was captured in any-cause outpatient HCC ($7,979 Belbuca and $6,332 BTP, $P = 0.027$). However, during the 6-month post-index, this difference diminished ($7,542 Belbuca and $8,066 BTP, $P = 0.471$) and Belbuca-treated patients had lower cLBP-related ED ($29 vs $73, $P = 0.038$) and total cLBP HCCs ($2,909 vs $4,124, $P = 0.047$) than BTP-treated patients. cLBP-related inpatient and outpatient HCCs were also lower in the Belbuca cohort, but statistical significance was not reached.

CONCLUSIONS: A stable cLBP HC trend in Belbuca vs increasing cLBP HC in BTP after treatment initiation led to lower cLBP treatment expenditures for patients being treated with Belbuca.

SPONSORSHIP: Collegium Pharmaceutical Inc.

M7 The economic impact of treatment initiation in Duchenne muscular dystrophy: A retrospective US claims analysis

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BACKGROUND: Duchenne muscular dystrophy (DMD), the most common severe form of muscular dystrophy, affects 1/3,500-6,000 live male sex births and is attributed to a lack of the dystrophin protein. Pharmacological treatment options for patients with DMD, including exon skipping therapy (EST) and glucocorticoids, are limited. No studies on the economic impact of initiating these treatments have been published.

OBJECTIVE: To assess the economic impact of initiating pharmacological treatment in DMD.

METHODS: A retrospective analysis used IBM MarketScan Commercial and Medicaid claims data (July 2018 to September 2021). Patients with DMD were identified using a validated and peer-reviewed published algorithm. Initial DMD diagnosis date was set as index date. Patient selection criteria included (1) diagnosis of DMD (*International Classification of Diseases, Tenth Edition* code G71.01); (2) aged 40 years or younger; and (3) continuous enrollment of 3-months pre-index and 12-months post-index. Patients with cancer diagnoses were excluded.

RESULTS: Of 782 patients with DMD identified, 432 fulfilled the criteria and were grouped into 4 categories based on the treatments they received post-index: EST (n = 43); branded glucocorticoids (BG) (n = 172); generic glucocorticoids (GG) (n = 149), and no treatment of DMD (NT) (n = 68). The average ages of the groups were EST = 13.4 ± 5.9 (mean ± SD), BG = 13.3 ± 4.9, GG = 12.4 ± 8.1, and NT = 18.6 ± 9.7. Medicaid was the primary payer among patients (>65%). The mean annual pharmacy costs for EST had the largest rise from the pre-to-post–index period with a 60-fold rise from $10,843.0 ± 24,830.2 to $648,868.5 ± 861,371.5. BG grew 26-fold from $2,539.8 ± 14,359.2 to $66,217.8 ± 47,671.4, GG had a 3-fold rise from $1,016.2 ± 2,580.7 to $2,808.5 ± 12,247.8, and NT rose from $616.0 ± 1,583.5 to $688.3 ± 1,484.9. Mean annual outpatient costs grew 3-fold from pre-to-post-index period in patients on EST, from $102,533.5 ± 311,707.6 to $356,985.1 ± 665,859.6. Conversely, BG, GG, and NT had only marginal increases of approximately 1-fold from their respective pre-index costs. Finally, mean total cost (medical+pharmacy) from pre-to-post-index period showed the highest increase for EST with a 9-fold rise from $115,934.1 ± 320,862.7 to $1,010,571.1 ± 898,471.2. BG had a 4-fold growth from $22,309.15 ± 3,696.9 to $91,318.9 ± 68,598.2, whereas GG and NT costs increased from $30,035.2 ± 86,292.4 to $35,019.6 ± 93,309.8 and from $36,080.1 ± 82,248.4 to $48,369.2 ± 87,468.8, respectively.

CONCLUSIONS: Post-index, EST was associated with higher pharmacy and total medical costs. Rank order of total treatment costs showed that EST were most expensive followed by BG, GG, and NT. This is the first study comparing the cost of treatment initiation in DMD.

SPONSORSHIP: Pfizer, Inc.

M10 Long-term effectiveness of a digital acceptance and commitment therapy for fibromyalgia

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BACKGROUND: Fibromyalgia (FM) is a chronic pain disorder that is often accompanied by pain and other central nervous system mediated symptoms (eg, sleep, dyscognition, and fatigue). Most clinical guidelines recommend cognitive behavioral therapy as an individual or adjunctive treatment. A smartphone-based, 12-week digital therapeutic (FM-ACT) has been developed to deliver self-guided Acceptance and Commitment Therapy, a form of cognitive behavioral therapy, for the management of FM. Previous trials have demonstrated the effectiveness of the FM-ACT treatment. Early data on the durability of the clinical benefits were previously reported from an ongoing extension clinical study.

OBJECTIVE: To expand the analysis to all currently accumulated long-term clinical data to evaluate the long-term effectiveness of FM-ACT.

METHODS: An analysis was performed on the ongoing accumulated data from 3 real-world extension clinical trials. Participants with FM first completed the 12-week FM-ACT active treatment during the main study, and then entered the associated extension trial, where they were followed through to month 12 (from treatment inception). In the extension trial, FM-ACT served as a maintenance therapy used at participant discretion to manage their FM symptoms. The analysis assessed the treatment responses at 3, 6, 9, and 12 months from treatment inception. Outcomes assessed included Patient Global Impression of Change (PGIC), Revised Fibromyalgia Impact Questionnaire (FIQ-R), and additional measures of FM-related symptoms.

RESULTS: At the time of analysis, follow-ups were collected on 75, 69, 57, and 46 participants at 3, 6, 9, and 12 months, respectively. At the end of the active treatment (month 3), 76% of the participants reported improvement on PGIC (responders). The PGIC responder rate remained consistent through month 12 (78%). The proportion of participants with at least 20% improvement on FIQ-R from baseline (FIQ-R responders) remained consistent from the end of active treatment to month 12 (65% and 70%, respectively). In addition, clinically meaningful improvements were observed on pain intensity, pain interference, sleep interference, and depression at month 3, which were maintained through month 12.

CONCLUSIONS: Analysis of currently accumulated real-world follow-ups supports the previously reported early data on the durability of the FM-ACT treatment effectiveness. The results suggest that FM-ACT offers clinically meaningful improvement of outcomes that are durable for at least 12 months.

SPONSORSHIP: Swing Therapeutics, Inc.

N00-N99 Diseases of the Genitourinary System

(eg, chronic kidney disease)

N1 Nephrotic syndrome: Patient characteristics, treatment patterns, and related outcomes after treatment with Acthar Gel or comparable standard of care in a large administrative claims database

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BACKGROUND: Nephrotic syndrome (NS) is a glomerular disorder, characterized by the loss of protein in the urine (proteinuria) and edema, with an incidence of 3-5 new cases per 100,000 people per year in the United States. First-line treatment consists of corticosteroids (CS) and/or calcineurin inhibitors (CNIs), but complications or nonresponse to first-line treatment warrant additional treatment options for these patients. Acthar Gel is a naturally sourced complex mixture of adrenocorticotropic hormone analogs and other pituitary peptides indicated for the treatment of proteinuria in NS and a short-term option for patients that do not respond to CS or CNIs.

OBJECTIVE: To characterize patients who initiated Acthar in NS treatment and to compare changes in treatment patterns and NS-related outcomes to similar therapies used after CS and CNIs.

METHODS: This study is a retrospective, observational cohort comparison of patients with NS who initiate treatment with Acthar or similar standard of care (SOC) comparators (azathioprine, chlorambucil, cyclophosphamide, mycophenolate mofetil, or rituximab) in a large commercial claims database (Symphony Health). Patients had a confirmed

diagnosis for NS, were aged 18 years or older, and had 12 months of continuous enrollment pre- and post-index.

RESULTS: Patients treated with Acthar were older (49 vs 46 years, P = 0.002) with less commercial coverage (15% vs 35%) and lower comorbidity index score (2.3 ± 1.8 vs 2.5 ± 2.0, P = 0.005) than the SOC comparator. The Acthar cohort had a significant reduction during follow-up in proportion of patients taking CS (66% vs 51%, P < 0.001), patients on extended use CS (≥60 days) (37% to 25%, P < 0.001), and average daily dose (32.1 ± 21.3 to 21.7 ± 21.1, P = 0.001) compared with baseline. Patients in the SOC comparator had a significant increase in the follow-up for patients on CS overall (69% to 81%, P < 0.001) and extended use CS (34% to 49%, P < 0.001), compared with baseline. The Acthar cohort had an increase in patients on dialysis in the follow-up (6% to 14%, P < 0.001), but no change in renal transplants (10% to 10%, P = 0.774) or transplant complications (6% to 6%, P = 1.000), while the SOC comparator had fewer patients on dialysis (16% to 12%, P < 0.001) but an increase in renal transplants (19% to 22%, P < 0.001) and transplant complications (8% to 10%, P < 0.001).

CONCLUSIONS: Acthar Gel is a viable treatment option for patients that do not respond to CS and/or CNIs. Treatment with Acthar shows a steroid-sparing effect and less need for renal transplant compared with the SOC comparator.

SPONSORSHIP: Mallinckrodt.

N2 Health care costs associated with development of cardio-renal-metabolic conditions in patients before and after incidence of chronic kidney disease

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BACKGROUND: The interconnectedness of chronic kidney disease (CKD) with cardio-renal-metabolic (CRM) conditions such as atherosclerotic cardiovascular disease (ASCVD), heart failure (HF) and type 2 diabetes (T2D) is well-known. However, the economic consequences of developing CRM comorbidities before and after incidence of CKD is not well understood.

OBJECTIVE: To determine the health care costs with the development of ASCVD, HF, or T2D, before and after incidence of CKD.

METHODS: This retrospective longitudinal study used electronic medical records from Kaiser Permanente Northwest to identify members aged 18 or older who had a serum creatinine measured between 2005 and 2017. CKD was considered present when an estimated glomerular filtration rate less than 60 ml/min/1.73m2 was recorded and confirmed by a second estimated glomerular filtration rate less than 60 within 3-12 months. Patients were followed through 2019. The total observation period for each patient was divided into quarters (91-day increments), and each patient contributed a record for every quarter in which they were members of the health plan; CRM status was determined for each quarter. Generalized estimating equation model was used to estimate mean annualized health care costs over all quarters, after adjusting for age, sex, race and ethnicity, smoking, blood pressure of at least 140/90 mmHg, use of antihyperglycemics, renin angiotensin aldosterone system inhibitors, and statins.

RESULTS: The cohort included 387,985 individuals (mean [SD] age: 50.7 [15.6] years; 44.2% male sex), with a mean follow-up of 6.9 (4.6) years. The mean adjusted annualized costs over the one-year period were $7,942 (95% CI = $7,921-$7,962) prior to CKD incidence, and $18,258 ($18,157-$18,359) or 130% higher following incident CKD. Costs were higher both before and after CKD incidence when other CRM conditions were present; the absolute annualized change in costs following CKD incidence was consistent, ranging from $4,993 to $6,644. The percentage increases ranged from 21% among patients with T2D+ASCVD+HF, to 92% among patients with none of these conditions. This was mainly driven by prediagnosis costs being higher as more conditions were present.

CONCLUSIONS: The study found high health care costs both before and after incidence of CKD in the presence of CRM conditions; development of CRM conditions was consistently associated with substantial increases in health care costs following incidence of CKD. The findings indicate a clear interplay of CRM conditions and emphasize the need for better simultaneous management of these disease states to reduce the economic burden on health care systems.

SPONSORSHIP: Boehringer Ingelheim International GmbH.

N3 Cost-effectiveness analysis of empagliflozin vs standard of care in patients with chronic kidney disease in the United States

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BACKGROUND: The EMPA-KIDNEY Phase 3 randomized controlled trial demonstrated that treatment with empagliflozin (EMPA) on top of standard of care (SoC) led to a statistically significant reduction of kidney disease

progression or death from cardiovascular (CV) causes by 28% in patients with chronic kidney disease (CKD), compared with SoC alone. Estimating the long-term economic and clinical impact of using EMPA to treat CKD will be valuable for decision-makers.

OBJECTIVE: To evaluate the cost effectiveness of EMPA+SoC vs SoC from US commercial and Medicare payer perspectives.

METHODS: A Markov microsimulation model was developed with 18 health states defined by Kidney Disease Improving Global Outcomes risk categories based on estimated glomerular filtration rate and urine albumin-creatinine ratio. The simulation tracked patients with CKD over a lifetime horizon in annual cycles, capturing the impact of variation in baseline risk factors on disease outcomes. The modeled population reflected the EMPA-KIDNEY trial cohort. Acute events, long-term complications, and death were incorporated in the model including end stage kidney disease, CV disease, mineral and bone disorder, infection, acute kidney injury, anemia, other comorbidities, and all-cause hospitalizations. Wholesale acquisition costs were used for treatment costs, while complication management and treatment of adverse event costs were obtained from the literature. Health state utilities and disutilities associated with complications and events were obtained from EMPA-KIDNEY trial and literature, respectively. Annual discount rate of 3.0% was applied on costs and outcomes. Outcomes included life years (LYs), quality-adjusted LYs (QALYs), and incremental cost-effectiveness ratios (ICERs). Probabilistic and deterministic sensitivity analyses were performed to quantify uncertainty and examine the impact of varying inputs.

RESULTS: Patients on EMPA+SoC had slower disease progression during treatment duration and had greater reductions in the risk of progression to end stage kidney disease or death, compared with SoC alone. In the base case analysis, EMPA+SoC was associated with lower cost and more benefits in terms of LYs and QALYs gained (dominant ICER) for commercial payer and higher cost but more benefits in Medicare with ICER less than $150,000/QALY. In most of the scenario analyses performed, resulting ICERs were well below the threshold of $150,000/QALY, indicating cost-effectiveness of EMPA.

CONCLUSIONS: Overall, the findings indicate that EMPA+SoC is a cost-effective treatment option compared with SoC alone in the management of CKD in the United States.

SPONSORSHIP: Boehringer Ingelheim Pharmaceuticals Inc.

N4 Risk factors for treatment failure among US female outpatients with uncomplicated urinary tract infection treated with empirically prescribed oral antibiotics

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BACKGROUND: Treatment failure (TF) in uncomplicated urinary tract infections (uUTIs) can prolong and intensify patient distress, leading to increased clinical and economic burden. Identifying characteristics linked to TF risk can inform empiric treatment decisions and limit suboptimal outcomes.

OBJECTIVE: To identify risk factors for TF in US female outpatients with uUTI to empirically prescribed oral antibiotics (ABX).

METHODS: Retrospective data from Optum's de-identified Electronic Health Record (EHR) database on female outpatients aged 12 years or older between January 2017 and September 2022 were assessed. Eligibility criteria included uUTI diagnosis (Dx) with no evidence of complicated UTI, at least 1 empiric prescription (Rx) for an oral ABX of interest within ±5 days of Dx (date of first Rx=index date), and at least 12 months of EHR activity before and after the index date. TF was defined as at least 1 of the following up to 28 days after the index date: second oral ABX Rx, administration of intravenous ABX, or an emergency department (ED) or inpatient stay with a primary Dx of UTI (excluding the index uUTI). 17 candidate risk factors of TF were identified based on clinical input, data availability, and multicollinearity considerations. Risk factors were selected using least absolute shrinkage and selection operator (LASSO) and reported using risk ratios and 95% CIs obtained from a Poisson regression model with robust SEs.

RESULTS: Of 376,004 empirically prescribed uUTI patients, 62,873 (16.7%) experienced TF. TF and non-TF patients were more than 80% White and more than 52% from the Midwest with a mean age of 48.9 and 46.5 years, respectively. Of the 12 risk factors selected by LASSO, ABX Rxs for any indication in the past year (2 Rxs: risk ratio [95% CI]=1.26 [1.23, 1.29], at least 3 Rxs: 1.60 [1.56, 1.64]; reference [ref]: no ABX Rxs), empiric ABX Rx at uUTI Dx (fosfomycin: 1.60 [1.38, 1.86]; ref: nitrofurantoin), health care setting of the uUTI Dx (ED: 1.49 [1.46, 1.52], telephone/online: 1.25 [1.22, 1.29]; ref: office/clinic), region of residence (South: 1.37 [1.35, 1.40]; ref: Midwest),

patient's age (65-74 years: 1.27 [1.22, 1.33], 75 years or older: 1.35 [1.29, 1.41]; ref: 12-17 years), and recurrent UTI Dx (1.12 [1.10, 1.14]) had the strongest associations with empiric TF.

CONCLUSIONS: This study found previous ABX Rxs and recurrent UTI Dx (also known risk factors for antimicrobial resistance) to be key patient-level risk factors for TF, highlighting the role of prior infections in subsequent TF. Clinicians should consider these risk factors when treating patients with uUTI empirically with oral ABX.

SPONSORSHIP: GSK study 219500.

N5 Real-world adherence and persistence of vibegron vs mirabegron and anticholinergics in patients with overactive bladder: A retrospective claims analysis

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BACKGROUND: Overactive bladder (OAB) management with pharmacotherapy is limited by low real-world adherence and persistence. Vibegron is a β3-adrenergic receptor agonist approved in December 2020 for the treatment of OAB.

OBJECTIVE: To compare real-world adherence and persistence of patients initiating vibegron with mirabegron and anticholinergics (ACHs).

METHODS: This retrospective study used pharmacy claims data from the Optum Research Database. Study criteria included patients aged 18 years or older with at least 1 pharmacy claim for vibegron, mirabegron, or ACH from April 1, 2021, to December 31, 2021; continuous enrollment in a commercial or Medicare Advantage health plan with pharmacy and medical benefits for 3 months pre-index (baseline) and at least 2 months post-index (follow-up); and no index medication during baseline. 2 independent propensity-score models were used to match patients treated with (1) vibegron vs mirabegron and (2) vibegron vs ACHs. Adherence was measured by proportion of days covered (PDC) from index to end of follow-up and defined as PDC at least 80%. Persistence was defined as days to discontinuation of index medication (first 30-day gap) or end of follow-up. Adherence and persistence were analyzed descriptively and by Kaplan-Meier analysis, respectively.

RESULTS: After matching, 1,655 and 3,310 patients were included in the matched vibegron and mirabegron cohorts, respectively; 1,595 and 3,190 patients were included in the matched vibegron and ACH cohorts. Cohorts were generally well balanced with respect to age, sex, and race. Patients receiving vibegron had greater adherence vs patients receiving mirabegron (0.71 vs 0.68, respectively; $P = 0.004$) or ACHs (0.71 vs 0.61; $P < 0.001$). A greater percentage of patients receiving vibegron were adherent vs those receiving mirabegron (53.4% vs 49.2%, respectively; $P = 0.005$) or ACHs (53.7% vs 43.2%; $P < 0.001$). Persistence was longer with vibegron vs mirabegron (median [95% CI] = 205 [162-246] vs 148 [126-162] days, respectively; $P < 0.001$) and ACHs (207 [167-246] vs 91 [91-95] days; $P < 0.001$).

CONCLUSIONS: In this retrospective analysis, real-world adherence and persistence was higher in patients initiating vibegron compared with patients initiating mirabegron or ACH when matched on baseline characteristics.

SPONSORSHIP: Urovant Sciences.

N7 The budget impact of adopting a new thermosetting, bioadhesive clindamycin phosphate vaginal hydrogel to treat bacterial vaginosis from the US health plan perspective

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BACKGROUND: Bacterial vaginosis (BV) is a common vaginal disorder characterized by a microbial imbalance in the vagina and has a high rate of recurrence. The US Food and Drug Administration recently approved a thermosetting, bioadhesive clindamycin phosphate vaginal hydrogel (XACIATO) for the treatment of BV in female patients aged 12 years and older. This new gel requires a single dose as opposed to the multiple doses required for other treatments.

OBJECTIVE: To estimate the budget impact of introducing the bioadhesive clindamycin phosphate hydrogel to a US health plan for the treatment of recurrent (≥2 courses) BV for female patients aged 12-64 years.

METHODS: A budget impact model with a 3-year time horizon was developed for hypothetical 1 million member commercial and Medicaid health care plans. The estimated size of the target patient population was based on plan sex and age distribution (female patients aged 12-64 years), age-adjusted BV rates, and the proportion with symptomatic BV. Comparators included the approved interventions, both oral and vaginal, that are recognized by the Centers for Disease Control or Prevention for the treatment of BV. The model focused on pharmacy costs with the median wholesale acquisition costs used as inputs. For each treatment course, the number and proportion of treated patients and prescribed treatments were obtained using claims data from the Merative MarketScan Database. Other inputs were derived from published literature and publicly available sources. Health care resource utilization and clinical efficacy of all BV treatments

were assumed to be equal. The market share of the new hydrogel was taken proportionally from all comparator treatments with a gradual uptake over 3 years.

RESULTS: In a 1 million member commercial and Medicaid plan, 17,570 patients were estimated to undergo BV treatment each year. Recurrent (≥2 course) treatments (for which the bioadhesive clindamycin hydrogel is assumed to be used) were estimated to be given to 8,453 and 10,499 patients in a commercial and Medicaid plan, respectively. The model-based budget impact analysis estimated that the introduction of the clindamycin hydrogel would result in a 3-year net budget impact of $0.01 per member per month (PMPM) for a commercial plan and $0.02 PMPM for a Medicaid plan. Sensitivity analysis confirmed the robustness of these results.

CONCLUSIONS: Introducing the new bioadhesive clindamycin hydrogel for recurrent BV treatment results in a minimal budget impact for both commercial and Medicaid plans. The new treatment of BV offers a new single-dose bioadhesive gel technology with minimal additional cost to the payer.

SPONSORSHIP: Organon.

N8 The impact of health benefit design on assisted reproductive technology utilization and pregnancy-related outcomes

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BACKGROUND: The global lifetime prevalence of female infertility is estimated at 17.5%. Assisted reproductive technology (ART) is increasingly used to address infertility.

OBJECTIVE: To evaluate the impact of infertility treatment health benefit coverage on ART utilization and pregnancy-related outcomes.

METHODS: A retrospective analysis of the Workpartners Research and Reference Database (January 2010, to December 2022, self-insured US employees) was conducted. Women aged 18 years or older with at least 1 infertility diagnosis and at least 2 years of continuous data after the initial infertility diagnosis were included and classified into the high cohort (with infertility treatment coverage) or the low cohort (with infertility diagnostic coverage only or no infertility coverage). Likelihood of using any ART medications or procedures, likelihood of becoming pregnant, rate of negative maternal, and perinatal outcomes were compared using stepwise regression models, controlling for differences in employee demographics (age, comorbidities, race, marital status, relation to employee, region), job-related variables (exempt status, full time status, hourly vs salary, annual salary), and number of insured dependents.

RESULTS: A total of 10,820 qualified female patients were identified with 7,589 (70.1%) in the high and 3,231 (29.9%) in the low cohort. The mean cohort ages were 34.4 vs 33.5 years, respectively ($P<0.0001$). The likelihood of using any ART medication or procedures were 55.8% for the high cohort compared with 36.7% for the low cohort ($P<0.0001$). The overall likelihood of becoming pregnant and likelihood of becoming pregnant with any ART utilization were both higher in the high cohort compared with the low cohort (59.9% vs 56.46; $P=0.0014$ and 69.6% vs 65.3%; $P=0.0089$, respectively). In maternal outcome, the rate of cardiomyopathy during pregnancy was lower for the high cohort than in the low cohort (0.03% vs 0.27%; $P=0.0260$). In perinatal outcome, more congenital malformations postdelivery but fewer pediatric intensive care unit admissions were reported in the high cohort than the low cohort during the study period (23.12% vs 19.58%; $P=0.0297$ and 0.32% vs 1.06%; $P=0.0074$, respectively). No statistically significant differences were found in other maternal and perinatal outcomes studied.

CONCLUSIONS: Health benefit design with infertility treatment coverage is associated with a higher utilization of ART medication and procedures, higher likelihood of achieving pregnancy, and improved maternal and perinatal outcomes.

SPONSORSHIP: Ferring Pharmaceuticals, Inc.

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)

U2 A conceptual framework representing patients' experiences with comprehensive medication reviews

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BACKGROUND: One of the required services the medication therapy management program offers to Medicare Part D

beneficiaries is an annual comprehensive medication review (CMR). A CMR is a systematic process of collecting patient-specific information, assessing medication therapies to identify medication-related problems, developing a prioritized list of medication-related problems, and creating a plan to resolve them with the patient, caregiver, and/or prescriber. Studies have shown both a clinical and business case for measuring and improving the patient experience; however, there are no patient-reported experience or outcome measures for CMRs that are scientifically valid.

OBJECTIVE: To assist patients to influence their CMR by providing clinicians with actionable information from their own perspectives and improve the quality of this service, this project conducted 52 interviews to identify aspects of CMR service that affected their experience and to then create a conceptual framework to enable the creation of a patient-reported experience or outcome measure.

METHODS: Interviews were conducted with patients who received a telephonic CMR using standard cognitive interview procedures. The interviews were aimed at eliciting aspects of the CMR experience that were most meaningful to patients. Interviews were recorded, transcribed, and coded using thematic analysis by 2 independent reviewers to develop a conceptual framework describing the domains of the CMR patient experience.

RESULTS: Of the 52 interviews, 44 were used to create a conceptual framework organized using the Donabedian health care quality model. The framework contains 3 domains representing the aspects of the CMR service that affected the patient experience: structural characteristics of the pharmacy professional conducting the CMR (subdomains: compassion, professionalism, and responsiveness); processes of the CMR related to the implementation of the service (subdomains: purpose of the CMR, perception of the caller, timing of the call, telephonic experience, and language); and outcomes related to the CMR content related to improving patient medication knowledge, addressing concerns, and empowering self-management. All domains of the patient experience were influenced by intrinsic patient factors, such as the patient's familiarity with medications and their regular care team and whether the service was conducted with the patient or their caregiver.

CONCLUSIONS: The results of the interviews represent specific structures, processes, and outcomes that were most influential to patients during their experience with the CMR service. Based on these results, a CMR-specific patient-reported outcome measure will be developed.

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

U3 Real-world impact of proactive formulary management on drug costs in the multiple sclerosis drug class

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BACKGROUND: Multiple sclerosis (MS) is the fifth-highest cost category in the nation at $11 per member per quarter (PMPQ). Brand Tecfidera (dimethyl fumarate [bDMF]) was approved by the US Food and Drug Administration (FDA) on March 27, 2013, and has been a market-leading product for MS. Tecfidera launched at a wholesale acquisition cost (WAC) of $55,000/year and as of 2019 was $95,000/year, a 73% increase. This trend of increasing drug cost is shared across other brand medications for MS. As a follow-up to bDMF, a similar drug Vumerity (diroximel fumarate [DRF]) was approved by the FDA on October 29, 2019, with a WAC price of $88,000/year. Despite the anticipated launch of generic dimethyl fumarate (gDMF) in 2020, DRF was added to many formularies. RealRx viewed the prospect of a gDMF to be an opportunity to impact this top 5 category spending. Therefore, a strategy of DRF exclusion and allowing upon medical exception was implemented.

OBJECTIVE: To evaluate the strategic, real-world impact of the initial exclusion of DRF from a multistate plan formulary on the total drug cost in the fumaric acid class space compared with national use.

METHODS: This historical, descriptive study compared the total cost of all fumaric acid derivatives (ie, gDMF, bDMF, DRF, and Bafiertam [monomethyl fumarate, MMF]) within a multistate health plan, which excluded DRF, vs the total cost expected if RealRx drug use followed national market shares between April 1, 2021, and March 31, 2022. RealRx PMPQ and total drug spending were calculated from published WAC, RealRx membership, and RealRx pharmacy administrative claims data. National PMPQ and drug spending were deduced by integrating the percentage of national drug market shares data with the aforementioned RealRx drug use data.

RESULTS: The PMPQ cost for RealRx drug use vs RealRx drug use under national market shares in the fumaric acid class was $1.66 vs $2.68 in Q2 2021 and $0.30 vs $1.71 in Q1 2022. Total drug spending during the study period was $456,613 vs $1,612,788, an estimated annual savings of $1.2 million.

CONCLUSIONS: In today's market, total drug spending in the MS class is ever increasing because of rising drug costs and market penetration of similar, costly, brand name medications (eg, DRF and MMF). Although these similar drugs may

benefit a subset of patients, managing to that clinical need vs open or equal access allows better alignment of goals. In conclusion, it is crucial that pharmacy benefit managers have long-term, proactive insight into both brand and generic pipelines when strategizing their formulary management, as this can lead to significant cost savings for payers and patients.

SPONSORSHIP: None.

U4 Payer reactions to the implementation of the Inflation Reduction Act: Forecasting future changes to Part D plans

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BACKGROUND: Drug pricing and the Part D benefit redesign provisions within the Inflation Reduction Act (IRA) will have sweeping implications for US health care payers. Insight into how US payers plan to respond to Part D policies included in the IRA is needed to forecast how IRA implementation may affect patient access and affordability.

OBJECTIVE: To assess payer perceptions of the IRA and its potential impact on Medicare Part D plans.

METHODS: A double-blind, web-based survey of US health care payers was fielded through Xcenda's research panel, the Managed Care Network, from February 23, 2023, to March 7, 2023 (N = 50).

RESULTS: Payers believe IRA-related changes to Medicare Part D will have a financial impact on their portfolio of Part D plans; some forecast an adverse financial impact (44%, n = 22), others expect a relatively limited financial impact (34%, n = 17), and some believe it will reduce the number of Part D plans they offer (20%, n = 10). Very few payers think the changes will result in a positive financial impact (10%, n = 5) or increase the number of Part D plans offered by their organization (8%, n = 4). The most significant outcome of the redesign is likely to be narrower formularies, hampering patient access. Most payers anticipate somewhat or significantly more narrow formularies (52% and 24%, respectively), whereas only 20% expect relatively similar formulary coverage compared with current designs. Additionally, most payers expect greater utilization management (UM) because of increased financial liability for Part D plans, with some anticipating greater UM across the board (42%, n = 21) whereas others anticipate greater UM for high-cost medications (32%, n = 16) or on a case-by-case basis (16%, n = 8). Very few expect no change in current UM levels (10%, n = 5). Most payers anticipate IRA implementation will result in increased premiums for Part D plans, ranging from those who expect an increase of up to 5% (18%, n = 9), between 5% to 10% (40%, n = 20), and greater than 10% (8%, n = 4). Few payers expect to maintain Part D plan premiums at current levels (12%, and n = 6), and no payers anticipate premiums will be reduced lower than current levels.

CONCLUSIONS: US payers expect IRA implementation to have a financial impact on Part D plans. As a result, most payers anticipate an increase in Part D premiums as well as greater use of UM strategies to contain costs. Additional analysis is needed to examine the extent to which these changes will impact patient access to treatments.

SPONSORSHIP: Xcenda/AmerisourceBergen.

U5 Digital therapeutics coverage and reimbursement evidence expectations among US payers

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BACKGROUND: Manufacturers of digital therapeutics (DTx) are increasingly seeking product coverage and reimbursement. Product characteristics and payers' limited experience with DTx presents unique challenges for evaluation, resulting in the need for additional evidence to inform policy decisions. As the DTx landscape continues to evolve, and as payers establish more standardized frameworks, data regarding payer evidence expectations are needed.

OBJECTIVE: To assess US payer perceptions on the impact of evidence-related factors on coverage determinations for DTx.

METHODS: A quantitative survey was fielded in June 2023. Respondents were payers involved in the formulary decision-making process at pharmacy benefit managers, integrated delivery networks, and regional and national health plans. Survey topics included minimal evidence requirements for product reviews, the impact of evidence-related factors on coverage determinations, and preferences for preapproval information exchange (PIE). Responses were evaluated using descriptive statistics.

RESULTS: A total of 62 respondents completed the survey. Most were medical directors (72%) and from a health plan organization (16% regional; 40% national). For 69% of respondents, a randomized controlled trial (RCT) was the minimal evidence required for DTx coverage consideration, with 28% indicating that real-world evidence (RWE) was also necessary. Payers indicated that evidence related to quality/functionality (52%), usability (49%), US Food and Drug Administration (FDA) authorization (49%), and engagement (42%) would have an impact on positive coverage decisions to a very high degree. A very high degree of impact was also

noted for tools and publications related to patient-reported outcomes (PROs) (58%), cost-effectiveness analyses (43%), Institute for Clinical and Economic Review evaluations (41%), and RWE (40%). The degree of impact was likely to vary based on the product's target patient population (39%), overall cost of the therapeutic area (31%), and duration of recommended use (27%). Regarding PIE, most payers (84%) preferred to engage in PIE at least 12 months prior to FDA authorization.

CONCLUSIONS: Most payers require RCTs, at a minimum, to support DTx product reviews. Data that allow for the assessment of key product functionality, along with economic and PROs, are likely to impact coverage decisions. Our findings provide important insights into early evidence generation and communication strategies that can accelerate DTx reviews and patient access.

SPONSORSHIP: Lumanity, Inc.

U6 Economic evidence on cost-sharing and novel insurance designs for addressing moral and behavioral hazard in health care: A systematic literature review

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BACKGROUND: In health insurance, "moral hazard" describes the concept that coverage without out-of-pocket cost to consumers could result in health care utilization beyond economically efficient levels. Cognizant of this, US payers have designed pharmaceutical benefit plans with significant cost exposure (eg, copays, coinsurance, or deductibles). Although substantial evidence links patient cost exposure to reduced drug spending, it remains unclear to what degree this reflects greater efficiency or an indiscriminate drop in overall consumption also reducing needed utilization.

OBJECTIVE: To assess how different cost-exposure policies and behavioral insurance designs (BIDs) impact health care consumption and moral hazard.

METHODS: We conducted a systematic literature review examining how cost-sharing policies and innovative insurance designs impact consumer spending. We particularly investigated if commonly implemented utilization management strategies (UMSs) and BIDs have been explored as tools to mitigate moral hazard. Eligible studies compared conventional cost-exposure policies with BIDs, including tiered cost sharing and other UMSs. Two experts independently reviewed titles, abstracts, and evaluated articles selected for inclusion. Additional authors arbitrated discrepancies between reviewers. Following title, abstract, and full-text screening, information from qualifying studies was extracted and assessed.

RESULTS: Initial searches in PubMed and EconLit yielded 705 unique abstracts; 30 were extracted. Most studies used moral hazard as implied justification for cost exposure but with notable variations. Behavioral studies of contemporary applications of cost exposure questioned whether it leads towards efficient use of high-value care, with some suggesting it undermines the risk-protection function of insurance for patients under liquidity constraints. Empirical studies examined responses to designs that either rewarded reduced use (like consumer rebates) or penalized it (like deductibles). Across reviewed studies, alternative designs led to distinct consumer responses, which warrant more differentiated conclusions on economic value and efficiency.

CONCLUSIONS: As alternative insurance models (eg, value-based designs) emerge, it is imperative to understand how use responds to changes in incentives and to systematically probe conventional notions of moral hazard in health care. Our study details the evolving evidence base to provide insight on the impact of BIDs on these questions.

SPONSORSHIP: Janssen Scientific Affairs, LLC.

U10 Clinical manifestations and disease burden of primary mitochondrial myopathies: Results from a patient journey analysis shows substantial health care resource utilization

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BACKGROUND: Primary mitochondrial myopathies (PMMs) are a group of underdiagnosed rare genetic disorders characterized by a range of clinical presentations and multisystemic impact. Diagnosis and management of PMM can be challenging due to this heterogeneity of clinical manifestations. With no approved treatments for PMM, current practices focus on symptom management and do not address the underlying cause.

OBJECTIVE: To quantify—using a patient journey analysis—the barriers that US patients face in their odyssey from clinical manifestation to diagnosis to symptom management.

METHODS: A cohort was extracted from Komodo closed-claims data for patients who had at least 1 relevant claim between 2016 and 2021. With no PMM-specific *International Classification of Diseases, Tenth Revision* (ICD-10) diagnosis code, a stepwise approach was needed to identify patients

with suspected PMM. This entailed using ICD-10 diagnosis codes that were specific to mitochondrial disorders (MDs), including chronic progressive external ophthalmoplegia, Kearns-Sayre syndrome, and Leigh syndrome. Analyses were limited to patients with at least 1 myopathy claim; those with a secondary MD ICD-10 code were excluded.

RESULTS: Of 3.7K patients included for analysis, 97% experienced multiorgan manifestation, with impact across an average of 6 different organ systems (eg, nervous, cardiac, and musculoskeletal). In the 12 months prior to diagnosis, 73% of patients reported nervous system manifestations and ~70% reported skeletal/muscular manifestations, compared with ~57% and 56% in the 24-36 months prior to diagnosis, respectively. These increases suggest that diagnosis often occurs when there is more multisystem involvement and more engagement with the health care system. When analyzed based on specific myopathy-related presentations (eg, impaired gait or mobility, fatigue, and myalgia), 36% of patients with suspected PMM had moderate to severe presentations, as indicated by inpatient admission or myopathy-related complications (eg, rhabdomyolysis). Health care resource utilization was high, including increased specialist engagement, with the majority of patients seeing a neurologist an average of ~6 times per year.

CONCLUSIONS: This patient analysis confirms that PMM encompass a broad spectrum of clinical manifestations that require utilization of extensive health care services. Moreover, it underscores the need for more health care provider education about the potential manifestations and multiorgan dysfunctions indicative of PMM, along with information that can help clinicians make an earlier clinical and genetic confirmatory diagnosis to provide appropriate management.

SPONSORSHIP: Reneo Pharmaceuticals, Inc.

U11 Evaluating the impact of the Inflation Reduction Act $2,000 out-of-pocket spending cap on Medicare Part D beneficiaries

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BACKGROUND: The Inflation Reduction Act (IRA) includes several provisions that will impact the price of prescription drugs and Medicare Part D enrollee liability. Beginning in 2025, the Part D benefit redesign will take effect with a $2,000 out-of-pocket (OOP) maximum for beneficiaries combined with increased plan and manufacturer liability throughout the benefit.

OBJECTIVE: To determine which patient demographics may be impacted by the new Part D design, to determine in which month patients surpass the $2,000 threshold, and to determine how high-cost drugs may be driving people over the $2,000 threshold.

METHODS: The 100% Part D Event (PDE) files from 2017 to 2022 were assessed. Patient liability (patient OOP, low-income subsidy payments, and other payers) was summed for each beneficiary across all drugs within the year. Demographic information was attributed from the Master Beneficiary Summary File.

RESULTS: Throughout the years of analysis, approximately 12% of beneficiaries with Part D coverage were above the $2,000 OOP threshold. In 2022, low-income subsidy (LIS) beneficiaries make up over 70% of people above the $2,000 OOP threshold. Black beneficiaries are 11% of Part D beneficiaries, but they make up a disproportionately high percentage of beneficiaries above the threshold (16%). Additionally, Black beneficiaries also averaged the highest amount of liability above the $2,000 threshold in both LIS and non-LIS beneficiaries. When above the $2,000 OOP threshold, LIS beneficiaries average $1,496 in additional spending, whereas non-LIS beneficiaries average $4,421. For LIS beneficiaries, half will reach the threshold in June, whereas for non-LIS beneficiaries half will reach the threshold by August. For both LIS and non-LIS beneficiaries, the main driver pushing people over the limit was not the variety of prescribed drugs but the volume of scripts over the course of the year.

CONCLUSIONS: Although the IRA will impact Medicare Part D through drug price negotiations, inflationary rebates, and other mechanisms, the most immediate result that beneficiaries may feel is the $2,000 OOP spending cap taking effect in 2025. Black Part D beneficiaries will be more affected by the OOP cap, as they spend more than any other racial group and are disproportionally represented among beneficiaries reaching the $2,000 OOP threshold. Beneficiaries with more than 6 prescriptions per month will also reach the threshold 1-2 months faster than beneficiaries filling fewer scripts per month.

SPONSORSHIP: None.

U12 Making the cut: A review of evidence trends in the Institute for Clinical and Economic Review's Unsupported Price Increase reports

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BACKGROUND: In its Unsupported Price Increase (UPI) reports, the Institute for Clinical and Economic Review (ICER) aims to identify drugs with substantial price increases that lack new evidence to justify the increases.

OBJECTIVE: To evaluate how ICER appraises evidence submitted by manufacturers and identify trends in manufacturer submissions and ICER's rejection and acceptance decisions.

METHODS: We reviewed evidence submitted by manufacturers for the 4 national UPI reports published from 2019 to 2022. A codebook was developed to compile and categorize types of evidence and ICER's reasons for rejecting or accepting evidence. We identified trends regarding the quantity and quality of evidence as well as study characteristics for evidence accepted in support of a price increase.

RESULTS: Manufacturers submitted evidence for 34 of the 44 drugs reviewed across the 4 reports, totaling 1,145 pieces of evidence and averaging 34 pieces per drug. This average declined over time (n = 67 in 2019, n = 28 in 2020 and 2021, and n = 17 in 2022). Overall, 97% of evidence submissions were rejected by ICER, with a slight downward trend (99% in 2019, 97% in 2020, 93% in 2021, and 94% in 2022). Across the 4 reports, 64% of rejected evidence submissions were rejected for not meeting UPI criteria and 36% for not meeting the criteria for new moderate- to high-quality evidence. Trends in ICER's rejection reasons shifted toward the latter (19% in 2019, 38% in 2020, 52% in 2021, and 61% in 2022). Only 38 pieces of evidence, representing 18 distinct randomized controlled trials (RCTs), were accepted as high-quality evidence in support of a price increase. All evidence was from RCTs in phase 3 (n = 17) or phase 4 (n = 1), with a majority double-blinded (n = 13). In 2019, ICER described the impact of accepted evidence using a single category: longer-term data with improved outcomes (n = 5). In subsequent years, ICER moved to more descriptive categories, including evidence that supported US Food and Drug Administration (FDA) label expansion for a new (n = 5) or existing (n = 4) indication, supported accelerated approval (n = 2), extended the evidence base to new populations excluded in previous trials (n = 1), and strengthened the existing guideline recommendations (n = 1).

CONCLUSIONS: Our findings demonstrate that ICER rejects the majority of UPI evidence submissions (97%). Accepted evidence was typically from phase 3 double-blinded RCTs that demonstrated new information on improved outcomes or supported FDA label expansion. Manufacturers appeared to become increasingly selective over time with the evidence they submitted to ICER's UPI reports.

SPONSORSHIP: Xcenda/AmerisourceBergen.

U13 Patient characteristics, disease profile, and treatment patterns in US patients with mild and moderate psoriasis in real-world practices

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BACKGROUND: This study described and compared patient characteristics, disease profile, and treatment patterns among patients with mild and moderate (mod) psoriasis (PsO) in the United States.

OBJECTIVE: To explore potential unmet needs among patients with mild and mod PsO in real-world practice.

METHODS: Data were drawn from the Adelphi 2022 PsO Disease Specific Programme, a cross-sectional survey of patients and their treating dermatologists. Based on physician-reported disease severity at diagnosis, patients were categorized as having mild or mod PsO. Patient demographics, disease profile, and prescribed treatment were analyzed using descriptive statistics and tests.

RESULTS: At diagnosis, of the 389 patients with PsO, 72 were mild and 317 were mod. Both groups (mild vs mod) had a similar mean age (38.8 vs 41.0 years), and sex (44.4% vs 49.5% male). Patients with mod PsO had a higher body mass index (25.4 vs. 27.0 kg/m^2, $P < 0.002$). Mild patients had a mean (SD) follow-up time since diagnosis of 2.0 (2.6) years vs 3.3 (3.9) years for mod ($P = 0.041$). At diagnosis, 87.3% of mild patients vs 86.04% ($P = 0.851$) of mod patients were prescribed topical therapy; 2.8% vs 12.0% conventional systemic therapy ($P = 0.017$); and 9.9% vs. 13.6% biologic therapy ($P = 0.556$), respectively. Of mild patients, the top 3 lesion locations were scalp (29.2%), elbows (23.1%), and knees (16.9%); for mod patients, the top 3 locations were the knees (45.7%), elbows (43.0%), and scalp (39.0%). Mild patients had mean 1.9 (1.2) areas affected vs 3.4 (1.8) for mod ($P \leq 0.001$). The top 3 symptoms experienced at diagnosis for mild patients were red inflamed skin (65.7%), scaling/flaking (64.2%), and itching (62.7%); for mod patients they were red inflamed skin (76.9%), itching (69.6%), and scaling/flaking (62.7%). Mild patients had a mean 2.8 (1.5) number of symptoms vs 3.8 (1.7) for mod ($P \leq 0.0001$). Mild patients had a mean body surface area percentage (BSA%) at diagnosis of 6.2 (5.8) vs 13.2 (8.3) for mod ($P \leq 0.001$). At the initiation of treatment, mild

patients had a mean BSA% of 5.6 (5.1) vs 10.2 (10.2) for mod ($P \leq 0.001$). At survey completion, mild patients had a mean BSA% of 4.4% (4.8) vs 7.9% (7.2) for mod ($P \leq 0.001$), and 11.4% (mild) vs. 6.8% (mod) ($P = 0.2117$) were experiencing a flare-up in their condition.

CONCLUSIONS: Patients with PsO who were diagnosed with mild or mod PsO by dermatologists were observed to have similar types of symptoms and affected areas. A higher proportion of mild patients experienced a flare at the time of survey completion vs mod patients (11.4% vs 6.8%, respectively). These findings offer insights regarding potential unmet medical needs of patients with PsO who may benefit from earlier treatment with advanced PsO therapy options.

SPONSORSHIP: None

U16 How do US commercial health plans cite health technology assessments in their specialty drug coverage policies?

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BACKGROUND: Health technology assessments (HTAs) provide important information regarding a treatment's clinical and economic value. Although HTAs play a vital role in determining patients' access to novel treatments internationally, its role in health care decision making in the United States remains unclear.

OBJECTIVE: To examine how frequently the largest US commercial health plans cite HTAs in their specialty drug coverage policies.

METHODS: We used the Tufts Medical Center Specialty Drug Evidence and Coverage (SPEC) Database, which includes information on specialty drug coverage policies issued by 18 large US commercial health plans. The SPEC Database also includes details on the evidence that plans cite in support of their coverage policies. We examined payer polices that were current in August 2022 (N=11,248). We categorized each HTA with respect to its country setting (United States or ex–United States). We determined the frequency that plans cite HTAs in their coverage policies.

RESULTS: HTAs comprised 0.92% of all cited clinical and economic evidence. Two health plans did not cite any HTAs. Health plans that cited HTAs did so with varying frequency (0.04%-1.61% of cited evidence). Health plans most often cited HTAs in coverage policies for treatments indicated for ophthalmologic diseases (4.01% of cited evidence), and least often for treatments indicated for endocrine diseases (0.54% of cited evidence). Of the cited HTAs, 39.0% were performed by a US organization, whereas 61.0% were performed by international HTA agencies.

CONCLUSIONS: HTAs make up a small share of the evidence that US commercial health plans cite in their specialty drug coverage policies. HTA citation frequency varied by health plan and by disease. Ex-US HTAs were cited more often than US HTAs.

SPONSORSHIP: None.

U17 Trends in US commercial health plan coverage of biosimilars

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BACKGROUND: Biosimilar introduction was expected to increase competition and lower prices for biologics. However, there is concern that biosimilar uptake has been slow, with payers playing a key role.

OBJECTIVE: To examine the frequency with which US commercial health plans granted biosimilars and reference products preferred coverage status and how coverage evolved from 2017 to 2022.

METHODS: We created a dataset of biosimilar coverage policies issued by 17 large US commercial health plans active in August in each year from 2017 to 2022 based on information from the Tufts Medical Center Specialty Drug and Evidence Database. We included biosimilars that were marketed in the United States as of August 2022 (n=21) and their reference products. We considered each US Food and Drug Administration–approved indication separately. Therefore, we included 84 biosimilar indication pairs in our analysis. We categorized biosimilar coverage as (1) "preferred," (ie, the plan covered the biosimilar as the sole first-line treatment or first-line among other available biosimilars and/or the reference product) or (2) as "non-preferred," (ie, the plan required patients to first try and fail an alternative biosimilar and/or reference product before being eligible for the product). We examined the frequency that plans granted biosimilars preferred status and how this frequency changed from 2017 to 2022, both across all biosimilars and within reference product families (eg, within infliximab biosimilars).

RESULTS: The number of coverage policies for biosimilars grew from 216 in 2017 to 1,367 in 2022, as additional biosimilars became available. Payers increasingly preferred biosimilars alongside the reference product or other biosimilars over time while the frequency that plans granted a product sole preferred coverage status declined. The median proportion of biosimilar coverage policies that included a biosimilar as "preferred" increased from 32% (interquartile range(IQR)=0%-100%) in

2017 to 63% (IQR=49%-72%) in 2022. Payers varied in the proportion of policies for which biosimilars were preferred. In 2022, 10 payers included at least 1 biosimilar among preferred treatments in all reference product families; 7 payers did so in a proportion of reference product families.

CONCLUSIONS: As biosimilar competition has increased payer coverage has evolved with more policies allowing patient choice between different biosimilars and the reference product. Further research on the relationship between prices, utilization, and coverage may further explain trends in the US biosimilars market.

SPONSORSHIP: Genentech, Inc.

Z00-Z99 Factors Influencing Health Status and Contact With Health Services

Z1 Exploring awareness and perceptions of genetic testing for cancer risks

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BACKGROUND: DNA-based screening is a pivotal tool in modern health care that can help us understand and manage genetic conditions. Genetic testing can empower individuals to make informed decisions about their care.

OBJECTIVE: To assess the awareness and likelihood of receiving genetic testing for potential cancer risks among a sample of US adults.

METHODS: An online convenience sample of US adults was recruited through the Qualtrics Online Panel platform. Participants aged 18 years or older and residing in the United States were eligible. Survey questions were developed to collect information about participant sociodemographics, awareness of genetic services, likelihood of receiving genetic testing, and reasons an individual may be less likely to receive genetic testing.

RESULTS: A total of 600 participants took part in the survey, with 524 participants never having received genetic testing. Of those who had never received genetic testing, 119, 126, and 279 participants said they were unlikely or very unlikely, neither likely nor unlikely, and likely or very likely to receive genetic testing, respectively. The unlikely/very unlikely group was 76% (n = 90) women, 77% (n = 92) White, and 74% (n = 141) had at least some college or technical school. The neither likely/unlikely group was 75% (n = 94) women, 74% (n = 93) White, and 67% (n = 84) have at least some college or technical school. The likely/very likely group was 74% (n = 207) women, 78% (n = 218) White, and 68% (n = 191) have at least some college or technical school. Of the individuals in the unlikely and neither likely/unlikely groups, most participants had never heard about genetic tests that analyze DNA for potential cancer risks (56% and 64%, respectively). The most important factor that individuals stated would make them unlikely or neither likely/unlikely to receive genetic testing is they are not concerned about hereditary cancer conditions (n = 76, 35%), they are too busy/do not have time (n = 39, 18%), and they do not like having their blood drawn (29, 13%). When asked what would make them likely to get the test, 42% (n = 103) stated that they would just not want the test, 14% (n = 35) stated having the option to provide a saliva sample instead of a blood sample, and 14% (n = 34) stated having more information about the test.

CONCLUSIONS: As knowledge of genetic testing for potential cancer risks remains low, even with widespread use, there is a need for targeted education to improve awareness. There are many factors that influence potential interest in receiving genetic testing such as the use of saliva-based testing and providing more information about testing.

SPONSORSHIP: University of North Carolina.

Z3 Specialty drug use varies by race and wage among employees with employer-sponsored health insurance

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BACKGROUND: The relationship between wage, race and ethnicity, and specialty medication (SpRx) use among employees with autoimmune conditions is poorly understood. Insight into demographic variations in SpRx use can inform health equity improvement efforts.

OBJECTIVE: To assess the association of race, ethnicity, and wage status on SpRx use and adherence patterns among employees with autoimmune conditions (AICs) enrolled in employer-sponsored health insurance.

METHODS: This was an observational, retrospective cohort study for the year 2018 among full-time, benefits-enrolled employees. Data were obtained from the IBM Watson MarketScan database for calendar year 2018. Employees were separated into race and ethnicity subgroups based on employer-provided data. Midyear employee wage data were used to allocate employees into annual income quartiles: $47,000 or less, $47,001-$71,000, $71,001-$106,000, and $106,001 or more. The lowest quartile was further divided

into 2 groups (≤$35,000 and $35,001-$47,000) to better evaluate subgroup differences. Outcomes included monthly days' SpRx-AIC supply, proportion of days covered (PDC) and medication discontinuation rates. Generalized linear regressions were used to assess differences while adjusting for patient and other characteristics.

RESULTS: From a sample of more than 2 million enrollees, race and ethnicity data were available for 617,117 (29.8%). Of those, 47,839 (7.8%) were identified as having an AIC of interest, with prevalence rates of AICs differing by race within wage categories. Among those with AICs, 5,358 (11.2%) had filled at least 1 SpRx-AIC prescription. Following adjustment, except for the highest wage category, the prevalence of SpRx-AIC use was significantly less among Black and Hispanic subpopulations. Black enrollees had significantly lower SpRx-AIC utilization rates than White enrollees (≤$35,000: 4.9% vs 9.4%; >$35,000-$47,000: 5.5% vs 10.6%; >$47,000-$71,000: 8.5% vs 11.1%; and >$71,000-$106,000: 9.1% vs 12.7%; P<0.001 for all). For Hispanic enrollees, prevalence rates were significantly lower than White enrollees in 3 different wage categories (≤$35,000: 4.5% vs 9.4%; >$35,000-$47,000: 6.1 vs 10.6%; and >$71,000-$106,000: 8.6% vs 12.7%; P<0.001). PDC and 90-day discontinuation rates did not differ among race and ethnicity groups within the respective wage bands.

CONCLUSIONS: Race and ethnicity and wage-related disparities in SpRx use for the treatment of autoimmune conditions likely contribute to inequities in health care outcomes among non-White and low-income populations with employer-sponsored insurance.

SPONSORSHIP: National Pharmaceutical Council.

Z4 A description of social health care needs and resource utilization within a large integrated health plan

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BACKGROUND: The Centers for Medicare & Medicaid Services (CMS) identify social determinants of health (SDoHs) as a range of social, economic, and environmental factors that affect health and wellness. Beyond health care access and quality, key areas to consider when assessing SDoHs include education, community context, economic stability, and the built environment. By addressing these social health care needs, managed care organizations may reduce health care costs and improve the health status of beneficiaries, as well as advance value-based care within their health systems.

OBJECTIVE: To describe the demographics, identify common comorbidities, assess the medication profile, and understand medical encounters for the member population determined to have social health care needs.

METHODS: This retrospective analysis was performed at a large integrated health plan located in western Pennsylvania. A review of administrative data from February 24, 2022, to May 31, 2022, was conducted for members of all ages and across all lines of business. Members with social health care needs were identified using *International Classification of Diseases, Tenth Revision* (ICD-10) diagnosis codes and clinical outreach with screening conducted by care management pharmacists. Target comorbid conditions were identified using ICD-10 diagnosis codes. Encounters in any setting and drug utilization data were collected via medical and pharmacy claims.

RESULTS: A total of 54,837 members were included in the analysis, representing 3.6% of the total pharmacy-covered lives at the health plan. Of the 41.2% of members with reported race information, 80.7% were identified as White. Common social health care needs diagnoses included tobacco use, adjustment disorder, severe stress, and unemployment. The most common diagnoses for all encounters were hypertension, opioid dependence, and general adult exam, with an average of 5 encounters per member in a 3-month period. The most prescribed drug class was antidepressants. Forty-five percent of members were actively using at least 6 medications.

CONCLUSIONS: The use of social health care needs diagnosis codes is uncommon. Furthermore, most recorded social health care needs diagnoses identified in this analysis were nonspecific. Among the social health care needs population, mental health conditions, substance and drug abuse, and common chronic conditions, such as hypertension and diabetes, were the most prevalent disease states. Health plan members with these conditions or discovered to be experiencing polypharmacy may be targeted for additional outreach and support.

SPONSORSHIP: None.

Z5 Patient engagement phone calls and medication pick-up behavior in an outpatient pharmacy

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BACKGROUND: Medication nonadherence leads to increased health care costs. Picking up medication at the appropriate time is key to achieving adherence without running out of supply. Late pick-up behavior can negatively impact adherence outcomes. Telephonic patient engagement calls can be

a useful intervention to promote adherence. It is important to study the impact of these calls on pick up behavior.

OBJECTIVE: To study patient engagement phone calls and their impact on medication pick-up behavior in an outpatient pharmacy.

METHODS: A retrospective, single-site, data analytical, quality improvement study was conducted at an outpatient pharmacy for the month of April 2023. All patients enrolled in Medication Synchronized at this pharmacy should receive a monthly telephonic patient engagement phone call. Two call attempts are made to reach a patient. This live telephone call occurred a week or so before medications were due to be processed. The live call was in addition to an automated system call that occurred on the day the first prescription was ready for pick up, days 3 and 7 after ready status. This study intended to evaluate the number of patients, time of call, reach rate, and associated pick-up behavior of the patients.

RESULTS: A total of 208 patients were called. One hundred and twenty-eight patients were reached on the first attempt, 40 patients were reached on the second attempt. Forty patients were not reached. The average number of days from ready status to medication pick-up was higher in the not reached patients (2.91 days). However, the percentage of patients who did not pick up was higher in the patient group that was reached on the first call attempt. Male patients had a higher first attempt reach rate than female patients. Calls between 9AM and 12PM and 4PM and 5PM had a higher percentage first attempt reach rate than calls between noon and 3PM. The reach rate of 20- to 40-year-old patients was lowest and 41- to 50-year-old patients had the highest. Sixty six percent of patients called were African American and 60% were reached within the first attempt.

CONCLUSIONS: The study found that students were able to call 208 patients and reached 168 patients and document call attempts' dates and times. There appears to be a difference in the average pick up dates between patients reached in the first attempt vs the second and third attempts. However, more robust study design and statistical analysis is required. The best time to call appears to be between 9AM and 11AM. This study helps us understand the best time to call, age differences in reach rate, effectiveness, and gaps in our telephonic patient engagement process for decision making.

SPONSORSHIP: None.

Z6 Abortion medications online in the post–*Roe v. Wade* era

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BACKGROUND: With the overturn of *Roe v. Wade*, some individuals in states with restrictive abortion laws may self-manage a medication through abortion-using services offered on the Internet. Medicines sold through the Internet do not go through regular supply chain management and quality assurance processes. Despite increased interest, little is documented about options for the self-procurement of abortion medications online.

OBJECTIVE: To assess the availability and legitimacy of online options for those seeking out abortion medication.

METHODS: Using 3 common search engines (Google, Bing, and DuckDuckGo), sites that sell misoprostol and/or mifepristone and ship to the United States were identified. Sites were characterized by legitimacy (as defined by Legitscript), accessibility, and price. Identified sites were cross-referenced with a previous study that tested the quality of abortion medications.

RESULTS: Of 83 unique sites selling abortion medications, 70 (84%) were unapproved, rogue, and unclassified pharmacies or forums, 7 were online abortion clinics, and 6 were legitimate pharmacies. Two online clinics located overseas shipped these medications to every US state, but shipping from 1 site could take up to 3 weeks. Legitimate online pharmacies did not sell mifepristone. Rogue, unapproved, and unclassified online pharmacies were the most common, the cheapest, and the most easily accessible, where 84% (59/70) did not require a prescription. Through cross-referencing, we found 2 sites that previously sold poor-quality misoprostol, and 6 sites linked to a pharmacy that failed to ship orders in the past.

CONCLUSIONS: The overturn of *Roe v. Wade* has led people to search for abortion medications online where the quality of medicines provided is not guaranteed. Abortion medications can be purchased online from every state, and the most accessible options are online clinics located overseas and unregulated online pharmacies. We identified unregulated sites that have previously sold poor-quality medicines or had not shipped orders. As individuals are pushed to make decisions about sources for their abortion medications, there needs to be better assurance of access to quality medicines to protect public health.

SPONSORSHIP: None.

Student Poster Titles and Presenters

B10 Identifying potential treatment populations for antiviral medications: An analysis of BlueKC Medicare patients at risk of severe COVID-19

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C18 Utilization of artificial intelligence and machine learning in precision medicine for breast cancer contributes to health care discrimination against minorities

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C46 Assessing differences in time to treatment among Black and White patients with multiple myeloma

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C47 An evaluation of the total cost of care for the treatment of relapsed/refractory multiple myeloma, with a focus on B-cell maturation antigen–targeting agents

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C48 Exploring key sources of social determinants of health and their impact on survival in patients with multiple myeloma

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D3 The impact of medication therapy management on patients taking oral chemotherapy medications

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D21 Beneficial and harmful effects of mosunetuzumab for the treatment of relapsed or refractory follicular lymphoma: A systematic review

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D22 Evaluation of a quantity limit on hemophilia factor products in a large managed care organization: Pharmacy cost and utilization outcomes

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E13 Real-world outcomes analysis of cardiac events among patients with type 2 diabetes mellitus utilizing insulin with or without a GLP-1 receptor agonist: A retrospective analysis of a US Medicare claims database

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E14 Finding the sweet spot: Minimizing concurrent use of sulfonylureas and insulin to optimize patient safety outcomes

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E15 A pharmacist's impact on diabetes quality measures in a primary care setting

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E16 COVID-19 pandemic: Association of type 2 diabetes and insulin management in patients from 2 family medicine clinics

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F2 Managing attention-deficit/hyperactivity disorder: Treating patients individually to improve health outcomes

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F6 Association between religious service attendance and illicit stimulant use in adolescents: Evidence from the 2015-2019 National Survey on Drug Use and Health data

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F7 Association between alcoholic binge drinking and unemployment status: Evidence from the 2015-2019 National Survey on Drug Use and Health data

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F12 Assessing demographics, clinical characteristics, and health care resource utilization of patients with schizophrenia with inadequate response to antipsychotic treatment

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F13 Economic impact of discontinuation and relapse rates among patients with schizophrenia newly initiated on Lybalvi vs olanzapine during first-year use

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F19 Association of depression with chronic illnesses, smoking, and alcohol use in racial and ethnic minority populations in the United States from 2017 to 2021

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G3 Evaluating body mass index effects of ocrelizumab administration in patients with multiple sclerosis

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G16 Assessing value of aducanumab for patients with early Alzheimer disease: A head-to head study

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G25 Comparing laboratory testing compliance of patients with multiple sclerosis receiving sphingosine 1-phosphate receptor modulators before and after specialty pharmacist involvement

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G32 Comparative efficacy and safety of rimegepant for the treatment of acute migraine: Systematic review

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G44 A retrospective observational analysis on the total cost of care associated with the utilization of calcitonin gene–related peptides

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I1 Economic burden of pulmonary arterial hypertension in the United States: A systematic literature review

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K14 Cost-effectiveness of immunotherapies for patients with metastatic colorectal cancer: Atezolizumab vs durvalumab based on randomized clinical trials

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L10 Efficacy of crisaborole ointment 2% vs topical corticosteroids in treatment of atopic dermatitis

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L11 A clinical and economic review of tralokinumab-ldrm

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L12 Getting to specialty treatment in dermatologic inflammatory conditions: Treatment requirements and patient journey

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M11 A review of tumor necrosis factor inhibitor cycling vs mechanism of action switching outcomes after failure of initial tumor necrosis factor inhibitor therapy in rheumatic conditions

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T1 Impact of formulary restrictions on opioid-related harms: A systematic review

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U19 Unlocking opportunities in managed care pharmacy: The crucial role of clinical laboratory monitoring for specialty drugs

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U20 Reimagining managed care pharmacy: A paradigm shift toward integrated patient-centric solutions

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U21 Impact of the Cost-Share Elimination Program on medication adherence

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U22 Assessing the evolving landscape of digital engagement between health care decision-makers and biopharma companies

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U23 Assessing pharmacy students' knowledge and perceptions of managed care pharmacy and pharmacy benefit managers: A survey-based approach

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U24 Unlocking potential for population health impact by harnessing the power of ambulatory pharmacists

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U26 Understanding barriers and social determinants of health to improve colorectal screening rates from the perspective of a New Jersey health plan

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U27 Formulary management: Incorporating a framework for health equity evaluation

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U28 Patient outcomes and preferences regarding hemophilia treatment within a commercially insured population: A prospective survey

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Z2 Association of social determinants of health and high out-of-pocket burden in older adults with multimorbidity in the United States

Clark R[1], *Zhou B*[1], *Pinnamraju J*[1], *Sambamoorthi U*[1]; *clark.rachel863@gmail.com*
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Encore Poster Titles and Presenters

B3 Development of a decision-analytic model to evaluate screening and treatment strategies for chronic hepatitis delta

Kim C[1], *Kaushik A*[2], *Dusheiko G*[3], *Smith N*[4], *Kinyik-Merena C*[4], *Di Tanna G*[5], *Wong R*[6]; *Chong.Kim9@gilead.com*; *ankita.kaushik@gilead.com*
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B7 A multinational study assessing treatment patterns, clinical outcomes, and health care resource utilization in solid organ transplant recipients with refractory/resistant cytomegalovirus infection or intolerance to anti-cytomegalovirus therapy

Schultz B[1], *Blumberg E*[2], *Braun F*[3], *Limaye A*[4], *Chow J*[5], *Len O*[6], *Rajack S*[7], *Witzke O*[8], *Alves D*[9], *Veloso L*[9], *Bo T*[1], *Sundberg A*[10], *Davis K*[10], *Hirji I*[10]; *bob.schultz@takeda.com*; *eblumber@pennmedicine.upenn.edu*
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B8 Multinational study assessing treatment patterns, outcomes, and health care resource utilization in hematopoietic stem cell transplant recipients with refractory/resistant cytomegalovirus infection or intolerance to anti-cytomegalovirus therapies

Schultz B[1], *Papanicolaou G*[2], *Peggs K*[3], *Sanz J*[4], *Fox M*[5], *Einsele H*[6], *Avery R*[7], *Mendonça I*[8], *Veloso L*[8], *Sundberg A*[9], *Bo T*[1], *Davis K*[9], *Hirji I*[9]; *bob.schultz@takeda.com*; *papanicg@mskcc.org*
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C7 Effectiveness and safety profile of lurbinectedin in second-line small cell lung cancer: A real-world study

Shear J[1], *Ganti A*[2], *Allan V*[1], *Merola D*[3], *Estrin A*[3], *Boccuti A*[1], *Rengarajan B*[1], *Baratta C*[1], *Prince P*[3], *Li W*[1], *Cao Y*[1], *D'Agostino Jr R*[4], *Poole E*[1]; *jennifer.shear@jazzpharma.com*; *aganti@unmc.edu*
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C11 Duration of response to sonidegib 200 mg daily treatment per best overall response in patients with locally advanced basal cell carcinoma: Results of the 42-month BOLT study

Migden M[1], *Spencer J*[2], *Gebauer K*[3], *Hauschild A*[4], *Grob J*[5], *Squittieri N*[6], *Arntz R*[7], *Martelli S*[8], *Dierlamm J*[7], *Robert C*[9]; *mrmigden@mdanderson.org*; *Nicholas.Squittieri@sunpharma.com*
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C12 Tumor burden reduction in patients with locally advanced basal cell carcinoma who responded to sonidegib 200 mg within 9 months of initiating treatment: Results of the 42-month BOLT study

Farberg A[1], *Kiecker F*[2], *Guminski A*[3], *Loquai C*[4], *Dummer R*[5], *Schadendorf D*[6], *Squittieri N*[7], *Arntz R*[8], *Martelli S*[9], *Dierlamm J*[8], *Gutzmer R*[10]; *aaron.farberg@gmail.com*; *Nicholas.Squittieri@sunpharma.com*
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C14 Abemaciclib linkage to care: A health system specialty pharmacist initiative

Giavatto C[1], *Fosnight S*[1], *Rees M*[1], *Mourani J*[1], *Skrtic A*[1], *Fitzpatrick C*[1], *Mosby C*[2], *Cash K*[1], *Lopez Medina A*[1]; *carly.giavatto@cps.com*
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C19 Maximizing cost savings: The impact of specialty pharmacist interventions at a community oncology center

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C24 Darolutamide, enzalutamide, and apalutamide for nonmetastatic castration-resistant prostate cancer patients in the United States (DEAR): Comparative real-world evidence

Khan N[1], *Morgans A*[2], *Shore N*[3], *Constantinovici N*[4], *Khan J*[5], *Chen G*[1], *Xu J*[6], *Ortiz J*[1], *George D*[7]; *nasreen.khan@bayer.com*
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C39 A budget impact analysis of the introduction of mosunetuzumab for treatment of third- or higher-line relapsed or refractory follicular lymphoma in the United States

Lin S[1], *Shapouri S*[1], *Parisé H*[2], *Bercaw E*[2], *Wu M*[3], *Kim E*[3], *Matasar M*[4]; *lin.shihwen@gene.com*
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D1 Improvement of patient-reported fatigue in IMerge phase 3 trial of imetelstat vs placebo in heavily transfused non-del(5q) lower-risk myelodysplastic syndromes relapsed/refractory/ineligible to erythropoiesisstimulating agents

Sekeres M[1], *Santini V*[2], *Díez-Campelo M*[3], *Komrokji R*[4], *Fenaux P*[5], *Savona M*[6], *Madanat Y*[7], *Valcárcel-Ferreiras D*[8], *Illmer T*[9], *Jonášová A*[10], *Bělohlávková P*[11], *Regnault A*[12], *Creel K*[13], *Sengupta N*[14], *Sun L*[14], *Navada S*[14], *Zeidan A*[15], *Platzbecker U*[16]; *msekeres@med.miami.edu*
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D9 Efanesoctocog alfa vs emicizumab in prophylactic treatment of adolescents and adults with severe hemophilia A without inhibitors: A matching-adjusted indirect comparison

Álvarez Román M[1], *Kragh N*[2], *Guyot P*[3], *Wilson A*[3], *Wojciechowski P*[4], *Margas W*[5], *Wdowiak M*[5], *Santagostino E*[2], *Arnaud A*[3]; *talvarezroman@gmail.com*; *alix.arnaud@sanofi.com*
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D10 Efanesoctocog alfa vs extended half-life factor VIII therapies for prophylaxis in adolescents and adults with severe hemophilia A: A matching-adjusted indirect comparison and meta-analysis

Klamroth R[1], *Guyot P*[2], *Arnaud A*[2], *Wilson A*[2], *Wojciechowski P*[3], *Wdowiak M*[4], *Margas W*[4], *Gresko E*[5], *Kragh N*[5]; *alix.arnaud@sanofi.com*
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D11 Efanesoctocog alfa vs standard half-life (octocog alfa) FVIII therapies for prophylaxis in adolescents and adults with severe hemophilia A: A matching-adjusted indirect comparison and meta-analysis

Tosetto A[1], *Arnaud A*[2], *Kragh N*[3], *Wilson A*[2], *Wojciechowski P*[4], *Wdowiak M*[5], *Margas W*[5], *Bystrická L*[3], *Guyot P*[2]; *alberto.tosetto@aulss8.veneto.it*; *alix.arnaud@sanofi.com*
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D12 An updated analysis of hemophilia patient utility study of treatment administration impact: A discrete choice experiment using time trade-off methodology

Benton M[1], *Hong D*[1], *Skinner M*[2], *Garrison L*[3], *Karimi M*[4], *Chen E*[4], *Mead H*[4], *Shi L*[1]; *mbenton@tulane.edu*; *er.chen@bmrn.com*
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D20 Cost-effectiveness of Acthar Gel for the treatment of advanced symptomatic sarcoidosis

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E17 Tirzepatide reduces the predicted risk of developing type 2 diabetes: Post hoc analysis of the SURMOUNT-1 trial

Hankosky E[1], *Wang H*[2], *Neff L*[1], *Kan H*[3], *Wang F*[1], *Ahmad N*[3], *Stefanski A*[1], *Garvey W*[4], *Lubelczyk B*[1]; *emily.hankosky@lilly.com*; *elizabeth.lubelczyk@lilly.com*
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E18 Tirzepatide reduces the predicted risk of developing type 2 diabetes: SURMOUNT-1 post hoc analysis by prediabetes status

Hankosky E[1], *Wang H*[2], *Neff L*[1], *Kan H*[3], *Wang F*[1], *Ahmad N*[3], *Stefanski A*[1], *Garvey W*[4], *Luy I*[1]; *emily.hankosky@lilly.com*; *irene.luy@lilly.com*
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E24 Tirzepatide reduces the predicted risk of developing atherosclerotic cardiovascular disease: A post hoc analysis of the SURMOUNT-1 trial

Raikar S[1], *Hankosky E*[1], *Wang H*[2], *Neff L*[1], *Kan H*[3], *Wang F*[1], *Ahmad N*[3], *Stefanski A*[1], *Garvey W*[4]; *sonya.raikar@lilly.com*; *emily.hankosky@lilly.com*
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E25 Tirzepatide vs semaglutide 2.4 mg for overweight and obesity: An indirect treatment comparison

Wallem A[1], *Wang D*[1], *Malik R*[1], *Yu M*[1], *Kan H*[2], *Bunck M*[1], *Stefanski A*[1], *García-Pérez L*[1], *Hankosky E*[1]; *wallem_alexandra@lilly.com*; *wang_duzhe@lilly.com*
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E28 Indirect treatment comparison of 3 treatments for late-onset Pompe disease: A network meta-analysis—cipaglucosidase alfa plus miglustat shows favorable results when enzyme replacement therapy–naive and –experienced patient data are incorporated

Fox B[1], *Fu S*[2], *Hummel N*[2], *Mozaffar T*[3], *Castelli J*[1], *Keyzor I*[4], *Raza S*[4], *Sitaraman Das S*[1], *Shohet S*[4]; *bfox@amicusrx.com*
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E29 Safety of home administration of cipaglucosidase alfa + miglustat in late-onset Pompe disease: Results from multiple clinical trials

Fox B[1], *Byrne B*[2], *Diaz-Manera J*[3], *Goker-Alpan O*[4], *Mozaffar T*[5], *Wasfi Y*[1], *Sitaraman Das S*[1], *Holdbrook F*[1], *Jain V*[1]; *bfox@amicusrx.com*
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F3 Variation in real-world pharmacologic and nonpharmacologic treatment of alcohol use disorder among patients with common chronic medical conditions

Grebla R[1], *Strand L*[1], *Zhao X*[2], *Zhou S*[2], *Keshishian A*[2], *McClain M*[3]; *regina.grebla1@alkermes.com*
[1]*Alkermes, Inc.*; [2]*Genesis Research*; [3]*Genesis Research*

G4 Real-world evidence for risdiplam-treated adults with spinal muscular atrophy: A multicenter study

Shapouri S[1], *Candrilli S*[2], *Miles L*[2], *Simpson A*[3], *Guittari C*[4]; *MTM.GNE.SMA@meditechmedia.com*
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G7 Analysis of path of therapy in the treatment of spasticity in adult post-stroke patients

Hull M[1], *Anupindi V*[1], *DeKoven M*[1], *Goldberg J*[2], *Bouchard J*[3]; *michael.hull@iqvia.com*; *jonathan.bouchard@ipsen.com*
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G8 Assessment of underdiagnosis of tardive dyskinesia by geographic region, social determinants, and other patient characteristics

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G9 Persistence, health care resource utilization, and costs among onabotulinumtoxinA-treated patients with cervical dystonia in the United States

Dashtipour K[1], *Charles D*[2], *Sadeghi M*[3], *Heath M*[4], *Rava A*[4], *Liu J*[4], *Sun H*[4], *Dong Y*[5], *Lee J*[3]; *kdashtipour@llu.edu*; *marjan.sadeghi@abbvie.com*
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G13 The societal costs of metachromatic leukodystrophy in the United States

Bean K[1], *Miller B*[2], *Howie K*[3], *Wilds A*[3], *Walz M*[3], *Fields C*[1], *Pang F*[1]; *karen.bean@orchard-tx.com*; *christopher.fields@orchard-tx.com*; *francis.pang@orchard-tx.com*
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G17 Identifying adult patients with nonrelapsing secondary progressive multiple sclerosis using algorithms in US-based health care databases

Greene N[1], *Gibbs S*[2], *Broder M*[2], *Farnett L*[1], *Chang E*[2], *Campos C*[2], *Higuchi K*[1], *Hemim I*[1]; *Nupur.Greene@sanofi.com*; *ines.hemim@sanofi.com*
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G18 Treatment patterns and cost of care among patients with metachromatic leukodystrophy in the United States: Results from a US claims data analysis

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G26 Persistence to onabotulinumtoxinA or calcitonin gene–related peptide monoclonal antibody therapy among patients with migraine: A retrospective cohort study

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G27 Real-world evidence of the effectiveness and satisfaction with eptinezumab treatment in patients with chronic migraine

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G28 The impact of ubrogepant on the use of other migraine acute treatments, opioid discontinuation, and medication overuse: Results from a pre-post opioid subcohort analysis

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G29 Treatment satisfaction and preferences in people with narcolepsy transitioning from sodium oxybate to low-sodium oxybate

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G35 Practical considerations for delandistrogene moxeparvovec gene therapy in patients with Duchenne muscular dystrophy

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G36 Diagnosed prevalence of idiopathic hypersomnia among adults in the United States

Saad R[1], *Black J*[2], *Bogan R*[3], *Jensen E*[4], *Lillaney P*[1], *Prince P*[5], *Estrin A*[5], *Whalen M*[1], *Macfadden W*[1], *Ni W*[1], *Plante D*[6]; *ragysaad@gmail.com*; *Jed.Black@jazzpharma.com*
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G37 Duration of continuous "Good On" intervals and number of motor fluctuations after treatment with IPX203 vs immediate-release carbidopa-levodopa in patients with Parkinson disease with motor fluctuations

Hauser R[1], *Fernandez H*[2], *Aldred J*[3], *Singer C*[4], *Shill H*[5], *Factor S*[6], *Visser H*[7], *D'Souza R*[8]; *rhauser@usf.edu*; *Hester.Visser@amneal.com*
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H1 Effect of OTX-101 0.09% on corneal staining and SANDE scores in patients with dry eye disease uncontrolled on cyclosporine ophthalmic emulsion 0.05%

Johnston J[1], *Adler R*[2], *Hessen M*[3], *Nichols K*[4], *Pflugfelder S*[5], *Truett K*[6], *Urbieta M*[7], *Mitchell B*[7]; *josh.johnston@gaeyepartners.com*
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H3 Pegcetacoplan vs avacincaptad pegol in patients with geographic atrophy: An anchored matching-adjusted indirect comparison of the phase 3 trials

Luo R[1], *Eichenbaum D*[2], *Sarda S*[3], *Jones D*[3], *Intorcia M*[3], *Bobbili P*[4], *Chang R*[4], *Catillon M*[4], *Xu C*[4], *Sarathy K*[5], *Sheng Duh M*[6], *Chaudhary V*[7], *Hahn P*[8]; *Roger.luo@apellis.com*
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I2 Impact of investigational, at-home, self-administered, intranasal etripamil on the need for additional medical intervention in patients with supraventricular tachycardia

Pokorney S[1], *Camm A*[2], *Dorian P*[3], *Ip J*[4], *Kowey P*[5], *Stambler B*[6], *Bharucha D*[7], *Piccini J*[8]; *sean.pokorney@duke.edu*
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J1 Household flu transmission and health care resource use among patients treated with baloxavir vs oseltamivir for influenza: An outpatient prospective survey in the United States

Best J[1], *Sadeghi M*[1], *Sun X*[2], *Seetasith A*[1], *Albensi L*[2], *Joshi S*[3], *Zervos M*[3]; *bestj1@gene.com*
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J4 Prior specialists consultations, diagnostic tests, and treatments in a refractory chronic cough population enrolled in a phase 2b study of the P2X3 antagonist camlipixant

Skinner E[1], *Dicpinigatis P*[2], *McGarvey L*[3], *Smith J*[4], *Blaiss M*[5], *Iyer V*[6], *Lanouette S*[1], *Yang R*[1], *Garin M*[1], *Bonuccelli C*[1]; *eskinner@bellushealth.com*; *pdicpin@gmail.com*
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J8 Characteristics of frequent exacerbators in the US Bronchiectasis and NTM Research Registry

Lapinel N[1], *Choate R*[2], *Aksamit T*[3], *Feliciano J*[4], *Winthrop K*[5], *Schmid A*[6], *Wu J*[4], *Hassan M*[4], *Fucile S*[4], *Metersky M*[7]; *nicole.lapinel@gmail.com*
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J9 Ensifentrine, a novel dual phosphodiesterase 3 and 4 inhibitor, improves lung function, symptoms, and quality of life and reduces exacerbation rate and risk in patients with chronic obstructive pulmonary disease: Results from replicate phase 3 trials

MacDonald-Berko M[1], *Sciurba F*[2], *Anzueto A*[3], *Rheault T*[1], *Bengtsson T*[4], *Rickard K*[1]; *margot.macdonald-berko@veronapharma.com*; *sciurbafc@upmc.edu*
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J13 Long-term effectiveness of Nucala (4 years) in patients with asthma: A real-world database analysis

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J14 Longitudinal analysis of bronchiectasis exacerbations in patients from the US Bronchiectasis and NTM Research Registry

Aksamit T[1], *Lapinel N*[2], *Choate R*[3], *Feliciano J*[4], *Winthrop K*[5], *Schmid A*[6], *Wu J*[4], *Hassan M*[4], *Fucile S*[4], *Metersky M*[7]; *aksamit.timothy@mayo.edu*
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J15 Real-world disease burden and mortality associated with bronchiectasis

Feliciano J[1], *Wassel C*[2], *Feld A*[2], *Maynard J*[2], *Batchu L*[2], *Lauterio M*[1], *Mohanty M*[1], *Dasenbrook E*[3]; *Joseph.Feliciano@insmed.com*; DASENBE@ccf.org
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J16 Treatment patterns and health care resource utilization among patients with potentially treatment-refractory *Mycobacterium avium* complex lung disease in the United States

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J17 Impact of health system specialty pharmacy management on clinical outcomes in patients with asthma

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J18 Ensifentrine, a novel dual phosphodiesterase 3 and 4 inhibitor, significantly reduces annualized exacerbations and delays the time to first exacerbation in chronic obstructive pulmonary disease: Pooled subgroup analyses of ENHANCE-1 and ENHANCE-2 phase 3 trials

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J21 Association between nintedanib adherence trajectories and healthcare use among idiopathic pulmonary fibrosis patients

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J22 Baseline characteristics of patients with asthma and prior systemic corticosteroid use in the rapid (Dupilumab) registry

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J23 Long-term safety of Dupilumab in patients with moderate to severe asthma: The Liberty Asthma Traverse Continuation study

Maspero J[1], *Peters A*[2], *Chapman K*[3], *Domingo C*[4], *Stewart J*[5], *Hardin M*[5], *Tawo K*[5], *Khokhar F*[6], *Mortensen E*[6], *Laws E*[5], *Radwan A*[6], *Jacob-Nara J*[5], *Deniz Y*[6], *Rowe P*[5]; *jorge.maspero@fundacioncidea.org.ar*; *megan.hardin@sanofi.com*
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J24 Real-world effectiveness of Dupilumab on oral corticosteroid use and asthma exacerbations in patients with moderate to severe asthma

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K3 Unmet need in patients with chronic erosive esophagitis: Results from the Study of Acid-Related Disorders

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K11 Cost benefit associated with the use of SITZMARKS for the diagnosis of constipation in an adult population

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K12 Cost savings associated with the use of SITZMARKS for the diagnosis of constipation in a pediatric population

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K15 Evaluation of inflammatory bowel disease treatment discontinuation rates in patients within health system specialty pharmacy

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K17 Analysis of long-term treatment effects of odevixibat on clinical outcomes in children with progressive familial intrahepatic cholestasis in odevixibat clinical studies vs external controls from the NAPPED database

Hansen B[1], *Verkade H*[2], *Valcheva V*[3], *Yu Q*[3], *Stein P*[3], *Ni Q*[3], *Clemson C*[3], *Mattsson J*[3]; *Bettina.Hansen@utoronto.ca*
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K21 Lower in-hospital mortality and rebleeding among patients with major gastrointestinal bleeding treated with andexanet alfa vs 4-factor prothrombin complex concentrate

Fermann G[1], *Coleman C*[2], *Danese M*[3], *Lesén E*[4], *Christoph M*[4], *Chang R*[4], *Ulloa J*[3], *Danese S*[3], *Koch B*[4], *Dobesh P*[5]; *fermangj@ucmail.uc.edu*
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L1 Real-world switch rates of biologics and associated costs in patients with psoriasis

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L4 Efficacy and safety of roflumilast cream 0.15% in adults and children aged 6 years and older with mild to moderate atopic dermatitis in two phase 3 trials (INTEGUMENT-1 and INTEGUMENT-2)

Simpson E[1], *Eichenfield L*[2], *Gooderham M*[3], *Gonzalez M*[4], *Hebert A*[5], *Papp K*[6], *Prajapati V*[7], *Krupa D*[8], *Burnett P*[9], *Berk D*[8], *Higham R*[8]; *simpsone@ohsu.edu*; *dberk@arcutis.com*
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L5 Efficacy and safety of roflumilast foam 0.3% in patients with scalp and body psoriasis in the phase 3 ARRECTOR trial

Gooderham M[1], Bagel J[2], DuBois J[3], Kircik L[4], Lockshin B[5], Papp K[6], Soung J[7], Krupa D[8], Burnett P[9], Berk D[8], Chu D[9]; mgooderham@centrefordermatology.com; dberk@arcutis.com
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L6 Efficacy and safety of roflumilast foam 0.3% in patients with seborrheic dermatitis in a phase 3 trial: Assessment of pruritus

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L13 Treatment patterns and unmet needs of patients with generalized pustular psoriasis with flares

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L14 Durability of efficacy and safety of roflumilast cream 0.3% in adults with chronic plaque psoriasis from a 52-week, phase 2 open-label safety trial

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L17 Psoriasis-related work productivity improvement from a phase 4 real-world study of tildrakizumab in patients with moderate to severe plaque psoriasis

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L18 Dupilumab improves urticaria signs and symptoms and quality of life in patients with chronic spontaneous urticaria

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L21 Dupilumab improves itch, skin pain, and sleep in adult patients with prurigo nodularis (LIBERTY PN-PRIME and PRIME2)

Murawski J[1], *Kwatra S*[2], *Yosipovitch G*[3], *Ständer S*[4], *Guillemin I*[5], *Msihid J*[1], *Wiggins S*[1], *Levit N*[6], *Bansal A*[6], *O'Malley J*[1], *Bahloul D*[1], *Thomas R*[6]; *jacob.murawski@sanofi.com*; *Skwatra1@jhmi.edu*
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L22 Efficacy and safety of clascoterone cream 1% in patients with acne vulgaris across subgroups defined by demographic characteristics

Eichenfield L[1], *Hebert A*[2], *Thiboutot D*[3], *Stein Gold L*[4], *Cartwright M*[5], *Moro L*[6], *Han J*[7], *Squittieri N*[8], *Mazzetti A*[6]; *leichenfield@gmail.com*; *Nicholas.Squittieri@sunpharma.com*
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L24 Long-term safety and efficacy of clascoterone cream 1% in patients aged 12 years and older with acne vulgaris

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L25 Spesolimab for the prevention of generalized pustular psoriasis flares: Results from the randomized, placebo-controlled trial Effisayil 2

Perchak A[1], *Lebwohl M*[2], *Strober B*[3], *Burden A*[4], *choon S*[5], *Anadkat M*[6], *Marrakchi S*[7], *Tsai T*[8], *Gordon K*[9], *Thaci D*[10], *Zheng M*[11], *Hu N*[12], *Haeufel T*[13], *Thoma C*[14], *Morita A*[15]; *andrea.perchak@envisionpharma.com*; *lebwohl@aol.com*
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L26 Treat-to-target outcomes and measures of treatment success in three phase 3 trials of tapinarof cream 1% once daily for mild to severe plaque psoriasis

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L27 Effisayil ON, an open-label, long-term extension study of spesolimab treatment in patients with generalized pustular psoriasis: Interim results for flare treatment

Perchak A[1], *Navarini A*[2], *choon S*[3], *Burden A*[4], *Zheng M*[5], *Morita A*[6], *Tanaka Y*[7], *Ye B*[8], *Thoma C*[9], *Lebwohl M*[10]; *aandrea.perchak@envisionpharma.com*; *Alexander.Navarini@usb.ch*
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M3 Biomarker testing in rheumatoid arthritis leads to lower total cost of care

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M6 Delayed pulmonary progression in golodirsen-treated patients with Duchenne muscular dystrophy vs mutation-matched external controls

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M8 Interim analysis of EVOLVE: Evaluating eteplirsen, golodirsen, or casimersen treatment in patients aged younger than 7 years in routine clinical practice

Patel B[1], Grabich S[1], Santra S[1], Waldrop M[2], Mathews K[3], Abid F[4], Ramos-Platt L[5], Scharf R[6], Zaidman C[7], Sehinovych I[1], McDonald C[8]; BaPatel@sarepta.com; sgrabich@sarepta.com
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N6 Maintenance of castration with concomitant relugolix and apalutamide in patients with high-risk localized prostate cancer: 1 year update

Brown G[1], Belkoff L[2], Hafron J[3], Aggarwal P[4], Potdar R[4], Bhaumik A[5], Phillips J[4], McGowan T[4], Neal Shore N[6]; gbrown@summithealth.com
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Q1 Cost of pediatric liver transplant among commercial and Medicaid-insured patients

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Q2 Maralixibat impact on concomitant medication use for the treatment of cholestatic pruritus in Alagille syndrome: Real-world experience in the United States

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Q3 Maralixibat persistency and adherence for the treatment of cholestatic pruritus in Alagille syndrome: Real-world experience in the United States

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U1 Leveling up real-world evidence adoption by US payers: The path toward optimizing its use in drug value assessments

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U7 Cardiorenal effectiveness of empagliflozin vs GLP-1 receptor agonists in patients with advanced chronic kidney disease: Results from the EMPRISE study

Than Htoo P[1], *Patorno E*[1], *Tesfaye H*[1], *Wexler D*[1], *Glynn R*[1], *Schmedt N*[2], *Déruaz-Luyet A*[2], *Koeneman L*[3], *Schneeweiss S*[1], *Paik J*[1]; *phtoo@bwh.harvard.edu*
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U14 Machine learning for imputing missing pharmacy costs in claims data

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U15 Marginal structural models for causal inference using observational health care data: Best practices and case studies

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U18 Impact of clinical dashboards for data capture and reporting across health system specialty pharmacies

Fitzpatrick C[1], *Kantoris C*[2], *Lopez Medina A*[1], *Giavatto C*[1], *Mourani J*[1], *Mayol Torres H*[1], *Rosa E*[1], *Skrtic A*[1]; *cfitzpatrick@trellisrx.com*
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U25 Biosimilar perceptions among autoimmune prescribers and pharmacists in health system specialty pharmacy

Lopez Medina A[1], *Mourani J*[1], *Hardin B*[1], *Evans A*[1], *Skrtic A*[1], *Giavatto C*[1], *Trieu S*[1], *Sredzinski E*[1], *Kobiska L*[1], *Setter A*[1], *Fitzpatrick C*[1]; *ana.lopezmedina@cps.com*; *casey.fitzpatrick@cps.com*
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Integrating social determinants of health indicators with administrative claims data to facilitate health equity research

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Z8 Addressing social determinants of health: A health system specialty pharmacy initiative

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