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SUPPLEMENT

Poster Abstracts

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AMCP POSTER ABSTRACT PROGRAM

The AMCP Poster Abstract Program provides a forum for authors to share their research with the managed care pharmacy community. Authors submit their abstracts to AMCP, and each abstract is reviewed by a team of peer reviewers and editors. All accepted abstracts are presented as posters at AMCP's Annual and Nexus meetings. These abstracts are also available through the AMCP meeting app. This JMCP supplement publishes all abstracts that were peer reviewed and accepted for presentation at AMCP Nexus 2025. Abstracts submitted in the Student and Encore categories did not undergo peer review; therefore, these abstracts are not included in the supplement.

ABSTRACT REVIEW PROCESS

Eighty-one reviewers and 4 JMCP editors completed the review process for AMCP Nexus 2025. Each abstract was reviewed and scored using a 1-5 scale with the following 5 criteria (15 rating scores per abstract), which are used by JMCP to evaluate manuscripts for publication:

• Relevance • Originality • Quality
• Bias • Clarity

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

The 15 rating scores and 3 accept/reject recommendations for each abstract were reviewed by a JMCP editor, who made an accept/reject decision. These decisions were reviewed and finalized by the JMCP editor-in-chief. The mean rating scores were used to award Platinum, Gold, and Silver medals for the best abstracts submitted. The abstract reviewers for AMCP Nexus 2025 were as follows:

Peer Reviewers

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Medal-Winning Abstracts

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

Toshi Chintala, BSc Computer Science. Beyond rule-based risk stratification: Redefining risk for better care coordination in managed care through artificial intelligence

Landon Marshall, PharmD, PhD. Trends in real-world persistence to weight loss glucagon-like peptide-1 receptor agonists from 2021 to 2024 among commercially insured adults without diabetes

Albert Truong, PharmD. Cost-inefficiency of high-dose opioids therapy in disease-free cancer survivors: A real-world, US payer-perspective decision-tree analysis

Jordan Pritzker, MD, MBA. Do claims data support use of CPT category II codes for real-world evidence clinical outcomes?

Shelley E. Hancock, MBA. Systematic literature review of health care resource use (HCRU), costs, and health-related quality of life (HRQoL) for brexucabtagene autoleucel in relapsed/refractory (R/R) mantle cell lymphoma (MCL) and Precursor B-cell lymphoblastic leukemia (B-ALL)

Sean P. Harrigan, MSc. Real-world health care utilization and costs associated with using dextromethorphan-bupropion extended-release tablets vs branded comparators for the treatment of major depressive disorder

Yang Zhao, PhD. The timing and characteristics of supplemental indications for small- and large-molecule medicines

Meng Li, ScM, PhD. Real-world characteristics and treatment patterns of patients with major depressive disorder initiating dextromethorphan-bupropion extended-release tablets, cariprazine, brexpiprazole, or esketamine

Grace E. Fox, PhD. Navigating artificial intelligence in evidence synthesis: A scoping review of current and developing guidelines

Nicholas J. Friedlander, PharmD. Validation of long-term savings from a pharmacist-to-prescriber telephonic intervention

Ann Leland, PharmD. Impact of a medical claims automated glucagon like peptide-1 drugs prior authorization program

Foram Patel, PharmD. Retention rates across clinical trials of anti-CGRP monoclonal antibodies for migraine prevention

Caroleen Drachenberg, PhD, MSPH. Health care resource utilization and costs among individuals with narcolepsy and idiopathic hypersomnia in the United States

Erika Horstmann, PharmD. Pharmacist-led interventions in comprehensive medication management: Impact on 90-day postdischarge A1c levels

Medal-Winning Abstracts

Jay D. Pauly, PharmD, BCPS, CPh. An analysis of solid tumor oncology patients' respiratory vaccination rates in accordance with ASCO guidelines

Yang Zhao, PhD. Real-world visual outcomes by health care insurance with prescription digital treatment for amblyopia: PUPiL registry analysis

Autumn Zuckerman, PharmD. Unmasking alternative funding programs: Patient outcomes and prescription journey

Vishal Saundankar, BPharm, MS. Descriptive analysis of ATTR-CM patients Initiating tafamidis among Medicare Advantage enrollees.

Montserrat Vera-Llonch, MD, MS. Olezarsen and plozasiran in the treatment of familial chylomicronemia syndrome (FCS): Results from a matching-adjusted indirect comparison (MAIC)

Ziqin Wong, PharmD. Payer policies and access restrictions for CRISPR-based gene therapy in sickle cell disease and beta-thalassemia: A systematic review of US coverage frameworks

Bhrigu Garg, Accelerating quality gap closure with artificial intelligence: Clinical natural language processing and large language model–driven extraction of HEDIS measures from structured and unstructured medical records

Molly T. Beinfeld, MPH. Examining the impact of specialty drug rebates on health plan coverage decisions

Anisha M. Patel, PhD, MS, BPharm. Quantifying the productivity burden of lupus nephritis and the potential value of obinutuzumab treatment

Jamie Lo, PhD, MPH. Impact of medications for opioid use disorder on infectious disease management

Terry Richardson, PharmD, BCACP. Managed care approaches to bispecific antibodies (BsAbs) in follicular lymphoma (FL) and diffuse large B-cell lymphoma (DLBCL): AMCP Market Insights Program

Bridgette Schroader, PharmD, MPA, BCOP. A survey of health care decision-maker (HCDM) formulary management perspectives in crowded oncologic markets: A focus on advanced non–small cell lung cancer (aNSCLC) and relapsed/refractory multiple myeloma (RRMM)

Katrine Wallace, PhD. Recent real-world treatment patterns of advanced melanoma in the United States

Bashir Kalayeh, PharmD. Budget impact of darolutamide + ADT for mCSPC from a US payer perspective

Zach Sheff, PhD, MPH. Health care costs associated with timely diagnosis of mild cognitive impairment and Alzheimer disease

Platinum Award-Winning Abstracts

118 Beyond rule-based risk stratification: Redefining risk for better care coordination in managed care through artificial intelligence

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BACKGROUND: Proactively identifying evolving risk and high-risk members is essential to improving outcomes and costs in managed care. Traditional rule-based models, built on static thresholds, often miss the full complexity of member health profiles. In contrast, Artificial Intelligence (AI) offers a dynamic, data-driven approach that captures evolving risk patterns across multiple variables with greater predictive accuracy.

OBJECTIVE: To evaluate how an AI algorithm outperforms traditional rule-based approaches in member risk stratification and how variables such as comorbidities, SDoH, demographics, lifestyle, utilization patterns, HEDIS care gaps, and lab results improve precision and granularity of risk differentiation.

METHODS: We conducted a retrospective analysis using de-identified medical, pharmacy claims, and clinical data from a large payer population. Natural Language Processing (NLP) was applied to longitudinal health data — including comorbidities, medications, HEDIS measures, and SDoH — to create unique health risk profiles. This captured the evolving, nonlinear nature of individual risk over time. Profiles were fused with structured data like lab results and utilization, then regressed against real-world cost metrics. This integrated approach enabled dynamic, personalized risk scoring and cohesive stratification into actionable risk categories.

RESULTS: To benchmark our in-house AI model, we compared its performance against the CMS-HCC risk adjustment model using the same member population. Risk strata—high, medium, and low—were derived based on predicted risk scores from both models. The AI model produced distinct strata with average per-member costs of $31,078 (high-risk), $2,680 (medium-risk), and $439 (low-risk), versus $22,219, $4,525, and $1,953 under CMS-HCC, showing AI better segregates members. Strata quality was quantified using the Davies-Bouldin Index (DBI), where lower values indicate better-defined strata. Across all risk tiers, the AI model outperformed the rule-based approach (DBI for high: AI = 0.47 vs. HCC = 0.55; medium: AI = 0.55 vs. HCC = 0.58; low: AI = 0.52 vs. HCC = 0.61), indicating more compact and well-separated member groupings by AI.

CONCLUSIONS: AI significantly improves member risk stratification over traditional models by recognizing complex variable interactions and dynamic risk signals. Incorporating AI-driven stratification into managed care workflows can enhance early intervention strategies, optimize resource allocation, and advance value-based care.

SPONSORSHIP: Datalink Software LLC

157 Trends in real-world persistence to weight loss glucagon-like peptide-1 receptor agonists from 2021 to 2024 among commercially insured adults without diabetes

Landon Marshall, PharmD, PhD, Health Outcomes Researcher, Principal, Prime Therapeutics, LLC, 2900 Ames Crossing Road, Eagan, Minnesota, 55121; landon.marshall@primetherapeutics.com

BACKGROUND: Despite substantial weight loss with glucagon-like receptor agonist (GLP-1), real-world persistence remains a challenge. Since 2021, GLP-1 shortages and changes in product availability have complicated access and persistence. This study examines the weight-loss GLP-1 products semaglutide (Wegovy) and tirzepatide (Zepbound) treatment persistence at one year, stratified by year of initiation.

OBJECTIVE: To evaluate one-year semaglutide (Wegovy) and tirzepatide (Zepbound) treatment persistence among commercially insured members without diabetes, by year of initiation.

METHODS: Prime Therapeutics' integrated pharmacy and medical claims data from an average monthly membership of 16.5 million commercially insured individuals were used to identify members without diabetes who newly initiated weight-loss GLP-1 treatment between January 1, 2021, and March 31, 2024 (index date period). Study inclusion was limited to members with continuous enrollment, defined as having no more than a total of 15 days of enrollment gaps in each 365-day study period, and no GLP-1 drug claim in the

365 days prior to index. Members were excluded if they had a pre-period medical claim indicating a diabetes diagnosis or diabetes drug claim and less than 19 years of age at index. Persistence was measured as no ≥60-day gap between the end of a claim's days' supply and the subsequent claim fill date in the 365-day period following index. GLP-1 product switching was allowed.

RESULTS: Among the 43,427 members without diabetes newly initiating a GLP-1, 23,025 (53.0%) met full study criteria. The mean age was 46.3 years, and 76.7% were female. Across the index years, weight-loss GLP-1 persistence across all products increased from 33.2% in 2021 to 62.6% in 2024. Semaglutide one-year persistence rates from 2021 to 2024 were 33.2%, 34.1%, 40.0%, and 62.7%. For tirzepatide, one-year persistence rates in 2023 and 2024 (the only years the product was available) were 64.0% and 62.2%.

CONCLUSIONS: This real-world analysis of weight loss GLP-1 products among individuals without diabetes found one-year treatment persistence has nearly doubled from 33.2% in 2021 to over 60% in 2024. Weight loss GLP-1 shortages resolved in 2023 and likely explain the improved persistence. Other potential explanations include improved GLP-1 dose escalation and side effect management, as well as lifestyle management programs. Additional research is needed to understand reasons for treatment discontinuation and the long-term cost-effectiveness of these products.

SPONSORSHIP: Prime Therapeutics, LLC

319 Cost-inefficiency of high-dose opioids therapy in disease-free cancer survivors: A real-world, US payer-perspective decision-tree analysis

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BACKGROUND: Advances in cancer diagnosis and treatment options have improved survival, which has resulted in a growing population of cancer survivors. During treatment, patients are exposed to opioids, a cornerstone of cancer pain management. Prior research showed that many survivors continue opioid therapy at progressively higher doses years after the conclusion of treatment. Prolonged exposure to high-dose opioids has been associated with negative health outcomes, including increased risk of opioid use disorder (OUD), adverse events, and increased mortality, and may lead to increased utilization of health care resources. Studies examining the economic inefficiency of increased opioid exposure in cancer survivors are, to our knowledge, non-existent.

OBJECTIVE: To evaluate the cost-inefficiency of long-term escalating high-dose opioids compared to rapid low-dose discontinuation of opioids among disease-free cancer survivors in the United States.

METHODS: A decision-tree model with a two-year time horizon was developed from the US health care payer perspective. Longitudinal opioid exposure data were obtained from a retrospective observational study of 610 disease-free survivors treated at VCU Massey Comprehensive Cancer Center. Model inputs regarding OUD, mortality, and costs were obtained from published peer-reviewed literature and public data. Utility values for the health states considered in the model were obtained from scientific literature and used to estimate quality-adjusted life-years (QALYs). Uncertainty of the model was assessed with a one-way sensitivity analysis.

RESULTS: The base-case results show that continued escalating high-dose opioid exposure resulted in higher costs ($41,072 vs $34,223) and fewer QALYs (1.143 vs 1.287) compared to rapid low-dose opioid discontinuation. Therefore, rapid discontinuation exhibited dominance in the analysis (ICER: −$47,785/QALY). The sensitivity analysis identified the utility value for survivors with OUD, mortality risk in survivors with OUD, and combined survivorship/OUD-related costs as primary drivers of uncertainty in this model. However, in almost all scenarios of the sensitivity analysis, rapid opioid discontinuation remained dominant.

CONCLUSIONS: High-dose therapy in disease-free cancer survivors is significantly cost-inefficient. High-dose therapy is associated with worse health outcomes and greater health care costs relative to low-dose therapy. Absent explicit clinical guidelines for tapering, opioid stewardship strategies for dose minimization in long-term survivorship care are critical for avoiding negative outcomes and preventing added costs.

SPONSORSHIP: None

386 Do claims data support use of CPT category II codes for real-world evidence clinical outcomes?

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BACKGROUND: Medical claims data include details on enrollment, procedures performed, diagnoses, and pharmacy dispenses; however, they typically lack detailed outcome measurements found in laboratory results. CPT Category II codes (Cat II) are a supplemental extension of the AMA's Current Procedural Terminology (CPT) that were intended to facilitate quality of care documentation without labor-intensive manual review of the medical record. Cat II topics range

from patient management and history to documenting laboratory result values. The suitability of Cat II for real-world evidence (RWE) research has been raised, but use of the optional coding was initially very low. However, in the past 5 years payors have implemented Cat II incentives while provider thought leaders (such as the AAP and AMA) recommend adopting Cat II codes for quality improvement purposes.

OBJECTIVE: The goal of this study is to quantify the concordance between laboratory results and claims-reported Cat II codes for two commonly performed laboratory tests: HbA1c and LDL cholesterol.

METHODS: This analysis examined closed claims and corresponding laboratory results representing 1.2 million insured members with available labs between January 2021 and December 2024. Concordance was defined as the occurrence of a corresponding Cat II code in claims within a 12-month window following laboratory test results.

RESULTS: In the diabetes cohort, 997,459 members had 1,950,297 HbA1c tests during the study period. In the cholesterol cohort, 1,048,005 members had 2,249,844 LDL tests during the study period. On average, 8.0% of the HbA1C tests and 1.5% of the LDL tests had corresponding Cat II codes. CPT II codes were reported more frequently in Medicare Advantage compared to Commercial Insurance (HbA1c: 85.9 v 55.8, LDL: 16.1 v 12.8 per 1,000).

CONCLUSIONS: The US FDA issued guidance for industry on the use of RWE to support regulatory decision-making for drug and biologic therapies, including underscoring the importance of assessing data reliably in RWE—specifically, whether CPT II codes are valid proxy for lab values and if claims data without lab integration is suitable for quality reporting or research. The average annual LDL Cat II code for the reporting period examined appears to have increased since it was last reported by Russo and Williams (15.6 per 1,000 v 11.1 per 1,000). Given the growing emphasis on clinical quality and the role they play in value-based-contracting, Cat II codes are likely to remain high in relevance. The potential value of using Cat II codes for RWE clinical outcomes remains worthy of continued examination.

SPONSORSHIP: CVS Health

Professional Reviewed Abstracts

Analgesics/Pain

2 Characteristics of new methadone use among older adults

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BACKGROUND: Methadone is an FDA-approved medication that, when taken as prescribed, can be a safe and effective method to treat opioid use disorder and pain. It is important for prescribers to be aware of current research and account for known risks, like overdose, falls, cognitive and psychomotor impairments, and drug interactions, when prescribing methadone to those aged 65 years and older. However, there is a paucity of recent research that describes the characteristics of methadone use among older adults.

OBJECTIVE: To describe demographic and clinical characteristics of new methadone users aged 65 years and older.

METHODS: This retrospective cohort analysis used pharmacy and medical claims data from the Humana Healthcare Research database to identify new users of methadone between 1/1/2022 and 12/31/2024. The cohort included members continuously enrolled in a Medicare Advantage prescription drug (MAPD) plan 12-months prior (baseline) to the first methadone claim during the study period (index), without a methadone prescription during baseline. Demographic characteristics (age, sex, race, population density, eligibility for Medicaid or Part D, low-income subsidy, original reason for Medicare) and prescribing provider were measured at index. Clinical characteristics (health risk estimates, comorbidities, medication use) were measured during baseline. Hospice use and mortality were measured in the 90 days post index.

RESULTS: We examined 3,321 MAPD members newly initiated on methadone. Average age was 65.9 years. Half were female (49.7%), 80.3% were White, 76.2% resided in a non-rural area, 50.5% were dually eligible for Medicaid or Part D low-income subsidy, and 68.1% were initially eligible for Medicare through disability. Mean (SD) Elixhauser condition count was 5.5 (3.3) and Rx-Risk score was 8.1 (3.4). Most patients (84.5%) were on opioid treatment prior to initiating methadone. Common prescribing specialties were primary care (34.8%), pain management (30.1%), and hospice/palliative care (16.2%). Baseline cancer diagnosis was observed in 39.3% of patients; drug abuse diagnosis (26.1%) was also common. Within 90 days of their first methadone prescription, 12.0% used hospice care, and 19.9% were deceased.

CONCLUSIONS: Methadone use was generally rare in this MAPD population. Patients initiated on methadone reflect a complex presentation that often included social risk factors, history of disability, cancer diagnosis, and/or history of substance abuse. Further research should examine factors and health outcomes associated with methadone initiation in the primary care setting.

SPONSORSHIP: CWSPC, HHR

3 Clinical and health economic outcomes with and without liposomal bupivacaine in Medicare-insured patients undergoing outpatient shoulder arthroplasty

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BACKGROUND: Total shoulder arthroplasty (TSA; anatomic and reverse) procedures have been progressively migrating away from inpatient settings toward hospital outpatient and ambulatory surgery venues, where effective perioperative pain management prior to discharge is critical. The NOPAIN Act has expanded reimbursement for qualifying nonopioid therapies, such as liposomal bupivacaine (LB), when used for Medicare-insured patients undergoing outpatient procedures. However, data regarding LB use for outpatient TSA in Medicare-insured patients are limited.

OBJECTIVE: To evaluate the impact of LB on opioid use and health care utilization for up to 12 months following TSA.

METHODS: Data on patients undergoing primary TSA with or without LB in hospital outpatient department settings from 2019 to 2021 were sourced from the 20% CMS-Medicare database (Parts A, B, and D). Cohorts were generated with 1:1 propensity score matching (PSM) between LB and non-LB groups. Opioid outcomes were evaluated in the pharmacy cohort (Part D) by chi-square test. Health care costs were

evaluated using Wald tests via generalized linear mixed-effect regression for TSA and via zero-inflated Poisson regression for follow-up total medical and pharmacy costs.

RESULTS: Overall, 4100 patients were included in the analysis (LB, n = 2050; non-LB, n = 2050); patient characteristics were similar between groups after PSM (median age, 74 years; female, 55.4%; White, 92.9%; osteoarthritis, 94.4%). In the pharmacy cohort (n = 3165), ~5% fewer patients in the LB group filled opioid prescriptions during the first week after TSA compared with the non-LB group ($P < 0.01$). This difference was primarily driven by significantly lower opioid use in opioid-experienced patients in the LB versus non-LB groups ($P = 0.007$). Overall, relatively lower follow-up emergency department visits were observed in the LB group versus the non-LB group. These differences contributed to total cost savings after discharge of > $300 for LB compared with the non-LB group at months 3, 6, and 12. These cost savings offset the higher initial pharmacy costs of LB and contributed to an estimated ~$100 cost savings with LB over the 12-month follow-up period.

CONCLUSIONS: Medicare-insured patients receiving LB for outpatient TSA experienced lower opioid use 1 week following surgery and had lower all-cause total health care costs over 1 year of follow-up compared with patients without LB, which may have been driven by more effective perioperative pain management. These data support the use of LB for outpatient TSA.

SPONSORSHIP: Pacira BioSciences, Inc.

4 Impact of liposomal bupivacaine on health care resource utilization and costs in patients undergoing total knee arthroplasty in real-world ambulatory surgical centers

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BACKGROUND: Total knee arthroplasty (TKA) is increasingly performed in outpatient ambulatory surgical centers (ASCs), with an estimated half of all joint replacements to be outpatient by 2026. Optimized perioperative pain management for outpatient TKA is critical to facilitate shorter length of stay and lower opioid consumption. Further, poorly managed acute pain can increase the risk of chronic pain, which may result in downstream health care resource utilization (HRU) and higher overall costs. Liposomal bupivacaine (LB) is a nonopioid option that can be used to prolong postoperative analgesia after TKA.

OBJECTIVE: To evaluate the real-world impact of postoperative analgesia with LB on HRU, costs, and opioid prescription refill following TKA in ASCs.

METHODS: Adults undergoing a TKA procedure between January 2019 and November 2022 at an outpatient ASC with moderate-to-high volume of LB use were retrospectively identified from IQVIA's New Data Warehouse. Patients were divided into 2 cohorts based on LB use on the date of TKA; 1:1 propensity score matching (PSM) was used to create balanced cohorts. All-cause and pain-related HRU and costs as well as opioid use were evaluated at 30, 90, and 360 days after surgery.

RESULTS: After PSM, each cohort included 2307 patients. Total all-cause costs were lower for patients with LB than without LB over 30, 90, and 360 days after surgery by $247, $438, and $1368, respectively (all $P < 0.01$). Patients with LB also demonstrated significantly lower pain-related costs than those without LB across all follow-up periods (all $P < 0.05$). Patients with LB had lower HRU, with fewer all-cause physical and occupational therapy (PT/OT) visits than patients without LB at all follow-up periods (30 days: 3.0 vs 3.5; 90 days: 7.1 vs 8.1; 360 days: 10.1 vs 11.6; all $P < 0.01$), with similar trends observed for pain-related PT/OT visits (all $P < 0.01$). There were fewer opioid-treated days on average over 360 days after surgery for patients with LB than without LB (30.4 vs 35.2 days; $P < 0.05$).

CONCLUSIONS: Use of LB for outpatient TKA was associated with lower all-cause and pain-specific health care costs, largely attributable to lower outpatient expenditure (eg, PT/OT visits) over 1 year of postsurgical follow-up. These results have important implications for enhancements to postsurgical analgesia pathways and reducing health care utilization and costs in patients undergoing TKA in outpatient care settings.

SPONSORSHIP: Pacira BioSciences, Inc.

Benefit Design and Management

12 Patient perspectives on employer-based health insurance: Experiences of employees with chronic diseases

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BACKGROUND: Discussions around insurance design policy, including employer-based coverage, usually center around "average" or healthy patients with acute conditions. However, people with chronic diseases are often more vulnerable to the burdens of cost exposure, access, and affordability. Without understanding the unique challenges employees with chronic disease face with health insurance, employers may be unknowingly missing or misunderstanding employee experiences.

OBJECTIVE: To explore overall chronic disease patient experience with employer-based insurance coverage, including how it does or does not accommodate chronic disease needs.

METHODS: Qualitative analysis of five virtual 120-minute focus group sessions (September 2024) with 27 participants (US residents with chronic disease and employer health insurance) recruited from Johnson & Johnson Innovative Medicine's Patient Engagement Research Councils (PERC), a diverse group of disease-aware participants living with chronic health conditions who provide their insights and feedback around specific, structured series of research activities. Key themes were identified from focus group transcripts and direct observations (Data managed by MAXQDA software).

RESULTS: Participants report that employer-based insurance often fails to meet the needs of patients with complex chronic conditions and is most often designed for healthy employees to cover occasional costs. There is a lack of communication and support from employers, especially around enrollment. Participants also describe the impact of insurance challenges on patient-employer relationships, including concerns around discrimination and feeling "tethered" to employment, and suggest improvements such as better awareness of chronic diseases, improved communication, and transparency around costs.

CONCLUSIONS: Employees with chronic diseases have unique needs, experiences, and outcomes regarding health insurance. Employers should focus more specifically on the chronic-disease employee population to learn more about their experiences and consider more targeted communications and engagement strategies to ensure health insurance and supporting communication meets the needs of these employees.

SPONSORSHIP: Johnson & Johnson Innovative Medicine

13 Implications of Wegovy utilization in the New York State Medicaid Program

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BACKGROUND: Wegovy is a semaglutide product approved by the Food and Drug Administration (FDA) in 2021 for weight loss and management in patients with obesity or overweight with ≥1 weight-related condition. In March 2024, the FDA approved Wegovy for reduction in the risk of major adverse cardiovascular (CV) events in patients with obesity and overweight and established CV disease. A review of Wegovy was presented to the New York State (NYS) Medicaid Drug Utilization Review Board (DURB) in October 2024 to implement coverage criteria aligned with the supplemental indication; coverage for weight loss alone is prohibited per NYS Code, Rules and Regulations.

OBJECTIVE: To evaluate the potential impact to NYS Medicaid of adding Wegovy to the Medicaid List of Reimbursable Drugs.

METHODS: Retrospective analyses of pharmacy and medical claims were conducted for state fiscal year (SFY) 2024. Diagnoses were identified through *International Classification of Diseases, Tenth Revision* codes and included overweight (body mass index [BMI] 25 to <30 kg/m^2), obesity (BMI ≥30 kg/m^2), type 2 diabetes mellitus (T2DM), and CV conditions. Utilization of CV drugs was identified from pharmacy claims and included drugs reported in the Semaglutide Effects on Cardiovascular Outcomes in People with Overweight or Obesity (SELECT) trial. The analysis population was defined as members with overweight or obesity and CV disease, without a diagnosis of T2DM; members with T2DM were excluded due to qualification for the semaglutide product Ozempic.

RESULTS: A total of 7.7 million members were enrolled in NYS Medicaid during SFY 2024. Of these, 1.26 million members had a diagnosis of overweight or obesity without T2DM. Over 85% were ≥18 years of age, 62% were male, and approximately 16% (n=200,000) had a diagnosis of CV disease. Specific BMI ranges were identifiable for 65% of these members; 22% had BMI 25 to <30 kg/m^2 and 43% had BMI ≥30 kg/m^2. Among members with CV disease, 54% used

drugs from ≥1 of the included classes, and 32% used drugs from ≥2 different classes. Approximately 46% of members had no claims for CV medications.

CONCLUSIONS: Nearly 200,000 NYS Medicaid members had diagnosis codes aligned with the supplemental indication of Wegovy during SFY 2024; however, almost half did not have claims for CV medications. Recommendations were made to the DURB to implement criteria including confirmation of overweight or obesity and CV disease, absence of T2DM, utilization of ≥1 CV medication in the past 30 days, no concurrent use of other semaglutide products, and dosing corresponding to the labeling.

SPONSORSHIP: New York State Department of Health

14 Impact of a medical claims automated glucagon like peptide-1 drugs prior authorization program

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BACKGROUND: Medication prior authorization (PA) generally requires prescribers to submit verifying information, e.g., diagnosis, to the health plan or pharmacy benefit manager (PBM) for coverage determination. Glucagon like peptide-1 products (GLP-1s) are frequently not covered for weight loss; however, they are covered for diabetes mellitus (DM). A GLP-1 PA requiring DM diagnosis is common. PBMs integrated with their health plan have access to medical claims data and can automate the PA DM diagnosis verification, allowing the GLP-1 PA authorization to occur at the pharmacy point of sale. However, little is known of the impact of this program on PA reviews.

OBJECTIVE: To measure the impact of the PBM using health plan medical claims diagnosis to automate the GLP-1 PA process through assessing the percentage of all DM FDA-approved GLP-1s PA reviews that were automatically approved.

METHODS: Prime Therapeutics' integrated pharmacy and medical claims data from 15.3 million commercially insured members were used to identify members with a DM GLP-1 pharmacy claim PA review between October 2024 and December 2024 (4Q2025). When a pharmacy submits a DM GLP-1 prescription claim for a member newly initiating DM GLP-1 therapy, a PA is required to verify the DM diagnosis. The automated PA process checks the member's medical claims for a DM diagnosis. If a DM diagnosis is found, the PA is authorized and claim is paid right at the pharmacy counter, bypassing traditional PA review. If no DM diagnosis is detected, the claim will not be paid, and standard PA process is required. All 4Q2025 DM GLP-1 claims that were approved via the automated review process were identified and divided by all DM GLP-1 PA reviews to determine the percent approved via the automated review process.

RESULTS: Among 15.3 million commercially insured members, in the 4Q2024, 466,683 (45.3%) DM GLP-1 claims were adjudicated via the automated process out of a total of 1,029,152 DM GLP-1 PA claims. These 466,683 automated DM GLP-1 PA claims assisted 200,021 members, or 1 in 77 of all 15.3 million members.

CONCLUSIONS: Automated PA, utilizing the medical claims diagnosis information, allowed for 45.3% of DM GLP-1 PA claims to adjudicate at point of sale, benefiting one in 77 of all insured members. While PA is an important part of PBM utilization management programs, automated PA helps avoid unnecessary reviews and manual review administrative costs. Clients also avoid paying claims for off-label use of GLP-1 medications. Automated DM GLP-1 PAs work to simplify the PA process, helping members get the medicine they need seamlessly.

SPONSORSHIP: Prime Therapeutics

15 Payer expectations for the impact of MFP pricing on management and profitability

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BACKGROUND: Under the Inflation Reduction Act (IRA), the Maximum Fair Prices (MFPs) for the first 10 drugs selected under the Medicare Drug Price Negotiation Program will take effect in 2026. Medicare Part D plans must include these drugs on their formularies to ensure reasonable access. The Centers for Medicare & Medicaid Services will monitor plan practices to prevent actions that undermine negotiated drugs.

OBJECTIVE: To assess how Medicare plans are preparing for MFP implementation in 2026, including formulary strategies for high-cost categories like immunology and oncology, and anticipated impact on competitor products and plan profitability.

METHODS: Precision AQ conducted a March 2025 survey with 25 health plan decision-makers overseeing Medicare formularies. All were actively involved in 2026 formulary planning.

RESULTS: MFP drug inclusion is expected to reshape formulary positioning for competitor products. Forty percent of respondents anticipate disadvantaging drugs competing with MFP products, and 8% plan to remove at least one

competitor from the formulary. A third expect no impact, and 20% will decide on a case-by-case basis. Nearly half (48%) of health plans intend to proactively move patients to or from therapies based on their MFP strategy. With 2 immunologics on the negotiation list facing biosimilar competition, 56% of respondents said biosimilar and brand access will be determined by net cost, while 28% plan to cover both at parity, and 12% will prioritize rebate value. Within the oncology category, in light of the IRA provisions and potential for multiple negotiated drugs, respondents reported potentially using the following measures to control costs: 56% of health plans will use step therapy protocols, 48% will apply preferred tiering, and 36% will implement Part B/D step therapy. Overall, 36% expect a somewhat positive effect on profitability, 28% anticipate no impact, 32% predict a somewhat negative effect, and 4% expected a strongly negative outcome. Looking to 2027, health plans expect to strengthen their focus on biosimilars (84%) and generics (68%). Forty percent plan to reduce brand coverage, and 28% will expand step edits.

CONCLUSIONS: MFP pricing is expected to intensify pressure on competitor drugs, particularly in classes with negotiated drugs and/or biosimilar alternatives. While profitability expectations remain mixed, health plans are clearly preparing for a more cost-conscious future. Heading into 2027, many are likely to pursue low wholesale acquisition cost strategies, increase scrutiny of drug value, and adopt more aggressive formulary management practices.

SPONSORSHIP: Precision AQ

16 The impact of copay accumulators and maximizers on treatment patterns and costs among patients with major depressive and bipolar disorders treated with branded mental health treatments

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BACKGROUND: Copay accumulator (CA) and copay maximizer (CM) programs prevent manufacturer copay assistance from counting toward patients' deductibles or out-of-pocket (OOP) maximums. Their increasing use raises concerns about cost, access, and health outcomes.

OBJECTIVE: To evaluate the impact of CA and CM compared with standard copay plans (SCPs) on treatment patterns, pharmacy costs, and OOP burden among patients with major depressive disorder (MDD) or bipolar disorder (BPD) treated with branded atypical antipsychotics (AAPs) and/or antidepressants (ADs).

METHODS: This retrospective claim study utilized Kythera commercial data (2020-2024). MDD and BPD populations were identified based on ≥1 diagnosis code and ≥1 branded AAP or AD prescription during the identification period (2021-2023). Continuous enrollment for 12 months pre- and post-index and ≥3 months of post-index branded medication use were required. Patients were stratified into CA, CM, or SCP cohorts using proxy indicators for copay design. Propensity score matching was used to evaluate risk-adjusted treatment abandonment, discontinuation, adherence, and costs.

RESULTS: Copay plan distribution was as follows: MDD+AAP: 8997 SCP, 1135 CA, 618 CM; BPD+AAP: 11,957 SCP, 1363 CA, 1221 CM; MDD+AD: 20,731 SCP, 1060 CA, 689 CM; BPD+AD: 2295 SCP, 93 CA, 134 CM. Compared with SCPs, both CA and CM cohorts had significantly higher median OOP costs across all subgroups (e.g., $75/$60 vs $16/$11 for MDD+AAP; $P<.0001$). Among adherent patients (medication possession ratio ≥0.80), all-cause pharmacy costs were higher for CAs and CMs (e.g., MDD+AAP: $16,156/$17,700 vs $15,013/$14,905; $P<.05$). CA patients had overall poorer adherence and persistence. For MDD+AD, CAs had lower proportion of days covered (PDC) (0.67 vs 0.70; $P=.0022$) and shorter treatment duration (89 vs 110 days; $P=.0252$). Among BPD+AD patients, CAs had higher discontinuation rates (35.1% vs 17.9%; $P=.0134$) and lower PDC (0.63 vs 0.73; $P=.0109$), while CM cohorts often had more favorable adherence patterns. BPD+AAP CMs had higher PDC (0.71 vs 0.68; $P=.0225$) and greater persistence (247 vs 213 days; $P=.0003$) than SCPs.

CONCLUSIONS: Patients in CA and CM programs experienced significantly higher OOP costs. CA plans were associated with worse adherence and higher treatment abandonment rates. Policymakers should consider these impacts when designing benefit structures for vulnerable populations with mental health conditions.

SPONSORSHIP: Otsuka Pharmaceutical Development & Commercialization, Inc.

17 Does time on market influence the evidence cited in US commercial health plan specialty drug coverage policies?

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BACKGROUND: Specialty drug coverage is a critical component of commercial health plans in the United States, providing access to treatments that address complex medical conditions. The type of evidence cited in support of coverage decisions may change over time.

OBJECTIVE: To explore the relationship between the duration a drug has been on the market and the types of evidence cited in coverage policies.

METHODS: We used the Tufts Medical Center Specialty Drug Evidence and Coverage (SPEC) database, which includes publicly available coverage decisions for 469 drugs from 18 large US commercial health plans, as well as the evidence cited in support of these decisions. We categorized evidence as (1) randomized controlled trial (RCT), (2) other clinical study (e.g., phase 2 clinical trial), (3) real-world evidence (RWE), (4) systematic review/meta-analysis, or (5) health technology assessment (HTA) or economic evaluation. For each study, we identified the drugs and FDA-labeled indications assessed, along with years since FDA approval for each drug-indication pair. We then assessed how the types of evidence cited varied by time on the market, grouped by years since FDA approval. Data were current as of August 2024.

RESULTS: A total of 8,490 citations were identified from coverage decisions active in August 2024. For treatments on the market for 1-5 years, RCTs and other clinical studies collectively accounted for 82.5% of citations (1,441 out of 1,746), with RWE comprising 3.7%, systematic reviews/meta-analyses 10.3%, and HTAs or economic evaluations representing 3.5%. For treatments on the market 10-15 years, RCTs and other clinical studies constituted 69.5% of citations (1,372 out of 1,975), with RWE accounting for 14.1% of citations, systematic reviews/meta-analyses 13.1%, and HTAs or economic evaluations representing 3.4%. For treatments on the market 25+ years, RCTs and other clinical studies comprised 51.1% of citations (283 out of 554), with RWE accounting for 21.8% of citations, systematic reviews/meta-analyses 19.7%, and HTAs or economic evaluations constituting 7.4%.

CONCLUSIONS: US commercial health plans initially rely on RCTs and clinical studies for coverage decisions of new specialty drugs. Over time, they increasingly refer to RWE, systematic reviews/meta-analyses, HTAs, and economic evaluations. Product manufacturers should anticipate these shifting evidence needs and focus on generating varied types of evidence as their products mature.

SPONSORSHIP: EMD Serono

18 Assessing commercial health plan responsiveness to FDA label changes

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BACKGROUND: Health plan coverage policies play a critical role in determining patient access to specialty drugs and should reflect the most current understanding of their use. Timely updates help ensure that coverage aligns with evolving standards of care. However, it is unclear how promptly health plans revise specialty drug coverage policies in response to new evidence. One way to assess this is by measuring plan responses to FDA label revisions.

OBJECTIVE: To evaluate how quickly commercial health plans update specialty drug coverage policies following FDA label revisions.

METHODS: We used the Tufts Medical Center Specialty Drug Evidence and Coverage (SPEC) database, which includes coverage decisions from 18 large US commercial health plans. We identified FDA label revisions from 2019 to 2022 for all drug-indication pairs in SPEC, categorizing each as an expansion (broader population) or contraction (narrower population). For each revision, we assessed the timing of corresponding policy updates. We used Kaplan-Meier (KM) curves to estimate and visualize time to update, stratified by revision category (expansion vs contraction), drug type (oncology, orphan status), and plan. We then used Cox proportional hazards models to examine how these factors influenced response time.

RESULTS: We identified 858 changes to coverage decisions corresponding to 87 FDA label revisions (763 across 79 expansions; 95 across 8 contractions). Overall KM-adjusted median response time to revision was 29.7 weeks (95% CI: 26.9-33.6 weeks). Health plans were slower to adopt label expansions (median 32.1 weeks) than contractions (21.4 weeks). Updates were faster for oncology than for non-oncology drug drugs (28.6 vs. 31.0 weeks) as well as for orphan vs non-orphan treatments (28.7 vs. 30.1 weeks). Median response time varied by plan (15.1 weeks to 55.4 weeks). In Cox models, contractions (HR = 1.38; P = 0.006)

and oncology status (HR = 1.35; P = 0.000) were associated with faster updates. Orphan status was not statistically significant (HR = 1.09; P = 0.296).

CONCLUSIONS: Health plans responded faster to label contractions than expansions, with substantial variation across plans for any type of label revision. Delays in updating coverage policies, particularly for label expansions, may limit access to broadened indications.

SPONSORSHIP: National Pharmaceutical Council

19 Estimating the budget impact of prevalence-adjusted willingness-to-pay thresholds using the generalized dynamic prevalence (GDP) theory

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BACKGROUND: The generalized dynamic prevalence (GDP) theory, proposed by Padula and Pontinha, offers a novel framework that links willingness-to-pay (WTP) thresholds with disease prevalence and relative risk, addressing inherent cost-effectiveness biases—particularly those disadvantaging individuals with rarer medical conditions. By incorporating time as a fixed effect, GDP enables modeling of prevalence dynamics influenced by natural disease progression or curative interventions such as gene therapies. Despite its conceptual utility, the real-world budget impact of applying GDP-informed, prevalence-adjusted WTP thresholds remains unclear.

OBJECTIVE: To project the 5-year budget impact of adopting varying WTP thresholds across seven medical conditions with diverse prevalence—ranging from hypercholesterolemia to Duchenne muscular dystrophy (DMD) —within a commercial health plan covering one million lives.

METHODS: GDP theory was applied using the mathematical relationship between WTP, relative risk, and time-dependent disease prevalence: $K(t) = M / [1 - (\text{prevalence}_t^2)^2]$. Prevalence estimates for seven medical conditions were derived from the 2016-2022 Medical Expenditure Panel Survey (MEPS) and standardized using Box-Cox transformations to address skewness. WTP thresholds were calibrated as a function of standardized disease prevalence factors. A fixed annual reduction in prevalence was assumed over a 5-year time horizon to simulate curative or disease-modifying treatment effects. Each condition was linked to a representative reference technology (e.g., PCSK9 inhibitors for hypercholesterolemia, gene therapy for DMD). Budget impact was calculated from the perspective of a US health plan covering one million lives and reported as per-member per-month (PMPM) costs for each condition.

RESULTS: US WTP could vary between $104,000/QALY for common conditions and $990,049/QALY for rare conditions. For example: sickle cell disease, with a prevalence of 0.03% and a standardized prevalence factor of 0.825, K = $326,233/QALY; Duchenne muscular dystrophy, with a prevalence of 0.015% and a standardized prevalence factor of 0.912, K = $621,247/QALY. PMPM budget impact was found to decrease with decreasing prevalence.

CONCLUSIONS: GDP offers a solution to incorporating dynamic prevalence in estimations of WTP thresholds and helping define resource allocation across rare disease cohorts for commercial payers. Additionally, GDP application could improve access to revolutionary health technologies for rare conditions with significant unmet medical needs.

SPONSORSHIP: None

20 Trends in commercial payer coverage of accelerated approval therapies

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BACKGROUND: The FDA's Accelerated Approval (AA) Pathway allows for expedited approval of therapies for serious conditions based on surrogate endpoints. Payers face challenges balancing timely access with managing high-cost therapies that often lack comprehensive data. Coverage decisions are complex, especially when alternatives are limited.

OBJECTIVE: To explore how accelerated approval drugs are covered by commercial payers.

METHODS: We identified all ongoing AA indications (excluding vaccines and hospital-only drugs) from the FDA AA list as of January 1, 2025. Orphan Drug Designation (ODD) was assessed via the FDA ODD database. We reviewed 80 non-oncology (N-O) and 156 oncology (O) policies from 4 of the largest US commercial payers between March 1 and May 27,2025.

RESULTS: Among AA indications, 83% had an ODD. Commercial coverage varied: some policies aligned with FDA labeling, while others were more restrictive or excluded coverage. In N-O: • 82.5% (n = 66) required prior authorization (PA) • 2.5% (n = 2) of policies considered the drug investigational • 15% (n = 12) lacked a PA policy. Of those requiring PA, 45% aligned with FDA labeling, 36% were more restrictive than the FDA label, and 18% included step therapy (ST). Of the 12 without policies, 4 were not publicly available, 4 covered

the drug with no utilization management (UM), and 4 were non-formulary with no PA. In O: • 70% (n = 109) applied PA [40% (n = 63) aligned with FDA labeling; 26% (n = 40) required additional criteria; 4% (n = 6) required ST] • 30% (n = 47) lacked policies; 5 of those were non-formulary with no PA. Initial and renewal durations also varied. N-O drugs were more likely to have shorter approval durations: 25% had initial approvals ≤6 months and 11% had renewals ≤6 months. No O policies had durations ≤6 months.

CONCLUSIONS: Most AA indications carry an ODD, underscoring the challenge of balancing access with evidence uncertainty. While most AA therapies are covered and have UM, gaps in policy transparency remain. Some plans may use exceptions or appeals to manage access. Many align with FDA labeling, but others apply more restrictions that may prevent or delay access to care. Furthermore, N-O drugs are more likely to face shorter approval periods, which may increase administrative burden and delay care.

SPONSORSHIP: None

21 Managed care insights on optimizing coverage coordination for therapies spanning medical and pharmacy benefits

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BACKGROUND: In the biopharmaceutical landscape, certain products require coverage coordination across both pharmacy and medical benefits. One of the most common scenarios is where one or more induction doses as intravenous infusion is managed through the medical benefit followed by subsequent subcutaneous, self-administered doses that are managed through the pharmacy benefit. This could occur in a carve-in arrangement where the plan sponsor contracts with one entity responsible for covering both benefits or a carve-out arrangement where the plan sponsor contracts for each benefit separately. It is important to understand payer perceptions and challenges in cross-benefits coordination to remove potential barriers to patient access.

OBJECTIVE: To understand how payers manage therapies that require coordination across medical and pharmacy benefits.

METHODS: A web-based survey of US payers was conducted through Cencora's Managed Care Network research panel, in February 2025.

RESULTS: In total, 10 advisors from health plans (70%) and pharmacy benefit managers or PBMs (30%) participated in the survey. Sixty percent manage coverage coordination between health plans and PBMs through integrated software platforms and direct communication between clinical teams. For the current cross-benefit scenario (induction dose falling under medical benefit and maintenance dose falling under pharmacy), 60% require a separate prior authorization (PA) for both benefits, and 20% indicated this would vary by product type. Payers who could require separate PAs for both benefits noted physician attestation of induction therapy (63%) would be part of the PA for the pharmacy benefit maintenance therapy. Cross-coordination of benefits is a smoother process in a carve-in (50%) vs carve-out (30%) arrangement. Thirty percent of advisors take on average less than 1 day to coordinate benefits in a carve-in arrangement compared to only 10% in a carve-out arrangement. Delays in getting required information from provider offices and submission of two PAs are identified as key challenges.

CONCLUSIONS: Overall, advisors encounter situations that require cross-coordination of benefits. For payers, integrated cross-benefit platforms that provide access to both pharmacy and medical claims can simplify this process. Manufacturers can support payers by making them aware of the potential cross-benefit coverage requirement via pre-approval information exchange (PIE) and educating providers and office staff on navigating the PA process.

SPONSORSHIP: Cencora

Cardiovascular

33 Economic burden associated with systemic inflammation in patients with established atherosclerotic cardiovascular disease and stage 3 to 4 chronic kidney disease

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BACKGROUND: Atherosclerotic cardiovascular disease (ASCVD) is a leading cause of morbidity and mortality in the United States, affecting over 26 million people. Further, patients with ASCVD and co-existing chronic kidney disease (CKD) have a greater risk of major adverse cardiovascular events (MACE) than patients without CKD. Clinical trials have documented a residual risk of MACE linked to systemic inflammation (SI) after guideline-directed medical therapy. However, the economic burden of SI in patients with established ASCVD and stage 3-4 CKD is unclear.

OBJECTIVE: To assess the association between SI and economic outcomes in patients with established ASCVD and stage 3-4 CKD.

METHODS: This retrospective study identified patients from the Komodo Healthcare Map (Jan 1, 2016, to Jun 30, 2024) based on diagnosis and procedure codes in medical claims. CKD and its stage were determined from medical claims or laboratory estimated glomerular filtration rate. SI was defined using high-sensitivity C-reactive protein (hsCRP) testing: with SI, ≥1 hsCRP value of 2-10 mg/L; without SI, all hsCRP values < 2 mg/L. HsCRP test results >10 mg/L or conducted during acute illness were excluded. The study endpoints were health care resource utilization and costs. Multivariable models were used.

RESULTS: Among 6,351 patients with ASCVD + stage 3-4 CKD and a qualifying hsCRP, mean age was 71 years, 44% were male, and the average follow-up was 38 months. Of the eligible patients, 3,600 (57%) had SI. During follow-up, the rates of inpatient admissions per patient per year for those with and without SI were 0.25 and 0.19, respectively, while the rates of outpatient services were 18.2 and 17.0. After adjusting for patient characteristics, SI was associated with a 30% increase (OR 1.30, 95% CI 1.15-1.47) in inpatient admissions and a 5% increase (RR 1.05; 95% CI 1.04-1.05) in outpatient services. The annual all-cause health care costs were $26,089 per patient with SI and $20,753 per patient without SI. Inpatient costs accounted for 34.3% and 29.8% of the total costs, respectively. After adjusting for patient characteristics and baseline costs, SI was associated with a 20% increase in total health care costs (RR 1.20, 95% CI 1.11, 1.30). SI was also associated with increased hospitalization costs due to myocardial infarction (RR 1.90; 95% CI 1.27, 2.90) and stroke (RR 2.65; 95% CI 1.71, 4.24).

CONCLUSIONS: SI is strongly associated with overall health care resource utilization and costs in patients with ASCVD and stage 3-4 CKD. This study highlights the economic burden related to SI in this population.

SPONSORSHIP: Novo Nordisk Inc.

34 Short-term impact on health care costs after modification to PCSK9i therapy clinical criteria

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BACKGROUND: To maintain clinically appropriate access and utilization for proprotein convertase subtilisin/kexin type 9 inhibitors (PCSK9i) aligning with evidence-based care, the clinical criteria were modified—removing the requirement of prior ezetimibe use, reducing the threshold for low-density lipoprotein cholesterol (LDL-C) from ≥70mg/dL to ≥55mg/dL, and prolonging initial approval duration.

OBJECTIVE: To evaluate the impact of PCSK9i clinical criteria modification, effective January 1, 2024, on the total all-cause costs' trend for patients with a submitted PCSK9i claim.

METHODS: Commercially insured patients with a new submitted PCSK9i claim identified using NDC/GPI codes between 1/1/2023 and 6/30/2024 from the Healthcare Integrated Research Database (HIRD) were included. Guideline-directed therapy (GDT) per ACC/AHA clinical guideline pre-requisites include presence of atherosclerotic cardiovascular disease (ASCVD) and/or type 2 diabetes mellitus (T2DM) diagnosis; LDL-C level ≥70 mg/dL (part of previous clinical criteria); prior ezetimibe use (part of previous clinical criteria); prior statin use; and high/moderate-intensity statin at the time of the latest PCSK9i claim. Quarterly per-patient-per-month (PPPM) all-cause health care costs were computed from Q1 2023 to Q2 2024 to assess trend. Pre- and post-criteria change to PPPM costs were compared using identical time periods in 2023 and 2024 to control for seasonality.

RESULTS: Patients with a submitted PCSK9i claim increased from 18,012 in Q1 2023 to 26,712 in Q2 2024. Quarterly median patient age was unchanged over 1.5 yrs of observation (range: 59-60 yrs), as was proportion of males (range 57.2%-58.6%). GDT based on proportion of patients with ASCVD/T2DM (75.1% vs 72%), LDL-C ≥70 mg/dL (80.9% vs 81.1%), ezetimibe (31.2% vs 30.7%), any statin use (63.5% vs 66.8%), high-intensity statin use (40.1% vs 42.5%), and moderate-intensity statin use (27.2% vs 29.9%) were similar in first half of 2023 vs 2024 after modification to the PCSK9i clinical criteria. Mean all-cause PPPM costs trended from $1,880 in Q1 2023 to $1,903 in Q2 2024. Comparing Q1 2023 ($1,880) to Q1 2024 ($1,844) and Q2 2023 ($1,982) to Q2 2024 ($1,903), there was no appreciable change in all-cause PPPM costs following the modification.

CONCLUSIONS: PCSK9i clinical criteria modification aligning with evidence-based care did not have any impact on all-cause costs in the first 6 months post-policy change. Policy updates evolving with evidence and guidelines can enhance clinically appropriate drug access and utilization without significant changes in patient costs.

SPONSORSHIP: CarelonRx

35 Descriptive analysis of ATTR-CM patients enrolled in Medicare Advantage.

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BACKGROUND: Transthyretin amyloid cardiomyopathy (ATTR-CM) is a progressive, infiltrative form of heart failure (HF) that results from misfolded transthyretin protein deposits in the myocardium. Tafamidis was the first treatment FDA approved in 2019, and therapies continue to evolve including the recent approval of acoramidis in 2024 and vutrisiran in 2025. There is a lack of real-world evidence from a US payer perspective on trends in the recognition and treatment of ATTR-CM and associated health care resource use and clinical outcomes among Medicare Advantage (MA) enrollees.

OBJECTIVE: To describe ATTR-CM diagnosis trends, and examine ATTR-CM patient characteristics, clinical outcomes, and health care resource use (HRU) among MA enrollees.

METHODS: This study was conducted using the Humana Research Database. Annual trend in number of MA members diagnosed with ATTR-CM (per 100,000 enrollees) was assessed from 2019 to 2023. A longitudinal cohort of MA members aged 18-89 years and newly diagnosed with ATTR-CM (index event) from 01/01/2020 and 02/28/2024 was identified. Twelve-month pre-index and at least 6 months post-index enrollment was required. Comparisons of baseline characteristics and HRU were conducted for treated versus untreated patients.

RESULTS: The number of ATTR-CM patients increased each year, from 3.4/100k in 2019 to 13.7/100k MA enrollees in 2023. We identified 529 newly diagnosed ATTR-CM patients with median of 19 months follow-up. Among these patients, 52.6% initiated tafamidis treatment during follow-up, and 29.1% of those discontinued tafamidis at a later point. Baseline characteristics were similar for treated and untreated. During follow-up, a greater proportion of treated patients had cardiologist visits (80.9% vs 72.9%; $P = 0.028$) and fewer treated patients had emergency department (ED) visits (54.0% vs 65.3%; $P = 0.008$). Overall, 21.9% had all-cause death during variable follow-up. Significant predictors of mortality were age (75-84 years, HR: 1.73, 95% CI: 1.02-2.95, $P = 0.044$; >85 years, HR: 3.72, 95% CI: 1.93-7.18, $P < 0.001$; reference group, 65-74), evidence of fatigue (HR: 1.62, 95% CI: 1.06-2.47, $P = 0.026$) and ED visits (HR: 1.64, 95% CI: 1.07-2.52, $P = 0.023$) prior to diagnosis, and ESRD as the original reason for Medicare enrollment (HR: 3.86, 95% CI: 1.38-10.80, $P < 0.010$).

CONCLUSIONS: The number of MA enrollees with ATTR-CM diagnosis increased from 2019 to 2023. Approximately half of newly diagnosed patients received tafamidis treatment. Factors associated with greater risk of mortality were identified.

SPONSORSHIP: None

36 Descriptive analysis of ATTR-CM patients initiating tafamidis among Medicare Advantage enrollees

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BACKGROUND: Transthyretin amyloid cardiomyopathy (ATTR-CM) is a progressive and often fatal condition, typically diagnosed in patients >65 years. Tafamidis was approved in 2019 for treatment of ATTR-CM, followed recently by acoramidis and vutrisiran. There is lack of real-world evidence on impact of ATTR-CM treatment on health care resource use, spending, and clinical outcomes among Medicare Advantage (MA) enrollees.

OBJECTIVE: To examine ATTR-CM treatment trends, health care resource use (HRU), spending, treatment patterns, and clinical outcomes among MA enrollees after initiating tafamidis.

METHODS: This study was conducted using Humana Research Database. Annual trend in number of MA members treated with tafamidis was assessed from 2019 to 2023. Longitudinal cohort of MA members aged 18-89 years newly initiating tafamidis (index event) between 01/01/2020 and 02/28/2024, with 12 months pre-index and at least 6 months post-index enrollment, was identified. Treatment patterns, mortality, HRU, and health care spending were assessed. Pre/post comparisons were conducted among patients with 12 months of pre- and post-index continuous enrollment.

RESULTS: The number of patients treated with tafamidis increased from 1.9/100k in 2019 to 8.0/100k MA enrollees in 2023. Total 420 patients initiating tafamidis were identified. Mean (SD) age of overall cohort was 77.4 (7.1). During mean (SD) follow-up of 1.4 (1.0) years, 28.6% patients had cardiovascular hospitalization, 35.7% patients discontinued tafamidis, and 13.8% patients died. Among 223 patients with 12-months post-index enrollment, pre- vs post-index median per-patient-per-month (PPPM) all-cause health care spending was $2,140 vs $ 21,736 ($P < 0.001$) and pharmacy spending was $443 vs $19,508 ($P < 0.001$), with hospitalization seen in 50.2% vs 35.0% ($P = 0.001$) patients, median

PPPM cardiologist visits 0.25 vs 0.17 ($P = 0.008$) and median PPPM PCP visits 0.50. vs 0.42 ($P = 0.011$). Significant predictors of tafamidis treatment discontinuation were age 18-64 years (HR: 3.08, 95% CI: 1.13-8.40, $P = 0.028$), LIS or dual eligibility (HR: 0.39, 95% CI: 0.25-0.61, $P < 0.001$), baseline cardiovascular hospitalization (HR: 1.81, 95% CI: 1.24-2.65, $P = 0.002$), and shortness of breath at baseline (HR: 0.61, 95% CI: 0.41-0.89, $P = 0.011$).

CONCLUSIONS: Among ATTR-CM patients, the tafamidis treatment uptake increased from 2019 to 2023. Inpatient hospitalizations reduced during 12 months of follow-up. Overall, health care spending significantly increased after initiation of tafamidis treatment, which was mainly driven by pharmacy spending.

SPONSORSHIP: None

37 Health care costs and delays in treatment escalation in hypertension patients in the United States: Results from the BREAKTHROUGH real-world study

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BACKGROUND: According to 2017 ACC/AHA guidelines, patients with elevated blood pressure are recommended to have their hypertension treatments reassessed every 3 or 6 months.

OBJECTIVE: To describe the treatment journey of individuals with hypertension in the United States, characterizing health care costs during the first four antihypertensive medication lines of therapy (LOTs) and describing delays in treatment escalation.

METHODS: This retrospective analysis used claims from the MORE2 Registry and 100% Medicare Fee-for-Service (MFFS) database from 1/1/2019 to 12/31/2022 (MFFS), or 3/31/2024 (MORE2). Patients had ≥1 primary inpatient or ≥ 2 outpatient claims with a hypertension diagnosis (index date), were ≥18 years of age, and had ≥12 months of continuous enrollment prior to and ≥30 days following the index date. Antihypertensive LOTs were identified as the number of unique classes, beginning with the first class(es) prescribed within 28 days of the index date or the start date of LOT and continuing until a new treatment was initiated or all treatments were discontinued. Endpoints included all-cause medical costs, evaluated during each LOT and reported per patient per month (PPPM), and delayed treatment escalation was defined as progression from first to second LOT after 90 days.

RESULTS: In total, 19,060,253 patients were identified. Mean (SD) age was 66.8 (15.3) years, and the majority were female (55.3%) and MFFS beneficiaries (61.0%). Of those identified, 89.6% received a first LOT; 51.0% received a second after a mean (SD) of 449.3 [452.5] days after first LOT. Of patients progressing from first to second LOT, 60.5% escalated after 90 days. PPPM mean (SD) medical costs were $1,866 ($8,371) in the first LOT and peaked at $2,591 ($14,635) in the second LOT, representing a 38.9% increase from the first LOT. Among Medicare patients, PPPM mean (SD) medical costs increased by 22.8% from $2,307 ($6,750) in the first LOT to $2,833 ($11,495) in the second LOT, while among commercial patients, medical costs rose by 31.8% from $1,136 ($7,730) in the first LOT to $1,497 ($22,971) in the second LOT.

CONCLUSIONS: Most patients experienced treatment escalation more than 90 days after initial therapy, suggesting potential delays in treatment intensification relative to guideline recommendations. Additionally, all-cause medical costs increased after the first LOT, underscoring the increased economic burden of hypertension disease progression. These findings emphasize the need for timely and effective hypertension management.

SPONSORSHIP: AstraZeneca

38 Payer analysis of cholesterol management in US individuals with atherosclerotic cardiovascular disease during 2023: A study from the Family Heart Database

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BACKGROUND: Individuals living with atherosclerotic cardiovascular disease (ASCVD) need optimized LDL-C lowering therapy to achieve evidence-based LDL-C goals. The current NCQA/HEDIS cholesterol quality measure focuses only on statin use which is insufficient to ensure appropriate LDL-C goal achievement. Payer type may impact achievement of LDL-C targets in this population at increased risk for recurrent events.

OBJECTIVE: To measure payer-specific population-based LDL-C goal achievement to elucidate gaps in care providing clinically meaningful information beyond the current statin-based quality measure.

METHODS: Retrospective cohort study of the Family Heart Database of individuals with ASCVD prior to January 2023 with at least one medical claim (including paid, abandoned or rejected) and LDL-C measurement within 2023. Primary measures included mean LDL-C and percent of treated population at goal LDL-C of <70 and <55 mg/dL across payers. Major payment categories (Commercial, Medicare, Managed Medicaid, Medicaid, Assistance Programs, and Cash) were identified from medication claims. If multiple medication claims indicated more than one payment category, the individual was represented in both categories.

RESULTS: Adults (n = 3,217,634) with ASCVD; mean age 67.4 years, 48.2% women, 10.6% Black and 11.1% Hispanic individuals. Mean LDL-C was 88.2 mg/dL, with LDL-C < 70 and < 55 mg/dL goals achieved in 33.6% and 15.6% of the population, respectively. Mean LDL-C, and percent of the treated population with LDL-C<70 and<55 mg/dL varied across payment types as follows from relative best to least favorable: Medicare (84.9, 36.8, 17.1), Assistance Programs (89.9, 32.4, 5.2), Cash (90.6, 31.5, 14.7), Commercial (91.6, 30.3, 14.0), Managed Medicaid (92.2, 29.5, 13.2), Medicaid (95.2, 26.9, 12.5). LDL-C population-based goal attainment for LDL-C < 70 and < 55 mg/dL also varied across specific health plans within each category with relative best achieved: Commercial-Tricare West Health Net Federal Services (42.2, 21.1); Medicare-United Health Rx AARP (40.1, 19.0); Managed Medicaid-MEDI-CAL (39.0, 18.7).

CONCLUSIONS: In this cohort of 3.2 million US individuals with ASCVD, achievement of evidence-based LDL-C goals remains suboptimal. There is notable variability in these measures across payer types and across specific health plans within each category. Identifying payer-specific variability of goal achievement and gaps in care as well as establishment of a specific LDL-C goal-based quality measure may provide opportunities to reduce event rates in this at-risk population.

SPONSORSHIP: Family Heart Foundation

39 Treatment, testing, and outcomes from ST-elevation myocardial infarction (STEMI) at an academic health care system: A retrospective analysis

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BACKGROUND: Acute coronary syndrome, particularly ST-elevation myocardial infarction (STEMI), imposes a lifelong treatment and financial burden on patients in the United States due to high incidence, intensive interventions, and risk of recurrent adverse cardiac events.

OBJECTIVE: To describe health care resource utilization for STEMI patients receiving percutaneous coronary intervention (PCI).

METHODS: Adult patients who received PCI for STEMI at the University of Utah between 1/1/2017 and 12/31/2023 were included. Patient identification and data collection occurred within National Cardiovascular Data Registries and electronic medical records. Descriptive statistics were used to analyze care received during the hospitalization for PCI and at 5 years post-discharge. High-risk subgroups by TIMI flow grade and infarct location were also assessed.

RESULTS: A total of 781 patients (mean (SD) age 63 (13)) were eligible; most were male (73%), were White (94%), and had private insurance (66%). Upon hospital admission for PCI, patients had a median (IQR) BMI of 29 (25-33) kg/m^2, heart rate of 79 (66-93), and mean (SD) systolic BP of 145 (32). Current smokers accounted for 27% of the cohort, while 37% were never smokers. A history of heart failure (HF) was seen in 13% of patients. Other common comorbidities at baseline included hypertension (60%), dyslipidemia (51%), and obesity (42%). During hospitalization, patients (>90%) received anticoagulants, antiplatelets, P2Y12 inhibitors, aspirin, long-acting nitrates, statins, and antiplatelets, individually. Patients spent a median (IQR) of 3 (2-4) days in emergency care and 5% received a coronary artery bypass graft (CABG) in addition to PCI. Pre-PCI TIMI grade of 0-1 was present in 428 patients (55%) and 305 patients (39%) had an anterior wall infarction. At 5 years post-discharge, the most common medications were antiplatelets (81%), P2Y12 inhibitors (77%), beta blockers (73%), and statins (69%). HF-related office visits and hospitalizations were 13% and 7%, respectively. Among patients with pre-PCI TIMI grades of 0-1, rates of office visits and hospitalizations

for HF increased to 16% and 7%, respectively, and among patients with an anterior wall infarction, rates of these same encounters increased to 20% and 10%, respectively.

CONCLUSIONS: HF-related encounters post-discharge were high among patients with STEMI who received PCI, especially in subgroups with pre-PCI TIMI grades of 0-1 or anterior wall infarctions. This highlights an opportunity for clinical interventions to prevent HF within this population.

SPONSORSHIP: Boehringer Ingelheim

40 Retrospective analysis of cardiovascular, renal, and metabolic conditions in the Medicare population using 100% FFS claims data

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BACKGROUND: Cardiovascular, renal, and metabolic (CRM) conditions impose a substantial burden on the US Medicare population. Leveraging national FFS claims can inform real-world prevalence, costs, and care patterns of CRM.

OBJECTIVE: To assess the prevalence, health care resource utilization (HCRU), and economic impact of CRM conditions in the Medicare FFS population from 2016 to 2023.

METHODS: This retrospective cohort study used de-identified 100% Medicare FFS claims data (Parts A, B, and D) from 2016 to 2023. Beneficiaries aged 65+ were included if diagnosed with atherosclerotic cardiovascular disease or heart failure (C), chronic kidney disease (R), and/or type 2 diabetes (M). Patients were categorized into mutually exclusive health states: C only, R only, M only; dual combinations (C+R, C+M, R+M); and triple multimorbidity (C+R+M). Annual prevalence, HCRU, and Medicare costs (2023 USD), were reported overall and by condition type.

RESULTS: Over 40 million beneficiaries with CRM diagnoses were included, with 20 million unique patients in 2022 and 19.6 million unique patients in 2023. CRM prevalence increased from 2016-2023, with the largest growth among multimorbid patients, particularly those in the C+R+M and C+M groups. In 2023, among patients with any CRM diagnosis, health states prevalences were as follows: C only (31.7%), M only (18.9%), C+M (15.8%), C+R+M (11.8%), C+R (9.9%), R only (7.2%), and R+M (4.8%). Medicare expenditures were significantly higher for patients with ≥2 CRM conditions. Median total all-cause annualized spending was $3,995 overall and $5,572 for C+R+M. Among utilizers, inpatient institutional care reached a median of $30,759 overall and $43,895 for C+R+M. Other high-cost services among utilizers included SNF care ($22,738 overall; $31,617 for C+R+M), outpatient ($6,440; $10,823), home health ($7,221; $9,016), and hospice ($43,039; $32,804). CRM-specific spending in 2023, defined by claims with a CRM-related principal diagnosis, were a median $743 across all patients and $1,364 for C+R+M. From 2016 to 2023, CRM-specific spending rose 18% in real terms, with the steepest growth in C+M patients (27%).

CONCLUSIONS: Prevalence of CRM conditions is increasing and associated with high utilization and spending across care settings in the Medicare FFS population. These results also underscore the disproportionate cost burden associated with CRM multimorbidity and its importance when developing population health strategy, targeted interventions, and benefit design in Medicare.

SPONSORSHIP: Boehringer Ingelheim Pharmaceuticals, Inc.

41 Olezarsen and plozasiran in the treatment of familial chylomicronemia syndrome (FCS): Results from a matching-adjusted indirect comparison (MAIC)

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BACKGROUND: FCS is a rare genetic form of primary hypertriglyceridemia with an increased risk of acute pancreatitis (AP). Alongside strict adherence to an extremely low-fat diet, emerging data support apolipoproteinC-III (apoC-III) inhibitors olezarsen and plozasiran as therapeutic approaches to reduce triglycerides (TG).

OBJECTIVE: To compare the efficacy and safety of olezarsen 80 mg to plozasiran 25 mg in the BALANCE and PALISADE phase 3 studies, respectively.

METHODS: Indirect treatment comparisons were made using an anchored MAIC to account for cross-trial differences, weighting BALANCE's individual patient-level data to match published baseline characteristics in PALISADE. Matching variables included fasting TG and variables that showed significant ($P < 0.2$) treatment-by-covariate interaction in BALANCE, indicating treatment effect modification, assessed per study outcome. Risk of AP was compared for olezarsen 50-80 mg and plozasiran 25-50 mg because dose-stratified plozasiran data were not publicly available. Sensitivity analyses were conducted using different sets of matching variables to test the robustness of the results.

RESULTS: The MAIC included 22 patients receiving olezarsen 80 mg and 23 patients receiving placebo in BALANCE, and 26 patients receiving plozasiran 25 mg and 25 patients receiving placebo in PALISADE. Both trials enrolled patients with a fasting TG ≥880 mg/dL, and PALISADE enrolled clinically diagnosed in addition to genetically confirmed FCS patients. After weighting, patient characteristics were nearly identical between BALANCE and PALISADE, and BALANCE had an effective sample size (ESS) of 29.2-63.3 depending on the outcome. At 52 weeks, olezarsen was associated with improvement in fasting TG (mean difference [MD]: –15.51%; 95% confidence interval [CI]: –76.21, 45.20; ESS: 29.2), apoC-III (MD: –8.36%; 95% CI: –69.71, 53.00; ESS: 31.6), and non-high-density-lipoprotein cholesterol (–16.26%; 95% CI: –77.63, 45.11; ESS: 30.2); however, these differences were not statistically significant. Olezarsen was also associated with 30% lower risk of an AP event (risk ratio [RR]: 0.70; 95% CI: 0.07, 6.66; ESS: 63.3) and 50% lower risk of a serious adverse event (RR: 0.50; 95% CI: 0.10, 2.58; ESS: 42.8); results non-statistically significant. Results from sensitivity analyses were similar to the base case.

CONCLUSIONS: Based on an MAIC, olezarsen was associated with non-statistically significant improvement in efficacy and safety at 52 weeks compared to plozasiran in the treatment of patients with FCS.

SPONSORSHIP: Ionis Pharmaceuticals Inc.

Cell and Gene Therapies

46 Integrating cell and gene therapies into managed care: An analysis of US payer insights

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BACKGROUND: Cell and gene therapies (CGTs) hold immense promise but present unique challenges for managed care.

OBJECTIVE: To explore payer perspectives, coverage barriers, reimbursement models, and operational strategies for CGT access and integration.

METHODS: From February to March 2025, we conducted a qualitative study using double-blinded interviews with key CGT decision-makers across the US payer landscape. Interviews were 45-60 minutes and semi-structured and included quantitative Likert-scale ratings and open-ended qualitative feedback. Discussion topics included CGT access and adoption, formulary and approval process, value and reimbursement, provider networks, and outlook on CGTs' future. Data were anonymized and analyzed to identify key trends, variations, and consensus areas among payers.

RESULTS: Twenty payers participated in the study, including 7 national health plans, 7 regional health plans, 2 national managed Medicaid, 2 national managed Medicare, and 1 regional and 1 national integrated delivery network. Eleven payers held leadership roles within Pharmacy services, 7 had medical officer or director positions, and 2 held other leadership positions. Interviewed payer organizations represented approximately 280 million covered lives. Payers generally expressed a favorable view of CGT clinical value, with 90% agreeing they are safe and 80% agreeing they are efficacious. Despite this overall confidence, 95% of payers generally agreed that the US health care system is not adequately prepared for broad CGT adoption. The two most cited challenges for CGT reimbursement are high costs and long-term uncertainty. To mitigate financial risk, payers ranked stop loss as the preferred strategy, followed by risk pools and outcomes-based agreements. However, barriers to implementing innovative payment models persist, with the most frequently cited being member portability risk and difficulty of long-term patient tracking. Coverage policies vary widely by payer type. Payers most commonly relied on clinical trial inclusion/exclusion criteria, as well as the FDA label for coverage decisions. Utilization management is stringent, typically aligning with clinical trial criteria over FDA labels for prior authorization requirements.

CONCLUSIONS: Payers recognized the transformative potential of CGTs but highlighted challenges, including long-term outcomes, high costs, and member portability. Addressing these barriers will require collaboration among payers, providers, manufacturers, and policymakers to ensure effective CGT integration into managed care.

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47 Payer policies and access restrictions for CRISPR-based gene therapy in sickle cell disease and beta-thalassemia: A systematic review of US coverage frameworks

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BACKGROUND: Exagamglogene autotemcel (Casgevy), a one-time CRISPR/Cas9 gene therapy, received FDA approval in December 2023 for sickle cell disease (SCD) and in January 2024 for transfusion-dependent beta-thalassemia (TDT). Although the therapy shows clinical promise, access has been constrained by high costs, limited treatment sites, and uncertain reimbursement. As availability expands, payer policies increasingly influence patient access.

OBJECTIVE: To examine how US payers, including Medicaid programs, Medicare contractors, and commercial insurers, define coverage for Casgevy in SCD and TDT. Areas of focus included eligibility requirements, prior authorization, dosing restrictions, site-of-care policies, and reimbursement models.

METHODS: A systematic review was conducted from January 2023 through May 2025 following PRISMA 2020 guidelines. Sources included PubMed, Embase, CMS.gov, Medicaid websites, Medicare Administrative Contractor (MAC) portals, and commercial payer documents. Of 119 records identified, 89 full texts were screened and 28 were included. These comprised peer-reviewed articles, 13 Medicaid bulletins, 4 Medicare MAC coverage determinations from Palmetto GBA and Novitas, and 11 commercial policies. Two reviewers independently screened and extracted data using a structured tool. Discrepancies were resolved by consensus. Findings were grouped by payer type and coverage characteristics.

RESULTS: All 28 policies required patients to be at least 12 years old with documented severe disease. For SCD, most criteria included two or more vaso-occlusive crises annually, prior hospitalization, and failure or contraindication to hydroxyurea. For TDT, transfusion requirements ranged from 8 to 12 units per year. Twenty-six policies (93%) allowed a single lifetime dose. Twenty policies (71%) required administration at certified gene therapy or transplant centers. All prior authorization protocols required genetic confirmation and review by a specialist. Ten of 13 Medicaid programs referenced the Cell and Gene Therapy Access Model launched in January 2025. Five commercial payers reported piloting outcomes-based or milestone-based contracts. As of early 2025, an estimated 40 to 50 patients had started treatment, reflecting limited uptake and operational barriers.

CONCLUSIONS: Coverage for Casgevy remains highly restrictive. Narrow criteria, constrained capacity, and uneven payment model adoption continue to limit access. Broader implementation will require coordination between payers and providers, expanded site readiness, and more consistent reimbursement approaches.

SPONSORSHIP: None

48 The impact of the Cell and Gene Therapy Access Model on state Medicaid coverage of sickle cell disease gene therapies

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BACKGROUND: The CMS Cell and Gene Therapy (CGT) Access Model supports value-based purchasing (VBP) between Medicaid and manufacturers, initially targeting SCD gene therapies (GTs) (exagamglogene autotemcel) and Lyfgenia (lovotibeglogene autotemcel). SCD was chosen due to the disproportionate share of people with SCD covered by Medicaid and high therapy costs. The Model launched in May 2025 with 35 states covering 84% of Medicaid SCD beneficiaries. Participating states require CMS approval for VBPs and must adopt a standardized access policy based on CMS-negotiated key terms.

OBJECTIVE: To evaluate if the CGT Model (1) impacted Medicaid SCD GT coverage and prior authorization (PA) criteria and (2) influenced these trends in states that recently gained VBP approval.

METHODS: In June 2024, January 2025, and May 2025, we reviewed state Medicaid websites to identify SCD GT coverage and PA criteria for changes that may have resulted from participation in the CGT Model. We compared SCD GT management changes in states receiving VBP approvals from CMS in 2024 and 2025.

RESULTS: From June 2024 to May 2025, states with SCD GT covered status increased from 9 to 20 and preferred status increased from 6 to 15. In May 2025, 9 of 15 states cover both GTs with no preferred product, up from 3 of 6 in June 2024. Four states prefer exagamglogene and 2 prefer lovotibeglogene. Following the January 2025 review, 2 states moved from preferring 1 GT to preferring both while 1 moved from non-preferring both to preferring 1. Vaso-occlusive crisis (VOC) thresholds were used in 21 of 22 states. Nine of 22 states followed clinical trials: ≥4 VOCs in 2 years for lovotibeglogene; ≥2 VOCs/year in 2 years for exagamglogene. Colorado required 7 VOCs in 2 years. Five of 22 states did not require genetic confirmation of SCD or failure of hydroxyurea. Ten of 22 states had criteria disqualifying the patient if a sibling donor was available and permitted stem cell transplant. Three states have criteria related to infertility risks. Of the states receiving VBP CMS approval in 2024 and 2025 with PA criteria, 4 of 6 had similar PA criteria, including VOC thresholds aligned with product labeling.

CONCLUSIONS: States showed changes in SCD gene therapy coverage and preferences that are potentially linked to CGT Model participation. However, varying PA criteria suggest the Model's key terms have not significantly influenced

requirements—though timing may play a role. States with recent VBP approvals tend to have aligned PA criteria; these approvals may support broader VBP adoption beyond SCD and the CGT Model.

SPONSORSHIP: IPD Analytics

49 Utilization management and coverage restrictions for gene therapies in rare pediatric diseases: A systematic review of US payer policies from 2019 to 2025

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BACKGROUND: Gene therapies for rare pediatric diseases offer curative potential but face access barriers due to payer-imposed restrictions and inconsistent coverage criteria. High upfront costs, specialized administration, and variation in benefit design contribute to delays in care. Differences in utilization management practices across payers raise equity concerns for pediatric patients.

OBJECTIVE: To evaluate US payer coverage of FDA-approved gene therapies for rare pediatric indications between 2019 and 2025, focusing on eligibility requirements, prior authorization, benefit design, and alignment with regulatory labeling.

METHODS: A systematic review was conducted of payer policy documents published from January 2019 to May 2025. We analyzed 126 coverage documents for seven gene therapies (Zolgensma, Luxturna, Skysona, Roctavian, Elevidys, Hemgenix, Upstaza) across 25 Medicaid programs, 15 commercial insurers, and 8 Medicare Advantage plans. Extracted data included clinical restrictions, site-of-care limits, value-based contract references, and out-of-pocket costs. FDA alignment was assessed based on concordance with approved indications.

RESULTS: All payers required prior authorization and genetic confirmation. Among commercial insurers, 87% applied criteria more restrictive than FDA labeling, including age limits, specific mutations, and functional status thresholds. In contrast, 48% of Medicaid programs imposed similar restrictions, though 64% relied on individualized reviews. Commercial policies included a median of five utilization management elements per therapy, versus three for Medicaid. Most payers required administration at specialized centers. Commercial cost sharing ranged from 20% to 40%, while Medicaid typically imposed minimal or no patient cost. Medicare Advantage plans followed Part B cost-sharing rules and generally lacked therapy-specific coverage guidance. From 2019 to 2025, alignment between commercial coverage and FDA labeling increased from 42% to 58%.

CONCLUSIONS: Coverage for pediatric gene therapies remains variable and often restrictive. Commercial payers frequently impose criteria that go beyond FDA-approved indications, while Medicaid offers more flexible but non-standardized approaches. Improved alignment with regulatory labeling and simplified authorization processes may reduce barriers to access and promote more equitable coverage.

SPONSORSHIP: None

Central Nervous System

63 Employment status and care requirements among people with amyotrophic lateral sclerosis in the United States

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BACKGROUND: Amyotrophic lateral sclerosis (ALS) is a rare, fatal condition characterized by progressive motor neuron degeneration. People living with ALS (pALS) require multidisciplinary care alongside substantial lifestyle changes relating to loss of function. Many pALS are forced to adjust or stop their employment. Extensive caregiver support, home modifications, and use of various medical equipment may be required, leading to changes in employment status.

OBJECTIVE: To describe the effect ALS has on employment status, and care requirements for pALS in the United States.

METHODS: Secondary analysis of data collected between March and December 2024 were drawn from the Adelphi Real World ALS Disease Specific Programme, a cross-sectional survey of US neurologists and pALS. Neurologists reported on demographics, employment status, and caregiver support for consecutively consulting pALS. Analyses were descriptive.

RESULTS: Neurologists (n = 48) provided data for 401 pALS. Mean (standard deviation [SD]) age of pALS was 55.8 (14.4) years; 62% were male, and 74% were White. Mean (SD) ALSFRS-R score was 33.1 (10.8). Physicians reported 9% of pALS were in full-time employment, while 81% of pALS were working part-time, unemployed, retired, or on disability. Of those out of full-time employment, 61% of cases were directly due to ALS (49% of total sample). Of the 87 pALS in full (n = 39) or part-time employment (n = 49), 41% required some adaptations or modifications to their workplace due to their ALS—most commonly a need for extra/longer breaks (15%). Overall, 68% of pALS were receiving caregiver support, requiring a mean (SD) 51.8 (42.7) hours/week of care; of these, 51% were cared for by their partner/spouse.

Professional caregivers provided support for 17% of these pALS, with a mean (SD) of 34.0 (35.9) hours/week of care. Caregivers assisted with a range of activities, the most reported being transportation (60%) and home maintenance (54%). Half of pALS made home modifications; and 72% of pALS utilized mobility aids.

CONCLUSIONS: ALS directly affected employment for 49% of pALS, resulting in an inability to work full-time, many of whom also required support from caregivers as well as use of supportive aids and modifications. The need for these additional supports coupled with a loss of income through employment changes may result in increased out-of-pocket costs for pALS.

SPONSORSHIP: ALS Wave II DSP is a wholly owned Adelphi Real World Product. Mitsubishi Tanabe Pharma America, Inc., was one of the multiple subscribers to the DSP, and funded the analyses described here.

64 Managed care approaches to address unmet patient needs in multiple sclerosis (MS): AMCP Market Insights Program

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BACKGROUND: Multiple sclerosis (MS) is a chronic, immune-mediated disease characterized by substantial heterogeneity in clinical presentation, progression, and treatment response. Despite therapeutic advances, many patients experience ongoing disease activity and disability, underscoring persistent unmet needs. Managed care organizations play a critical role in improving access to effective treatments, optimizing disease management, and supporting value-based care strategies to address these gaps.

OBJECTIVE: To identify unmet patient needs in MS, review disease pathogenesis and evolving subtypes, examine advances in therapies targeting MS biology and disability, and highlight payer perspectives on treatment value, endpoints, and the move toward biologically based diagnosis.

METHODS: A multidisciplinary roundtable was convened by AMCP in December 2024, bringing together 10 participants, including health plans, integrated delivery networks, PBMs, an insurance brokerage firm, an MS patient organization, and a neurology specialist. The program included live polling to capture quantitative feedback and facilitated discussions to gather qualitative insights.

RESULTS: Polling among 10 participants identified top unmet needs in MS: preventing disability (80%); affordable treatments, access to specialists, and timely use of effective therapies (70% each); and disparities in communities of color and social determinants of health, along with timely diagnosis (60% each). All respondents agreed on the importance of addressing disability progression not related specifically to relapses and early detection, supporting use of the 2024 McDonald criteria. Participants emphasized the need for real-world evidence, updated guidelines, and early use of high-efficacy disease-modifying therapy (DMT). Key challenges included care fragmentation, lack of comparative data, need for standardized diagnostics and ICD-10 codes, and improved budget predictability tools. Participants expressed cautious optimism about Bruton's tyrosine kinase (BTK) inhibitors, viewing them as a novel approach with potential to address unmet needs, particularly in progressive MS.

CONCLUSIONS: These AMCP Market Insights program findings underscored the need for earlier diagnosis, timely access to high-efficacy therapies, and updated guidelines to improve MS outcomes. Payer and clinical stakeholders expressed cautious optimism about emerging therapies like BTK inhibitors. Collaborative, evidence-based approaches will be essential for managed care organizations to address persistent unmet needs and enhance care for individuals living with MS.

SPONSORSHIP: Sanofi

65 Use of health services by people living with Angelman syndrome

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BACKGROUND: Angelman syndrome (AS) is a rare genetic leukodystrophy affecting people of all ages. The prevalence is suspected to be 1 in 15,000 live births in the United States. While there have been previous reports of the cost of care, the burden to the health care system, and, ultimately, families, is not fully understood.

OBJECTIVE: To characterize the economic burden of medical care, in terms of dollars expended and frequency of health service utilization, for people living with AS.

METHODS: A retrospective cohort study was conducted using Komodo Health claims. Patients with AS were identified based upon two claims at least 30 days apart between January 2021 and December 2023 with an ICD-10 code of Q93.51. Patient characteristics and direct health care costs are reported for each calendar year. Costs were adjusted to 2024 US dollars using the Consumer Price Index for Medical Care. Health care utilization is described for inpatient, emergency room visits, and outpatient services. We also

provide some demographic description. We report charges for 2023 and 2024. Utilization is reported only for 2023 due to completeness of data.

RESULTS: A total of 1,109, 1,119, and 1,010 people living with AS were identified in 2021, 2022, and 2023 respectively. They were, on average, 19 years of age, 52% were male, and 50% were Medicaid beneficiaries. The most common comorbidities were seizures (76%), respiratory complications (36%), gastrointestinal disorders (41%), movement and mobility disorders (31%), sleep disorders (28%), and scoliosis (12%). Average total costs per person ranged from $33,989 in 2021 to $41,281 in 2023. In 2023, 14.6% of people with AS were hospitalized for at least one day and 38% made at least one visit to the emergency department during the year, with approximately 1/4 of those visits resulting in an inpatient admission. Of those with an inpatient visit, 36% included a stay in the ICU. The mean length of stay in the hospital was 11 days, the median was 5 days. Home health services were used by 52% of people with AS, and nearly 100% used outpatient and pharmacy services.

CONCLUSIONS: People living with AS make substantial use of health services. The average annual cost in excess of $35,000 represents a substantial cost to payers and the health system, but this cost represents but a fraction of the burden of AS to caregivers, families, and society.

SPONSORSHIP: Ionis Pharmaceuticals

66 Analysis on the net costs of administering a prior authorization policy for onabotulinumtoxinA in the chronic migraine population

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BACKGROUND: Prior authorizations (PAs) are a common utilization management technique meant to ensure the proper usage of certain medication per clinical treatment guidelines and/or approved indications. While cost containment may be another goal of PAs, the cost of administering and reviewing PAs must also be considered.

OBJECTIVE: To understand the annual net financial impact of administering a PA policy for onabotulinumtoxinA (onabotA) in the chronic migraine (CM) population.

METHODS: A cost calculator was constructed from the perspective of a hypothetical large national health plan of 10 million members using Microsoft Excel. First, the administration costs were calculated by multiplying the expected annual onabotA CM patient volume by the cost of reviewing each PA, renewal, and appeal, which was set at $80 per review and sourced from survey research data. Renewals were assumed to be required every 6 months. These costs were then compared to the annual cost-savings from the PA policy, which were calculated by the cost of onabotA therapy averted based on PA and renewal approval rates (91.2% and 98.1%, respectively). Approval rates were sourced from open health care claims data in PurpleLab. Cost-savings were then subtracted from administration costs to calculate the net financial impact of the PA policy.

RESULTS: In a hypothetical health plan of 10 million members, there was a total of approximately 8000 expected users of onabotA for CM. The annual net financial impact of administering the PA policy was approximately -$366,000, indicating a net loss to the health plan. It is important to note that this result is only when considering the CM indication, while onabotA has multiple approved indications for which a PA policy may be in place.

CONCLUSIONS: The cost of administering a PA policy for onabotA in the CM population exceeds the cost savings from the policy.

SPONSORSHIP: AbbVie Inc.

67 Characteristics of Medicare Part D–eligible patients at risk for qualifying for the concurrent use of opioids and benzodiazepines Star Measure

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BACKGROUND: The Medicare Star Ratings system is used by consumers to compare the quality of health plans. The ratings are published each year by the Centers for Medicare and Medicaid Services (CMS). Beginning in January of 2025, the concurrent use of opioids and benzodiazepines (COB) measure will be included in the rating calculation.

OBJECTIVE: To explore the characteristics of Medicare Part D members at risk of qualifying for the COB measure.

METHODS: Medicare eligible members who had at least one day of overlap during calendar year 2024 of both an opioid (OP) and benzodiazepine (BZD) prescription claim were gathered and followed from the date of the initial claim to the end of the calendar year. Members had to have an index date in the first six calendar months. To be classified as qualifying for the measure, members had to have two separate claims for both OPs and BZDs and reach a minimum of 30 days of overlap. Characteristics of age, sex, initial claim type, total OP and BZD claims, and time from index to qualifying were compared for those who qualified versus those who did not reach the threshold.

RESULTS: A total of 2,835 members were identified during 2024 as being at risk of qualifying for the COB measure. Of those, 1,364 (48.1%) reached the 30 day overlap requirement. Compared to non-qualifiers, those who qualified had a mean age of 67.6 years (vs 69.8, $P < 0.0001$), were more likely to be female (72.8% vs 69.3%, $P = 0.04$), have a mean BZD claim count of 7.8 (vs 4.1, $P < 0.0001$), a mean OP claim count of 9.7 (vs 5.5, $P < 0.0001$), and have a mean days from index claim to qualifying of 92.6 ($P < 0.0001$). For those who qualified, the largest proportion met the 30 day overlap criteria between 45 to 90 days post index claim (n = 414, 30.4%).

CONCLUSIONS: With the CMS addition of COB to the Star Measure ratings beginning with calendar year 2025 data, it is important for plans to understand the population at risk of qualifying in order to tailor interventions and improve their Star Ratings. This study indicates that the key time frame for intervention is within the first 90 days post index claim.

SPONSORSHIP: MedImpact Healthcare Systems, Inc.

68 Health care resource utilization and costs in patients with multiple sclerosis treated with ofatumumab vs ocrelizumab

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BACKGROUND: Multiple sclerosis (MS), a chronic autoimmune disease, imposes substantial economic burden for health care systems. Ofatumumab (OMB) and ocrelizumab (OCR) are CD20-directed monoclonal antibodies approved for treating relapsing MS. Real-world data can inform the economic impact of OMB vs OCR in a broad MS population.

OBJECTIVE: To compare MS-related health care resource utilization (HCRU) and associated costs between patients treated with OMB vs OCR.

METHODS: A retrospective cohort study was performed using Optum Clinformatics claims data (8/2019 to 7/2024) for adults with ≥1 OMB or OCR claim on or after 8/20/2020, ≥1 inpatient (IP) or ≥2 outpatient (OP) MS diagnoses ≥30 days apart, continuous enrollment for ≥12 months (M) pre- and ≥6M post-index, and persistent OMB or OCR use for ≥6M post-index. Treatment (tx)-naïve sub-cohorts included patients without MS-specific disease-modifying therapy (DMT) use 12M pre-index. Patients were matched 1:1 in overall and tx-naïve cohorts to balance demographics, disease characteristics, and resource use. MS-related HCRU and costs were defined as IP stays with primary MS diagnosis or OP/emergency department (ED) visits with MS diagnosis in any position, excluding claims with MS-related DMT codes. Rate ratios were used to compare HCRU outcomes; cost ratios were used to compare costs.

RESULTS: Of 2604 eligible patients (mean age: 49 years; 70% female), 751 were in OMB cohort (315 tx-naïve) and 1853 in OCR (1104 tx-naïve). Over a mean follow-up of 1.5 years, mean OP visits per patient-year (PPY) (95% CI) was 8.64 (8.19-9.11) in OMB vs 9.51 (9.03-10.01) in OCR, demonstrating 9% lower incidence for OMB (incidence rate ratio: 0.91; 95% CI: 0.84-0.98; $P < 0.05$). Mean OP cost PPY (95% CI) in follow-up was $3928 ($3448-$4475) in OMB vs $4807 ($4246-$5442) in OCR, equating to 18% lower OP costs for OMB (ratio: 0.82; 95% CI: 0.68-0.98; $P < 0.05$). Mean ED costs PPY (95% CI) in follow-up was $212 ($139-$326) in OMB vs $383 ($265-$555) in OCR, equating to 45% lower ED costs for OMB (ratio: 0.55, 95% CI: 0.31-0.98; $P < 0.05$). ED visits, IP visits, and costs were similar between groups. Consistent patterns were observed in the tx-naïve cohort, except ED costs.

CONCLUSIONS: OMB had significantly lower MS-related OP visits and costs and lower ED costs compared to OCR. These findings highlight a potential economic advantage of OMB for patients, providers, and health system managers aiming to reduce facility-based utilization and costs.

SPONSORSHIP: Novartis Pharmaceuticals Corporation

69 Effect of managed care educational interventions in multiple sclerosis during a period of advancing innovation

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BACKGROUND: While few new multiple sclerosis (MS) therapies were approved over the past decade, understanding of the disease—particularly smoldering inflammation and neurodegeneration—advanced significantly. This shift outpaced treatment guideline updates and payer policies, creating a gap between emerging evidence and managed care decision-making. To address this, a multi-year, multi-format continuing education (CE) program was launched to update managed care professionals on MS. The curriculum included consistent outcomes measurements across diverse learning formats. In 2023, the program featured a live AMCP symposium, webcast, on-demand activity, and infographic. The 2024-2025 series added another live symposium with simulcast and a podcast.

OBJECTIVE: To evaluate changes in knowledge and competence among managed care professionals regarding evolving MS pathophysiology and therapies, characterize learners and their engagement across formats, and describe payer coverage updates.

METHODS: This review analyzed data from multi-year CE activities. Learner demographics, engagement patterns, and post-activity changes in knowledge and confidence were assessed across activities.

RESULTS: Seven hundred fifteen individuals registered for at least one CE activity from March 2023 to April 2025; 255 learners completed pre- and post-surveys. Learners were primarily clinical pharmacists (20%), specialty pharmacists (19%), pharmacy directors (9%), and nurses (9%) with varying years of experience; 14% of learners completed more than one CE activity. Confidence in describing neuroinflammation rose from 37% to 81% ($P < .01$), and in assessing BTK inhibitors from 33% to 70% ($P < .01$). Learners improved 33% in identifying disease-modifying therapies that cross the blood-brain barrier and increased confidence in interpreting real-world evidence by 30% post-activity. Reported intent to change or maintain practice/policies because of the education was 84%, with planned changes including applying evidence to drug evaluations (37%), adopting collaborative care (31%), and incorporating pharmacoeconomic evaluations (18%). The highest engagement occurred with live webcasts (33%).

CONCLUSIONS: CE for managed care professionals can fill gaps in disease state knowledge and competence to support payer policy changes in the absence of updated guidelines. Participation across multiple CE activities reflects sustained interest in emerging science. Participation across formats underscores the value of diverse educational interventions in informing payer decision-making during periods of rapid innovation.

SPONSORSHIP: Sanofi

70 Managed care approaches to address unmet patient needs in idiopathic hypersomnia (IH): AMCP Market Insights program

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BACKGROUND: Idiopathic hypersomnia (IH) is a sleep disorder that causes excessive daytime sleepiness, sleep inertia, and substantially decreased quality of life and that affects nearly 100,000 Americans by some estimates. Comorbidities are frequent, and delays in diagnosis complicate treatment. IH is primarily managed with off-label stimulants and wakefulness-promoting agents; currently, lower sodium oxybate is the only Food and Drug Administration (FDA)–approved treatment option.

OBJECTIVE: To gain insights into health plan best practices for IH diagnosis and management.

METHODS: A multidisciplinary virtual panel was convened by AMCP in November 2024, bringing together 9 participants, including representatives from health plans, a patient advocacy group, and a sleep medicine specialist, among others. The program included live polling to capture quantitative feedback and facilitated discussions to gather qualitative insights.

RESULTS: Panelists acknowledge that disease burden and delays in diagnosis significantly impact the quality of life of patients with IH and identified improving timely, accurate diagnoses as a key issue in IH. Regarding drug management interventions, diagnosis by a sleep medicine specialist is required as part of the coverage criteria according to most panelists, as is an adequate trial of lower-cost generic options prior to coverage of branded agents. Panelists appreciate the utility of FDA approval; however, in a condition like IH where most recommended medications are off-label but have a supporting body of evidence for their use, consensus guidelines are often the primary driver of coverage decisions rather than solely FDA approval. Panelists suggested the following health plan best practices as part of an overall management strategy for IH: provider education, facilitating referrals to sleep medicine specialists and laboratories, reviewing coverage policies according to the FDA label and available consensus guidelines, and evaluating the safety of individual medications and the presence of comorbidities.

CONCLUSIONS: These AMCP Market Insights program findings underscore the need for more timely diagnoses in IH via education in primary care and streamlined referrals to sleep specialists, for example. Sleep specialists can facilitate optimal treatment by assessing individual patient characteristics against available off-label and FDA-approved agents.

SPONSORSHIP: Jazz Pharmaceuticals, Inc.

71 Health care resource use and clinical burden in narcolepsy: An analysis of the All of Us research program

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BACKGROUND: Narcolepsy is a central disorder of hypersomnolence primarily characterized by excessive daytime sleepiness. While the clinical burden of narcolepsy is known, key social determinants of health (SDoH) and the economic burden remain poorly understood.

OBJECTIVE: To describe health care resource utilization (HCRU) and comorbidity burden among US individuals with narcolepsy, overall and stratified by household income (HHI).

METHODS: A retrospective, observational study analyzed electronic health record (EHR) and survey data from the All of Us research program. Individuals with narcolepsy were identified using SNOMED codes (1/1/2009 to 1/31/2022). Non-narcolepsy participants were matched 3:1 to those with narcolepsy at index (earliest narcolepsy diagnosis date) on age, sex, earliest EHR encounter, time in EHR, and SDoH survey completion. Regression models estimated adjusted incidence rate ratios (IRRs) and odds ratios (ORs) with 95% confidence intervals (CIs) for HCRU (reported per patient per month [PPPM]) and comorbidities over baseline and follow-up periods, overall and by HHI (<$50k, ≥$50k).

RESULTS: In total, 2766 participants (narcolepsy: n = 694; non-narcolepsy: n = 2072) were identified (mean age: 49 years; 70% female). In unadjusted analyses among those with HCRU >0, individuals with vs without narcolepsy had higher mean (standard deviation) numbers of inpatient days (IP; 0.25 [0.55] vs 0.14 [0.23]), outpatient visits (OP; 1.34 [1.84] vs 0.77 [1.16]), and emergency department visits (ED; 0.21 [0.36] vs 0.15 [0.30]) PPPM. Similar trends were observed when stratified by HHI. In adjusted models, those with vs without narcolepsy had higher IRRs (95% CI) for IP days (2.07 [1.55, 2.78]) and OP (1.51 [1.35, 1.70]) and ED visits (1.70 [1.19, 2.43]) in baseline, as well as in follow-up. Higher proportions of those with vs without narcolepsy had cardiometabolic (CM) comorbidities, particularly among the lower HHI group (hyperlipidemia: <$50k: 34.0% vs 24.7%; ≥$50k: 32.8% vs 28.4%; obesity: <$50k: 38.0% vs 23.5%; ≥$50k: 22.7% vs 16.7%). The associations between narcolepsy and any CM comorbidity and obesity were stronger among the lower- vs higher-income groups (OR [95% CI]: any CM comorbidity: <$50k: 2.29 [1.70, 3.10]; ≥$50k: 1.69 [1.21, 2.34]; obesity: <$50k: 2.09 [1.54, 2.83]; ≥$50k: 1.52 [1.05, 2.20]).

CONCLUSIONS: Narcolepsy is associated with a higher economic and comorbidity burden, which is exacerbated by socioeconomic disparities. Earlier or more intensive interventions may be warranted to improve outcomes, particularly among lower-income individuals.

SPONSORSHIP: Jazz Pharmaceuticals

72 Treatment patterns among patients with newly diagnosed epilepsy in the United States

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BACKGROUND: While prior studies have evaluated treatment patterns among patients with epilepsy in the United States, many predate recent therapeutic advancements and do not categorize antiseizure medications (ASMs) by mechanism of action (MOA).

OBJECTIVE: To describe treatment patterns among newly diagnosed patients with epilepsy, including treatment duration, sequencing, and transitions based on MOA.

METHODS: This retrospective study used 100% Medicare Fee-for-Service claims and the Inovalon MORE2 closed claims database (01/01/2016 to 12/31/2023) to identify patients with incident epilepsy (01/01/2017 to 12/31/2019), defined by ≥2 outpatient or ≥1 inpatient claims with specific ICD-10 codes (G40.0X, G40.1X, G40.2X, G40.5X, G40.80X, G40.89, G40.9X). The index date was defined as the initiation of the first line of therapy (LOT1) lasting ≥30 days. LOTs were constructed using daily drug arrays, with agents started within 30 days of index considered part of LOT1. LOTs ended at discontinuation (≥60-day gap in all treatment), switch (new agent with <30 days overlap), augmentation (new agent with ≥30 days overlap), or partial drop (discontinuation of one or more agents for ≥60 days). Up to four LOTs were captured per patient. ASMs were grouped by MOA: GABA, sodium channel blockers, calcium channel blockers, SV2A, AMPA, and other/mixed.

RESULTS: A total of 90,738 patients met inclusion criteria (median age 58 years; 55% female; 61% Caucasian). Among those initiating treatment, 87% of patients began with a single MOA regimen, with 41% of patients specifically initiating therapy with an SV2A. Sankey analysis revealed that 34% of patients remained on the same MOA from LOT1 to LOT2. A notable portion who changed therapies eventually returned to their index MOA; by LOT3, 27% of those who had changed therapies in LOT2 had reverted to their index MOA. The median duration of treatment was 5.4 months in LOT1, 3.8 months in both LOTs 2 and 3, and 3.3 months in LOT4. The median time from the start of LOT1 to the initiation of LOT2 was 10.0 months, decreasing to 6.4 months between LOTs 2 and 3, and 5.8 months between LOTs 3 and 4.

CONCLUSIONS: Patients with newly diagnosed epilepsy appear to cycle through ASMs with previously tried MOAs, with a notable portion eventually returning back to their

index MOA. Time to next treatment shortens with each line of therapy, indicating faster treatment changes in later lines. This pattern underscores not only the limited long-term effectiveness of existing ASMs but also the lack of novel MOAs in the current therapeutic landscape.

SPONSORSHIP: Xenon Pharmaceuticals Inc.

73 Persistence with eptinezumab and other preventive treatments for chronic migraine in the United States: Results of a retrospective, observational cohort study

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BACKGROUND: In 2018, a new class of anti–calcitonin gene–related peptide (aCGRP) preventive treatments was introduced. Given the entry of these newer agents, it is important to understand persistence among these therapies alongside onabotulinumtoxinA, which is commonly used for migraine prevention.

OBJECTIVE: To evaluate persistence in adults with chronic migraine (CM) prescribed preventive aCGRP therapies or onabotulinumtoxinA.

METHODS: This claims-based, observational cohort study used data from the Aetna commercially insured (CI) and Medicare Advantage (MA) database collected between February 2020 and July 2024. This study included adults ≥18 years with a CM diagnosis within the 24-month observation period, defined as ≥12 months of pre- and post-index continuous coverage, who had a claim for an FDA-approved migraine-specific preventive treatment (gepants [atogepant or rimegepant (preventive dosing)], subcutaneous [SC] aCGRP monoclonal antibodies [mAbs], eptinezumab, or onabotulinumtoxinA). Index was the initiation date of the most recent qualifying treatment episode. The following outcomes were evaluated separately for the CI and MA subgroups over the 12 months post-index: persistence (based on days on therapy), proportion of days covered (PDC), and medication possession ratio (MPR). Weighted sensitivity analyses were also conducted on these outcomes.

RESULTS: This study included 76 and 164 participants on eptinezumab; 642 and 797 on gepants; 2073 and 2194 on SC aCGRP mAbs; and 1671 and 2638 on onabotulinumtoxinA in the CI and MA subgroups, respectively. Twelve-month unweighted persistence with eptinezumab (52.6% and 31.7%) was comparable to that with onabotulinumtoxinA (48.4% and 39.6%) and higher than with gepants (21.7% and 16.8%) and SC aCGRP mAbs (40.8% and 29.6%). Twelve-month unweighted PDC and MPR results paralleled 12-month persistence findings based on days on therapy. Participants were significantly more likely to discontinue SC aCGRP mAbs and gepants than eptinezumab (all $P \leq 0.003$) in both populations. Unweighted results were validated by the weighted sensitivity analysis.

CONCLUSIONS: As an important component of migraine care, it is critical to assess real-world treatment persistence. This analysis focused on preventive aCGRP therapies and onabotulinumtoxinA. Eptinezumab was similar to onabotulinumtoxinA and higher than gepants and SC aCGRP mAbs across multiple persistence and compliance measures, indicating favorable prospects for long-term, real-world adherence.

SPONSORSHIP: H. Lundbeck A/S (Copenhagen, Denmark)

74 Longitudinal assessment of treatment costs in patients with spinal muscular atrophy receiving disease-modifying therapies

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BACKGROUND: Spinal muscular atrophy (SMA), a rare neuromuscular disorder, was a leading genetic cause of infant mortality prior to the introduction of disease-modifying therapies (DMTs). Three DMTs are approved in the United States for SMA: nusinersen (initial approval 2016; intrathecal injection; 4 loading doses over 3 months followed by once every 4 months; all ages), risdiplam (initial approval 2020; once-daily oral solution/tablet; all ages), and onasemnogene abeparvovec-xioi (initial approval 2019; one-time intravenous infusion; patients aged <2 years).

OBJECTIVE: To assess, given their expected long-term use, real-world treatment costs (medication and administration) associated with nusinersen and risdiplam.

METHODS: Patients with SMA receiving nusinersen or risdiplam aged ≥2 years were identified from the 2016-2024 Komodo Health Research Database Plus. Dosing patterns and treatment costs were assessed each year separately for nusinersen (up to 5 years) and risdiplam (up to 4 years).

RESULTS: A total of 2743/1121 patients treated with nusinersen/risdiplam, respectively, were included, with the median (IQR) age at 17(9, 30)/23(10, 36) years, close to half covered by Medicaid (42.5%/46.5%), followed by commercial plans (41.1%/31.5%) and Medicare (14.5%/20.6%). Median

(IQR) follow-up was 5.5 (3.7, 6.7) years for nusinersen-treated patients and 1.1 (0.6, 3.1) years for risdiplam-treated patients. Among nusinersen-treated patients, 2511 (91.5%) had evaluable data in year 2: 1683 (67.0%) maintained on treatment, while others discontinued or switched to risdiplam; in year 5, 1905 (69.4%) had evaluable data and 753 (39.5%) maintained on nusinersen, with an overall median 3 injections per year. Median annual treatment cost of nusinersen was $504,173 in year 1 and $438,788-$548,608 in years 2-5. Among patients treated with risdiplam, about half (544, 48.5%) discontinued in the first 3 months; in year 2, 556 (49.6%) had evaluable data: 413 (74.3%) maintained on risdiplam, while others discontinued or switched to nusinersen; in year 4, 273 (24.4%) had evaluable data and 174 (63.7%) maintained on risdiplam. High discontinuation of risdiplam in year 1 resulted in a median annual risdiplam cost of $143,331 in year 1. Among those continuing risdiplam, median costs were $257,681-$289,340 in years 2-4.

CONCLUSIONS: Among patients with SMA treated with nusinersen or risdiplam, low treatment persistence was observed. Patients who maintained on the respective therapies consistently incurred high treatment costs over time.

SPONSORSHIP: Novartis Pharmaceuticals Corporation

75 What aspects of treatment are important to people living with neuromyelitis optica spectrum disorder (NMOSD)? A qualitative study

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BACKGROUND: NMOSD is a rare autoimmune disease that affects the optic nerve and spinal cord, leading to vision loss and paralysis. Several treatments aim to suppress inflammation and prevent future relapses. There has been little research exploring patients' experience of NMOSD and what matters most to people when making treatment decisions.

OBJECTIVE: To explore patients' experiences of NMOSD and treatment and to identify aspects of NMOSD treatments that are important to patients.

METHODS: A review of published literature and one-to-one virtual interviews with expert physicians were used to develop study materials for virtual focus groups with adults living with NMOSD. Ethics approval was obtained. Participants were asked to rank a list of treatment attributes in order of importance before taking part in the focus group. Focus group discussions followed a semi-structured guide. Deidentified transcripts were thematically analyzed using MAXQDA.

RESULTS: The literature searches identified 9 clinical trials, 6 qualitative studies, and 6 quantitative studies exploring patients' experiences of NMOSD and treatment. The list of treatment attributes identified from the review were refined in interviews with two expert physicians. Seven women living with NMOSD in the United States (mean age 37 years) took part in two focus groups. Themes identified from the focus groups included 1) symptoms and their impact, 2) impacts on quality of life, 3) experiences and perceptions of relapse, 4) experiences and perceptions of treatment, and 5) important aspects of treatment. Participants reported experiencing symptoms including nerve pain, visual impairment, fatigue, swelling, and paralysis. Symptoms impacted activities of daily living (e.g., walking, personal care), family life, the ability to work, and independence (e.g., being unable to drive because of vision loss). Participants identified the prevention of relapse and disability as the most important aspects of NMOSD treatment. Other attributes of importance to participants were improvement of symptoms, the risk of side effects, the need for additional treatment (e.g., steroids), regulatory approval, out-of-pocket costs, mode and frequency of administration, safety in pregnancy, and requirement for vaccination.

CONCLUSIONS: This qualitative study highlighted the impacts of NMOSD and identified aspects of treatment that may be important to people living with NMOSD when making decisions about treatment. The findings will be used to develop a quantitative survey to assess the relative importance of each attribute.

SPONSORSHIP: The study is sponsored by Amgen Inc.

76 Retention rates across clinical trials of anti-CGRP monoclonal antibodies for migraine prevention

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BACKGROUND: Eptinezumab, an anti–calcitonin gene–related peptide (CGRP) monoclonal antibody (mAb), has demonstrated early and sustained migraine-preventive effects and a favorable safety profile in adults with migraine in clinical trials.

OBJECTIVE: To assess retention rates across select phase 3/3b trials of eptinezumab, as well as similarly designed trials of subcutaneous anti-CGRP mAbs.

METHODS: Clinical trial data were used to assess retention rates for adults treated with eptinezumab and other anti-CGRP mAbs for prevention of migraine. Included eptinezumab trials were the 104-week, open-label, single-arm PREVAIL trial and 72-week DELIVER trial (included 24-week placebo [PBO]-controlled and 48-week dose-blinded extension period). Similar trials of other anti-CGRP mAbs relative to PREVAIL (≥48-week trials in chronic migraine [CM]) were included: REGAIN (galcanezumab), phase 2 trial (erenumab) and HALO CM (fremanezumab). For DELIVER (trial in participants for whom 2-4 migraine-preventive treatments have failed), similar trials of other anti-CGRP mAbs were included: CONQUER (galcanezumab), LIBERTY (erenumab), and FOCUS (fremanezumab). In general, retention rates were calculated by dividing number of participants who completed the trial/visit by number of participants enrolled/randomized to active treatment.

RESULTS: Eptinezumab demonstrated high retention rates of 78.1% at the end of the PREVAIL trial (Week 104) and 90.4% at the end of the DELIVER extension period (Week 72). Eptinezumab exhibited high long-term retention rates throughout PREVAIL in participants with CM, with retention rates of 92.2% and 89.8% at Weeks 48 and 60, respectively. The retention rate for galcanezumab was 80.7% at Week 48 (end of REGAIN); retention rates for erenumab and fremanezumab were 74.1% and 79.0%, respectively, at Week 64 (end of the phase 2 and HALO CM trials, respectively). Among individuals with migraine for whom 2-4 prior migraine-preventive treatments have failed, retention rates were high (>95%) across anti-CGRP mAbs at Weeks 12 and 24. Retention rates for included trials beyond 24 weeks were only available for eptinezumab (DELIVER; >90% through Week 72) and erenumab (LIBERTY; 85% by Week 64).

CONCLUSIONS: Eptinezumab demonstrated high, long-term retention rates for preventive treatment in participants with CM and those with migraine for whom 2-4 prior migraine preventive treatments have failed. These findings suggest a high level of participant satisfaction with continued treatment of eptinezumab.

SPONSORSHIP: H. Lundbeck A/S (Copenhagen, Denmark)

77 Productivity losses among individuals diagnosed with narcolepsy or idiopathic hypersomnia

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BACKGROUND: Narcolepsy and idiopathic hypersomnia (IH) are associated with higher comorbidity burden and health care costs, compared to the general population; however, data on productivity losses and associated indirect costs are limited.

OBJECTIVE: To describe productivity losses and direct and indirect costs in individuals with narcolepsy or IH compared with individuals without narcolepsy or IH, respectively.

METHODS: MarketScan linked to the Health and Productivity Management (HPM) Database (01/2017 to 12/2023) was used to identify individuals with narcolepsy or IH (using ICD-10 diagnosis codes), propensity score matched 1:2 to individuals without narcolepsy or IH, respectively, on demographics and matched diagnosis (index) date. Inclusion criteria included age 18 to 65 years and 365 days of continuous medical, pharmacy, and HPM enrollment in both the pre- and post-index periods. Short-term disability (STD), long-term disability (LTD), workplace absence (WA), and workers' compensation (WC) days missing from work and their corresponding indirect costs were descriptively analyzed.

RESULTS: A higher proportion of individuals with narcolepsy had a claim for STD (n = 351/2553; 13.7%) compared with non-narcolepsy (n = 404/5106; 7.9%); LTD (n = 16/2553; 0.6% vs n = 28/5106; 0.5%) and WC (n = 56/1812 vs n = 111/3624; both 3.1%) claims were similar between groups. A smaller proportion of individuals with narcolepsy had WA claims (n = 205/407; 50.4% vs n = 509/814; 62.5%). Individuals with narcolepsy had 18 more days of STD off, 30 more days of LTD off, and 0.5 more days of WA off but had 6 fewer days of WC off. This corresponded to higher STD ($2983), LTD ($4977), and WA ($74) indirect costs but lower WC ($882) indirect costs in individuals with narcolepsy compared with non-narcolepsy. A higher proportion of individuals with IH vs non-IH had a claim for STD (n = 99/950; 10.4% vs n = 151/1900; 7.9%), LTD (n = 7/950; 0.7% vs n = 8/1899; 0.4%), WC (n = 23/597; 3.9% vs n = 34/1194; 2.9%), and WA (n = 140/179; 78.2% vs n = 243/358; 67.9%). Compared with non-IH individuals, individuals with IH had more STD (1), LTD (6), WC (14), and WA (1) days off, corresponding to higher STD ($144), LTD ($899), WC ($2372), and WA ($129) indirect costs.

CONCLUSIONS: Individuals with narcolepsy or IH had higher indirect costs than those without these conditions, due to higher disability work absences and associated productivity losses. Findings underscore the need for improved management to mitigate excess personal and societal costs.

SPONSORSHIP: Jazz Pharmaceuticals

78 Sustained reductions in monthly headache days with long-term eptinezumab treatment for chronic migraine: Post hoc analysis of the phase 3 PREVAIL study

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BACKGROUND: The phase 3 PREVAIL study, a single-arm, open-label, long-term safety trial, demonstrated a favorable safety profile that aligned with other trials and showed reductions in migraine burden over a 2-year period for participants treated with eptinezumab.

OBJECTIVE: To evaluate whether early clinical response (ie, ≥50% or ≥75% reduction in headache days within the first 1 or 2 doses) using headache frequency from the Migraine Disability Assessment (MIDAS) predicted long-term maintenance of response.

METHODS: PREVAIL was a single-arm, open-label trial that evaluated the long-term outcomes of eptinezumab treatment in adults aged 18 to 65 years with chronic migraine (CM). Participants received 300 mg of eptinezumab administered intravenously every 12 weeks. This post hoc analysis assessed the proportion of participants with a ≥50% or ≥75% reduction in monthly headache days (MHDs), based on the reduction in MIDAS-derived headache frequency after the first (Weeks 1-12) or second (Weeks 13-24) dosing intervals, who sustained that reduction through the subsequent 12-week dosing intervals up to Week 84.

RESULTS: Out of the 128 participants enrolled in PREVAIL, 100 had complete MIDAS-derived headache frequency data at all time points through Week 84 and were included in this post hoc analysis. Among the 78 (78%) participants who achieved ≥50% reduction in MHDs at Weeks 1-12, 78% (61) maintained that reduction through the subsequent dosing intervals up to Week 84. Likewise, of the 77 (77%) participants who attained ≥50% reduction in MHDs at Weeks 13-24, 83% (64) maintained that reduction through the remaining dosing intervals. For the participants with ≥75% reduction in MHD at Weeks 1-12 (63 participants [63%]) and Weeks 13-24 (55 participants [55%]), 54% (34) and 69% (38), respectively, maintained that reduction through the subsequent dosing intervals.

CONCLUSIONS: More than half of the participants who achieved ≥50% or ≥75% reduction in MHDs following the first or second dose continued to experience reductions in headache frequency with ongoing eptinezumab treatment. This suggests that an early response may serve as a predictor of sustained response.

SPONSORSHIP: H. Lundbeck A/S (Copenhagen, Denmark)

79 Prevalence and incidence of generalized anxiety disorder among adults in the United States

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BACKGROUND: Generalized anxiety disorder (GAD) is a chronic psychiatric illness characterized by excessive, diffuse, and uncontrollable worry. GAD impairs functioning, diminishes quality of life, and is associated with a substantial economic burden. Yet despite its widespread impact, prior estimates of incidence and prevalence and burden of GAD are outdated and have varied widely in the literature.

OBJECTIVE: To characterize the incidence and prevalence of GAD in adults in the United States using claims data.

METHODS: This retrospective study used closed claims data from the Komodo Healthcare Map database to examine patients with GAD. Patients were identified using ICD-10 diagnosis codes and GAD-related pharmacological treatments. Payer-complete claims were used to estimate annual and multi-year prevalence and incidence. Prevalence estimates were calculated by applying diagnosis rates (by age, gender, and payer channel strata) over each time period from the Komodo database and scaling these estimates to the US population using Census data. The denominator for diagnosis rates included patients with continuous enrollment during each reported year. Incidence was estimated by identifying patients with a new GAD diagnosis in a given year, following at least two years of continuous enrollment without a prior GAD diagnosis.

RESULTS: The annual 1-year prevalence of GAD among US adults steadily increased from 5.4% (13.3M) in 2020 to 6.6% (16.4M) in 2023. For the years 2021-2023, the projected 3-year prevalence was 25.3M (10.3% of the US adult population).

Patients were predominantly female (67.4%), middle-aged (mean age: 43.7), and commercially insured (60.6%; as compared to 21.5% for Medicare and 17.9% for Medicaid). Demographic distributions stayed relatively consistent year over year over this time frame, with a median age of 41 years. Annual incidence rate ranged from 2,082 cases per 100,000 in 2020 to 2,267 cases per 100,000 in 2023, suggesting an influx of newly diagnosed cases year over year.

CONCLUSIONS: These findings suggest that more than 1 in 10 US adults were affected by GAD over a three-year period, with annual prevalence steadily increasing from 2020 to 2023. Given the lack of current data, these real-world findings highlight the substantial and growing burden of GAD in the US population; this research sheds light on the magnitude of GAD, utilizing real world data. Future research could elucidate this burden by identifying the clinical, economic, and humanistic challenges underlying these epidemiologic estimates.

SPONSORSHIP: Mind Medicine (MindMed) Inc.

80 Health care resource utilization and costs among individuals with narcolepsy and idiopathic hypersomnia in the United States

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BACKGROUND: People with narcolepsy or idiopathic hypersomnia (IH) often have sodium-associated comorbidities, which may contribute to economic burden.

OBJECTIVE: To quantify health care resource utilization (HCRU) and costs for individuals with vs without narcolepsy or IH.

METHODS: Komodo Research Data (01/01/2016 to 01/31/2024) were used to identify continuously enrolled individuals diagnosed with narcolepsy or IH (index: first diagnosis) and 2 comparator cohorts without narcolepsy or IH (index: randomly selected), entropy balanced 1:5 on demographics. Individuals with narcolepsy or IH with ≥1 sodium-associated risk factor (RF) in the 12 months pre-index were classified as high-risk (HR); those without any RFs were low-risk (LR). Negative clinical outcomes (NCOs) were new-onset or progression of sodium-associated events occurring after index. Annual all-cause HCRU and costs (2024 USD) were assessed over ≥12 months post-index and compared between individuals with narcolepsy or IH vs comparators and HR vs LR subgroups using log link generalized linear models, reported as incidence rate ratios (IRRs) or mean differences (MDs) with 95% confidence intervals.

RESULTS: Among individuals with narcolepsy or IH (narcolepsy: n = 29,317; IH: n = 11,951) vs comparators (non-narcolepsy: n = 146,585; non-IH: n = 59,755), annual mean inpatient (IP) days (narcolepsy: IRR = 2.18 [1.99-2.40]; IH: IRR = 1.35 [1.18-1.56]), and outpatient (OP; narcolepsy: IRR = 2.13 [2.09-2.16]; IH: IRR = 2.17 [2.12-2.22]) and emergency department (ED; narcolepsy: IRR = 1.74 [1.66-1.82]; IH: IRR = 1.52 [1.42-1.62]) visits were higher. Mean annual costs for individuals with narcolepsy or IH were higher vs comparators, including all-cause (narcolepsy: MD = $9234 [$8815-$9653]; IH: MD = $6966 [$6453-$7478]), RF-related (narcolepsy: MD = $1865 [$1706-$2023]; IH: MD = $1399 [$1250-$1549]), and NCO-related (narcolepsy: MD = $2517 [$2331-$2704]; IH: MD = $1713 [$1470-$1955]) costs. Individuals with narcolepsy or IH were more likely to see specialists (neurology/sleep medicine [narcolepsy: 57.4% vs 12.9%; IH: 57.6% vs 12.3%]; cardiology [narcolepsy: 37.7% vs 22.3%; IH: 38.2% vs 21.2%]). Annual mean IP days, OP and ED visits, and all-cause annual costs were higher in HR individuals (narcolepsy: n = 17,227; IH: n = 7542) vs LR individuals (narcolepsy: n = 12,090; IH: n = 4409), with 77%-80% of total mean cost differences attributable to RFs or NCOs.

CONCLUSIONS: Individuals with vs without narcolepsy or IH have higher economic burden, often due to sodium-associated RFs and NCOs. Risk management to mitigate avoidable HCRU and costs is needed.

SPONSORSHIP: Jazz Pharmaceuticals

81 The global societal burden of Alzheimer disease by severity: A targeted literature review

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BACKGROUND: Alzheimer disease (AD) is among the costliest illnesses for older individuals and is increasingly straining health care systems and caregivers alike. Previous reviews fail to present a comprehensive perspective, overlooking the nuanced interplay, and totality of, unmet medical needs.

OBJECTIVE: To characterize the total societal burden of AD by care setting and disease severity.

METHODS: A targeted literature search of systematic reviews, cost-of-illness, and observational studies published between 2013 and 2024 was conducted on MEDLINE and Embase to identify articles reporting the economic burden of AD. Gray literature was hand-searched. Both direct and

indirect costs were assessed, including societal burdens not often reported by AD-specific cost-of-illness studies such as financial delinquencies.

RESULTS: A total of 81 articles were reviewed, including 20 systematic reviews and 61 studies or reports. Most studies focused on community-dwelling (41%) or mixed-care settings (40%). More than 70% of studies reported costs separately by disease stage, with 23% addressing patients with MCI. Findings consistently showed that the societal costs of AD increased significantly with advancing disease stages, with some variations across regions (Europe: 32%-150%; North America: 29%-67%; Asia: 34%-144%). Direct costs also rose with disease progression, with non-medical expenses (e.g., social care, home assistance, institutionalization), increasing disproportionately compared to medical costs. This review identified direct costs that are unique to AD, such as additional heating bills due to limited mobility (additional £118-£913 PPY) and costs related to police call outs to find lost and wandering individuals with AD (£7-£48 PPPY). Indirect costs, particularly informal caregiving, accounted for approximately half of total societal costs, regardless of care setting, disease severity, region, or cost calculation method. Across studies, caregivers were predominantly female, retired, and often the spouses of patients. Where reported, the average number of caregivers per patient ranged from 1.60 to 2.62 for those with MCI or AD, increasing as disease progressed. Informal caregiving was sometimes reported to exceed 30 hours per week for mild disease, reaching up to 120 hours per week in severe disease, and remained a substantial burden even in institutionalized settings.

CONCLUSIONS: This review offers a comprehensive analysis, drawing from studies conducted over more than a decade, to illustrate the significant societal economic burden AD across care settings, cost categories, disease stages, and regions.

SPONSORSHIP: Eisai Inc.

82 Impact of specialty referral timing on treatment start and cost outcomes in amyotrophic lateral sclerosis (ALS): A real-world claims analysis

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BACKGROUND: Amyotrophic lateral sclerosis (ALS) is a rapidly progressive neurodegenerative condition where early access to neurologic care and treatment can potentially modify disease trajectory and health care utilization. However, real-world evidence assessing the role of referral timing on treatment initiation and downstream clinical and economic outcomes remains limited.

OBJECTIVE: To evaluate the association between timing of specialty neurology referrals and symptoms management, treatment initiation, and downstream health care utilization and costs.

METHODS: We conducted a retrospective analysis utilizing anonymized claims data covering both medical and pharmacy benefits and the period from Jan 2017 to Apr 2025. Adults diagnosed with ALS (ICD-10 G12.21) between 2021 and 2023. Patients with any missing relevant data were excluded. We tracked two phases of the patient journey: (1) symptom onset to ALS diagnosis and (2) diagnosis to treatment initiation. Referral timing was defined as the interval between onset of symptoms and first neurology visit. Patients were categorized as having timely (≤90 days), moderate (91–180 days), or delayed (180+ days) referrals. Outcomes included use of disease-modifying therapies, hospitalizations, emergency department visits, and total health care costs within 6 and 12 months after diagnosis.

RESULTS: Among 8,294 ALS patients eligible for our analysis identified, 60% received a neurology referral within first 6 months of symptoms onset (45% within 90 days and 15% between 90 and 180 days), while 40% had referrals delayed beyond 6 months. Median time from onset of symptoms to neurologist visit was 118 days. ALS-specific medication initiation was faster in the early referral group (≤90 days) with a median of 173 days for therapy initiation, while it was 198 days for moderate referrals (90-180 days) compared to 474 days in the delayed referral group (180 days+). An additional analysis to be explored is whether timely referral was associated with lower total health care costs over 12 months post-diagnosis compared to delayed referrals.

CONCLUSIONS: Timely specialty referral following ALS symptom onset is associated with earlier treatment initiation and better alignment with clinical guidelines. Interventions to streamline referral pathways in ALS care could enhance patient outcomes. This analysis underscores the value of real-world data in optimizing care transitions in rare, high-cost neurological conditions.

SPONSORSHIP: Syneos Health

Clinical Programs

88 Impact of a diabetes deprescribing detailing initiative among commercially insured members

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BACKGROUND: Dipeptidyl peptidase-4 (DPP4) inhibitors and glucagon-like peptide-1 (GLP-1) receptor agonists are options for glycemic management in type 2 diabetes patients. These medications overlap in mechanism of action, both targeting the incretin pathway. Diabetes clinical guidelines do not include this combination in treatment recommendations. Blue Cross Blue Shield of Michigan (BCBSM) implemented a diabetes deprescribing academic detailing initiative targeting the GLP-1 and DPP4 combination to improve patient safety and enable cost savings.

OBJECTIVE: To assess proportion of GLP-1 and DPP4 combination use before vs after prescriber academic detailing during 2022, 2023, and 2024.

METHODS: Retrospective study of commercial BCBSM pharmacy claims from 5/26/2021 to 8/31/2024. Included members were assigned by detailing year (DY): 2022, 2023, and 2024. Two pharmacists provided academic detailing by telephonic outreach to the provider office followed by a faxed report with a list of the practice's identified members with opportunity for deprescribing. Members were excluded from analysis if they terminated pharmacy coverage prior to the assessment date for each evaluation year. Primary outcome evaluated was change in combination use within 7 months post-detailing start date. Inferred due to detailing was defined as the final fill of discontinued medication was on or after the detailing begin date of DY evaluated.

RESULTS: Total diabetes deprescribing opportunity targets were 651 members (DY 2022), 70 members (DY 2023), and 161 members (DY 2024). After applying exclusion criteria, total population evaluated was 547 members (DY 2022), 58 members (DY 2023), and 148 members (DY 2024). For DY 2022, 235 members continued combination therapy (43%), 75 members stopped both (13.7%), 237 members stopped one of the therapies (43.3%). For DY 2023, 4 members continued combination therapy (6.9%), 18 members stopped both (31%), 36 members stopped one of the therapies (62.1%). For DY 2024, 81 members continued combination therapy (54.7%), 11 members stopped both (7.4%), and 56 members stopped one of the therapies (37.9%). Across each DY, stopping DPP4 only or GLP-1 only was inferred due to detailing for 80 members (33.8%, DY 2022 [n = 237]), 9 members (25%, DY 2023 [n = 36]), and 13 members (23.2%, DY 2024 [n = 56]).

CONCLUSIONS: Although the proportion of members who stopped either DPP4 or GLP-1 varied by DY, academic detailing remains a valuable strategy to deliver prescriber education to impact current and future diabetes deprescribing behaviors.

SPONSORSHIP: BCBSM

89 Validation of long-term savings from a pharmacist-to-prescriber telephonic intervention

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BACKGROUND: Managed care pharmacist (MCP) programs to optimize cost-effective drug therapy via a pharmacist-to-prescriber telephonic intervention may result in drug therapy changes and savings. To derive and report annualized intervention savings, programs often assume full adherence and enrollment for a year after intervention for a drug therapy regimen change. As these assumptions may not be accurate, a forensic evaluation of actual savings allows for a more accurate understanding of program impact and can be used to validate initial estimates.

OBJECTIVE: To validate savings for an MCP program following all drug therapy optimization change cases for up to 2 years from therapy change date compared to an annualization intervention savings methodology.

METHODS: Drug therapy optimization change cases from Jan 2021 through Oct 2022 for the HighTouchRx product, servicing ~6.6 million commercially insured members per month, were tracked for up to 2 years from the claims change date. Initial annualized savings estimates were calculated by an MCP and assumed continuous enrollment and adherence to therapy for 1 year from the claims change date. Forensic evaluation assessed savings from actual claims through the earliest of a stop, reversion, or change to the drug regimen, disenrollment, or 2 years. Drug regimen stopping was defined as a 60-day gap in supply. Savings from the two methods were compared descriptively.

RESULTS: All 611 drug regimen change cases over 22 months were reviewed. One hundred twenty (19.6%) involved single claim savings and therefore were not annualized, resulting in $1,941,028 savings not included in the savings validation. Of the remaining 491 (80.4%) cases, the initial annualized savings estimate calculated a savings of $16,747,305 and the 2-year forensic evaluation method calculated a savings of $21,423,531. Savings from the forensic method were greater than or equal to the annualized estimates for 287 (58.5%) of 491 cases. Elimination of duplicate drug therapy was the most common savings case category that persisted beyond a year, accounting for 151 (53.0%) of 287 cases with greater

or equal savings. The most common reason for lower case savings was disenrollment prior to 1 year, 75 (36.8%) of 204.

CONCLUSIONS: Overall, a forensic review of 611 MCP intervention drug therapy change cases demonstrated $21.4 million savings, a 28% higher savings than $16.7 million savings reported when using an annualized method. These results support using a 1-year annualization savings methodology as a pragmatic and conservative approach for savings calculations resulting from MCP interventions.

SPONSORSHIP: Prime Therapeutics

90 Transplant readiness achieved through novel solutions for obesity reduction and management

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BACKGROUND: One of the prevailing trends in the managed care space is GLP-1 hyper-utilization. This trend of utilizing high-cost medication for a relatively broad patient population poses potential concerns for the future. With increasing need to balance access with affordability, research needs to be conducted to understand the clinical value of these types of therapies. In addition, obesity prevalence among transplant candidates is increasing and poses an increased risk for complications post-transplant. Patients with obesity are less likely to be referred, waitlisted, and transplanted, and these disparities are especially prevalent among minorities. Options for pre-transplant weight loss include diet, exercise, and bariatric surgery. With incretin-based therapies (IBT) such as GLP-1 receptor agonists (GLP1-RA) and dual GLP-1RA/glucose-dependent insulinotropic polypeptide (GLP-1RA/GIP) agonists, there are now more options for pre-transplant weight loss.

OBJECTIVE: To compare the early effectiveness and value of IBT in pre-transplant patients initiating IBT versus those that did not initiate IBT.

METHODS: This was a single-center, retrospective cohort study of adult patients referred to the TRANSFORM clinic for pre-transplant weight loss from 1/2024 to 12/2024 and started on IBT in addition to diet and exercise recommendations. The primary descriptive endpoint was the percent weight loss from baseline. Secondary endpoints included BMI reduction from baseline, dialysis-free survival, dialysis-free, patient survival, and organ transplant.

RESULTS: This analysis included pre-transplant patients that initiated IBT (n = 41) and pre-transplant patients that did not initiate IBT (n = 34). The off-IBT group had a significantly lower EPTS at baseline and significantly fewer insurance approvals overall. At the date of analysis, patients on IBT lost an average of 9.65% body weight compared to 0.33% body weight for those that did not receive IBT ($P < 0.001$). BMI reduction was 3.9 kg/m^2 in the IBT group versus 0.15 kg/m^2 in the off-IBT group ($P < 0.001$). Despite the significant difference in EPTS at baseline, patient survival, dialysis-free survival, and organ transplant at 6 months were similar between groups.

CONCLUSIONS: Early analysis of IBT for pre-transplant weight loss reveals promising results in percent weight loss and BMI reduction but is less clear with respect to overall transplant outcomes. Longer follow-up studies are needed to assess further effectiveness and value. IBT could be an important tool for increasing access to successful organ transplantation for patients with obesity.

SPONSORSHIP: None

Dermatology

105 Economic burden of moderate to severe chronic hand eczema in the United States: A retrospective claims analysis

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BACKGROUND: Chronic hand eczema (CHE) is an inflammatory skin disease of the hands and wrists, marked by dryness, itchiness, pain, fissures, and blistering and is defined as symptoms lasting ≥3 months or relapsing twice in a year. Despite its burden, no FDA-approved treatments are currently indicated for CHE and real-world data on its economic impact are limited.

OBJECTIVE: To assess the economic burden of moderate to severe CHE by evaluating health care resource utilization (HRU) and costs in the United States.

METHODS: This retrospective claims study used Komodo Research Data (01/2016 to 04/2024). Adults with ≥1 SNOMED CT code for CHE or hand eczema (first observed: index date) and ≥1 ICD-10-CM code for eczema/dermatitis (L20.x; L23.x–L25.x; L30.x) were included. Moderate to severe CHE was defined by eczema-related systemic or phototherapy use, and patients were further categorized into non-mutually exclusive cohorts based on treatment(s) received at any time post-index: cohort 1 (≥2 systemic

therapy claims; n = 3,529), cohort 2 (≥1 claim for immunosuppressants, retinoids, monoclonal antibodies, or oral JAK inhibitors; n = 551), and cohort 3 (≥1 claim for monoclonal antibodies or oral JAK inhibitors; n = 239). Baseline characteristics were assessed in the 12-month pre-index period. Eczema-related HRU and costs were reported per patient per year (PPPY; 2023 USD) during treatment, from first prescription fill to last day of supply.

RESULTS: The study included 6,295 patients with moderate to severe CHE (mean age: 48.2 years; 63.8% female; 76.6% commercially insured). Comorbidities included allergic rhinitis (15.6%), asthma (12.3%), anxiety (21.0%), and depression (16.2%), with higher rates in cohort 3. Average treatment duration was 2 years in cohort 1 and 1.5 years in cohorts 2 and 3. Outpatient visits accounted for most eczema/dermatitis-related HRU, with 1.3, 3.0, and 4.7 visits PPPY in cohorts 1-3, respectively. Total eczema/dermatitis-related costs PPPY increased with treatment intensity, totaling $1,876 in cohort 1, $9,505 in cohort 2, and $21,682 in cohort 3. Pharmacy costs were the primary driver, contributing $1,221, $8,898, and $20,760 PPPY, respectively.

CONCLUSIONS: This real-world analysis underscores the economic burden of moderate to severe CHE in the United States, particularly among patients treated with monoclonal antibodies or oral JAK inhibitors. These findings highlight the need for effective, targeted treatments that reduce reliance on costly and potentially misaligned therapeutic escalation, especially in the absence of FDA-approved therapies specific to CHE.

SPONSORSHIP: LEO Pharma Inc.

106 Budget impact analysis of tralokinumab-ldrm for moderate to severe atopic dermatitis in the United States

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BACKGROUND: Atopic dermatitis (AD) is a chronic inflammatory skin condition characterized by intense itching, redness, dry skin, and recurring eczematous lesions. Treatment options include topical therapies (e.g., corticosteroids) and systemic treatments (e.g., biologics and JAK inhibitors). Tralokinumab is indicated for the treatment of moderate to severe AD in adult and adolescent patients whose disease is not adequately controlled with topical therapies, or when those therapies are not advisable.

OBJECTIVE: To evaluate the budget impact of tralokinumab in a hypothetical US commercial health plan with 1 million (M) members.

METHODS: Budgetary impact of tralokinumab was estimated by comparing the expected 3-year differences in costs of systemic therapy in adult and adolescent patients with moderate to severe AD across two scenarios: Including Tralokinumab and No Tralokinumab. Other available treatments included dupilumab, abrocitinib, upadacitinib, lebrikizumab, and nemolizumab. Patients could initiate systemic therapy with any treatment or switch from dupilumab to an alternative treatment option. Adults receiving tralokinumab, and adults or adolescents receiving lebrikizumab or nemolizumab who achieved clear, or almost clear skin, could transition to a less frequent dosing schedule (e.g., Q2W to Q4W), leading to fewer doses and lower overall treatment costs. Market shares for treatments were informed by forecasting data and treatment costs were based on 2025 wholesale acquisition costs. Dosing and administration of treatments aligned with FDA prescribing information.

RESULTS: Of the 1M plan members, 412, 518, and 652 are estimated to receive systemic treatment in years 1-3, respectively. Total costs without tralokinumab in years 1-3 total $21.0M, $27.7M, and $35.9M, respectively. Comparable costs with tralokinumab total $20.6M (Δ-0.5M), $26.6M (Δ-1.1M), and $34.1M (Δ-1.8M). This results in an estimated cumulative cost saving of $3.4M (adults = $2.3M; adolescents = $1.1M) by year 3. Over 3 years, the cumulative cost savings per member and per member per month totaled $3.4 and $0.09, respectively. These results are largely driven by competitive skin clearance rates, low monthly treatment costs of tralokinumab vs other treatments, and the option to transition from tralokinumab Q2W to Q4W dosing among adults.

CONCLUSIONS: Use of tralokinumab in patients with moderate to severe AD as an alternative treatment option to dupilumab, abrocitinib, upadacitinib, lebrikizumab, and nemolizumab could result in significant cost savings for US health plans.

SPONSORSHIP: LEO Pharma, Inc.

107 Real-world effect of ruxolitinib cream: decreased use of additional topical therapies and limited escalation to systemic treatments

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BACKGROUND: Ruxolitinib cream has shown efficacy with a well-tolerated safety profile in patients aged ≥2 years with mild to moderate atopic dermatitis (AD) in clinical trials. Early real-world data in adolescents and adults have shown efficacy and safety results consistent with clinical trial observations.

OBJECTIVE: To examine the long-term effect of ruxolitinib cream on real-world treatment patterns in AD, including among patients previously treated with topical (corticosteroids [TCS], calcineurin inhibitors [TCI], phosphodiesterase-4 [PDE-4] inhibitors) or systemic (corticosteroids, biologics) therapy.

METHODS: A retrospective cohort analysis was conducted using claims data from the Healthcare Integrated Research Database (HIRD) to identify ruxolitinib cream users aged ≥12 years from October 1, 2021, to July 31, 2022. The index date was the first ruxolitinib cream claim. The study included a 6-month baseline period and an 18-month follow-up, divided into 3 intervals: months 1-6, 7-12, and 13-18. Biologic therapy experience was determined based on baseline treatment history.

RESULTS: Ruxolitinib cream users (N = 1269) with a mean (SD; range) of 2.4 (2.3; 1-19) ruxolitinib cream fills over 18 months were included. Of biologic-naive patients (n = 1038), 92.7%, 91.8%, and 91.0% did not receive biologic therapy during months 1-6, 7-12, and 13-18, respectively. Of biologic-experienced patients (n = 231), 17.3%, 28.6%, and 35.5% did not receive biologic therapy during months 1-6, 7-12, and 13-18, respectively. TCS use declined from 53.0% at baseline to 29.8% in months 1-6, 26.3% in months 7-12, and 25.5% in months 13-18. TCI use decreased from 14.2% at baseline to 5.9% in months 1-6, 4.3% in months 7-12, and 5.3% in months 13-18. Topical PDE-4 inhibitor use was reduced from 4.3% at baseline to 2.2% in months 1-6, 1.4% in months 7-12, and 1.3% in months 13-18. Systemic corticosteroid use declined steadily, with cumulative prednisone-equivalent dose reduced from 78.4 mg at baseline to 67.5 mg in months 1-6, 56.0 mg in months 7-12, and 53.7 mg in months 13-18.

CONCLUSIONS: At 18 months after initiation of ruxolitinib cream, biologic-experienced patients continued to show reduced biologic treatment fills. Among biologic-naive patients, the majority (>90%) did not escalate to biologic therapy. Additionally, use of both topical and systemic corticosteroids decreased over time. These trends suggest that ruxolitinib cream remains an effective treatment option for adolescents and adults with AD, reducing the need for additional topical therapies and limiting escalation to systemic treatments.

SPONSORSHIP: Incyte Corporation

108 Examining the shifts in atopic dermatitis: A retrospective study of patient demographics and insurance coverage from 2018 to 2023

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BACKGROUND: Atopic dermatitis (AD) is a chronic inflammatory skin condition affecting both children and adults, often leading to reduced quality of life and increased health care utilization. Recent years have seen growing interest in the epidemiology of AD, particularly how trends vary by age, insurance coverage, and access to care.

OBJECTIVE: To analyze shifts in AD prevalence, patient age, and insurance coverage from 2018 to 2023.

METHODS: This retrospective study analyzed data from the STATinMED RWD Insights database, an all-payer medical and pharmacy claims source, to evaluate trends in atopic dermatitis (AD) from January 1, 2018, to December 31, 2023. The analysis focused on patients with a diagnosis of AD identifying both pediatric (<18 years) and adult (≥18 years) populations. Patient demographics including age, sex, race, and insurance type were extracted for each year.

RESULTS: The percentage of AD patients as a proportion of the total population remained consistent over the years, ranging between 0.17% and 0.19%. In 2018, AD patients represented 0.17% of the population (465,067 out of 267 million), increasing slightly to 0.19% in 2019 (499,283 out of 267 million). The percentage then stabilized at 0.18%, reaching the same proportion in 2023 (495,297 out of 277 million), indicating a steady prevalence relative to the overall population. A notable shift occurred toward an older AD population. The number of pediatric AD patients (< 18 years) decreased significantly, from 109,010 (23.4%) in 2018 to 19,169 (3.87%) in 2023, while adult AD patients (≥18 years) rose substantially, from 356,057 (76.6%) in 2018 to 476,128 (96.13%) in 2023. Insurance coverage trends also shifted. Commercial insurance for AD patients grew from 50.59% (235,299 patients) in 2018 to 56.80% (281,329 patients) in 2023. Conversely, the proportion of AD patients covered by Medicare decreased from 25.98% (76,395 patients) in 2018 to 19.62% (74,003 patients) in 2023. Similarly, Medicaid coverage dropped from 16.43% (120,804 patients) in 2018 to 14.94% (97,176 patients) in 2023.

CONCLUSIONS: This study highlights key trends in AD epidemiology from 2018 to 2023. The proportion of pediatric AD patients declined from 23.4% in 2018 to 3.87% in 2023, while the adult population grew from 76.6% to 96.13%. Insurance coverage patterns also shifted: commercial coverage increased from 50.59% to 56.80%, while Medicare and Medicaid coverage declined. These findings emphasize the need for targeted policies to address the growing adult AD population and the impact of insurance changes on care management.

SPONSORSHIP: STATinMED, LLC

Digital Health and Technology

116 Integration of artificial intelligence in clinical decision-making at leading health systems

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BACKGROUND: To engage effectively with health systems adopting AI in clinical decision-making, manufacturers need a clear understanding of current capabilities and integration levels. This insight can inform how they structure evidence, deliver data, and collaborate with AI-enabled providers.

OBJECTIVE: To assess how health systems are using AI platforms, the degree of integration with clinical systems, and perceived benefits from using AI in clinical decision-making.

METHODS: Precision AQ conducted a survey of 25 health system decision-makers in March 2025. Participants were selected from a database and screened based on their organization's use of AI in clinical decision-making, either extensively or in pilot stages, and their involvement in AI policy.

RESULTS: When screening potential participants, two-thirds reported their organizations are either extensively using or piloting AI for clinical decision-making. Among respondents completing the survey, all confirmed their organizations use AI in clinical decision-making, either extensively (76%) or in a pilot capacity (24%). Most health systems (72%) report using commercial AI platforms such as Tempus or Epic, while fewer developed platforms in-house (16%) or partnered with third-party vendors (8%). Few organizations (28%) have achieved full integration of their AI solutions with their electronic health records (EHRs), while 72% report partial integration. No respondents selected "no integration." Perceived benefits of using AI in clinical decision-making included improved adherence to treatment guidelines (84% of respondents), reduced clinician workload (80%), improved patient outcomes (80%), and reduced time to treatment decisions (72%). When asked how AI decisions are aligned with clinical guidelines, 56% of respondents indicated that systems are regularly updated to reflect changes in guidelines, while 24% rely on clinician validation of AI recommendations. Pharmaceutical manufacturers are not widely perceived as influential in shaping AI-driven drug selection. Only 8% of respondents believed biopharma has a significant influence, while 52% said they have some influence, 32% said minimal, and 8% said none.

CONCLUSIONS: Health systems have rapidly adopted commercial AI platforms with high expectations for improved care delivery, but integration with EHRs and alignment with clinical guidelines remain incomplete. It will be essential for manufacturers, clinicians, and payers to better understand how these AI-driven workflows evolve over time, shape patient care and treatment decisions, and impact clinical outcomes and costs.

SPONSORSHIP: Precision AQ

117 Accelerating quality gap closure with artificial intelligence: Clinical natural language processing and large language model–driven extraction of HEDIS measures from structured and unstructured medical records

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BACKGROUND: Improving patient health outcomes is a core objective of value-based care models, which reward health care organizations for delivering high-quality, efficient care. A critical component of achieving these outcomes is the timely identification and closure of quality gaps. However, variability in clinical documentation formats, especially CCDs, CCDAs, and PDFs, significantly hinders timely HEDIS measure abstraction and substantially increases the manual effort required to collect and validate clinical evidence. Artificial intelligence (AI) solutions, particularly clinical NLP and large language models (LLMs), are reshaping this landscape by enabling large-scale accurate extraction of quality indicators from diverse clinical data formats—both structured and unstructured.

OBJECTIVE: To design and validate an AI-based solution leveraging Clinical NLP and LLMs for rapid, accurate extraction of HEDIS measures from heterogeneous clinical data sources, thereby enabling providers and payers to

accelerate quality gap closure, enhance reporting workflows, and advance population health initiatives.

METHODS: A modular AI framework was developed, integrating targeted clinical NLP pipelines with context-aware extraction algorithms powered by LLMs. The system was trained and tested on a diverse dataset of CCDs, CCDAs, and unstructured PDFs sourced from multiple EHRs. A comparative analysis was conducted against manual review processes, focusing on key outcomes such as extraction precision, time to gap closure, and a positive financial impact resulting from improvements in operational efficiency.

RESULTS: The deployment of the AI solution for depression screenings, mammograms, and colonoscopies led to a 45% reduction in the time required to identify open gaps, achieved 92% extraction accuracy, and resulted in a 2.5× increase in chart review throughput. Providers reported increased confidence in documentation workflows, while payers observed accelerated reporting cycles and a positive impact on Star Ratings trajectory.

CONCLUSIONS: AI-powered HEDIS measure extraction from both structured and unstructured clinical records presents a significant opportunity for health plans and provider groups to enhance quality performance, maximize incentive revenues, and optimize resource utilization. Clinical NLP and LLMs are emerging as key enablers of scalable, data-driven care management strategies within value-based care frameworks.

SPONSORSHIP: Datalink Software LLC

118 Beyond rule-based risk stratification: Redefining risk for better care coordination in managed care through artificial intelligence

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BACKGROUND: Proactively identifying evolving risk and high-risk members is essential to improving outcomes and costs in managed care. Traditional rule-based models, built on static thresholds, often miss the full complexity of member health profiles. In contrast, artificial intelligence (AI) offers a dynamic, data-driven approach that captures evolving risk patterns across multiple variables with greater predictive accuracy.

OBJECTIVE: To evaluate how an AI algorithm outperforms traditional rule-based approaches in member risk stratification and how variables such as comorbidities, SDoH, demographics, lifestyle, utilization patterns, HEDIS care gaps, and lab results improve precision and granularity of risk differentiation.

METHODS: We conducted a retrospective analysis using de-identified medical, pharmacy claims, and clinical data from a large payer population. Natural language processing (NLP) was applied to longitudinal health data—including comorbidities, medications, HEDIS measures, and SDoH—to create unique health risk profiles. This captured the evolving, non-linear nature of individual risk over time. Profiles were fused with structured data like lab results and utilization, then regressed against real-world cost metrics. This integrated approach enabled dynamic, personalized risk scoring and cohesive stratification into actionable risk categories.

RESULTS: To benchmark our in-house AI model, we compared its performance against the CMS-HCC risk adjustment model using the same member population. Risk strata—high, medium, and low—were derived based on predicted risk scores from both models. The AI model produced distinct strata with average per-member costs of $31,078 (high-risk), $2,680 (medium-risk), and $439 (low-risk), versus $22,219, $4,525, and $1,953 under CMS-HCC, showing AI better segregates members. Strata quality was quantified using the Davies-Bouldin Index (DBI), where lower values indicate better-defined strata. Across all risk tiers, the AI model outperformed the rule-based approach (DBI for high: AI = 0.47 vs. HCC = 0.55; medium: AI = 0.55 vs. HCC = 0.58; low: AI = 0.52 vs. HCC = 0.61), indicating more compact and well-separated member groupings by AI.

CONCLUSIONS: AI significantly improves member risk stratification over traditional models by recognizing complex variable interactions and dynamic risk signals. Incorporating AI-driven stratification into managed care workflows can enhance early intervention strategies, optimize resource allocation, and advance value-based care.

SPONSORSHIP: Datalink Software LLC

119 AI meets evidence synthesis: A comparative review of AI performance in systematic literature screening

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BACKGROUND: Artificial intelligence (AI) based tools are used to assist with the time-consuming screening process and support systematic literature reviews (SLRs). The AI models vary on their designs—ranging from general-purpose foundational models to custom or disease-state-specific pipelines to tools purpose-built for systematic reviews.

OBJECTIVE: This AI-assisted review attempts to methodically analyze and compare the performance of different AI approaches used for SLR screening: foundational models, custom-built systems, and SLR-specific platforms. In addition to offering recommendations for choosing AI solutions for systematic review tasks, the objective is to evaluate which tools are most appropriate for scalable, high-quality evidence synthesis.

METHODS: We included all studies reporting accuracy statistics for AI-based screening for SLRs. This review was completed in AutoLit (Nested Knowledge). An AI-driven Smart Search identified 3,251 candidate studies, of which 20 were included based on Robot Screener–assisted screening. Accuracy, sensitivity, specificity, and F1 scores were extracted from underlying studies and compared across model types qualitatively and with summary/descriptive statistics.

RESULTS: The performance of various AI techniques for screening systematic reviews differs widely. Foundational models (GPT-4, Claude-3.5, Gemini-1.5, BONSAI + KRS) averaged 81.7% accuracy and 0.77 F1 score; custom models (NLP-assisted classifier, Deep learning classifier, FastText + SVM with AL, pBERT) show great metrics show high sensitivity in some cases (e.g., up to 98.7%) but had average 81.2% accuracy and 0.50 F1 score. Tools designed specifically for systematic reviews, while most included a human-curation step, provided the best performance, exhibiting 99% accuracy on average and 96.1% sensitivity, though F1 was not available.

CONCLUSIONS: Purpose-built SLR technologies are more accurate and more appropriate for large-scale screening in SLRs than foundational models and custom models, which exhibit varied performance and may lack specialization in the SLR screening task. Curation may be needed in any AI-assisted methodology, but AI tools displayed consistently high accuracy and sensitivity.

SPONSORSHIP: None

120 Coverage gaps and reimbursement barriers for FDA-authorized prescription digital therapeutics: A systematic review of US health plan policies from 2018 to 2025

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BACKGROUND: Prescription digital therapeutics (PDTs) are FDA-authorized software-based treatments for conditions such as substance use disorder, ADHD, insomnia, and type 2 diabetes. Despite strong clinical evidence and regulatory approval, coverage by US payers has remained limited due to challenges in benefit classification, billing infrastructure, and reimbursement policies.

OBJECTIVE: To assess trends in US payer coverage of FDA-cleared PDTs from 2018 to 2025, focusing on benefit designation, formulary status, billing practices, and policy-level access barriers.

METHODS: A systematic review of literature published from January 2018 to June 2025 was conducted using PubMed, Embase, and CINAHL. A total of 12 studies met inclusion criteria. Eligible sources described Medicare, Medicaid, or commercial payer coverage of FDA-authorized digital therapeutics. Data were extracted on benefit type (e.g., pharmacy, medical, or telehealth), billing codes, coverage policies, and formulary placement. Additional gray literature, including CMS documents, payer websites, and trade publications, was reviewed to capture recent developments.

RESULTS: Coverage remained inconsistent across payers. By 2022, around 20% of PDTs, including reSET-O, Somryst, and EndeavorRx, were included on commercial formularies, typically under pharmacy or specialty tiers. Roughly 30% of commercial plans covered at least one PDT for diabetes, while fewer than 15% covered behavioral health-related PDTs. Medicare lacked a defined benefit category for PDTs, creating reimbursement challenges. Although CMS introduced a general billing code for digital behavioral therapies in 2022, product-specific codes were not yet available. Medicaid coverage varied by state, with limited adoption through pilot programs. Most payers had not formally incorporated PDTs into their technology assessment or formulary review processes. Coverage was often limited to case-by-case approvals or short-term initiatives.

CONCLUSIONS: Despite clinical and regulatory advancement, prescription digital therapeutics face persistent coverage and reimbursement barriers across US payers. The absence of formal benefit categorization, product-specific billing codes, and consistent evaluation frameworks limits widespread adoption. Addressing these gaps through CMS guidance, standardized coding, and evidence-based coverage criteria may improve access and support broader integration into care delivery.

SPONSORSHIP: None

Drug Pricing, Payment, and Reimbursement

125 Cost-effectiveness of epcoritamab vs glofitamab in relapsed/refractory diffuse large B-cell lymphoma (R/R DLBCL) after at least 2 lines of therapy in the United States

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BACKGROUND: Subcutaneous (SC) epcoritamab and intravenous (IV) glofitamab are US-approved CD3×CD20 bispecific antibody treatments for third-line plus relapsed/refractory diffuse large B-cell lymphoma (3L+ R/R DLBCL).

OBJECTIVE: To evaluate the cost-effectiveness of epcoritamab vs glofitamab in R/R DLBCL after ≥2 therapy lines from a US health care perspective.

METHODS: A partitioned survival model with 3 health states (progression free, progressive disease, and death) based on overall survival (OS) and progression-free survival (PFS) was developed. Epcoritamab patient-level data were obtained from the DLBCL cohort of the EPCORE NHL-1 trial (NCT03625037, data cutoff April 2023, N = 139). Publicly available aggregate data were used for the glofitamab trial cohort (NCT03075696, Dickinson et al 2022, N = 155). Parametric survival models were evaluated for statistical fit and clinical plausibility of epcoritamab extrapolated OS, PFS, and time to treatment discontinuation. Based on an unanchored matching-adjusted indirect comparison, a statistically significant OS benefit was demonstrated for epcoritamab vs glofitamab from 6 months onward (hazard ratio [HR] [95% CI]) (<6 months: 1.12 [0.72-1.74]; ≥6 months: 0.57 [0.34-0.94]). The PFS HR was 1.04 [0.77-1.40]. Health states utilities were based on EPCORE NHL-1 EQ-5D-3L data and published US value sets. Drug costs and other resource use data were based on package inserts, US standard sources (Redbook WAC, CMS physician fee schedules), and literature. Based on expert opinion, no additional drug costs were incurred for epcoritamab after 2 years in the base case. Outcomes and costs were discounted by 3% annually. Probabilistic, one-way sensitivity analyses and scenario analyses were used to assess model robustness.

RESULTS: Epcoritamab use resulted in a mean gain of 2.35 life-years (LYs) and 1.33 quality-adjusted LYs (QALYs) vs glofitamab, with a cost difference of $125,797 over a lifetime horizon, leading to an incremental cost-effectiveness ratio (ICER) of $94,585 per QALY. Scenario analyses using a 3-year treatment duration and an unlimited epcoritamab treatment duration led to ICERs of $111,727 and $129,635, respectively. Epcoritamab was cost-effective vs glofitamab at a US willingness-to-pay threshold of $150,000 per QALY in the base case and scenario analyses. The average cost per LY was $53,140 less for epcoritamab vs glofitamab.

CONCLUSIONS: SC epcoritamab provides meaningful LY and QALY gains vs IV glofitamab. This analysis demonstrates that epcoritamab is a cost-effective option for managing R/R DLBCL from a US health care perspective.

SPONSORSHIP: AbbVie; Genmab A/S

134 Budget impact of Symbravo (MoSEIC meloxicam and rizatriptan) to health plans in the United States for the acute treatment of migraine in adults

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BACKGROUND: Migraine is a debilitating neurologic condition that often requires prompt and effective acute treatment to limit healthcare resource utilization; however, existing treatments are often suboptimal. Symbravo (MoSEICTM meloxicam and rizatriptan [mMR]; formerly AXS-07), a novel, multimechanistic oral therapy, recently received US approval for the acute treatment of migraine with or without aura in adults.

OBJECTIVE: To estimate the budget impact of adding mMR to the formulary of a US third-party health plan (commercial or Medicare) for acute migraine treatment.

METHODS: A budget impact model was developed to estimate costs before and after the adoption of mMR to a health plan with 1 million covered lives over 3 years. This model included existing acute migraine therapies such as dihydroergotamine mesylate, gepants (rimegepant, ubrogepant, zavegepant), lasmiditan, and triptans (eletriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan). We sourced inputs from published literature, clinical trial data, and real-world prescription data. We assumed a 1.3% annual growth rate for migraine and a 1% annual market uptake for mMR. Eligible populations included adults aged 18-64 (commercial) and ≥65 years (Medicare) who receive prescription

medications for acute migraine treatment. The model accounted for drug acquisition costs, adverse event management, rescue medication use in 2-hour nonresponders, and additional health care resource use (outpatient, emergency department, hospitalization) in 12-hour nonresponders. We compared total annual costs with and without mMR and conducted one-way sensitivity analyses.

RESULTS: In a commercial plan, mMR added $24,822, $50,289, and $76,415 to total annual costs in years 1-3, respectively, for 10,808, 10,948, and 11,090 patients treated for migraine. For Medicare, mMR added $46,603, $94,418, and $143,469 annually for 12,394, 12,555, and 12,719 patients. The modest increase in drug acquisition costs was largely offset by reductions in adverse event costs and health care resource utilization. Incremental per-member-per-month costs remained negligible over years 1-3: $0.0021, $0.0042, and $0.0064 for commercial and $0.0039, $0.0079, and $0.0120 for Medicare plans. Sensitivity analyses confirmed the robustness of these findings.

CONCLUSIONS: mMR adoption at a 1% annual uptake for the acute treatment of migraine results in negligible budget impact for US health plans over a 3-year horizon. Its cost profile, coupled with reductions in associated health care resource use, supports its formulary inclusion.

SPONSORSHIP: Axsome Therapeutics, Inc.

135 Understanding state Medicaid spending on prescription drugs: A 10-state comprehensive analysis of net state Medicaid drug spending as part of the total Medicaid budget

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BACKGROUND: In recent years, the cost of health care, and specifically prescription drugs, has become a topic of interest for policymakers. US state legislatures are considering and advancing legislation on payment limits and other drug pricing policies, including establishing Prescription Drug Affordability Boards (PDABs) and Health Care Availability and Access Boards.

OBJECTIVE: To put these policy discussions into context, this research aims to provide an estimate of net state Medicaid spending on prescription drugs in 10 states (CA, CO, FL, MA, MI, NY, OH, OR, PA, and WA) in FY 2023 with significant Medicaid spend and/or policy discussions around spend in fiscal year (FY) 2023 based on publicly available sources (e.g., state budgets, Centers for Medicare and Medicaid Services (CMS) reports).

METHODS: State Medicaid drug expenditures and drug rebate income were analyzed to generate an overview of state spending on prescription drugs and estimate Medicaid drug spending as a percentage of total Medicaid expenditures for 10 states in FY 2023. Medicaid data from sources included Medicaid State Drug Utilization Data, Medicaid Budget and Expenditure System/State Children's Health Insurance Program (CHIP) Budget and Expenditure System (MBES/CBES) Form CMS-64, and state budget documents. Limitations include uncertainty regarding inpatient hospital spending on drugs due to bundled payments (i.e., drug costs not separately identified from hospital costs), MCO spending on prescription drugs due to limited public reporting, and a lack of transparency across states as to what types of information states publish relating to Medicaid spending. This analysis does not consider state 340B drug spending because of the lack of available information about the use of 340B drugs for Medicaid beneficiaries.

RESULTS: Using publicly available data, state Medicaid net prescription drug spending as a percentage of overall Medicaid budget ranged from 4.7% to 14.3% across 10 states. These findings are near or below the national rate of drug spending as a share of overall health care spending of 14%, which is also below the average drug spending share of medical spending across comparable countries. Manufacturer drug rebates back to states ranged from $83M (OR) to $1.9B (NY).

CONCLUSIONS: This analysis demonstrates that state Medicaid programs are estimated to be spending near, or below, the US national average on prescription drugs. While high drug pricing makes headlines and is often the focus of legislation and policymaker attention, drug pricing is not the main driver of state Medicaid spending based on this estimate.

SPONSORSHIP: Johnson & Johnson

136 Unmasking alternative funding programs: Patient outcomes and prescription journey

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BACKGROUND: Alternative funding programs (AFPs) exclude high-cost medications from patients' pharmacy benefits and seek to obtain medication through alternative sources. Research describing the methods and outcomes of AFPs is needed.

OBJECTIVE: To evaluate the prescription journey and patient outcomes in patients forced to use an AFP.

METHODS: A multisite prospective cohort study including patients identified as enrolled in an AFP with a specialty medication referral sent to a health-system specialty pharmacy (HSSP) in 2024 was conducted. Data were collected by each site and imported into a shared data warehouse for analysis. Patients were followed until referral outcome was determined.

RESULTS: There were 252 patients identified to be in an AFP in 2024 among 12 sites. Overall, 80% of new and 93% of continuing therapy patients were able to access the prescribed therapy or an alternative in a median of 29 days (IQR [interquartile range] 18, 57) and 33 days (IQR 12, 52) from referral, respectively. AFP enrollment was most commonly recognized by the HSSP after prior authorization (PA) or appeal approval followed by forced AFP enrollment (28%), after insurance denial with forced AFP enrollment (21%), or when no PA/appeal option existed and patients were directed to manufacturer patient assistance programs (PAPs) (18%). A PA and/or appeal was submitted for 73% and 28% of referrals, respectively. Sixty-five percent of patients applied for manufacturer PAP; 54% were denied, most commonly because of their enrollment in an AFP (51%). A courtesy fill was required for 16% of patients and 12% required a sample during the access process. Patients eventually had their medication filled through PAP (32%), the original or an alternative medication filled by a preferred US pharmacy (30%), or filled internationally (14%). Fewer patients had to change insurance to get approved (5%), were lost to follow-up (5%), or used internal HSSP grants for coverage (2%). Thirty-six percent of patients experienced a gap in therapy during the access process. Eleven percent of patients had documented poor clinical outcomes while awaiting therapy. Seven percent of patients contacted their human resources department due to access issues.

CONCLUSIONS: AFPs increase complexity in accessing life-altering specialty medication therapies, take advantage of manufacturer assistance programs meant for uninsured/underinsured patients, and often result in treatment gaps that can lead to poor clinical outcomes.

SPONSORSHIP: None

137 Lower total cost of care of first-line fixed-duration venetoclax + obinutuzumab vs treat-to-progression Bruton's tyrosine kinase inhibitor regimens in patients with chronic lymphocytic leukemia in the United States: A population-based model

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BACKGROUND: Venetoclax + obinutuzumab (VenO), the only US FDA-approved B-cell lymphoma 2 inhibitor fixed-duration treatment (FDT), has demonstrated cost savings over 3 years (yrs) vs Bruton's tyrosine kinase inhibitor (BTKi) treat-to-progression (TTP) regimens in previous economic models. The broader, longer-term population-level impact is not well established.

OBJECTIVE: To estimate the annual total cost of care (TCC) in the United States for treating chronic lymphocytic leukemia (CLL) with first-line FDT VenO vs TTP BTKi regimens among all adults and a subset of Medicare-eligible adults.

METHODS: A US population model was developed to calculate the TCC for previously untreated CLL across all adults (≥18 yrs) and a subset of Medicare-eligible adults (≥65 yrs) over 10 yrs (2019-2028). The model compared a hypothetical all-VenO-treated (assumed duration of 1 yr) vs an all-BTKi-treated (ibrutinib ± rituximab/obinutuzumab or acalabrutinib ± obinutuzumab) population. Patient cohorts entered annually and were followed for 3 and 5 yrs. CLL incidence rates were sourced from the Surveillance, Epidemiology, and End Results Program and applied to a population from the US census. Per-patient yearly costs by treatment were derived from a published TCC model, incorporating treatment, adverse event management, routine care, and monitoring costs. Drug costs used average wholesale acquisition costs from Truven Health Analytics Red Book (2019-2024); post-2024 prices were projected based on historic trends.

RESULTS: In 2019, the estimated management cost of previously untreated CLL in the United States was $1.93 billion (B) and $1.94B (Medicare subset: $1.41B and $1.42B) for hypothetical all-VenO-treated and all-BTKi-treated populations, respectively. By 2028, the estimated cost for an all-VenO-treated and all-BTKi-treated population was $3.78B vs $7.10B (Medicare subset: $2.73B vs $3.72B) with a 3-yr follow-up, and $4.53B vs $11.55B (Medicare subset: $3.28B vs $6.05B) with a 5-yr follow-up, respectively. Over 10 yrs, an all-BTKi-treated population would incur an extra $26.0B (Medicare subset: $15.6B) vs an all-VenO-treated population with a 3-yr follow-up, and an additional $48.1B (Medicare subset: $29.8B) with a 5-yr follow-up, primarily due to continued drug costs.

CONCLUSIONS: Over 10 yrs, a hypothetical all-VenO-treated population could save the United States up to $48.1B vs an all-BTKi-treated population for previously untreated CLL. Of this, $29.8B is attributed to savings among Medicare-eligible patients. Despite rising overall CLL costs, FDT regimens resulted in substantial cost savings vs TTP regimens.

SPONSORSHIP: Genentech, Inc., AbbVie Inc.

138 Forced alternatives: The impact of alternative funding programs on specialty medication access vs traditional coverage

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BACKGROUND: More employers are requiring employees who need high-cost medications to use alternative funding programs (AFPs), which aim to secure medications through non-insurance sources.

OBJECTIVE: To evaluate specialty medication access outcomes in patients required to use an AFP versus those using traditional pharmacy benefits.

METHODS: This prospective cohort study included patients referred to a health-system specialty pharmacy in 2024, enrolled in an AFP from 12 sites. As a matched control (non-AFP), patients enrolled in traditional pharmacy benefits were randomly selected with 1:2 ratio (or all patients were included if the ratio is smaller than 1:2) within each site, using matching criteria of clinical area and therapy status (new vs continuing medication). The primary outcome was medication access, defined as the referred medication or an appropriate alternative being covered. Secondary outcomes included referral outcome, time to access (from referral to receiving medication), therapy gaps, and poor clinical outcomes during the access process. A mixed-effects logistic regression model was used to analyze medication access and clinical outcomes, while a mixed-effects ordinal logistic regression model evaluated time to access.

RESULTS: A total of 754 patients were included (AFP = 252, non-AFP = 502). Median age was 52 years (IQR 39, 62); 81% were White, and 44% were new to therapy. Common clinical areas included rheumatology (24%), oncology/hematology (19%), and GI/IBD (16%). AFP patients were significantly less likely to be able to access their prescribed medication (OR 0.3 [CI 0.17, 0.54], $P < 0.001$); 87% of AFP vs. 93% of non-AFP patients accessed therapy. Referral outcomes differed: AFP patients received medications via manufacturer assistance (32%), an AFP-preferred US pharmacy (30%), or non-US pharmacy (14%), while 88% of non-AFP patients used a US pharmacy and 5% filled through manufacturer PAP. More than half of AFP patients applied for manufacturer assistance programs (65% vs 10%). AFP patients had 8.4 times the odds of having longer time to access medication ($P < 0.001$) compared to non-AFP patients; median 31 days (IQR 16, 54) vs 8 days (IQR 4, 16). AFP patients had more treatment gaps and sample use than non-AFP (36% vs 2% and 12% vs 2%, respectively). Poor clinical outcomes were more frequent in AFP patients (11% vs 1%) than non-AFP.

CONCLUSIONS: Use of AFPs significantly reduces the likelihood of accessing therapy, increases time to treatment, and is associated with more therapy gaps and adverse clinical outcomes compared to traditional pharmacy benefits.

SPONSORSHIP: None

139 Balancing promise and prudence: Addressing stakeholder concerns about the use of artificial intelligence for pricing and reimbursement

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BACKGROUND: Artificial intelligence (AI) has the potential to enhance pricing and reimbursement (P&R) processes in health care. Its applications range from supporting evidence generation to forecasting pricing. However, what payers think about AI use in this context is largely unknown. Understanding AI's perceived value and limitations in P&R is critical to inform its responsible and effective use.

OBJECTIVE: To explore perceived benefits and concerns regarding AI use in P&R among global payers, focusing on actionable recommendations for future implementation.

METHODS: A three-phased approach was used. Desk research identified current applications of AI in P&R and related challenges. A survey gathered perspectives from payers in France (n = 1), Germany (n = 1), Italy (n = 2), Spain (n = 1), and the United States (n = 1). Respondents rated AI's perceived benefit across P&R activities, shared thoughts about the reliability of AI outputs, and identified factors they deemed critical to ensuring the reliability of AI in P&R processes. In-depth interviews provided further qualitative insights (n = 2).

RESULTS: Payers expressed interest in AI's potential to enhance efficiency in evidence synthesis and health economic modeling, including applications such as meta-analysis, model calibration, and cost-effectiveness projections. There was also notable interest in the application of AI for price prediction and monitoring, competitor analysis, and reimbursement planning. However, payers consistently expressed reservations about the reliability of AI-generated outputs. Key concerns included opaque algorithms, limited external validation, insufficient data source documentation, and insufficient internal expertise. Some payers also faced barriers in testing AI tools, noting that formal vendor partnerships or in-house development may be required due to regulatory or institutional constraints. This may limit the ability to explore, assess, and train staff on these technologies going forward. To build trust, payers recommended robust validation processes, algorithmic transparency, and the development of tailored AI tools.

CONCLUSIONS: AI has the potential to support more efficient and rigorous P&R decision-making, especially in evidence synthesis and health economic modeling. However, AI adoption will remain limited unless data quality and reliability concerns are addressed. Stakeholders must collaborate on creating transparent, validated, and fit-for-purpose AI tools for P&R decision-making.

SPONSORSHIP: OPEN Health HEOR & Market Access

140 Health care decision-maker insights on Academy of Managed Care Pharmacy Format Version 5.0 formulary dossiers

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BACKGROUND: Since its release in 2000, the Academy of Managed Care Pharmacy (AMCP) Format has provided a framework for biopharma manufacturers to communicate clinical and economic evidence to health care decision-makers (HCDMs) to inform formulary, coverage, policy, and reimbursement decisions for new and existing medical products. The latest version of the AMCP Format—Version 5.0—was released in April 2024 and included updated guidance on digital therapeutics, health disparities, and pre-approval information exchange (PIE).

OBJECTIVE: To assess HCDM insights on the use and value of AMCP Format formulary dossiers.

METHODS: A double-blinded, web-based survey was fielded to FormularyDecisions users from March 7, 2025, to April 17, 2025. FormularyDecisions is a digital platform that supports the exchange of information between HCDMs and biopharma manufacturers.

RESULTS: A total of 31 HCDMs responded to the survey, representing national and regional health plans (58%), pharmacy benefit managers (PBMs; 19%), and integrated delivery networks (IDNs; 10%), among other organizations, with roles as pharmacy directors (65%), clinical pharmacists (19%), and medical directors (16%). Most respondents (94%) represented commercial plans. All HCDMs agreed that AMCP Format dossiers contain the information needed for, and improved their ability to make, formulary decisions. Three-quarters (75%) of HCDMs agreed that product review and formulary placement could be delayed if an AMCP Format dossier was not provided by a manufacturer; and nearly half (48%) agreed that patient access to the product could be delayed. Over half (55%) of HCDMs were less likely to request a dossier for a manufacturer's future products if a previous dossier request went unfulfilled. In regard to PIE, 71% of HCDMs indicated a desire to first receive a product's AMCP Format dossier before FDA approval. Among respondents who had requested pre-approval dossiers (n = 13), 54% noted an increase in the provision of pre-approval dossiers during the past year (vs prior years). HCDMs were also surveyed on health equity and digital therapeutics, topics updated in Format Version 5.0, with variable results.

CONCLUSIONS: The results of this survey indicated that AMCP Format dossiers contain the information needed by HCDMs and improved their ability to make timely formulary decisions. More than two-thirds of HCDMs would prefer to have an AMCP Format dossier ahead of FDA approval timing, representing an opportunity for increased PIE between biopharma manufacturers and HCDMs.

SPONSORSHIP: Cencora

141 Lipoprotein(a) and testing policies: A health plan claims analysis

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BACKGROUND: Lipoprotein(a) is an independent, causal risk factor for atherosclerotic cardiovascular disease (ASCVD) in 20% of individuals and identifies people at high risk of ASCVD progression. Lp(a) modifying therapies, currently in phase 3 studies, could reduce ASCVD progression and decrease a health care system's CV disease burden.

OBJECTIVE: To determine, considering the autonomy of commercial health plans and separate review committees evaluating tests and therapies, if health plans have concordant Lp(a) testing policies and coverage as observed in a claims data analysis.

METHODS: An analysis of 2024 Lp(a) testing coverage policies from 25 health plans (85% of insured US population)

categorized policies as covered, not covered, or silent. Claims data from 1/1/2024 to 9/30/2024 was analyzed, with a threshold for inclusion. A threshold was established so that a minimum number of claims had to be observed for each payer included in the analysis. Concordance status was assessed by comparing the ratio of a health plan's paid and partially paid claims versus denied, unpaid, or patient only paid claims compared to the policy status determined above.

RESULTS: Out of 25 possible policies for tests where claims data was available, 5 policies covered Lp(a) testing(20%), while 8(32%) were silent and 12(48%) did not cover Lp(a) testing. The policy coverage analysis suggests that 4.41% of Americans have an insurance policy that covers Lp(a). In contrast, analyzing the claims data at a threshold of more than 50% of a payer's claims approved to be considered implied coverage of the test, 48.64% of Americans have an insurance policy that has implied coverage of Lp(a). Increasing that threshold to more than 65% of claims approved results in an implied coverage of 31.78%.

CONCLUSIONS: Providers and patients are faced with many difficult decisions regarding their medical care. Ambiguity among policy and payment could lead to not ordering a test that could be clinically relevant and paid for by insurance. Relying on a published policy may not reflect how a claim will be processed for coverage. In fact, in one instance, it was observed that a payer whose policy stated that Lp(a) was covered had a lower ratio of paid versus not paid claims than another payer whose policy did not cover Lp(a) testing. As Lp(a) modifying therapies may be approved in the coming years, it is imperative that clarity and consistency is achieved in the testing policies and the processing of claims for payment.

SPONSORSHIP: Roche Diagnostics

142 A descriptive study comparing artificial intelligence (AI)–driven preferred specialty drug network versus traditional specialty drug network on drug costs in a multi-state regional health plan

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BACKGROUND: Amid escalating health care expenditures, pharmacy benefit managers (PBMs) are under increasing pressure to deploy data-driven, innovative strategies to manage drug costs effectively. The rapid adoption of artificial intelligence (AI) across the health care sector—particularly in applications such as predictive analytics, utilization management, and network optimization—has positioned it as a transformative tool for PBMs. While early adoption has demonstrated operational promise, real-world evidence evaluating AI's impact on drug cost containment remains limited. PBMs contract with specialty pharmacies at varying reimbursement rates; however, patient self-selection may lead to utilization of higher-cost, non-preferred pharmacies. RealRx leverages artificial intelligence (AI) within the prior authorization process to direct fulfillment to the lowest-net-cost pharmacy for each drug. This evaluation addresses a key evidence gap in AI-driven network optimization strategies in managed care.

OBJECTIVE: To evaluate the cost impact of implementing an AI-optimized preferred specialty pharmacy (PSP) network compared to a traditional specialty pharmacy (TSP) network within a multi-state regional health plan.

METHODS: This retrospective, descriptive analysis used pharmacy administrative claims data and contracted specialty pharmacy network rates from a regional health plan between April 1, 2024, and March 31, 2025. The analysis focused on the 10 highest-expenditure specialty drugs by average wholesale price (AWP). Per-drug costs were calculated by applying the best network rate (PSP rate) and the third-best network rate (TSP rate) to each claim's AWP. These calculated costs were then compared for each individual drug and aggregated.

RESULTS: Annual costs across all 10 drugs were lower under the PSP model, resulting in a total cost differential of $1.726 million. The savings observed for all 10 drugs were as follows: Trikafta ($609k), Humira ($231k), Stelara ($205k), Rinvoq ($163k), Enbrel ($155k), Dupixent ($106k), Skyrizi ($84k), Taltz ($78k), Verzenio ($55k), and Cimzia ($41k).

CONCLUSIONS: AI-driven specialty network optimization yielded substantial cost savings compared to traditional specialty pharmacy selection methods. These findings suggest that integrating AI into PBM core operations can enhance financial performance by aligning high-cost therapies with the most cost-effective dispensing channels. Nevertheless, further research is warranted to explore AI's broader implications on clinical outcomes, operational efficiency, and effective drug utilization in managed care.

SPONSORSHIP: None

Endocrine and Metabolic

151 Modelling total health care cost offsets and treatment costs associated with treating adults with obesity with tirzepatide and semaglutide in US clinical practice settings

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BACKGROUND: Obesity poses a substantial economic burden on individuals and society, making clinically effective and cost-effective therapies essential.

OBJECTIVE: To model total health care cost offsets and drug treatment costs associated with weight reduction from 6 months of tirzepatide (TZP) or semaglutide (SEMA) treatment based on a comparative effectiveness research (CER) study in patients with obesity.

METHODS: The underlying clinical inputs for this economic model were obtained from the CER study of TZP vs SEMA that included adults with a body mass index (BMI) of ≥30 kg/m^2 or ≥27 and <30 kg/m^2 with ≥1 obesity-related complication and without type 2 diabetes (T2D) initiating TZP or SEMA between Dec 2023 and June 2024. Patients were followed for 6 months and were required to adhere to initial treatment (proportion of days covered ≥80%). Mean absolute BMI and weight changes and proportions of patients achieving ≥5%, ≥10%, ≥15%, and ≥20% weight loss at 6 months were estimated using multivariable regression models weighted with propensity scores. Total annual health care costs at treatment initiation and at 6 months of treatment were projected for TZP and SEMA groups based on a previous study that estimated the causal relationship between BMI and annual total health care costs. Cost offsets were calculated by subtracting projected annual total health care costs at 6 months from that at treatment initiation. Treatment costs per responder and costs per pound lost were calculated as dividing drug treatment costs over 6 months (using wholesale acquisition cost) by % of patients achieving weight reduction response categories and by mean absolute weight reduction for TZP and SEMA groups, respectively.

RESULTS: The CER study included 1,003 TZP and 1,393 SEMA patients, with a mean (SD) age of 48.4 (12.2) and 49.1 (11.9) years, 69.9% and 73.2% female, and mean (SD) BMI of 38.3 (7.2) and 38.4 (7.1) kg/m^2, respectively. Annual total health care cost offsets post-treatment were projected to be $683 higher in TZP-treated patients ($3,037) than in SEMA-treated patients ($2,354). TZP was projected to incur lower treatment costs per pound lost than SEMA ($260 vs. $422) and lower treatment costs per responder than SEMA: ≥5% ($8,154 vs $11,502); ≥10% ($11,889 vs $23,463); ≥15% ($23,005 vs $65,662); and ≥20% ($62,705 vs $231,546).

CONCLUSIONS: Among adults with obesity without T2D, real-world TZP treatment for 6 months was projected to result in lower annual total health care costs and lower treatment costs per weight reduction responder and per pound of weight lost than SEMA.

SPONSORSHIP: Eli Lilly and Company

152 Leveraging clinical direct messaging to impact pharmacist-provider collaboration in diabetes management

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BACKGROUND: Diabetes currently affects 11% of adults in the United States. Incretin-based therapy has increased in popularity for effectively improving diabetes outcomes, by mimicking the incretin hormone used to regulate blood sugar. There are two diabetes drug classes that target this hormone: glucagon-like-peptide-1 receptor (GLP-1) and dipeptidyl peptidase–4 inhibitor (DPP-4). Despite their individual clinical benefit, when used concomitantly, there is only a marginal improvement due to similar mechanisms. The concurrent use of these two products has implications, including increased out-of-pocket costs for patients, extended administration time, and implications for the providers with additional monitoring. Pharmacists can aid with identifying and effectively communicating with providers to optimize diabetes therapy.

OBJECTIVE: To evaluate concomitant diabetes therapy through pharmacist-led outreach focusing on de-prescribing by communicating to providers using the electronic health record (EHR) to send clinical direct messages.

METHODS: This evaluation utilized 10 months of pharmacy claims from an Evernorth reporting platform. A pharmacist identified patients, who were on concomitant therapy of GLP-1 and DPP-4 medications with an overlapping supply of 30 days. Pharmacists outreached providers utilizing the EHR to send patient-specific messages along with medical literature supported rationale. Once messages were sent, providers responded to discuss the patients through the

EHR, phone, or fax. Success was determined by discontinuing either the GLP-1 or DPP-4 medication. The control group was defined by patients whose providers did not receive any form of communication from the pharmacist. Bivariate tests and multivariable logistic regression were used to assess the impact of the program on discontinuation.

RESULTS: We identified 371 patients through pharmacy claims that were concomitantly on GLP-1 and DPP-4 medications from January 2023 through October 2023. Of those, 96 patients' providers received a clinical direct message through the EHR, compared to 275 patients in the control group. Of those in the intervention group, 44.8% discontinued one of the drugs compared to 28% in the control ($P = 0.0025$). Multivariable logistic regression, controlling for age and gender, showed intervention group with a 1.9 increase in odds of discontinuing compared to controls ($P = 0.0132$).

CONCLUSIONS: Pharmacist-led outreach using clinical direct messaging demonstrates an effective way to communicate with providers on patient-specific information.

SPONSORSHIP: Express Scripts, an Evernorth Company

153 Pharmacist-led interventions in comprehensive medication management: Impact on 90-day post-discharge A1c levels

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BACKGROUND: Transitions of care (TOC) pose a significant risk for patients with poorly controlled diabetes, particularly those lacking access to timely outpatient follow-up. Pharmacists integrated into transitional care teams can address medication issues, reinforce self-management, and initiate and adjust therapy, bridging gaps until follow-up occurs. Through early intervention and ongoing support, pharmacists lay the groundwork for more efficient and effective visits and improve clinical outcomes.

OBJECTIVE: To compare glycemic control in recently hospitalized patients with poorly controlled diabetes (A1c >8%) discharged home, comparing those who received Comprehensive Medication Management (CMM) services versus those who did not. The primary goal was a 1.1% point A1c reduction within 90 days.

METHODS: Between October 2024 and April 2025, adults (≥18 years) with A1c >8%, a valid phone number, and a hospital-affiliated provider were enrolled after discharge. Pharmacists conducted up to six telehealth CMM visits over 90 days, identifying therapy gaps through patient consultation, provider collaboration, and record review. A driver diagram guided interventions, focusing on provider uptake, patient engagement, and follow-up. Descriptive statistics and paired t-tests were used.

RESULTS: As of April 2025, 96 patients enrolled in the treatment group; 60 completed at least one pharmacist visit and reached the full 90-day period, forming the evaluable cohort. Patients, on average, completed three visits; 75% completed three or more visits. The average baseline A1c was 10.73%. Among 40 patients with both baseline and follow-up A1c results, the average reduction was 2.6% points (SD: 2.34), a statistically significant change ($t = -7.03$, $P < 0.0001$), indicating meaningful glycemic improvement. Pharmacists made 131 recommendations for 53 patients (88%) to modify medication therapy. Of the 112 provider responses, 84% were accepted. At study completion, outcomes will be compared to a control group of recently discharged patients not enrolled in CMM.

CONCLUSIONS: Telehealth CMM by a pharmacist resulted in a statistically and clinically significant reduction in A1c within 90 days post-discharge in patients with poorly controlled diabetes. High provider acceptance and strong patient engagement support the model's feasibility. These findings highlight pharmacist-led care as a scalable solution to close transitional care gaps, optimize therapy, and improve outcomes. Future direction includes exploring delegation protocols to further expand pharmacist impact.

SPONSORSHIP: Scriptology/White Plains Hospital

154 The impact of vasomotor symptoms on women in the workplace in the United States of America: Results of an online survey

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BACKGROUND: Vasomotor symptoms (VMS), characterized by hot flashes and/or night sweats, affect up to 80% of women throughout their menopause transition and can impact midlife women's work experience and careers.

OBJECTIVE: To determine the impact of menopause-related VMS on women in the workplace, including the effect on work productivity, absence and exit, and the importance of support from employers.

METHODS: This was an online survey of women experiencing VMS. The study population was drawn using random

sampling from an existing large, national, US panel (Dynata). Inclusion criteria were women aged 40-65 years; currently experiencing VMS (≥2 hot flash/night sweat episodes per day in past 2 weeks); and currently employed or stopped working/retired within the last year and after VMS onset. Women who had participated in a clinical trial for treating VMS in the preceding 2 years or those with iatrogenic menopause/VMS were excluded.

RESULTS: Of approximately 180,000 invites, 16,551 respondents interacted with the survey. Post quality control, 1,011 respondents provided completed responses: mean (SD) age was 49.6 (6.4) years and most were White (72.9%) or Black/African American (18.3%). Respondents were employed full time (76.1%), part-time (16.6%), unemployed (5.0%), or retired (2.3%). Mean (SD) number of hot flashes/night sweats per day in the previous 2 weeks was 7.5 (11.1). Overall, 17.3% of total respondents either stopped working or reduced/considered reducing their work hours owing to VMS, with the estimates as high as 34.4% among those with high VMS severity. Mean (SD) absenteeism (percentage of work missed) and presenteeism (percentage of impairment while working) owing to VMS were 6% (15) and 32% (26), respectively. The most commonly reported coping mechanisms used at work were temperature control (71.0%) and wearing layered breathable clothing (46.0%). Employer support of VMS was strongly associated with all work satisfaction variables and emerged as one of the strongest predictors of employer and job satisfaction, with statistically significant positive effects across all categories of support. When asked how employers could better accommodate VMS, respondents most often cited temperature control (41.7%), flexible or remote work options (23.2%), increased VMS awareness (25.7%), and expanded benefits (27.9%); 42.3% reported they did not see a need for additional accommodations.

CONCLUSIONS: More severe VMS increased work exit, consideration of work exit, and absenteeism and decreased work productivity. Employer support strongly predicted work satisfaction.

SPONSORSHIP: Astellas Pharma Inc.

155 Cost-effectiveness analysis of somapacitan-beco versus somatropin in the treatment of patients with pediatric growth hormone deficiency (GHD) in the United States

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BACKGROUND: Growth hormone therapy is a critical intervention for patients with GHD that impacts clinical outcomes and overall costs. Pediatric GHD can be treated with an established once-daily GH (somatropin) or with a once-weekly GH such as the recently approved somapacitan-beco. Hence, there is a need to assess the economic impact of somapacitan-beco compared to established somatropin.

OBJECTIVE: To evaluate the cost-effectiveness of somapacitan-beco versus somatropin in the treatment of pediatric GHD in the United States.

METHODS: A Markov model was developed to evaluate the costs and clinical outcomes of somapacitan-beco relative to somatropin in the treatment of pediatric GHD. Model inputs, including drug efficacy, drug acquisition costs, and utility values, were estimated from publicly available data and literature. Drug acquisition costs for somatropin were based on Omnitrope. The incremental cost-effectiveness ratio (ICER) was calculated as the cost per quality-adjusted life-year (QALY) gained from a US payer perspective. Further, various scenarios for improvement of adherence rate of once-weekly GH vs once-daily GH were developed to assess the impact of adherence on somapacitan-beco cost-effectiveness.

RESULTS: The use of somapacitan-beco compared to somatropin resulted in an additional 0.21 incremental QALYs and $422,088 incremental costs with an ICER of ~$1.98M (million) per QALY gained in the base case. While somapacitan-beco had a slight drug administration–related utility gain, it was associated with marginal lower effectiveness in terms of maximum height gain and substantially higher drug acquisition costs compared to somatropin. Scenario outcomes for the improvement of adherence rate of once-weekly GH vs once-daily GH estimated that somapacitan-beco ICER ranges between $0.6M and $2.08M per QALY gain against somatropin.

CONCLUSIONS: Compared to somatropin, somapacitan-beco does not seems to be a cost-effective option for the treatment of pediatric GHD, even when considering adherence differences. The resulting ICER for somapacitan-beco was greater than ten times the commonly accepted willingness-to-pay (WTP) threshold of $150,000 per QALY.

SPONSORSHIP: Sandoz Inc (Omnitrope is a product of Sandoz)

156 Three-year real-world adherence and persistence to glucagon-like peptide-1 receptor agonists among commercially insured adults with obesity without diabetes

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BACKGROUND: Real-world evidence has found most patients without diabetes newly initiating GLP-1 drug therapy for weight loss discontinue within the first two years. Little is known of the long-term GLP-1 obesity treatment adherence and persistency.

OBJECTIVE: To measure adherence and persistence to obesity GLP-1 therapy at the end of 3 years of follow up in a real-world cohort of non-diabetic commercially insured members.

METHODS: Prime Therapeutics' integrated pharmacy and medical claims data from an average of 16.5 million commercially insured lives were used to identify members without diabetes newly initiating GLP-1 obesity treatment between 1/1/2021 and 3/31/2022 (index date period). GLP-1 new initiation was defined as no GLP-1 claim in the 365 days prior to the member's first GLP-1 found in the index period (pre-period). Study inclusion was limited to members with continuous enrollment, meaning no more than a total of 15 days without enrollment in the pre-period and each year in the three-year post-period and no GLP-1 drug claim in the pre-period. During the pre-period, members were required to have a medical claim indicating obesity without a diabetes diagnosis or diabetes drug claim and aged 19 years or older. Adherence was measured as the proportion of days covered (PDC) in the post-period and members with a PDC ≥80% considered adherent. Persistence was measured as no ≥60-day gap between a claim days' supply ending and a subsequent claim fill date in the post period. GLP-1 product switching was allowed during the assessment period and switch rates were descriptively assessed.

RESULTS: Among the 10,292 obese members without diabetes with a GLP-1 claim during the index date period, 5,781 (56.2%) were continuously enrolled in the 3-year post-period. The mean age was 46.7 years and 79.9% were female. Overall GLP-1 persistency was 8.1% at 3 years. The highest and lowest persistency rates at three years were observed for weekly semaglutide (14.3%; Wegovy) and daily liraglutide (2.5%; Victoza), respectively. Average GLP-1 PDC over 3 years was 37.5%, with 12.5% of members adherent and 32.9% switching GLP-1 drugs.

CONCLUSIONS: Three-year GLP-1 weight-loss treatment persistence was poor, with 1 in 12 members remaining on therapy. These findings highlight GLP-1 therapy investment risk due to poor persistence leading to unachieved clinical benefits for members who initiated in 2021 and early 2022. Obesity care management programs and value-based contracts from pharmaceutical manufacturers may help mitigate financial risk.

SPONSORSHIP: Prime Therapeutics, LLC

157 Trends in real-world persistence to weight loss glucagon-like peptide-1 receptor agonists from 2021 to 2024 among commercially insured adults without diabetes

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BACKGROUND: Despite substantial weight loss with glucagon-like receptor agonist (GLP-1), real-world persistence remains a challenge. Since 2021, GLP-1 shortages and changes in product availability have complicated access and persistence. This study examines the weight-loss GLP-1 products semaglutide (Wegovy) and tirzepatide (Zepbound) treatment persistence at one year, stratified by year of initiation.

OBJECTIVE: To evaluate one-year semaglutide (Wegovy) and tirzepatide (Zepbound) treatment persistence among commercially insured members without diabetes, by year of initiation.

METHODS: Prime Therapeutics' integrated pharmacy and medical claims data from an average monthly membership of 16.5 million commercially insured individuals were used to identify members without diabetes who newly initiated weight-loss GLP-1 treatment between January 1, 2021, and March 31, 2024 (index date period). Study inclusion was limited to members with continuous enrollment, defined as having no more than a total of 15 days of enrollment gaps in each 365-day study period, and no GLP-1 drug claim in the 365 days prior to index. Members were excluded if they had a pre-period medical claim indicating a diabetes diagnosis or diabetes drug claim and younger than 19 years of age at index. Persistence was measured as no ≥60-day gap between the end of a claim's days' supply and the subsequent claim fill date in the 365-day period following index. GLP-1 product switching was allowed.

RESULTS: Among the 43,427 members without diabetes newly initiating a GLP-1, 23,025 (53.0%) met full study criteria. The mean age was 46.3 years, and 76.7% were female. Across the index years, weight-loss GLP-1 persistence across all products increased from 33.2% in 2021 to 62.6% in 2024. Semaglutide one-year persistence rates from 2021 to

2024 were 33.2%, 34.1%, 40.0%, and 62.7%. For tirzepatide, one-year persistence rates in 2023 and 2024 (the only years the product was available) were 64.0% and 62.2%.

CONCLUSIONS: This real-world analysis of weight loss GLP-1 products among individuals without diabetes found one-year treatment persistence has nearly doubled from 33.2% in 2021 to more than 60% in 2024. Weight loss GLP-1 shortages resolved in 2023 and likely explain the improved persistence. Other potential explanations include improved GLP-1 dose escalation and side effect management, as well as lifestyle management programs. Additional research is needed to understand reasons for treatment discontinuation and the long-term cost-effectiveness of these products.

SPONSORSHIP: Prime Therapeutics, LLC

158 Understanding GIP/GLP-1 treatment dynamics: Switching and re-initiation in Medicare Advantage beneficiaries

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BACKGROUND: Despite growing use of glucose-dependent insulinotropic polypeptide and glucagon-like peptide-1 receptor agonists (GIP/GLP-1 RA) for type 2 diabetes and obesity, persistence to initial therapy remains low. Among older adults, real-world data on treatment progression is limited. Drug shortages and the perceived clinical benefits of newer agents may further drive movement between GIP/GLP-1 RA agents.

OBJECTIVE: To describe treatment progression between GIP/GLP-1 RA agents, including switching and re-initiation patterns, among Medicare Advantage beneficiaries over 1-year follow up.

METHODS: This retrospective cohort study used the Humana Research Database to identify patients who newly initiated semaglutide, tirzepatide, or other GLP-1 RAs (dulaglutide, liraglutide, exenatide) in 2023 (first prescription = index). Treatment progression was defined as any post-index prescription for a different GIP/GLP-1 RA agent. We described the proportion who switched between GIP/GLP-1 RA agents, those who reverted to their original treatment, and the duration of use on each therapy.

RESULTS: Among 77,745 new GIP/GLP-1 RA users in 2023, 62.4% started on semaglutide (mean age: 67.4 years; 62% female), 20.7% on tirzepatide (mean age: 66.2 years; 62% female), and 16.9% on other GLP-1 RAs (mean age: 68.3 years; 57% female). Semaglutide initiators had an average duration on therapy of 4.7 months and 6.9% switched to tirzepatide. Following a mean of 4.1 months on tirzepatide, 11.4% re-initiated semaglutide. Tirzepatide initiators had an average duration on therapy of 4.6 months and 10% switched to semaglutide. Following a mean of 3.5 months on semaglutide, 22.1% re-initiated tirzepatide. Switching to other GLP-1-RAs from semaglutide (2.2%) or tirzepatide (1.9%) was less common, but patients had high rates of re-initiation of index therapy (18.6% for semaglutide, 20.5% for tirzepatide). Patients who initiated other GLP-1-RAs had higher rates of switching to both semaglutide (12.5%) and tirzepatide (7.3%) and longer mean duration on therapy following the switch but lower rates of returning to index therapy (5.3%-7.2%) compared to the other cohorts.

CONCLUSIONS: Switching between GIP/GLP-1 RA agents was common. Tirzepatide and semaglutide initiators who switched therapies had a high rate of index therapy re-initiation, indicating that patients may have substituted an available GIP/GLP-1 RA therapy during ongoing drug shortages. Further research can explore underlying factors for switching behaviors and their impact on patient outcomes.

SPONSORSHIP: None

159 Comparing the effects of glucagon-like peptide-1 receptor agonists and sodium-glucose cotransporter-2 inhibitors on the incidence of neuropathy in patients with type 2 diabetes

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BACKGROUND: Diabetic neuropathy is a common complication of type 2 diabetes (T2D) affecting up to 50% of these individuals during their lifetime. While the cardiovascular and renal benefits of glucagon-like peptide-1 receptor agonists (GLP-1RAs) and sodium-glucose cotransporter-2 inhibitors (SGLT2is) have been well established, few studies have compared neuropathy-specific outcomes between these drug classes. As a result, their role in preventing diabetic neuropathy remains unclear.

OBJECTIVE: To compare the effects of GLP-1RAs and SGLT2is on the onset of neuropathy in patients with T2D.

METHODS: A retrospective cohort study was conducted using de-identified electronic health record (EHR) data from the University of Pittsburgh Medical Center from March 2013 to August 2023. The study included new users of GLP-1RAs or SGLT2i's with baseline HbA1c ≥6.5% and no prior diagnosis of neuropathy within 1 year before index date (first date of GLP-1RA or SGLT2i ordered on or after March 2014). Patients with <1 year of pre-index EHR data and those exposed to both drug classes in the follow-up period were excluded. The primary outcome was diagnosis of neuropathy identified by ICD-9 or ICD-10 codes from any visit type. Patients were followed from index until the earliest of neuropathy diagnosis, 2 years post-index, 90 days after the last GLP-1RA or SGLT2i

medication order date, or death. GLP-1RA and SGLT2i groups were matched using 1:1 propensity score matching (PSM) on demographics and baseline HbA1c, body mass index, antidiabetic medication use, and clinical conditions. Extended Cox model with time-varying coefficients, restricted mean survival time (RMST), and restricted mean time loss (RMTL) analyses were conducted to compare time to neuropathy incidence between GLP-1RAs and SGLT2is.

RESULTS: After PSM, 1,790 of the 12,423 eligible patients (1,791 SGLT2i and 10,632 GLP-1RA users) remained in each arm. RMST analysis estimated that over 2 years, GLP-1RA users had an average of 718.8 neuropathy-free days vs 700.8 days in SGLT2i users, with a difference of 18 days favoring GLP-1RA users (95% CI = 10.1-26.0 days, $P < 0.0001$). The Cox model with time interaction resulted in a positive treatment × log(time) interaction coefficient ($P < 0.0001$), suggesting that the difference in protective effect between GLP-1RAs and SGLT2is narrowed over time.

CONCLUSIONS: Our study suggests that GLP-1RAs may offer modest protective benefits against the development of neuropathy compared to SGLT2i in patients with T2D. Future research should validate these findings with longer follow-up and more refined characterizations of neuropathy.

SPONSORSHIP: None

160 Trends in characteristics and anti-obesity medication use among US employees in the era of glucagon-like peptide-1 receptor agonists (GLP-1 RAs)

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BACKGROUND: Obesity rates in the United States are substantial and increasing over time. The Centers for Disease Control (CDC) reports a 40% US prevalence of obesity between 2021 and 2023. Obesity is associated with many comorbid conditions, accounting for ~16.5% of all health expenditures, and poses a significant burden on the US healthcare system. The introduction of glucagon-like peptide-1 receptor agonists (GLP-1 RAs) may have affected trends in use and costs associated with obesity therapy.

OBJECTIVE: To understand trends in obesity diagnoses (Dx), comorbid conditions, pharmacotherapy (including GLPI-RA medications), and related costs among US working-age employees.

METHODS: Retrospective analysis of Workpartners Research Reference Database (RRDb) of US employees from all 50 states from 2001 to present. Employee patients were identified as obese if they had medical claims with ICD-10 codes for obesity (E66) between 2016 and 2022. Patients were also included if they had a prescription claim for a drug indicated only for treatment of obesity (orlistat, phentermine, phentermine-topiramate, naltrexone-bupropion, or a weight loss–approved GLP-1 RA) with first prescription date as the index date for obesity diagnosis. Trends in comorbidities, medical, total prescription, and obesity-prescription costs were examined based on paid claims. Absence and short-term disability days were examined based on employer human resource data. Costs inflation adjusted to December 2023.

RESULTS: From 2016 to 2023, there were 127,408 employees with an obesity diagnosis; prevalence increased from 11.5% in 2020 to 16.9% in 2023 with mean age 44.6 years and 56.7% female. Study employees had low Charlson Comorbidity Index scores, mean 0.51 (range 0.46-0.58). Rates of comorbid conditions remained stable over time for T2DM (11.3%-16.1%), cardiovascular disease (4.4 to 5.3%), chronic kidney disease (1.4% to 1.7%), sleep apnea (12.4% to 14.7%) and NASH (0.25% to 0.43%). Patients had a mean of 5.9 drug classes prescribed each year, with $2,687 mean total prescription costs (range $2,198-$3,862). The uptake of GLP1-RAs among employees with obesity increased yearly, (3.6% in 2016; 18.3% in 2023) and contributing substantially to annual drug costs (~30% by 2023). However, medical costs and work-related costs remained stable with time. Overall GLP1-RA persistence was 78% in the year following the index year.

CONCLUSIONS: The uptake of GLP1-RAs for obesity has increased substantially since their initial approval, but their impact on medical and work-related costs are yet to be realized.

SPONSORSHIP: None

161 Benchmarking GLP-1 patient access across products using a comprehensive score derived from real-world pharmacy claims

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BACKGROUND: GLP-1 receptor agonists have seen significant uptake for the management of type 2 diabetes and obesity, yet disparities in patient access persist across products. These disparities may result from differences in benefit design, payer management, and manufacturer patient support programs. This analysis developed a comprehensive Patient Support Access Score (PSAS) to quantify access score, which can help payers, providers, and manufacturers understand relative strengths and gaps in patient support and access services.

OBJECTIVE: To develop and validate a comprehensive PSAS that quantifies and ranks products based on real-world access barriers and to evaluate the correlation between access scores and patient persistence outcomes.

METHODS: This retrospective analysis utilized anonymized claims data, covering the period from Jan 2024 to Apr 2025. Six key access-related metrics were extracted: Rx written rate, time to first fill, patient out-of-pocket costs, paid claims rate, PA denial rates, and copay card utilization. Each metric was normalized and weighted based on stakeholder-assigned importance (weights ranging from 5% to 24%). A comprehensive PSAS ranging from 1 to 100 was calculated (higher = better access). Products were ranked and compared using descriptive statistics, trend analyses, and multivariable regression models adjusting for patient demographics, comorbidities, and insurance type.

RESULTS: Across 11 GLP-1 products analyzed, PSAS ranged from 40 to 77, demonstrating significant variability ($P < 0.01$). Top-performing products showed higher paid claim rates (71%) and copay card utilization (6%), while lower-performing ones exhibited longer time to first fill (mean: 9 days) and higher denial rates due to prior authorization (PA) (40%). Commercial plans had better access metrics compared to Medicare.

CONCLUSIONS: The PSAS successfully identified significant variation in patient access support across GLP-1 products. Products with comprehensive patient assistance programs, lower denial rates due to PA, and effective copay support achieved superior access scores. This standardized metric provides managed care decision-makers with an objective tool for formulary evaluation and benefit design optimization. Implementation of PSAS-based formulary strategies could improve patient access while maintaining cost-effectiveness in GLP-1 diabetes and obesity management.

SPONSORSHIP: Syneos Health

162 Preliminary associated characteristics of the top 10% of GLP-1 spenders in a self-insured health plan

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BACKGROUND: The utilization of GLP-1 therapies has increased substantially in recent years, resulting in a sharp rise in medication costs for health plans. Identifying characteristics of the top spenders on GLP-1 drugs may support strategic planning for cost control within this drug class.

OBJECTIVE: To determine the characteristics associated with the top 10% of GLP-1 spenders in a large, self-insured health plan.

METHODS: A self-insured commercial health plan covering over 18,000 members, primarily in Western states, was analyzed. The study included all GLP-1 pharmacy claims from 01/01/2024 to 12/31/2024. Top spenders were defined as the top 10% of members based on total plan-paid costs for GLP-1 therapies. Statistical comparisons between top and non-top spenders were conducted across age, gender, GLP-1 utilization patterns, diagnosis (based on ICD-10 codes), comorbidities (hypertension and hyperlipidemia), and appropriateness of use. Logistic regression was performed on selected variables to identify predictors of high spending.

RESULTS: A total of 761 unique GLP-1 users were identified, generating a total GLP-1 cost of $4,493,990. The top 10% (77 members) accounted for $965,226.30 in plan-paid costs. Compared to non-top spenders, top spenders were significantly older, had more claims and days supplied, had more comorbidities, were more likely to have hyperlipidemia, and were more likely to use Mounjaro and Wegovy but less likely to use Zepbound ($P < 0.01$). Logistic regression indicated that being older than 50 years and using Wegovy or Mounjaro were strong positive predictors of being in the top 10%. Use of Zepbound was associated with a 77% lower likelihood of being a top spender.

CONCLUSIONS: This study identified key characteristics of the top 10% of GLP-1 spenders: older age, use of Wegovy and Mounjaro, and lack of Zepbound use. Targeted educational and strategic initiatives may help control costs and improve outcomes. These findings are limited to one large, self-insured commercial plan; broader studies are needed to generalize the results.

SPONSORSHIP: MedImpact Healthcare Systems, Inc.

163 Characteristics associated with being adherent in patients experiencing late refills before and after the implementation of a refill reminder program

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BACKGROUND: Pharmacy benefit managers (PBMs) are tasked with improving member engagement and promoting medication adherence. Refill reminder programs can increase members' likelihood of refilling their medications and maintaining their health.

OBJECTIVE: To evaluate the association of various plan member characteristics and the outcome of having a proportion of days covered (PDC) greater than 80% (adherent) for three medication classes—diabetes (DM), hypertension (HTN), and statins—in four Medicare Part D health plans with populations of less than 3,000.

METHODS: Two cohorts for calendar years 2023 and 2024 were identified. Members had to be eligible in both years, filled refill reminder target drugs (once in the first and last halves of the calendar year), and have one late claim within a target drug group in the first six months of the year. Descriptive statistics and general linear regression for a binary outcome was used to model the odds of being adherent with member characteristics (year, age at study midpoint, sex, month of first late refill, drug class, use of multiple drug classes, use of 90-day supplies, total annual late refills, and total annual late refills refilled).

RESULTS: A total of 3,006 members were included in the study. Total nonadherent members were 233 (14.6%) in 2023 and 189 in 2024 (13.4%) (*P* value 0.3103). Characteristics with increased odds of being adherent included having the first late refill in February or March (OR 5.89, *P* value 0.0012; OR 2.14, *P* value 0.0093) and being in year 2024 and in the DM drug group (OR 1.84, *P* value 0.0437). Being female and in the DM drug group (OR 0.51, *P* value 0.0337) and being in the DM drug group and in more than one drug group (OR 0.23, *P* value 0.0305) had decreased odds of adherence. Having an increasing number of late claims and in the DM drug group (1.36, *P* value 0.0032) or using 90-day supplies (2.22, *P* value 0.0009) had increased odds of being adherent, while having an increasing number of late claims and an increasing number of late claims refilled had decreased odds of being adherent (0.9, *P* value < 0.0001).

CONCLUSIONS: Being adherent involves complicated factors related to the individual's unique characteristics. In this study refilling late medications, being on multiple drug groups, and using 90-day supplies were associated with increased odds of being adherent. Being in the 2024 cohort and being on a DM medication also had increased odds of adherence. Further research is needed to explore the effects of the refill reminder program on adherence in similar populations.

SPONSORSHIP: MedImpact Healthcare Systems, Inc.

Eye (or Ophthalmic)

170 A novel low-dose atropine eye drop slows the progression of pediatric myopia: Evidence from the STAR study

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BACKGROUND: Pediatric myopia is a chronic, progressive disease affecting an estimated 27 million children in the United States. Earlier-onset cases are associated with faster progression to moderate or severe myopia and greater risk of complications, including retinal detachment, myopic maculopathy, and glaucoma. There are currently no FDA- approved pharmacologic treatments to slow myopia progression in children, underscoring the need for evidence-based strategies that address the underlying disease process and reduce comorbidities.

OBJECTIVE: To evaluate long-term myopia progression and treatment outcomes in children enrolled in the STAR study who were treated for 3 years with a novel low-dose atropine formulation.

METHODS: STAR is a 36-month, multicenter, randomized, double-masked, vehicle-controlled study evaluating SYD-101, an investigational low-dose atropine eye drop formulation, in children aged 3-14 years with myopia between -0.50 and -6.00 diopters (D). A total of 847 participants were randomized 1:1:1 to receive 0.01%, 0.03%, or vehicle, administered nightly in both eyes. Safety was assessed through standard ocular examinations and patient-reported tolerability questionnaires.

RESULTS: Among 847 randomized participants, significantly fewer children treated with 0.01% experienced myopia progression worse than -0.75 diopters (D) over 36 months (primary endpoint) compared with those receiving vehicle ($p = 0.0226$) in the ITT population. Treatment effects were observed as early as Month 12 and were sustained through Month 36. Mean myopic annual progression rate at Month 36 (secondary endpoint) was significantly less in the 0.01% treated group compared with that in the vehicle group ($p = 0.0002$) and time-to-progression of worse than -0.75D at Month 36 was also significantly reduced ($p = 0.007$). Additional sub-groups demonstrated even greater benefits from SYD-101. The treatment was well tolerated, with no unexpected adverse events reported.

CONCLUSIONS: Pediatric myopia progresses predictably and increases the risk of irreversible ocular complications. In a large, diverse population, data from the STAR study demonstrate statistically significant and clinically meaningful benefits from treatment with SYD-101. These data support the need for early disease-modifying treatment and may help inform future payer considerations, pending regulatory review of SYD-101. SYD-101 is investigational and not approved by the U.S. Food and Drug Administration.

SPONSORSHIP: Sydnexis, Inc.

171 Real-world prescription drug treatment patterns in patients with dry eye disease

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BACKGROUND: Dry eye disease (DED) is a prevalent ocular condition characterized by discomfort, visual disturbance, and ocular surface damage. While the treatment landscape has expanded beyond immunomodulators to include newer therapeutic classes such as anti-evaporatives and neuromodulators, significant unmet needs remain. Real-world data on treatment persistence, adherence, and class-switching behavior remain limited.

OBJECTIVE: To describe real-world treatment patterns among patients with DED and evaluate patient demographics, treatment behaviors, and switching patterns across therapeutic classes.

METHODS: A retrospective analysis of dry eye disease (DED) patients used Symphony Health Solutions claims data (2018-2024). Patients were identified by prescriptions for immunomodulators (Restasis, Xiidra, Cequa, Vevye, ophthalmological cyclosporines), anti-evaporatives (Miebo), neuromodulators (Tyrvaya), or ≥2 DED diagnosis claims (ICD-10 HO4.12). The index date was defined as the first prescription or diagnosis date, with 24 months of continuous data required (12 months before and after index). Switching patterns were analyzed in monotherapy patients. Persistence (Kaplan-Meier methods) was assessed in single-line therapy patients, while adherence (medication possession ratio, MPR) was analyzed in single-line patients with ≥2 first-line prescriptions. Adherence was defined as MPR ≥ 80%.

RESULTS: A total of 3,440,818 patients with dry eye disease (DED) were identified; 73% were female and 27% male, with a mean age of 62.6 years (SD 14.3). As first-line treatment, 98.2% received immunomodulators, 1.4% neuromodulators, and 0.4% anti-evaporatives. At 90 days post-index, 75% of patients or more had discontinued treatment in each of the three treatment classes. Among the 10.8% who switched to second-line therapy, 82.9% switched within the immunomodulator class, 1.8% switched to immunomodulators, 8.3% switched to anti-evaporatives, and 7.0% to neuromodulators. Adherence (MPR ≥80%) was 33.9% (immunomodulators), 49.5% (anti-evaporatives), and 54.9% (neuromodulators).

CONCLUSIONS: High discontinuation rates and limited switching across therapeutic classes underscore the need for more durable and diverse treatment options in DED management. The relatively low adherence across all classes suggests that current therapies may not adequately meet patient needs. Emerging treatments may enhance treatment persistence by addressing underlying factors contributing to discontinuation.

SPONSORSHIP: Alcon

172 Two-year real-world clinical outcomes in patients with diabetic macular edema treated with faricimab in the United States: The FARETINA-DME study

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BACKGROUND: Limited real-world evidence on patients with DME, their treatment patterns, and clinical outcomes with novel therapeutic agents.

OBJECTIVE: To describe outcomes in DME patients treated with faricimab (FAR) who were either treatment naive or previously treated with another anti–vascular endothelial growth factor (aVEGF) agent.

METHODS: FARETINA-DME is a retrospective study using electronic health record (EHR) data from US ophthalmology practices contributing to the American Academy of Ophthalmology IRIS Registry (Intelligent Research in Sight). Patients with DME who initiated FAR treatment between Feb and Sep 2022, had ≥12 months of EHR data prior to FAR initiation, and had known laterality were considered in the initial cohort. Patients with ≥24 months of follow-up and ≥2 best corrected visual acuity (BCVA) measures were included in the analyses.

RESULTS: A total of 953 patients (1,254 eyes) with DME had 2 years of treatment with FAR. One hundred fifty-seven eyes were aVEGF treatment naive. Among the 838 patients (1,097 eyes) who were previously treated, 601 eyes were treated with aflibercept 2 mg (AFL) and 54 eyes were treated with bevacizumab (BEV) prior. The AFL prior cohort injection intervals increased by 12 days through FAR injection 8, while the BEV prior cohort intervals increased by 11 days through FAR injection 8. VA remained stable in both cohorts. In treatment-naive eyes, mean (standard deviation [SD]) VA at baseline was 60.4 (19.8) letters and improved to 63.1 (21.6) letters at 24-month follow-up. In previously treated eyes, mean (SD) VA at baseline was 65.0 (17.5) letters and remained stable at 64.4 (20.1) letters at 24-month follow-up. A decreasing trend in mean (SD) number of FAR injections in the first vs second half of year one was noted (4.1 [1.4] vs 2.1 [1.8] for treatment-naive eyes and 4.1 [1.3] vs 2.8 [1.6] for previously treated eyes). Further decrease was noted in the first vs second half of year two (1.8 [1.7] vs 1.6 [1.6] for treatment-naive eyes and 2.3 [1.5] vs 2.2 [1.6] and for previously treated eyes). Safety profile of FAR was consistent with the overall safety of the phase 3 clinical trials.

CONCLUSIONS: In this real-world study of 2 years FAR treatment, vision improved in treatment-naive eyes and remained stable in previously treated eyes. Eyes that were previously treated with AFL or BEV were able to extend further following FAR initiation. There were fewer FAR injections observed in year 2, suggesting further treatment interval extension and decreased injection burden for patients. These findings support the real-world effectiveness, safety, and durability of FAR for treatment of DME.

SPONSORSHIP: Genentech, Inc

173 Payer-identified practice gaps and educational needs in the management of retinal diseases: Improving outcomes with streamlined referral to specialists and earlier access to treatments

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BACKGROUND: Anti–vascular endothelial growth factor (anti-VEGF) therapies are considered first-line treatment in the management of retinal diseases such as age-related macular degeneration (AMD) and diabetic retinopathy (DR). Many current payer coverage policies include a step therapy protocol requiring a first-line trial of off-label bevacizumab prior to accessing FDA-approved anti-VEGF agents. Payers may benefit from medical education to continuously improve coverage policy and utilization management interventions.

OBJECTIVE: To assess payer-perceived practice gaps and educational needs in the management of retinal diseases and identify opportunities for improved access and outcomes.

METHODS: Two surveys were distributed by Impact Education, LLC, to managed care professionals regarding educational needs in the management of AMD (n = 28) and DR (n = 45) in January 2025. Results were compiled and compared to assess payer-perceived gaps in knowledge and practice.

RESULTS: Delayed referral to retinal specialists was the most common reported deviation from standard of care in both AMD (64%) and DR (56%). Earlier access to FDA-approved anti-VEGF agents in patients affected by social determinants of health was the most frequently chosen gap in patient access that needed to be addressed for both AMD (64%) and DR (58%). For AMD, the next most cited gap was the need to remove prior authorization to access formulary preferred bevacizumab (46%); while for DR, it was the need for earlier access to FDA-approved anti-VEGFs for patients based on disease severity (51%). Excessive documentation to meet prior authorization criteria was ranked as the most prominent barrier to high-quality retinal disease management in both disease states (average rank: 2.0). Payers cited improved efficacy as the most valuable attribute of FDA-approved anti-VEGF agents over bevacizumab in both disease states (AMD average rank: 2.2; DR average rank: 1.8). Greater durability of treatment effect was the next most valuable attribute for both disease states (average rank: 2.6 for both).

CONCLUSIONS: Managed care professionals identified consistent gaps in timely referral, access to FDA-approved anti-VEGF therapies, and burdensome PA processes across both AMD and DR. These findings point to opportunities for targeted policy refinement and streamlined utilization management strategies for anti-VEGF agents.

SPONSORSHIP: Regeneron Pharmaceuticals, Inc.

174 Real-world glaucoma prescription adherence patterns in Medicare fee-for-service patients with comorbid dry eye disease

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BACKGROUND: Open-angle glaucoma (OAG) is a chronic degenerative disease that can lead to progressive vision loss if untreated. Patient adherence to glaucoma medications is critical in preserving vision. Dry eye disease could impact adherence to glaucoma medications, potentially worsening outcomes.

OBJECTIVE: To identify open-angle glaucoma OAG prescription adherence patterns among patients with dry eye disease (DED).

METHODS: 100% Medicare FFS Parts A/B/D claims (January 2016-June 2022) were used to identify OAG patients aged ≥65 years with incident DED. Patients with more than one diagnosis or prescription for DED within 6-months of the OAG diagnosis or treatment during January 2017 to June 2020 were included in the study sample. Index date was the earliest DED diagnosis or treatment during the 6-month period following OAG identification. Patients were continuously enrolled for a 12-month pre- and 24-month post-index period. Patients were excluded if they had any other diagnosed forms of glaucoma, a DED procedure, or pre-index diagnosis or prescription for DED. Comorbid conditions were identified in the 12-month pre-index period. Medication adherence was described over 2 years using group-based trajectory modeling (GBTM).

RESULTS: After applying all the attrition criteria, 98,453 OAG-DED patients were identified. Cataract (35%) and neovascular age-related macular degeneration (12%) were the most common ocular comorbidities observed. Most patients were female (65%) and Caucasian (79%), with mean (SD) age of 78.3 (8.7). Of the full sample, 66,097 (67.1%) patients had one or more OAG prescriptions within 90 days of index and were therefore used in GBTM modeling. The GBTM identified five distinct adherence patterns. Twelve percent of OAG-DED patients were highly adherent (mean 2-year PDC = 93%), 15% were partially adherent (PDC = 70%), 26% had plateauing adherence (PDC = 55%), 10% had rapid decline (PDC = 34%), and 37% were non-adherent (PDC = 17%). OAG prescription adherence varied in patients with overall PDC of 66.4%.

CONCLUSIONS: Only 12% patients with DED were adherent and approximately 15% were partially adherent to their OAG prescription medication through 2 years of follow-up. A significant proportion of OAG-DED patients (73%) had declining adherence to their OAG prescription medications over the 2-year period. Significant variation exists in OAG medication adherence for patients with comorbid dry eye, showing decline in all groups over the two-year period.

SPONSORSHIP: Bausch and Lomb Americas Inc.

Gastrointestinal

182 Real-world economic burden of biliary atresia in infants younger than 1 year: A US claims-based analysis

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BACKGROUND: Biliary atresia (BA) is a rare, progressive pediatric liver disease requiring early intervention to prevent irreversible liver damage. Without timely Kasai portoenterostomy (KP), many patients progress to liver failure, with BA accounting for approximately one-third of pediatric liver transplantations (LT) in the United States.

OBJECTIVE: To evaluate the health care resource utilization (HCRU) and direct medical costs associated with BA in commercially insured infants in the United States who were younger than 1 year and received KP.

METHODS: A retrospective cohort analysis was conducted using Merative MarketScan Commercial Database data from 2016 to 2023. Infants with a first observed diagnostic claim of BA (index date) during their birth year and a claim for KP were included. LT rates and time-to-procedure intervals were assessed using unrestricted follow-up. HCRU and cost outcomes were evaluated descriptively per patient per year (PPPY) within the 12-month post-index period.

RESULTS: Among 72 infants (53% female), a total of 21 (29%) progressed to LT. The median follow-up was 1.24 years (interquartile range [IQR]: 0.42-3.20) for the KP-only cohort and 2.02 years (IQR: 1.56-3.79) for those who received both KP and LT (KP + LT cohort). Median time from index to KP among infants who underwent KP only (n = 51) was 2 days (IQR: 0-7). Among infants who underwent both KP + LT (n = 21), the median time from index to KP was 0 days (IQR: 0.0-1.0) and time from KP to LT was 274 days (IQR: 149-367).

Compared with the KP only cohort, infants in the KP + LT cohort experienced higher mean numbers of inpatient admissions (3.05 vs 1.73 PPPY) and outpatient visits (64.71 vs 21.94) during the 12 months post-index. The KP + LT cohort also demonstrated modestly higher intensive care unit (1.14 vs 0.45) and emergency department (ED) utilization (2.00 vs 1.04). Median total all-cause costs PPPY were $123,264 (IQR: $49,184-$248,297) for the KP-only cohort and $412,820 (IQR: $101,344-$739,121) for the KP + LT cohort. Median inpatient costs per visit were $61,655 (KP only) and $100,571 (KP + LT). Outpatient and ED per-visit costs were also elevated in the KP + LT cohort.

CONCLUSIONS: This study highlights the substantial burden of care among infants with BA, greatest among those with suboptimal outcomes post-KP leading to LT, and underscores the unmet need for disease-modifying therapies. Additionally, persistently high costs driven by hospitalizations suggest that coordinated care pathways and targeted interventions may improve patient outcomes and reduce economic impact.

SPONSORSHIP: Ipsen

183 Impact of COVID-19 on non–COVID-related treatment patterns and outcomes in patients with inflammatory bowel disease (IBD)

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BACKGROUND: The COVID-19 epidemic disrupted health care delivery and access to non–COVID-related care globally.

OBJECTIVE: To determine the effect of COVID-19 restrictions on treatment patterns, COVID vaccination rates, and outcomes among patients treated with advanced therapies for IBD.

METHODS: Adult patients diagnosed with Crohn disease (CD) or ulcerative colitis (UC) were identified in PearlDiver's Mariner170 claims database. Included patients were treated with advanced therapy (adalimumab, certolizumab, golimumab, infliximab, vedolizumab, ustekinumab, etanercept, rituximab, natalizumab, baricitinib, or tofacitinib) between 2018 and 2022. Rates of COVID vaccination visible in claims (ICD-10-P-XW013S6, ICD-10-P-XW013T6, ICD-10-P-XW013U6, ICD-10-P-XW023S6, ICD-10-P-XW023T6, ICD-10-P-XW023U6, CPT-0001A, CPT-0002A, CPT-0003A, CPT-0011A, CPT-0012A, CPT-0013A, CPT-0031A) COVID infection (ICD-10-D-U071), changes in IBD treatment patterns, and IBD-related hospitalizations were evaluated by calendar year. Patients were matched using propensity scores 1:1 with individuals with no history of IBD diagnosis (controls).

RESULTS: A total of 143,806 patients (58% female) with IBD were included. Overall, patients with IBD were more likely to receive a COVID-19 vaccine (5.4%) vs controls (2.6%). COVID-19 infection rates were higher in the IBD population (13.0%) vs controls (9.2%). From 2018 to 2022, adalimumab was the most common treatment (38.6%), followed by ustekinumab (17.9%), infliximab (3.7%), certolizumab (2.9%), and tofacitinib (2.7%). Adalimumab use declined from 44.7% in 2018 to 35.9% in 2022, and certolizumab use declined from 3.9% (2018) to 2.5% (2022); however, ustekinumab use increased from 10.0% (2018) to 27.9% (2022), and tofacitinib, one of the only orally administered options, use increased from 1.4% (2018) to 3.0% (2022). Non-COVID hospitalizations decreased from 13.8% in 2019 to 13.3% in 2020, 12.5% in 2021, and 10.4% in 2022.

CONCLUSIONS: We observed higher COVID-19 vaccination and infection rates among patients with IBD. Non-COVID hospitalizations decreased from 2018 to 2022. Adalimumab was most utilized, but its use decreased over time. Ustekinumab use increased over the same period.

SPONSORSHIP: Biologics and Biosimilars Collective Intelligence Consortium (BBCIC)

184 Real-world health care resource utilization and costs among 100% fee-for-service Medicare beneficiaries with metabolic dysfunction–associated steatohepatitis

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BACKGROUND: The health care burden of metabolic dysfunction–associated steatohepatitis (MASH) among Medicare beneficiaries remains under-documented.

OBJECTIVE: To estimate all-cause health care resource utilization (HCRU) and costs among Medicare fee-for-service (FFS) beneficiaries with diagnosed MASH vs those without diagnosed MASH.

METHODS: This observational study utilized 100% Medicare FFS claims to assess HCRU and costs associated with MASH among those ≥66 years of age from Jan 1, 2016, to Dec 31, 2022. The MASH cohort included those with ≥1 ICD-10-CM diagnosis code of K75.81. The non-MASH cohort was a random sample of those without a MASH diagnosis that was five times the size of the MASH cohort. Stabilized inverse probability weighting (IPW) for MASH status was used to adjust for differences in baseline covariates, including differences in cardiometabolic conditions. Baseline characteristics were summarized descriptively, and IPW all-cause HCRU and costs during follow-up were reported as visits and costs (in 2022 USD) per patient per year (PPPY).

RESULTS: The study included 128,622 beneficiaries in the MASH cohort and 642,774 in the non-MASH cohort. Prior to IPW, those with MASH were younger (mean age: 73.4 vs 74.7 years), included more female patients (60.4% vs 56.8%), and with more cardiometabolic conditions including type 2 diabetes (58.3% vs 26.6%), obesity (45.3% vs 16.5%), and atherosclerotic cardiovascular disease (43.9% vs 31.9%). After IPW, MASH was associated with higher HCRU PPPY, including 48% greater inpatient (IP) visits (0.39 vs 0.26), 20% greater outpatient (OP) visits (37.47 vs 31.31), 32% greater emergency department (ED) visits (0.80 vs 0.60), 20% greater skilled nursing facility (SNF)/hospice visits (0.22 vs 0.18), and 7% greater prescription fills (31.81 vs 29.66). Total costs PPPY were 21% higher for MASH vs non-MASH ($24,890 vs $20,542), including OP ($11,107 vs $9,565), IP ($6,855 vs $4,604), ED ($635 vs $498), SNF/hospice ($1,874 vs $1,653), and prescription costs ($4,634 vs $4,039). All HCRU and cost differences and ratios were statistically significant based on a $P < 0.05$.

CONCLUSIONS: Among older Medicare beneficiaries, HCRU and costs were greater among those with diagnosed MASH compared to those without diagnosed MASH, likely due to management of liver disease, which may include advanced liver fibrosis or cirrhosis. Understanding the real-world health care burden of MASH is important for guiding health care decisions including treatment and screening.

SPONSORSHIP: Novo Nordisk, Inc.

185 Real-world analysis of treatment patterns and health care resource utilization among patients with alcohol-associated hepatitis from 2016 to 2024

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BACKGROUND: Alcohol-associated hepatitis (AH) is characterized by acute liver injury, hepatic dysfunction, and high morbidity/mortality. There are limited data describing real-world treatment (tx) patterns and health care resource utilization (HCRU) in this population.

OBJECTIVE: To evaluate pharmacological tx patterns and both all-cause and AH-related HCRU in a real-world cohort of patients (pts) with AH.

METHODS: Adult pts with ≥2 inpatient claims for alcoholic hepatitis (ICD-10-CM codes K70.10 and K70.11) were identified from the Optum Clinformatics Data Mart database between 2017 and 2024. Pts were required to have continuous enrollment for ≥12 months pre-index and ≥1 day post-index, with the index date defined as the date of first claim with an AH diagnosis (dx). AH-related HCRU was defined as a medical claim for an AH dx plus liver transplant, dialysis, or paracentesis; a dx of acute renal injury, hepatorenal syndrome, hepatic failure, hepatic encephalopathy, variceal bleeding, or sepsis; or a pharmacy claim for pentoxifylline or systemic corticosteroids within 7 days of the AH dx. HCRU was assessed descriptively during the baseline, fixed (3, 6, and 12 months), and variable follow-up (f/u) periods. Pharmacological tx patterns focused on outpatient alcohol use disorder (AUD) tx and first-line interventions occurring within 30 days of the initial tx.

RESULTS: A total of 2415 pts (64.8% male) met criteria for variable f/u, with a mean (SD) age of 53.9 (12.9) y. Overall, 23.4% of pts received AUD tx, including acamprosate, disulfiram, and naltrexone. During f/u, 33.8% of pts received lactulose, and 21.1% initiated lactulose as monotherapy. Pharmacological tx combinations for AUD were rare. At baseline, 91.1% and 61.9% of pts had ≥1 all-cause ambulatory and emergency department (ED) visit, respectively. During the 12-month

fixed f/u period, 99.2% and 98.3% of pts had ≥1 all-cause ambulatory and ED visit, respectively. AH-related HCRU during this period included ambulatory visits in 27.6% of pts, inpatient stays in 59.1%, and ED visits in 51.7%. Over the variable f/u period, 96.2% of pts had all-cause ambulatory visits and 98.4% had all-cause ED visits; 74.2% and 66.7% of pts had AH-related inpatient and ED visits, respectively.

CONCLUSIONS: Pts with AH experience a high burden of HCRU. Despite frequent engagement with the health care system, <1 in 4 pts received pharmacological tx targeting AUD. These data highlight an unmet need for AH management and an opportunity for targeted interventions to improve outcomes and reduce HCRU.

SPONSORSHIP: Intercept Pharmaceuticals, Inc., a wholly owned subsidiary of Alfasigma S.p.A.

Genitourinary

190 Budget impact analysis of generic mirabegron in Medicare Part D: Translating savings into access

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BACKGROUND: Anticholinergic drugs for overactive bladder and urinary incontinence (OAB/UI) have significant side effects in older adults. Safer β3–agonists are more costly.

OBJECTIVE: To estimate the budget impact in Medicare Part D associated with recently available generic mirabegron and determine the degree that generic pricing permits more patients to access mirabegron at the current level of Part D spending for OAB/IU drugs.

METHODS: A budget impact model was developed to estimate Medicare Part D savings after the introduction of generic mirabegron in 2024. Baseline utilization and expenditure data for anticholinergics, brand mirabegron, and brand vibegron were obtained from the 2023 Medicare Part D Prescribers by Provider and Drug dataset. In the new environment, brand vibegron utilization remained constant, while all patients using mirabegron were assumed to use the generic product, at a 14% price reduction (reflecting the current wholesale acquisition cost). A two-way sensitivity analysis varied both generic price reduction (10%-75%) and mirabegron utilization (0%-200% increase). Additionally, we devised a spending-neutral scenario to determine the number of beneficiaries who could shift from anticholinergics to generic mirabegron at the 2023 level of overall spending, according to varying levels of generic mirabegron price reduction (10%-50%). A scenario analysis incorporated fracture and fall costs associated with anticholinergic use to evaluate their effect on overall spending

RESULTS: In 2023, prior to the introduction of generic mirabegron, the estimated annual Part D spending for drugs for OAB/UI was $2.813B. In the new environment spending was reduced by $295M, assuming a 14% mirabegron price reduction. Redirecting these savings could allow 140,838 patients to switch from anticholinergics to mirabegron without raising total annual costs. In the two-way sensitivity analysis, a 14% price reduction and 50% increase in the use of mirabegron resulted in $547M in additional spending. If the generic mirabegron price was reduced by 50% of brand cost, more than half (51.5%) of patients using anticholinergics could switch to generic mirabegron while maintaining current levels of spending. Incorporating costs for anticholinergic-associated falls/fractures added $85.4M to the current environment. This cost would be reduced by $6.8M in the new environment where 140,838 patients switched to mirabegron at neutral overall spending.

CONCLUSIONS: Managed care can expand access to a safer alternative for OAB/UI without increasing overall spending.

SPONSORSHIP: None

191 Utilization of medications for overactive bladder/urinary incontinence during 2018-2022: Analysis of the Medicare Part C and D Prescribers - by Provider and Drug Dataset

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BACKGROUND: Anticholinergic drugs for overactive bladder (OAB) and urinary incontinence (UI) can have significant side effects among older adults.

OBJECTIVE: To determine trends in Medicare utilization of anticholinergic and β3-agonist medications for OAB/UI, overall, and by US region and by prescriber type.

METHODS: We conducted a series of cross sectional analyses using the Medicare Part C and D Prescribers - by Provider and Drug databases. Claims for anticholinergic OAB/UI agents and β3-agonists were extracted, and we examined the total number of 30-day equivalent fills. To account for yearly changes in enrollment, we calculated the number of 30-day claims per 1,000 Medicare beneficiaries. The annual number of claims for anticholinergic and β3 agonist OAB/UI drugs per 1,000 beneficiaries was determined for each year during 2018-2022, by US Census region, and for urologist and non-urologist prescribers, with 99% confidence intervals.

RESULTS: The number of claims for anticholinergic OAB/UI drugs per 1,000 beneficiaries decreased over time, from 233.88 in 2018 (99% CI: 233.69-234.07) to 203.06 in 2022 (99% CI: 202.90-203.22), representing a 13.2% decline. Conversely, the number of claims for β3 agonist OAB/UI drugs per 1,000 beneficiaries increased over time, from 60.29 in 2018 (99% CI: 60.20-60.39) to 96.04 in 2022 (99% CI: 95.93-96.15), representing a 59.3% rise. Annual claims for any OAB/UI medication rose slightly during this timeframe by 1.7%. The proportion of OAB/UI claims that were β3-agonists rose from 20.49% (99% CI: 20.48-20.51) in 2018, to 32.00% (99% CI: 31.98-32.02) in 2022. In 2022, the Northeast had the highest proportion of OAB/UI claims for β3-agonists, at 36.61% (99% CI: 36.56-36.65), while the Midwest had the lowest proportion at 27.69% (99% CI: 27.66-27.73). In 2022, urologists prescribed β3-agonists for 40.02% (99% CI: 39.98-40.05) of OAB/UI claims, while the proportion was 29.29% (99% CI: 29.27-29.31) for non-urologists. From 2018 to 2022, claims for β3-agonists rose by 8.99 percentage points (28.96% relative) among urologists and 12.55 points (74.97% relative) among non-urologists.

CONCLUSIONS: Claims for medications for OAB/UI remained steady between 2018 and 2022, yet the use of β3-agonists increased over time, while the use of anticholinergic drugs declined. Differences in β agonist use were observed by US region and by prescriber specialty. While urologists prescribed β3-agonists at higher rates than non-urologists, the increase in β3-agonist claims among non-urologists suggests a broader shift toward these safer therapies in general practice.

SPONSORSHIP: None

192 Real-world characteristics of patients with overactive bladder initiating vibegron or mirabegron

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BACKGROUND: Real-world comparison of the characteristics of patients with overactive bladder (OAB) initiating vibegron or mirabegron is limited.

OBJECTIVE: To compare baseline characteristics of patients with OAB initiating vibegron vs mirabegron.

METHODS: This retrospective cohort analysis used the IQVIA PharMetrics Plus Closed Health Plan Claims database to identify adults with OAB with ≥2 prescription fills for vibegron or mirabegron from January 2016 to May 2024 and no use of either in the past 6 months. The index date was the first dispense date of vibegron or mirabegron (April 2021 to February 2024). Patients had ≥6 months of preindex and ≥2 months of postindex continuous medical and pharmacy benefits. Demographics were assessed at index. Comorbidities were extracted using all available baseline medical claims. Procedure, medication, and health care resource utilization (HCRU) were assessed during the 183-day preindex period. HCRU was normalized to per person per year (PPPY). Standardized mean differences (SMD) were used to compare patient characteristics.

RESULTS: In total, 40,729 patients (vibegron cohort, n = 6490; mirabegron cohort, n = 34,239) were identified. Patient cohort entry occurred later for vibegron vs mirabegron. Mean age of new vibegron (vs mirabegron) users was 63.4 years (vs 62.6 years). Among patients initiating vibegron vs mirabegron, 29.7% vs 26.9% were male, and among those, 23.4% vs 20.5% had evidence of benign prostatic hyperplasia, respectively. Pre-index, more patients with OAB initiating treatment (vibegron vs mirabegron; SMD) had diagnosis of arrhythmia (27.5% vs 23.3%; 0.1), hypertension (71.5% vs 66.7%; 0.1), and stress incontinence (19.0% vs 14.0%; 0.1); and undergone cystoscopy (11.5% vs 8.5%; 0.1), urinalysis (69.0% vs 56.3%; 0.3), post-void residual volume (38.0% vs 22.2%; 0.4), and urodynamics procedures (8.7% vs 5.6%; 0.1). Prior medications for vibegron (vs mirabegron) users were OAB anticholinergics (33.1% vs 31.8%), alpha blockers (15.8% vs 15.6%), CYP2D6 substrates (72.9% vs 72.1%), beta blockers (29.6% vs 25.0%), and antiarrhythmics (7.2% vs 5.1%). Mean ± SD preindex HCRU and costs were higher for vibegron vs mirabegron initiators: PPPY outpatient visits (32.9 ± 26.8 vs 28.7 ± 25.1), pharmacy encounters (53.9 ± 49.0 vs 47.7 ± 44.0), and total costs ($26,919.55 ± $58,200.49 vs $25,770.65 ± $68,748.20), respectively.

CONCLUSIONS: This analysis showed clinically meaningful differences in baseline characteristics of patients with OAB initiating vibegron vs mirabegron. Patients initiating vibegron had a more complex clinical history.

SPONSORSHIP: Sumitomo Pharma America, Inc.

193 Proton pump Inhibitors are associated with an increased risk of mortality among patients with kidney disease: A systematic review and meta-analysis

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BACKGROUND: Proton pump inhibitor (PPI) use has been linked to various serious adverse outcomes, including an increased risk of death from all causes. Notably, higher mortality rates related to kidney disease have been reported among PPI users. However, the relationship between PPI use and mortality in patients with kidney disease remains uncertain.

OBJECTIVE: To evaluate the association of PPI use on mortality among patients with kidney disease.

METHODS: We searched Ovid-MEDLINE, Ovid-EMBASE, and Cochrane CENTRAL through April 2025 to identify randomized controlled trials (RCTs) and observational studies examining the relationship between PPI use and mortality risk in patients with kidney disease. Study outcomes included mortality rates among PPI users and non-users, as well as adjusted hazard ratios (HRs) comparing the risk of death between groups, accounting for demographic and clinical variables. To calculate pooled HRs with 95% confidence intervals (CIs), a random-effects meta-analysis was conducted using the Hartung-Knapp method for confidence interval adjustment. Between-study variance (τ^2) was estimated using the restricted maximum likelihood (REML) method. Statistical heterogeneity was assessed using the I^2 statistic and Cochran's Q test. Subgroup analyses were performed based on follow-up duration, patient population, and study location.

RESULTS: This systematic review encompassed 216,032 patients with kidney diseases from 24 cohort studies and ad hoc analyses of randomized controlled trials. Included patients had dialysis, chronic kidney disease, renal cancer, or a kidney transplant. Among 20 cohorts from 17 observational studies, mortality was observed in 23.2% of PPI users (15,755 out of 67,853) and 22.1% of non-users (28,986 out of 131,009). After adjusting for confounding variables in 18 studies (20 cohorts), PPI use was significantly associated with a 26% increased risk of mortality in patients with kidney disease compared to those not using PPIs (HR 1.26; 95% CI, 1.11-1.42). Substantial heterogeneity was observed across the studies. The subgroup analyses further confirmed that this elevated mortality risk among PPI users remained consistent across different subgroups.

CONCLUSIONS: Our meta-analysis found a potential risk of death associated with PPI use in patients with kidney disease. While additional studies are necessary to confirm this risk, the prescription of PPIs in this population should be approached with caution.

SPONSORSHIP: None

Health Disparities/Equity

198 Comparative outcomes for transgender patients: Gaps in HIV preexposure prophylaxis (PrEP) adoption between transgender and cisgender individuals

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BACKGROUND: Health challenges facing the transgender population differ from those of the cisgender population. There has been minimal research using large national claims databases to investigate such health disparities.

OBJECTIVE: To investigate, using a large, national, all-payer database, gaps in the adoption of PrEP among the transgender community in relation to adoption rates with the cisgender population.

METHODS: Utilizing the Mariner170 all-payer national claims database, the transgender cohort was defined as patients with ≥1 claim of gender identity disorder occurring between January 2010 and April 2023 using ICD-9 and ICD-10 codes. Propensity score matching was performed against a control group. T-tests and chi-square tests were used to compare the transgender cohort to the cisgender cohort across 32 comorbidities. Patients must have ≥2 outpatient claims or ≥1 inpatient claim of each respective comorbidity to be considered a member of the comorbidity cohort. Patient age at first appearance in the database was used.

RESULTS: Within the database, 71,741 individuals with ≥1 ICD-9 or ICD-10 diagnosis for gender identity disorder (ICD-9 302.50:302.53, 302.6, 302.85, ICD-10 F64.0:F64.9, Z87.890) as a method of identifying transgender individuals. The highest risk ratio among attributes studied was HIV (12.4) followed by self-inflicted injuries (10.3), schizophrenia (5.1), and mood disorders (4.3), for the transgender population. The rate of transgender patients with no HIV diagnosis having ≥1 claim for PrEP is 5.2% (3,567/68,725). This is significantly lower than national estimates of 35%-45% adoption

among the high-risk group of gay male individuals. An analysis of the cisgender adopters of PrEP was performed to identify key indicators of PrEP adoption. A logistic regression was performed to identify contributing factors to adopting PrEP. Age was confirmed to be a significant factor, with a t-test confirming significance in difference of mean age between the groups (31.4, 40.3).

CONCLUSIONS: The adoption rate of PrEP in the transgender community aged ≥16 years without a diagnosis for HIV (3,058/45,024) is significantly lower than rates among other high-risk populations. It is recommended further research be conducted concerning this gap in treatment and that targeted programs be implemented to increase PrEP adoption rates in the transgender community.

SPONSORSHIP: PearlDiver Technologies

199 The Centers for Medicare & Medicaid Services' definition of social risk may be missing those in need

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BACKGROUND: The Centers for Medicare and Medicaid Services (CMS) seeks to utilize social risk factors (SRF) in several proposals affecting Medicare Advantage (MA) Organizations, such as self-evaluation of Part D utilization management criteria. Utilizing membership data from a major health plan, we noticed about half of MA membership met CMS's definition of SRF. This high prevalence begs the question of if this definition of SRF is precisely able to identify those with health-related social needs (HRSNs), the targeted, more immediate requirements arising from SRF, and more broadly, calls for clarification of the constructs CMS desires to assess.

OBJECTIVE: To elucidate if health plan members identified with having SRF as defined by CMS had unmet HRSNs and if there were differences in HRSNs among MA membership identified with SRF by CMS compared to those who were not.

METHODS: Data flagging CMS SRF were extracted for members of a major health plan from CMS member restated monthly files as a binary variable. These were joined to member-level assessment data, including Accountable Health Communities (AHC) HRSN Screening Tool, and Protocol for Responding to & Assessing Patients' Assets, Risks, and Experiences (PRAPARE), as well as a social risk survey (SRS) deployed in-house across one midwestern and one southern state providing information on nine HRSNs. Measures were transformed into binary variables to indicate presence of social need and were correlated against the variable denoting CMS SRF. The population studied was any of the MA members identified in the CMS member restated monthly files in 2021 or 2022, which were included in at least one of the sources of HRSN assessment.

RESULTS: The correlation between CMS social risk and self-reported HRSN was weak to moderate across all measures, with Pearson correlation coefficients of 0.10 and 0.29 for AHC and PRAPARE, respectively, and ranging from 0.10 to 0.45 among the nine HRSNs measured in the SRS. All correlations except the "internet" HRSN in the SRS were significant at the $P < 0.05$ level.

CONCLUSIONS: There is limited concordance between CMS RF and HRSNs, as self-reported on member assessments—individuals flagged with RF by CMS may not have attested to self-reported HRSNs, and vice-versa. It is critical for stakeholders across the Medicare sphere to synergize efforts to identify and support individuals in need, and this starts with ensuring concepts such as RF applied in the context of a greater social needs framework rather than in a vacuum.

SPONSORSHIP: Elevance Health

200 Fragmented access to Alzheimer plasma biomarkers: A Medicaid policy review of coverage for early detection and anti-amyloid therapy eligibility

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BACKGROUND: Plasma biomarkers including phosphorylated tau (pTau-181), amyloid beta 42/40 ratio (Aβ42/40), glial fibrillary acidic protein (GFAP), and neurofilament light chain (NfL) are transforming Alzheimer disease (AD) diagnostics by enabling earlier, less invasive confirmation of amyloid pathology. Their relevance has grown with the approval of anti-amyloid monoclonal antibodies requiring biomarker evidence prior to treatment. However, Medicaid coverage remains fragmented, raising concerns about delayed diagnosis, inefficiencies, and restricted access, particularly among racially and ethnically minoritized populations disproportionately affected by AD.

OBJECTIVE: To evaluate Medicaid coverage of plasma-based AD biomarkers across all 51 jurisdictions and assess alignment with therapy eligibility. The review also assessed CPT-based coverage clarity, reimbursement structure, and attention to health equity.

METHODS: A systematic review of Medicaid policies was conducted in accordance with PRISMA 2020 guidelines (January 2022 to May 2025). Sources included state Medicaid websites, CMS portals, and policy bulletins. Inclusion required references to plasma biomarkers, CPT codes (e.g., 0346U for Aβ42/40, 0412U for pTau-181, 0443U for NfL), or diagnostic criteria for therapy approval. Coverage was classified as explicit (biomarker named with CPT and billing guidance), partial (biomarker named without CPT/billing), or absent. Two reviewers independently extracted and validated data. Equity was defined as any mention of disparities or targeted access.

RESULTS: Among 51 jurisdictions, 18 (35%) referenced at least one plasma biomarker. Eleven (22%) included CPT codes, primarily for Aβ42/40 or pTau-181. Nine (18%) required biomarker evidence for therapy approval, while 72% permitted cerebrospinal fluid (CSF) or PET testing through existing benefits. Seventeen states (33%) limited plasma testing to select labs, often CLIA-certified or manufacturer-designated. Only six jurisdictions (12%) referenced health equity, and fewer than 10% addressed plasma assays in diagnostic stewardship. Ambiguities in benefit designation and lack of federal standards contributed to inconsistent reimbursement.

CONCLUSIONS: Medicaid coverage for plasma-based AD biomarkers remains inconsistent and misaligned with treatment eligibility criteria. Delays in diagnostic access and uneven reimbursement reflect broader gaps in coverage infrastructure. Federal guidance, CPT standardization, and equity-focused reforms are needed to improve early detection and reduce disparities in AD care.

SPONSORSHIP: None

201 The implementation and evaluation of a medication adherence program segmenting by social and clinical risk

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BACKGROUND: A cornerstone of effective management of chronic conditions is medication adherence. Interventions addressing barriers to timely medication refills are essential due to a significant impact on health outcomes and costs and can be augmented by segmenting the population of interest to focus resources for the most comprehensive intervention to the individuals who would most benefit.

OBJECTIVE: To describe the medication adherence impact of assessing and supporting health-related social needs (HRSN) within a medication adherence program for individuals at high risk for overdue or missed refills across three chronic conditions.

METHODS: The quality improvement program focused on Medicare Advantage (Part D) members of a major health plan with prescriptions for diabetes (non-insulin), hypertension (RAS agonists), and hyperlipidemia (statin), including techniques such as high-touch outreach from a clinical pharmacy care center, with telephonic and text outreach. A subset of participants (SDOH cohort) received HRSN screenings to identify resources and aid in management of health conditions and ensure timely refills, identified by the lowest quartile of composite Whole Health Index (WHI) and its Social Driver domain. WHI is a reliable and valid measure of whole-person health, covering clinical and social drivers. Seventy-eight percent of the SDOH cohort had social risk factors as identified by the Centers for Medicare and Medicaid Services, compared to 67% among non-SDOH.

RESULTS: 38% of the SDOH cohort were reached and 28% were engaged, compared to 29% reached and 21% engaged in the non-SDOH cohort.. Members in the SDOH cohort participated in the program at a rate of four percentage points (pp) higher than non-SDOH. Year-end adherence among engaged compared to nonengaged for cholesterol, diabetes, and hypertension was 16.0, 12.3, and 15.5 pp higher in the SDOH cohort, respectively. These values were 12.8, 10.1, and 11.7 pp higher in the non-SDOH cohort. This yields a difference-in-difference estimate for the SDOH program of 3.2, 2.2, and 3.8 pp, respectively. Overall, SDOH cohort members had both lower baseline adherence rates and greater improvements in medication adherence compared to the non-SDOH across all three conditions.

CONCLUSIONS: High-touch outreach, including screening for and addressing social needs, is an effective intervention for improving medication adherence in a population with a high prevalence of social risk factors. Utilization of measures of health such as WHI to segment the population allows for optimal distribution of resources for maximal impact.

SPONSORSHIP: Elevance Health

Health Policy

206 The timing and characteristics of supplemental indications for small and large molecule medicines

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BACKGROUND: The Inflation Reduction Act (IRA) Drug Price Negotiation Program (DPNP) aims to reduce prices for certain drugs but subsequently introduces disincentives for

companies to pursue supplemental indications, especially as medications approach the effective date for the maximum fair price (MFP)—nine years for small molecules and thirteen years for biologics.

OBJECTIVE: To investigate the number and characteristics of supplemental indications approved ≥9 (small molecules) or ≥13 years (biologics) after initial approval across all disease areas and drug types.

METHODS: Using the Food and Drug Administration (FDA) databases, we identified brand-name small molecule drugs initially approved between 2004 and 2015 and biologics approved between 2004 and 2011, allowing at least 9 and 13 years of follow-up, respectively. We reviewed each drug's label as of 2024 to identify supplemental indications. We characterized supplemental indications approved ≥9 years or ≥13 years after approval by FDA expedited review pathway; whether it had an orphan designation; whether it was approved for pediatric and geriatric populations; and its therapeutic class.

RESULTS: In our sample of 250 supplemental indications, 24.2% of 182 small molecule supplemental indications were approved ≥9 years after approval, while 10.3% of 68 biologic supplemental indications were approved ≥13 years. Of the 51 supplemental indications approved (regardless of small molecule or biologic) ≥9 or ≥13 years after initial approval, 56.9% received at least one FDA expedited review designation (59.1% for small molecules vs 42.9% for biologics), 39.2% had orphan status (36.4% vs 57.1%), 49.0% were approved for pediatric use (50.0% vs 42.9%), and 62.7% for older adults (61.4% vs 71.4%). The most common therapeutic areas for supplemental indications for small molecules were oncology (34.1%), infectious disease (15.9%), and circulatory disease (9.1%); for biologics they were oncology (28.6%), musculoskeletal disease (28.6%), and circulatory disease (14.3%).

CONCLUSIONS: We found that a sizeable proportion of supplemental indications were approved many years after a drug's first approval, and many of these longer-term supplemental indications received expedited or orphan designations and addressed high-need populations, including children, older adults, and patients with cancer, infectious disease, and cardiovascular diseases. Our finding further suggests that DPNP may disproportionately impact small molecules, as their supplemental indications were developed over longer timelines and more likely to be approved after the MFP effective time.

SPONSORSHIP: Eli Lilly and Company

207 Examining the impact of specialty drug rebates on health plan coverage decisions

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BACKGROUND: Manufacturers offer rebates to secure preferred coverage for specialty drugs, but the extent of their influence remains unclear. Current policy discussions often cite list prices, overlooking rebates and negotiated discounts between manufacturers, PBMs, and payers. Understanding how rebates affect coverage decisions is critical for improving patient access.

OBJECTIVE: To evaluate how net prices and rebates affect payer coverage of specialty drugs.

METHODS: We analyzed 161 specialty drugs with pricing and commercial health plan coverage information in the SSR Health US Brand Rx Net Pricing Tool and the Specialty Drug Evidence and Coverage (SPEC) Database for all four quarters of 2023. We conducted a multivariate logistic regression analysis to identify factors influencing payer coverage decision-making. We classified coverage decisions as unrestricted—covering the full FDA-approved population—or restricted—imposing additional access requirements such as clinical criteria or step therapy protocols. Variables included rebate size, net price, drug type (e.g., oncology, orphan), route of administration, number of indications, competition, FDA approval pathway, and time since FDA approval.

RESULTS: The median estimated net price was $48,700 (IQR: $20,800 to $166,400) with a median rebate of $29,400 (IQR: $16,000-$47,900), reflecting a median discount of 28% off list price (IQR: 16%-67%). Among 6,688 coverage decisions analyzed, 54% included at least one restriction. Drugs with higher net prices (≥$166,400) were more likely to face restrictions compared to lower-priced drugs (<$20,800) (OR: 2.56 ($P<0.001$). In contrast, drugs with higher rebates (≥$47,900) were less likely to face restrictions than those with lower rebates (<$16,000) (OR: 0.56, $P<0.001$). Oncology drugs, orphan drugs, drugs with expedited approval, self-administered drugs and those FDA designated as second-line or later use were less likely to face restrictions. Older drugs and those in highly competitive therapeutic classes were more likely to be restricted.

CONCLUSIONS: Net prices and rebates significantly influence health plan coverage decisions for specialty drugs. Greater transparency in rebate and pricing negotiations is needed to promote equitable access and manage affordability challenges for patients.

SPONSORSHIP: argenx, Inc.

208 US commercial health plan use of corticosteroids in step therapy protocols

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BACKGROUND: Health plans often impose step therapy protocols requiring patients to try and fail alternative therapies before accessing to higher-cost specialty drugs. Corticosteroids (CS), due to their wide availability and low cost, are commonly used in these protocols. While short-term CS use can reduce inflammation, chronic systemic use may lead to serious clinical side effects. Requiring CS failure before specialty drug access may delay initiation of more effective therapies and cause patient harm.

OBJECTIVE: To estimate how often commercial health plans include CS in step therapy protocols and describe the nature of CS failure requirements and variation across plans.

METHODS: We analyzed data from the Tufts Medical Center Specialty Drug Evidence and Coverage Database, which tracks coverage decisions for 18 large US commercial health plans. We identified drug-indication pairs for which at least one plan included CS in step therapy. For each, we reviewed coverage decisions to determine whether CS failure was included, reviewed CS failure criteria, and categorized specifics of CS failure requirement by characteristics such as route of administration of CS (systemic vs local use).

RESULTS: As of August 2024, we identified 201 drug-indication pairs for which at least one plan CS in step therapy. Of these drug-indication pairs, 33 (16.4%) had an FDA label indication recommending prior CS use, while 168 (83.6%) did not. Among 557 coverage decisions involving drug-indication pairs with FDA-indicated prior CS use, 76.5% required CS failure—typically featuring the use of systemic CS (78.4% of decisions with CS failure requirement). For the 2,210 decisions for drug-indication pairs lacking FDA-indicated prior CS use, 43.1% still included CS in step therapy. In these, 63.8% specified systemic CS use and 48.4% required additional steps beyond CS. Use of CS in step therapy varied widely across plans, ranging from 15% to 74% of relevant decisions. Examples of drug-indication pairs most likely to include CS steps beyond FDA label recommendations included deflazacort for Duchenne muscular dystrophy (100% of coverage decisions), adalimumab for uveitis (93.3%), and apremilast for Behcet disease (85.7%).

CONCLUSIONS: Commercial plans frequently include CS failure, often beyond the FDA label. Substantial variation across plans highlights inconsistencies in application of CS failure criteria. Further research should examine the clinical appropriateness and patient impact of CS failure requirements.

SPONSORSHIP: argenx, inc

209 Does delaying coverage for accelerated approval treatments disproportionately impact patients with high unmet needs?

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BACKGROUND: Payers are increasingly considering delaying coverage for new non-oncology treatments approved via the Food and Drug Administration's (FDA) accelerated approval (AA) pathway. It is unclear to what extent this decision would impact patients with high unmet needs.

OBJECTIVE: To compare the economic burden and disease characteristics of non-oncology conditions targeted by AA medicines and those treated with non-AA medicines.

METHODS: All conditions for which there was an FDA approval via AA between Jan 2015 and Feb 2025 were identified; the comparison group comprised the 100 diseases with the most recent non-AA medicines approved prior to Feb 2025. Data on economic burden and disease characteristics were sourced from published literature. The economic burden was estimated from the US societal perspective, including direct medical costs, direct non-medical costs, indirect costs from patient productivity loss, and indirect costs from informal caregiving if available. Costs were inflated to 2025 USD using the Medical Care Component of the BLS' Consumer Price Index. Disease characteristics measures included life-years, quality of life, prevalence, and age of onset. Mann-Whitney U tests were applied to test whether the differences between AA and non-AA conditions were statistically significant.

RESULTS: The 34 non-oncology AA treatments represented n = 18 unique diseases and were compared against n = 100 non-AA diseases. Average annual societal costs for AA diseases were 1.50 times higher than for non-AA conditions ($94,857 vs $63,219, $P < 0.01$). Compared with non-AA conditions, the annual average productivity loss and caregiver burden were 1.35 ($21,538 vs $9,177) and 1.59 times ($19,846 vs $7,678) greater in the AA conditions, respectively. On average, AA conditions were characterized by shorter post-diagnosis life expectancy (25.9 vs 31.0 years), lower quality of life (0.651 vs 0.688), and lower prevalence (277 vs 2,250 per

100,000). Diseases treated by AAs also disproportionately affect children (<18 years: 29.4% vs 24.2%) and older adults (>65 years: 27.5% vs 23.1%).

CONCLUSIONS: Diseases targeted by AA treatments imposed greater economic burden and reflect more severe disease characteristics than non-AA conditions. Delaying coverage of AA treatments would disproportionately impact patients with high unmet needs.

SPONSORSHIP: National Pharmaceutical Council

210 Navigating artificial intelligence in evidence synthesis: A scoping review of current and developing guidelines

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BACKGROUND: The integration of artificial intelligence (AI) is transforming health economics and outcomes research and market access by offering efficiencies in evidence synthesis, including systematic and pragmatic literature reviews. As AI tools become more sophisticated, it is essential that transparent, ethical guidelines are in place to promote the responsible application of those tools and maintain the integrity of managed care decision-making processes.

OBJECTIVE: To identify and characterize existing global guidelines and recommendations for the use of AI in evidence synthesis, with a particular focus on applicability and gaps relevant to systematic and pragmatic literature reviews.

METHODS: A scoping review was conducted in January 2025 and updated in April 2025, drawing from diverse sources including PubMed, Cochrane, the Centre for Reviews and Dissemination (CRD), Responsible AI in Evidence Synthesis (RAISE), and ISPOR - The Professional Society for Health Economics and Outcomes Research. The scoping review sought to delineate recommended AI workflows (e.g., human-in-the-loop), specific phases of evidence synthesis where AI is advised, and any identified limitations or ethical considerations.

RESULTS: Current guidelines broadly advocate for AI as an augmentative tool rather than a replacement for human expertise in evidence synthesis. Recommendations predominantly address systematic literature reviews, particularly focusing on tasks such as title/abstract screening and data extraction. However, substantial gaps were identified in existing guidelines regarding the application of AI to less structured, pragmatic literature reviews. Limitations on the use of AI for literature reviews included concerns about scientific validity, potential bias, and ethical implications.

CONCLUSIONS: The landscape of AI in evidence synthesis is rapidly evolving, necessitating continuous development and refinement of guidance. This scoping review highlights a critical need for standardized, comprehensive, and adaptable guidelines that specifically address the unique challenges and opportunities of AI in pragmatic literature reviews and ensure robust, transparent, and equitable evidence generation.

SPONSORSHIP: OPEN Health HEOR & Market Access

211 Payer reactions to the Inflation Reduction Act and manufacturer financial assistance

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BACKGROUND: The Inflation Reduction Act (IRA) introduced key Medicare Part D reforms, including a $2,000 out-of-pocket cap and the Medicare Prescription Payment Plan (MPPP) in 2025, which allows patients to spread out-of-pocket costs throughout the year, as well as Medicare drug price negotiations starting in 2026. While these reforms aim to improve affordability, their impacts on payer strategies and plan design remain unclear.

OBJECTIVE: To evaluate the impact of Medicare Part D reforms on plan design and affordability and to assess payer strategies for 2026 in response to drug price negotiations and manufacturer financial assistance programs.

METHODS: A double-blind, web-based survey of US health care payers was conducted through Cencora's Managed Care Network research panel in May 2025.

RESULTS: A total of 40 payers, representing health plans (n = 18), integrated health delivery systems (n = 14), and pharmacy benefit managers (n = 8), shared insights on how the IRA impacts plans and informed predictions for 2026 plan design and strategies. In 2026, half (50%) of payers anticipate adverse financial effects on their portfolio of Part D plans, with 65% planning to consolidate or eliminate Medicare Part D plans to manage financial pressures. Premiums are expected to rise, with 78% of standalone prescription drug plans and 83% of Medicare Advantage plans projecting increases, most commonly up to 10%. Narrower formularies are expected by 85% of plans, with 88% expecting greater use of utilization management tactics. For drugs under Medicare price negotiation, 50% of plans anticipate increased prior authorization and 53% foresee expanded step therapy. Payers perceive the MPPP as confusing for patients (63%) and difficult to implement (48%), though 58% of payers see it as beneficial for patient affordability. Communication strategies on the IRA with providers and

patients remain limited, with many payers focusing on mandated updates. Regarding biopharmaceutical-sponsored financial assistance, 25% of payers do not restrict use, while the remainder employ copay accumulators (65%), maximizers (60%), or alternative funding programs (20%) or outright deny assistance (8%).

CONCLUSIONS: The IRA's reforms aim to improve affordability, but they have also created significant financial and operational challenges for payers. Going into 2026, payers anticipate narrower formularies, expanded utilization management, and plan consolidation. Manufacturers must engage payers with innovative strategies to balance affordability and coverage.

SPONSORSHIP: Cencora

213 What evidence packages did CMS consider for maximum fair price determination? A comparative analysis of apixaban, rivaroxaban and sacubitril/valsartan

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BACKGROUND: The Inflation Reduction Act (IRA) grants the Centers for Medicare & Medicaid Services (CMS) the authority to negotiate prices for high-expenditure Medicare drugs. As part of this process, manufacturers are required to submit comprehensive evidence packages to inform CMS's determination of a drug's maximum fair price (MFP). Analyzing these submissions offers valuable insights into CMS's negotiation strategies and MFP determination.

OBJECTIVE: To compare the evidence packages submitted for three cardiovascular drugs—apixaban, rivaroxaban, and sacubitril/valsartan—which together accounted for nearly 50% of total Medicare Part D spending among the first drugs selected for MFP negotiation.

METHODS: A systematic review was conducted to evaluate the evidence packages submitted by manufacturers for the three drugs. Submissions included data from pivotal clinical trials, real-world evidence (RWE), economic models, registry data, and network meta-analyses.

RESULTS: For apixaban and rivaroxaban, both indicated for nonvalvular atrial fibrillation (NVAF), manufacturers submitted data derived from Medicare fee-for-service (FFS) and administrative claims. Submissions also included evaluations from the Institute for Clinical and Economic Review (ICER), with ratings provided for both drugs. Economic models utilized Equal Value of Life Years (evLY) and cost per evLY metrics. Due to the absence of head-to-head trials, network meta-analyses were employed. For sacubitril/valsartan, indicated for heart failure with reduced ejection fraction (HFrEF), the manufacturer asserted the absence of therapeutic alternatives. Evidence emphasized unmet need and clinical effectiveness, supported by RWE demonstrating reductions in cardiovascular mortality and hospitalizations. Additional studies highlighted improvements in health disparities among specific patient populations. Economic evaluations included both all-cause and disease-specific costs. Patient-reported outcomes, including health-related quality of life measured by the Kansas City Cardiomyopathy Questionnaire, were also submitted. All three submissions incorporated RWE from Medicare FFS and registry data from both US and international sources. Stakeholder input included perspectives from physicians, pharmacists, patient advocacy groups, and individual patients and caregivers.

CONCLUSIONS: The CMS negotiation process revealed distinct evidence strategies across the three drugs. The submitted evidence packages underscored the critical role of real-world data (RWD) and RWE in supporting transparent, evidence-based pricing decisions under Medicare.

SPONSORSHIP: None

214 Factors associated with variation in drug costs in states with prescription drug affordability boards

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BACKGROUND: Five states have created similar prescription drug affordability boards (PDABs) to address concerns on drug affordability, which may be influenced by a number of factors related to patient insurance/benefit design and characteristics. At present, there are limited data to fully inform PDAB deliberations; thus, this study aims to investigate factors associated with variations in drug spending.

OBJECTIVE: To describe factors that contribute to the variation in drug spend in states with similar PDABs.

METHODS: The IQVIA PharMetrics Plus closed claims database was used to conduct a retrospective analysis of pharmacy and medical claims (2018-2022) for patients on select drugs to assess plan spend and patient liability by patient- and insurance-related factors including the Charlson Comorbidity Index (CCI), cost-sharing types (copays, deductibles, and coinsurance), plan type (e.g., PPO, high-deductible health plan) and funding (fully insured [FI] vs self-funded [SF]). Based on drugs generally eligible for review by state PDABs, 20 drugs used to treat rheumatoid arthritis, psoriasis, multiple sclerosis, and cancer were included. Patients were required to have at least 3 claims throughout a

calendar year for a given drug and be continuously enrolled in a SF or FI plan throughout at least one calendar year to be included in the study. Descriptive statistics were used to assess plan drug spending and patient liabilities for drugs.

RESULTS: A total of 174,761 patients were included, of whom 12,935 patients were located in states with PDABs (CO, MD, MN, OR, WA). Nationwide, there was significant variation in both median annual plan spend amounts ($57,826 [IQR: $35,502, $77,395]) and patient liability ($624 [IQR: $200, $1,717]). Those patients with a low-deductible, self-funded, point-of-service plan with copays had significantly lower median patient liabilities than those patients with a fully insured high-deductible plan and coinsurance ($338 vs $6,469, $P < 0.001$). Among PDAB states, high-deductible plans had consistently the largest median annual patient liabilities (range: $2,039 to $3,600) while PPOs generally had the lowest (range: $0 to $874). Comorbidities was a substantial factor in payer spending with differences in median plan paid costs between CCI scores of 0 to 3+ of >$5,000 in MN to >$20,000 in OR.

CONCLUSIONS: Variations in health plan drug spend and patient liabilities are shaped by the interplay of insurance benefit designs and patient characteristics. State-level solutions for drug affordability require a multi-faceted approach to address these complex associations.

SPONSORSHIP: Genentech, Inc.

Hematologic

223 Fitusiran prophylaxis reduces episodic treatment-associated costs of managing breakthrough bleeds in hemophilia

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BACKGROUND: The ATLAS-OLE (NCT03754790) assessed the long-term safety and efficacy of the fitusiran's antithrombin-based dosing regimen (AT-DR) in people with hemophilia (PwH). This antithrombin (AT)-lowering siRNA therapeutic was compared to clotting factor concentrate (CFC) and bypassing agent (BPA) prophylaxis in a subset of participants.

OBJECTIVE: To quantify the potential cost-savings associated with the results from the ATLAS-OLE trial, which demonstrated that fitusiran AT-DR was associated with reduced CFC/BPA use for breakthrough bleeds management compared to CFC/BPA prophylaxis.

METHODS: A cost-calculation model was developed in Microsoft Excel including following parameters: episodic treatment doses of CFC/BPA, the number of CFC/BPA doses required to treat a bleed during CFC/BPA prophylaxis, mean body weight, the US wholesale acquisition costs for CFC/BPA treatment, the administration costs in US health care setting, and the reduction in CFC/BPA episodic usage among PwH receiving fitusiran AT-DR. For PwH A without inhibitors, episodic treatments included in the analysis were octocog alfa, efmoroctocog alfa, and rurioctocog alfa pegol, while those for PwH B without inhibitors were nonacog alfa, albutrepenonacog alfa, and eftrenonacog alfa. For PwH with inhibitors, factor VIII inhibitor bypassing activity (FEIBA) and eptacog alfa were included. The base case assumed no vial sharing. For each episodic treatment, drug cost per bleed, administration cost per bleed, and combined total cost were calculated for PwH receiving CFC/BPA prophylaxis and for those receiving fitusiran AT-DR. The difference in the costs between CFC/BPA prophylaxis and fitusiran AT-DR was presented as potential cost savings with fitusiran prophylaxis. A scenario analysis assessed the impact of vial sharing.

RESULTS: Fitusiran AT-DR demonstrated cost savings ranging from $4,039 (efmoroctocog alfa) to $5,801 (rurioctocog alfa pegol) per bleed in PwH A without inhibitors and $5,247 (nonacog alfa) to $15,262 (albutrepenonacog alfa) per bleed in PwH B without inhibitors. In PwH with inhibitors, fitusiran AT-DR led to savings of $56,802 (FEIBA) to $78,826 (eptacog alfa) per bleed. Scenario analysis considering vial sharing yielded results consistent with the base case.

CONCLUSIONS: Fitusiran AT-DR prophylaxis demonstrated potential for considerable cost-savings in episodic treatment costs for managing breakthrough bleeds in PwH compared with CFC/BPA prophylaxis. Cost-saving benefits appear more pronounced in PwH with inhibitors than in those without inhibitors.

SPONSORSHIP: Sanofi

224 Real-world experience with efanesoctocog alfa in patients with moderate and severe hemophilia A: Final analysis of the Adelphi Hemophilia Wave III Disease Specific programme

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BACKGROUND: Efanesoctocog alfa is a first-in-class, once-weekly Factor VIII replacement therapy that provides high, sustained factor levels for patients with hemophilia A (PwHA).

OBJECTIVE: To describe the clinical outcomes and treatment landscape among PwHA who received efanesoctocog alfa prophylaxis.

METHODS: This retrospective, observational study analyzed data collected between July 2023 and December 2024 from the US-based real-world Hemophilia Wave III Disease Specific Programme. The cross-sectional survey included male PwHA (moderate or severe) receiving efanesoctocog alfa. Data were obtained via physician-completed patient record forms. Patient characteristics and treatment landscape were analyzed for patients receiving prophylactic efanesoctocog alfa for any duration (Group 1) and those receiving for ≥170 days (Group 2). Bleed outcomes were analyzed only for Group 2.

RESULTS: This analysis included 84 patients in Group 1 and 44 patients in Group 2. Mean (SD) age was 23.4 (13.0) and 24.2 (11.3) years, respectively, with 89.3% and 93.2% never having had inhibitors. Mean (SD) duration since initiating efanesoctocog alfa until data collection was 192.3 (118.4) days in Group 1 and 263.3 (77.3) days in Group 2. Among Group 2 (n = 40), estimated mean (SD) annualized bleed rate (ABR) significantly decreased from 0.97 (2.25) in 12 months prior to initiating efanesoctocog alfa to 0.21 (0.6) post-initiation ($P = 0.0091$). Prior to initiation, 62.5% patients had no bleeds, 22.5% had 1 bleed, and 5% (each) had 2, 3, 5+ bleeds. Following initiation, 87.5% reported no bleeds, 7.5% had 1 bleed, and 5% had 2 bleeds. In Groups 1 and 2, mean (SD) dosing interval for efanesoctocog alfa was every 7.0 (0.2) and 7.0 (0.3) days, respectively, with mean (SD) dose of 49.7 (2.4) and 49.5 (3.1) IU/kg. Physicians reported satisfied or completely satisfied with following treatment attributes in Groups 1 and 2, respectively: managing patients' hemophilia (91.8% and 97.7%), overall safety (96.5% and 97.7%) and efficacy (94.1% and 100%), administration frequency (92.9% and 97.7%) and duration (90.6% and 100%).

CONCLUSIONS: Results from this real-world survey demonstrate that prophylactic efanesoctocog alfa use in PwHA was associated with lower ABRs than in the 12 months prior to treatment initiation. Dose and frequency of efanesoctocog alfa administration were consistent with the US prescribing information. Physicians reported satisfaction with its efficacy, safety, and administration attributes. These findings highlight efanesoctocog alfa as an effective alternative to existing prophylactic treatments for PwHA.

SPONSORSHIP: Sanofi

225 Treatment patterns, health care resource utilization (HCRU), and costs in adolescent and young adult (AYA) patients (pts) with acute lymphoblastic leukemia (ALL)

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BACKGROUND: The treatment (Tx) landscape for ALL has evolved significantly over the past decade with protocol updates and newer therapies. Asparaginase (ASP)-containing pediatric-inspired regimens (PIRs) have shown improved survival and decreased relapse rates over conventional cytotoxic regimens such as hyper-CVAD. However, ASP-containing PIRs are not widely adopted despite guideline recommendations.

OBJECTIVE: To examine Tx patterns, HCRU, and costs for AYA pts with newly diagnosed ALL in the United States.

METHODS: This retrospective descriptive analysis used the Optum deidentified Market Clarity claims and electronic heath records database from Jul 2018 to Dec 2023. Index date (ID) was defined as the earliest non-diagnostic medical claim for ALL. Pts were followed until earliest of disenrollment/end of study (min 3 months) or death. Eligible pts aged 15-39 years had ≥2 non-diagnostic claims for ALL on separate days, with continuous enrollment and without another primary cancer or pregnancy in a 6-month baseline (prior to ID) and follow-up period, without any history of oncology medication or ALL diagnosis prior to ID, and initiated Tx ≤60 days of ID.

RESULTS: Pts (N = 157) received ASP (n = 43), hyper-CVAD (n = 29), nelarabine (n = 8), regimens without core components of a PIR (non-PIR, n = 55), or other regimens (n = 22). Mean follow-up duration was ~2 years. Pt characteristics were similar across groups (overall median age 19 years; 66% male) except for age and sex of hyper-CVAD–treated pts. Median (IQR) time from diagnosis to Tx was 22 (10-34), 29 (15-40), 17 (13-24), 15 (11-25), and 17 (9-34) days overall, with ASP, hyper-CVAD, nelarabine, and non-PIR regimens, respectively. Most pts (>90%) were admitted to the ER and/or had ≥1 inpatient stay during follow-up. Per-pt per-month (PPPM) number of visits (mean [SD]) were similar across Txs; ASP-treated pts had fewer PPPM inpatient days (2.9 [3.4]) vs the other 3 cohorts (hyper-CVAD, 4.0 [3.9]; nelarabine, 3.7 [3.7]; non-PIR regimens, 5.4 [7.3]). PPPM total all-cause costs (mean [SD]) were lowest with ASP regimens ($44381 [28456]) and highest with nelarabine ($86270 [67338]). PPPM

pharmacy costs (mean [SD]) were higher with ASP ($1940 [5073]) and nelarabine ($1928 [4141]) compared with hyper-CVAD ($1506 [2623]) and non-PIR regimens ($1426 [2824]).

CONCLUSIONS: In this descriptive analysis, we observed <30% of pts receiving ASP regimens despite guideline recommendations and survival benefits in AYA pts. Analysis also suggests ASP-treated pts have lower all-cause Tx costs and fewer days in the hospital compared to other Txs, supporting adoption of PIR regimens in AYA pts.

SPONSORSHIP: Jazz Pharma

226 Health care resource utilization and costs before and after diagnosis of idiopathic multicentric Castleman disease in the United States

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BACKGROUND: Idiopathic multicentric Castleman disease (iMCD) is a rare cytokine-driven hematologic disorder. Characterization of disease epidemiology is complicated by diagnostic challenges, and the economic burden of iMCD is largely undefined.

OBJECTIVE: To assess changes in health care resource utilization (HCRU) and costs pre- and post-diagnosis among patients with iMCD using real-world data.

METHODS: iMCD patients were identified in the MarketScan Research Databases between January 1, 2016, and June 30, 2024. Patients were included if they had ≥1 claim for CD (ICD-10-CM diagnosis code D47.Z2) and met either (1) an algorithm incorporating established iMCD diagnostic criteria or (2) predefined treatment-based criteria. Index was the date of earliest claim with a CD diagnosis. Patients with >1 claim for CD mimics post-diagnosis were excluded. Eligible patients had continuous medical and pharmacy benefits for >6 months pre- and post-index. HCRU and inpatient, outpatient, and pharmacy costs were compared pre- and post-diagnosis. Post-diagnosis iMCD-related costs—including claims with the CD diagnosis code, lymph node biopsy procedures, and CD-related therapies—were reported.

RESULTS: There were 114 eligible iMCD patients (mean age 49.6 years; 50% female; 85% commercially insured). In the 6 months post-diagnosis, patients were significantly more likely to have ≥1 inpatient admission compared to the 6 months prior (46.5% vs 29.0%; $P = 0.003$); 34.0% of these admissions were iMCD-related. Use of CD-related therapies post-diagnosis was limited: 16.7% siltuximab,12.3% rituximab, 2.6% tocilizumab, and 0.9% chemotherapy. Mean (SD) all-cause health care costs more than doubled ($49,311 [$94,418] pre-diagnosis and $114,027 [$165,096] post-diagnosis; $P < 0.001$), significantly driven by higher inpatient and outpatient costs (↑$62,308; $P < 0.001$). Median post-diagnosis costs were also more than 3× higher ($62,210 vs $19,191) versus pre-diagnosis. iMCD-related costs averaged $58,219 ($122,438), accounting for 51.1% of all-cause costs post-diagnosis, including 67.3% of outpatient and 39.3% of inpatient costs.

CONCLUSIONS: Economic burden increased significantly during the 6 months post-diagnosis and uptake of recommended treatments remained limited. Findings underscore the need for earlier diagnosis and treatment interventions to improve disease management and reduce health care burden in iMCD patients.

SPONSORSHIP: Recordati Rare Diseases

227 Impact of acute pain and fatigue on health care resource utilization and costs in sickle cell disease in the United States

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BACKGROUND: Pain and fatigue are common symptoms of sickle cell disease (SCD), but the economic burden associated with these symptoms remains unclear.

OBJECTIVE: To evaluate whether acute pain and fatigue in patients with SCD are associated with increased health care resource utilization (HCRU) and costs in the United States.

METHODS: A retrospective, longitudinal cohort study was conducted among patients aged ≥12 years who were diagnosed with SCD between October 1, 2015, and June 21, 2024, using the TriNetX Linked Network claims database and TriNetX Dataworks-USA electronic health record data, excluding those with sickle cell trait. Clinical characteristics and treatments were assessed during a 12-month baseline period. Acute pain was defined as an emergency department (ED) or inpatient encounter with an ICD-10-CM code for generic pain or SCD crisis, where intravenous pain medication was administered, or when an opioid prescription was given within 7 days of the respective ED/inpatient encounter. Fatigue was defined as hemoglobin levels ≤10.0 g/dL (a proxy for fatigue) or a diagnosis using ICD-10-CM codes for fatigue. Cases were required to meet both definitions of

acute pain and fatigue within a 12-month period. Controls included patients without pain and without fatigue throughout the study period. Incremental annual HCRU and costs (2023 US dollars) to payers were estimated via multivariable regression models, adjusting for SCD genotype, baseline treatments, and clinical and demographic characteristics.

RESULTS: Overall, 1,075 cases and 451 controls were included. Compared with controls, patients with pain and fatigue were more likely to be female (58% vs 51%; $P<.05$) and to have received hydroxyurea treatment (40% vs 9%; $P<.001$) and transfusions (46% vs 9%; $P<.001$) at baseline. Patients with pain and fatigue experienced significantly more comorbidities, including chronic pulmonary disease (37% vs 15%; $P<.001$) and hypertension (34% vs 18%; $P<.001$). The probability of inpatient, outpatient, ED, and pharmacy utilization was much greater among patients with pain and fatigue than controls (all $P<.001$), leading to an average increase in all-cause cost of $7,689 per patient per year ($30,415 in total costs, a 250% increase compared with controls).

CONCLUSIONS: This study highlights the substantial and previously underrecognized economic burden of acute pain and fatigue among patients with SCD, including increased probability of 12-month HCRU. These findings reinforce the need for treatments that address unmet needs for the management of acute pain and fatigue among patients with SCD.

SPONSORSHIP: Novo Nordisk Inc.

228 Resource utilization and economic burden among a cohort of patients with hemophilia without inhibitors in the United States

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BACKGROUND: Hemophilia is a rare bleeding disorder with complex manifestations and potentially expensive treatment options for patients with hemophilia A or B without inhibitors (PwHAwoI or PwHBwoI). Patients with hemophilia experience significant economic burden associated with their disease and its management.

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

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

RESULTS: Data were collated from 6606 patients, well distributed across the United States with 17% to 37% in each geographical quadrant. The 5095 PwHAwoI and 1511 PwHBwoI had a median age of 25.5 and 26.2 years, respectively. Almost all patients were male (91% HAwoI and 90% HBwoI). Joint-related problems were reported for many patients (36% HAwoI and 35% HBwoI). Mean annualized bleeding rate (ABR) was 1.1 in both groups. Fifty-eight percent of PwHAwoI (n = 2967) and 59% (n = 887) of PwHBwoI experienced ≥1 bleeding event. Of the 1449 (28%) PwHAwoI receiving prophylaxis, bleeds were experienced by 52% (n = 752), with a mean ABR among those with ≥1 bleed of 1.8. Of the 271 (18%) PwHBwoI on prophylaxis, bleeds were experienced by 55% (n = 150), with a mean ABR of 2.6. On an annualized basis, patients demonstrated significant hemophilia-related HCRU. Fourteen percent of PwHAwoI were hospitalized (mean [SD] duration of 3.0 [7.5] days), 97% had outpatient visits, and 39% visited the emergency department (ED). Seventeen percent of PwHBwoI were hospitalized (mean [SD] duration of 2.6 [4.5] days), 97% had outpatient visits, and 38% visited the ED. Mean all-cause total costs (PwHAwoI, $133,527; PwHBwoI, $85,778) were largely composed of pharmacy costs for HAwoI (54%) and medical costs for HBwoI (77%).

CONCLUSIONS: Patients with hemophilia without inhibitors incur substantial economic burden. There is an urgent need for improved prophylactic options and targeted interventions to optimize patient care and mitigate costs.

SPONSORSHIP: Novo Nordisk

229 Mitapivat treatment usage, satisfaction, and adherence among adults with pyruvate kinase deficiency in the United States

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BACKGROUND: Pyruvate kinase (PK) deficiency is a rare, inherited, autosomal recessive enzyme disorder characterized by chronic hemolytic anemia. Mitapivat is a first-in-class oral allosteric activator of PK approved in the United States for the treatment of hemolytic anemia in adults with PK

deficiency, and in the EU and UK for the treatment of PK deficiency in adults. Data on patient satisfaction and adherence to mitapivat treatment in a real-world setting are limited.

OBJECTIVE: To understand mitapivat usage, satisfaction, and adherence among adults with PK deficiency.

METHODS: Consenting adults (≥18 yrs) with PK deficiency in the United States were recruited between May and Sep 2024. This observational study utilized medical records (MRs) and bespoke patient-completed questionnaires asking about patients' experience with PK deficiency, its management, their mitapivat treatment history, and the Patient-Reported Outcomes Measurement Information System (PROMIS) Medication Adherence Scale (PMAS). Patients enrolled in a mitapivat clinical trial were excluded. Data were summarized descriptively.

RESULTS: Of 17 patients with MR data, 16 (94%) completed the questionnaires. Median (min, max) age at enrollment and age at diagnosis were 47 (20, 63) yrs and 7 (0, 57) yrs, respectively; 71% (12/17) were female, and 76% (13/17) were White. Lifetime history of PK deficiency complications included high iron levels (88%, 14/16), deep vein thrombosis (31%, 5/16), and osteoporosis (25%, 4/16). Mitapivat treatment was documented in 94% (16/17) of MRs. At the time of questionnaire, 94% (15/16) reported ever taking mitapivat and 88% (14/16) reported current use. Median (min, max) treatment duration was 1.14 (0.21, 2.26) yrs. MR data showed only 1/16 discontinued mitapivat, which was due to side effects/poor tolerance. All 14 patients currently on mitapivat stated that they rarely (14%) or never (86%) stop taking mitapivat due to bothersome side effects. Of 14 currently on mitapivat, mean (SD) PMAS Medication-Taking Behaviors subscale score was 24 (1) of 25, and mean (SD) PMAS total score was 43 (1) of 45, indicating high adherence. Mean (SD) PMAS Medication Beliefs and Knowledge subscale score was 19 (1) of 20, indicating positive beliefs about mitapivat's benefit and good understanding of its use. Of the 15 patients that ever took mitapivat, 67% were satisfied/very satisfied with mitapivat, and 20% were neutral.

CONCLUSIONS: In this small, real-world study of adults with PK deficiency, preliminary evidence suggests that mitapivat treatment is satisfactory, with desirable levels of medication adherence reported.

SPONSORSHIP: Agios Pharmaceuticals, Inc.

230 The economic burden of immune thrombocytopenia in the United States: Insights from a systematic literature review and key evidence gaps

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BACKGROUND: Immune thrombocytopenia (ITP) is a rare autoimmune disorder characterized by low platelet levels, leading to clinical presentations that range from asymptomatic to uncontrolled bleeding. Severe cases often require hospitalization and costly treatments, including infusions, transfusions, and splenectomy. Understanding the economic burden associated with ITP is critical to inform health care decision-making in the United States.

OBJECTIVE: To summarize data on the economic burden associated with ITP in the United States and identify evidence gaps to inform future research.

METHODS: Systematic searches were conducted in MEDLINE and Embase on April 26, 2025. English language articles published since January 2015 were evaluated for inclusion. Supplementary searches of recent major conferences and gray literature were conducted. Studies were screened for relevance at 2 levels (title/abstract and full text) by 2 researchers independently using the same prespecified PICOS criteria, with disagreements adjudicated by a third reviewer.

RESULTS: Overall, 737 publications were identified, and 58 unique studies met inclusion criteria and described economic outcomes among patients with ITP in the United States. Several large claims-based analyses were included (average sample size of 3,688 patients with ITP). Most studies (84%) reported health care resource utilization (HCRU) metrics, most commonly hospitalizations and length of stay, splenectomies, and infusion (IVIG, steroids) and transfusion (platelets, red blood cells) rates. The National Inpatient Sample was the most common data source (17 studies). Direct costs were reported in 25 studies. While costs associated with hospitalization were the most common (15 studies), costs associated with bleeding-related episodes, treatments, and adverse events were also reported. No studies reported indirect costs specific to patients with ITP in the United States. Additionally, 7 economic models were identified, including cost-effectiveness analyses, cost-consequence models, and a cost-minimization model. The cost associated with severe bleeding events was

consistently identified as a key driver. Other key parameters included costs associated with drug administration, treatment discontinuation, and drug wastage.

CONCLUSIONS: Direct costs and HCRU associated with ITP in the United States are well characterized. Key direct cost drivers include hospitalizations, bleeding events, and treatments. Indirect costs, including work loss and caregiver burden, specific to US patients with ITP represent an important evidence gap.

SPONSORSHIP: Novartis

231 Real-world impact on work and school among adults with pyruvate kinase deficiency in the United States

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BACKGROUND: Pyruvate kinase (PK) deficiency is a rare, inherited, autosomal recessive enzyme disorder characterized by chronic hemolytic anemia, causing complications and reduced quality of life. Though data are limited, patients have reported daily social and physical limitations, including the inability to reach full potential at work or school.

OBJECTIVE: To describe the lifetime impact of PK deficiency on work and school among adults in a real-world setting.

METHODS: Consenting adults (≥18 yrs) with PK deficiency in the United States were recruited between May and Sep 2024 to participate in this observational study that used a cross-sectional survey about their disease, its management, and impact on their lives, including questions about its impact on lifetime work and school performance. Patients enrolled in a mitapivat clinical trial were excluded. Data were summarized descriptively.

RESULTS: Seventeen patients enrolled in the study, of whom 16 completed the survey; 71% (12/17) were female and 76% (13/17) were White. Median (min, max) age at enrollment was 47 (20, 63) yrs. Overall, 38% of patients (6/16) were receiving disability allowance, 31% (5/16) worked full time, 13% (2/16) were retired, 13% (2/16) were not working but seeking employment, and 6% (1/16) were working part time. The majority, 69% (11/16), of patients reported negative impacts of PK deficiency on work, including reduced performance (38%, 6/16), taking on fewer responsibilities than desired (38%, 6/16), and unplanned time off (31%, 5/16). Among the 6 with reduced performance, PK deficiency symptoms with negative impact included fatigue (100%), brain fog/impaired concentration (83%), memory difficulties (33%), and appearance causing unwanted attention (33%). The majority, 63% (10/16), of patients also reported their schooling had been negatively impacted by PK deficiency, including reduced performance (38%, 6/16), unplanned time off from school (25%, 4/16), and reduced study duration (25%, 4/16). Among the 10 with negatively impacted schooling, PK deficiency symptoms included fatigue (70%), brain fog/impaired concentration (70%), memory difficulties (50%), and appearance causing unwanted attention (40%).

CONCLUSIONS: In this observational, small real-world study, most patients reported negative impacts of PK deficiency on both work and school. Fatigue and brain fog/impaired concentration markedly contributed to decreases in work or school performance. PK deficiency symptoms also contributed to unplanned time off from work and school.

SPONSORSHIP: Agios Pharmaceuticals, Inc.

232 Impact of emicizumab on real-world health care resource utilization in the United States

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BACKGROUND: Clinical trial and real-world data have shown that emicizumab prophylaxis significantly improves bleeding outcomes in people with hemophilia A (PwHA). Additional real-world evidence on the impact of emicizumab on health care resource utilization (HCRU), as a result of fewer bleed events, would further support its value.

OBJECTIVE: To evaluate changes in real-world HCRU in PwHA in the United States pre- and post-emicizumab prophylaxis initiation.

METHODS: This retrospective, observational cohort study used US adjudicated health plan claims data from IQVIA PharMetrics Plus. PwHA were included if they had ≥1 emicizumab prescription filled between Nov 1, 2017, and Jun 30, 2023 (index date defined as first fill); continuous medical and pharmacy benefits for ≥12 months pre- and post-index; and ≥1 inpatient or ≥2 outpatient *International Statistical Classification of Diseases, Tenth Revision* hemophilia A (hereditary Factor [F]VIII deficiency) diagnosis codes pre-index or on the index date. PwHA were excluded if they were diagnosed with hemophilia B or other rare bleeding disorders during the study period. HCRU outcomes were evaluated during the 12 months pre- and post-emicizumab initiation and included all-cause hospitalizations; outpatient hospital, emergency department (ED) and physician office visits; and FVIII prescription fills. Pre- and post-emicizumab outcomes in the same PwHA were compared using descriptive statistics and $\chi 2$ and Wilcoxon signed-rank tests.

RESULTS: Among 472 PwHA, mean age was 24.7 years (SD, 17.3) and 98.7% were male. Most PwHA were from the South (37.3%) or Midwest (26.2%) and had commercial (60.2%) or self-funded (21.2%) insurance. In the 12 months pre-emicizumab, 53.7% of PwHA had claims for FVIII and/or bypassing agents. Following emicizumab initiation, fewer PwHA had any hospitalization (11.2% pre-emicizumab vs 5.5% post-emicizumab; $P=0.001$), outpatient hospital visit (86.7% vs 76.7%; $P<0.001$) or ED visit (37.1% vs 24.8%; $P<0.001$). Per PwHA, fewer average hospitalizations (mean [SD], 0.6 [3.9] vs 0.4 [3.6]; median, 0 vs 0; $P=0.002$) and ED visits (mean [SD], 0.8 [2.5] vs 0.4 [1.4]; median, 0 vs 0; $P<0.001$) were observed post-emicizumab. Physician office HCRU did not change. FVIII prescription fills were significantly reduced post-emicizumab (mean [SD], 6.0 [9.7] vs 1.8 [3.7]; median [IQR], 1 [0-13] vs 0 [0-2]; $P<0.001$).

CONCLUSIONS: Based on real-world data, initiating emicizumab was associated with significantly decreased FVIII prescription fills, hospitalizations, and ED visits among PwHA in the United States.

SPONSORSHIP: F. Hoffmann-La Roche Ltd.

Immunology

241 Comparative effectiveness and economic evaluation of immunomodulatory therapies in generalized myasthenia gravis

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BACKGROUND: Generalized myasthenia gravis (gMG) is a rare, chronic autoimmune disorder characterized by potentially life-threatening muscle weakness. In recent years, multiple novel immunomodulatory therapies have been approved or are under review in the United States based on trials demonstrating improved outcomes versus placebo. In the absence of head-to-head trials, comparing the effectiveness and costs of these treatments is essential to support informed treatment and coverage decisions.

OBJECTIVE: To evaluate the relative clinical benefits and costs per improved outcome (CPIO) of efgartigimod, ravulizumab, rozanolixizumab, zilucoplan, inebilizumab, and nipocalimab for anti–acetylcholine receptor antibody–positive (anti-AChR Ab+) gMG.

METHODS: A network meta-analysis (NMA) was conducted using data from placebo-controlled trials of efgartigimod IV (ADAPT), rozanolixizumab (MycarinG), ravulizumab (CHAMPION-MG), zilucoplan (RAISE), inebilizumab (MINT), and nipocalimab (VIVACITY-MG3) in patients with anti-AChR Ab+ gMG. Where feasible, trials were included in NMAs evaluating ≥3- and ≥5-point improvements in Myasthenia Gravis–Activities of Daily Living (MG-ADL) and Quantitative Myasthenia Gravis (QMG) scores. NMA results were used to estimate the number needed to treat (NNT) vs placebo and relative to the therapy with the lowest NNT. CPIO (2025 USD) was calculated based on efficacy outcomes and treatment-specific drug and administration costs, using real-world weight distributions of gMG patients.

RESULTS: Efgartigimod IV had the lowest NNT vs placebo across three endpoints. For a ≥3-point QMG reduction, its NNT was 2.18, significantly lower than inebilizumab (4.69), nipocalimab (5.13), ravulizumab (4.42), and zilucoplan (3.98) (all $P<0.05$). For ≥5-point QMG reduction, efgartigimod IV had an NNT of 1.88, significantly lower than zilucoplan (4.85). For a ≥5-point MG-ADL reduction, it had the lowest NNT (1.94), outperforming ravulizumab (4.68) and zilucoplan (4.78) ($P<0.05$). Rozanolixizumab had the lowest NNT vs placebo ≥3-point MG-ADL reduction, though the differences were not significant compared to other treatments. Efgartigimod IV also had the lowest CPIO vs placebo across all outcomes, with significantly lower costs than all comparators for QMG outcomes and all except rozanolixizumab for MG-ADL outcomes.

CONCLUSIONS: All therapies demonstrated benefit; however, efgartigimod IV showed the lowest NNTs and lowest CPIO compared to ravulizumab, rozanolixizumab, zilucoplan, inebilizumab, and nipocalimab for anti-AChR Ab+ gMG.

SPONSORSHIP: argenx, Inc.

242 Treatment patterns and outcomes of Acthar Gel in ankylosing spondylitis and psoriatic arthritis: A physician-reported chart review

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BACKGROUND: The prevalence for ankylosing spondylitis (AS) has been estimated to be ranging from 0.2 and 1% within the United States, while approximately 64 per 100,000 adults are diagnosed with psoriatic arthritis (PsA). Patients are typically managed with biologics, nonbiological disease-modifying antirheumatic drugs (DMARDs), and nonsteroidal anti-inflammatory drugs (NSAIDs). Acthar Gel is a naturally sourced complex mixture of adrenocorticotropic

hormone analogs and other pituitary peptides. Acthar Gel is approved by the US Food and Drug Administration (FDA) for the treatment of several autoimmune inflammatory disorders, including ankylosing spondylitis (AS) and psoriatic arthritis (PsA).

OBJECTIVE: To describe the characteristics of patients with AS or PsA treated with Acthar Gel, medication utilization, and physicians' assessments of the effects of Acthar Gel on patients' health status.

METHODS: A prospectively designed, cross-sectional, medical chart review study with a predefined protocol and analysis plan was conducted in November 2024, with data abstracted from patient records between April 2022 and November 2024. Eligible patients were aged ≥18 years, had AS or PsA, and had received Acthar Gel within ≤24 months.

RESULTS: On average, patients with AS were aged 44 years, and those with PsA were 51 years—primarily Caucasian/non-Hispanic. Most patients with AS were male (67%, 42/63), whereas PsA had a similar gender distribution (49% [38/77] each). Common comorbidities included arthritis/osteoarthritis, chronic joint disease, and hypertension. Before receiving Acthar Gel, physicians reported 41% (26/63) of patients with AS and 44% (34/77) with PsA had fair-to-poor health status. Frequent symptoms in AS were back pain, lower back/hip stiffness, and fatigue, and those in PsA were joint swelling and pain, reduced range of motion, and fatigue. Based on physician assessment, 95% (60/63) with AS and 88% (68/77) with PsA had improved health after Acthar Gel treatment. Improvements included reduction in overall symptoms (AS: 70% [42/60]; PsA: 63% [43/68]), decreased pain (AS: 68% [41/60]; PsA: 62% [42/68]), improved physical function (AS: 53% [32/60]; PsA: 54% [37/68], improved fatigue (AS: 35% [21/60]; PsA: 32% [22/68]), and reduced corticosteroid use (AS: 30% [18/60]; PsA: 31% [21/68]).

CONCLUSIONS: Findings of this chart review reinforce Acthar Gel as an important treatment option for appropriate patients with AS or PsA. A majority of patients evaluated experienced a reduction in overall symptoms, decreased pain, improved physical function, improved fatigue, and reduced corticosteroid use.

SPONSORSHIP: Mallinckrodt Pharma

243 Economic burden of allogeneic hematopoietic stem cell transplantation in severe leukocyte adhesion deficiency-I: A US database study of primary immunodeficiencies

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BACKGROUND: Leukocyte adhesion deficiency-I (LAD-I) is a rare primary immunodeficiency disorder (PIDD), causing life-threatening infections and inflammatory complications. Most patients present with a severe phenotype, which is associated with significant infant mortality. Allogeneic hematopoietic stem cell transplantation (allo-HSCT) is the only current definitive treatment. However, many patients only receive best supportive care (BSC) due to donor availability and access limitations in some healthcare systems.

OBJECTIVE: To more broadly characterize, given the paucity of available data on the long-term health care resource use and costs of allo-HSCT for severe LAD-I, the economic burden of patients with severe LAD-I and PIDDs.

METHODS: This retrospective database analysis uses US health care data from the Optum administrative claims research database (Oct 2015 to Aug 2023). LAD-I has no defined ICD-10-CM diagnosis code. Patients with conditions determined suitably analogous to severe LAD-I via clinical validation were identified with ≥1 medical claim for PIDD and ≥1 claim for allo-HSCT during the study period. Date of first allo-HSCT was the index date, from which allo-HSCT costs were estimated; a 12-month pre-index period represented costs for BSC.

RESULTS: There were 92 patients with a severe PIDD in receipt of allo-HSCT, with a mean duration of exposure of 36 months and a mean age of 39.3 years. Most received one transplant (82.6%) and 16 received two transplants (17.4%). Post-index, 58 experienced graft versus host disease without graft failure (63.0%), 19 experienced graft failure (20.7%), and 20 patients died in the first year following allo-HSCT (21.7%). Patients incurred $1,525,864 in mean all-cause health care costs, mainly from an inpatient setting ($1,000,232; 65.6%). Patients incurred mean costs of $487,538 (32.0% of total costs) during the pre-index year (under BSC), with the first-year post-index associated with the greatest cost ($815,041;

53.4%), primarily within the first 100 days ($538,612; 35.3%). Estimated costs were higher if exposure-adjusted and/or stratified by age or by transplant-related complications.

CONCLUSIONS: PIDDs such as severe LAD-I exert a substantial burden on the US health care system. Allo-HSCT is associated with significant long-term costs and HCRU, especially in younger patients and those experiencing transplant-related complications. An unmet need exists for therapies that avoid transplant-related inpatient care, morbidity and mortality.

SPONSORSHIP: Rocket Pharmaceuticals, Inc.

244 Health care costs associated with the care of patients with chronic inflammatory demyelinating polyneuropathy receiving immunoglobulin or neonatal fragment crystallizable receptor inhibitor therapies in the United States

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BACKGROUND: Chronic inflammatory demyelinating polyneuropathy (CIDP) is a rare disease characterized by peripheral neuropathy and sensory and/or motor impairment. Maintenance therapies include intravenous immunoglobulin (IVIG), subcutaneous immunoglobulin (SCIG), facilitated SCIG (fSCIG), and neonatal fragment crystallizable receptor inhibitor (anti-FcRn).

OBJECTIVE: To assess health care costs associated with the care of US patients with CIDP receiving maintenance therapy.

METHODS: This noninterventional, retrospective cohort study used the Komodo Health Research Database Plus (January 1, 2016, to March 31, 2025). Adults (aged ≥18 years at index [date of first treatment claim]) with ≥2 claims for CIDP diagnosis (ICD-10-CM G61.81) and continuous enrollment for ≥6 months pre- and ≥3 months post-index were included. Patients were stratified into cohorts based on CIDP treatment: IVIG, SCIG, fSCIG, or anti-FcRn. Demographics and disease characteristics were described for the baseline period (6 months pre-index); health care costs were evaluated from index to the earliest of death, end of enrollment, or end of data availability. Costs are presented as median (Q1-Q3) in US dollars per patient per month (PPPM).

RESULTS: A total of 4,098, 544, 12, and 59 patients, respectively, were represented in the IVIG, SCIG, fSCIG, and anti-FcRn cohorts, with median follow-up periods of 24.0, 24.5, 6.6, and 4.8 months. At baseline, median age ranged from 55.5 years (anti-FcRn) to 66.0 years (SCIG); typically, patients were male (50.0%-71.2%) and White (58.3%-81.4%). Total all-cause costs (presented as PPPM) were highest for anti-FcRn ($44,073 [26,544-72,594]) followed by fSCIG ($14,504 [8,488-17,839]), SCIG ($12,687 [7,293-20,267]), and IVIG ($8,857 [4,406-15,303]). Total CIDP-related costs were $43,214 (24,555-70,216) for anti-FcRn, $11,202 (5,941-15,903) for fSCIG, $11,187 (5,640-18,552) for SCIG, and $6,520 (2,529-12,611) for IVIG. Costs of treatments of interest were $43,069 (23,081-68,961) for anti-FcRN, $10,352 (5,597-15,820) for fSCIG, $9,399 (4,332-16,684) for SCIG, and $4,586 (1,416-9,541) for IVIG. CIDP-related medical costs (excluding treatment-of-interest costs) were highest for IVIG ($685 [217-1,979]), followed by SCIG ($535 [202-1,420]), anti-FcRn ($323 [125-1,355]), and fSCIG ($177 [80-1,425]).

CONCLUSIONS: CIDP is associated with high monthly health care costs, primarily driven by treatments of interest, particularly in the anti-FcRn cohort. CIDP-related medical costs, excluding treatment, were lowest in the fSCIG cohort.

SPONSORSHIP: Takeda Pharmaceuticals USA, Inc.

245 Advancing managed care decision-making through cross–disease state understanding of type 2 (T2) inflammation to treat the underlying disease mechanism

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BACKGROUND: Evolving knowledge of type 2 (T2) inflammation has transformed the management of conditions like eosinophilic esophagitis (EoE), atopic dermatitis (AD), asthma, and some forms of COPD. As biologic therapies targeting T2 pathways improve patient care, managed care professionals face challenges assessing their value across multiple indications. A deeper understanding of the inflammatory pathway is key to support evidence-based coverage decisions for newly approved therapies.

OBJECTIVE: To increase knowledge of the clinical rationale of managing T2 inflammation and competence with treatment guidelines through a continuing education (CE) series for managed care professionals across four disease states.

METHODS: The CE curriculum included four sequenced series (Oct 2024 to Mar 2025), each with six activities: 2 discussion-based webcasts; 2 podcasts; and 2 infographics per disease state. Learners were encouraged to participate in all tracks to maximize cumulative learning and application to practice. Across all activities, outcomes questions measured identification of key T2 mediators, knowledge of relevant guidelines, and intended practice changes.

RESULTS: A total of 415 managed care professionals completed at least one of 24 activities: EoE (n = 93), AD (n = 112), asthma (n = 193), and COPD (n = 145), with 33% (n = 137) participating in multiple disease tracks. Learner knowledge improved notably: correct identification of IL-13 and IL-4 as key mediators rose from 29% to 68% and from 35% to 74%, respectively (n = 339), while "unsure" responses dropped from 40% to 8%. Guideline knowledge improved from 30% to 66% (n = 394), and "unsure" answers fell from 35% to 8%. Learners reported intentions to apply updated clinical guidance, improve care coordination, and reassess utilization management. Asthma and COPD had the most implementation barriers, including cost, coverage complexity, and comorbidities.

CONCLUSIONS: This multi-disease CE series addressed gaps in knowledge of T2 inflammation, guideline-based care, and the evolving role of biologics with a cross-disease mechanism of action. Building knowledge across multiple disease states supports consistent evidence-based decision-making where condition-specific barriers can affect implementation and equip payers to evaluate therapies with cross-indication relevance. Improved understanding of shared inflammatory pathways can inform formulary and utilization management strategies beyond individual drug reviews.

SPONSORSHIP: Regeneron Pharmaceuticals, Inc., and Sanofi.

246 Quantifying the productivity burden of lupus nephritis and the potential value of obinutuzumab treatment

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BACKGROUND: Lupus nephritis (LN) is a severe complication of systemic lupus erythematosus (SLE), which disproportionately affects women of childbearing age during their prime working years. The REGENCY trial (NCT04221477) evaluated obinutuzumab (OBI), a humanized type II anti-CD20 monoclonal antibody, plus standard therapy (ST) for treatment of LN. While productivity loss in SLE has been studied, data on the specific impact and benefits of advanced therapies, like OBI, on productivity loss in LN are limited. To address this, we used an algorithm (Jiao and Basu, 2023) to indirectly estimate productivity impacts on LN based on age and health-related quality-of-life, considering both market (labor) and non-market activities (including caregiving and volunteering).

OBJECTIVE: To estimate the lifetime productivity burden of LN and gains from OBI treatment.

METHODS: Using a Markov cost-effectiveness model, we simulated progression of patients with LN treated with ST (mycophenolate mofetil plus glucocorticoids) or OBI plus ST across chronic kidney disease stages 1-3b, 4, and 5. Transition probabilities were obtained from the REGENCY trial and literature. Health state utilities were derived from prior health technology assessment submissions. Age-specific general US population utilities were from Jiang et al 2023. Patient time was valued by applying average US hourly wage (market and non-market) and fringe benefits (market only), sourced from the US Bureau of Labor Statistics 2025. Patient-level estimates were extrapolated to the US population using the LN incidence rate (1.3 per 100 000 person-years) from Hocaoglu et al 2023.

RESULTS: Patients with LN on ST incurred an average lifetime productivity loss of $345 327 per person compared with the general population, with 79% ($271 119) attributed to market productivity loss. Addition of OBI to ST resulted in a lifetime productivity gain of $36 958 per person due to improved disease prognosis. At the population level, treating patients with OBI plus ST over 10 years could avert an estimated $1.63B in lifetime productivity losses versus ST alone. This includes savings of $1.33B in market productivity and $305M in non-market productivity, translating to an estimated $972M in averted lost wages and $140M in increased national tax revenue.

CONCLUSIONS: Treatment with OBI could significantly mitigate the lifetime productivity burden of LN by reducing lost wages and increasing tax revenue. These findings, alongside clinical efficacy shown in the REGENCY trial, support the value of OBI in LN treatment regimens.

SPONSORSHIP: Genentech, Inc.

Infectious Disease

256 Impact of medications for opioid use disorder on infectious disease management

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BACKGROUND: Opioid use disorder significantly impacts overall health, leading to increased morbidity with the exacerbation of other severe health conditions. For instance, injection drug use has been linked to the spread of infectious diseases (ID), yet there is a lack of data on the effects of medications for opioid use disorder (MOUD) utilization on ID outcomes.

OBJECTIVE: To compare the effect of MOUD on acute ID incidence and ID-specific healthcare resource utilization (HCRU) across two buprenorphine-based treatment cohorts.

METHODS: This retrospective observational cohort study utilized the Veradigm outpatient electronic health records linked to a claims database between July 2018 and Dec 2023 to identify patients treated with either transmucosal buprenorphine (TM-BUP) or extended-release buprenorphine (XR-BUP) for ≥90 consecutive days. Both unweighted analyses and analyses adjusted using inverse probability of treatment weighting (IPTW) were conducted to assess the impact of TM-BUP compared to XR-BUP on acute ID incidence rates and ID-specific HCRU 6 months following treatment initiation, employing a difference-in-difference approach.

RESULTS: Among 467 XR-BUP and 118,112 TM-BUP patients, those receiving XR-BUP had a 37% lower incidence (95% confidence interval: 12%-55%) of acute skin infections (e.g., cellulitis) during the 6 months following treatment initiation compared to TM-BUP in unweighted analyses. In IPTW-weighted acute ID incidence analyses, bacteremia incidence was found to be 62% (26%-81%) lower in the XR-BUP cohort 6 months following treatment initiation compared to the TM-BUP cohort. Unweighted ID-related HCRU analyses revealed XR-BUP patients had significant reductions in inpatient (81%; 18%-96%) and outpatient (55%; 24%-74%) skin infection visits. Outpatient visits for the treatment of hepatitis B/C (63%; 11%-138%) and bone/joint infections (823%; 17%-7192%) were higher for XR-BUP patients, possibly suggesting improved chronic care treatment. After adjusting for IPTW, there was a significant reduction in sexually transmitted infection (STI) outpatient visits (77%; 43%–91%) among XR-BUP versus TM-BUP patients.

CONCLUSIONS: XR-BUP treatment was associated with larger reductions in acute skin infections and bacteremia incidence as well as STI-related outpatient visits compared to TM-BUP, suggesting a potential benefit for XR-BUP in mitigating acute ID complications. Increased hepatitis B/C and bone-joint infection outpatient visits among XR-BUP patients may reflect improved chronic ID management through regular clinical follow-ups.

SPONSORSHIP: Indivior

257 Economic burden of liver progression in patients with chronic hepatitis B virus infection in the United States

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BACKGROUND: Chronic hepatitis B virus (cHBV) infection is a long-term condition associated with a risk of liver disease progression: compensated / decompensated cirrhosis (CC, DC), hepatocellular carcinoma (HCC), and liver transplant (LT).

OBJECTIVE: To describe all-cause health care resource utilization (HRU) and costs of patients with cHBV following a liver disease progression ("progression") event in the United States.

METHODS: This retrospective cohort study used administrative claims from the Merative MarketScan Database. Patients were first indexed on the chronologically first occurring cHBV infection diagnosis between Jan 2017 and Jun 2022 and then re-indexed upon diagnosis of each progression event observed in order of increasing severity: CC, DC, HCC, or LT. Patients aged ≥18 years had no progression events at baseline. For each progression event state, all-cause HRU per year and costs per patient per year (PPPY) (2022 USD) were evaluated from the progression event date until the end of follow-up or the next more severe progression event. Data were analyzed descriptively overall and by payer type.

RESULTS: A total of 7,661 patients were included (Commercial n = 5,303; Medicaid n = 1,981; Medicare n = 377). Mean (standard deviation [SD]) age 47.2 (12.1) years; 52.7% female. Over a mean (SD) follow-up of 2.8 (1.8) years, 956 (12.5%) patients progressed (CC n = 497; DC n = 355; HCC n = 191; LT n = 23) with rates varying by payer: Medicaid 20.3%; Medicare 14.3%; Commercial 9.4%. Except for LT (78.3%), less than half across all progression event types were treated with nucleos(t)ide analogues/Peg-interferon (CC 46.5%; DC 36.6%; HCC 48.2%), and treatment rates differed by payer type, being highest for Commercial. Following progression, total costs PPPY increased with progression severity (CC $33,341; DC $56,160; HCC $84,363; LT $207,020). The highest proportion of patients with inpatient (73.9%) and outpatient (78.3%) visits were observed during the LT event state. However, among the other 3 events, patients in the DC event state had the highest proportion with inpatient (67.0%) or ED (65.6%) admission but lowest with outpatient visits (44.2%) relative to CC (32.0%, 46.7%, 50.1%) and HCC (31.4%, 40.3%, 55.0%). Similar trends were noted for the number of visits. Costs and HRU varied by payer type across all progression event types.

CONCLUSIONS: Liver disease progression in cHBV infection incurs substantial economic burden. Results highlight the need for therapies that provide an opportunity for functional cure with the potential of reducing or eliminating these complications.

SPONSORSHIP: GSK (Study 209383)

258 Public health impact of increasing RSV vaccination uptake among US adults aged ≥60 years: A modeling analysis based on real-world uptake data through February 2025

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BACKGROUND: In 2023, respiratory syncytial virus (RSV) vaccination was first recommended by the Advisory Committee on Immunization Practices among adults aged ≥60 years in the United States. Based on claims data analyses through February 2025, only 16.4% of US adults aged ≥60 years had received an RSV vaccination.

OBJECTIVE: To model the public health impact of increasing RSV vaccination uptake among US adults aged ≥60 years.

METHODS: A multicohort Markov model estimated RSV-related cases, health care resource use, and deaths with and without adjuvanted RSVPreF3 vaccination of US adults aged ≥60 years. Vaccination uptake was based on age-specific cumulative uptake between August 2023 and February 2025 (ranging from 8.1% for adults aged 60-64 years to 23.3% for adults aged 75-79 years). As a simplifying assumption, vaccination with adjuvanted RSVPreF3 was modeled to occur in August 2023. Other inputs were based on clinical trial data and a targeted review of literature and public sources. Avoided RSV disease burden was estimated for the 5-year period between August 2023 and July 2028. In addition to modeling actual RSV vaccination uptake in the base case, two scenarios of increased uptake were assessed: assuming all age groups achieved the highest uptake observed for 75- to 79-year-olds (23.3%) and assuming a 5-percentage-point increase in uptake for all age groups.

RESULTS: Using actual age-specific RSV vaccination uptake, the model estimated that 13.4 million US adults aged ≥60 years were vaccinated through February 2025. Assuming vaccination in August 2023, these vaccinations resulted in an estimated 714,362 fewer RSV lower respiratory tract disease (LRTD) cases, 74,082 fewer hospitalizations, and 6,025 fewer deaths over 5 years versus no vaccination. If all age groups would have achieved the highest-observed uptake of 23.3%, an additional 5.8 million adults would have been vaccinated. These vaccinations would have resulted in an additional 319,771 RSV-LRTD cases averted, 21,411 hospitalizations averted, and 1,589 deaths averted over 5 years versus the base case. A 5-percentage-point increase from the base case uptake would have resulted in an additional 4.1 million vaccinations versus the base case, avoiding an additional 222,145 RSV-LRTD cases, 20,513 hospitalizations, and 1,636 deaths over 5 years.

CONCLUSIONS: Results highlight the substantial RSV disease burden that is already being avoided by RSV vaccination. Even relatively small increases in RSV vaccination uptake may result in further measurable public health benefits.

SPONSORSHIP: GSK VEO-001295

Mental Health

271 Discontinuation of long-acting injectable versus oral antipsychotics in US patients with schizophrenia: A new-user survival analysis

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BACKGROUND: The American Psychiatric Association suggests the use of long-acting injectable (LAI) antipsychotics for patients with schizophrenia if they have a history of poor adherence. As most LAI antipsychotics require administration only every 2 weeks to 3 months, treatment discontinuation may possibly be reduced compared to daily oral administration. However, LAI antipsychotics are still underutilized in the United States, and the costs are still high. With newer LAI antipsychotics available on the market in recent years, there is a critical need to evaluate the benefits of LAI antipsychotics in contrast to oral antipsychotics.

OBJECTIVE: To compare discontinuation rates between LAI and oral antipsychotics in new users diagnosed with schizophrenia.

METHODS: This study was a survival analysis with a new-user design using Merative MarketScan claims data in the United States from 2020 to 2022. Patients aged 18 years or older with a diagnosis of schizophrenia or schizoaffective disorder and at least one prescription of an LAI or oral antipsychotic initiated after a six-month washout period were included. Inverse probability of treatment weighting (IPTW) was used to control for confounders including age, sex, geographic region, urban residence, and psychiatric and somatic comorbidities. Time to discontinuing LAI versus oral antipsychotics (defined as a 90-day gap in days' supply) after initiating the first antipsychotic prescription was compared using Kaplan-Meier curves. Cox proportional hazards model estimated the hazard ratio, with additional adjustment for Elixhauser readmission score and number of therapeutic drug classes. Subgroup analyses were also conducted to exclude patients on clozapine, first-generation antipsychotics, or both.

RESULTS: A total of 2,936 patients were included, of whom 183 were using LAI antipsychotics and 2,753 were taking oral

antipsychotics. After IPTW, standardized differences of the confounders were less than 0.1, indicating a good balance between groups. Median time to discontinuation was 195 days for LAI users, while that of oral antipsychotics was 133 days. Comparing LAI versus oral antipsychotics, the hazard ratio of discontinuation was 0.786 (95% CI: 0.734-0.842), meaning that LAI users had a 21.4% lower hazard of discontinuing their antipsychotic than oral users. Subgroup analyses also showed similar hazard ratios.

CONCLUSIONS: LAI antipsychotics have a lower hazard of discontinuation compared to oral antipsychotics. These findings support broader formulary coverage and clinical use of LAI antipsychotics to improve adherence among patients with schizophrenia.

SPONSORSHIP: None

272 Risk factors for post-injury mental health conditions: A retrospective cohort study using the Cox proportional hazards model

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BACKGROUND: Physical injuries can trigger mental health (MH) conditions, yet the role of demographic and clinical factors in this progression is not well defined. Prior research is often limited in scope, and the impact of medication duration as a risk indicator remains unclear.

OBJECTIVE: To evaluate the impact of demographic and clinical factors on the risk of developing an MH condition following a physical injury.

METHODS: A retrospective cohort study of 326,636 individuals with physical injuries in 2024 examined time to first mental health (MH) diagnosis within one year post-injury. The primary outcome was the time from injury to the first MH diagnosis. Individuals without a diagnosis during follow-up were right censored at the end of the observation period or upon loss to follow-up. A Cox proportional hazards model was used to assess the impact of age, gender, injury type, and medication supply duration on MH outcomes. Multicollinearity among predictors was minimal, and no significant interaction terms were detected. Model performance was evaluated using the concordance index (C-index).

RESULTS: Among the eligible members, 17,476 individuals (5.4%) developed an MH condition post-injury. Most were aged 35 or older (94.3%) and male (58%). The median follow-up time was 312 days (IQR: 198-365 days). The median time from injury to MH diagnosis was 70 days. Compared to the reference group, hazard ratios (HRs) were significantly higher for individuals aged 35-44 (HR: 1.27; $P < 0.001$), 45-55 (HR: 1.44; $P < 0.001$), and older than 55 (HR: 1.69; $P < 0.001$), while those younger than 25 had a lower risk (HR: 0.54; $P < 0.001$). Both female and males exhibited elevated risks, with HRs of 1.42 ($P < 0.001$) and 1.45 ($P < 0.001$), respectively. Injuries involving multiple head regions were significantly associated with an elevated risk (HR: 2.21; $P < 0.001$), whereas injuries affecting multiple body parts were linked to a modest increase in risk (HR: 1.02; $P = 0.018$). Conversely, vertebral injuries did not show a statistically significant association (HR: 1.00; $P = 0.856$). A medication supply duration of 61-90 days significantly increased the risk (HR: 2.26; $P < 0.001$), whereas a supply of 30 days or less was protective (HR: 0.57; $P < 0.001$).

CONCLUSIONS: Age, gender, injury location, and medication duration significantly influence post-injury MH risk. Individuals with middle age and above, both male and female individuals, and those with injuries involving multiple head regions or extended medication use are at elevated risk. These findings highlight the need for targeted screening and tailored interventions for high-risk groups.

SPONSORSHIP: Optum

273 Assessment of the impact of physical injuries on mental health among commercially insured workers' compensation beneficiaries

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BACKGROUND: Workplace injuries remain a major challenge for employers and insurers, often leading to prolonged recovery and higher health care costs. Emerging evidence shows that mental health (MH) conditions like depression and anxiety frequently co-occur with physical injuries, complicating recovery and increasing resource use. However, there is limited research exploring the relationship between physical injuries and subsequent MH conditions within the commercially insured workers' compensation population.

OBJECTIVE: To evaluate health care resource utilization among commercially insured workers' compensation members who experienced a physical injury followed by an MH condition.

METHODS: A retrospective claims analysis was conducted using workers' compensation data from Jan 01 to Dec 31, 2024. Members were grouped into two cohorts: injury only and injury followed by MH condition. The index date was the first eligible injury-related prescription, with a 12-month washout period. Descriptive analysis assessed demographic and clinical characteristics.

RESULTS: A total of 326,636 eligible members were identified. Of these, 69.0% had injury-only claims and 5.3% had both

injury and MH claims. Among those with injury claims, 7.8% later developed an MH condition. The average age was 49 years in the injury-only group and 56 years in the injury + MH group; 55%-58% were male. Most members were older than 35 years: 84.3% in the injury-only group and 94.3% in the injury + MH group. Common injury types in injury-only vs injury + MH groups included strains (34% vs 25%), sprains (15% vs 11%), contusions (11% vs 8%), fractures (6% vs 7%), and multiple injuries (3.4% vs 4.7%). Among those who developed MH conditions, the most prescribed therapeutic classes were antidepressants (73.0%), antianxiety agents (26.3%), sedatives (12.9%), antipsychotics (5.4%), neurological agents (2.9%), and anti-narcolepsy meds (2.6%). Per-member per-year (PMPY) costs were significantly higher in the injury + MH group, averaging $7,295.37 vs $369.81 in the injury-only group.

CONCLUSIONS: Most affected members were middle-aged or older and often had multiple chronic conditions. Resource utilization was substantially higher among those who developed MH conditions post-injury. These findings highlight the importance of early MH identification and intervention in injured workers. Targeted support programs and early-stage therapies may improve outcomes and reduce preventable health care costs.

SPONSORSHIP: Optum

274 Treatment patterns and health care resource utilization in patients with schizophrenia or bipolar I disorder in the 6 months following initiation of olanzapine/samidorphan versus other atypical antipsychotics

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BACKGROUND: Combination olanzapine and samidorphan (OLZ/SAM) is approved for the treatment of adults with schizophrenia (SZ) or bipolar I disorder (BD-I). In prior real-world studies, initiating OLZ/SAM was associated with significant reductions in hospitalizations and emergency department (ED) visits, which are proxies for relapse.

OBJECTIVE: To assess 6-month acute care events and treatment patterns in patients with SZ or BD-I after initiating OLZ/SAM vs comparator oral atypical antipsychotics.

METHODS: This retrospective (4/19/21 to 12/31/22) claims analysis used data from Komodo Healthcare Map. Eligible adults had 1 or more claims for OLZ/SAM or aripiprazole, cariprazine, olanzapine, risperidone (SZ and BD-I cohorts), brexpiprazole, lumateperone, or lurasidone (SZ cohort only). Continuous enrollment for at least 6 months before and after the index claim was required. Follow-up acute care events (inpatient [IP] admissions, ED visits) and treatment patterns (persistence, adherence, discontinuation) were compared for OLZ/SAM and comparator antipsychotics. Outcomes were stratified by disease cohort and adjusted with inverse probability weighting ($P < 0.05$ considered statistically significant).

RESULTS: There were 51,921 patients in the SZ cohort (OLZ/SAM, n = 848; comparators, n = 51,073) and 39,698 in the BD-I cohort (OLZ/SAM, n = 685; comparators, n = 39,013). In the SZ cohort, likelihoods of all-cause IP admissions and ED visits were significantly lower with OLZ/SAM vs all comparators (IP admission odds ratio [OR] range 0.59-0.73; ED visit OR range 0.67-0.74) except brexpiprazole (IP admission OR 0.80; ED visit OR 0.79). OLZ/SAM was associated with significantly better adherence, longer persistence, and lower likelihood of discontinuation vs all comparators in the SZ cohort. In the BD-I cohort, likelihoods of all-cause IP admissions and ED visits were significantly lower with OLZ/SAM vs olanzapine (IP admission OR 0.71; ED visit OR 0.79); likelihoods of all-cause IP admissions were significantly lower with OLZ/SAM vs risperidone (OR 0.80) and not significantly different from those with cariprazine or aripiprazole. OLZ/SAM initiation was associated with significantly better adherence, longer persistence, and lower likelihood of discontinuation vs all comparators except cariprazine for those with BD-I.

CONCLUSIONS: Real-world treatment with OLZ/SAM resulted in lower use of acute inpatient care than most comparators and better adherence, persistence, and discontinuation vs all comparators in the SZ cohort and most comparators in the BD-I cohort.

SPONSORSHIP: Alkermes, Inc.

275 Health care resource utilization and cost among commercially insured patients with opioid use disorder treated with monthly injectable buprenorphine: A retrospective claims analysis

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BACKGROUND: Buprenorphine is an effective medication for opioid use disorder (MOUD), available in various formulations. Few studies have examined the association between adherence to monthly injectable buprenorphine and health care resource utilization (HCRU) and costs.

OBJECTIVE: To examine HCRU and cost among patients with varying levels of adherence to MOUD.

METHODS: A retrospective claims analysis was conducted using the Merative MarketScan Commercial and Medicare Database with index selection period: March 1, 2019, to December 31, 2022, and study period: March 1, 2018, to

December 31, 2023. The index date was the first claim for extended-release buprenorphine injection (BUP-XR; i.e., SUBLOCADE) during the index selection period. Patients were required to have continuous enrollment with medical, pharmacy, and behavioral health benefits 12 months prior to index (baseline period) and 12 months after and including index (follow-up period). Patient profiles including demographics, clinical characteristics, and medication use were assessed at baseline. HCRU and cost were assessed during the follow-up period. Patients were categorized into sub-cohorts by proportion of days covered (PDC) to BUP-XR during the first 6 months of the follow-up period.

RESULTS: The 663 BUP-XR patients identified were on average 37.5±11.4 years old, were male (67.4%), and resided in the South (45.1%). Patients had high rates of alcohol use disorder (22.2%), other (non-alcohol or opioid) substance use disorder (52.8%), depression/bipolar disorder (47.1%), anxiety (52.2%), and chronic pain (39.5%). Patients with low adherence to BUP-XR (PDC< 0.2) had an average PDC of 0.5 to all other forms of MOUD during the first 6 months of the follow-up period. Patients with high adherence to BUP-XR (PDC≥0.8) had lower rates of all-cause emergency department use (24.2% vs 38.9%), all-cause inpatient admissions (6.4% vs. 6.5%), and evidence of recurrence of opioid use disorder (OUD) symptoms (i.e., return to use) (5.7% vs 16.7%) compared to patients with low adherence (PDC<0.2). After excluding MOUD-related pharmacy costs, patients with high adherence had lower all-cause ($21,319 vs $41,946) and opioid-related health care cost ($8,975 vs. $19,623) compared to patients with low adherence.

CONCLUSIONS: A benefit is seen among patients with high adherence to BUP-XR, including fewer emergency department visits, inpatient admissions, and evidence of recurrence of OUD symptoms compared to patients with low adherence to BUP-XR.

SPONSORSHIP: Indivior

276 Health care resource utilization among patients with opioid use disorder insured by Medicaid and treated with monthly injectable buprenorphine: A retrospective claims analysis

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BACKGROUND: Buprenorphine is an effective medication for opioid use disorder (OUD), available in various formulations. Few studies have examined the health care resource utilization impact associated with monthly injectable buprenorphine adherence.

OBJECTIVE: To examine health care resource utilization (HCRU) among patients with varying levels of adherence to medications for opioid use disorder (MOUD).

METHODS: A retrospective claims analysis was conducted using the Merative MarketScan Medicaid Multi-State Database. The index selection period was from March 1, 2019, to December 31, 2022, and the study period from March 1, 2018, to December 31, 2023. The index date was the first claim for extended-release buprenorphine injection (BUP-XR; i.e., SUBLOCADE) during the index selection period. Patients were required to have continuous enrollment with medical, pharmacy, and behavioral health benefits 12 months prior to index (baseline period) and 12 months after and including index (follow-up period). Patient profiles including demographics, clinical characteristics, and medication use were assessed at baseline. HCRU was assessed during the 12-month follow-up period. Patients were categorized into sub-cohorts by patient's proportion of days covered (PDC) to BUP-XR during the first 6 months of the follow-up period.

RESULTS: The 2,741 BUP-XR patients identified were on average 35.9±8.1 years old and 51.3% female, and 71.4% resided in urban areas. Common baseline comorbidities were substance use disorder other than opioids or alcohol (84.0%), depression/bipolar disorder (64.1%), generalized anxiety disorder (62.1%), chronic pain (39.7%), and alcohol use disorder (23.7%). Patients with low adherence to BUP-XR (PDC< 0.2) had an average PDC of 0.5 to all other forms of MOUD during the first 6 months of the follow-up period. Among BUP-XR patients with high adherence (PDC≥0.8) compared to patients with low adherence (PDC<0.2), lower rates of all-cause (48.3% vs 65.9%) and opioid-related (3.8% vs 12.9%) emergency department use (excluding for detoxification), all-cause (7.7% vs 18.2%) and opioid-related (0.1% vs 0.5%) inpatient admissions (excluding for detoxification), and evidence of recurrence of OUD symptoms (i.e., return to use) (7.6% vs 27.6%) were observed.

CONCLUSIONS: A benefit is seen among patients with high adherence to BUP-XR, including fewer all-cause and opioid-related emergency department visits, inpatient admissions, and evidence of recurrence of OUD symptoms compared to patients with low adherence to BUP-XR.

SPONSORSHIP: Indivior

277 Impact of manufacturer coupon use on product switching in major depressive disorder (MDD) treatment

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BACKGROUND: Manufacturer-sponsored coupons are widely used to reduce patient out-of-pocket costs for branded medications, but limited research exists to understand their impact on switching behavior among MDD patients. In chronic mental health conditions like MDD, continuity of care is critical for optimal outcomes, yet affordability barriers may prompt patients to switch medications prematurely.

OBJECTIVE: To evaluate whether initiation of antidepressant therapy using coupons is associated with continued use of the index therapy among commercially insured patients with MDD.

METHODS: This retrospective cohort study utilized real-world claims data covering more than 300 million lives from January 2021 to April 2025. Adult patients aged 18-65 with MDD diagnosis initiating branded antidepressants (TRINTELLIX, AUVELITY, VRAYLAR, REXULTI, EXXUA, FETZIMA) were included. Patients required 6-month pre-index enrollment, ≥2 prescription fills, and 12-month follow-up. Manufacturer coupon use was identified through secondary payment methods or low copay indicators ($0-$10). Patients were grouped into cohorts based on the use of a coupon at therapy initiation. The primary outcome was switching patterns: no switching, intraclass switching (different brand same class), interclass switching (different therapeutic class).

RESULTS: Among 44,474 patients, 22.3% initiated treatment using manufacturer coupons. Coupon users exhibited a 25.9% higher likelihood of interclass switching (95% CI: 16.5%-36.0%) and a 71.6% lower likelihood of intraclass switching (95% CI: 63.5%-77.9%) compared to non-users. The median time to first treatment change was 117 days for coupon users versus 112 days for non-users. Preliminary findings indicate the need to incorporate generic therapies in future analyses to comprehensively evaluate treatment switching patterns among patients initiating therapy with coupons.

CONCLUSIONS: Manufacturer-sponsored coupon use at initiation demonstrate greater medication persistence and reduced switching to alternative therapies among branded antidepressant users with MDD. These findings highlight the need for managed care organizations to consider coupon dynamics in patient access policies to optimize MDD treatment continuity.

SPONSORSHIP: Syneos Health

278 Socioeconomic vulnerabilities and postpartum depression: Assessing the aftermath of Dobbs v. Jackson in trigger and non-trigger states

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BACKGROUND: The US Supreme Court's Dobbs v. Jackson Women's Health Organization decision (June 2022) returned abortion regulation to individual states, activating previously enacted trigger laws in several states.

OBJECTIVE: To examine the changes in postpartum depression (PPD) diagnoses resulting from abortion restrictions implemented after the Dobbs decision.

METHODS: A retrospective cohort study was conducted using Medicaid data from January 2019 to December 2024. Women aged 12 to 55 years were categorized into high, medium, and low socioeconomic status (SES) groups based on a summary measure derived from 2021 US Census data. Two analytic samples were created for each SES group, representing the periods before and after the Dobbs decision. A Difference-in-Differences (DiD) approach was used to estimate changes in PPD diagnoses among residents of trigger states post-Dobbs relative to pre-Dobbs changes in non-trigger states.

RESULTS: The pre-Dobbs period included 34,836 (high-SES), 33,854 (medium-SES), and 34,017 (low-SES) individuals. The post-Dobbs period included 20,581 (high-SES), 20,342 (medium-SES), and 20,207 (low-SES) individuals. Residents of trigger states were younger, were more often located in the South, had a higher rate of teenage pregnancy, and faced greater socioeconomic challenges but had lower rates of maternal comorbidities, lifestyle risk factors, and obstetrical complications. Residence in a trigger state was significantly associated with an increased likelihood of PPD diagnosis only for patients residing in low-SES areas (DiD estimate 0.055, 95% CI: 0.045-0.066).

CONCLUSIONS: Analysis of Medicaid data from December 2019 to December 2024 revealed statistically significant differences in PPD diagnosis rates between trigger and non-trigger states following Dobbs among women in lower-SES areas.

SPONSORSHIP: None

279 The impact of extreme heat on mental health utilization and prescriptions

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BACKGROUND: Extreme heat is recognized as a driver of adverse health outcomes, yet its impact on mental health remains underexplored. Prior research shows higher temperatures are linked to increased emergency department (ED) utilization for mental health. Some studies suggest a linear relationship between mental health–related ED visits and suicide, underscoring the severity of these outcomes.

OBJECTIVE: To examine the impact of extreme heat on mental health care utilization and costs across ED, inpatient, outpatient, and telehealth settings. We focused on conditions such as schizophrenia, mood disorders, and nonpsychotic disorders. Additionally, we analyzed prescription fills and costs for antianxiety, antidepressant, and antipsychotic medications.

METHODS: We analyzed claims at the Census tract-week level to estimate Poisson fixed effect regressions, incorporating tract-week, tract-year, and cumulative week effects. This compared unseasonably hot or cold weeks to temperate ones in a tract, while controlling for economic and temporal factors. Our dataset included 35 million individuals across the United States with commercial, Medicare Advantage, or Medicaid coverage from 2016 to 2023.

RESULTS: Our findings reveal that mental health care utilization was more sensitive to extreme heat than general health care. On days when the heat index (HI) exceeded 100°F, relative to days in 60-70°F HI, mental health–related ED visits increased by 1.4%, compared to a 0.9% rise for all-cause ED visits. Further, associated mental health–related ED costs increased by 2.6% on days over 100°F. The increase in cost compared to the relative increase in utilization may suggest the heightened severity of mental health episodes. This effect compounds with additional hot days; a week with temperatures consistently over 100°F could see an 18% rise in mental health–related costs and an almost 10% rise in visit counts. The analysis of prescription data reveals complex associations. On unseasonably cold days, weekly fills for anxiety and antidepressants tended to decrease, although these results vary by medication type and overlap in treatment use.

CONCLUSIONS: Our study suggests that temperature extremes may exacerbate mental health conditions, driving an increase in utilization and costs. This underscores the need for adaptive strategies in mental health services to address climate-related risks, such as expanding telehealth options, improving access to mail-order pharmaceuticals, and preparing health care systems for surges in mental health needs during extreme weather events.

SPONSORSHIP: Elevance Health

280 An economic model assessing costs, relapses, and antipsychotic adherence of switching Medicaid beneficiaries with schizophrenia from oral antipsychotics to once-monthly, once-every-three-months, and once-every-six-months paliperidone palmitate

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BACKGROUND: Among patients with schizophrenia, nonadherence to oral antipsychotics (OAPs) increases the risk of relapse, leading to a substantial economic burden.

OBJECTIVE: To evaluate the plan-level impact on health care costs, relapse rates, and average antipsychotic (AP) adherence of switching Medicaid beneficiaries with schizophrenia from OAPs to once-monthly paliperidone palmitate (PP1M) alone, and with subsequent transitions to once-every-three-months (PP3M) and once-every-six-months paliperidone palmitate (PP6M).

METHODS: A 36-month Markov model with 3-month cycles was developed from a Medicaid payer perspective. Three cohorts of adults were included: those treated with once- or twice-daily OAPs, those switching to PP1M only, and those switching to PP1M with on-label transitions to PP3M and PP6M. At each 3-month cycle, patients may or may not be adherent to AP treatment, may or may not experience a relapse, and could continue receiving the same treatment or switch treatments. Literature-based model inputs included treatment-specific relapse and adherence rates. Outcomes reported by cohort comprised plan-level health care costs, relapses, and average AP adherence.

RESULTS: In a hypothetical health plan of 1 million Medicaid beneficiaries, an estimated 13,419 adult members with schizophrenia treated with OAPs incurred plan-level costs of $1,253.5 million, based on 33,671 relapses and average AP adherence of 69.5%. Switching 20% of patients from OAPs to PP1M only (n = 2,684), plan-level costs were $1,147.3 million, 29,322 relapses were observed, and average AP adherence among switchers was 76.9%, translating to plan-level cost savings of $106.2 million, 4,349 avoided relapses, and an increase in AP adherence of 7.4%. Incorporating transitions to PP3M and PP6M, plan-level costs were $1,137.4 million, 28,672 relapses were observed, and average AP adherence among switchers was 85.4%, representing plan-level

cost savings of $116.1 million, 4,999 avoided relapses, and an improvement in AP adherence of 15.9% compared to patients treated with OAPs. Relative to patients treated with PP1M only, incorporating transitions to PP3M and PP6M resulted in plan-level cost savings of $9.9 million, 650 avoided relapses, and an increase in AP adherence of 8.5%.

CONCLUSIONS: Switching Medicaid beneficiaries with schizophrenia from OAPs to PP1M resulted in substantial plan-level cost savings, driven by reduced relapse rates and increased AP adherence. Incremental cost savings, further reductions in relapse rates, and continued adherence improvements were observed when incorporating transitions to PP3M and PP6M.

SPONSORSHIP: Johnson & Johnson

Musculoskeletal

289 Economic burden of macrophage activation syndrome (MAS) in patients with Still disease (systemic juvenile idiopathic arthritis [sJIA] and adult-onset Still disease [AOSD]): Analysis of a US national administrative claims database

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BACKGROUND: Macrophage activation syndrome (MAS), a form of secondary hemophagocytic lymphohistiocytosis, occurs most frequently in patients with Still disease (systemic juvenile idiopathic arthritis [sJIA] or adult-onset Still disease [AOSD]). MAS may progress to multiple organ failure and mortality. However, there is currently no FDA-approved therapy for MAS and corticosteroids remain the mainstay of treatment.

OBJECTIVE: To assess the economic burden of MAS in patients with Still disease.

METHODS: A retrospective claims-based analysis (IQVIA PharMetrics Plus) from 2019 to 2024 was used to identify: Patients with Still disease ([(ICD-10:M082) including AOSD (ICD-10:M061) and sJIA (ICD-10:M08)]) with ≥6 months of continuous enrollment prior to Still diagnosis (index date) and ≥12 months of continuous enrolment post-index without MAS (ICD-10:D76.1); and patients with Still disease with ≥6 months of continuous enrollment prior to earliest MAS diagnosis observed in the study period and ≥12 months of continuous enrollment post-MAS diagnosis. Patients were matched (1:1) using a propensity score. All-cause HCRU (inpatient [IP] admission, emergency department [ED] visits, and outpatient [OP] visits) and costs (all-cause and rheumatologic; adjusted to 2024 US dollars) were ascertained in the post-index period.

RESULTS: After matching, 45 patients with Still and 45 patients with Still and MAS were included (mean [SD] age, 26.8 [15.1] and 26.8 [16.0] years at Still diagnosis, respectively; female, 55.6% and 60.0%, respectively). Mean (SD) Elixhauser Comorbidity Index was 1.6 (1.5) and 2.1 (2.8) and the most common comorbidities were rheumatoid arthritis (48.9% and 42.2%) and cardiac arrythmia (13.3% and 22.2%) in patients with Still with and without MAS, respectively. Patients with MAS were significantly more likely to have an ED visit ($P = 0.04$) and/or IP admission ($P < 0.001$) than patients without MAS in the 12-month post-index period. They also had significantly more frequent IP admissions ($P < 0.001$), ED visits ($P < 0.001$), and OP visits ($P \leq 0.001$) and longer IP stays ($P < 0.001$) than patients without MAS. In addition, patients with MAS incurred significantly ($P = 0.008$) higher total all-cause ($318,828 vs $19,233) and rheumatologic-related ($163,099 vs $1,930) health care costs ($P = 0.02$) than patients without MAS.

CONCLUSIONS: Patients with Still and MAS incurred significantly higher HCRU and costs compared with patients without MAS. Therapies targeting MAS may reduce the overall burden of disease to patients and the health care system.

SPONSORSHIP: Sobi Inc.

290 Economic burden of osteoporosis in the United States: A systematic literature review

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BACKGROUND: In the United States, approximately 10.2 million people older than 50 years are affected by osteoporosis. As the population ages, it is important to evaluate its economic impact on the health care system.

OBJECTIVE: To summarize the latest available evidence on the economic burden of osteoporosis in the United States.

METHODS: A systematic literature search was conducted on Embase and MEDLINE (via Embase.com) from January 2014 to September 2024. The bibliographical review of recent studies and relevant conference screening were also performed for additional relevant studies. Studies investigating the economic burden of osteoporosis in the United States published in English language were included. Reviews, clinical trials, case series/reports, and economic modeling studies were excluded. Key details of the eligible studies, including study and patient characteristics (i.e., study design, follow-up, age, gender, and comorbidities) were

extracted and summarized qualitatively. Cost outcomes, such as all-cause total health care costs and resource use, were descriptively analyzed.

RESULTS: A total of 6,158 records were identified initially, of which 25 studies met the eligibility criteria and were included. All 25 studies reported direct costs and/or resource use. Additionally, one study reported indirect costs. Most of the included studies focused on patients with fractures. The annual average all-cause total health care costs for patients with osteoporotic fractures ranged from $19,386 to $47,163 and were significantly higher compared to patients without fractures. Inpatient costs were the primary contributor to higher all-cause health care costs in patients with fractures. Among different fracture types, hip fractures were linked to the highest costs (ranged from $35,536 to $86,427). Having subsequent fractures (vs no subsequent fractures), being male (vs female), older age, and a higher Charlson Comorbidity Index were also associated with higher all-cause total health care costs. Patients with fractures had significantly more days of workplace absenteeism and short-term disability than patients without fractures, with the related costs also being significantly higher for patients with fractures.

CONCLUSIONS: The economic burden of osteoporosis is substantial, with associated costs rising significantly in the presence of fractures. Early identification and prevention strategies aimed at reducing the risk of fractures is an essential step to alleviate the impact on both patients and the health care system.

SPONSORSHIP: Sandoz

Oncology

302 Managed care approaches to bispecific antibodies (BsAbs) in follicular lymphoma (FL) and diffuse large B-cell lymphoma (DLBCL): AMCP Market Insights Program

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BACKGROUND: BsAbs are a class of off-the-shelf therapies that activate immune cells by simultaneously targeting tumor antigens and T or natural killer cells. Compared to CAR T-cell therapy, BsAbs offer simpler logistics and promising clinical outcomes. In FL and DLBCL, BsAbs have shown efficacy in improving survival and reducing hospitalizations.

OBJECTIVE: To assess oncology experts' perspectives on the use of BsAbs in FL and DLBCL; identify key challenges related to access, cost-effectiveness, and site-of-care; and outline best practices to support appropriate use and coverage decisions within managed care settings.

METHODS: A multidisciplinary roundtable of oncology experts from managed care organizations and cancer treatment centers was held in March 2025 to discuss the clinical integration, access challenges, and value considerations of BsAbs in FL and DLBCL. The program included polling questions to quantify participant perspectives and facilitated discussions to generate qualitative insights on managed care strategies and emerging best practices. A post-meeting survey confirmed participant agreement on health plan best practices proposed during the discussion.

RESULTS: Polling among 6 participants showed very high (17%) to high (83%) confidence in BsAbs' clinical effectiveness for reducing mortality, adverse events, and hospitalizations in FL and DLBCL. Clinical efficacy was the top consideration when evaluating BsAbs (100%), followed by safety (57%), cost (57%), and site-of-care logistics (29%). Key challenges identified included lack of head-to-head studies (71%), site-of-care complexities (57%), and the need for long-term outcomes data (57%). Qualitative insights emphasized optimizing sequencing with other therapies, addressing geographic and socioeconomic disparities, and supporting outpatient management. The post-meeting survey showed strong agreement (weighted averages from 3.50 to 3.67 of 4) on 8 best practices including evaluating total cost of care, advancing outpatient administration models, and developing health plan policies for appropriate BsAb use and equitable access.

CONCLUSIONS: Oncology experts recognize BsAbs as a promising treatment option for FL and DLBCL, with high confidence in their clinical value. Addressing challenges related to long-term data, cost-effectiveness, and site-of-care logistics will be critical to optimize their use. Program insights highlight actionable best practices for payers and the importance of supporting outpatient care models and promoting equitable access to maximize the clinical and economic benefits of BsAbs within managed care settings.

SPONSORSHIP: Genmab.

303 Real-world (RW) sequential regorafenib and trifluridine/tipiracil + bevacizumab (BEV) treatment for metastatic colorectal cancer (mCRC) in the US community oncology setting A post hoc analysis of SEQRT2 study

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BACKGROUND: Regorafenib (R) and Trifluridine/Tipiracil (T) ± BEV are widely used treatments for mCRC after patients advance on standard of care.

OBJECTIVE: To evaluate optimal sequencing and associated outcomes among patients who initiated R and T in sequential lines of therapy (LOT) between LOT 3 and 6 within community oncology settings in the US.

METHODS: A retrospective study utilizing electronic medical record data from The US Oncology Network examined adult patients with mCRC who initiated R and T ± BEV sequentially between third and sixth LOT between 09/01/2015 and 11/30/2022 (index date), with follow-up until 05/31/2023. Treatment patterns and overall survival (OS) were assessed R first (R-T) and T first (T-R).

RESULTS: In total, 238 mCRC patients initiated R and T (R-T, 119pts [107 R-T and 12 R-T+BEV]; T-R, 119 pts [108 T-R and 11 T+BEV-R]) as 3rd- to 6th-line therapy. Baseline demographic consisted of mean age 63.5 yrs, 55.9% < 65 years old, and males 55%. Clinical characteristics included 70% colon cancer, ECOG 0-1 (63.1% R-T and 59.7% T-R), and ECOG 2 (7.6% R-T and 5.9% T-R). Death (74.8%) was comparable among the groups. The median IQR sequence durations were 7.0 (5.1, 10) and 6.4 (4.7, 8.7) months, for R-T and T-R. Median (95% CI) OS was 12.2 (10.6,14) months among R-T and 9.8 (8.6,12.8) months among T-R patients. Survival probability at 12 months was 51.6% (41.8, 60.6) for R-T and 41.9% (32.4, 51.2) for T-R.

CONCLUSIONS: Patients initiating R first in third to sixth LOT appeared to have a longer duration of treatment and survival, although not statistically significant. The one-year median duration of survival in this real-world setting for R-T sequence confirms the importance of access to these treatments in patients with mCRC and can inform physicians regarding the choice of medications while sequencing therapies in mCRC.

SPONSORSHIP: Bayer Healthcare

304 Real-world analysis of health care resource utilization and costs among patients with high-risk non–muscle-invasive bladder cancer with papillary-only disease who are unresponsive to Bacillus Calmette-Guérin treatment using SEER-Medicare data

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BACKGROUND: Bladder cancer (BC) is associated with high costs related to disease recurrence and progression. Bacillus Calmette-Guérin (BCG) intravesical therapy is administered as standard of care for patients with high-risk non–muscle-invasive BC (HR-NMIBC), but nearly 50% of patients become unresponsive. There is limited real-world evidence quantifying the economic burden among patients with BCG-unresponsive HR-NMIBC with papillary-only disease.

OBJECTIVE: To characterize health care resource utilization (HRU) and costs among patients with BCG-unresponsive HR-NMIBC with papillary-only disease.

METHODS: A retrospective, longitudinal cohort study using SEER-Medicare data (01/01/2007 to 12/31/2020) was conducted. Medicare Fee-for-Service patients aged ≥65 years (enrolled in Parts A, B, and D) with BCG-unresponsive HR-NMIBC with papillary-only disease (i.e., without carcinoma in situ) were included. BCG unresponsiveness was assessed based on a claim for a guideline-recommended next treatment within 365 days after BCG discontinuation following a period of adequate induction (≥5 instillations within 70 days) and maintenance (≥2 instillations within 180 days after end of induction). All-cause and BC-related HRU and costs (2025 US dollars; comprehensive patient and payer perspective) per patient per year (PPPY) were measured during follow-up from next treatment post-BCG discontinuation to the earliest of 12 months, end of continuous enrollment, enrollment plan switch, death, or end of data availability.

RESULTS: Among 94 patients with BCG-unresponsive HR-NMIBC with papillary-only disease, mean age was 77 years, 80% were male, 93% were White, mean Quan-CCI was 1.6, and 26% had a history of smoking. Over a mean follow-up of 11 months, patients had a mean number of days with all-cause outpatient (OP) services of 50.9 PPPY (BC-related: 29.3), 1.7 inpatient (IP) admissions PPPY (BC-related: 1.3), 13.6 IP days PPPY (BC-related: 12.5), and 1.6 emergency department (ED) visits PPPY (BC-related: 1.2). Patients incurred mean total all-cause health care costs PPPY of $79,272, including $29,160 in OP costs, $41,004 in IP costs, and $9,108 in other medical and pharmacy costs. Most costs were BC-related; mean BC-related total health care costs PPPY were

$52,344, including $22,692 in OP costs, $24,660 in IP costs, and $4,992 in other medical and pharmacy costs.

CONCLUSIONS: Patients with BCG-unresponsive HR-NMIBC with papillary-only disease had substantial HRU and costs following BCG unresponsiveness, highlighting the need for effective and safe bladder-sparing treatment options that can help reduce this burden.

SPONSORSHIP: Johnson & Johnson

305 Real-world analysis of treatment patterns and disease recurrence among patients with high-risk non–muscle-invasive bladder cancer with papillary-only disease who are unresponsive to Bacillus Calmette-Guérin therapy using SEER-Medicare data

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BACKGROUND: Although Bacillus Calmette-Guérin (BCG) therapy has been the standard of care for patients with high-risk non–muscle-invasive bladder cancer (HR-NMIBC) for nearly five decades, nearly half of treated patients eventually become unresponsive. Little is known about treatment patterns and recurrence rates among patients with BCG-unresponsive HR-NMIBC with papillary-only disease.

OBJECTIVE: To evaluate treatment patterns and disease recurrence among patients with BCG-unresponsive HR-NMIBC with papillary-only disease treated with bladder-sparing therapies.

METHODS: A retrospective longitudinal cohort study was designed using SEER-Medicare data (01/01/2007 to 12/31/2020) to include patients aged ≥65 years with HR-NMIBC and papillary-only disease (T1 disease or high-grade Ta, excluding carcinoma in situ) unresponsive to BCG. Unresponsiveness was defined as starting another guideline-recommended therapy within 365 days of BCG discontinuation after adequate induction (≥5 installations in 70 days) and maintenance (≥2 installations within 180 days). Kaplan-Meier analysis was used to estimate time to recurrence (i.e., claim for transurethral resection of bladder tumor, biopsy, radical cystectomy, chemotherapy, intravesical therapy, pembrolizumab, radiotherapy, progression to muscle-invasive or metastatic bladder cancer, or bladder cancer–related death) among patients initiating intravesical chemotherapy or pembrolizumab as next therapy.

RESULTS: Among 1,662 patients with HR-NMIBC and papillary-only disease, 108 (6%) were BCG-unresponsive and initiated another guideline-recommended treatment with 365 days following BCG discontinuation. Mean age was 77 years, 77% were male, 93% were White, 27% had a history of smoking, and mean Quan-CCI score was 1.5. Following BCG discontinuation, most patients received intravesical therapy (69%) as next treatment, including mitomycin (70%), gemcitabine (18%), and valrubicin (7%), while 7% received pembrolizumab. Among patients receiving intravesical chemotherapy or pembrolizumab as next treatment, recurrence was observed in 30% at 3 months and 45% at 6 months, reaching 72% at 36 months.

CONCLUSIONS: Patients with BCG-unresponsive HR-NMIBC with papillary-only disease were primarily treated with bladder-sparing therapies as next treatment, but nearly half of these patients experienced early recurrence within 6 months. Novel bladder-sparing treatments that can more effectively treat HR-NMIBC with papillary-only disease following BCG unresponsiveness are needed.

SPONSORSHIP: Johnson & Johnson

306 Life-year and quality-adjusted life-year results from a US cost-effectiveness model for belantamab mafodotin, bortezomib, and dexamethasone in relapsed/refractory multiple myeloma

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BACKGROUND: The phase 3 DREAMM-7 study (NCT04246047) demonstrated significant improvement in progression-free and overall survival with belantamab mafodotin, bortezomib, and dexamethasone (BVd) vs daratumumab, bortezomib, and dexamethasone (DVd) in patients with relapsed/refractory multiple myeloma (RRMM) who received ≥1 prior line of therapy.

OBJECTIVE: To measure the value of BVd vs that of alternative treatment options, a de novo US cost-effectiveness model was developed to estimate life-years (LYs) and quality-adjusted LYs (QALYs) for BVd vs relevant comparator treatments in RRMM in the second-line or later.

METHODS: A de novo partitioned survival model with 4 health states (progression-free disease on treatment,

progression-free disease off treatment, progressed disease, and death) evaluated BVd vs 7 comparators: carfilzomib and dexamethasone (Kd), daratumumab and Kd (DKd), DVd, isatuximab and Kd (Isa-Kd), pomalidomide and Vd, and selinexor and Vd, and Vd. The model used a 1-week cycle length with a US Medicare perspective over a lifetime horizon, and discounted outcomes at 3.0%. Efficacy data for BVd and DVd were sourced from DREAMM-7, while relative treatment effects for other comparators were informed by a network meta-analysis. Health utilities were informed by DREAMM-7 EQ-5D-3L data, and adverse event disutilities were sourced from previous Institute for Clinical and Economic Review reports and supplemented with National Institute for Health and Care Excellence appraisals. The incidence of grade ≥3 adverse events based on trial data was used to calculate the disutilities for each comparator. Sensitivity analyses (deterministic and probabilistic) explored the level of uncertainty of the results. The overall intention-to-treat (ITT) population and subpopulations (second line, lenalidomide refractory, and lenalidomide exposed) were evaluated.

RESULTS: In the ITT population, BVd resulted in the highest LYs (9.2) and QALYs (7.5) among all treatments. LYs for comparators ranged from 4.9 (Vd) to 7.8 (Isa-Kd and DKd). QALYs for comparators ranged from 4.0 (Vd) to 6.3 (Isa-Kd and DKd). Subgroup results were consistent with those from the ITT population.

CONCLUSIONS: BVd consistently resulted in the highest LYs and QALYs.

SPONSORSHIP: GSK. Drug-linker technology licensed from Seagen Inc; monoclonal antibody produced using POTELLIGENT Technology, licensed from BioWa.

307 Epidemiology and diagnostic landscape for gastroesophageal adenocarcinomas with a HER2 focus

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BACKGROUND: There is limited evidence on the epidemiology of gastric cancer (GC), esophageal cancer (EC), and gastroesophageal junction (GEJ) cancer (collectively known as gastroesophageal adenocarcinomas [GEAs]) and on laboratory diagnostic methods used to characterize GEA, particularly in patients with HER2+ status.

OBJECTIVE: To retrieve evidence via a targeted literature review on incidence, prevalence, mortality, and survival in GEA and to characterize diagnostic methods used for GEA, with an emphasis on HER2+ status.

METHODS: Embase and MEDLINE were searched from 2014 to July 2024, without restrictions on country or language. These were supplemented with data from 2022 Global Cancer Observatory (GLOBOCAN) in key markets—the United States, Canada, Japan, and EU5.

RESULTS: Thirty-two studies presenting HER2 positivity rates in patients with GEA were included from 2,308 initial records. The majority of epidemiological evidence in HER2+ GEA came from Asia (8 studies). HER2+ prevalence in patients with GEA ranged from 13.6% in Brunei Darussalam to 47.9% in China, and from 6% in Latin America to 14% in Europe. Five-year survival rates were higher in GC as compared to EC across geographies, irrespective of HER2+ status. Epidemiological data for all-comers GEA (irrespective of HER2+ status) from GLOBOCAN indicated global crude incidence rate of 12.3 per 100,000 for GC and 6.5 per 100,000 for EC. Incidence rates were higher in males than females for GC (15.8 vs 8.7 per 100,000) and EC (9.2 vs 3.7 per 100,000). Five-year prevalence rates of GC were considerably higher in Japan (274.6 per 100,000) compared with EU5 (11.4-27.7 per 100,000), Canada (14.5 per 100,000) and US (11.2 per 100,000). Mortality rates were higher with EC than GC in the United States (2.4 vs 1.6 per 100,000), United Kingdom (4.9 vs 2.3 per 100,000), and Canada (2.8 vs 2.4 per 100,000). Among the 32 studies in patients with HER2+ GEA, HER2 status was tested most commonly by combining immunohistochemistry (IHC) and in situ hybridization (ISH) (14 studies). High concordance rates were reported for HER2 positivity assessed using next generation sequencing with ISH (up to 98.3%) or IHC with ISH (up to 99.5%). Evidence on epidemiology and diagnostic performance for PD-L1 expression in patients with HER2+ GEA was limited.

CONCLUSIONS: This review presents variability in GEA prevalence, incidence, and mortality rates by geography, gender, and GEA subtype. High concordance was observed with the use of IHC and ISH techniques in determining HER2+ status in GEA.

SPONSORSHIP: Jazz Pharmaceuticals

308 A survey of health care decision-maker (HCDM) formulary management perspectives in crowded oncologic markets: A focus on advanced non–small cell lung cancer (aNSCLC) and relapsed/refractory multiple myeloma (RRMM)

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BACKGROUND: Although novel technology and innovation are driving advances in oncology, many disease areas have crowded markets with multiple treatment options for the same indication and/or drugs sharing the same mechanism of action (MOA). This presents challenges and opportunities for HCDMs in formulary management.

OBJECTIVE: To assess HCDMs' perspectives on formulary management in crowded oncology therapeutic areas proxied by aNSCLC and RRMM.

METHODS: A double-blind, web-based survey was fielded through Cencora's Managed Care Network from April 17, 2025, to April 15, 2024. The survey utilized hypothetical narratives describing 1) addition of an oral tyrosine kinase inhibitor (TKI) for 1st- or 2nd-line treatment of patients with aNSCLC and a fictitious "XYZ" gene fusion; 2) addition of an injectable antineoplastic with a novel MOA for patients with previously treated RRMM. The hypotheticals included 2 comparator products already on formulary; these 2 products and the fictitious new product had similar efficacy and safety in each scenario. The survey questions assessed HCDM perspectives on formulary considerations and product or disease concerns.

RESULTS: A total of 20 HCDMs responded to the survey, representing health plans (45%; n = 9), integrated delivery networks (30%; n = 6), and pharmacy benefits managers (25%; n = 5) completed the survey representing national (40%; n = 8) and regional (60%; n = 12) organizations. Most respondents were pharmacy directors (60%; n = 12). The largest considerations for coverage and reimbursement in both scenarios were cost of therapy (both 55%) and appropriate evidence (25%-30%). Approximately three-quarters (70%-75%) of respondents reported they would add the new products to formulary, 20%-25% reported removing 1 or both current products to add the new product, and 5% in each scenario would not add the new product. Highly ranked product attributes when considering adding oral or injectable products to formulary included durability of therapy, cost, and size of the patient population. Dosing schedule, supportive care and procedures, and novelty of therapeutic platform were not highly ranked considerations.

CONCLUSIONS: Most payers support adding novel oncology products to their formularies, even when differentiation from existing products is minimal. Key drivers in decision-making are clinical evidence (survival, treatment landscape, etc) and cost. These findings offer valuable insights for biopharma companies, highlighting the importance of prioritizing clinical and economic value during clinical development and market access discussions.

SPONSORSHIP: Cencora

309 Systematic literature review of health care resource use (HCRU), costs and health-related quality of life (HRQoL) for brexucabtagene autoleucel in relapsed/refractory (R/R) mantle cell lymphoma (MCL) and precursor B-cell lymphoblastic leukemia (B-ALL)

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BACKGROUND: Brexucabtagene autoleucel (brexu-cel) is an autologous CD19-directed chimeric antigen receptor (CAR) T-cell therapy approved and highly effective for the treatment of adults with R/R MCL and R/R B-ALL. Demonstrating its full value requires a comprehensive understanding of its HCRU, costs, and HRQoL impact in trials and the real world (RW).

OBJECTIVE: To systematically identify and summarize evidence on HCRU, costs, and HRQoL associated with brexu-cel treatment in adult patients with R/R MCL and B-ALL.

METHODS: A systematic literature review (SLR) was conducted per PRISMA guidelines, using Embase, Medline, and CENTRAL (2020-2024; search on Dec 16, 2024), and hand searches of pre-selected conferences. Studies were selected using separate PICOS frameworks for HCRU, costs, and HRQoL. Real-world evidence (RWE) was eligible for all outcomes, and clinical trials were eligible for HRQoL only. All steps were performed in duplicate, and data were synthesized descriptively.

RESULTS: Through the systematic searches, we identified 31 publications on HCRU and/or costs from 19 unique RW cohorts and 5 HRQoL publications from 2 trials (ZUMA-2 in R/R MCL and ZUMA-3 in R/R B-ALL). Most HCRU and costs cohorts focused on MCL (n = 13), with fewer on B-ALL (n = 4) or both (n = 2). Studies were conducted in the United States and Europe. Hospital length of stay ranged 15-22

days, and was generally longer in MCL. ICU admission rates varied, being higher in MCL (11%-34%) than in B-ALL (0%-20%). RW costs were reported for one US MCL cohort, with post-infusion per-patient-per-month costs of $9,096 (Medicare) and $4,822 (commercial), 24% and 70% lower costs vs non–CAR T patients, respectively. HRQoL was assessed using EQ-5D-5L/EQ-5D-VAS, and improved over time in both ZUMA-2 and ZUMA-3. Patients treated with brexu-cel experienced transient decline post-infusion (month 1), followed by a recovery to baseline or improvement from month 3 onward for some EQ-5D-5L functional domains (mobility, self-care and usual activity). For symptoms domains (anxiety/depression and pain/discomfort) the trends suggested stability over the same period.

CONCLUSIONS: This SLR found brexu-cel to be associated with notable reduction in post-infusion hospitalization and ICU use, as well as lower post-infusion costs compared to non–CAR T patients. In trial settings, brexu-cel was also associated with HRQoL improvements in patients with R/R MCL and R/R B-ALL. More RWE is needed to evaluate HRQoL, capture a broader range of HCRU and cost outcomes, and support future value assessments of brexu-cel in clinical and policy decision-making.

SPONSORSHIP: Kite Pharma

310 Multicomponent interventions to improve adherence and symptom management in patients receiving CDK4/6 inhibitors: A real-world US evidence review

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BACKGROUND: Cyclin-dependent kinase 4/6 (CDK4/6) inhibitors are a cornerstone of treatment for hormone receptor–positive, HER2-negative advanced breast cancer. However, real-world adherence is often undermined by toxicity, financial strain, and fragmented care, which can compromise progression-free survival and patient-reported outcomes.

OBJECTIVE: To systematically evaluate US-based interventions aimed at improving medication adherence, symptom control, and treatment continuity in patients receiving CDK4/6 inhibitors.

METHODS: We reviewed 12 studies published between 2020 and 2025, including randomized trials, retrospective cohorts, and health system implementation programs. Interventions included digital adherence platforms, nurse-led symptom triage, financial navigation services, and pharmacy-integrated models. Extracted outcomes included medication adherence rates, early discontinuation, dose reductions, patient satisfaction, and health care utilization.

RESULTS: Mobile adherence tools were associated with 12% to 25% reductions in missed doses. Nurse-led toxicity monitoring reduced unplanned interruptions by 18% to 30% and enabled earlier therapeutic adjustments. Financial navigation services reduced early discontinuation in underinsured patients by up to 40%. One large health system reported an average of $2,100 per patient in cost savings due to fewer emergency department visits. Interventions that combined digital, clinical, and financial components showed the most consistent gains in persistence and patient experience. However, most programs lacked standardized protocols, limiting scalability. Equity-focused adaptations were rare, and payer engagement was minimal, contributing to inconsistent implementation across systems.

CONCLUSIONS: Real-world support interventions can improve adherence, reduce toxicity-related disruptions, and enhance patient outcomes for individuals receiving CDK4/6 inhibitors. To enable broader and more equitable adoption, future programs should prioritize standardized implementation, culturally responsive design, and alignment with payer reimbursement strategies to support sustainable delivery.

SPONSORSHIP: None

311 Belantamab mafodotin individual patient dosing in patients with relapsed/refractory multiple myeloma treated in the phase 3 DREAMM-7 and DREAMM-8 clinical trials

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BACKGROUND: Belantamab mafodotin (belamaf) is an antibody-drug conjugate that targets B-cell maturation antigen, which is present on the surface of multiple myeloma cells. Robust clinical efficacy was observed with belamaf combinations (belamaf +bortezomib [V]+dexamethasone [d] vs daratumumab [D]+Vd in DREAMM-7 [NCT04246047] and belamaf+pomalidomide [P]+d vs PVd in DREAMM-8 [NCT04484623]) in patients (pts) with relapsed/refractory multiple myeloma. Dose modifications were used to manage belamaf-associated adverse events, which affected the dose and dosing frequency over time, resulting in belamaf median relative dose intensity (mRDI) of 51.0% and 52.5% for BVd and BPd, respectively.

OBJECTIVE: To quantify, given the mRDI of belamaf in DREAMM-7/DREAMM-8, differences between protocol

planned belamaf dosing and actual belamaf dosing (per weekly aggregate individual pt dosing [IPD] and RDI based on pt data) from DREAMM-7/DREAMM-8 to help inform costs as part of a budget impact model (BIM).

METHODS: A BIM was developed to estimate the cost of belamaf over 3 years, including an analysis of the weekly number of pts on treatment, administered doses, and administration frequency during DREAMM-7 and DREAMM-8. Per protocol, BVd-treated pts in DREAMM-7 were to receive belamaf 2.5 mg/kg Q3W and BPd-treated pts in DREAMM-8 were to receive belamaf 2.5 mg/kg for cycle 1, then 1.9 mg/kg Q4W thereafter. The aggregate IPD and mRDI of daratumumab in the DREAMM-7 comparator, DVd, were also assessed.

RESULTS: Per protocol-planned dosing, BVd-treated pts were planned to receive 18/17/17 belamaf doses and 49.6/46.8/46.8 belamaf vials in year (Y) 1/Y2/Y3; aggregated IPD data showed pts actually received 9/7/6 doses and 22.1/13.6/11.5 vials (24.3/22.9/22.9 vials per mRDI) in Y1/Y2/Y3. BPd-treated pts were planned to receive 13/13/13 belamaf doses and 27.9/27.2/27.2 belamaf vials per year for Y1/Y2/Y3; aggregated IPD data showed pts actually received 6/3/3 doses and 13.5/6.8/8.5 vials (14.6/14.3/14.3 vials per mRDI) in Y1/Y2/Y3. For daratumumab in DVd, both the IPD and RDI (mRDI 97%) remained stable and similar to the planned dose from initiation through Y3. The impact of belamaf dose modifications on total cost of care will be reported.

CONCLUSIONS: Both IPD and RDI measures of belamaf dosing in the BVd and BPd combinations resulted in substantially lower values than the planned protocol dosing, indicating that use of these measures would provide a more accurate view of costs associated with BVd and BPd treatment as part of a budget impact assessment.

SPONSORSHIP: GSK

312 Leveraging causal analysis to identify trastuzumab biosimilar adoption drivers and patient outcomes: A real-world claims data analysis

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BACKGROUND: With the increasing availability of biosimilars, understanding utilization dynamics is essential to optimize health care costs and outcomes. Trastuzumab biosimilars have shown significant potential to lower treatment costs while maintaining clinical efficacy for oncology patients. However, adoption rates vary considerably across different patient populations, health care organizations (HCOs), and geographic regions. Traditional analytics identify correlations but cannot determine which factors causally drive biosimilar selection, limiting actionable insights for managed care decision-makers.

OBJECTIVE: To establish causal relationships for drivers of biosimilar trastuzumab adoption patterns using advanced causal inference methodologies.

METHODS: We analyzed medical and pharmacy claims for patients initiating trastuzumab therapy between 2022 and 2024. Causal discovery algorithms identified relationships between patient characteristics (age, gender, comorbidities), treatment setting (duration, switching rates, dosing frequency, adherence, out-of-pocket [OOP]), total aggregated health care costs (inclusive of drug, hospital visits, ED visits, and physician fees), payer factors (formulary coverage, copay differentials), provider attributes (specialty, practice setting), margin percentage (reimbursed amount vs average sales price [ASP]), and biosimilar utilization and adoption. Treatment duration and adherence were also measured.

RESULTS: Among 26,547 eligible patients, 83% initiated biosimilars, with notable variation across payer channels (Originator vs Biosimilar—Commercial: 43% vs 48%, Medicare: 44% vs 34%). Descriptive analyses suggest that provider economics may be a key driver of biosimilar adoption. Preliminary findings show a median treatment duration of 5.1 months for biosimilar users versus 6.3 months for originator users. Adherence rates were 67% among biosimilar users compared to 55% for originator users.

CONCLUSIONS: Causal AI analysis of real-world claims data highlights critical factors driving biosimilar utilization, such as formulary coverage, geographic and organizational practices, and reimbursement policies. Insights derived from causal modeling can inform targeted strategies to improve data-driven adoption rates and patient outcomes and optimize health care expenditure.

SPONSORSHIP: Syneos Health

314 Recent real-world treatment patterns of advanced melanoma in the United States

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BACKGROUND: Melanoma has a good prognosis if diagnosed at a localized stage. However, despite significant recent advances in therapy, treatments for patients with unresectable or metastatic melanoma are most often not curative.

OBJECTIVE: To characterize recent real-world treatment patterns of advanced, unresectable melanoma patients who progress to second-line (2L) systemic treatment.

METHODS: Adults in a large administrative claims database between 1/2019 and 12/2024 were included in the analysis if they had ≥2 claims for melanoma ≥7 days apart, melanoma as the primary tumor, ≥1 code for a systemic melanoma treatment after 1/1/2023, and ≥1 code for metastatic disease and had progressed to 2L treatment. Included patients had ≥3 months of continuous enrollment before the index date (first melanoma claim). Claims-based algorithms were used to identify monotherapy/combination regimens by line of treatment (LOT). A Sankey diagram was constructed to illustrate the exact treatment pattern flows between LOT1 and LOT2.

RESULTS: A total of 1252 patients met study criteria and had progressed to a 2L regimen; 57% were male and the median age was 63.5 years. Among these patients, the most common first-line (1L) regimens were immune checkpoint inhibitors (ICIs; n=1029, 82.2%): pembrolizumab (n=386, 30.8%), nivolumab + ipilimumab (n=367, 29.3%), nivolumab + relatlimab (n=144, 11.5%), nivolumab (n=128, 10.2%), or other anti–PD-1 therapy (n=4, 0.3%). Other 1L treatments received were targeted therapy for BRAF V600 mutation (n=147, 11.7%), chemotherapy (n=28, 2.2%), or other regimens (n=48, 3.8%). After progression to 2L therapy, the treatments became more heterogeneous with decreased utilization of ICI therapy (n=795, 63.5%). The most common 2L therapies were targeted therapy for a BRAF V600 mutation (n=325, 26.0%), nivolumab + ipilimumab (n=240, 19.2%), nivolumab + relatlimab (n=193, 15.4%), nivolumab (n=178, 14.2%), pembrolizumab (n=178, 14.2%), chemotherapy (n=68, 5.4%), or other (n=70, 5.6%).

CONCLUSIONS: Patients with advanced melanoma for whom 1L therapy fails have no clear standard of care as the 2L treatment landscape is heterogeneous.

SPONSORSHIP: Replimune, Inc.

315 Economic burden of neutropenia among patients treated for HR+/HER2- and triple-negative metastatic breast cancer in the United States: A retrospective claims analysis

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BACKGROUND: Neutropenia is a common adverse event associated with metastatic breast cancer (mBC) treatments. Little is known about the economic burden of neutropenia in mBC to US health systems.

OBJECTIVE: To evaluate all-cause and neutropenia-related costs and health care resource utilization (HCRU) among patients with HR+/HER2- and triple-negative (mTNBC) mBC.

METHODS: Patients with ≥1 ICD-10 diagnosis code for mBC were identified in IQVIA PharMetrics Plus claims database from 9/2019 to 6/2024. Selection criteria included continuous enrollment 6 months before and ≥3 months after the index (diagnosis of mBC) date, receipt of mBC treatment post-index, and no diagnosis codes for other cancers ≤15 months pre-index. Study patients were categorized into HR+/HER2- mBC or mTNBC cohorts based on mBC treatment post-index using treatment-based proxies. All-cause and neutropenia-related HCRU and costs per patient per month (PPPM) were reported by treatment category across the duration of any line of mBC treatment.

RESULTS: Among HR+/HER2- patients with mBC (n=4,650; 98.1% female; mean age, 55 years; 94.0% NCI comorbidity index < 1), neutropenia was experienced by 48.5%, 32.4%, 24.8%, and 8.8% of patients over the duration of sacituzumab govitecan (SG) (n=68), chemotherapy (CT) (n=4,507), other targeted therapy (TT) (n=1,690), and endocrine therapy (ET) (n=3,325) regimens, respectively. Among patients with mTNBC (n=1,409; 99.4% female; mean age, 56 years; 91.1% NCI comorbidity index < 1), neutropenia was experienced by 43.9%, 36.1%, and 39.4% of patients over the duration of SG (n=246), CT (n=482), and TT (n=1,299) regimens. All-cause (and neutropenia-related, %) costs (PPPM) were $44,921 ($8,046, 18%), $13,386 ($1,502, 11%), $19,299 ($232, 1%), and $6,110 ($75, 1%) during receipt of SG, CT, TT, and ET regimens, respectively, for patients with HR+/HER2- mBC, and $44,568 ($7,720, 17%), $13,892 ($2,294, 17 %), and $25,980 ($1,825, 8%) over the duration of SG, CT, and TT regimens for patients with mTNBC. The proportion of patients making a neutropenia-related inpatient and outpatient visit was 18% and 35%, 5% and 31%, 2% and 24%, and 0% and 9% during receipt of SG, CT, TT, and ET regimens, respectively, for patients with HR+/HER2- mBC, and 9% and 40%, 8% and 34%, and 10% and 36% during the receipt of SG, CT, and TT regimens for patients with mTNBC.

CONCLUSIONS: Neutropenia is a common adverse event with substantial impact to the overall economic burden among patients with mBC. An unmet need exists for treatments that balance costs of care with clinical benefit for these patients.

SPONSORSHIP: Daiichi Sankyo

316 Cost-effectiveness of sotorasib vs adagrasib in KRAS G12C-mutated previously treated non–small cell lung cancer (NSCLC): An economic evaluation on phase 3 trial results

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BACKGROUND: Sotorasib and adagrasib are the only KRAS G12C inhibitors approved in the United States for previously treated non–small cell lung cancer (NSCLC). Past economic evaluations relied on phase 2 data and indirect comparisons. This study presents the first cost-effectiveness analysis (CEA) using phase 3 evidence via matching-adjusted indirect comparison (MAIC) of the CodeBreaK 200 and KRYSTAL-12 trials to assess comparative efficacy and safety.

OBJECTIVE: To evaluate the cost-effectiveness of sotorasib versus adagrasib in previously treated KRAS G12C-mutated advanced NSCLC, from a US third-party payor perspective using phase 3 data.

METHODS: A partitioned survival model was developed with a 20-year horizon, weekly cycle length, and a 1.5% annual discount rate. Progression-free survival (PFS) and overall survival (OS) for the sotorasib arm were modeled using parametric curves fitted to individual patient data from CodeBreaK 200. In the absence of mature OS data from KRYSTAL-12 and no significant PFS differences in the Phase 3 MAIC (HR = 0.93; 95% CI: 0.70-1.22), equivalent efficacy was assumed. Adverse event (AE) rates were derived from the MAIC, which showed a consistently lower incidence of treatment-related AEs with sotorasib. Utilities were sourced from CodeBreaK 200 and adjusted for grade 3-4 disutilities. Costs included drug acquisition, AE management, concomitant medications, KRAS G12C testing, and terminal care. Probabilistic sensitivity analysis (PSA) assessed uncertainty.

RESULTS: Sotorasib was associated with comparable health outcomes (incremental QALYs: 0.0002) and lower total costs, yielding savings of $18,004 per patient compared with adagrasib. Cost differences were mainly driven by lower acquisition and AE management costs for sotorasib. AE incidence was lower across multiple categories, notably diarrhea (OR = 0.50), nausea (OR = 0.43), and vomiting (OR = 0.11). Sotorasib was also associated with fewer dose reductions and interruptions compared to adagrasib, indicating a potentially lower management burden for care teams. At a $150,000/QALY willingness-to-pay threshold, the net monetary benefit of sotorasib was $18,031. PSA showed a 62.0% probability of cost-effectiveness at this threshold.

CONCLUSIONS: This phase 3–informed analysis suggests sotorasib offers similar clinical outcomes to adagrasib with better safety and reduced overall costs, supporting its value as a cost-effective treatment option for previously treated KRAS G12C-mutated advanced NSCLC in the United States.

SPONSORSHIP: Amgen Inc.

317 Similarities of oral oncology drugs excluded by large pharmacy benefit managers (PBMs)

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BACKGROUND: Since formulary exclusions were introduced in 2012, the number of excluded products has grown considerably, from fewer than 100 products to well over 600 products in 2025 across CVS Health, Express Scripts (ESI), and OptumRx alone. While exclusions aim to decrease health care spend by encouraging the use of lower cost alternatives, they also limit provider choice and patient access.

OBJECTIVE: To understand the similarities of oral oncology drugs selected for formulary exclusion and identify trends among the exclusions that shape the current treatment landscape.

METHODS: Formulary exclusions were gathered from publicly available formulary listing and categorized by cancer type, mechanism of action (MOA), indication, and the presence of black box warnings. A descriptive analysis was conducted of 2025 Commercial formulary exclusions for CVS Health, ESI, and OptumRx, to isolate exclusions specific to oral oncolytics.

RESULTS: Thirty-four oral oncolytics are excluded on one or more commercial formularies for CVS Health, Express Scripts, and OptumRx; of these products, only 1 is excluded by all three PBMs. While exclusions have historically been placed on brands with a generic alternative, 82% of the oral oncology agents excluded are single-source products without a generic alternative. Common cancers are more likely to face access restrictions than rare conditions, where there may be a limited number of treatment options available. Cancer types most often targeted in formulary exclusions were NSCLC (5 products), Prostate (5 products), and Renal Cell Carcinoma (4 products). Other common cancer types include breast, CML, AML, and GIST. NCCN recommendations, mechanism of action, presence of mutations, black box warnings, orphan designation, and accelerated approval all impact the potential for exclusion. NCCN recommendations have a variable influence; the majority of excluded agents (62%) have one or more Category 1 NCCN recommendations. Kinase inhibitors make up the majority

of products identified (59%), followed by PARP inhibitors (9%) and CYP17 inhibitors (6%). Thirty-nine percent of the excluded agents are targeted therapies for specific mutations, while only 24% of the excluded agents carry a black box warning. Sixty-five percent of excluded drugs have orphan drug designation and 24% have at least one indication with an accelerated approval.

CONCLUSIONS: While crowded classes and common cancers seem to be correlated with more frequent exclusions, factors like guideline recommendations and single-source status are insufficient to protect oral oncolytics from exclusion.

SPONSORSHIP: Precision AQ

319 Cost-inefficiency of high-dose opioids therapy in disease-free cancer survivors: A real-world, US payer-perspective decision-tree analysis

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BACKGROUND: Advances in cancer diagnosis and treatment options have improved survival, which has resulted in a growing population of cancer survivors. During treatment, patients are exposed to opioids, a cornerstone of cancer pain management. Prior research showed that many survivors continue opioid therapy at progressively higher doses years after the conclusion of treatment. Prolonged exposure to high-dose opioids has been associated with negative health outcomes, including increased risk of opioid use disorder (OUD) and adverse events and increased mortality, and may lead to increased utilization of health care resources. Studies examining the economic inefficiency of increased opioid exposure in cancer survivors are, to our knowledge, non-existent.

OBJECTIVE: To evaluate the cost-inefficiency of long-term escalating high-dose opioids compared to rapid low-dose discontinuation of opioids among disease-free cancer survivors in the United States.

METHODS: A decision-tree model with a two-year time horizon was developed from the US health care payer perspective. Longitudinal opioid exposure data were obtained from a retrospective observational study of 610 disease-free survivors treated at VCU Massey Comprehensive Cancer Center. Model inputs regarding OUD, mortality, and costs were obtained from published peer-reviewed literature and public data. Utility values for the health states considered in the model were obtained from the scientific literature and used to estimate quality-adjusted life years (QALYs). Uncertainty of the model was assessed with a one-way sensitivity analysis.

RESULTS: The base-case results show that continued escalating high-dose opioid exposure resulted in higher costs ($41,072 vs $34,223) and fewer QALYs (1.143 vs 1.287) compared to rapid low-dose opioid discontinuation. Therefore, rapid discontinuation exhibited dominance in the analysis (ICER: –$47,785/QALY). The sensitivity analysis identified the utility value for survivors with OUD, mortality risk in survivors with OUD, and combined survivorship/OUD-related costs as primary drivers of uncertainty in this model. However, in almost all scenarios of the sensitivity analysis, rapid opioid discontinuation remained dominant.

CONCLUSIONS: High-dose therapy in disease-free cancer survivors is significantly cost-inefficient. High-dose therapy is associated with worse health outcomes and greater health care costs relative to low-dose therapy. Absent explicit clinical guidelines for tapering, opioid stewardship strategies for dose minimization in long-term survivorship care are critical for avoiding negative outcomes and preventing added costs.

SPONSORSHIP: None

320 Trends in industry payments to US oncologists: Insights from the 2014-2023 CMS Open Payments datasets

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BACKGROUND: Prior research using the CMS Open Payments data found that from 2014 to 2018, annual number of payments and total value increased for oncology drugs, with oncologists (medical, hematology, radiation, and surgical) receiving 92% of all cancer drug payments in 2018. In oncology, where the drug market has experienced substantial growth and where treatments often carry high costs, it is critical to understand the landscape of industry payments to inform potential strategies for physician contracting and to guide the development of transparency-related performance measures.

OBJECTIVE: To understand financial conflict of interest and oncologist prescribing patterns. In this analysis, we focus on the CMS Open Payments data to characterize payments received by US oncologists.

METHODS: We identified physicians specializing in oncology from the 2014 to 2023 CMS Open Payments datasets. To capture all payments made to oncologists, we took a broad approach, excluding only ownership or investment interest and acquisition payments, and did not limit to only transactions associated with cancer drugs. We conducted descriptive statistics to compare payments (adjusted in 2023 dollars) by program year, form of payment, and reporting entities.

RESULTS: Total payments to oncologists increased to approximately $123 million in 2023, reflecting an annual average increase of 4.5% since 2014. While total payments grew, median and average payment amount remained relatively steady, reaching $22.0 (0.9% annual increase) and $295.1 (1.3%) in 2023, respectively. In 2023, 10.5% of oncologists (n =1931) received >$10,000 in annual payments and 1.2% (n = 228) received >$100,000. Total payments to oncologists had the largest increase from 2014 to 2019, followed by a sharp decline in 2020, likely reflecting impacts of the COVID-19 pandemic, and then payments began to rise again from 2021 to 2023.

CONCLUSIONS: This initial analysis highlights substantial and growing financial interactions between the pharmaceutical industry and oncologists over the past decade. Ongoing work will incorporate claims data to better understand how these financial relationships may relate to prescribing behaviors and inform managed care strategies.

SPONSORSHIP: Elevance Health

321 Total cost of care (TCOC) and adverse effects (AEs) assessment of bispecific T-cell engagers (BiTEs) and chimeric antigen receptor T-cell (CAR T) therapies for relapsed refractory follicular lymphoma (RRFL)

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BACKGROUND: Follicular lymphoma (FL) makes up 20%-30% of new non-Hodgkin lymphoma cases. FL is hard to cure, with frequent relapses. In the third-line RRFL setting, there is a debate between treatment with BiTE or CAR T. Unlike other hematologic cancers, BiTEs are often preferred over CAR T in RRFL due to their strong, lasting responses, low toxicity, and no need for lymphodepleting chemotherapy. Also, BiTEs offer ease of access due to off-the-shelf availability and lower rates of serious AEs. In a survey of RRFL patients and treating providers, even though progression-free survival (PFS) was the key factor for both, decreased AEs ranked above lower PFS. These attributes support BiTEs increased use and potentially lower TCOC. Understanding the real-world TCOC and AE between BiTEs and CART can inform drug management strategies.

OBJECTIVE: To compare the 12-month TCOC and AE incidence for patients treated with CAR T versus BiTE therapy in RRFL.

METHODS: Medical and pharmacy claims from 17 million Commercial (COM) and 950k Medicare members were queried to identify members' first index drug (axicabtagene ciloleucel, tisagenlecleucel, lisocabtagene maraleucel, mosunetuzumab) for RRFL between 12/2021 and 03/2024. Members requirements included continuous enrollment (CE) 6 months prior to and after their index date and no pre-index BITE/CAR T claims. All members' claims were used to assess TCOC and post-index AEs (i.e., cytokine release syndrome, immune effector cell–associated neurotoxicity syndrome). AE claims were classified using ICD-10 and/or tocilizumab product-specific codes. Nonparametric and association tests assessed the relationship between index drug and outcomes. No statistically significant differences were found between cohorts (age, sex, rural-urban status, insurance type; $\alpha = .05$).

RESULTS: The study consisted of 30 and 31 members in the BiTE and CAR T cohorts, respectively. The mean age was 63 years, 41% were female, 61% had COM coverage, and 74% lived in urban areas. The CAR T cohort had significantly ($P < 0.05$) higher average TCOC ($702k vs $372k), index drug cost ($521k vs $183k), and AE cost ($9k vs <$500) than the BiTE cohort. Index drug costs accounted for 49% and 74% of the total cost of care for the BiTE and CAR T cohorts, respectively. AEs occurred in 23% and 52% of the BiTE and CAR T cohort, respectively. The CAR T cohort was 3.5 times more likely to experience an AE compared to the BiTE cohort (OR = 3.5; $P = 0.03$; 95% CI: 0.09-0.86).

CONCLUSIONS: Strong response rates, ease of access, lower drug and total cost, plus reduced AEs make BiTE therapy a feasible alternative to CAR T in RRFL.

SPONSORSHIP: Prime Therapeutics

322 Health care resource utilization and costs of patients with high-risk non–muscle-invasive bladder cancer with carcinoma in situ who are unresponsive to Bacillus Calmette-Guérin treatment: A real-world analysis using SEER-Medicare data

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BACKGROUND: Among patients with high-risk non–muscle-invasive bladder cancer (HR-NMIBC) treated with Bacillus Calmette-Guérin (BCG), nearly half become unresponsive. However, there are limited real-world data on health care resource utilization (HRU) and costs among patients with BCG-unresponsive HR-NMIBC with carcinoma in situ (CIS).

OBJECTIVE: To describe HRU and costs among patients with HR-NMIBC with CIS receiving guideline-recommended treatment after becoming BCG-unresponsive.

METHODS: A retrospective, longitudinal cohort study using SEER-Medicare Data from 01/01/2007 to 12/31/2020 was conducted. Patients covered by Medicare fee-for-service (Parts A, B, and D) who were aged ≥65 years and had BCG-unresponsive HR-NMIBC with CIS (± papillary disease) were included. Patients with CIS were identified based on staging or diagnoses codes. BCG unresponsiveness was defined as the receipt of a guideline-recommended next treatment within 365 days after BCG discontinuation following adequate induction (≥5 instillations within 70 days) and maintenance (≥2 instillations within 180 days of end of induction). All-cause and bladder cancer (BC)–related HRU and costs (2025 US dollars; comprehensive patient and payer perspective), measured per patient per year (PPPY), were described during follow-up (from next treatment post-BCG discontinuation to the earliest of 12 months, end of continuous enrollment, enrollment plan switch, death, or end of data availability).

RESULTS: A total of 182 patients had BCG-unresponsive HR-NMIBC with CIS (mean age: 74 years, 80% male, 93% White race, mean Quan-CCI: 1.4, 30% with history of smoking). Over a mean follow-up of 11 months, patients had a mean number of days with all-cause outpatient (OP) services of 46.8 PPPY (BC-related: 23.6), 3.0 inpatient (IP) admissions PPPY (BC-related: 2.8), 19.9 IP days PPPY (BC-related: 16.8), and 0.7 emergency department (ED) visits PPPY (BC-related: 0.2). Patients incurred mean total all-cause health care costs PPPY of $131,364, including $26,964 in OP costs, $89,772 in IP costs, and $14,628 in other medical and pharmacy costs. Most costs were BC-related; total BC-related health care costs PPPY were $92,856, including $19,452 in OP costs, $66,204 in IP costs, and $7,200 in other medical and pharmacy costs.

CONCLUSIONS: Patients with BCG-unresponsive HR-NMIBC with CIS had substantial HRU and costs following BCG unresponsiveness, driven by frequent outpatient visits and high inpatient costs, highlighting the need for effective and safe bladder-sparing treatment options that can help reduce this burden.

SPONSORSHIP: Johnson & Johnson

323 Advancing the management of multiple myeloma via a multiphase initiative centered on regional payer-provider forums

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BACKGROUND: Multiple myeloma (MM) is a key cost driver in oncology, owing to disease progression and the overall chronicity of the condition. Treatment requires a nuanced approach using several different classes of drugs, with chimeric antigen receptor T-cell and bispecific antibody therapies representing the latest additions.

OBJECTIVE: To identify regional trends in managing MM, barriers to optimal treatment, best practices in patient care, and opportunities for collaboration via an open forum among regional clinical specialists and managed care decision-makers.

METHODS: Two virtual roundtables were held in the Southwest and Northeast regions in November 2024 among managed care professionals (n = 8), oncology specialist providers (n = 4), and one patient advocacy representative. Participants heard testimony from patients with MM and reviewed relevant clinical information prior to engaging in moderated discussions. The findings were shared via webcast as part of a larger initiative to disseminate continuing education for managed care professionals.

RESULTS: Regional trends in the Southwest included the challenges associated with geography and transportation to tertiary treatment centers for specialized MM care, which are exacerbated by social determinants of health (SDOH). A push for increased adoption of bispecific antibodies in the community oncology setting with oversight by tertiary care centers and non-punitive integration of clinical pathways were identified as best practices. In the Northeast, drug shortages and high costs associated with generic alternatives were cited as key challenges. Participants noted coordination among community oncology providers and tertiary care centers as a key best practice, in addition to provider alignment with evidence-based treatment protocols. Opportunities for collaboration across both regions included consultation with oncology specialists on coverage policies as a cost management strategy. Participants also suggested an organized means to coordinate care between community oncology practices and centers of excellence to facilitate the utilization of newer targeted therapies.

CONCLUSIONS: Increased coordination between payers and providers has the potential to improve patient access

to newer targeted therapies for MM regardless of geography and/or SDOH. Future efforts will include additional roundtable meetings with payers and oncology specialist providers in other regions to advance collaboration.

SPONSORSHIP: Regeneron Pharmaceuticals, Inc.

324 Discovering current gaps in care and curating health plan best practices in the management of ER+/HER2- mBC: AMCP Market Insights program

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BACKGROUND: Estrogen receptor–positive/human epidermal growth factor–negative metastatic breast cancer (ER+/HER2- mBC) accounts for 70% of all breast cancer cases and is characterized by favorable overall survival in early stages. However, disparities in progression-free survival (PFS) in second-line therapy and beyond highlight an unmet need in the affected patient population.

OBJECTIVE: To assess payer perspectives on the management of ER+/HER2- mBC, identify key challenges related to access, and outline best practices to support appropriate drug utilization and coverage decisions within managed care settings.

METHODS: A multidisciplinary virtual forum of managed care oncology experts, a breast cancer specialist, and a patient advocacy representative was held in February 2025 to discuss the clinical, economic, and humanistic considerations surrounding the management of ER+/HER2- mBC. The program included polling questions to quantify participant perspectives and facilitated discussions to generate qualitative insights on managed care strategies and emerging best practices.

RESULTS: In polling among the 8 participants, 50% cited addressing disparities in care and outcomes as the most important consideration for managing ER+/HER2- mBC. Qualitative insights also called out the need for intensive support services and comprehensive care in the management of patients with ER+/HER2- mBC. Noting an unmet need in second-line therapy with current treatment regimens, investigational treatments offer improvements in progression-free survival, which 100% of payer and patient advocacy panelists cited as the most important outcome in ER+/HER2- mBC. Likewise, 100% of participants cited care pathways and/or treatment algorithms for ER+/HER2- mBC, and 60% noted that companion diagnostics play an integral role in coverage policy and utilization management. Qualitative insights highlighted that companion diagnostics coverage lags substantially behind the associated therapy coverage, causing administrative burden and delays in appropriate treatment.

CONCLUSIONS: Payer and patient advocacy representatives acknowledge a need for comprehensive support services in the management of ER+/HER2- mBC, with special consideration given to disparities in care and outcomes. Emerging therapies can potentially address unmet therapeutic needs in second-line therapy and beyond, but payers will be tasked with developing an appropriate coverage policy with timely access to companion diagnostics.

SPONSORSHIP: Arvinas

325 Treatment patterns and disease recurrence among patients with high-risk non–muscle-invasive bladder cancer with carcinoma in situ who are unresponsive to Bacillus Calmette-Guérin treatment: A real-world analysis using SEER-Medicare data

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BACKGROUND: Bacillus Calmette-Guérin (BCG) has been the standard of care for high-risk non–muscle-invasive bladder cancer (HR-NMIBC) for nearly five decades; however, up to 50% of patients become unresponsive to BCG. Among patients who are BCG-unresponsive HR-NMIBC with carcinoma in situ (CIS), there are limited data on recurrence and next treatments received.

OBJECTIVE: To describe real-world treatment patterns and disease recurrence among patients with BCG-unresponsive HR-NMIBC with CIS receiving bladder-sparing treatment.

METHODS: This retrospective longitudinal cohort study used SEER-Medicare Data (01/01/2007 to 12/31/2020) to identify patients aged ≥65 years with BCG-unresponsive HR-NMIBC with CIS (± papillary disease). Patients were considered BCG-unresponsive if they received guideline-recommended treatment within 365 days of BCG discontinuation after adequate induction (≥5 installations in 70 days) and maintenance (≥2 installations within 180 days). Disease recurrence (i.e., claim for transurethral resection of bladder tumor, biopsy, intravesical or systemic chemotherapy, radiotherapy, radical cystectomy, pembrolizumab, progression to MIBC or metastatic cancer, or bladder

cancer–related death) for patients initiating intravesical chemotherapy or pembrolizumab as next treatment was described using Kaplan-Meier (KM) analyses.

RESULTS: Among 1,700 patients with HR-NMIBC with CIS receiving adequate BCG induction and maintenance, 193 (11%) received another guideline-recommended treatment within 365 days after BCG discontinuation and were considered BCG-unresponsive (mean age 74 years, 81% male, 93% White race, mean Quan-CCI 1.4, 29% history of smoking). Most (64%) received another intravesical chemotherapy as their next treatment after BCG discontinuation (mitomycin [64%], valrubicin [15%], gemcitabine [12%]); 4% received pembrolizumab. Among patients initiating intravesical chemotherapy or pembrolizumab as next treatment, median time to recurrence was 3.4 months (95% confidence interval: 2.9, 4.6). KM rates of recurrence were 45% at 3 months, 65% at 6 months, 75% at 12 months, 83% at 24 months, and 90% at 36 months.

CONCLUSIONS: Patients with HR-NMIBC with CIS have limited options following BCG unresponsiveness, and among those who are BCG-unresponsive, most received bladder-sparing treatments (i.e., intravesical chemotherapy or pembrolizumab), with 75% experiencing disease recurrence within one year. These findings underscore a significant unmet need for more effective bladder-sparing treatments for patients who are BCG-unresponsive HR-NMIBC with CIS.

SPONSORSHIP: Johnson & Johnson

326 Real-world treatment patterns, costs, and burden of illness in advanced or unresectable cutaneous melanoma following discontinuation of frontline PD-1 inhibitor therapy: A claims database analysis

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BACKGROUND: Several programmed cell death protein-1 (PD-1) inhibitor agents and combination regimens have been approved as frontline (1L) therapies for advanced or unresectable melanoma; however, treatment with these therapies in 1L is most often not curative. Despite approved therapies, there is no established standard of care for these patients (pts) after disease progression on anti–PD-1 agents.

OBJECTIVE: To examine the real-world treatment patterns and cost burden of commercial insurance enrollees with advanced or unresectable melanoma who discontinued 1L anti–PD-1 therapies.

METHODS: A retrospective claims analysis was conducted including adult pts with ≥2 primary codes for melanoma ≥30 days apart, occurring between 1/1/2021 and 12/31/2024. Pts had no melanoma diagnoses 2 years prior to the first diagnosis and had ≥1 health care claim per month. Pts were required to have initiated and subsequently discontinued 1L anti–PD-1 therapy (monotherapy or combination). The index date for this analysis was the start of subsequent second-line (2L) systemic treatment. Pts were followed until the end of treatment, death, or end of follow-up. Treatment patterns, health care reimbursement costs per-treated-member-per-month (PTMPM), and durations of therapy (DOTs) were calculated by line of therapy.

RESULTS: A total of 15,436 pts were diagnosed with advanced melanoma between 1/1/2021 and 12/31/2024 and received a 1L anti–PD-1 therapy; 59% of pts were male, and the median age was 67 years. Overall, 10.8% (n = 1662) of 1L pts progressed to a 2L systemic treatment (72.1% [n = 1198] anti–PD-1 agent or combination, 17.9% [n = 298] BRAK/MEK–targeted therapy, 10.0% [n = 166] other), and 17.0% (n = 283) of 2L pts received subsequent third-line (3L) therapy (67.8% [n = 192] anti–PD-1 agent or combination, 17.7% [n = 50] BRAK/MEK–targeted therapy, 14.5% [n = 41] other). Total costs PTMPM for 1L, 2L, and 3L were $19,317, $30,803, and $59,503, respectively. DOTs by line were 11.2, 5.8, and 6.5 months for 1L, 2L, and 3L, respectively.

CONCLUSIONS: These findings show that monthly treatment costs for these pts rise substantially with each line of therapy, while treatment durations decline. This negative correlation suggests that later-line therapies are more expensive on a monthly basis while providing limited durability, leading to higher costs for less benefit. These results suggest a need for novel, more effective treatment options for pts with melanoma who experience disease progression after anti–PD-1 therapy.

SPONSORSHIP: Replimune, Inc.

327 Health care resource utilization (HCRU) and costs among chemotherapy-naïve patients with metastatic castrationresistant prostate cancer (mCRPC): A real-world assessment using data from the Veterans Affairs Healthcare System (VAHCS)

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BACKGROUND: Patients with mCRPC are treated with either androgen receptor pathway inhibitors (ARPI) or chemotherapy in the first-line (1L) based on patient symptoms and prior treatments received. However, mCRPC treatment can generate substantial HCRU and costs through symptom management and treatment-related adverse events (AE). To better understand the impact of the optimal treatment sequence of mCRPC, we assessed the differences in HCRU and cost between the two most common 1L mCRPC treatments and quantified differences in AE-related HCRU.

OBJECTIVE: To determine HCRU and costs among chemotherapy-naïve patients with mCRPC who received ARPI or taxane as 1L systemic treatment at the VAHCS, an equal-access health care system.

METHODS: This retrospective, observational study used VAHCS data from patients diagnosed with mCRPC between January 2018 and February 2024, who received 1L treatment with ARPI (abiraterone, enzalutamide, darolutamide, or apalutamide) or taxane (docetaxel or cabazitaxel). Index date was the date of 1L treatment initiation. HCRU and costs were evaluated from index date to date of most recent follow-up or death. AE-related costs were evaluated over a 30-day period from the date of first inpatient or emergency department (ED) claim for an AE.

RESULTS: We included 2,982 patients (ARPI: 2,828 [95%]; taxane: 154 [5%]) who initiated 1L therapy for mCRPC during the study period. Overall, 24% of patients had at least 1 inpatient hospitalization during the first year of follow-up (ARPI: 23%; taxane: 40%), with a mean length of stay of 5 days and a mean admission cost of $22,356 (ARPI: $22,000; taxane: $28,881) per patient per year (PPPY). Furthermore, 37% of patients had at least 1 ED visit (ARPI: 36%; taxane: 59%) with a mean cost of $1,097 (ARPI: $1,584; taxane: $1,071) PPPY. In total, 35% of patients had 3 or more documented AEs (ARPI: 34%; taxane: 61%), with 4% requiring at least 1 inpatient hospitalization due to an AE (ARPI: 4%; taxane: 13%), and 13% requiring at least 1 ED visit due to AEs (ARPI: 13%; taxane: 22%). In comparison, a mean of 42 outpatient visits PPPY was observed in total between the two cohorts with a mean cost of $38,194 (ARPI: $37,970; taxane: $42,313) PPPY.

CONCLUSIONS: HCRU and costs among patients with mCRPC were substantial regardless of whether they received 1L ARPI or taxane chemotherapy, leading to a significant burden on the health care system. Attempts to delay castration-resistance in prostate cancer and further research into treatment sequencing are needed to optimize care.

SPONSORSHIP: Novartis Pharmaceuticals Corporation

328 Health care resource utilization (HCRU) and costs during second-line (2L) treatment for small-cell lung cancer (SCLC)

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BACKGROUND: SCLC accounts for 10%-15% of lung cancers and has poor prognosis; most patients (pts) relapse within <6 months of first-line (1L) treatment (tx). Limited 2L tx options include chemotherapy, which is often myelosuppressive and poorly tolerated, and immuno-oncology (IO). A recent publication reported the mean total all-cause per patient per month (PPPM) for 2L to be $21,446, reflecting the overall economic burden of SCLC.

OBJECTIVE: To report all-cause and myelosuppressive event (MYSPE)–related HCRU and associated costs among pts with SCLC during 2L tx.

METHODS: Pts from the Optum Market Clarity database had received 1L platinum-based chemotherapy (PBC) and initiated 2L tx for SCLC (index date) between 01 January 2020 and 31 May 2023, with continuous health insurance enrollment ≥6 months pre- and ≥1 month post-diagnosis. HCRU and costs were reported as PPPM to account for the variable

follow-up. Lin's regression analysis predicted 12-month costs comparing tx groups (adjusted for baseline characteristics and prior HCRU/costs).

RESULTS: A total of 1063 pts received 2L tx: Zepzelca (lurbinectedin) monotherapy (lurbi; n = 350; 33%), PBC (n = 249; 23%), topotecan-based (T; n = 138; 13%), IO (alone or in combination; n = 154; 14%), and others (n = 172; 16%). Median age was 64 years; most pts were non-Hispanic and White. Median NCI Comorbidity Index score was similar across groups, but comorbidity profiles varied; pts in the lurbi group were older (median age: 65 years) with more metastatic sites (mean: 1.3). Mean all-cause ambulatory visits PPPM were similar across most groups. Other HCRU (ED visits, hospitalization) were low and comparable. The mean all-cause costs PPPM were $25,074 (PBC), $24,274 (lurbi), $24,069 (IO), and $17,762 (T). Predicted 12-month all-cause costs were highest for PBC ($249,914) vs IO ($220,258), lurbi ($168,975), and T ($121,865). Newly identified MYSPE (anemia, thrombocytopenia, pancytopenia, or neutropenia) were less frequent with IO (30%) and lurbi (41%) vs PBC (50%) and T (59%). Mean standard deviation (SD) MYSPE-related ambulatory visits PPPM were IO, 0.1 (0.5) lurbi, 0.2 (0.6); PBC, 0.3 (0.6); T, 0.4 (0.9). Mean (SD) MYSPE-related medical costs PPPM were lower for IO, $737 ($2595) and lurbi, $1407 ($4489) vs PBC, $1791 ($4999) and T, $2315 ($5033). Predicted 12-month costs for new MYSPE were IO ($6095); lurbi ($11,729); PBC ($12,111); T ($14,706).

CONCLUSIONS: 2L lurbi monotherapy and IO are associated with less frequent MYSPE and potentially lower MYSPE-related HCRU and costs vs both PBC and T. Mean all-cause costs PPPM were lower for lurbi vs PBC and comparable to IO.

SPONSORSHIP: Jazz Pharmaceuticals

329 A systematic review of economic evidence of advanced or metastatic gastroesophageal adenocarcinoma

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BACKGROUND: With the introduction of targeted therapies for gastroesophageal adenocarcinoma (GEA) (including gastric [GC], esophageal, and gastroesophageal junction cancers [GEJC]), an economic evidence review is warranted to identify key drivers of economic burden.

OBJECTIVE: To describe, via a systematic literature review (SLR), economic evidence in unresectable advanced or metastatic GEA, analyzing health care cost and resource use (HCRU), utilities, and cost-effectiveness (CE).

METHODS: Electronic databases (e.g., MEDLINE, Embase, and EconLit) and supplementary data from reimbursement agencies were searched in July 2024 (PROSPERO ID: CRD42024581806).

RESULTS: Among 31 studies with HCRU data, total annual treatment cost per patient was as high as €144,188, largely driven by the cost of PD-L1 targeted therapies. In the United States, the per-cycle costs for nivolumab and pembrolizumab was $6,638-$21,601, while chemotherapy costs were lower ($183-$2,368 per cycle). Cost of managing AEs was also substantial, with neutropenia management incurring $17,181 per event in the United States. Similar findings were observed in other geographies for managing AEs. More than half of patients with GC were hospitalized early, particularly within the first six months of treatment initiation. More than 90% of patients required frequent outpatient care for ongoing treatment and symptom management. Among 32 studies reporting health state utilities, patients with GC/GEJC consistently had higher utility scores during progression-free (0.66-0.80) than post-progression (0.54-0.72) state, reflecting better quality of life earlier in the disease course. Twenty-seven economic models were identified across the United Kingdom (6), China (4), Japan (3), and Canada (2), among other countries; nivolumab (14) and pembrolizumab (5) were most frequently assessed. Across geographies, and irrespective of HER2 status, nivolumab and pembrolizumab were unlikely to be cost-effective due to their higher cost compared with chemotherapies. Although results improved for nivolumab and pembrolizumab in PD-L1 expressing subgroups, neither treatment was cost-effective compared with chemotherapy. Addition of chemotherapies to targeted therapies like trastuzumab was cost-effective compared to targeted therapy alone, even in the HER2+ population.

CONCLUSIONS: This SLR highlights the contribution of targeted therapies to the high overall treatment cost in GEA, especially in managing the burden of AEs and quality of life. Substantial economic burden is seen with current treatments even at an early stage, implying an unmet need for cost-effective treatment options in GEA.

SPONSORSHIP: Jazz Pharmaceuticals

330 Budget impact of darolutamide + ADT for mCSPC from a US payer perspective

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BACKGROUND: Prostate cancer is the most common cause of cancer and a leading cause of cancer death among male individuals in the United States. Darolutamide with docetaxel and androgen deprivation therapy (ADT) is approved for the treatment of metastatic castration-sensitive prostate cancer (mCSPC). Recently, the efficacy and tolerability of darolutamide + ADT was demonstrated in the ARANOTE study. In anticipation of an FDA approval, there is a need for US health care plans to understand the potential economic impact for expanded use of darolutamide + ADT for the treatment of mCSPC.

OBJECTIVE: To estimate the budget impact of expanded access of darolutamide + ADT from label expansion for the treatment of mCSPC from a US payer perspective.

METHODS: An Excel-based budget impact model (BIM) was developed to evaluate the incremental costs between a scenario without darolutamide + ADT approval and a scenario with approval for a 1-million-member mixed (commercial and Medicare) US plan. In the scenario without approval, both real-world utilization and no utilization of darolutamide + ADT were assessed. The target population included newly diagnosed and newly progressed mCSPC patients. Comparators included doublet and triplet intensified regimens with ADT (enzalutamide, apalutamide, abiraterone, abiraterone + docetaxel, and darolutamide + docetaxel). The BIM accounted for the costs for drug acquisition, administration, adverse events (AE) management, and disease progression. Treatment dosing, efficacy, and AE rates were obtained from clinical trial publications and package inserts. Costs were reported in 2025 USD. Model outputs included annual budget impact, and per-member per-month cost (PMPM) differences calculated over a 3-year time horizon. Sensitivity analyses tested the impact of input uncertainty on outcomes.

RESULTS: Each year an estimated 44 men within a 1-million-member plan will be newly diagnosed or present with mCSPC progression and will receive intensified treatment. The incremental cost from approval and expanded use of darolutamide + ADT was estimated to be $57,709 in year 1 and $309,015 in year 3 ($0.005 to $0.026 PMPM respectively). In a scenario assuming no use of darolutamide + ADT without approval, the budget impact was similar and ranged from $0.004 to $0.025 PMPM. Higher drug acquisition costs in the first year were partially offset by lower AE and disease progression–related costs.

CONCLUSIONS: For US health plans, providing expanded access to darolutamide + ADT for the treatment of mCSPC results in minimal budget impact.

SPONSORSHIP: Bayer HealthCare Pharmaceuticals Inc,

332 Burden of administration: Belantamab mafodotin (Belamaf) combinations vs isatuximab (Isa) + carfilzomib (K) + dexamethasone (d), daratumumab (D) + K + d, and K + d in relapsed/refractory multiple myeloma (RRMM)

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BACKGROUND: Belamaf is being investigated after first relapse or later in phase 3 RRMM studies: DREAMM-7 (NCT04246047; belamaf with bortezomib and dexamethasone [BVd]) and DREAMM-8 (NCT04484623; belamaf with pomalidomide and dexamethasone [BPd] in lenalidomide-exposed patients [pts]). The regimens demonstrated significant progression-free survival (both BVd/BPd) and overall survival (BVd) benefits, and 88% (DREAMM-7)/90% (DREAMM-8) of pts had extended dosing intervals to manage ocular events, with administration (admin) burden reducing over the first year (Y).

OBJECTIVE: To evaluate admin burden in pts on treatment for BVd/BPd vs intravenously (IV) administered second-line-or-later standards of care, IsaKd/DKd/Kd.

METHODS: A model estimating admin burden per pt receiving BVd/BPd/IsaKd/DKd/Kd for the first 2 years of treatment was developed. Dosing regimens were obtained using weekly individual pt-level dosing data from DREAMM-7/DREAMM-8 (BVd/BPd), and from published protocols (IsaKd/DKd/Kd). Admin burden inputs (admin number, clinic visits, and admin/monitoring [including ocular exam for BVd/BPd] durations) for the IV and subcutaneous (SC) agents were sourced from published protocols/clinician input. Oral agents were assumed to not require admin visits. Admin/monitoring costs were determined using the CMS Physician Fee Schedule 2025/Physician's Fee and Coding Guide. Reported results are means per pt on treatment.

RESULTS: For BVd, 9.1/9.7 IV belamaf/SC bortezomib admins and 10.7 admin/monitoring hours (hrs) were required in Y1, with 6.6/0.0 admins and 6.6 hrs in Y2, totaling $972/$1,126 for admin/monitoring across Y1-Y2. For BPd, 6.2 IV belamaf admins and 6.2 admin/monitoring hrs were required in Y1, with 3.3 admins and 3.3 hrs in Y2, totaling $551/$686 for admin/monitoring across Y1-Y2. For IsaKd, 28.0/78.0

IV isatuximab/carfilzomib admins and 80.3 admin/monitoring hrs were required in Y1, with 26.0/78.0 admins and 78.0 hrs in Y2, totaling $12,197/$2,170 for admin/monitoring across Y1-Y2. For DKd, 24.0/78.0 SC daratumumab/IV carfilzomib admins and 70.3 admin/monitoring hrs were required in Y1, with 13.0/78.0 admins and 67.2 hrs in Y2, totaling $9,586/$2,170 for admin/monitoring across Y1-Y2. Kd required 78.0 IV carfilzomib admins in each year, with 66.3 (Y1) and 65.0 (Y2) admin/monitoring hrs, totaling $9,071/$2,170 for admin/monitoring across Y1-Y2. Sensitivity analyses were consistent with primary analyses. Alternative admin times were explored.

CONCLUSIONS: BVd/BPd are associated with substantially lower admin burden/costs vs IsaKd/DKd/Kd.

SPONSORSHIP: GSK

333 Opportunities to improve care in HER2-positive gastrointestinal cancers: Recommendations from payer and oncologist regional forums

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BACKGROUND: Gastroesophageal adenocarcinoma (GEA) and biliary tract cancers (BTC) impose a significant burden on patients with gastrointestinal cancers. Managed care professionals desire more awareness of disease severity and have limited knowledge of evidence-based treatment and biomarker testing recommendations, contributing to gaps in coverage policies.

OBJECTIVE: To identify opportunities and develop actionable recommendations by analyzing insights on clinical evidence, biomarker testing, multidisciplinary care, and health plan utilization management strategies for HER2-positive gastrointestinal cancers, gathered through collaborative discussions between oncology specialists and managed care decision-makers.

METHODS: Three virtual forums were conducted across the South, North, and West US regions in January and February 2025. Participants provided quantitative insights through polling and engaged in discussions to identify opportunities and recommend strategies to improve patient care.

RESULTS: Insights from 27 participants (14 managed care professionals, 12 oncology specialists, 1 patient) highlighted key challenges in managing HER2-positive GI cancers, including insufficient biomarker testing guidance, limited payer awareness of clinical trial data, and inconsistent coverage policies. Polling showed top collaboration opportunities in guideline-directed treatment (33.3%), biomarker testing alignment (25.9%), and targeted therapy coverage (25.9%). Major gaps included lack of testing guidance (53.8%) and limited awareness of trial data and therapy costs (50% each). Developing HER2 testing and treatment guidance was the most effective strategy (63.0%) to address known barriers in HER2-positive GI cancers.

CONCLUSIONS: Open communication between managed care professionals, oncology specialists, and a patient proved to be an effective approach for identifying treatment barriers and providing recommendations for payer strategies with HER2-positive GI cancers. The insights highlight that informed collaborative interactions can inform meaningful improvements in payer utilization management strategies in oncology.

SPONSORSHIP: Jazz Pharmaceuticals

334 Nivolumab plus ipilimumab as a first-line treatment for MSI-H/dMMR metastatic colorectal cancer: A cost-per-outcome analysis

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BACKGROUND: In CheckMate-8HW (CM-8HW), centrally confirmed microsatellite instability high (MSI-H)/deficient mismatch repair (dMMR) metastatic colorectal cancer (mCRC) patients treated with nivolumab (NIVO)+ipilimumab (IPI) showed significantly longer progression-free survival (PFS) vs chemotherapy (chemo) (HR first-line NIVO+IPI vs chemo: 0.21 [95%CI 0.14-0.32]) or nivolumab monotherapy (HR all-lines NIVO+IPI vs NIVO: 0.62 [95%CI 0.48-0.81]). In KeyNote177 (KN-177), pembrolizumab (PEMBRO) improved PFS vs chemo in locally confirmed first-line MSI-H/dMMR mCRC patients (HR PEMBRO vs chemo: 0.60 [95%CI 0.45-0.80]). However, first-line comparisons between NIVO+IPI and PEMBRO are lacking, highlighting the need for clinical and economic comparisons of first-line mCRC treatments to inform health care decision-making.

OBJECTIVE: To compare the total costs, PFS, and the costs per PFS month gained of NIVO+IPI vs chemo, PEMBRO vs chemo, and NIVO+IPI vs PEMBRO in first-line MSI-H/dMMR mCRC patients.

METHODS: A three-state semi-Markov model comprising progression-free, progressed, and dead health states was developed. Results were presented for 24-, 36- (trial) and 60-month (model) time horizons. Effectiveness data

from locally assessed MSI-H/dMMR mCRC patients for NIVO+IPI, chemo, and PEMBRO was sourced from CM-8HW (DBL Sep2024), CM-142 and KN-177. An indirect treatment comparison (ITC) was performed between NIVO+IPI and PEMBRO using four METHODS: time-varying parametric analysis, anchored matching adjusted indirect comparisons (MAIC), unanchored MAICs, and fractional polynomial network meta-analyses. Treatment acquisition, administration, disease management, and adverse event costs were sourced from US databases and reported in 2025 USD.

RESULTS: At 24, 36, and 60 months, NIVO+IPI demonstrated superior clinical outcomes vs chemo and PEMBRO in first-line MSI-H/dMMR mCRC. Although upfront drug acquisition costs were higher for NIVO+IPI, disease management costs were higher for PEMBRO and increased over time. NIVO+IPI showed lower costs per PFS gained when compared to chemo at 24, 36, and 60 months ($35,475; $18,570; $8,743) vs PEMBRO ($68,253; $31,253; $14,286). Compared to PEMBRO, the costs per PFS month gained of NIVO+IPI were $23,526, $12,826 and $5,939. Despite higher acquisition costs, NIVO+IPI lies on the cost-effectiveness efficiency frontier, offering greater value than PEMBRO.

CONCLUSIONS: Given its significant PFS benefits, and lower costs per PFS month gained vs chemo, NIVO+IPI provides superior value compared to PEMBRO as a first-line treatment for MSI-H/dMMR mCRC patients.

SPONSORSHIP: Bristol Myers Squibb

335 Patient characteristics, treatment patterns, and real-world outcomes among patients in the United States with human epidermal growth factor receptor 2 (HER2)–expressing solid tumors

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BACKGROUND: In April 2024, trastuzumab deruxtecan (T-DXd) was granted accelerated approval in the United States for patients (pts) with unresectable/metastatic HER2-positive (immunohistochemistry [IHC] 3+) solid tumors following disease progression after prior treatment (Tx) and with no alternative Tx options. Prior to this US approval, HER2 IHC testing was primarily performed in pts with breast and gastric tumors; thus, real-world data on the Tx patterns and outcomes of pts with other HER2 IHC 3+/2+ solid tumors are limited.

OBJECTIVE: To describe demographic and clinical characteristics and Tx patterns and real-world response rates (rwRRs) by HER2 IHC status among pts in the United States with HER2 IHC 3+/2+ solid tumors.

METHODS: This retrospective cohort study used data from the Tempus multi-modal database (a primarily US-based population combining curated sources and electronic health records). Adult (≥18 years) pts with HER2 IHC 3+ or 2+ advanced (Stage IV) solid tumors, diagnosed from Jan 2016 to Dec 2023, were selected for analysis. Pts with multiple solid tumors, breast or gastric cancer, clinical trial enrollment during the study period, or Tx with T-DXd were excluded.

RESULTS: Among 392 identified pts (median age 66 years [IQR 57.0-72.0]; 66.6% female; 42.5% White), tumor types included endometrial (26.5%), colorectal (25.5%), NSCLC (18.9%), and other solid tumors (29.1%, <15 pts per tumor type). A total of 127 and 265 pts had HER2 IHC 3+ and 2+ tumors, respectively. First-line (1L) Tx was received by 276 pts. In pts with HER2 IHC 3+ tumors, the most common Tx was immunotherapy-based regimens (32.6%; n/N = 30/92) at 1L, chemotherapy or HER2-targeted therapy (28.9%; n/N = 11/38) at second line (2L), and chemotherapy (36.8%; n/N = 7/19) at third line (3L); rwRRs (95% CI) were 40% (30, 51), 8% (2, 22), and 21% (7, 46) with 1L, 2L, and 3L Tx, respectively. In pts with HER2 IHC 2+ tumors, the most common Tx was chemotherapy (44.6%; n/N = 82/184) at 1L, chemotherapy or immunotherapy-based regimens (28.8%; n/N = 23/80) at 2L, and chemotherapy or biologic ± chemotherapy (28.2%; n/N = 11/39) at 3L; rwRRs (95% CI) were 39% (32, 47), 19% (11, 29), and 21% (10, 37) with 1L, 2L, and 3L Tx, respectively.

CONCLUSIONS: These data provide valuable insights into the Tx patterns and rwRRs for pts with IHC 3+/2+ solid tumors between 2016 and 2023. The poor rwRRs shown here, particularly with 2L/3L Tx, highlight the need for effective biomarker-directed Tx options in these pts. However, results should be interpreted with caution owing to the selective pt population who underwent HER2 IHC testing when it was not routinely performed.

SPONSORSHIP: AstraZeneca, Daiichi Sankyo

Precision Medicine

340 Coverage fragmentation and diagnostic access barriers in US payer policies for tumor-agnostic oncology: A systematic review of NTRK-, RET-, and MSI-H–based therapies

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BACKGROUND: Tumor-agnostic therapies are approved based on molecular alterations rather than tumor origin. Between 2017 and 2021, the FDA approved TRK inhibitors

(larotrectinib, entrectinib), RET inhibitors (selpercatinib, pralsetinib), and immunotherapies for mismatch repair–deficient (MSI-H) tumors (pembrolizumab, dostarlimab). These therapies span a range of solid tumors, including rare and pediatric cancers. However, payer policies have not consistently kept pace with regulatory approvals, especially in diagnostic reimbursement and access for underrepresented populations.

OBJECTIVE: To evaluate how US payers, including commercial insurers, Medicaid programs, and Medicare contractors, define coverage for tumor-agnostic therapies, with focus on biomarker testing, pediatric eligibility, prior authorization, and reimbursement for diagnostics.

METHODS: A systematic review was conducted using PRISMA 2020 guidelines. Sources included PubMed, Embase, CMS.gov, state Medicaid portals, Medicare contractor websites, and commercial payer policy databases. From 843 records (2018 to 2025), 92 full texts were reviewed and 27 met inclusion. Including 14 commercial policies, 9 Medicaid documents, and 4 Medicare determinations. Two reviewers independently extracted and cross-verified data using a standardized abstraction tool. Discrepancies were resolved by consensus. Findings were synthesized by payer type.

RESULTS: Eighteen policies addressed tumor-agnostic therapies: six for NTRK inhibitors, five for RET inhibitors, and seven for MSI-H immunotherapies. All required biomarker confirmation. Eleven recognized next-generation sequencing (NGS) as clinically appropriate. Only three of nine Medicaid programs provided NGS reimbursement guidance. Pediatric coverage appeared in all NTRK policies but only one RET policy. Pralsetinib remained limited to tumor-specific indications. Rare tumors and histologies not cited in NCCN or compendia guidelines were inconsistently addressed. Policy updates lagged FDA approvals by 6 to 24 months. Authorization criteria varied. Diagnostic workflows often began with immunohistochemistry, then confirmatory NGS. Reimbursement for genomic profiling was inconsistent.

CONCLUSIONS: Coverage of tumor-agnostic therapies remains fragmented. Inconsistent diagnostic reimbursement, limited pediatric inclusion, and delayed policy updates hinder access. Aligning payer criteria with clinical evidence and regulatory approvals is essential. Targeted reforms may expand access to precision oncology.

SPONSORSHIP: None

Real-World Evidence

359 Health care resource utilization in patients with primary immune thrombocytopenia treated with avatrombopag in the United States: REAL-AVA 2.0 study results

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BACKGROUND: Immune thrombocytopenia (ITP) is an autoimmune disorder marked by low platelet counts (PCs), which may increase bleeding risk and require ongoing medical care. Avatrombopag (AVA) is an FDA-approved treatment for adults with chronic ITP that aims to increase PCs. Clinical trials and real-world studies have shown AVA's efficacy in achieving target PC levels, but real-world data on AVA's impact on health care resource utilization (HRU) is limited. The REAL-AVA 2.0 study examined clinical effectiveness and HRU among adult patients (pts) treated with AVA in routine ITP management in the United States.

OBJECTIVE: To assess ITP-related inpatient (IP), emergency department (ED), and outpatient (OP) visits following AVA treatment among adult pts with primary ITP.

METHODS: REAL-AVA 2.0 was a retrospective, multi-site chart review of pts with primary ITP who initiated AVA (index date) from 07/2019 to 12/2024 across 11 US medical centers. Pts were required to have complete medical records for 3 months pre-index (baseline) and ≥6 months post-index unless the patient died. The follow-up (FU) period spanned from index until earliest of death, end of data, or study end. ITP-related visits were evaluated during the baseline and FU periods, with FU visits assessed while the pt remained on AVA, for up to 1 year in 3-month intervals (Q1-Q4). A visit was classified as ITP-related if it was associated with ITP, ITP treatment, or related complications. Quarterly FU analyses included only pts with adequate FU through the end of each respective quarter.

RESULTS: The study included 177 pts; 151 (85%) had sufficient FU for Q1 analysis, 131 (74%) for Q2, 110 (62%) for Q3, and 95 (54%) for Q4. At index, pts had a mean (standard deviation [SD]) age of 56 (19) years and a mean (SD) ITP disease duration of 5.4 (9.0) years. In the 12 months post-AVA initiation, ITP-related HRU declined consistently across all visit types. The

proportion of pts with any ITP-related IP admission dropped from 25.4% at baseline to 7.3% in Q1, 4.6% in Q2, 1.8% in Q3, and 1.1% in Q4. ED visits followed a similar trend: 18.6% of pts had ≥1 visit during the baseline vs. 7.3% in Q1, 3.8% in Q2, 3.6% in Q3 and 1.1% by Q4. OP visits also declined from 63.8% of pts at baseline to 56.3% in Q1, 52.7% in Q2, 50.0% in Q3, and 49.5% in Q4. The mean number of ITP-related OP visits declined from 3.1 visits during the baseline to 1.0 visit in Q4.

CONCLUSIONS: Real-world data from the REAL-AVA 2.0 study suggest that treatment with AVA is associated with sustained reductions in ITP-related HRU.

SPONSORSHIP: Sobi, Inc.

360 Real-world clinical outcomes and disease management costs among high-risk patients with non–muscle invasive bladder cancer treated with Bacillus Calmette-Guérin: A SEER-Medicare Analysis

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BACKGROUND: High-risk (HR) non–muscle invasive bladder cancer (NMIBC) is typically managed with transurethral resection of the bladder tumor followed by Bacillus Calmette-Guérin (BCG), with novel treatments under investigation. Understanding the clinical outcomes and associated disease management costs (DMC) under current standard of care is essential for guiding the adoption of emerging treatments.

OBJECTIVE: To estimate real-world recurrence, survival, post-recurrence cystectomy, and DMC among HR-NMIBC patients treated with BCG.

METHODS: Adult patients with HR-NMIBC who received BCG were identified using SEER-Medicare data (2007-2020). Recurrence was categorized as NMIBC recurrence, muscle-invasive bladder cancer (MIBC) progression, and distant metastasis (DM) based on diagnosis and treatment records. Recurrence-free survival (RFS; from BCG initiation to any recurrence or all-cause death) and overall survival (OS; from BCG initiation to all-cause death) were assessed via Kaplan-Meier analysis. Post-recurrence cystectomy was described. Bladder cancer–related DMC by health state (excluding costs of procedures, pharmacological treatments and adverse events) were summarized: recurrence-free (RF; in years 1-2, 3-5, and 6+), NMIBC recurrence, MIBC progression, and terminal care (30 days before death). Radical and partial cystectomy costs were also estimated.

RESULTS: A total of 5,490 patients (median follow-up: 2.9 years) were included in this study, with a median age of 76 years, 80% male, and 91% White. Approximately 40% of patients experienced recurrence (1,528 NMIBC recurrence; 372 MIBC progression; 278 DM) and an additional 14% died. Median RFS and OS were 2.8 (95% CI: 2.7–3.1) years and 8.2 (95% CI: 7.9–8.9) years, respectively. Among those with recurrence, 14% underwent cystectomy. Mean (standard deviation [SD]) monthly DMC substantially increased from NMIBC recurrence ($378 [1,167]) to MIBC progression ($1,195 [2,789]); in contrast, the costs declined over time in the RF state ($286 [939] in years 1-2, $171 [1,058] in years 3-5, and $105 [472] in years 6+). Mean (SD) costs per procedure for radical and partial cystectomy were $18,985 (15,463) and $15,367 (11,896), respectively. Terminal care costs were $2,823 (7,466).

CONCLUSIONS: Patients with HR-NMIBC experienced high rates of recurrence, with a significant proportion undergoing subsequent cystectomy. Disease recurrence was associated with substantial economic burden, which increased with the stage of recurrence. Novel treatments that delay recurrence may help reduce the clinical and economic burden for patients with HR-NMIBC.

SPONSORSHIP: Merck & Co., Inc.

361 Real-world demographics, clinical characteristics, and medication utilization in biopsy-confirmed primary C3 glomerulopathy: A 20-year single-center EHR cohort study

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BACKGROUND: C3 glomerulopathy (C3G) is a rare progressive nephropathy with limited real-world characterization.

OBJECTIVE: To describe baseline demographics, clinical features, and medication utilization in primary C3G using EHR data.

METHODS: In this retrospective cohort study (2002-2022), we identified 56 biopsy-confirmed primary C3G cases from nference nSights de-identified EHR database, representing 7.3 million patients primarily across five US states (MN, WI, IA, FL, and AZ). C3G was defined by ≥2 structured ICD codes ≥15 days apart and/or ≥2 positive NLP mentions (or one of each) ≥15 days apart, plus biopsy confirmation within ± 60 days of the earliest qualifying ICD code or positive NLP mention. Patients with secondary etiologies (e.g., infections, monoclonal gammopathies, systemic diseases, neoplasms) were excluded. Baseline demographics, comorbidities, clinical manifestations, and lab measurements were captured in the 12 months before diagnosis. Medication orders for disease-related classes (immunosuppressants and renin-angiotensin system blockers) and select individual agents were captured during baseline and the first 12 months follow up.

RESULTS: The cohort (N = 56) was young (median age 22 years, IQR 13.5), with 27% in the pediatric age group (<18 years); half were female, and the majority were White (86%). Comorbidity burden was low (Elixhauser score 0 in 59%, 5-10 in 32%). In the baseline period, mean eGFR was 69.9 ± 45.8 mL/min/1.73 m², 43% exhibited proteinuria ≥1 g/24 h (25% nephrotic-range ≥3 g/24 h), and 23% had hematuria. 73% of patients underwent 24-hour protein collection at baseline, whereas spot ACR/PCR testing was less common (21%). At baseline, only 21.4% of patients had at least one medication order (mean 1.75 ± 0.87 orders/patient). After diagnosis, 75% of patients were started on therapy, with mean orders rising to 2.19 ± 1.38 by 12 months. Monotherapy accounted for 35.7% of regimens; 2/3-agent therapy made up 23.2%; and intensive combinations (4-5 agents) were used in 14.3% (1.8% received ≥6 agents). Class-specific use increased substantially: RAS blockade (ACE-I/ARB) rose from 12% at baseline to 51%, corticosteroids from 11% to 41%, and mycophenolate mofetil from 2% to 21% at 12 months.

CONCLUSIONS: Primary C3G presents with heterogeneous renal impairment and is often managed with multi-agent therapy, imposing substantial patient burden (high pill counts, frequent monitoring, drug-drug interactions) and adherence challenges, underscoring the need for more effective therapies.

SPONSORSHIP: Apellis Pharmaceuticals USA, Inc.

362 Real-world characteristics and treatment patterns of patients with major depressive disorder initiating dextromethorphan-bupropion extended-release tablets, cariprazine, brexpiprazole, or esketamine

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BACKGROUND: Auvelity (dextromethorphan-bupropion) is an oral N-methyl-D-aspartate (NMDA) receptor antagonist and sigma-1 agonist approved in the United States in August 2022 for the treatment of major depressive disorder (MDD) in adults.

OBJECTIVE: To examine the real-world characteristics and treatment patterns of patients initiating 1 of 4 branded pharmacotherapies for MDD: dextromethorphan-bupropion, cariprazine, brexpiprazole, or esketamine.

METHODS: Adults with MDD initiating dextromethorphan-bupropion, cariprazine, brexpiprazole, or esketamine were identified in the Merative MarketScan Commercial and Medicare databases (Jan 2021 to Mar 2024; index date = 1st prescription date). Included patients had 6 months of continuous enrollment pre- and post-index. Patient characteristics were assessed over the 6 months pre-index; MDD-related medication use was assessed in the 6 months pre- and post-index.

RESULTS: The dextromethorphan-bupropion, cariprazine, brexpiprazole, and esketamine cohorts included 1,472, 11,061, 4,958, and 853 patients, respectively. Demographics were similar across cohorts (mean age 39-43 years; 64.0-73.2% female; 43.8-56.6% in the southern United States). In all cohorts, most patients had 2+ prior MDD treatments (52.9-65.3%). Selective serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs), and norepinephrine-dopamine reuptake inhibitors (NDRIs) were the most common prior MDD-related medications across cohorts (47.2-58.1%, 25.0-38.3%, and 22.0-37.0% of patients, respectively). Reductions in MDD-related medication use after dextromethorphan-bupropion initiation were significant ($P < 0.05$), including a decrease of 20.9% in NDRIs and 13.5% in SSRIs. Reductions were also evident but less pronounced in the other cohorts.

CONCLUSIONS: Patients initiating dextromethorphan-bupropion had similar characteristics and prior medication use to those initiating cariprazine, brexpiprazole, or esketamine. Reductions in MDD-related medication use after initiation of a treatment were most notable for patients treated with dextromethorphan-bupropion.

SPONSORSHIP: Axsome Therapeutics, Inc.

363 Real-world insights on tardive dyskinesia: A claims-based analysis of demographics and health care utilization

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BACKGROUND: Tardive dyskinesia (TD), a persistent movement disorder associated with prolonged antipsychotic exposure, can have disabling impacts on social, physical, and emotional functioning. Older adults have a higher risk for TD, and the presence of multiple comorbidities and polypharmacy in this population can complicate clinical management in long-term care (LTC) settings.

OBJECTIVE: To examine the potential impact of TD on health care and resource utilization (HCRU) and LTC admissions.

METHODS: The STATinMED Real-World Data Insights Database, which captures 80% of US claims data, was used for analysis. Patients with an LTC stay and ICD-10 code indicative of TD (G24.01) during the study period (Jan 2018 to Dec 2022) were identified, with index defined as the earliest date with a claim of TD diagnosis. Demographics and comorbidities were analyzed for patients who had continuous capture of medical and pharmacy benefits for ≥12 months before the index date ("baseline"). Medication use, HCRU, and LTC admissions were analyzed for the baseline period and for ≥12 months after the index date ("follow-up"). Mean values are presented with standard deviation (±SD).

RESULTS: Among 54,890 patients with TD who were included for analysis, 35,500 (65%) were female and the mean age was 60 (±14) years; 38,960 (71%) were 55 years or older. Common comorbidities included mood disorders (58%), sleep disorders (32%), schizophrenia (31%), and bipolar disorder (30%). The mean Charlson Comorbidity Index (CCI) score was 2.2 (±3.5), and 8,782 (16%) patients had a CCI score ≥5, indicating high comorbidity burden and health care needs. Use of antidepressants declined from baseline to follow-up (from 56% to 52%); use of drugs with anticholinergic properties (e.g., benztropine) remained stable (23% in both periods). Medical visits (outpatient office, outpatient hospital, emergency department) and inpatient care increased from baseline to follow-up. The percentage of patients with ≥1 LTC admission increased from baseline to follow-up (from 7% to 11%).

CONCLUSIONS: The population of patients included in this real-world claims data tended to be older, aged ≥55 years, with high comorbidity burden. The increase in outpatient visits, inpatient visits, and LTC admissions from before to after the index date suggests a potentially greater need for health care services and long-term care after patients received a TD diagnosis (index date).

SPONSORSHIP: Neurocrine Biosciences, Inc.

364 Real-world health care utilization and costs associated with using dextromethorphan-bupropion extended-release tablets versus branded comparators for the treatment of major depressive disorder

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BACKGROUND: Major depressive disorder (MDD) is a prevalent condition associated with substantial economic costs. Auvelity (dextromethorphan-bupropion) is an oral N-methyl-D-aspartate (NMDA) receptor antagonist and sigma-1 agonist that was approved in the United States in 2022 for the treatment of MDD in adults. This study examined real-world health care resource utilization (HCRU) and costs in patients in the United States treated with dextromethorphan-bupropion vs other recently approved branded treatments for the symptoms of depression.

OBJECTIVE: To compare total HCRU and costs during 6 months of follow-up among patients who initiated dextromethorphan-bupropion vs cariprazine, brexpiprazole, or esketamine.

METHODS: Adults with MDD initiating dextromethorphan-bupropion, cariprazine, brexpiprazole, or esketamine were identified in the Merative MarketScan Commercial and Medicare databases (Jan 2021 to Mar 2024). The index date was defined as the first prescription claim. Patients were required to have continuous enrollment for 6 months pre- and post-index. Using propensity scores to adjust for demographics, comorbidities, and prior medication use, the respective comparator cohorts were weighted to the dextromethorphan-bupropion cohort. Regression analyses were conducted for total HCRU and costs during the 6-month post-index period, controlling for pre-index costs.

RESULTS: After weighting, each cohort had 1,472 patients (mean age: 43 years, female: 66.7%). Patients in the cariprazine, brexpiprazole, and esketamine cohorts were more likely to have emergency department (ED) visits (odds ratio [OR]: 1.35, 1.23, and 1.34, respectively; all $P < 0.05$) and inpatient admissions (OR: 1.40, 1.19, and 1.11, respectively; $P < 0.05$ for cariprazine) than those initiating dextromethorphan-bupropion. Adjusted mean total costs were $18,715 for dextromethorphan-bupropion vs $19,931, $20,762, and $41,954 for cariprazine, brexpiprazole, and esketamine, respectively ($P = 0.053$ vs cariprazine; $P < 0.05$ vs brexpiprazole and esketamine). Adjusted medical costs were $9,154 vs $10,335, $10,352, and $23,934, and pharmacy costs were $9,272 vs $10,060, $11,015, and $21,561, respectively (all $P < 0.05$).

CONCLUSIONS: These data from a large US claims database indicate that patients treated with dextromethorphan-bupropion were less likely to have ED visits or inpatient admissions and had significantly lower total health care costs (medical and pharmacy) over 6 months following the start of treatment compared with those receiving cariprazine, brexpiprazole, or esketamine.

SPONSORSHIP: Axsome Therapeutics, Inc.

365 Mapping the cirrhosis journey: Cirrhosis etiologies and rates, timing, and cost of complications in a US claims database

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BACKGROUND: Cirrhosis is a progressive liver disease that can lead to serious complications and rising health care costs. As severity advances, patients face higher risk of complications, adding clinical and economic burden. Understanding the timing and costs of complications is critical for timely intervention and resource planning.

OBJECTIVE: To assess the clinical and economic burden of cirrhosis by evaluating complication patterns and all-cause health care costs across disease stages in a real-world US population.

METHODS: This retrospective cohort study used Komodo Research Data (2016-2023) to identify adults newly diagnosed with cirrhosis. Patients were followed from the index date, defined as diagnosis or first complication (ascites, overt hepatic encephalopathy [OHE], or varices with/without bleeding) until the earliest of end of enrollment, liver transplant, secondary neoplasm of liver, death, or data cutoff. Complications were described overall and by etiology: alcohol-associated liver disease [ALD], metabolic dysfunction–associated steatohepatitis [MASH], viral hepatitis, or other. Time to first complication was estimated using Kaplan-Meier methods. All-cause health care costs (2024 USD) per patient per month (PPPM) were evaluated across six periods: at any time, pre-diagnosis, 3-month diagnostic workup, stable disease, 3-month pre-complication, and up to 3-month post-complication.

RESULTS: Among 110,359 adults with cirrhosis (median age: 60; 55.5% male; 56.9% White, median follow-up: 23.5 months), cirrhosis was attributed to ALD in 34.7% of patients, MASH in 22.8%, viral hepatitis in 13.8%, and other in 28.8%. Within 36 months, 62.3% developed a complication, with the highest risk in ALD (84.6%) and the lowest in viral hepatitis (41.5%). The most common initial complication was ascites (63.6%), followed by varices without bleeding (27.2%), OHE (14.6%), and varices with bleeding (8.5%). Among 66,563 patients with complications, total cost PPPM was $5,597, compared to $2,808 for those without. In patients with complications, costs fluctuated over time; total cost PPPM was $2,606 pre-diagnosis, $5,483 during diagnostic workup, $2,639 during the stable disease period, $4,818 pre-complication, and $12,695 post-complication.

CONCLUSIONS: Complications are common within 3 years of cirrhosis diagnosis and are linked with higher health care costs. These findings highlight the need for early intervention and monitoring to reduce burden and improve outcomes. Patients who experience complications incur higher costs, with a marked increase following onset of complications.

SPONSORSHIP: Bausch Health

366 Health care costs for patients with major depressive disorder initiating dextromethorphan-bupropion extended-release tablets as a first or subsequent line of treatment

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BACKGROUND: Major depressive disorder (MDD) is a chronic condition with unmet needs despite many established treatment options. Auvelity (dextromethorphan-bupropion [DM-BUP]) is an oral, N-methyl-D-aspartate (NMDA) receptor antagonist and sigma-1 agonist approved in the United States for the treatment of adults with MDD. This study evaluated real-world health care costs in patients with different pharmacologic treatment histories initiating DM-BUP for MDD.

OBJECTIVE: To examine health care costs over 6 months among patients with MDD initiating DM-BUP who were treatment-naïve or had 1 or 2+ prior MDD treatments.

METHODS: Adults with MDD who initiated DM-BUP were identified in the Merative MarketScan Commercial and Medicare databases (Jan 2021 to Mar 2024). Included patients had continuous enrollment for 6 months pre- and post-initiation of DM-BUP (index date = 1st prescription date). Patients were divided into subgroups according to the number of MDD treatments in the pre-initiation period: 0, 1, or 2+. Multivariate regressions were conducted to examine health care costs, adjusting for differences in age, gender, and comorbidities.

RESULTS: Among 1,472 patients initiating DM-BUP, 160 (10.9%), 367 (24.9%), and 945 (64.2%) were MDD treatment-naïve or had 1 or 2+ prior MDD treatments, respectively. Treatment-naïve patients were younger, were more likely to be male, and had fewer mental health–related comorbidities than those with 1 or 2+ prior MDD treatments (all $P < 0.05$). Treatment-naïve patients had lower total costs vs patients with 1 or 2+ prior MDD treatments ($13,025 vs $15,054 and $23,484, respectively; $P < 0.05$ for 2+ vs 0 prior treatments). Similarly, inpatient ($434 vs $583 and $2,922, respectively),

outpatient ($5,446 vs $6,384 and $9,112), and pharmacy costs ($7,056 vs $7,926 and $11,537) were lower for treatment-naïve patients than those with 1 or 2+ prior MDD treatments (all $P < 0.05$ for 2+ vs 0 prior treatments). MDD-related and mental health–related costs were also significantly lower among treatment-naïve patients than those with 1 or 2+ prior MDD treatments (both $P < 0.05$). Across all analyses, costs were also lower for patients receiving 1 vs 2+ prior MDD treatments (all $P < 0.05$).

CONCLUSIONS: In this retrospective analysis of DM-BUP in the United States, patients who were MDD treatment-naïve prior to initiating DM-BUP had lower health care costs (total, MDD-related, and mental health–related) in the 6 months after starting DM-BUP than those with prior MDD treatments; costs were also lower for patients with 1 vs 2+ prior treatments.

SPONSORSHIP: Axsome Therapeutics, Inc.

367 Health care costs associated with timely diagnosis of mild cognitive impairment and Alzheimer disease

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BACKGROUND: Mild cognitive impairment (MCI) and Alzheimer disease (AD) affect millions of Americans. MCI, characterized by cognitive decline with intact daily living activities, progresses to AD, where functional independence declines. Understanding the cost implications and progression rates of these conditions, particularly in relation to the timing and setting of diagnosis, is crucial for optimizing patient outcomes and managing health care expenditures.

OBJECTIVE: To estimate longitudinal costs and time to death, disease progression, and institutionalization associated with MCI and AD.

METHODS: This retrospective, observational, case-control study utilized Medicare Research Identifiable Files from 2016 to 2021. Patients aged 65 and older with at least 24 months of continuous Medicare enrollment were included and categorized into incident MCI or AD cohorts if there were no diagnosis codes for either condition in the prior 12 months. Subjects with an MCI or AD diagnosis were matched to non-diagnosed controls using set criteria. Costs and time-to-institutionalization and -death were assessed using Kaplan-Meier survival analysis and regression models.

RESULTS: The incident cohorts included 422,866 individuals with MCI and 560,313 with AD diagnoses. At 24 months post-index diagnosis, the survival probability was 65% vs 84% ($P<0.05$) for MCI and 33% vs 71% ($P<0.05$) for AD compared to their respective matched controls. Average costs for subjects with MCI|AD during the index month were approximately $27,071|$20,186 for the inpatient setting, $17,069|$14,039 for the institutional setting, and $3,520|$3,409 for the outpatient setting. A sub-analysis comparing incident MCI subjects to matched AD subjects found that monthly per subject costs were $552 lower for the MCI cohort compared to their AD matched cohort.

CONCLUSIONS: Health care expenditures were significantly higher for individuals diagnosed in inpatient or institutional settings compared to diagnosis in outpatient settings. Diagnosis at an earlier stage (MCI) was associated with lower initial and long-term costs and increased probability of survival compared to those at a later stage (AD). These results underscore the potential benefits of timely diagnosis in appropriate settings to reduce the economic burden of dementia. Timely diagnosis of MCI and AD significantly reduces health care costs, enhances survival, and delays institutionalization. The findings of this study emphasize the need for strategies promoting early and outpatient diagnosis for those with MCI or AD to potentially improve patient outcomes and reduce health care expenditures.

SPONSORSHIP: Eli Lilly & Company

368 Comparisons of pharmacy-dispensed medications in the 2022 Medical Expenditure Panel Survey and the Healthcare Integrated Research Database

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BACKGROUND: Drug shortages pose serious public health risks that can be difficult to predict. The US Agency for Healthcare Research and Quality's (AHRQ) Medical Expenditure Panel Survey (MEPS) provides national data on pharmacy-filled medications each year. However, the ability of the MEPS to inform public health responses to drug shortages is limited due to timeliness and small sample sizes. Pharmaceutical claims databases may provide timely, reliable data on pharmaceutical use, but their representativeness is uncertain.

OBJECTIVE: To compare the utility of data on prescription drug dispensing events from two sources to inform drug shortage occurrence and impacts.

METHODS: We used data from the Medical Expenditure Panel Survey (MEPS) and the Healthcare Integrated Research Database (HIRD), a large, commercial health insurance claims database to identify drugs dispensed in

2022. We categorized National Drug Codes (NDCs) associated with each event into 14 Multum Lexicon therapeutic categories. For each data source and therapeutic category, we calculated the number of fills, the number of unique NDCs, and the average number of fills per NDC within each therapeutic category. We used standardized mean differences (SMDs) to compare the share of fills and NDCs within each therapeutic category across the two data sources.

RESULTS: MEPS recorded 191,514 fills, a value roughly 14 times higher than the 163.5 million HIRD-recorded fills. MEPS recorded 8% more unique NDCs than did the HIRD (7,661 vs 7,038, respectively). The shares of total fills across data sources differed most for anti-infectives and metabolic agents (SMDs = 0.23 and 0.11, respectively). Counts of NDCs within therapeutic categories were more similar (SMDs ≤ 0.02). The number of fills per NDC in each therapeutic category ranged between 8 and 48 in the MEPS and 6,000 and 34,801 in the HIRD.

CONCLUSIONS: Results suggest data on pharmacy-dispensed medications from the HIRD are highly similar to those reported in the MEPS, despite the widely varying measurement methodologies. The larger number of NDCs reported in the MEPS suggests it more fully represents national variation in prescription drug benefit coverage. At the same time, the substantially larger number of fills per NDC in the HIRD demonstrates that claims databases can facilitate reliable analysis of shortages affecting narrow drug classes. Future research should explore how claims data can complement nationally representative data to promote timely detection and response to drug shortages.

SPONSORSHIP: Carelon Research, RAND Corporation

369 Burden of anti-seizure medication titration on health care resource utilization and costs among patients with focal onset seizures: A physician panel-based chart review

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BACKGROUND: Anti-seizure medications (ASMs), the standard treatment for focal onset seizures (FOS), often require careful titration to improve tolerability, delaying therapeutic dosing and risking suboptimal seizure control. This trade-off may increase health care costs due to higher dosing requirements and more frequent monitoring.

OBJECTIVE: To compare health care resource utilization (HRU) and costs between the titration and maintenance periods of ASM treatments among patients with FOS in the United States.

METHODS: A retrospective physician panel-based chart review completed by neurologists and epileptologists was used to collect data on adult patients with FOS initiating an ASM between 1/1/2021 and 12/31/2023 (index date). Epilepsy-related HRU and costs were assessed from the index date to the earliest of index ASM discontinuation, loss-to-follow-up, or end of data collection. Based on reported HRU, costs were imputed using literature-based estimates of epilepsy-related costs in the United States. Physician-evaluated titration end date was used to divide follow-up time into titration and maintenance periods. Multivariate regression models adjusting for patient characteristics observed during the 6-month period pre-ASM initiation (baseline period) were used to compare HRU and costs between titration and maintenance periods.

RESULTS: Overall, 148 neurologists/epileptologists provided data on 399 patients (mean age: 36.5 years, 60.7% male, 69.2% White, 70.2% commercially insured). The median duration of the titration and maintenance periods was 3.1 and 16.0 months, respectively. Per-patient-month (PPM) HRU was significantly higher in the titration versus maintenance period for all HRU types: inpatient admissions (adjusted incidence rate ratio [IRR]: 5.70), emergency department (ED) visits (IRR: 3.39), outpatient visits (IRR: 1.52), lab monitoring (IRR: 1.89), diagnostic services (IRR: 3.24) and office phone calls (IRR: 2.52; all $P < 0.001$). PPM health care costs were also significantly higher during the titration versus maintenance period (adjusted total mean monthly cost difference: $879; inpatient: $717; ED: $98; outpatient: $37; lab monitoring: $1; diagnostics: $20; all $P < 0.001$).

CONCLUSIONS: Among patients with FOS, epilepsy-related HRU was 1.5-6 times higher during titration than maintenance periods. Epilepsy-related costs were also higher during titration, driven by higher inpatient and ED costs. Safe, efficacious treatments that avoid prolonged titration periods may help reduce titration-related HRU and costs for patients with FOS.

SPONSORSHIP: Xenon Pharmaceuticals Inc.

370 Triptans, opioids, and rescue medications use among patients with migraines prescribed CGRP for migraine prophylaxis

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BACKGROUND: Migraines are a prevalent and debilitating neurological condition, affecting 40 million adults in the United States. Multiple studies have shown the detrimental impact of migraines, such as loss of time in work and life domains and overall decline in quality of life. Patients can be prescribed prophylaxis (e.g., beta blockers, anticonvulsants, antidepressants), and rescue medications (e.g., triptans, opioids [which are not recommended for use to treat migraines]) to treat and/or relieve migraines. Approximately 38% of migraine patients would benefit from prophylaxis. Calcitonin gene–related peptide receptor antagonists (CGRP) are the newest class of drugs approved for migraine prophylaxis. Patients taking CGRPs report reduced migraine frequency and severity, which should result in lower utilization of rescue migraine medications.

OBJECTIVE: To examine the use of triptans, rescue medications, and opioids for patients with migraines prescribed CGRPs and patients who are not prescribed CGRPs.

METHODS: This retrospective, cross-sectional study examined health and pharmacy claims using data from Komodo Health from 2018 to 2023. Patients were aged between 18 and 60 years, had commercial, Medicaid, or Medicare coverage, and had a migraine diagnosis. Inclusion criteria include being prescribed a migraine drug during the index period, and with 12 months of continuous health coverage before and after the migraine prescription index date. Opioid use was operationalized as morphine milligram equivalent (MME). Pearson's chi-square was used to compare pre and post period within each group.

RESULTS: A total of 94,990 patients were included in this study. Among those on CGRP medications (n = 18,835), triptan use decreased in post period (58.7% vs 53.7%; $P < 0.001$) while increased among patients on non-CGRP medications (n = 76,155; 37.4% vs 49.3%, $P < 0.001$). For both cohorts, the use of opioids increased post index period (CGRP: 18.7% vs 19.3%, $P = 0.2$) (non-CGRP: 14.8% vs 16.4%, $P < 0.001$). Rescue medications increased in the post period among those on non-CGRP medications (64.5% vs 68.6%, $P < 0.001$) but decreased in the post period among those on CGRP medications (69.1% vs 69.0%, $P = 0.8$).

CONCLUSIONS: In the cohort prescribed CGRPs, there was a statistically significant correlation with lower triptan use. While an increase in opioid use was observed in the post period, the increase was not statistically significant. Comparatively, the non CGRP cohort had statistically significant increases in the use of triptans and opioids. Further research can elucidate how CGRPs may reduce the need for migraine rescue medications.

SPONSORSHIP: Evernorth Research Institute

371 Clinical and economic burden of patients with Hunter syndrome in the United States: A retrospective cohort study

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BACKGROUND: Mucopolysaccharidosis II (MPS II) is a rare genetic disease caused by the lack of iduronate-2-sulfatase enzyme leading to a buildup of complex sugars in cells. This leads to progressive damage to organs and tissues, affecting physical and cognitive development. Although idursulfase has been approved for MPS II, real-world evidence evaluating the clinical and economic burden among treated patients remains limited.

OBJECTIVE: To evaluate the clinical and economic burden of patients of MPS II treated with idursulfase in the United States.

METHODS: A retrospective study was conducted using Komodo claims data from Jan 2015 to Feb 2025. The MPS II on idursulfase cohort was selected based on 1) >1 claim of idursulfase between Jan 2017 and Dec 2023 (index date); 2) >2 claims for MPS II 90-365 days apart, and within 365 days of index, 3) male, and 4) continuous enrollment 1 year pre- and up to 3 years post-index. The MPS II cohort was 1:3 direct matched to a 1% random sample of the general population in Komodo. Outcomes for clinical burden and health resource utilization (HCRU) were evaluated over the follow-up period and compared using statistical testing.

RESULTS: A cohort of 329 patients with MPS II on idursulfase and 987 matched controls were included. Both cohorts were primarily pediatric (mean [SD] age: 12.3 [9.3]) with a mean (SD) follow-up period of 2.94 years (0.25). The MPS II cohort had a higher proportion of patients on Medicaid compared to the matched controls (50% vs 39%, $P < 0.0001$). MPS II patients had a higher proportion of patients experiencing comorbidities across all categories assessed ($P < 0.0001$). The most frequent comorbidities in MPS II patients were hearing loss (47%), valvular hear disease (42%), developmental delay (41%), and sleep apnea (41%). MPS II patients

also experienced higher HCRU compared to the matched controls (Inpatient: 43% vs 11%, Emergency: 64% vs 43%, Surgeries: 63% vs 29%; P<0.0001). Mean admissions and visits in each of the health care settings were significantly higher among MPS II patients compared to the matched controls (Inpatient: 3.23 vs 1.29; Outpatient: 26.56 vs 16.13; Prescriptions: 11.50 vs 4.99; Surgery: 1.08 vs 0.64, respectively; P<0.0001).

CONCLUSIONS: Patients with MPS II on idursulfase experience significantly higher clinical and economic burden compared to the general population. These findings underscore the importance of identifying new therapies that can reduce the burden of both CNS and peripheral disease for patients with MPS II.

SPONSORSHIP: Denali Therapeutics

372 A retrospective cohort study examining the real-world disease progression, HCRU, and costs among patients with T2D with newly diagnosed CKD stage III or IV with and without finerenone use

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BACKGROUND: Finerenone (FIN), a non-steroidal mineralocorticoid receptor antagonist approved in 2021, demonstrated promising efficacy in patients with type 2 diabetes (T2D) and chronic kidney disease (CKD).

OBJECTIVE: To characterize the progression of disease, HCRU, and costs of T2D patients after CKD stage III or IV diagnosis with and without FIN.

METHODS: A retrospective cohort study of T2D patients newly diagnosed with CKD stage III or IV from Optum Clinformatics Database between 07/2021 and 06/2023 was conducted. A 12-month continuous lookback and follow-up period were used to identify demographics, index diagnoses, incident heart failure (HF), atrial fibrillation (AF), CKD stage progression, HCRU, and costs. A 6-month washout period identified incident FIN users, and 3 months of FIN use was required. Proportions and means (SD) are reported for HCRU and costs.

RESULTS: The FIN and non-FIN cohorts contained 424 and 161,880 patients, respectively. Baseline CKD stage, CCI score, gender, and use of steroidal mineralocorticoid receptor antagonist during the lookback period were similar between cohorts. The FIN cohort, however, had a higher prevalence of other medication classes for CKD/T2D. Other differences between FIN and non-FIN cohorts at baseline included age (71 and 75), prevalence of HF (18% and 20%), and AF (13% and 16%). After follow-up, incident HF was 12% in the FIN cohort and 19% in the non-FIN cohort. Incident AF was 4% in the FIN cohort and 10% in the non-FIN cohort. Progression from CKD stage III to IV was 11% in the FIN cohort and 6% in the non-FIN cohort. Progression to ESRD from stage III or IV was 1% and 2% in the FIN group and 7% and 19% in the non-FIN group. Mean inpatient visits were 2.5 (7.5) in the FIN group and 4.9 (12.3) in the non-FIN group, corresponding to mean inpatient costs of $11,774 ($37,907) and $23,075 ($54,591). Mean outpatient costs were $19,544 ($21,779) in the FIN group and $24,255 ($40,534) in the non-FIN group. These costs corresponded to the following mean HCRU measures among the FIN and non-FIN groups: ED visits 0.9 (1.9) and 1.3 (2.3), outpatient visits 5.9 (7.9) and 7.4 (10.9), and office visits 19 (11.7) and 16.3 (13.6). In the FIN and non-FIN groups, mean pharmacy costs were $20,631 ($18,605) and $7,594 ($18,367). Mean total costs for the FIN and non-FIN groups were $51,949 and $54,924, respectively.

CONCLUSIONS: In this analysis, T2D patients with newly diagnosed CKD stage III and IV who received FIN were associated with lower incident HF, AF, and progression to ESRD. Although pharmacy costs were higher, HCRU shifts yielded similar total costs.

SPONSORSHIP: Bayer

373 Real-world visual outcomes by health care insurance with prescription digital treatment for amblyopia: PUPiL registry analysis

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BACKGROUND: Amblyopia ("lazy eye") is a neurodevelopmental disorder causing reduced vision in an eye despite use of corrective lenses; it affects 2-5% of children. Previous studies show Medicaid patients with amblyopia have poorer outcomes with traditional treatments. Luminopia, an FDA-cleared prescription digital treatment for anisometropic and/or mild strabismic amblyopia in children aged 4 to <13 years, may address these disparities.

OBJECTIVE: To evaluate real-world evidence including visual outcomes and treatment adherence with Luminopia across insurance types using the Patients Using Prescription Luminopia (PUPiL) Registry (NCT06429280).

METHODS: Retrospective analysis of PUPiL registry patients aged <18 years who completed Luminopia treatment based on data available up to 3/4/25, including amblyopia of any cause and severity. Children enrolled had at least 12 weeks of Luminopia at 14 participating centers. Amblyopic eye best-corrected visual acuity (BCVA) improvement from start to

end of treatment and treatment usage were analyzed by amblyopia severity. Multivariable analysis was used to identify significant predictors of vision improvement. Outcomes were analyzed by insurance type.

RESULTS: A total of 182 registry-enrolled children were eligible; 46% were female. Mean age was 7.3±2.5 years, 81% had received prior treatment for amblyopia, and 34% had Medicaid insurance. Children with severe (<20/100, 14%), moderate (20/40 up to 20/100, 60%), and mild (>20/40, 25%) amblyopia gained +1.7, +1.1, and +0.3 lines BCVA, respectively. Treatment usage and duration varied by severity: mild (102±78 hours), moderate (111±76 hours), and severe (124±105 hours) over approximately 8 months for all groups. Significant predictors of improvement were prior treatment status ($P = 0.03$), baseline vision ($P < 0.0001$), and treatment hours ($P = 0.03$). After adjusting for these factors in the multivariable model, the difference in VA outcomes between insurance groups was not significant (adjusted means: Medicaid 1.3 vs commercial 1.1 lines, $P = 0.40$). Treatment adherence was similar between groups (Medicaid: 3.4 hr/week, 57% adherence; commercial: 3.2 hr/week, 54% adherence; $P = 0.48$). No serious adverse events were reported.

CONCLUSIONS: Unlike real-world outcomes observed with traditional monocular amblyopia treatments, Medicaid-insured children achieved comparable visual outcomes and treatment adherence rates to commercially insured children using Luminopia. This therapeutic intervention may help address differences in amblyopia treatment outcomes across socioeconomic groups, potentially reducing long-term health care costs.

SPONSORSHIP: Luminopia, Inc.

374 Data linkage and tokenization in action: A systematic review of North American clinical trials utilizing linkage to real world data

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BACKGROUND: Data linkage and tokenization are increasingly being adopted to address challenges in clinical trials, such as higher costs, evaluating unique endpoints, providing long-term surveillance of patient outcomes, and more.

OBJECTIVE: To quantify examples of published clinical trials that have used data linkage and evaluate the uses of linked data in trial analyses.

METHODS: Relevant articles were identified through PubMed and ClinicalTrials.gov searches implemented on Nested Knowledge, an artificial intelligence–assisted systematic literature review software platform, for articles published from 2014 to 2024. Gray literature was identified on congress websites and via Google Scholar searches. Articles were included if the clinical study population was in North America (USA and Canada) and the study had a medical intervention. Data on study sponsor, objective, patient disease state, type of linked data, linked data elements, and linkage methods were extracted from each study.

RESULTS: A total of 698 abstracts were screened, and 20 articles reporting trials with linkage were included in this review. There were 8 interventional trials, 1 phase II, 8 phase III, and 3 phase IV trials The key objectives in data linkage were safety and efficacy (10), cost (3), feasibility (3), survival (3), and prior medical history (1). The disease state of the trial populations were Cancer/Tumors (6), Cardiovascular Risk (3), Aortic Stenosis (2), Kidney Disease (2), and 1 each: Perianal, Rheumatoid Arthritis, Alzheimer, Joint Replacement, Depression, COVID-19, and Spinal Muscular Atrophy. The studies were sponsored by industry (7), academic (7), and government institutions (6). Studies linked trial data with real-world datasets, including Medicare claims, registries, and administrative health records. The methods used included probabilistic matching, deterministic matching, tokenization, secure data transfer to link patient data across different datasets, unique identifiers for longitudinal tracking, and integrating registry data, and/or manual review for validation. The percentage of the study population that was successfully linked was 74.1% on average (range: 13%-100%).

CONCLUSIONS: The small number of clinical trial publications involving data linkage indicates that this practice is still in the early stages of adoption. This adoption is seen broadly across private and public sectors and generally targets registries, insurance, and health records for safety and efficacy data.

SPONSORSHIP: Novo Nordisk Inc.

375 Socioeconomic disparities in health care resource utilization and costs among Medicare fee-for-service beneficiaries with progressive pulmonary fibrosis

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BACKGROUND: Fibrosing interstitial lung disease (ILD) that progresses is known as progressive pulmonary fibrosis (PPF). Socioeconomic factors affect access to care and health outcomes, yet evidence on related disparities is limited.

OBJECTIVE: To describe potential disparities in health care resource utilization (HCRU) and costs among Medicare fee-for-service (FFS) beneficiaries with PPF by socioeconomic status (SES).

METHODS: This retrospective cohort study used the Medicare FFS claims database to identify beneficiaries with PPF between January 2017 and June 2024. First, patients newly diagnosed with ILD were identified by ≥2 claims with a relevant diagnosis code on separate dates within 365 days. Then, patients with evidence of progression were identified using claims-based proxy measures, with the earliest date of progression set as the index date. Continuous enrollment for 12 months before and ≥1 month after index date was required. All-cause and PPF-related HCRU and costs were assessed, stratified by separate covariates that indicate lower SES (i.e., eligibility for Part D low-income subsidy [LIS] and dual-eligibility [DE] for Medicare and Medicaid). All outcomes were analyzed descriptively.

RESULTS: A total of 257,280 patients with PPF were identified (mean age: 74 years), and the majority were female (61.5%) and non-Hispanic White (80.4%). The majority were of higher SES, as reflected by distributions for DE status (full DE: 22.9%; partial DE: 5.9%; not DE: 71.2%) and LIS eligibility status (eligible with full subsidy: 29.5%; eligible with partial subsidy: 2.8%; ineligible: 74%). Patients in lower SES groups consistently had higher HCRU and costs. Mean (SD) all-cause inpatient visits per patient per month (PPPM) were highest among patients with full DE (0.40 [0.68]), followed by partial DE (0.30 [0.38]), and not DE (0.23 [0.33]). All-cause emergency department visits showed a similar gradient (full DE: 0.42 [0.57]; partial DE: 0.37 [0.45]; not DE: 0.25 [0.29]). Mean (SD) all-cause total medical costs PPPM were $10,429 [$14,337] for full DE, $7,771 [$11,220] for partial DE, and $6,818 [$10,470] for not DE patients. Similar trends were observed for LIS status.

CONCLUSIONS: Among Medicare beneficiaries with PPF, lower SES was associated with higher HCRU and costs, reflecting potential disparities in access to care and disease burden. These findings underscore the need for targeted strategies and interventions to address underlying disparities in care and enhance outcomes in this vulnerable population.

SPONSORSHIP: Boehringer Ingelheim

376 Real-world persistence of first-line advanced therapies in patients with psoriatic arthritis

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BACKGROUND: Advanced therapies such as interleukin (IL)-23, IL-12/23, IL-17, phosphodiesterase-4 (PDE-4), and tumor necrosis factor (TNF) inhibitors (i) have been approved for first-line treatment of active psoriatic arthritis (PsA). Risankizumab (RZB), an IL-23i, was approved for the treatment of PsA in the United States on 1/21/22. Real-world evidence on treatment persistence for PsA does not fully include recently approved therapies.

OBJECTIVE: To evaluate real-world persistence in patients with PsA initiating first-line advanced therapies (1LAT) over 12 months.

METHODS: Adults with ≥1 PsA diagnosis at baseline who initiated a new 1LAT between 1/21/22 and 10/31/24 were identified using the Merative Marketscan databases covering 1/1/16 to 10/31/24 and ≥6 months of continuous enrollment pre-index date (baseline) and ≥12 months of continuous enrollment post-index date. Persistence was defined as no treatment switch or discontinuation. Treatment switch was defined as a claim for a different 1LAT after the index date; treatment discontinuation was defined as a gap in treatment without refill equal to 90 days of the assumed days of supply of the last prescription fill. Multivariate logistic regression was used to compare persistence rates among individual drugs (reference: RZB), accounting for differences in baseline characteristics.

RESULTS: A total of 2181 patients met the inclusion criteria for the study and were treated with adalimumab (ADA; n = 600), apremilast (APR; n = 577), etanercept (ETN; n = 147), golimumab (GOL; n = 70); guselkumab (GUS; n = 221), ixekizumab (IXE; n = 163), risankizumab (RZB; n = 266), or secukinumab (SEC; n = 137). Switch rates varied across 1LAT from 5.3% to 30.7% and discontinuation rates varied from 21.8% to 53.2%, with RZB having the lowest switch and discontinuation rates within 12 months following treatment initiation. Persistence rates were the highest for RZB (76.3%) followed by SEC (65.7%), GUS (61.1%), ETN (59.2%), GOL (52.9%), IXE (52.8%), ADA (49.2%), and APR (41.6%). Compared with RZB, the odds of persistence were SEC 0.63 (95% CI 0.40-0.99), GUS 0.50 (95% CI 0.34-0.74), ETN 0.48 (95% CI 0.30-0.74), GOL 0.38 (95% CI 0.22-0.67), IXE 0.35 (95% CI 0.23-0.54), ADA 0.31 (95% CI 0.22-0.44), and APR 0.23 (95% CI 0.17-0.32), all $P < 0.05$.

CONCLUSIONS: In this real-world US claims data study of adults with PsA initiating 1LAT, persistence rates at 12 months were significantly higher with RZB relative to all other treatments.

SPONSORSHIP: AbbVie

377 Health care costs and resource utilization in Medicaid-insured people with overweight or obesity and knee osteoarthritis in the United States: A retrospective database study

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BACKGROUND: Overweight or obesity increases the risk of onset and progression of knee osteoarthritis (OA-K). The American College of Rheumatology and Osteoarthritis Research Society International recommends weight reduction of ≥5% for people with OA-K. With continuous advancements in OA-K treatment and innovation in weight management, understanding the economic impact of OA-K in people with overweight or obesity is crucial.

OBJECTIVE: To describe health care costs and resource utilization in Medicaid-insured people with overweight or obesity and OA-K in the United States.

METHODS: This retrospective, observational study used Optum's de-identified Market Clarity Data, linking medical and pharmacy claims with electronic health records. Adults (≥45 years) with ≥1 diagnosis code for OA-K (earliest as index date) between Oct 1, 2016, and Mar 31, 2023 (index period), with baseline body mass index (BMI) ≥25 kg/m^2, and classified as having moderate to severe OA-K pain based on previously validated real-world data algorithms were included. All participants had continuous medical and pharmacy Medicaid enrollment benefits, 12-month pre-index through ≥12-month post-index, after the earliest observed claim with OA-K diagnosis. Results were stratified by BMI categories: Overweight (≥25 to <30 kg/m^2), Class 1 obesity (≥30 to <35 kg/m^2), Class 2 obesity (≥35 to <40 kg/m^2), and Class 3 obesity (≥40 kg/m^2). All-cause and OA-K-related annualized health care costs were calculated post-index for different BMI categories and adjusted using a generalized linear model with gamma distribution (adjusted for age, sex, payor type, baseline Charlson Comorbidity index score, and baseline costs).

RESULTS: A total of 10,392 people with OA-K were included (Overweight: 26.2%; Class 1 obesity: 28.3%; Class 2 obesity: 20.1%; Class 3 obesity: 25.4%). The mean (SD) adjusted annualized all-cause total health care costs increased in the higher BMI categories: Overweight: $42,735 (44,565); Class 1 obesity: $44,803 (42,142); Class 2 obesity: $51,308 (46,385); Class 3 obesity: $57,555 (49,754). Similarly, mean (SD) OA-K-related total health care costs also increased in the higher BMI categories: Overweight: $3,430 (341); Class 1 obesity: $4,091 (393); Class 2 obesity: $4,701 (431); Class 3 obesity: $4,717 (428).

CONCLUSIONS: This real-world study highlights the increasing economic impact of overweight or obesity in Medicaid-insured people with OA-K. Future studies evaluating the impact of weight management strategies focusing on OA-K-related health care costs should be undertaken.

SPONSORSHIP: Eli Lilly and Company

378 Use of health services by people living with Alexander disease

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BACKGROUND: Alexander disease (AxD) is a rare genetic leukodystrophy affecting people of all ages. The prevalence is suspected to be 1 in one million people in the United States. The economic burden of the condition on the health care system has not be described. We provide that information here using a recently implemented ICD-10 code.

OBJECTIVE: To characterize the economic burden of medical care, in terms of dollars expended and frequency of health service utilization, for people living with AxD.

METHODS: A retrospective cohort study was conducted using a nationally representative claims data set from Komodo Health. AxD patients were identified by the presence of at least two insurance claims with an ICD-10-CM code G31.86 at least 30 days apart between January 01, 2023, and October 31, 2024. Paid charges from 2023 were adjusted to 2024 using the Consumer Price Index for Medical Care and 2024 charges were extrapolated to 12 months. Health care utilization is described for inpatient, emergency department (ED) visits, and outpatient services. We also provide some demographic description. We report charges for 2023 and 2024. Utilization is reported only for 2023 due to completeness of data.

RESULTS: Fifty-five patients living with AxD were identified in 2023 and 76 in 2024. Drawing demographic and clinical factors from 2024, the average age was 28; 45% were <18, and 20% were ≥55. A total of 58% had claims indicating seizures, 58% respiratory conditions, 38% movement conditions, and 30% scoliosis. Mean paid charges for all services

were $107,261 in 2023 and $63,483 in 2024. In 2023, 43.6% of people with AxD were hospitalized for at least one day and 66% made at least one visit to the ED during the year. Of those admitted for inpatient services, 1/3 were admitted from the ED. Of those with an inpatient visit, 48% included a stay in the ICU. The mean length of stay in the hospital was 11 days, and the median was 5 days. Home health services were used by 56.2% of people with AxD, and nearly 100% used outpatient and pharmacy services.

CONCLUSIONS: This is the first report of health care utilization for people living with Alexander disease. While rare, people living with AxD are heavy users of health services, particularly inpatient, ICU, and ED care. At an annual mean of $63,000 to $107,000, the cost represents a burden of care higher than other severe chronic diseases. However, even this represents a fraction of the total burden of AxD to families and society.

SPONSORSHIP: Ionis Pharmaceuticals

379 Antipsychotic medication utilization and treatment patterns among patients with schizophrenia: A real-world evidence study

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BACKGROUND: The primary treatment option for schizophrenia is antipsychotics; however, these are associated with a variety of tolerability issues that impact adherence.

OBJECTIVE: To assess treatment patterns among patients with a diagnosis of schizophrenia receiving antipsychotic medications. Subgroup analyses were conducted among patients with comorbid hypertension to assess any differences in adherence to antipsychotics and antihypertensive medications.

METHODS: This was a retrospective analysis of the MORE2 Registry and 100% Medicare Fee-for-Service (MFFS) claims databases spanning 1/1/2016 to 9/30/2023. Inclusion criteria: 1) ≥1 inpatient or ≥2 outpatient claims with a schizophrenia diagnosis, 2) ≥2 claims for an antipsychotic (earliest claim = index date), 3) ≥18 years on index, 4) ≥6 months of continuous enrollment prior to and ≥12 month following index, and 5) absence of claims for antipsychotics during the 6 month pre-index period. Subgroups were created based on route of administration (oral [OAP] vs long-acting injectable [LAI]–containing), and evidence of comorbid hypertension. Medication adherence at the class level was assessed and defined as a proportion of days covered (PDC) ≥0.80 during follow-up. Antipsychotic treatment augmentation, treatment switching, and antihypertensive treatment adherence among the subgroup with hypertension were also assessed.

RESULTS: Overall, 212,770 patients with schizophrenia were included. Mean (SD) age was 46.3 (16.3) and the majority were male (54.9%). Most patients received OAPs only (82.3%); 15.9% received an LAI-containing regimen. Most common index antipsychotics were risperidone (21.1%), quetiapine (19.8%), and olanzapine (19.2%). Adherence was low for both OAPs (39.6%) and LAI-containing regimens (50.2%). Treatment switching was observed among 9.3% of the sample, while augmentation was observed among 4.8%. Augmentation and switching were two-fold more frequent among patients receiving LAI-containing regimens compared to OAPs. Among patients with comorbid hypertension (23.1%), only 47.4% were adherent to antipsychotics, while 66.1% were adherent to antihypertensives.

CONCLUSIONS: Adherence to antipsychotic medication remains suboptimal among patients with schizophrenia living in the United States. Among patients adherent to oral antihypertensives medications, adherence to antipsychotics remained low, suggesting selective nonadherence due to potential barriers specific to antipsychotics. Development of newer antipsychotics with improved tolerability may lead to increased adherence and improved clinical outcomes.

SPONSORSHIP: Bristol Myers Squibb

380 Treatment patterns among patients with neuromyelitis optica spectrum disorder (NMOSD): A real-world evidence study

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BACKGROUND: Neuromyelitis optica spectrum disorder (NMOSD) is a rare, inflammatory, autoimmune condition that primarily affects the optic nerves and spinal cord. Treatment for NMOSD focuses on the management of acute attacks and prevention of relapses.

OBJECTIVE: To describe current treatment patterns among patients with a diagnosis of NMOSD.

METHODS: This study was an observational, retrospective analysis of the MORE2 Registry and 100% Medicare Fee-for-Service databases spanning 6/11/2019 to 12/31/2023. Inclusion criteria were as follows: ≥2 claims with a diagnosis of NMOSD, or ≥1 claim with a diagnosis of NMOSD, transverse myelitis, or optic neuritis + ≥1 claim for treatment (earliest diagnostic evidence = index date), 2) aged ≥18 years on the index date, and 3) ≥12 months of continuous enrollment prior to and ≥6 months following the index date.

Maintenance NMOSD treatment lines of therapy (LoTs) were assessed, and treatment patterns were reported, which included the time to treatment, duration of therapy, time to next treatment, co-administration with steroids, and switching.

RESULTS: A total of 3,130 patients qualified for the study, with a mean (SD) age of 53.2 (16.9) years and the majority being female (80.7%) and receiving Medicare benefits (57.8%). Three-fourths of patients (74.6%) received an initial LoT, while 51.6% showed a second LoT (396.3 [273.1] days after the initial LoT). The majority of LoT 1 and LoT 2 regimens were off-label treatments (86.2% and 79.7%), and most were for biologic monotherapy (72.9% in LoT1, and 61.3% in LoT2). The most common biologics were rituximab (LoT1 54.6%; LoT2 43.9%), eculizumab (LoT1 6.7%; LoT2 5.6%), and inebilizumab-cdon (LoT1 4.1%; LoT2 5.1%). Utilization of combination therapy was more frequent during LoT 2 compared to LoT 1 (12.5% vs. 2.0%). Patients receiving inebilizumab-cdon were the least likely to switch to another maintenance medication (<10%), compared to those receiving rituximab (11.0%) and eculizumab (19.8%). During LoT 1, receipt of oral steroids was more frequent among patients receiving rituximab (40.7%) and eculizumab (40.8%) compared to patients receiving inebilizumab-cdon (34.4%).

CONCLUSIONS: The majority of patients with NMOSD received off-label treatment, largely with biologic monotherapy. Switching, a key indicator of suboptimal disease management, was least common among patients on inebilizumab-cdon. As patients remain on therapy for well over a year, findings emphasize the importance of appropriate treatment selection early in the patient journey.

SPONSORSHIP: Amgen Inc.

381 Cost-effectiveness of VOWST (fecal microbiota spores, live-brpk; VOS, formerly SER-109) for prevention of recurrent *Clostridioides difficile* infection in the United States

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BACKGROUND: *Clostridioides difficile* infection (CDI) may result in debilitating, potentially life-threatening complications. VOS is the first FDA-approved orally administered microbiome treatment indicated for prevention of recurrent CDI (rCDI) following antibiotics treatment of rCDI in patients aged 18 years and older. Results of a recent budget impact analysis suggest VOS is cost saving to a US health plan.

OBJECTIVE: To assess the cost-effectiveness of VOS for the prevention of rCDI from a US perspective.

METHODS: A cost-effectiveness model with a Markov structure over a 1-year time horizon was developed in Microsoft Excel comparing VOS versus antibiotics alone and versus Rebyota (RBL, formerly RBX2660). Baseline recurrence risks were obtained from published literature while reduction in recurrence risk with VOS and with RBX come from published randomized clinical trials. Treatment and recurrence costs and quality-of-life parameters were obtained from published literature. Recurrences, deaths, quality-adjusted life-years (QALY), and costs (in 2025 US dollars) were estimated from a third-party commercial payer perspective and from a Medicare perspective. Incremental cost-effectiveness ratios were calculated. One-way deterministic sensitivity analyses (OWSA) and multivariate probabilistic sensitivity analyses (PSA) were conducted.

RESULTS: In the Medicare setting, the base-case analysis found treating with VOS was estimated to result in $38,531 in total direct medical costs and 0.78 QALY per patient, compared with $39,919 and 0.73 for RBL, and $41,935 and 0.66 for antibiotics alone. As such, VOS was more effective and less costly (i.e., the dominant strategy) compared with either RBL or antibiotics alone. Results were similar for a commercial population. The OWSA found that the estimated relative risk reduction compared with antibiotics alone and the baseline risk of recurrence were the most influential parameters. However, only at the lower bound of relative risk reduction for VOWST did VOWST cease being cost-effective. In the PSA at a willingness-to-pay threshold of $100,000/QALY, VOS was the dominant strategy in 62% of simulations and cost-effective in 78% of simulations.

CONCLUSIONS: Treatment with VOS has been shown to significantly reduce recurrences for patients with rCDI compared to antibiotics alone. This study illustrates that VOS is a cost-saving and cost-effective treatment compared with antibiotics alone and with RBX. As such, VOS provides clinical and economic value compared with available treatments for rCDI in the United States.

SPONSORSHIP: Nestlé Health Science

382 A claims-based analysis of the real-world economic burden of illness in patients with Sjögren disease in the United States

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BACKGROUND: Sjögren disease is an autoimmune disorder characterized by dry eyes/mouth, fatigue, pain, and systemic manifestations often resulting in significant additional health care costs.

OBJECTIVE: To describe the all-cause and disease-specific health care resource utilization (HCRU) and costs associated with Sjögren disease.

METHODS: Two claims databases were used to identify prevalent and incident patients with Sjögren disease between 01/01/2020 and 12/31/2021 (100% Medicare Fee-for-Service [FFS]) or 12/31/2022 (MORE2 Registry). Adult patients with at least 2 outpatient claims with a Sjögren ICD-10 diagnosis code at least 30 days apart within a 1-year period (earliest claim = index date) and 12 months of continuous enrollment pre-index and a variable follow-up of at least 12 months post-index were included. Absence of a Sjögren ICD-10 code in all available history pre-index was required for the incident cohort. All-cause and Sjögren-specific HCRU (per patient per month [PPPM]) and costs (per patient per year [PPPY]) were evaluated at baseline and follow-up.

RESULTS: The prevalent cohort consisted of 133,033 patients, of whom 30% (n = 39,596) were classified as incident. Overall, mean age was 66 years, 90% were female, and 62% were insured by Medicare FFS. At baseline, 34% of the prevalent cohort and 33% of the incident cohort had at least 1 all-cause emergency department (ED) visit PPPM; during follow-up, this increased to 58% of the prevalent cohort and 53% of the incident cohort. At baseline, 13% of the prevalent cohort and 11% of the incident cohort had at least 1 inpatient (IP) admission PPPM; during follow-up, this increased to 28% of the prevalent cohort and 23% of the incident cohort. During follow-up, 17% and 13% of the prevalent cohort and 13% and 5% of the incident cohort had at least 1 Sjögren-specific ED visit and IP admission PPPM, respectively. Total all-cause baseline costs PPPY in prevalent and incident cohorts were $23,532 and $21,324, respectively. These costs increased during follow-up (prevalent: $29,820 PPPY; incident: $28,476 PPPY). About 23% and 24% of the baseline and follow-up all-cause costs for prevalent patients and 13% and 19% of the baseline and follow-up all-cause costs for incident patients was identified as Sjögren related.

CONCLUSIONS: Findings highlight the substantial economic burden associated with Sjögren disease, including significant HCRU and high costs. This underscores the need for Sjögren-specific treatments to effectively manage the disease and mitigate the economic burden faced by patients. Future research should focus on the long-term economic burden as the disease progresses.

SPONSORSHIP: Amgen

383 Health care burden of eosinophilic esophagitis by disease severity: A retrospective cohort study of US health insurance claims data

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BACKGROUND: Eosinophilic esophagitis (EoE) is a chronic, immune-mediated disease. If inadequately treated, it can progress from an inflammatory to a more severe, fibrostenotic phenotype.

OBJECTIVE: To assess EoE-related health care resource utilization (HCRU) and costs, stratified by disease severity, in patients with EoE in the United States.

METHODS: This retrospective, observational cohort study examined US health insurance claims data from the Merative MarketScan Commercial, Medicare Supplemental and Medicaid databases between July 1, 2020, and June 30, 2023. Patients with ≥1 inpatient/outpatient claim for EoE (ICD-10-CM: K20.0) were included. The date of the first observed EoE claim during the selection window (July 1, 2021, to June 30, 2022) was the index date. Patients required continuous enrollment 12 months before (baseline) and 12 months after the index date (follow-up). Using a claim-based algorithm adapted from the Index of Severity for EoE, disease severity was classified as mild, moderate, or severe based on EoE-related diagnoses, procedures, and complications reported during the baseline period + 30 days post-index date. EoE-related HCRU and costs during the baseline and follow-up periods, stratified by severity, were reported.

RESULTS: Overall, 19,169 patients with EoE were identified. EoE severity was classified as mild, moderate, and severe in

67.5%, 24.9%, and 7.6% of patients, respectively. In general, EoE-related HCRU increased from baseline to follow-up and from mild to severe disease (data not shown). Mean (SD) total health care costs/patient/year (medical + pharmacy) during baseline versus follow-up periods were as follows: mild, $2623 ($6883) vs $4608 ($9054); moderate, $3596 ($6961) vs $5399 ($8077); and severe, $10,317 ($19,661) vs $12,787 ($22,334). Mean (SD) pharmacy costs/patient/year during baseline versus follow-up periods were as follows: mild, $818 ($4136) vs $1308 ($5688); moderate, $500 ($3823) vs $1026 ($5464); and severe, $1505 ($4518) vs $2135 ($6190). Overall, 414 (2.2%) patients with EoE had a claim for dupilumab (the only FDA-approved medication at the time of this study); most patients with claims for dupilumab had mild EoE (mild, 69.1%; moderate, 19.8%; severe, 11.1%). During the follow-up period, patients who had a claim for dupilumab had higher total mean (SD) EoE-related health care costs than those who did not ($31,591 [$21,023] vs $4852 [$9567]).

CONCLUSIONS: The higher HCRU and health care costs associated with severe EoE highlight the importance of early diagnosis and prompt treatment.

SPONSORSHIP: Takeda Pharmaceuticals USA, Inc.

384 Economic burden among patients with high-risk and low-to-intermediate-risk localized prostate cancer receiving radical prostatectomy in the United States

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BACKGROUND: Radical prostatectomy (RP) is a potentially curative treatment option for patients with localized prostate cancer (LPC). Although prognosis for patients receiving RP is favorable, patients presenting with high-risk (HR) features (e.g., T4 staging, Gleason score ≥8, and prostate-specific antigen [PSA] level ≥20 ng/mL) may experience recurrence and greater risk of progression to metastasis. To date, there is limited information on economic burden of patients with HR-LPC treated with RP in the United States.

OBJECTIVE: To describe health care costs for patients with LPC treated with RP stratified by HR and low-to-intermediate-risk (L/IR) status.

METHODS: Clinical data from private, community-based urology practices (PPS Analytics) were linked with insurance claims data (Komodo Research Database) between 1/1/2016 and 8/31/2024. The date of the first claim for an RP procedure was defined as the index date. HR and L/IR status was based on NCCN guidelines incorporating pre-index tumor staging, Gleason score, and PSA levels. Patients with metastasis, castration resistance, or advanced treatment prior to the index date, or <12 months of continuous pre-index insurance eligibility were excluded. Baseline (i.e., 12-month pre-index) and follow-up total health care costs (i.e., medical and pharmacy) per-patient-per-month (PPPM; 2024 USD) were described from the payer's perspective.

RESULTS: In total, 1,488 patients with HR-LPC (mean age 63 years, 52% White, 14% Black, 60% commercially insured, median time between diagnosis and RP 2.7 months, mean Quan-CCI 2.8) and 2,572 patients with L/IR LPC (mean age 61 years, 50% White, 15% Black, 69% commercially insured, median time between diagnosis and RP 2.9 months, mean Quan-CCI 2.6) who received an RP were identified. Mean total baseline costs were $912 PPPM for HR patients and $789 PPPM for L/IR patients. Mean total index date (RP) costs were $21,409 (HR) and $20,930 (L/IR). During a mean overall follow-up of 29.7 months (HR) and 33.2 months (L/IR), mean total follow-up costs were numerically higher among HR patients ($3,716 PPPM) than L/IR patients ($2,749 PPPM). Outpatient costs accounted for 86% of the observed cost difference. LPC-period specific costs prior to recurrence or progression were also numerically higher among HR patients ($4,831 PPPM) than L/IR patients ($3,480 PPPM).

CONCLUSIONS: Although patients with HR and L/IR LPC had similar baseline costs, costs increased for HR patients following RP, overall and prior to recurrence or progression, suggesting an unmet need of effective treatment options for this patient population.

SPONSORSHIP: Johnson & Johnson

385 Real-world treatment history and economic outcomes of CD38 antibody-based regimens in relapsed/refractory multiple myeloma in the United States

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BACKGROUND: Multiple myeloma (MM) accounts for approximately 2% of all cancer diagnoses and deaths in the United States, with 36,110 new cases and 12,030 deaths expected in 2025. Despite therapeutic advances, most patients eventually relapse and develop drug resistance. Anti-CD38 monoclonal antibodies, including isatuximab (Isa) and daratumumab (Dara), are indicated in relapsed/refractory MM (RRMM), but limited evidence exists on treatment patterns and economic outcomes.

OBJECTIVE: To describe treatment history and costs associated with anti-CD38 agents in combination with pomalidomide and dexamethasone (Pd) or carfilzomib and dexamethasone (Kd), in RRMM in a real-world setting.

METHODS: A retrospective cohort study was conducted using the Komodo Health's Research Grade claims data (Jan 2016 to Feb 2024) on adults with RRMM who initiated Isa- or Dara-based regimens after Mar 2020 (post-FDA approval of Isa). The index date was the CD38 regimen initiation. Treatment history (number of prior lines of treatment, CD38 exposure, stem cell transplant [SCT] status), and 12-month post-index direct health care costs were reported descriptively.

RESULTS: A total of 154 Isa- (53% Isa-PD, 47% Isa-Kd) and 1,262 Dara-treated (67% Dara-Pd, 33% Dara-Kd) RRMM patients were included, with median age of 67 and 66 years, 43% and 47% female, 43% and 44% non-White, and 57% and 53% covered by Medicare, respectively. Isa-treated patients had higher baseline comorbidity burden compared with Dara-treated patients: 23% vs 16% with anemia, 25% vs 23% with renal impairment, and 12% vs 9% with skeletal-related events (similar hypercalcemia at 8%). Prior use of SCT was lower (21% vs 25%) and prior use of anti-CD38 agents was higher (58% vs 4%) in Isa- than Dara-treated patients. Isa-based regimens were received in later lines than Dara-based, with 32% and 17% observed with ≥3 prior lines of therapy, respectively. Mean total 12-month health care costs (2023 USD) were $365,456 in Isa- and $439,673 in Dara-treated patients. During this period, mean per-patient-per-month costs were $36,983 in Isa- and $39,130 in Dara-treated patients, with cost difference primarily driven by lower MM treatment costs in Isa-treated patients ($24,835 vs $29,880).

CONCLUSIONS: Despite a higher disease burden at treatment initiation, Isa-treated patients incurred lower economic burden than those receiving Dara-based regimens, which was mainly driven by the cost of medication. Given similar efficacy and safety profile, Isa may be a compelling treatment option for RRMM from the health care payer's perspective.

SPONSORSHIP: Sanofi

386 Do claims data support use of CPT category II codes for real-world evidence clinical outcomes?

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BACKGROUND: Medical claims data include details on enrollment, procedures performed, diagnoses, and pharmacy dispenses; however, they typically lack detailed outcome measurements found in laboratory results. CPT Category II codes (Cat II) are a supplemental extension of the AMA's Current Procedural Terminology (CPT) that were intended to facilitate quality of care documentation without labor-intensive manual review of the medical record. Cat II topics range from patient management and history to documenting laboratory result values. The suitability of Cat II for real-world evidence (RWE) research has been raised, but use of the optional coding was initially very low. However, in the past 5 years payors have implemented Cat II incentives while provider thought leaders (such as the AAP and AMA) recommend adopting Cat II codes for quality improvement purposes.

OBJECTIVE: To quantify the concordance between laboratory results and claims-reported Cat II codes for two commonly performed laboratory tests: HbA1c and LDL cholesterol.

METHODS: This analysis examined closed claims and corresponding laboratory results representing 1.2 million insured members with available labs between January 2021 and December 2024. Concordance was defined as the occurrence of a corresponding Cat II code in claims within a 12-month window following laboratory test results.

RESULTS: In the diabetes cohort, 997,459 members had 1,950,297 HbA1c tests during the study period. In the cholesterol cohort, 1,048,005 members had 2,249,844 LDL tests during the study period. On average, 8.0% of the HbA1C tests and 1.5% of the LDL tests had corresponding Cat II codes. CPT II codes were reported more frequently in Medicare Advantage compared to Commercial Insurance (HbA1c: 85.9 v 55.8, LDL: 16.1 v 12.8 per 1000).

CONCLUSIONS: The US FDA issued guidance for industry on the use of RWE to support regulatory decision-making for drug and biologic therapies, including underscoring the importance of assessing data reliably in RWE. Specifically, whether CPT II codes are valid proxy for lab values and if claims data without lab integration is suitable for quality reporting or research. The average annual LDL Cat II code for the reporting period examined appears to have

increased since last reported by Russo and Williams (15.6 per 1000 v 11.1 per 1000). Given the growing emphasis on clinical quality and the role they play in value-based contracting, Cat II codes are likely to remain high in relevance. The potential value using of Cat II codes for RWE clinical outcomes remains worth continued examination.

SPONSORSHIP: CVS Health

387 A propensity score–matched analysis of health care utilization and cost in Medicaid beneficiaries with epilepsy

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BACKGROUND: Epilepsy (EPI) is a chronic recurring neurological condition characterized by unprovoked seizures that affects approximately 1.1% of adults in the United States. The PPPY economic burden associated with EPI is significant, with EPI-related medical costs ranging from $1,022 to $19,749. Use of rescue medications can reduce EPI-related medical costs to patients. It has been reported that large gaps in treatment exist in patients with epilepsy covered under Medicaid insurance and that EPI-related costs are high among some epilepsy patients.

OBJECTIVE: To better understand the health care and economic burden of epilepsy among Medicaid patients utilizing rescue medications.

METHODS: A retrospective claims analysis was conducted using the STATinMED RWD Insights database. Patients (≥2 years) with ≥1 inpatient or outpatient EPI/convulsion diagnosis (ICD-10 G40*, R56*) between July 1, 2020, and October 31, 2023, were included. Eligibility required ≥80% adherence to anti-seizure medications (ASMs) via PDC, ≥6 months of continuous data pre- and post-index, a 6-month EPI/convulsion-free baseline, and Medicaid coverage at index (first ASM fill). Propensity score matching was performed on mean QCI, age, and sex. Annual health care resource utilization (HCRU) and costs were assessed for matched cohorts; costs were average monthly costs over the follow-up period.

RESULTS: A total of 33,846 patients were prescribed rescue medications (RM) and 48,703 were not. RM patients were younger (mean age 40 vs 42) and had higher QCI scores (1.3 vs 0.8) and more frequent diagnoses of depression (16.8% vs. 12%) and anxiety (20.1% vs 13%). Both groups were majority male and White (43.5%, 42.7%). In EPI-related HCRU, RM users had ≥1 IP visit (56.6% vs 37.5%, $P<0.001$) and ≥1 ED visit (44.4% vs 36.3%, $P<0.001$). Mean IP length of stay (2.76 vs 2.25 days) was also higher among RM users ($P<0.001$). Readmission within 7 days was also elevated among RM users (30-day: 17.5% vs 11.6%, $P<0.001$). RM patients had double the total cost ($10,064 vs $4,682; $P<0.001$), with higher IP ($9,150 vs $4,150), ED ($104 vs $53) (all $P<0.001$), and pharmacy costs ($3,634 vs $2,873; $P=0.008$).

CONCLUSIONS: ASM-adherent Medicaid patients prescribed RM had higher HCRU and costs compared to patients who were not. This suggests patients utilizing RM have more severe or uncontrolled EPI. PSM enabled the comparison of similar patients across cohorts to maintain accuracy of results. Further research comparing specific RM would assist in determining which treatments to recommend while stabilizing a patient's epileptic status.

SPONSORSHIP: STATinMED, LLC.

388 Cost savings from pharmacist-led deprescribing in older adults: A real-world economic perspective

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BACKGROUND: Polypharmacy is common among older adults and is associated with adverse drug events, increased hospitalizations, and rising health care costs. Deprescribing—systematically reviewing and discontinuing inappropriate medications—has shown promise in improving outcomes. Despite this, its adoption across health care systems remains limited. Pharmacists, due to their medication expertise and patient accessibility, are well positioned to lead deprescribing interventions, particularly in managed care and outpatient settings.

OBJECTIVE: To evaluate the cost savings and clinical outcomes associated with pharmacist-led deprescribing interventions among adults aged 65 years and older using real-world data from Medicare, EHRs, and pharmacy dispensing systems between 2018 and 2025.

METHODS: This study used a mixed-methods design combining retrospective analysis of Medicare Part D claims, EHRs from managed care clinics, and pharmacy records with predictive economic modeling. Outcomes measured included changes in hospitalizations, emergency department visits, prescription costs, medication adherence, and high-risk medication use before and after pharmacist-led deprescribing. Cost-benefit and cost-effectiveness analyses were conducted, and sensitivity analyses evaluated subpopulation variability.

RESULTS: Pharmacist-led deprescribing interventions were associated with an average annual cost savings of $1,872 per patient, with 68% of savings attributed to direct medical costs (e.g., reduced hospitalizations and medication expenses) and 32% to indirect savings. Medication-related

hospitalizations declined by 32%, and emergency department visits decreased by 28%. Patients also experienced improved adherence rates (18% increase) and a 44% reduction in the use of high-risk medications flagged by Beers Criteria. Compared to physician-led models, pharmacist interventions required less time and produced higher patient satisfaction scores.

CONCLUSIONS: Pharmacist-led deprescribing significantly reduced health care utilization and costs among older adults in managed care settings. These findings highlight the clinical and economic value of involving pharmacists in medication management and deprescribing efforts. Broader adoption of pharmacist-driven deprescribing—supported by standardized protocols and real-world implementation strategies—could help address the growing burden of polypharmacy and improve care quality for aging populations.

SPONSORSHIP: None

389 Health care resource utilization and costs in patients with metabolic dysfunction–associated steatohepatitis: A comparison between patients with diagnosed MASH, with probable MASH, and without MASH

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BACKGROUND: There is a high economic burden associated with metabolic dysfunction–associated steatohepatitis (MASH). Most studies have reported on the health care resource utilization (HCRU) and costs in patients with diagnosed MASH. However, MASH is often underdiagnosed and the burden in this group is unknown.

OBJECTIVE: To compare HCRU and costs among patients with probable MASH, those with diagnosed MASH, and those without MASH.

METHODS: The study used Komodo Healthcare Map data (Jan 2017 to Dec 2022) and identified patients with probable MASH via an adapted MASLD Decision Tree (hepatic steatosis index >36 or ICD-10-CM code K76.0) plus ≥1 cardiometabolic risk factor. Patients with diagnosed MASH required ≥1 primary inpatient or ≥2 outpatient codes (K75.81) ≥30 days apart. Patients without MASH met none of these criteria. Propensity score weighting adjusted for baseline differences. HCRU (inpatient [IP], outpatient [OP], emergency department [ED] visits, prescriptions) and associated costs were assessed for all-cause, major adverse liver outcomes (MALO)–related, and major adverse cardiovascular events (MACE)–related categories using weighted generalized linear or two-part models.

RESULTS: The study included patients with probable MASH (n = 1,549,485), with diagnosed MASH (n = 15,000), and without MASH (n = 513,862). Mean all-cause costs per patient per year (PPPY) were $18,562 for patients with probable MASH, compared to $14,611 for those without MASH and $26,624 for those with diagnosed MASH. The mean cost ratio (MCR) for probable MASH vs without MASH was 1.27 (95% CI: 1.26-1.28). In contrast, the MCR for patients with probable MASH vs diagnosed MASH was 0.70 (95% CI: 0.67-0.72). Patients with probable MASH incurred significantly higher all-cause IP ($3,406), OP ($9,490), and ED ($855) costs compared to those without MASH ($2,663, $8,088, and $666, respectively). Additionally, patients with diagnosed MASH had costs of $5,225, $13,196, and $1,150, respectively. The associated MCRs were IP: 1.28 (1.26, 1.29); OP: 1.17 (1.61, 1.87); and ED: 1.29 (1.27, 1.30) for patients with probable MASH vs those without MASH. For patients with probable MASH vs those with diagnosed MASH, the MCRs were IP: 0.65 (0.64, 0.66); OP: 0.72 (0.69, 0.75); and ED: 0.74 (0.74, 0.75), respectively. Comparable patterns were observed in MALO- and MACE-related costs and HCRU.

CONCLUSIONS: Patients with probable MASH show higher HCRU and costs than patients without MASH, but lower than patients with diagnosed MASH, highlighting the economic burden of MASH and the importance of early diagnosis and intervention.

SPONSORSHIP: Novo Nordisk Inc.

390 An analysis of solid tumor oncology patients' respiratory vaccination rates in accordance with ASCO guidelines

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BACKGROUND: Cancer is a complex disease, requiring management that very often extends well beyond just treating the malignancy itself. Patients with cancer often experience compromised immune systems due to a variety of factors including disease progression leading to chronic inflammation and/or direct cancer treatments that impair the immune system. As a result, patients are often at a higher risk of infection, making addressing vaccine-preventable diseases paramount. In 2024, ASCO updated their guidelines on vaccine recommendations in oncology patients.

OBJECTIVE: To describe vaccination rates for respiratory diseases in patients with solid tumor malignancies in accordance with ASCO guidelines.

METHODS: A retrospective, cohort analysis was conducted using the Optum CDM. Adult patients (>18 years), unless

otherwise specified by ASCO guidelines (RSV > 60 years, Pneumococcal > 19 years), with an ICD-10-CM diagnosis code for a solid tumor malignancy as the index event (breast, colon, lung, prostate) between 4/1/2023 and 3/31/2024 were included. For each index event within each of the four solid tumor types, a vaccine-specific pre/post index event period was identified looking for a claim representing administration of each of the 4 respiratory vaccinations (Influenza, COVID-19, RSV, Pneumococcal) using 2024 ASCO recommendations as guidance.

RESULTS: We identified the following number of patients with each solid tumor malignancy: Breast (BC) (n = 259,182), Colorectal (CRC) (n = 68,704), Lung (LC) (n = 97,699), and Prostate (PC) (n = 296,700). For those with BC, rates were 27% for Flu, 40% for COVID-19, 18% for RSV, and 26% for Pneumococcal. For those with CRC, rates were 24% for Flu, 33% for COVID-19, 13% for RSV, and 23% for Pneumococcal. For those with LC, rates were 28% for Flu, 36% for COVID-19, 18% for RSV, and 27% for Pneumococcal. For those with PC, rates were 15% for Flu, 43% for COVID-19, 20% for RSV, and 27% for Pneumococcal. Highest overall rates for malignancy, vaccination, and malignancy/vaccination combination were LC at 27%, COVID-19 at 38%, and PC/COVID-19 at 43%. Lowest overall rates for malignancy, vaccination, and malignancy/vaccination combination were CRC at 24%%, RSV at 17%, and CRC/RSV at 13%.

CONCLUSIONS: This analysis shows that there is a significant gap in care for this vulnerable population. This is likely due to a combination of factors including but not limited to discordant care, vaccine hesitancy, patient and provider awareness, and others. Additional research is likely necessary to better understand this patient population, barriers, and strategies to improve vaccination rates.

SPONSORSHIP: None

391 Trends in opioid abuse disorder diagnoses, hospitalizations, and receipt of guideline-recommended treatment after hospitalization by insurance type, sex, and age (2021-2024)

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BACKGROUND: Opioid misuse continues to be a public health crisis, but there is limited information on opioid use disorder (OUD) in privately insured populations. In spite of high costs related to OUD-related hospitalizations and the efficacy of medication-assisted therapy, previous evidence has shown that many patients do not receive guideline-recommended therapies to treat OUD.

OBJECTIVE: To evaluate 2021-2024 trends in OUD diagnoses rates, opioid-related hospitalizations, and receipt of recommended therapy.

METHODS: Retrospective analysis using Inovalon's MORE2 database that includes nationally representative samples of commercially insured, Managed Medicaid (MM), and Medicare Advantage (MA) populations. Individuals were aged ≥18 years with continuous enrollment during the measurement year. An OUD diagnosis was classified as 1 inpatient or 1 outpatient claim with an ICD-10-CM code for any OUD-related disorder (F11.XX). OUD-related hospitalizations were identified by an opioid ICD-10-CM code in any position on the inpatient claim. Buprenorphine, naltrexone, and methadone were considered recommended therapies (RT) based on US FDA guidelines. Descriptive statistics for diagnoses, hospitalizations, and receipt of RT within 30 days of hospital discharge were generated for 2021-2024 stratified by insurance type, sex, and age group.

RESULTS: The MM population had the highest OUD diagnoses rates (e.g., 2024, 3.1% vs 2.0% of MA and 0.6% of commercial). The proportion of OUD patients with an OUD-related hospitalization increased from 2021 to 2024 for commercial (14.0% to 16.1%) and MA (11.2% to 12.2%) but decreased for MM (17.0% to 15.9%). The percent of OUD patients receiving RT after hospitalization was highest in commercial patients (31.3% in 2024) and lower in MA patients (19.8% in 2024). A larger share of males had an OUD-related hospitalization compared to females (16.4% vs 14.6% 2024) and more males received RT (31.0% vs 28.5%). OUD-related hospitalizations were highest in those aged 18-34 (18.8%) and lowest in those aged ≥65 (12.0%). Conversely, 36.0% of OUD patients aged 18-34 received RT after hospitalization compared to just 11.8% of those older than 65.

CONCLUSIONS: Disparities in OUD diagnosis rates, hospitalizations, and receipt of recommended therapies were apparent by age, sex, and insurance type. Notably, fewer than one-fifth of MA and one-third of commercial OUD patients received RT within 30 days of opioid-related hospitalization. Treatment after hospitalization represents a critical opportunity window for interventions that can greatly reduce risk of overdose and death.

SPONSORSHIP: Inovalon

392 Impact of dupilumab on health care resource utilization and its treatment patterns in patients with atopic dermatitis and comorbid asthma: A non-interventional study utilizing a US claims database

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BACKGROUND: Atopic dermatitis (AD) affects about 7% of US adults and 6-11% of children, while impacting 15-20% of children and 1-3% of adults globally. Patients with AD have an increased asthma risk and reduced life quality. Although dupilumab is approved for treating both conditions, real-world data on its impact on health care usage and asthma exacerbations in patients with both AD and asthma are limited.

OBJECTIVE: To evaluate dupilumab's real-world effects on health care use and asthma exacerbations in patients aged 12+ with AD and asthma, over 12 months pre- and post-treatment initiation.

METHODS: This retrospective, observational cohort study used the Healthcare Integrated Research Database (HIRD) with US health claims from commercial and Medicare Advantage plans. Included were patients aged 12+ diagnosed with AD and asthma, prescribed dupilumab for AD between March 1, 2017, and April 30, 2023. The first dupilumab claim was the index event. Healthcare Resource Utilization and asthma exacerbations were measured 12 months pre- and post-index; treatment patterns including adherence and switching were assessed for 12 months post-index.

RESULTS: Among 1,907 patients that received dupilumab and met inclusion criteria, 60.5% were male and 82.4% were aged 18+ at first prescription. Dermatologists prescribed dupilumab for 65.1% and allergists/immunologists for 9.1%. Although declines in AD-related hospitalizations and ED visits are insignificant, the 12-month follow-up shows fewer overall outpatient (98.8 to 89.8%) and dermatologist visits (75.1 to 66.1%); prescription fills rose from 5.6 to 12.7 ($P<0.01$). Asthma-related hospitalizations decreased (5.6% to 4.1%); ED and outpatient visits also declined (10.4% to 8.2% and 94% to 59.6%, respectively) ($P<0.01$). Systemic corticosteroid and inhaled short-acting beta-2 agonists medication use also decreased. A 60-day non-refill discontinuation gap was noted in 34.3%; 30.4% restarted dupilumab after 60 days of discontinuation, and 4.0% switched to other AD-related medications. Asthma exacerbations decreased from 23.5% to 10.2%, and the episodes per patient fell from 0.3 to 0.1 ($P<0.01$).

CONCLUSIONS: In the 12 months post-dupilumab, health care utilization significantly declined, including fewer asthma-related hospitalizations, ED, and outpatient visits. AD-related visits decreased, while prescription fills increased, possibly driven by dupilumab use. Asthma exacerbations and frequency significantly decreased, highlighting dupilumab's benefits in patients with AD and comorbid asthma.

SPONSORSHIP: Sanofi

393 Incremental health care costs of psychoses and agitation/aggression among Medicare beneficiaries with Alzheimer disease

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BACKGROUND: A particularly challenging aspect of Alzheimer disease (AD) is the frequent occurrence of neuropsychiatric symptoms such as psychoses and agitation/aggression. In the absence of effective treatments—antipsychotics are often used despite well-known side effects and limited efficacy—these symptoms can substantially increase costs.

OBJECTIVE: To estimate the incremental health care costs associated with neuropsychiatric symptoms in a national sample of patients covered by Medicare, the primary payer for AD care in the United States.

METHODS: This cross-sectional analysis used 2022 Medicare fee-for-service claims to identify adults with ≥1 inpatient or ≥2 outpatient claims with a diagnosis of AD, continuous Medicare Parts A, B, and D enrollment during the year, and no evidence of bipolar disorder or schizophrenia. Based on ≥1 inpatient or ≥2 outpatient claims with relevant ICD-10 codes, four mutually exclusive groups were created: AD with psychoses, AD with agitation/aggression, AD with both, and AD without either (i.e., control group). All-cause and AD-related costs (adjusted to 2024 USD) were reported. Multivariable generalized linear models estimated adjusted incremental costs for psychosis alone, agitation/aggression alone, and both symptoms relative to patients without either, controlling for sociodemographic and clinical covariates.

RESULTS: The final sample included 272,685 beneficiaries with AD: 4,785 (1.8%) with psychoses, 70,200 (25.7%) with agitation/aggression, 14,904 (5.5%) with both, and 182,796 (67.0%) without either. Characteristics were similar across the four study groups (mean age 82.5-83.5 years; 67.3-74.8% female; 82.4-85.4% White). Compared to patients without neuropsychiatric symptoms, risk-adjusted all-cause costs were higher in patients with psychoses ($37,733; $\Delta = \$5,577$; $P<.0001$), agitation/aggression ($39,029; $\Delta = \$6,131$; $P<.0001$), and both symptoms ($45,523; $\Delta = \$12,974$; $P<.0001$). Similarly, risk-adjusted AD-related costs were higher in patients with psychoses ($11,038; $\Delta = \$1,311$; $P<.0001$), agitation/aggression ($14,048; $\Delta = \$3,996$; $P<.0001$), and both symptoms ($16,108; $\Delta = \$6,185$; $P<.0001$).

CONCLUSIONS: Among Medicare beneficiaries with AD, psychoses and agitation/aggression are associated with significantly higher health care costs. These findings underscore the economic burden of these symptoms and the need for more effective and better-tolerated treatments. As AD prevalence grows, targeted treatments for psychosis and agitation/aggression may offer important clinical and economic benefits.

SPONSORSHIP: AbbVie, Inc.

394 Improved outcomes in patients with multiple sclerosis initiating cladribine tablets compared with those denied health insurance coverage in the United States

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BACKGROUND: Cladribine tablets (CladT) are indicated for relapsing forms of multiple sclerosis (MS), including relapsing-remitting and active secondary progressive disease. Despite clinical evidence demonstrating its effectiveness, safety, and benefits, barriers from third-party payers may limit access to CladT.

OBJECTIVE: To assess the impact of access to CladT versus denied coverage on clinical outcomes, health care resource utilization (HCRU), and costs among patients with MS (PwMS).

METHODS: This retrospective cohort study used US claims data from Kythera Labs between April 1, 2018, and December 31, 2024. Adult PwMS with ≥2 claims for MS at least 30 days apart were included. The index date was defined as the date of the first prescription dispensing for CladT (approved cohort) or first denied prescription claim for CladT (denied cohort). Continuous eligibility was required for 12 months pre- and 24 months post-index. Cohorts were matched 1:1 using nearest-neighbor propensity score matching (PSM). Outcomes included MS-related treatments, relapse measures (annualized relapse rate [ARR], time to first relapse), all-cause and MS-related HCRU, and health care costs, analyzed using generalized linear and Cox models post-PSM.

RESULTS: A total of 1,718 PwMS met the inclusion criteria. Of the 1,382 approved patients, 24.0% had at least one prior denial before gaining access to CladT. Among the 336 consistently denied patients, 69.3% had more than one denial of CladT. At baseline, the approved patients were older (mean age: 49.5 vs 46.6 years), had higher comorbidity burden (mean Charlson Comorbidity Index: 0.41 vs 0.26), and had greater use of dalfampridine (9.8% vs 3.9%) and disease-modifying therapies (38.9% vs 34.5%) compared to the denied patients. Post-PSM, the approved patients exhibited a lower ARR than the denied patients (risk ratio = 0.57; 95% confidence interval [CI]: 0.38, 0.84; P = 0.03). The approved patients also had fewer physical therapy/rehabilitation claims per patient per year (PPPY; incidence rate ratio = 0.51; 95% CI: 0.39, 0.67; P = 0.013). All-cause outpatient costs (mean cost difference [MCD] PPPY: –$4,634; 95% CI: –$6,336, –$2,932; P < 0.001) and total medical costs (MCD PPPY: –$6,166; 95% CI: –$9,011, –$3,322; P < 0.001) were significantly lower in the approved versus denied patients.

CONCLUSIONS: Initiation of CladT was associated with significant reductions in MS relapse rates, decreased rehabilitation services use, and lower total medical costs, particularly outpatient costs, compared with patients denied coverage.

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

395 Impact on accountable care organization diabetes population; health plan pharmacist value-based care engagement

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BACKGROUND: Value-based care partnerships with accountable care organizations (ACOs), such as Blue Cross NC's Blue Premier (BP), offer a pathway to improving quality of care for members with diabetes. Research is essential to assess the long-term impact of these partnerships on both clinical and economic outcomes.

OBJECTIVE: To assess the impact on cost trends of a health plan led diabetes initiative within a value-based care framework.

METHODS: Health plan pharmacists shared data regularly with ACOs specific to diabetes for financially accountable members. Member history, including medical and pharmacy claims, adherence, and lab data, was presented through reports, verbal discussions, and integrated visual tools, highlighting member examples from the ACO attributed population. Actions were focused on deprescribing duplicate therapies such as glucagon like peptide-1 receptor agonist (GLP1) and dipeptidyl peptidase-4 inhibitor medications, stockpiling of GLP1 medications, cost-efficient use of medications, and gaps in diabetes quality measures. This study analyzed 52,074 commercial members who maintained continuous coverage from 2023 through 2024. It included active members with a diabetes episode and at least one fill of an antidiabetic medication within the past 27 months. The study population was divided into two groups: members attributed to a BP primary care provider

(intervention group) and those not attributed to a BP primary care provider (comparison group). Members with an annual total cost of care exceeding $250,000 were excluded. A risk adjusted fixed-effects analysis was conducted to evaluate temporal changes in total and diabetes-related costs between the intervention group and the comparison group.

RESULTS: The health plan and ACO partnership supported control of the financial trend of members with diabetes in Blue Premier. From 2023 to 2024, increasing trends in total medical expenses and diabetes-related medical expenses were significantly smaller by $51 and $11 per-member-per-month (*P* values = 0.038 and 0.001), respectively, among the intervention group compared to the comparison group. In contrast, no statistically significant differences were observed between the groups in the temporal trends of total prescription expenses and diabetes-related prescription expenses (*P* values = 0.158 and 0.332).

CONCLUSIONS: The value-based care partnership incentivized ACOs to increase uptake of diabetes-related initiatives. By integrating pharmacy discussions and facilitating shared data, health plans and ACOs may further improve patient care while managing health care utilization.

SPONSORSHIP: None

396 Long-term impact of elexacaftor/tezacaftor/ivacaftor on healthcare resource utilization and costs among people with cystic fibrosis aged ≥6 years in the US: A retrospective analysis of commercial claims in the Forsyth Health proprietary database

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BACKGROUND: TRIKAFTA or elexacaftor/tezacaftor/ivacaftor (ETI) is a cystic fibrosis (CF) transmembrane conductance regulator modulator (CFTRm) first approved for the treatment of people with cystic fibrosis (pwCF) aged ≥12 years in the United States in October 2019; the label was expanded to include pwCF aged 6-11 years in June 2021. Real-world studies have demonstrated the significant impact of ETI on health care resource utilization (HCRU) and economic benefits but have been limited to short-term (<1 year) trajectories.

OBJECTIVE: The goal of the study was to investigate the long-term impact of ETI therapy on pulmonary exacerbations (PEx), HCRU, concomitant medication use, and associated medical costs using Forsyth Health's proprietary claims database, which represents the lives of a large US Commercial national payer. Vertex Pharmaceuticals (a manufacturer) and Forsyth Health (a Real-World Data & Analytics company affiliated with Evernorth) collaborated on the design of the study protocol and interpreting results.

METHODS: We identified pwCF aged ≥6 years who had their first-ever recorded outpatient (OP) prescription for ETI (date of first fill for ETI = index date) on or after October 21, 2019, and were continuously enrolled for 1 year pre- and ≥2 years post-index. We compared annualized rates of PEx (inpatient or IV antibiotics), HCRU, and associated costs pre- and post-index. Exploratory analyses were conducted for a subset of patients continuously enrolled for ≥3 years post-index.

RESULTS: A total of 645 patients aged ≥12 years (mean age 27.4, 43.3% female) were identified in the Forsyth commercial database. A total of 48.2% were CFTRm treatment naïve. The annualized rate of PEx was 0.49 (95% CI 0.41, 0.57) in the 1-year pre-index period and 0.19 (0.15, 0.24) over 2 years post-index—a 61.2% reduction. Similarly, the annualized rate of inpatient hospitalizations was 0.43 (0.35, 0.51) pre-index vs 0.18 (0.13, 0.23) over 2 years post—a 58.1% reduction. The annualized rate of OP visits (inclusive of ED, office, home health, and other outpatient visits) was 30.9 (28.6, 33.2) pre-index vs. 23.0 (21.2, 24.8) over 2 years post—a 25.6% reduction. These reductions were maintained in the subset of n = 466 pwCF continuously insured for 3 years (reductions of 64.2% in PEx, 59.1% in hospitalizations, and 30.4% in OP visits vs pre-index). Additional analyses of concomitant medication use, costs, and outcomes for the 6-11 population will be available at time of presentation.

CONCLUSIONS: ETI demonstrates durable reductions in disease burden associated with CF over time and meaningful reductions in HCRU within a large US payer.

SPONSORSHIP: Vertex Pharmaceuticals Inc.

Respiratory

413 The most common comorbidities leading to a diagnosis of chronic lung allograft dysfunction (CLAD)–bronchiolitis obliterans syndrome (BOS) subsequent to lung transplant (LTx) using an open administrative claims database in the United States

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BACKGROUND: Chronic lung allograft dysfunction (CLAD)–bronchiolitis obliterans syndrome (BOS) is a rare disease and severe form of chronic rejection after lung transplantation (LTx) affecting an increasing proportion of LTx recipients after transplant. CLAD-BOS is characterized by

airflow restrictions and progressive shortness of breath resulting in increased morbidity and mortality after LTx. Recent updates to the ICD-10-CM for the United States now include BOS (J44.81), CLAD (J4A8, J4A9), and restrictive allograft syndrome (RAS, J4A.0), effective 10/1/2023. CLAD-BOS previously had no specific ICD-10-CM codes, thereby making claims-based analysis difficult.

OBJECTIVE: To assess the most frequent comorbidities associated with a CLAD-BOS diagnosis using open administrative claims as the data source.

METHODS: We used a licensed open administrative claims database (Ambit, Inc.) to build a cohort of CLAD-BOS patients after LTx. The cohort was indexed to a claim for LTx (diagnosis and procedure claims) between 11/01/2017 and 10/31/2022. The second index event was a CLAD-BOS diagnosis ≥12 months post-LTx possible in two ways: 1) having a code for BOS, CLAD, or RAS; 2) having two CLAD symptom codes and a pulmonary evaluation (i.e., CT, lung biopsy, or bronchoscopy) in a pre-specified sequence. We then assembled time aligned cohorts of LTx patients without CLAD-BOS for all comparisons.

RESULTS: The open claims database yielded a large LTx population (n = 7440) with sufficient CLAD-BOS or RAS patients (n = 204) forming the basis for all analyses. We further subdivided the CLAD-BOS or RAS groups into faster (1-2 years, n = 116) and slower (> 2 years, n = 88) development subgroups. The top four comorbidities demonstrating differences were identical in the faster and slower CLAD-BOS or RAS development subgroups, respectively, including bronchitis (2.5× and 1.7×), interstitial lung disease (ILD)/fibrosis (2.2× and 1.6×), gastroesophageal reflux disease (GERD, 1.6× and 1.2×), and infection (1.4× and 1.1×).

CONCLUSIONS: Comorbid conditions most closely associated with CLAD-BOS development after LTx were bronchitis, interstitial lung disease (ILD)/fibrosis, gastroesophageal reflux disease (GERD), and infection in our analysis utilizing open claims data. These data represent an opportunity for intervention when these comorbid conditions are present prior to CLAD-BOS diagnosis.

SPONSORSHIP: Zambon USA Ltd.

Specialty Pharmacy

419 Evaluating the real-world effects of biosimilar introduction on stable patients with rheumatologic and inflammatory bowel diseases: A three-month post-switch analysis

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BACKGROUND: The expanded availability of adalimumab biosimilars is accelerating transitions from the originator. Biosimilars improve cost-containment and have demonstrated similar effectiveness and safety compared to originators in clinical trials. Real-world evidence is needed to highlight outcomes for patients stable on an originator who switch to a biosimilar.

OBJECTIVE: To evaluate biosimilar switches and patient outcomes (adverse events and dose escalations) in rheumatology or inflammatory bowel disease (IBD) patients who switched to an adalimumab biosimilar.

METHODS: A single-center, retrospective review was conducted. Included patients were switched to an adalimumab biosimilar by a rheumatology or IBD provider between January and June 2024 and had been stable on the originator (same dose and frequency with no dose escalations) for at least 3 months before switching. Patients were excluded if they never started the biosimilar. Patients were followed for 3 months after biosimilar initiation. Outcomes included number of dose escalations, number of adverse effects or worsening of symptoms, number of switches (branded to unbranded product or another biosimilar) post-biosimilar initiation, and reason for switch. Data were analyzed using descriptive statistics.

RESULTS: Included patients (n = 269) were predominantly White (89%) female individuals (61%) with a median age of 46 years (interquartile range [IQR] = 35-56 years). The top three indications for adalimumab were rheumatoid arthritis (n = 84, 31%), Crohn disease (n = 84, 31%), and psoriatic arthritis (n = 37, 14%). Most patients initiated adalimumab-adaz

(n = 193, 72%) upon switching from adalimumab originator. Post-biosimilar initiation, 13 patients (n = 5%) had a dose escalation with a median of 82 days (IQR = 30-153) from biosimilar initiation to escalation. Ten patients (4%) reported experiencing an adverse event with 66 patients (25%) experiencing worsening symptoms or flares. Almost half of patients required a second switch (n = 130, 46%) to unbranded adalimumab-adaz (n = 108/130, 83%), back to the adalimumab originator (n = 10/130, 8%), or to a non-adalimumab product (n = 5/130, 4%). Medication availability/stock issues (n = 104/130, 81%) was the most common reason for the second switch.

CONCLUSIONS: Biosimilars were well tolerated during the first 3 months of therapy with a low number of patients experiencing adverse events; however, 25% of patients stable on adalimumab originator experienced worsening symptoms or flares. Many patients stable on adalimumab originator who switch to an adalimumab biosimilar require subsequent switches within 3 months, using clinic/pharmacy resources.

SPONSORSHIP: None

420 The value of medical and pharmacy integration in managing oral oncologic medications

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BACKGROUND: Medically integrated pharmacies, also known as medically integrated dispensing (MID) care models, are dispensing pharmacies that use a patient-centered and multidisciplinary team approach to provide medications, often in oncology practices. The integration of prescriptions through an onsite physician dispensing practice allows the dispensing team to have a comprehensive understanding of the patient's health record, which facilitates follow-up care. MID systems have demonstrated the potential to transform oncology practices by creating a more comprehensive care model, reducing waste, saving costs, and improving clinical outcomes.

OBJECTIVE: To expand on previous analysis by measuring adherence to orally administered oncolytic medications in two cancer types at multiple oncology practices.

METHODS: This was a retrospective study of adult patients treated with Xtandi (enzalutamide) for prostate cancer and Imbruvica (ibrutinib) for chronic lymphocytic leukemia from July 1, 2016, to July 30, 2022. Oncology care model pharmacy claims data were obtained from three US-based practice sites and merged with Medicare oral dispensing data. The study groups were MID, comprising patients who filled all their prescriptions at MID pharmacies, and non-MID, consisting of patients who filled prescriptions on- and off-site. Therapy adherence for each medication was measured by calculating the medication possession ratio (MPR) for patients in the MID and non-MID groups who had >1 prescription. The numerator was capped at the number of days in the follow up period, since MPR is overinflated if patients obtain early refills. The standardized mean difference (SMD) of the adjusted MPR was used to quantify the difference between the groups. A value ≥20% was considered meaningful.

RESULTS: A total of 133 patients were included; the number of MID and non-MID patients for each medication were enzalutamide (36:10) and ibrutinib (58:15). The mean age (SD) for enzalutamide patients was 76 (8) years and 77 (9) years for ibrutinib patients. For the MID subgroups, the MPR for patients receiving enzalutamide was 0.83 and 0.75 for patients receiving ibrutinib. The SMD between the MID and non-MID subgroups (n = 119) was 48.1% for enzalutamide and 40.3% for ibrutinib.

CONCLUSIONS: Oral oncolytic therapy adherence was meaningfully higher in the MID group vs the non-MID for the two medications. These findings support the potential benefits of MID care models in oncology; further analysis of impact of MID on total cost of care is ongoing.

SPONSORSHIP: Cencora

Student Poster Titles and Presenters

Benefit and Design

9 Improving access and equity in the United States through a uniform national formulary

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Biosimilars

25 Real-world utilization and patient characteristics of biologic vs biosimilar rituximab from a specialty pharmacy

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Cell and Gene Therapies

45 Coverage practices and pricing of FDA-approved gene therapies in the United States

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Central Nervous System

50 Real-world discontinuation risk and adverse events with anti-amyloid therapies in patients with Alzheimer disease

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51 Economic and clinical impact of dual orexin receptor antagonists versus zolpidem in Medicare Part D beneficiaries with chronic insomnia

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52 Impact of medication adherence on clinical and economic outcomes in multiple sclerosis: A scoping review of real-world evidence

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53 Real-world patterns in preventive CGRP use pre and post AHS 2024 position statement update in a commercially insured population

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54 Methods for dopamine delivery across the blood-brain barrier in treating Parkinson disease: A systematic literature review

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Clinical Programs

84 Facilitators for implementation of pharmacist billing for medication therapy management (MTM)

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Dermatology

95 Bridging the beauty gap: Evaluating access barriers to aesthetic dermatology in underserved populations through a managed care lens

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Digital Health and Technology

114 Generative artificial intelligence (GenAI) in the biopharmaceutical sector: A survey on perceptions, use cases, and barriers to implementation

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115 Impact of telehealth on hydroxyurea adherence and clinical outcomes in sickle cell disease management: A systematic review and meta-analysis

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Drug Pricing, Payment, and Reimbursement

124 Cost-effectiveness of a hypothetical outpatient RSV treatment for older patients in the United States

Chen J[1], *Wu A*[2], *Hutton D*[3], *Lai S*[4], *Ozawa S*[4]; *jiaweichen32@yahoo.com*
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126 Cost-effectiveness of osimertinib for consolidation in EGFR-mutated stage III NSCLC

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127 PDABs in motion: Tracing the development of state-led drug cost regulation

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Endocrine and Metabolic

143 Clinical, economic, and patient-reported outcomes from continuous glucose monitoring in patients with type 2 diabetes

Gadd S[1], *Willis C*[2], *Rashid I*[1], *Park K*[1], *Holland K*[1], *Asche C*[3], *Ghule P*[4], *Brixner D*[1]; *shannon.gadd@hsc.utah.edu*; *Connor.Willis@pharm.utah.edu*; *ishfaqrashid139@gmail.com*; *carl.asche@pharm.utah.edu*; *diana.brixner@utah.edu*
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144 Racial disparities associated with total health care expenditures (THEs) in type 2 diabetes mellitus (T2DM): Impact of GLP1 RAs

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145 Misdiagnosis of adult-onset type 1 diabetes and associated DKA risk and timing in adults with autoimmune risk factors

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146 The impact of continuous glucose monitors on pharmacy and medical benefit costs in patients with diabetes: A claims-based analysis

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Health Disparities/Equity

194 Social determinants of health and migraine management: A real-world analysis using the Area Deprivation Index

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195 Methods for imputing race and ethnicity in real-world data: A scoping review

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202 Identification of factors that may contribute to vaccine hesitancy in high-risk members of a commercial health plan

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Infectious Disease

249 Tenofovir alafenamide– versus non–tenofovir alafenamide–containing antiretroviral regimens and the effects on changes of proteinuria biomarkers in the treatment of HIV type 1: A systematic literature review and meta-analysis

Liu H[1], Rashid I[2], Rashid M[3], Kalati J[2], Willis C[4], Rogers R[5], Navadeh S[6], Weinberg A[6], Chaiyakunapruk N[2]; u6061412@umail.utah.edu
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Mental Health

265 Effect of antihypertensive medications on economic burden among Alzheimer disease and related dementia (ADRD): ADRD registry data linked to Medicaid

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Musculoskeletal

285 Preoperative depression and anxiety as predictors of persistent opioid use after orthopedic surgery: A retrospective claims-based analysis

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Oncology

291 A development of monocarboxylate transporter 4 inhibitor/docetaxel-loaded smart layer-by-layer nanoparticles for prostate cancer therapy

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292 Real-world patterns of intravenous immunoglobulin (IVIG) and antimicrobial use in members with multiple myeloma treated with chimeric antigen receptor T-cell (CAR T) or bispecific antibody (BsAbs) therapies

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293 Real-world clinical outcomes and health care resource utilization with covalent BTK inhibitors in CLL/SLL (2020-2025): A systematic review

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294 Health care resource utilization and costs among patients with vs without biomarker testing in metastatic colorectal cancer (mCRC): A real-world analysis of Horizon BCBSNJ members

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295 Machine learning performance in diagnosis and treatment of head and neck and esophageal cancers: A scoping review

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296 Cost-effectiveness of xofigo in bone-metastatic castration-resistant prostate cancer: A Markov model analysis

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297 Assessing the cost-utility of predictive biomarkers in oncology treatment compared to traditional approaches

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298 Assessing tumor volume: A scoping review of measurement methods and clinical utility in head and neck and lung cancers

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336 Safety of combined radioligand and systemic therapies in neuroendocrine tumors: A systematic review

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337 Evaluating early-onset colorectal cancer incidence trends and geographic disparities among adults aged 20-50 years in Michigan

Mercado P[1], Reiter D[1], Walters T[2], Cochran M[3], Moormeier M[1], Richard-Mitchell D[4], Jean-Mary R[5]; Philip1.mercado@famu.edu
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Real-World Evidence

342 Factors affecting autologous stem cell transplant access in patients with multiple myeloma at a comprehensive cancer center

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343 Research topics addressed in observational claims-based studies in pharmacy

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344 Disruption and adaptation in inflammatory bowel disease: Impact of the COVID-19 pandemic on treatment patterns, health care utilization, and vaccination in the United States

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345 Cost-effectiveness analysis of lenacapavir compared with cabotegravir and generic oral FTC/TDF for HIV preexposure prophylaxis among cisgender women in the United States

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399 Real-world uptake of respiratory syncytial virus vaccination among older adults on immunosuppressive therapies

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400 Patterns of postpartum contraceptive use within an academic health care setting: A descriptive study

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Respiratory

403 Real-world primary nonadherence to biologic therapies in moderate to severe asthma: A retrospective claims analysis

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Specialty Pharmacy

418 Frequency and impact of insurance changes among patients with IBD using specialty medications

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Encore Poster Titles and Presenters

Analgesics/Pain

1 Intraoperative liposomal bupivacaine is associated with improved pain, opioid use, functional, and length of stay outcomes after total knee arthroplasty: Real-world evidence

Ng M[1], *Lin J*[2], *Spitzer A*[3], *Dasa V*[4], *Rivadeneyra A*[5], *Rogenmoser D*[6], *Concoff A*[7], *DiGiorgi M*[8], *Urban J*[9], *Mihalko W*[10], *Mont M*[11]; *mitchng77@gmail.com*; *Mary.Digiorgi@pacira.com*
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Benefit Design and Management

10 Economic impact of early vs late initiation of atogepant for the preventive treatment of migraine

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11 Patient perspectives on health insurance design: Experiences of beneficiaries with chronic diseases

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Biosimilars

26 The economic benefit of biosimilars in North America: A targeted literature review

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27 Clinical similarity of eculizumab-aeeb (BKEMV, Amgen) and eculizumab reference product in patients with PNH supports interchangeability designation

Budsberg S[1], *Kulasekararaj A*[2], *Lanza F*[3], *Arvanitakis A*[4], *Langemeijer S*[5], *Chonat S*[6], *Cao J*[7], *Chow V*[7], *Henary H*[7]; *budsberg@amgen.com*; *austin.kulasekararaj@nhs.net*
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Cardiovascular

30 Increased adoption of IL-1 pathway inhibition and the steroid-sparing paradigm shift: Temporal trends in recurrent pericarditis treatment from the RESONANCE patient registry

Khan A[1], *Cremer P*[2], *Garshick M*[3], *Luis S*[4], *Raisinghani A*[5], *Weber B*[6], *Parameswaran V*[1], *Curtis A*[1], *Klein A*[7], *Paolini J*[1]; *akhan@kiniksa.com*; *paul.cremer@nm.org*
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31 Efficacy and safety of long-term treatment with aficamten in patients with symptomatic obstructive hypertrophic cardiomyopathy: Results from FOREST-HCM

Tower-Rader A[1], Masri A[2], Nassif M[3], Abraham T[4], Barriales-Villa R[5], Choudhury L[6], Cooper R[7], Elliott P[8], Maron M[9], Olivotto I[10], Oreziak A[11], Owens A[12], Solomon S[13], Melloni C[14], Saberi S[15], Richards A[14]; atower-rader@mgh.harvard.edu; arichards@cytokinetics.com
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32 Impact of switching from high- to low-sodium oxybate on ambulatory blood pressure in people with narcolepsy

Somers V[1], Kovacs R[2], Alexander J[3], Baranak C[3], Nichols D[3], Dai J[3], Whalen M[3], Ajayi A[4], Hutchinson B[5], Dauvilliers Y[6], White W[7]; somers.virend@mayo.edu
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Central Nervous System

56 Efficacy and safety of AXS-05 in Alzheimer disease agitation: Results from ACCORD-2, a phase 3 randomized withdrawal double-blind placebo-controlled study

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57 Tuberous sclerosis complex–associated neuropsychiatric disorders (TAND) outcomes following adjunctive cannabidiol (CBD) treatment: 3-month analysis of the open-label phase 3b/4 trial EpiCom

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58 Efficacy and safety of Symbravo (MoSEICTM meloxicam and rizatriptan) in participants with migraine experiencing an inadequate response to oral CGRP inhibitors: Topline results from the EMERGE trial

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59 Indirect treatment comparison for early efficacy of VMAT2 inhibitors for tardive dyskinesia and chorea associated with Huntington disease

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60 Valbenazine improves the impacts and symptoms of tardive dyskinesia: Results from the phase 4 kinect-pro study

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61 Epidemiology, patient characteristics, real-world treatment patterns, and outcomes for patients with multifocal motor neuropathy (MMN)

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62 Efficacy and safety of ecopipam for Tourette syndrome: Results from a phase 3, randomized, double-blind, placebo-controlled withdrawal trial

Gilbert D[1], *Atkinson S*[2], *Kim D*[2], *Miller M*[2], *Rice P*[2], *Karkanias G*[2], *Munschauer F*[2], *Wanaski S*[3], *Cunniff T*[3], *Tomczak K*[4]; *Donald.Gilbert@cchmc.org*
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Clinical Programs

85 Efficacy and safety of fixed-dose tavapadon, an oral, once-daily, selective D1/D5 dopamine agonist for the treatment of early Parkinson disease

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86 Efficacy and safety of flexible-dose tavapadon, an orally administered, once-daily, selective D1/D5 dopamine agonist for the treatment of early Parkinson disease

Fernandez H[1], *Bhatia P*[2], *Cloud L*[3], *Fietzek U*[4], *Matarazzo M*[5], *Molho E*[6], *Peckham E*[7], *Tarakad A*[8], *Combs C*[9], *Leoni M*[10], *Chang I*[11], *Tringali S*[9], *Boiser J*[11], *Zadikoff C*[11], *Sanchez R*[12]; *FERNANH@ccf.org*; *cindy.zadikoff@abbvie.com*
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87 Efficacy and safety of tavapadon, an orally administered, once-daily, selective D1/D5 dopamine agonist, adjunctive to levodopa for treatment of Parkinson disease with motor fluctuations

Fernandez H[1], *Isaacson S*[2], *Hauser R*[3], *Agarwal P*[4], *Ondo W*[5], *Park A*[6], *Elmer L*[7], *Kremens D*[8], *Leoni M*[9], *Duvvuri S*[9], *Combs C*[10], *Koenig E*[10], *Chang I*[11], *Pastino G*[11], *Tringali S*[10], *Golonski N*[10], *Sanchez R*[12]; *FERNANH@ccf.org*
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91 Epinephrine delivered via sublingual film (Anaphylm) elicits rapid and consistent pharmacokinetic and pharmacodynamic responses

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Dermatology

96 Navigating specialty treatment for dermatologic inflammatory conditions: Patient journey and treatment persistence

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97 A cost-per-responder analysis of ritlecitinib and baricitinib: Assessing the impact of clinical efficacy and dosing variability on overall treatment costs of severe alopecia areata

Cha-Silva A[1], *Zhang K*[2], *Graham C*[2], *Kurosky S*[1], *Tran H*[1], *Law E*[1], *Song E*[3]; *Ashley.Cha@pfizer.com*
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98 Real-world treatment patterns in patients with psoriasis receiving tildrakizumab compared with ustekinumab

Han G[1], *Huynh L*[2], *Zanardo E*[2], *Haque F*[2], *Simpson R*[2], *Yenikomshian M*[2], *Barghout V*[3], *Ferro T*[4], *Mathew J*[4]; *georgehan@gmail.com*
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99 Long-term efficacy and safety of ritlecitinib in adults and adolescents with alopecia areata: 3-year results from the ALLEGRO-LT phase 3, open-label study

Senna M[1], *Figueras I*[2], *Kinoshita-Ise M*[3], *Hanna S*[4], *Wu W*[5], *Wajsbrot D*[6], *Woodworth D*[7], *Wolk R*[8], *Chaudhry A*[7], *Lejeune A*[9], *Tran H*[6], *Waltzer A*[6]; *Helen.Tran@pfizer.com*; *Aaron.Waltzer@pfizer.com*
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100 The economic impact of ustekinumab in the treatment of psoriasis: A targeted literature review

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101 Improvement in atopic dermatitis signs and symptoms with once-daily and proactive twice-weekly roflumilast cream 0.15% or 0.05%: Results from the 52-week phase 3 INTEGUMENT-OLE trial in patients aged 2 years and older

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102 Caregiver-reported outcomes from the phase 3 INTEGUMENT-PED trial of children aged 2 to 5 years with atopic dermatitis and treated with roflumilast cream 0.05%

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103 Efficacy and safety of roflumilast foam 0.3% in patients with psoriasis of the scalp and body 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*[8], *Stephenson B*[9], *Berk D*[8]; *mgooderham@centrefordermatology.com*; *bstephenson@arcutis.com*
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104 Prevalence and advanced systemic treatment prescription patterns for scalp psoriasis in the real-world dermatology setting in the United States

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Drug Pricing, Payment, and Reimbursement

128 Evaluating the role of drug pricing tiers in shaping health care outcomes for older patients

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129 Cost consequence analysis of hormonal contraception in the United States

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130 Cost consequence analysis of immediate postpartum contraception in the United States

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131 Impact of triptan insufficient response on medication use, health care utilization, and costs: A retrospective claims study

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132 Health care resource utilization and economic burden in patients cycling through multiple triptans for migraines: A retrospective analysis

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133 Suitability of cost-effectiveness thresholds for drug reimbursement decision-making in the US market

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Endocrine and Metabolic

147 Expected vs observed mortality rates, expressed as number needed to treat, from a phase 3 clinical trial program of patients with hyperphagia and Prader-Willi syndrome treated with diazoxide choline extended release (DCCR)

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148 The burden of Prader-Willi syndrome on patients and the health care system: A cross-sectional examination of emergency department visits and inpatient stays in US claims

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149 Effects of demographics on outcomes with empagliflozin vs DPP4i

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150 Efficacy of elinzanetant in previous or never users of HT: Pooled analysis

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Gastrointestinal

180 A real-world analysis of recently approved short bowel syndrome (SBS) ICD-10 codes: Adoption and utilization among patients with SBS dependent on parenteral support in the United States

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181 Multivariable analysis of baseline variables associated with efficacy outcomes in the ELEVATE UC clinical program

Feagan B[1], Kayal M[2], Schreiber S[3], Abreu M[4], Banerjee R[5], Fellmann M[6], Abbatemarco A[7], Woolcott J[8], Wu J[9], Goetsch M[6], Keating M[7], Rubin D[10]; brian.feagan@alimentiv.com; arcangelo.abbatemarco@pfizer.com
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Health Disparities/Equity

196 Barriers to oral HIV preexposure prophylaxis (PrEP) perceived by those receiving an initial prescription: US survey analysis

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197 Whose health is impacted by income inequality? Associations between county-level income inequality and pharmacy spending in an insured population

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Health Policy

205 Income, health, and racial gaps between 340B hospitals, child sites, and nearby neighborhoods

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Hematologic

220 Economic burden of cytopenia in patients with myelofibrosis: Analysis of a US national administrative claims database

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221 Transfusion-related cost and time burden offsets in patients with myelofibrosis treated with pacritinib compared with best available therapy based on PERSIST-2 trial

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222 Real-world iptacopan use among US patients with paroxysmal nocturnal hemoglobinuria

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Immunology

235 Dupilumab improves signs and symptoms of chronic spontaneous urticaria regardless of baseline body mass index

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236 Dupilumab monotherapy vs topical corticosteroids in prurigo nodularis: Impact on signs and symptoms in the PRIME/PRIME2 studies

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237 Patient, caregiver, and physician perspectives on the burden of disease in uncontrolled gout and its treatment: Concept elicitation

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238 Association between dupilumab and repeated exacerbations of chronic obstructive pulmonary disease: BOREAS and NOTUS

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239 Dupilumab efficacy in patients with chronic obstructive pulmonary disease (COPD) and type 2 inflammation with and without emphysema

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240 Estimating the economic impact of dupilumab in type 2 inflammatory disease: Cost offset analysis of atopic dermatitis with comorbid asthma in the US healthcare system

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Infectious Disease

250 Characteristics associated with RSV vaccination among adults aged 60 years and older in the United States between August 2023 and February 2025

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251 Preference for twice-yearly injections vs daily oral pills for HIV PrEP in cisgender men, transgender women, transgender men, and gender nonbinary people enrolled in PURPOSE 2

Phanuphak N[1], *Hinojosa J*[2], *Mngadi K*[3], *Mounzer K*[4], *Vasconcelos R*[5], *Ramgopal M*[6], *Wong P*[7], *Brown L*[8], *Jarrett J*[8], *Carter C*[8], *Shah N*[9]; *nittaya.p@ihri.org*; *james.jarrett@gilead.com*
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252 Treatment switch among Medicare-insured people with HIV and gaps in care

Li S[1], *Christoph M*[2], *Mordi U*[2], *Guo H*[1], *Gilbertson D*[1], *Cui T*[1], *Lim T*[2], *Prata Menezes N*[2]; *suying.li@cdrg.org*; *mary.christophschubel1@gilead.com*
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253 Treatment switch among US Medicare beneficiaries with HIV

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254 Antiretroviral therapy persistence among treatment-experienced people with HIV and mental health disorders in the United States

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255 Antiretroviral therapy persistence following a change or restart in regimen among people with HIV

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Mental Health

266 Dosing to effect with weekly and monthly subcutaneous buprenorphine: Post hoc analysis of a phase 3, open-label study

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268 Economic impact of experiential negative symptoms among patients living with schizophrenia: Medical expenditure panel survey

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269 Health care resource utilization and costs of schizophrenia among Medicaid beneficiaries

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270 Indirect treatment comparison of somnolence or sedation with dopamine partial agonists vs D2 receptor antagonists in major depressive disorder and schizophrenia

Nabulsi N[1], *Ta J*[1], *Haile F*[1], *Parikh M*[1], *Cheng N*[1], *Mirza N*[1], *Onishchenko K*[1], *Adham N*[1], *Varughese S*[1], *Adams J*[1]; *nadia.nabulsi@abbvie.com*
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Musculoskeletal

286 Real-world effectiveness of interleukin-6 receptor inhibitors compared with methotrexate in steroid-refractory frail patients with polymyalgia rheumatica

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287 Analyzing the economic impact of denosumab in the treatment of osteoporosis

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288 Indirect treatment comparison of efgartigimod vs immunoglobulins in chronic inflammatory demyelinating polyneuropathy (CIDP)

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Oncology

299 Patient-reported outcomes evaluating physical functioning and symptoms in patients with pretreated human epidermal growth factor receptor 2–mutant advanced non–small cell lung cancer: Results from the Beamion LUNG-1 trial

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300 Economic burden of recurrence in early-stage hepatocellular carcinoma (HCC) treated with curative intent: A retrospective analysis of SEER-Medicare data

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301 Zongertinib in patients with pretreated human epidermal growth factor receptor 2–mutant advanced non–small cell lung cancer: Beamion LUNG-1

Heymach J[1], Ruiter G[2], Ahn M[3], Girard N[4], Smit E[5], Planchard D[6], Wu Y[7], Cho B[8], Yamamoto N[9], Sabari J[10], Zhao Y[11], Tu H[7], Yoh K[12], Nadal E[13], Sadrolhefazi B[14], Rohrbacher M[15], von Wangenheim U[15], Eigenbrod-Giese S[16], Zugazagoitia J[17]; jheymach@mdanderson.org; ute.von_wangenheim@boehringer-ingelheim.com
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Real-World Evidence

346 Real-world health care resource utilization and economic burden associated with idiopathic pulmonary fibrosis in commercially insured and Medicare Advantage populations in the United States

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347 Estimation of the minimal clinically important difference (MCID) and longitudinal change in the tardive dyskinesia impact scale (TDIS), a validated, tardive dyskinesia–specific, patient-reported outcome measure

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348 Real-world health care resource utilization and economic burden associated with progressive pulmonary fibrosis in commercially insured and Medicare Advantage populations in the United States

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349 AUVI-Q (epinephrine, USP) vs other epinephrine auto-injector prescription was associated with reduced inpatient hospitalizations for anaphylaxis in a US retrospective commercial claims analysis

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350 Real-world incremental economic burden of fatigue among patients with obstructive sleep apnea in the Medicare fee-for-service population

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351 The economic burden of narcolepsy in the United States: Matched analysis of National Health and Wellness Survey data

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352 Transportability to the EU population of the efficacy of belumosudil vs best available therapy for the treatment of chronic graft-versus-host disease

Wolff D[1], Solano C[2], Michonneau D[3], Bonifazi F[4], Mehra V[5], Hall K[6], Lazaryan A[7], Lee C[8], Logan A[9], van der Laan M[10], Gruber S[11], Kabadi S[12], Khan I[12], Nicholls C[13], Rota L[12], Nikai E[14], Ponomareva E[15], Koumas A[15], Waller E[6]; Daniel.Wolff@klinik.uni-regensburg.de; shaum.kabadi@sanofi.com
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353 Real-world assessment of manic events among patients with bipolar I disorder treated with cariprazine vs other atypical antipsychotics

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354 Health care resource utilization following cariprazine initiation among Medicare beneficiaries with bipolar I disorder

Parikh M[1], Wade S[2], Nabulsi N[1], Barthel A[3], Rava A[3], Sun H[3], Kandukuri L[1], Wu Z[3], Zhao Y[3], Yee T[4], Wasser T[3], Ta J[1]; mousam.parikh@abbvie.com; jamie.ta@abbvie.com
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355 Real-world switch rates of injectable migraine preventive therapies in patients with chronic migraine

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356 Evaluation of unmet needs and quality-of-care indicators among patients with migraine in the United States: 2021-2022

Martin V[1], *Ailani J*[2], *Parikh K*[3], *Deng H*[3], *Dong Y*[4], *Bodhani A*[3], *Lipton R*[5]; *martinvt@ucmail.uc.edu*; *krutika.parikh@abbvie.com*
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358 Increased health care resource utilization in children and adolescents with Tourette syndrome treated with dopamine D2 receptor antagonists/partial agonists: An electronic health records database analysis

Isaacs D[1], *Swindle J*[2], *Dabbous F*[2], *Gilbert D*[3], *Karkanias G*[4], *Atkinson S*[4], *Munschauer F*[4], *Mazhar F*[5], *Pettersson C*[5], *Wanaski S*[6], *Cunniff T*[6], *Tomczak K*[7]; *david.a.isaacs@vumc.org*
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Respiratory

404 Efficacy of as-needed albuterol-budesonide vs albuterol on systemic corticosteroid exposure in participants with mild asthma: BATURA prespecified analysis

Panettieri Jr. R[1], *Bacharier L*[2], *Kraft M*[3], *Beasley R*[4], *Chipps B*[5], *Israel E*[6], *Cappelletti C*[7], *Clancy M*[8], *Papi A*[9], *LaForce C*[10], *Albers F*[11], *Danilewicz A*[12], *Jeynes-Ellis A*[12], *Rees R*[12], *Bardsley S*[13], *Dunsire L*[13], *Harrison T*[14], *Pandya H*[13], *Sobande O*[15], *Hirpara S*[16]; *rp856@rbhs.rutgers.edu*; *sunny.hirpara@astrazeneca.com*
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405 Efficacy of brensocatib in patients with non–cystic fibrosis bronchiectasis (bronchiectasis) with vs without maintenance use of macrolides: An analysis of the ASPEN trial

Haworth C[1], *McShane P*[2], *Mauger D*[3], *Metersky M*[4], *Lauterio M*[5], *Shih V*[5], *Teper A*[5], *Fernandez C*[5], *Griffis D*[5], *Mange K*[5], *Chalmers J*[6]; *charles.haworth@nhs.net*; *melanie.lauterio@insmed.com*
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406 The effect of brensocatib vs placebo on symptom burden in patients with non–cystic fibrosis bronchiectasis (bronchiectasis) with or without on-study pulmonary exacerbations: A post-hoc analysis from the ASPEN trial

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407 As-needed albuterol-budesonide decreases risk of severe asthma exacerbation in the first 3 months after randomization compared with albuterol in patients treated for moderate to severe asthma: MANDALA post hoc analysis

Robb E[1], Chipps B[2], Papi A[3], Beasley R[4], Panettieri Jr. R[5], Israel E[6], Kuchera S[7], Gilbert I[1], Dunsire L[8], Sobande O[9], Motawakel O[1], Harrison T[10], Fogel R[11], Skolnik N[12]; Emily.robb@astrazeneca.com; bradleychipps@gmail.com
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408 Reduction in asthma exacerbations following initiation of benralizumab among Medicare beneficiaries: Results from the ZEPHYR-5 study

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409 Dupilumab effectiveness through 24 months in patients from the United States with CRSwNP enrolled in the global AROMA registry

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410 Baseline characteristics of patients on medium- vs high-dose inhaled corticosteroids in patients initiating dupilumab in a real-world clinical setting: The RAPID registry

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411 Real-world outcomes after 2 years of dupilumab therapy for severe asthma: The ProVENT study

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412 The relationship between wildfire smoke exposure and childhood asthma in California

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