

October 2026
Volume 33, Number 10-d



JMCP

Journal of
Managed Care +
Specialty Pharmacy

SUPPLEMENT

Poster Abstracts

NEXUS

San Diego, CA | OCT. 26-29, 2026



AMCP

Optimizing medicine.
Improving lives.

JMCP

October 2026 | Volume 33 | Number 10-a

EDITORIAL STAFF

Laura E. Happe, PharmD, MPH, University of Florida, Gainesville, FL; 727.488.2700, lhappe@jmcp.org; *Editor-in-Chief*

Anna Hung, MS, PharmD, PhD, Duke University, Durham, NC; *Assistant Editor*

Stephen J. Kogut, MBA, RPh, PhD, University of Rhode Island, College of Pharmacy; *Assistant Editor*

Karen L. Rascati, PhD, University of Texas College of Pharmacy, Austin, TX; *Assistant Editor*

Phil Schwab, PhD, Genesis Research Group, Louisville, KY; *Assistant Editor*

Carrie McAdam-Marx, BSPHarm, MS, PhD, University of Nebraska Medical Center, Omaha, NE; *Section Editor*

Jennifer A. Booker, 703.317.0725, jmcpreview@amcp.org; *Managing Editor*

SUPPLEMENT POLICY STATEMENT

Standards for Supplements to the Journal of Managed Care + Specialty Pharmacy

Supplements are a separate issue of *JMCP* that is funded by a sponsor rather than by the journal's publisher. Supplements must align to *JMCP*'s mission to advance science, expertise, and evidence-based decision making to improve patient health through access to high-quality, cost-effective medications and other therapies. The following apply to all *JMCP* supplements:

All supplements are sent to peer review.

- The editor has the authority to reject supplement submissions, before or after peer review.
- The introductory materials of the supplement must clearly state the (1) source of the idea of the supplement, (2) the source of funding for the supplement's research, (3) the source of funding for the supplement's publication, and (4) the products of the funding source related to the supplement content.
- Authors must meet International Committee of Medical Journal Editors (ICMJE) [criteria for authorship](#) as described in the *JMCP* author guidelines.
- Authors must disclose all financial and personal relationships that may impact their work by completing the ICMJE [Disclosure of Conflicts of Interest](#) form as described in the *JMCP* author guidelines.
- Product trade names are only used once, generally at the first reference to the generic name. Use of trade and generic naming conventions may be adjusted at the editor's discretion to provide clarity.
- Supplements are identified by the addition of an alpha character to the issue number (eg, issue 10-d) and an S to the page number (eg, page S1-S150).

PUBLISHER

Susan A. Cantrell, RPh, CAE, AMCP; *Publisher*

Brittany V. Henry, PharmD, MBA, *Director, Education Programs*

ADVERTISING

Advertising for *JMCP* is accepted in accordance with the advertising policy of AMCP. A media kit is posted online at www.jmcp.org/advertising. For additional information, contact BulletinHealthcare, A Cision Company, atamcpteam-dl@bulletinhealthcare.com

Please contact **Noreen Matthews** at nmatthews@amcp.org for information on other partnership opportunities.

This Supplement to the **Journal of Managed Care + Specialty Pharmacy**® (ISSN 1944-706X) is a publication of AMCP, 675 N. Washington St., Suite 220, Alexandria, VA 22314; 703.684.2600.

DISCLAIMER + COPYRIGHT

All articles published represent the opinions of the authors and do not reflect the official policy or views of AMCP or the authors' institutions unless so specified. Copyright© 2025, Academy of Managed Care Pharmacy. All rights reserved. No part of this publication may be reproduced or transmitted in any form or by any means, electronic or mechanical, without written permission from AMCP.

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 2026. Abstracts submitted in the Student and Encore categories did not undergo peer review; therefore, these abstracts are not included in the supplement.

ABSTRACT REVIEW PROCESS

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 2026 were as follows:

Peer Reviewers

Victor Agboli, MSc
Chris Bell, MS
Jessica Benitez-Burke, PharmD
Kenechukwu Ben-Umeh, BPharm
Kaustuv Bhattacharya, MS, PhD
Satabdi Chatterjee, MS, PhD
Ashley Chiara, MBA, PharmD
Melanie Claborn, PharmD
Callahan Clark, PharmD, RPh
Jenny Craven, PharmD
Eric Culley, PharmD, MBA
Stacey DaCosta Byfield, PhD, MPH
Saba Dangpiaei, PharmD, MBA
Anandaroop Dasgupta, PhD

Joseph Dye, RPh, PhD
 Frank Ernst, PharmD, MS
 Renee Fleming, PRh, MBA
 Moshe Fridman, PhD
 Nilesch Gangan, PhD
 Teresa Gibson, PhD
 Noelle Gronroos, PhD, MPH, CPH
 Shweta Kamat, PhD
 Melanie Kuester, PharmD
 Lena Kwan, PharmD, CSP
 Nguyen Le, BPharm, MBA
 Haitao Li, PharmD, MS
 Mia Lussier, PharmD, MS
 Elizabeth MacLean, PharmD, PhD
 Zachary Marcum, PharmD, PhD
 Carrie McAdam-Marx, RPh, PhD
 Scott McDowell, PharmD, BCPS, BCACP, CDCES
 Stanton Mehr, BS
 Millie Mo, PharmD
 Sasikiran Nunna, PhD
 Blessing Okoye, BPharm, MS
 Busuyi Olotu, PhD
 Niveditha Palleria, RPh
 Chanhyun Park, PhD
 Maryam Pathan, BPharm, PhD Candidate
 Samuel Peasah, PhD, MBA, RPh
 Lai Peng, MS
 Michael Polson, MS, PharmD
 Sujith Ramachandran, PhD
 Kali Raval, PharmD
 Claiborne Reeder, RPh, MS, PhD
 Sanika Rege, MS, PhD
 Chelsea Renfro, PharmD
 Susmita Roy Riya, MSc, PhD
 Elan Rubinstein, PharmD, MPH
 Jason Shafrin, PhD
 Patty Taddei-Allen, PharmD, MBA, BCACP, BCGP, FAMCP
 Tara Thomas, RPh
 Patrica Thornewell, PharmD
 Fiston Vuvu, PharmD, MS
 Rolin Wade, MS
 Yan Wang, PhD
 Alyssa Wong, PharmD
 Benjamin Wong, PhD
 Shawn Xiong, PhD

Michelle Zeigler, PhD, PharmD, BCACP
 Yajin Zhao, MS in Epidemiology
 Candace Zheng, PharmD, BCBS

JMCP Assistant Editors

Stephen J. Kogut, PhD, MBA, BSPharm
 Karen L. Rascati, PhD
 Phil Schwab, BS, MS, PhD

S2	Medal-Winning Abstracts	S40	Genitourinary
S5	Platinum Winners	S41	Health Disparities/Equity
S8	Professional Reviewed Abstracts	S42	Health Policy
S8	Analgesics/Pain	S44	Hematologic
S10	Benefit Design and Management	S46	Immunology
S13	Biosimilars	S47	Infectious Disease
S16	Cardiovascular	S52	Managed Care Clinical Programs
S19	Cell and Gene Therapies	S54	Mental Health
S19	Central Nervous System	S58	Oncology
S23	Clinical Trials/Drug Development	S78	Ophthalmic
S24	Dermatology	S80	Quality and Safety Programs
S25	Digital Health and Technology	S81	Real-World Evidence
S30	Drug Pricing, Payment, and Reimbursement	S98	Respiratory
S34	Endocrine and Metabolic	S101	Specialty Pharmacy
S39	Gastrointestinal	S104	Student Abstract Titles
		S110	Encore Abstract Titles



Medal-Winning Abstracts

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



Samuel Peasah, PhD, MBA, RPh [124] GLP-1-RA documented reasons for discontinuation: Analysis of a national online survey

Saba Dangpiaei, PhD Student [260] Real-world evidence evaluating the association between the number of HPV vaccine doses and the incidence of cervical cancer

Reema Mody, PhD [312] Demographic and clinical characteristics of adults with elevated lipoprotein(a) without prior ASCVD events: Implications for managed care

Emilie Scherrer, MSc [324] Validation of a composite mortality variable among patients with integrated electronic health records in a large multimodal database



Kenneth C. Hohmeier, PharmD [16] “Everything else is downstream of payment”: Payer and stakeholder perspectives on reimbursement infrastructure for pharmacist-delivered buprenorphine

Elias C. Pittos, PharmD [53] Access, reimbursement, and risk management challenges for cell and gene therapies: U.S. payer perspectives

Terry Richardson, PharmD, BCACP [86] AMCP Market Insights: Beyond skin deep on the role of managed care in moderate-to-severe atopic dermatitis

Wendy Smith Begolka, MBS [88] Atopic dermatitis prescriptions in rural vs. urban areas in the United States: Analysis of claims data

Danny Sheinson, PhD [167] Evaluating price controls and patient affordability: Lessons from the historical PCSK9 price reductions and Medicare Part D formularies

Elizabeth Perry, PharmD [261] Real-world discontinuation rates among patients with metastatic castration-sensitive prostate cancer who initiated novel androgen receptor inhibitors: A US claims analysis

Amy Nguyen, PhD [269] IMforte: Characterization of hospitalization and health care resource utilization with lurbinectedin + atezolizumab maintenance therapy for extensive-stage small cell lung cancer in a phase 3 randomized trial

Aimee A. Metzner, PharmD [310] Real-world adherence trajectories of cabotegravir long-acting and oral PrEP in the United States: A latent class growth analysis from the PrEPFACTS study using healthcare administrative claims data



Medal-Winning Abstracts



Jacinda Tran, PharmD, PhD, MBA [318] Gastrointestinal adverse effects following initiation of glucagon-like peptide-1 receptor agonists to treat obesity among commercially insured members without diabetes: A three-year real-world assessment

Jacinda Tran, PharmD, PhD, MBA [319] Antiemetic utilization following initiation of glucagon-like peptide-1 receptor agonists to treat obesity among commercially insured members without diabetes: A three-year real-world assessment

Shannon Gallagher, MSc [360] Patient journey from symptom onset to treatment of idiopathic pulmonary fibrosis (IPF): Data from the Mayo Clinic



Jennifer H. Lin, PhD [5] Association of liposomal bupivacaine with opioid use and medical costs following surgery of lower-extremity fractures in Medicare fee-for-service beneficiaries

Rachel Day, MD [25] Longitudinal analysis of Medicare Part D formulary design for high-cost dermatology systemics

Tasmina Hyder, PharmD, MBA, BCGP, FAMCP [27] Payer formulary strategies for adalimumab and ustekinumab biosimilars in the United States: Results from a 2026 survey

Evelyn F. Sarnes, PharmD, MPH [42] Real-world assessment of LDL-C response of patients taking bempedoic acid or bempedoic acid plus ezetimibe for primary prevention in routine practice

Shelley E. Hancock, MBA [92] Budget impact of a prescription digital therapeutic for pediatric amblyopia: US commercial and Medicaid payer perspectives

Terry Richardson, PharmD, BCACP [123] Managed care considerations in Barth syndrome: Insights from an AMCP Market Insights program on coverage decision-making for an ultra-rare disease

Poorva M. Nemlekar, MS Pharm [127] Continuous glucose monitoring use is associated with improved glycemic status assessment performance in non-insulin-treated adults with type 2 diabetes

Bashir Kalayeh, PharmD, RPh [258] Safety profile of darolutamide + androgen deprivation therapy compared to enzalutamide, apalutamide, and abiraterone in metastatic castration-sensitive prostate cancer: Results from the first safety matching-adjusted indirect comparison

Kiersten Merida, PharmD [267] Comparison of oral oncology drugs excluded by large pharmacy benefit managers (PBMs)

Salome Samant, MBBS, DHSc [272] Melanoma recurrence comes at a cost : Real-world economic burden in the US as assessed by a nationally representative matched cohort analysis

Yizhen Lai, MSc [273] Health and economic impact of pembrolizumab in advanced cancer among U.S. Medicare beneficiaries

Amy Nguyen, PhD [278] Real-world healthcare resource utilization and costs among patients with small cell lung cancer receiving second-line and third-line therapy in the US



Shelley E. Hancock, MBA [313] Real-world impact of prior treatment duration on response to an FDA-cleared dichoptic digital therapeutic for pediatric amblyopia

Jacinda Tran, PharmD, PhD, MBA [317] Major adverse cardiovascular events following initiation of GLP-1 receptor agonists to treat obesity among commercially insured members without diabetes: A three-year real-world assessment

Joseph P. Tkacz, MS [328] Quantifying pharmacy claim denial rates, demographic disparities, and outcomes associated with prescription abandonment in the U.S.

Carmela Benson, MS, MSHP [338] Association of hospitalization history prior to long-acting injectable antipsychotic initiation and subsequent hospitalizations and costs in young dual-eligibles with schizophrenia: The CRITICAL PERIOD Study

Platinum Winners

124 GLP-1-RA documented reasons for discontinuation: Analysis of a national online survey

Samuel Peasah, PhD, RPh, MBA, Director, HVHC Value-Based Pharmacy Initiatives, UPMC Health Plan, 600 Grant St., Pittsburgh, Pennsylvania, 15219; peasahsk@upmc.edu

BACKGROUND: GLP-1 receptor agonists (GLP-1-RAs) are increasingly prescribed for obesity, type 2 diabetes mellitus (T2DM), and off-label indications such as substance use disorder. However, many patients discontinue these therapies, which may undermine clinical, economic, and formulary management goals. Because favorable economic analyses of GLP-1-RAs are often predicated on sustained use, understanding reasons for discontinuation is important for clinical practice and policy.

OBJECTIVE: To summarize reasons for discontinuing GLP-1-RA therapy by indication.

METHODS: This study examined responses from a national online survey fielded in August 2024 and commissioned by Evernorth Research Institute. The sample included 900 commercially insured U.S. adults aged 18–65 years with a GLP-1-RA prescription filled in the prior six months. The data were analyzed across four indications: weight loss, T2DM, substance use disorder, and others. This descriptive analysis focused on weight loss, T2DM, and substance use disorder.

RESULTS: Weight loss was the most common indication for a GLP-1-RA prescription (58%), followed by T2DM (41%) and substance use disorder (14%). Side effects were the leading reason for discontinuation among patients with T2DM (55%). In contrast, reaching treatment goals was the leading reason for discontinuation among patients using these medications for weight loss (43%) and substance use disorder (48%). Across all indication groups, the most frequently reported discontinuation reasons were side effects and tolerability concerns, goal achievement or perceived improvement, high medication cost or loss of insurance coverage, difficulty with the method of administration such as injections, and recommendations from a healthcare provider to stop treatment. Patients with T2DM had the highest persistence (77%), compared to weight loss (59%) and substance use disorder (66%). Patients using GLP-1-RAs for weight loss had the highest fully out-of-pocket payment rate (8%), approximately four times that of T2DM users (2%).

CONCLUSIONS: Discontinuation of GLP-1-RAs is multifactorial and varies by clinical indication. While financial considerations appear to be a consistent barrier across patient groups, other factors, such as tolerability, perceived goal attainment, and clinical guidance, also play a substantial role. These findings may inform benefit design, support clinician-patient discussions, and contribute to efforts to promote access to GLP-1-RA therapies.

SPONSORSHIP: None

260 Real-world evidence evaluating the association between the number of HPV vaccine doses and the incidence of cervical cancer

Saba Dangpiaei, PharmD, MBA, PhD Student, West Virginia University, 35 Metro Towers Ln., Morgantown, West Virginia, 26505; sd00087@mix.wvu.edu

BACKGROUND: Cervical cancer is a major global health burden, with approximately 660,000 cases and 350,000 deaths reported in 2022, ranking fourth among cancers in women. Prophylactic HPV vaccines (bivalent, quadrivalent, and 9-valent) are highly effective in preventing persistent HPV infection and cervical precancer. Current guidelines in 2026 support a 2- or 3-dose series depending on age, with 2 doses recommended for those initiating vaccination before age 15 and 3 doses for those starting at ages 15–26, immunocompromised individuals, and adults aged 27–45 years based on shared clinical decision-making. Emerging evidence suggests that a single dose may provide sufficient protection; however, real-world evidence comparing dose effectiveness remains limited.

OBJECTIVE: To assess the efficacy of different numbers of HPV vaccine doses on the incidence of cervical cancer.

METHODS: A retrospective cohort study using TriNetX data included patients aged 9–45 years, representing the eligible population for HPV vaccination who received any of the three vaccine types (bivalent, quadrivalent, or nonavalent). Propensity score matching balanced baseline covariates. Cox proportional hazards models with clustering estimated hazard ratios for cancer across vaccine dose groups, and Kaplan–Meier curves assessed differences in cancer-free survival.

RESULTS: A total of 512 patients with cancer were matched to 512 without cancer from an initial cohort of 1,174 controls.

Most participants were White (55.3% vs 58.2), and the majority received their first vaccine at ages 18-29 (61.3% vs 61.1%), followed by <18 years (12.3% vs 13.15) among those with cancer and without, respectively. After adjustment for the age at index (first vaccine), race, prior malignancy, sexually transmitted infections, and nicotine dependence, receiving 2 doses versus 1 was associated with a lower cancer risk (HR = 0.68, 95% CI: 0.53-0.89, $p = 0.004$). Similarly, 3 versus 1 dose showed greater risk reduction (HR = 0.54, 95% CI: 0.42-0.68, $p < 0.001$). No significant difference was observed between 2 and 3 doses ($p = 0.053$). Moreover, older age at first HPV vaccination was associated with a higher risk of cervical cancer (HR = 1.06, 95% CI: 1.04-1.07, $p < 0.001$).

CONCLUSIONS: HPV vaccination was associated with a reduced risk of cancer, with greater protection observed with increasing number of doses and when administered at younger ages. These findings demonstrate the effectiveness of HPV vaccination, particularly with completion of at least two doses, supporting early vaccination and cost-reducing preventive strategies in managed care.

SPONSORSHIP: None

312 Demographic and clinical characteristics of adults with elevated lipoprotein(a) without prior ASCVD events: Implications for managed care

Reema Mody, PhD, Executive Director, Health Economics and Outcomes Research (HEOR) Eli Lilly and Company, 381 Torrey Pines Way, Vernon Hills, Illinois, 60061; MODY_REEMA@LILLY.COM

BACKGROUND: Lipoprotein(a) [Lp(a)] is a genetically determined, independent risk factor for atherosclerotic cardiovascular disease (ASCVD). ACC/AHA 2026 guidelines recommend measuring Lp(a) at least once in adulthood, yet testing remains underutilized. Mendelian randomization studies demonstrate that lower Lp(a) levels sustained over longer periods produce greater reductions in cardiovascular (CV) risk, reinforcing the importance of early identification. Characterizing patients with elevated Lp(a) is important to optimize management of modifiable CV risk factors while preparing for emerging treatments.

OBJECTIVE: To compare demographic and clinical characteristics between adults without prior ASCVD events with normal (<125 nmol/L) vs elevated (≥ 125 nmol/L) Lp(a) in a commercially insured US population.

METHODS: This retrospective cohort study used claims and laboratory data from the Healthcare Integrated Research Database (HIRD). Adults (≥ 18 y) with ≥ 1 Lp(a) result (nmol/L) from Jan 2017 to Oct 2024 (first Lp(a)=index), ≥ 12 months of enrollment pre/post index, and no prior ASCVD events were

included. Demographics, CV risk factors, lipid profile and medications were compared between the cohorts stratified by their Lp(a) level.

RESULTS: Among 66,531 patients (mean Lp(a): 81.6 [SD 87.1] nmol/L), 24.1% had elevated Lp(a). Most Lp(a) tests (90.3%) accompanied a routine lipid panel; 50.6% of Lp(a) tests had a plan-paid amount of \$0, suggesting the patient paid out of pocket. Non-Hispanic Black patients made up 9.5% of the elevated Lp(a) vs 4.9% of the normal Lp(a) cohort ($p < 0.001$). The mean Lp(a) levels were higher in Black vs White patients (120.5 vs 80.5 nmol/L), with Black female patients having the highest mean Lp(a) (128.3 nmol/L). Elevated Lp(a) cohort had modestly higher prevalence of dyslipidemia (72.2 vs 66.1%), hypertension (35.4 vs 32.3%), CAD (22.4 vs 19.6%), and CHF (2.3 vs 1.7%; all $p < 0.01$) compared to normal Lp(a) cohort. Among the elevated Lp(a) cohort, 28.2% had LDL-C <100 mg/dL; 34.1% were on lipid-lowering therapy; 13.3% on high-intensity statins; 1.3% on PCSK9i.

CONCLUSIONS: This analysis among adults without prior ASCVD events confirms a high prevalence of elevated Lp(a). Despite a higher CV risk burden, significant gaps in lipid management were evident—over two-thirds had LDL-C levels above recommended levels, yet only one-third received any lipid-lowering therapy. Broader Lp(a) testing in those without prior ASCVD event can enable early identification of high CV risk, prompting intensified CV risk management until dedicated Lp(a)-lowering therapies are evaluated for CV risk reduction.

SPONSORSHIP: Eli Lilly and Company

324 Validation of a composite mortality variable among patients with integrated electronic health records in a large multimodal database

Emilie Scherrer, MSc, Senior Director and Head of Strategy, Tempus AI, 600 West Chicago Avenue, Chicago, Illinois, 60654; emilie.scherrer@tempus.com

BACKGROUND: Real-world data (RWD) from electronic health records (EHRs) are important for evaluating treatment effectiveness and overall survival in oncology. Accurate mortality data are essential in studying treatment effectiveness; however, EHR data have known limitations in completeness that can be mitigated by combining with other data sources.

OBJECTIVE: To evaluate the performance of a composite mortality variable that integrates structured and unstructured data sources, including EHRs, with an external mortality data source and claims data by benchmarking against the National Death Index (NDI).

METHODS: We evaluated deidentified clinical and molecular data from a cohort of 17,597 patients diagnosed with advanced solid tumors from 2016 to 2020 from the Tempus real-world

multimodal database. Cancer types included non-small cell lung cancer (NSCLC), breast (BC), ovarian (OC), pancreatic (Panc), prostate (PC), and colorectal cancer (CRC). All data were linked with third-party mortality and claims datasets using deterministic tokenization, and performance metrics were calculated using NDI data as ground truth. Date agreement was assessed at 0, ± 15 , and ± 30 -day tolerances. All analyses were restricted to patients with ongoing direct EHR integrations ($n = 4,795$).

RESULTS: The sensitivity of mortality data in the EHR was 56.7%. Adding third-party data increased the sensitivity to 84.3%, and adding claims on top brought the final sensitivity to 86.6%. This composite mortality variable demonstrated a specificity of 96.2% when benchmarked against the NDI. All cancer types had at least 84% sensitivity: BC 84.1%, CRC 84.4%, NSCLC 88.0%, OC 90.2%, Panc 87.4%, PC 87.6%; Sensitivity was stable by sex: 86.7% male, 86.5% female.

Sensitivity was generally stable by age at diagnosis but was highest for older populations (age <35 : 84.4%; age 35-49: 86.3%; age 50-64: 85.7%; age 65-74: 85.4%; age ≥ 75 : 91.2%). Overall, the positive predictive value (PPV) was 96.7% and the negative predictive value (NPV) was 84.7%. Exact date agreement with the NDI database was 74.6%; this increased to 91.8% with a ± 15 -day tolerance, and to 96.1% with a ± 30 -day tolerance. Exact date agreement was highest for mortality dates directly from the EHR (81.1%) but was similar to the composite for ± 30 tolerance (96.4% ± 30 day).

CONCLUSIONS: The composite mortality variable demonstrated robust performance and high sensitivity (86.6%) and specificity (96.2%) in the EHR-integrated population. These findings suggest that the composite mortality variable is a reliable endpoint for real-world evidence analyses.

SPONSORSHIP: Tempus AI



Please see additional Platinum Winners

Darsh Devani, MS [94] Comparative performance of general-purpose large language model-based approaches for title/abstract screening in literature reviews

Ching-Hsuan Lin, MD, MPH [106] Do prices and doses differ for initial and follow-on indications? An analysis of multi-indication orphan drugs

Arvin Sequeira, PharmD [129] Payer perspectives on direct-to-patient (DTP) offerings for anti-obesity medications (AOMs): Results from a 2026 US national payer survey

Nicholas J. Friedlander [204] Optimizing secukinumab dispensing for cost containment: results from a pharmacist-to-prescriber outreach program

Professional Reviewed Abstracts

Analgesics/Pain

4 Modeling the economic impact of opioid utilization reduction in a mixed commercial and Medicare health plan

Vu H¹, Qiu W², Keast S³, Hendricks J², Patel B³; huyen.vu09@yahoo.com; shellie.keast@medimpact.com

¹MedImpact Healthcare Systems, Inc.; ²MedImpact Healthcare Systems; ³MedImpact

BACKGROUND: Prescription opioid use is associated with increased morbidity, mortality, and healthcare utilization. Evidence suggests targeted interventions can reduce opioid utilization for individuals with chronic pain, yielding economic benefits for healthcare systems. However, evidence on the economic impact of reducing prescribed opioid use within U.S. health plans remains limited.

OBJECTIVE: To estimate the economic impact of opioid utilization reduction in a one-million-member U.S. health plan with mixed commercial and Medicare populations.

METHODS: A budget impact analysis was conducted for a hypothetical one-million-member health plan comprising commercial (53.8%) and Medicare (46.2%) beneficiaries over a one-year time horizon. Total costs and per-member-per-month (PMPM) cost differences were estimated for two scenarios: 1) baseline scenario in which 4.12% of commercial members and 9.66% of Medicare members were prescribed at least one opioid during the year, and 2) intervention scenario assuming a 2% reduction in opioid-utilizing members in both populations. Model inputs included pharmacy costs (PC) (opioids and reversal agents), outpatient medical services utilization and costs (OSU) (emergency department, physical therapy, chiropractic, primary, and specialist visits), and overdose-related mortality medical costs (MC) attributable to prescribed opioids. Inputs were derived from pharmacy claims data and published literature. The opioid-reduction intervention was assumed to incur no direct cost to the health plan.

RESULTS: A 2% reduction in opioid-utilizing members resulted in meaningful cost savings in both populations, primarily driven by reduced OSU. In the baseline scenario, 22,166 commercial members and 44,692 Medicare members received opioid prescriptions, declining to 21,722 and 43,734 members

in the intervention scenario. Total annual cost savings were \$587,196.56 in the commercial population (PC: \$43,576.27; OSU: \$543,059.57; MC: \$560.72) and \$1,309,599.53 in the Medicare population (PC: \$157,537.65; OSU: \$1,144,506.37; MC: \$7,515.51). Total plan-level savings translated to \$1.90 PMPM, including \$0.59 PMPM for commercial members and \$1.31 PMPM for Medicare members.

CONCLUSIONS: Reductions in opioid prescribing resulted in meaningful cost savings for a mixed U.S. commercial and Medicare health plan. Findings support the value of payer-led opioid reduction strategies and highlight potential for opioid stewardship initiatives to improve affordability. Future research should examine additional economic impacts, including productivity loss and caregiver burden.

SPONSORSHIP: MedImpact Healthcare Systems, Inc.

5 Association of liposomal bupivacaine with opioid use and medical costs following surgery of lower-extremity fractures in Medicare fee-for-service beneficiaries

Scuderi G¹, Wang K², Lin J²; GScuderi@northwell.edu; jennifer.lin@pacira.com

¹Northwell Health; ²Pacira BioSciences, Inc.

BACKGROUND: Effective postoperative pain management is essential after lower-extremity fracture procedures to avoid subsequent chronic neuropathic pain development. The recent NOPAIN Act has expanded reimbursement for qualifying nonopioid therapies, including liposomal bupivacaine (LB), when used for outpatient procedures in Medicare-insured patients. However, clinical and economic data on LB use are limited.

OBJECTIVE: To evaluate the impact of LB on opioid use and healthcare costs 30 days after lower-extremity procedures in Medicare beneficiaries.

METHODS: Data on patients (year range, 2018-2023) undergoing lower-extremity procedures including the tibia, fibula, ankle, and foot with or without LB in hospital outpatient department settings were sourced from the 20% Centers for Medicare & Medicaid Services-Medicare database (Parts A, B, and D). The LB and non-LB groups were generated with 1:1 propensity score matching (PSM). Comparisons between groups of opioid consumption (in morphine milligram equivalents [MMEs]), duration of use, opioid-related adverse

events (ORAEs), and total medical costs were done via generalized linear regression with appropriate distributions.

RESULTS: In total, 1844 patients (922 in each group) were included. Patient characteristics were balanced between groups after PSM (standardized mean difference, <15%; mean age 72 years, 71% female, 91% White, 51% osteoarthritis). Approximately half the cohort (49%) had prior opioid exposure. LB use was marginally associated with lower (~10%) MMEs (331 vs 361 MMEs; rate ratio [RR], 0.91 [95% confidence interval (CI)], 0.83, 1.01; $P = 0.066$) and was significantly associated with fewer (10%) opioid-treated days (6.5 vs 7.2 d; RR, 0.90 [95% CI, 0.86, 0.94]; $P < 0.001$) over 30 days after surgery versus non-LB use. LB use was also associated with a significantly lower rate of ORAEs by ~30% (10.4% vs 14.0%; odds ratio, 0.71 [95% CI, 0.52, 0.98]; $P = 0.037$) and ~30% lower total medical cost at 30 days after surgery (\$1528 vs \$2093; RR, 0.73 [95% CI, 0.66, 0.81]; $P < 0.001$) versus non-LB use. The cost savings were primarily attributable to inpatient costs ($P < 0.001$) followed by emergency department and outpatient costs ($P \leq 0.03$ for both).

CONCLUSIONS: Medicare-insured patients receiving LB for outpatient lower-extremity fracture procedures experienced fewer opioid-treated days, a lower ORAE rate, and lower all-cause total medical cost over 30 days after surgery versus those with non-LB use, supporting the clinical and economic benefits of LB in lower-extremity procedures.

SPONSORSHIP: Pacira Biosciences, Inc.

6 Costs and healthcare resource utilization of liposomal bupivacaine and ropivacaine in total hip arthroplasty in the commercial hospital outpatient department: A propensity score-matched cohort

Wong G¹, Asche C², Lin J³; Gabewong7@gmail.com; jennifer.lin@pacira.com

¹Pacira Biosciences Inc.; ²University of Utah College of Pharmacy; ³Pacira BioSciences, Inc.

BACKGROUND: Total hip arthroplasty (THA) aims to relieve pain and restore function in patients with hip arthritis. Effective postoperative pain management is essential for recovery and outcomes. Liposomal bupivacaine (LB) is a long-acting local anesthetic that may offer extended pain relief compared with traditional agents.

OBJECTIVE: To assess the real-world effectiveness of LB versus ropivacaine in THA, focusing on cost and healthcare resource utilization (HCRU).

METHODS: This retrospective cohort study used deidentified data from NorstellinQ, a nationwide US closed claims database from January 2020 to March 2025 in the Commercial setting. The index date was the day of THA in the hospital

outpatient department, identified via Current Procedural Terminology and *International Classification of Diseases, Tenth Revision* procedure codes. Propensity score matching (1:1) was performed between the LB and ropivacaine groups on the basis of age, sex, race, region, year of surgery, comorbidities, and prior 6-month medical costs, with an exact match applied at the facility level. Mean HCRU per patient was evaluated over 30 days since surgery, including emergency department (ED), inpatient, and outpatient visits. Inpatient, ED, long-term care, and home health utilization were also assessed. Mean costs per patient were calculated from the day of surgery until 30 days to reflect the full episode of care. Group differences were analyzed using chi-square test for categorical and Wilcoxon rank-sum test for continuous variables (significance level: $P < 0.05$).

RESULTS: After matching, the LB ($n = 1091$) and ropivacaine ($n = 1091$) groups were well balanced (standardized mean difference, <0.1; mean age 59 years, 50% female). No significant HCRU differences were observed except for slightly higher outpatient visits in the LB versus ropivacaine group (5.83 vs 5.24; $P < 0.05$). The mean outpatient costs per patient were significantly lower for LB, driven by reduced day-of-surgery costs, versus ropivacaine (\$37,433 vs \$38,957; $P < 0.01$). The mean total episode-of-care costs per patient were also lower with LB versus ropivacaine (\$39,653 vs \$40,962; $P < 0.05$).

CONCLUSIONS: Limitations include potential coding gaps and unmeasured confounding. LB was associated with significantly lower mean total costs per patient (-\$1309) than ropivacaine in the hospital outpatient setting over a 30-day THA episode, primarily due to reduced outpatient surgery costs. These findings support LB as a cost-effective strategy in outpatient surgical care.

SPONSORSHIP: Pacira BioSciences Inc.

7 12-Month post-launch JOURNAVX (suzetrigine) prescription fill patterns in real-world settings: Age 65-and-older subgroup analysis

Dasa V¹, Keating S², Mehta J², Princic N³, Moynihan M³, Menzie A²; vdasa@lsuhsc.edu; Scott_Keating@vrtx.com

¹Department of Orthopedic Surgery, Louisiana State University Health Sciences Center; ²Vertex Pharmaceuticals Incorporated; ³Merative

BACKGROUND: An estimated 80 million people are prescribed medication for acute pain annually in the United States (US). Managing acute pain in older adults can be challenging, particularly in patients with certain comorbidities that may limit pharmacologic options. Suzetrigine (SUZ) is a novel oral, sodium channel 1.8 (NaV1.8) pain signal inhibitor

approved for the management of moderate-to-severe acute pain.

OBJECTIVE: To describe the demographic and clinical characteristics, prescription fill patterns, and surgery characteristics among patients aged ≥ 65 years with SUZ prescription fills in real-world settings.

METHODS: This retrospective, observational study used claims data from the Merative MarketScan Commercial and Medicare databases. Adult patients aged ≥ 17 with ≥ 90 days of baseline enrollment and ≥ 1 SUZ prescription fill in the retail setting (index date = earliest fill) between 2/1/2025 and 1/29/2026, were identified and followed for 30 days. SUZ fill patterns were described at index and during follow-up. Concomitant analgesic prescription fills were assessed within ± 3 days of the index date. Evidence of surgery was identified within 30 days of index. Results are reported for the subgroup of patients aged ≥ 65 years.

RESULTS: The analysis included 985 patients aged ≥ 65 years (mean age: 74.8 years; 63.1% female). The median index SUZ fill was 15 days; nearly two-thirds of patients ($n = 609$, 61.8%) received an initial days' supply of ≤ 15 days. SUZ was the only prescription analgesic filled within ± 3 days of index for most patients (80.2%), while concomitant prescription analgesic fills (e.g., acetaminophen, NSAIDs, opioids) were observed among 19.8% of patients. Evidence of an inpatient or outpatient surgical procedure within 30 days of index was identified in 24.2% of patients, most commonly orthopedic surgeries (e.g., joint replacement, spinal fusion), cataract removal, and Mohs micrographic surgery. Patients without evidence of surgery experienced emergency room, urgent care, and outpatient acute care visits (17.3%, 3.9%, and 51.7%, respectively). These findings reflect the first 9 months post-launch; 12 months of prescription fill data will be included in the conference presentation.

CONCLUSIONS: In this real-world analysis, SUZ prescription fills were observed among adults aged ≥ 65 years, across surgical and non-surgical settings. For most patients, SUZ was the only analgesic filled, with a median days' supply of 15 days. These findings provide early insight into SUZ fill patterns among Medicare-aged patients.

SPONSORSHIP: Vertex Pharmaceuticals Incorporated

Benefit Design and Management

11 Impact of step therapy and quantity limits on treatment utilization, clinical outcomes, and healthcare resource use and costs across chronic disease areas: A systematic literature review

Iyengar R¹, Lee J², Yip O¹, Puckett J³, Thomas A⁴, Kamal-Bahl S³, Doshi J⁵; reethi.iyengar@abbvie.com

¹AbbVie Inc.; ²AbbVie Inc.; ³COVIA Health Solutions; ⁴AbbVie;

⁵University of Pennsylvania

BACKGROUND: Payers increasingly use utilization management (UM) such as step therapy (ST) and quantity limits (QL) to control drug use and spending. The impact of these policies on treatment access and downstream clinical and economic outcomes warrants evaluation.

OBJECTIVE: To review published evidence on the impact of ST and QL restrictions on treatment utilization, clinical outcomes, healthcare resource utilization (HCRU), and costs across chronic disease areas in the U.S.

METHODS: A systematic MEDLINE review identified U.S. studies (published 2005-2025) evaluating the impact of ST and QL on treatment utilization, clinical, and economic outcomes in chronic diseases. Articles only focused on acute conditions were excluded. Data were abstracted using a standardized template capturing restriction, therapeutic area, payer type, and outcomes and were verified by two reviewers.

RESULTS: Thirty-four studies were identified that examined ST ($n = 31$, 91%) or QL ($n = 6$, 18%) restrictions across commercial ($n = 14$, 41%), Medicare ($n = 12$, 35%), Medicaid ($n = 2$, 6%), and mixed ($n = 6$, 18%) payer types. Therapeutic areas included cardiometabolic conditions ($n = 11$, 32%), psychiatric disorders ($n = 9$, 26%), pain management ($n = 5$, 15%), neurology ($n = 4$, 12%), rheumatology ($n = 2$, 6%), and other conditions ($n = 4$, 12%). Study outcomes included treatment utilization ($n = 29$, 85%), clinical outcomes ($n = 10$, 29%), HCRU ($n = 10$, 29%), and costs ($n = 18$, 53%). Positive effects of ST/QL restrictions were rare and limited to select therapeutic classes (e.g., opioids). Two-thirds ($n = 22$, 65%) of all studies identified negative effects of ST or QL restrictions on outcomes. Among utilization studies ($n = 29$), ST/QL reduced use of needed treatments overall ($n = 23$, 79%), resulting in higher rates of discontinuation/switching, delaying initiation, and reducing adherence. Among clinical outcomes studies ($n = 10$), ST/QL restrictions led to higher rates of adverse events ($n = 8$, 80%). Among HCRU studies ($n = 10$), 90% ($n = 9$) reported increased rates of hospitalization, ER visits, and outpatient service use. Cost studies ($n = 18$) reported that ST/QL

restrictions offer no cost savings ($n=13$, 72%) and/or increased overall healthcare costs ($n=11$, 61%).

CONCLUSIONS: Evidence across chronic disease areas suggests that ST and QL often hinder timely access to treatment, contribute to discontinuation or switching, worsen clinical outcomes, and may increase avoidable healthcare resource use and costs. These findings underscore the need for more balanced and patient-centered approaches to UM design and implementation.

SPONSORSHIP: AbbVie Inc.

12 The United States fertility benefit landscape for insurance from self-insured employers

Brook R¹, Beren I², Rosenberg E³; Rich@bh-ww.com

¹Better Health WorldWide; ²Workpartners; ³WorkPartners, LLC

BACKGROUND: Infertility is one of the most common health conditions among reproductive-aged individuals, with a global lifetime prevalence of 17.5% among women. Assisted reproductive technology (ART)—including fertility medications, in vitro fertilization (IVF), and other procedures involving the handling of eggs or embryos—plays a central role in infertility treatment. Fertility medications are typically dispensed through specialty pharmacies due to storage requirements and complex injection protocols. Although some employers offer infertility benefits to support recruitment and retention, evidence describing the scope and structure of these benefits remains limited. Within an employer, the employee often can select the plan offering the best benefit for their needs.

OBJECTIVE: To evaluate infertility-related benefits offered by US self-insured employers, including benefit limits, coverage levels, and provisions for ARTs such as IVF, IUI, and fertility medications.

METHODS: Benefit plan information from >500 self-insured employer plan years in the Workpartners Research Reference Database (RRDb, 2010–2025) was reviewed. Employers in the RRDb provide a choice of different insurance plans to their employees. Plans were characterized by diagnostic-only coverage, outsourced services, annual or lifetime maximums, exclusions, medication coverage, number of covered IVF cycles, and other ART-related treatments.

RESULTS: Employer benefit designs varied widely. Many plans provided diagnostic-only coverage, some covered only underlying conditions, and others excluded infertility benefits entirely. Several plans limited coverage to individuals under age 44. A portion outsourced fertility benefits to external vendors. Among plans with maximums, annual limits ranged from \$10,000 to \$20,000 and lifetime maximums ranged from \$2,500 to \$50,000. Some plans covered one lifetime IVF cycle,

while others covered two cycles. When covered fertility medications were covered under the plan's drug benefit, some plans imposed a \$2,500 lifetime fertility medication limit. Higher-benefit plans were associated with greater utilization: four times more follicle-stimulating and gonadotropin-releasing hormones, 1.5 times more selective estrogen receptor modulators, 2.2 times more IUI procedures, and five times more IVF procedures.

CONCLUSIONS: Employer infertility benefits vary widely in scope, maximums, and coverage of ARTs. Benefit designs may continue to shift in response to governmental guidance and financial pressures.

SPONSORSHIP: None

13 US payer perceptions and use of resources from professional organizations: Results of a payer survey and in-depth interviews

Lach K¹, Darkow T², Ma J¹, Meletiche D¹; krzysztof.lach@maplehealthgroup.com; theodore.darkow@boehringer-ingenheim.com

¹Maple Health Group; ²Boehringer Ingelheim Pharmaceuticals, Inc.

BACKGROUND: Professional and academic organizations in the US provide guidance and tools that shape evidence-based drug assessment, including health economic evaluation and real-world evidence studies. As resources may be used in many ways, understanding payer perceptions and use of these resources is critical.

OBJECTIVE: To characterize US payer perceptions and use of guidelines and related resources from professional and academic organizations in drug assessment and coverage decisions.

METHODS: We conducted a mixed-methods study, including a survey and in-depth interviews with payers, to evaluate perceived value and current and intended use of drug assessment resources (e.g., guidelines/reports, conferences) from professional and academic organizations. Survey and interview questions covered four domains: methodology/health policy; drug assessment, benefit design, and coverage; training/education; and event participation. We pre-selected 20 organizations based on prior research, allowing respondents to cite additional organizations.

RESULTS: Fourteen payers were surveyed from a convenience sample, and nine were later interviewed. The sample was well-balanced across scope (national/regional) and function (medical/pharmacy). AMCP, ICER, and NCCN were the most frequently cited organizations across all survey domains. Four interviewed payers noted current or former membership with AMCP and considered AMCP's journal, digital resources, and

conferences highly valuable to engage in clinical discussions, share information, and network with peers and manufacturers. All payers used NCCN guidelines for clinical pathway design, guidance for off-label use, or coverage criteria. All respondents referenced ICER reports in drug contracting negotiations (e.g., citing ICER's target rebate in pricing discussions) or as comparative clinical evidence to inform P&T assessment and coverage criteria determinations. Eight payers either have personally attended or have staff who attended AMCP, Asembia, PCMA, or Beckers' events, focusing on networking with peers and educational programs.

CONCLUSIONS: Resources such as guidelines and reports from AMCP, ICER, and NCCN were the most frequently used by payers in drug assessment and coverage decisions. These resources offer guidance and inform clinical pathway design and coverage criteria and may be referenced in drug contracting negotiations. Payers anticipate that these resources may be more frequently referenced in future assessments, especially with increased competitiveness in select therapeutic areas.

SPONSORSHIP: Boehringer Ingelheim Pharmaceuticals, Inc.

14 An expectation for proactive pre-approval information exchange (PIE): Healthcare decision-maker preferences for PIE engagements

Penley B, Gaiser A, Bannister B, Zheng C;
ben.penley@xcenda.com
Cencora

BACKGROUND: The PIE Act of 2022 codified a permanent safe harbor for biopharma companies to proactively engage in pre-approval information exchange (PIE) with healthcare decision-makers (HCDMs). Past surveys indicate that PIE can improve formulary decision-making; however, opportunities remain to better align biopharma-led pre-approval communications with HCDM expectations.

OBJECTIVE: To understand evolving HCDM perceptions and preferences for PIE engagements and the impact of PIE on formulary decision-making.

METHODS: A web-based survey was fielded to HCDMs from Cencora's Managed Care Network from November 10, 2025, to January 2, 2026.

RESULTS: A total of 40 HCDMs responded to the survey, representing national and regional health plans (50%), pharmacy benefit managers (PBMs; 28%), and integrated delivery networks (IDNs; 23%). Respondents were pharmacy directors (65%), medical directors (25%), and clinical pharmacists (10%). Most represented several lines of business, including commercial (90%), Medicare Advantage (70%), and Managed Medicaid (65%). Overall, 96% of HCDMs reported that PIE

at least somewhat improved formulary decision-making and cited negative implications if this information was unavailable, including less informed decisions (53%), delayed product review (43%) and patient access (30%), and more restrictive coverage policies (20%). Although HCDMs did not consistently receive pre-approval information, nearly three-quarters (73%) expected PIE engagements to be initiated proactively by a biopharma company. HCDMs valued methods for pre-approval engagement, including medical information requests (90%), individual web-based meetings (85%), in-person meetings (85%), FormularyDecisions (85%), and PIE webinars (80%). HCDMs emphasized the importance of succinct and focused PIE meetings that were fair and balanced. Finally, HCDMs preferred that pre-approval information be provided by a field medical representative (53%) or field medical and commercial representatives jointly (43%).

CONCLUSIONS: This survey supports existing evidence that HCDMs value PIE for formulary decision-making. These findings demonstrate that the absence of PIE is associated with negative consequences and reveal a clear expectation for proactive, biopharma-initiated engagements that are tailored to meet HCDM needs. However, gaps persist between HCDM expectations and current biopharma PIE delivery.

SPONSORSHIP: Cencora

15 Does copay assistance affect the likelihood of a successful appeal of a rejection due to utilization management?

Majda T¹, Sheinson D², Hung A³, Wong W⁴; majdat@gene.com
¹Genentech, Inc.; ²Genentech Inc.; ³Duke University School of Medicine; ⁴Genentech

BACKGROUND: Because copay assistance programs can reduce patients' out of pocket drug costs, there is a belief that these programs influence patients' willingness to try to overturn a denial due to payer utilization management (UM). Despite this belief, there is limited real-world evidence on copay assistance and patients' ability to overcome denials due to UM.

OBJECTIVE: To assess the association between prior copay assistance use and successful appeal of drug claim denials due to UM.

METHODS: Claims from the IQVIA Longitudinal Access and Adjudication Data (LAAD) were assessed for immunology and oncology drugs from 2018 to 2024. Patients whose first drug claim in a given year was rejected twice for UM reasons (prior authorization, non-coverage, and step therapy), had 3+ claims for the same drug in the prior year, and were under the age of 65 and commercially insured were included. Years in which a drug had generic or biosimilar options were excluded

to help control for uniform UM strategies across time and drugs. Two rejections were required to ensure that the entire sample appealed the initial coverage rejection. Copay assistance users were defined by its use at any time in the prior year and were matched to non-users 1:1 on age, drug, year and month of rejection, rejection reason, and payer name. Kaplan-Meier curves were estimated to assess the likelihood of a claim being unpaid within 90 days of the second rejection, and the log-rank test was used to test for a difference between the copay assistance users and non-users.

RESULTS: An estimated 358 patients prescribed 13 different drugs (11 immunology, 2 oncology) were matched. Patients were generally over the age of 50 (48%) and experienced their rejection in January (72%), and the most common rejection reason was non-coverage (57%) followed by prior authorization (43%). Copay assistance was not associated with the likelihood of a denied drug claim being paid within 90 days of rejection ($p = 0.639$).

CONCLUSIONS: In an analysis of drugs with no generic or bio-similar options, we found no association between prior use of copay assistance and successful appeals of claim denials due to UM. This suggests that beliefs that copay assistance may make it more likely for patients to win an appeal of a denial due to UM may not be supported by evidence, although more research is needed in other therapeutic areas.

SPONSORSHIP: Genentech, Inc.

16 “Everything else is downstream of payment”: Payer and stakeholder perspectives on reimbursement infrastructure for pharmacist-delivered buprenorphine

Tyszko M¹, Saunders J¹, Cox N², Holtyn A³, Carlston K⁴, Cochran G¹, Barenie R⁵, Hohmeier K⁶; m.tyszko@utah.edu; khohmeie@uthsc.edu

¹University of Utah; ²University of Utah College of Pharmacy; ³Health Scientist Administrator; ⁴University of Utah School of Medicine; ⁵University of Tennessee Health Science Center; ⁶Department of Clinical Pharmacy and Translational Science, University of Tennessee Health Science Center

BACKGROUND: Medications for opioid use disorder (MOUD), including buprenorphine, are associated with lower overall medical costs. However, limited access to MOUD continues to drive reliance on high cost acute care. Recent policy changes have expanded pharmacists' authority to deliver buprenorphine under collaborative practice in some states; however, whether these models are implemented and sustained depends on reimbursement and billing infrastructure. Payer perspectives on financing pharmacist delivered MOUD remain underexplored.

OBJECTIVE: To examine payer, insurer, and multi-stakeholder perspectives on reimbursement pathways, billing infrastructure, and incentive alignment for pharmacist-delivered buprenorphine care.

METHODS: A qualitative study used purposeful and snowball sampling to recruit stakeholders, including pharmacists, prescribers, payers/insurers, patient support organizations, and patients. Semi-structured interviews were conducted, transcribed, and analyzed guided by the Consolidated Framework for Implementation Research, emphasizing payment and incentive structures relevant to payer implementation decisions.

RESULTS: Forty-four participants from 15 states completed interviews. Across stakeholders, the absence of viable reimbursement pathways emerged as a critical barrier to scaling the model. Participants described three billing pathways—facility fee billing, incident to billing, and direct pharmacist billing—none of which function reliably for standalone community pharmacy under current payer contracting structures. Payers highlighted misaligned incentives whereby upfront costs accrue to plans while downstream savings accrue elsewhere. Medicaid was identified as the most critical but most fragmented payer. California and Colorado were cited as the only current examples of payer-recognized pharmacist billing, though operational barriers persist.

CONCLUSIONS: In states where pharmacist delivered MOUD is legally permissible, reimbursement policy—not workforce readiness—is a primary constraint to scale. Pharmacists represent a highly accessible provider group; limiting payment sustains higher-cost emergency and inpatient care, while payer-recognized pharmacist billing has the potential to improve access and reduce overall OUD-related medical spend.

SPONSORSHIP: National Institute on Drug Abuse (NIDA), National Institutes of Health

Biosimilars

23 Voluntary adoption of adalimumab biosimilars in a regional health plan: A retrospective cohort analysis

Do S¹, Huang Y², Peasah S², Culley E², Good C²; scd99@pitt.edu
¹University of Pittsburgh; ²UPMC Health Plan

BACKGROUND: When adalimumab (Humira) biosimilars entered the US market in 2023, managed care organizations implemented various strategies to promote biosimilar adoption. A large regional health plan utilized a voluntary switching approach until the beginning of 2026.

OBJECTIVE: To evaluate adalimumab biosimilar persistence, time to discontinuation, and adherence among patients who voluntarily switched from adalimumab reference product to adalimumab biosimilars.

METHODS: A retrospective cohort study was conducted using claims data from a large regional health plan. Patients with at least one adalimumab biosimilar fill between January 2024 and June 2025 were included. Eligible patients required continuous enrollment during the 12-month baseline period prior to the index biosimilar fill, continuous enrollment for 6 months following the index fill, at least one adalimumab reference product fill during baseline, and age ≥ 18 years at the beginning of 2023. Patients were stratified by indication, payer types, and prescriber type. Discontinuation was defined as a gap >60 days from end of days' supply. Switching was defined as a discontinuation with a fill of a therapeutic alternative or adalimumab reference product. The proportion of patients remaining on the index biosimilar at 6 months was reported. Among those who discontinued, time to discontinuation was estimated. Adherence was measured using proportion of days covered (PDC).

RESULTS: 316 patients switched from adalimumab reference product to an adalimumab biosimilar (Commercial: $n=107$, Medicaid: $n=184$, Medicare/SNP: $n=25$). Top indications included rheumatoid arthritis (27%), Crohn's disease (15%), and psoriatic arthritis (11%). 256 patients (81%) continued on the index biosimilar, 23 patients (7%) returned to adalimumab reference product, 15 patients (5%) switched to a therapeutic alternative, and 22 patients (7%) discontinued the adalimumab biosimilar without switching to a medication of interest. Mean time to discontinuation was 68 days ($SD=33$) for those who returned to the reference product and 66 days ($SD=40$) for those who switched to a therapeutic alternative. The mean adalimumab biosimilar PDC was 0.81 ($SD=0.24$).

CONCLUSIONS: A voluntary adalimumab biosimilar switching approach was effective. Results were comparable to adalimumab biosimilar continuation rates from mandatory switching approaches reported in the literature.

SPONSORSHIP: None

24 Pharmacists' perspectives on biosimilars worldwide: Insights from a targeted literature review

Shastri K¹, Gummerson D², Clarke K²; kunal.shastri@fresenius-kabi.com

¹Fresenius Kabi; ²EVERSANA

BACKGROUND: Since being introduced into the healthcare system, biosimilars have provided more affordable treatment

options for patients, thereby improving access to essential biologics. The optimal use and uptake of biosimilars is influenced by pharmacists' willingness and level of comfort in counseling patients as well as promoting, prescribing, and using biosimilars across a variety of pharmacy settings.

OBJECTIVE: To evaluate, using a targeted literature review, pharmacists' knowledge, perspectives, attitudes, and roles in biosimilar adoption, globally.

METHODS: A PubMed (MEDLINE) search was conducted on 02/17/2026 for primary research studies (surveys, interviews) that reported pharmacists' knowledge, preferences, opinions, and/or attitudes of biosimilars. Key words included [PHARMACIST], [POSITION], [GUIDANCE], [RECOMMENDATION], and [BIOSIMILAR]. Grey literature searching was also conducted to supplement the search strategy. No date limits were applied and only studies in English were included.

RESULTS: Of the 345 records identified, 28 were deemed relevant. Studies reported pharmacist perspectives from Europe ($n=6$), the United States ($n=7$), the Middle East ($n=10$), Nigeria ($n=1$), Malaysia ($n=1$), and global settings ($n=4$). Most pharmacists reported good familiarity with biosimilars, though knowledge ranged from "poor" to "excellent" across studies. 36% of studies included questions about biosimilar training; many pharmacists indicated additional education would be beneficial. Attitudes toward biosimilars were generally positive, with cost savings frequently cited as a benefit. Many pharmacists believed biosimilars offer comparable safety and efficacy to reference biologics, though some expressed concerns regarding their benefit-risk profile.

CONCLUSIONS: Findings from this TLR suggest pharmacists play an important role in biosimilar use; however, variation in pharmacists' knowledge and confidence was apparent. Many pharmacists expressed positive views and recognized the financial benefits of biosimilars. The FDA and EMA both require biosimilars to demonstrate high similarity to an approved reference medication in quality, safety, and efficacy, yet concerns regarding these factors remain amongst pharmacists. These mixed perspectives point to the growing need for clearer guidance and more consistent education. Strengthening training and implementation support may help build confidence and encourage broader biosimilar adoption across pharmacy settings.

SPONSORSHIP: Fresenius Kabi

25 Longitudinal analysis of Medicare Part D formulary design for high-cost dermatology systemics

Day R, Jairath N, Pianin S, McGowan F; rachel.d@joinzest.com; neil.j@joinzest.com
Zest Health

BACKGROUND: Dermatologic specialty drugs are among Medicare's fastest-growing cost drivers, having reached \$2.95 billion in Part D spending by 2022, with average annual growth over 16% and a 42% expansion in agents between 2022 and 2025. Adalimumab biosimilars, launched in 2023, were expected to curb this trajectory. Yet Klebanoff et al. found that just 1.5% of Part D plans placed adalimumab biosimilars on preferred tiers one year post-launch, and a 2024 survey of US dermatologists found only 35% felt moderately knowledgeable about biosimilar interchangeability. This updated longitudinal analysis examines whether Part D formulary design has evolved to support high-value dermatologic care, encourage biosimilar adoption, and enable cost containment.

OBJECTIVE: To quantify formulary tier placement, utilization management requirements, and cross-plan concordance for dermatologic biologics and oral targeted therapies in Medicare Part D, and to evaluate whether formulary design supports preferential placement of high-value therapies, including adalimumab and ustekinumab biosimilars.

METHODS: Longitudinal cross-sectional analysis of CMS Medicare Part D Formulary Files (Q4 2022 to Q4 2025) covering 27 dermatologic biologics and oral targeted therapies across 1,585 formularies, 23,274 plans, and 85,879 formulary-drug-NDC entries. Cross-plan tier disagreement was measured using normalized Shannon entropy. Biosimilar and reference product tier placement were compared with Mann-Whitney U tests.

RESULTS: Specialty Tier 5 placement dominated (72-76% of entries) with near-universal prior authorization (99%) and no tier differentiation between reference biologics and biosimilars. Quantity limits rose 43% over the study period (54.6% to 78.2%). Cross-plan tier agreement was poor (mean entropy 0.35-0.50; modal agreement as low as 63%). Most critically, adalimumab biosimilars achieved no tier advantage over reference Humira after 3 years and 9 biosimilars on market (both median Tier 5; $P = 0.67$). In contrast, ustekinumab biosimilars achieved a 2-tier advantage at launch (median Tier 3 vs. Tier 5; $P < 0.001$).

CONCLUSIONS: Formulary design alone is insufficient to steward high-value dermatologic care for Medicare beneficiaries. Biosimilar adoption is hindered by formulary uniformity. Rising specialty dermatology spend signals continued prescriber preference for branded products over biosimilars.

Realizing the full savings potential of biosimilars in dermatology will require pairing formulary design with prescriber-level incentives, network stewardship, and value-based contracts that drive use of high-value alternatives.

SPONSORSHIP: Zest Health

27 Payer formulary strategies for adalimumab and ustekinumab biosimilars in the United States: Results from a 2026 survey

Hydery T, Yoshida S, Nelson D, Biehn B; hyderyt@gmail.com
Cencora

BACKGROUND: As of May 2026, there were 10 adalimumab and 8 ustekinumab biosimilars launches in the US market. In addition, several other versions, including unbranded and private label versions, were introduced. While the adalimumab market is more established with biosimilars available since 2023, the ustekinumab market is emerging with several biosimilars launched in 2025. This study aimed to better understand payer coverage of these products and identify differences in their formulary strategies.

OBJECTIVE: To compare how US payers are covering adalimumab and ustekinumab biosimilars, including switching policies and WAC-based coverage approaches.

METHODS: An online survey was conducted among US payers from March 31 to April 23, 2026. A total of 43 payers from health plans (56%), integrated delivery networks (26%), and pharmacy benefit managers (19%) completed the survey, representing over 200 million covered lives. The sample consisted of pharmacy (74%) and medical (26%) directors; 93% were voting members on their organization's Pharmacy and Therapeutics committee.

RESULTS: Most payers cover at least 1 adalimumab biosimilar and 1 ustekinumab biosimilar (98% and 93%, respectively). Payers cover more adalimumab biosimilars on formulary (mean: 3.1) than ustekinumab (mean: 2.3). Formulary strategies vary: for adalimumab, 65% cover/will cover only biosimilars while 28% also cover/will cover reference drug; for ustekinumab, 51% cover/will cover only biosimilars and 40% also cover/will cover the reference drug. Adalimumab biosimilars Hyrimoz, Amjevita, and Hadlima are covered by roughly half of organizations; Yesintek and Selarsdi lead ustekinumab coverage. About 1 in 3 incentivize switching to adalimumab biosimilars, slightly higher than ustekinumab (35% vs. 30%); tactics include lower copays and formulary exclusions of reference/other biosimilars. For adalimumab, 49% cover both high and low WAC versions while 42% cover only the low WAC version. For ustekinumab, 47% cover only low WAC versions vs 40% covering both high and low WAC versions.

Contracting, rebates, and net price were top reasons driving coverage of both WAC types.

CONCLUSIONS: Payers manage adalimumab biosimilars more aggressively than the newer ustekinumab biosimilar market, with broader biosimilar formulary inclusion and greater reference product exclusion. However, experience gained from adalimumab biosimilar implementation may be accelerating payer management and adoption of ustekinumab products. Across both molecules, WAC-based pricing adds complexity to payer decision-making, with contracting and net cost remaining key drivers of coverage.

SPONSORSHIP: Cencora

29 US commercial health plan step therapy requirements for ranibizumab products, 2017–2025

LaMountain F¹, Beinfeld M², Chambers J²; *Fariel.LaMountain@tuftsmedicine.org*

¹Center for the Evaluation of Value and Risk in Health, Institute for Clinical Research and Health Policy Studies, Tufts Medical Center; ²The Center for the Evaluation of Value and Risk in Health, Institute for Clinical Research and Health Policy Studies, Tufts Medical Center

BACKGROUND: Despite recommendations from the American Academy of Ophthalmology against the use of step therapy requirements, many payers require patients to try off-label bevacizumab products before granting access to ranibizumab. There is concern that these requirements may delay access to approved therapies and expose patients to complications.

OBJECTIVE: To examine trends in step therapy requirements for ranibizumab and ranibizumab biosimilars in US commercial health plan coverage policies from 2017 to 2025.

METHODS: We identified ranibizumab coverage policies issued by 18 large US commercial health plans active each August from 2017 to 2025 using the Tufts Medical Center Specialty Drug Evidence and Coverage database. We included ranibizumab and all available biosimilars as of August 2025 (n = 4). Each FDA-approved indication was evaluated separately, yielding 16 drug-indication pairs. We categorized policies as having no-step, 1-step, or 2-step therapy requirements through bevacizumab, bevacizumab biosimilars, aflibercept, and/or ranibizumab biosimilars. We evaluated trends overall and by payer, product, and indication.

RESULTS: Use of step therapy for ranibizumab products increased from 18% (13/73) of coverage decisions in 2017 to 47% (110/234) in 2025. All step therapy decisions in 2025 included or required bevacizumab as a first-line treatment. In 2025, 10% (14/234) of decisions required patients to step

through 2 products before accessing ranibizumab. Use of step therapy varied substantially across payers, with 28% (5/18) of plans covering ranibizumab products without step therapy requirements. Payers more frequently imposed 2-step requirements for originator ranibizumab (16%, 13/85) than for biosimilars (ranibizumab-nuna: 4%, 2/51; ranibizumab-eqrn: 10%, 8/80; ranibizumab injection: 6%, 1/18). Step therapy also varied by indication, with the percentage of decisions without step therapy ranging from 44% for age-related macular degeneration to 58% for myopic choroidal neovascularization.

CONCLUSIONS: Off-label bevacizumab products may offer substantial cost savings. However, concerns remain that requiring use of off-label products before access to approved therapies may delay treatment and affect patient outcomes. Further research examining the relationship between pricing, utilization management, and biosimilar uptake may help explain evolving trends in the US ophthalmology market and bevacizumab's impact on biosimilar development.

SPONSORSHIP: None

Cardiovascular

39 Role of bempedoic acid and bempedoic acid plus ezetimibe in patients on moderate- to high-intensity statin therapy: LDL-C lowering in a real-world cohort

Coleman C¹, Nelson J², Powell H³, Lewandowski D², Ajose M², Bonafede M², Sarnes E³, Shapiro M⁴, Vaduganathan M⁵; *esarnes@esperion.com*

¹University of Connecticut School of Pharmacy; ²Veradigm; ³Esperion Therapeutics, Inc.; ⁴Wake Forest University School of Medicine; ⁵Brigham and Women's Hospital

BACKGROUND: The 2026 ACC/AHA Guideline recommend (Class 2a) bempedoic acid (BA) with or without ezetimibe (EZE) in adults with clinical atherosclerotic cardiovascular disease (ASCVD) who are on maximally tolerated statin therapy and not at LDL-C goals (<70 mg/dL for not very high-risk patients, <55 mg/dL for very high-risk patients). While clinical trials have demonstrated the LDL-C reduction to BA and BA+EZE in patients with ASCVD on maximally tolerated statin therapy, data on the real-world reduction in patients on moderate to high intensity statins are limited.

OBJECTIVE: To evaluate the LDL-C response to BA or BA+EZE patients on moderate- to high-intensity statins in routine practice.

METHODS: This retrospective study identified adults starting BA or BA+EZE between 1/1/2022 and 10/31/2025 (earliest

claim=index) in the Veradigm Network EHR linked to Komodo Health open claims. Inclusion criteria required ≥ 1 moderate to high intensity statin in the 30 days pre-index, ≥ 1 LDL-C result 6 months before or on the index (baseline) and within 2 years post-index, and continuous BA or BA+EZE use (< 60 -day gap) up to a valid follow-up LDL-C result. Patients initiating BA+EZE with EZE in the 30 days pre-index were included in the BA cohort. LDL-C values closest to 3 and 12 months post-index were assessed based on data availability.

RESULTS: Of 3,204 BA and 1,738 BA+EZE patients identified, 1,222 (38.1%) and 697 (40.1%) were on moderate to high statins at baseline, respectively. More than half had a history of ASCVD (62.2% and 56.0% for BA and BA+EZE, respectively); in the prior 12 months, 23.1% and 19.5% experienced an ASCVD event. ASCVD risk factors were common, including diabetes (45.3% and 46.6%), body mass index ≥ 30 kg/m² (45.0% and 45.5%), and hypertension (78.1% and 78.0%). Most BA patients received 2 lipid-lowering therapies (LLTs) in the 12 months pre-index (53.3%); majority of BA+EZE users received 1 LLT (72.5%). Median (IQR) baseline LDL-C was 99 (77-136) and 114 (86-149) mg/dL for BA and BA+EZE. Following BA or BA+EZE start, median LDL-C decreased by 3 months (11.1% and 33.8%) and 12 months (23.2% and 40.4%) ($p < 0.0001$ for both cohorts at all time points). At last follow-up, median LDL-C was reduced to 76 (55-105) for BA and 68 (49-93) mg/dL for BA+EZE users.

CONCLUSIONS: These data suggest that BA and BA+EZE were associated with clinically meaningful LDL-C lowering in patients already on moderate- to high-intensity statin therapy who were not at LDL-C goal, supporting the place of these LLTs in patients at high ASCVD risk.

SPONSORSHIP: Esperion Therapeutics, Inc.

40 Heart failure treatment patterns and post-discharge care across primary care payment arrangements in Medicare Advantage

Sheer R¹, Daviano A¹, Barve K², Jacobs E³, Sylwestrzak G¹, Suehs B¹; rsheer1@humana.com; bsuehs6@humana.com

¹Humana Healthcare Research; ²Humana Inc.; ³Centerwell

BACKGROUND: Heart failure (HF) is a leading cause of hospitalizations, healthcare costs, and poor quality of life in older adults. Guideline-directed medical therapy for patients hospitalized with reduced ejection fraction (HFrEF) has evolved over time to recognize essential components of optimal treatment, including aggressive drug combination therapy and prompt follow-up with a physician. Value-based care (VBC) payment arrangements shift the focus of care to outcomes, rewarding providers for managing disease and keeping patients healthier. This study seeks to understand the

relationship between primary care provider payment arrangement and outcomes in hospitalized patients with HFrEF after discharge.

OBJECTIVE: To examine medication therapy and post-discharge follow-up during a six-month period in patients with HFrEF hospitalized for HF with providers in value-based and fee-for-service (FFS) payment arrangements.

METHODS: This study was conducted using the Humana Research Database. Patients aged 18-89 enrolled in an MA plan diagnosed with HFrEF and hospitalized for HF between 1/1/2023 and 6/30/2025 were identified. Six months of continuous enrollment was required both before and after hospitalization. Demographics, medication therapy, and physician follow-up were assessed. Logistic regression models were used to assess outcomes based on the value arrangement of their primary care providers, controlling for age, sex, race, dual eligibility, Elixhauser score, and baseline treatment (in the model of post-discharge treatment intensity).

RESULTS: A total of 2,012 patients were included in this study. Mean age (SD) was 71.7 (9.8) years, 57.4% were male, and 74.1% were White. Patients receiving triple or quadruple therapy increased from 21.4% pre-hospitalization to 48.9% for VBC and from 17.0% to 43.1% for FFS post-discharge. Patients of VBC providers had 25% higher odds of achieving at least triple therapy (OR 1.25, 95% CI 1.03-1.52, $p = 0.024$). Post-discharge, 44.5% and 62.8% of patients with VBC providers had a follow-up office visit within 7 and 14 days, respectively, compared to 36.4% and 54.2% for FFS. VBC was associated with 39% (OR = 1.39, 95% CI 1.14-1.68, $p = 0.001$) and 43% (OR 1.43, 95% CI 1.18-1.73, $p = 0.002$) greater odds of having follow-up at 7 and 14 days of post-discharge, respectively.

CONCLUSIONS: Among patients hospitalized for HF with reduced ejection fraction, patients whose PCP was in a value-based payment arrangement showed greater levels of treatment intensification and higher frequency of timely transitional care post-discharge.

SPONSORSHIP: Humana, Inc.

41 Healthcare resource utilization and cost of atherosclerotic cardiovascular disease events among adults with hyperlipidemia in the United States

Cook C¹, Haley V², Stanek E², Tan H², Sidelnikov E¹, Peterson B³; ccook04@amgen.com

¹Amgen; ²Carelon Research; ³Intermountain Medical Center

BACKGROUND: Atherosclerotic cardiovascular disease (ASCVD) remains a top cause of morbidity and mortality. Contemporary payer-relevant estimates of healthcare costs and resource utilization (HCRU) attributable to ASCVD events among patients

diagnosed with hyperlipidemia (HLD) are needed to inform prevention strategies and value-based decision-making.

OBJECTIVE: To quantify HCRU and costs associated with ASCVD among U.S. adults with HLD stratified by age and baseline ASCVD risk using contemporary data and risk definitions.

METHODS: This retrospective cohort study used commercially insured/Medicare Advantage administrative claims (Healthcare Integrated Research Database, January 2018–October 2025) to identify adults with HLD. Patients were stratified by baseline risk (12 months pre-HLD): secondary prevention (SP: prior ASCVD hospitalization or arterial revascularization), high risk (HR: ASCVD diagnoses or risk factors without acute ASCVD hospitalization or revascularization), and primary prevention (PP; neither SP nor HR), and by age: younger (Y, 18–64); older (O, 65+ years). ASCVD events were defined as hospitalization for MI/unstable angina/ischemic stroke, or revascularization. Within risk strata, patients with events in year 1 post-HLD diagnosis (cases) were propensity score matched to controls without an event. All-cause, 2-year HCRU and costs were assessed post event date, overall and by event type.

RESULTS: The analysis included 43,532 cases and 43,532 matched controls: 8% PP-Y, 5% PP-O, 28% HR-Y, 22% HR-O, 19% SP-Y, and 17% SP-O; 26% had an MI, 13% coronary artery bypass graft (CABG), 41% percutaneous coronary intervention (PCI). Mean 2-year case vs control cost differences associated with MI were \$75,936 (\$82,248 PP-Y, \$61,011 PP-O, \$94,135 HR-Y, \$65,935 HR-O, \$89,181 SP-Y, and \$67,367 SP-O), and \$101,553 for CABG, \$79,691 unstable angina, \$73,711 stroke, \$56,888 PCI, and \$76,491 for other revascularization. While costs and HCRU peaked at index event (64% in month 1), higher inpatient, emergency, outpatient, and pharmacy utilization and costs persisted over follow-up. Overall, inpatient care accounted for 72% of costs. Older patients had higher utilization but lower costs, likely due to reimbursement differences by insurance type. HCRU was higher for SP > HR > PP within cases and controls.

CONCLUSIONS: ASCVD events in the first year following HLD diagnosis were associated with substantial HCRU and costs that peaked at index and persisted for 2 years. Costs were higher for younger (commercially insured) individuals and CABG procedures.

SPONSORSHIP: Amgen

42 Real-world assessment of LDL-C response of patients taking bempedoic acid or bempedoic acid plus ezetimibe for primary prevention in routine practice

Shapiro M¹, Nelson J², Powell H³, Lewandowski D², Ajose M², Bonafede M², Sarnes E³, Coleman C⁴; esarnes@esperion.com

¹Wake Forest University School of Medicine; ²Veradigm;

³Esperion Therapeutics, Inc.; ⁴University of Connecticut School of Pharmacy

BACKGROUND: Diabetes is a well-established risk factor for atherosclerotic cardiovascular disease (ASCVD). As such, clinical guidelines recommend primary prevention with statin therapy to achieve LDL-C <100 mg/dL or <70 mg/dL in patients with additional ASCVD risk factors. For patients who are statin intolerant, bempedoic acid (BA) and/or ezetimibe (EZE) are recommended to lower LDL-C and reduce ASCVD risk. Currently, real-world data assessing BA and BA+EZE in primary prevention patients are limited.

OBJECTIVE: To evaluate LDL-C response of BA and BA+EZE in patients with diabetes without ASCVD in routine practice.

METHODS: This retrospective study identified primary prevention patients (18+) starting BA or BA+EZE between 1/1/2022 and 10/31/2025 (earliest claim=index) in the Veradigm Network EHR linked to Komodo Health open claims. Patients were required to have the following: a diabetes diagnosis in the 12-month pre-index period, no history of ASCVD, ≥ 1 LDL-C result 6 months before or on the index (baseline) and within 2 years post-index, and continuous BA or BA+EZE use (< 60-day gap) up to a valid follow-up LDL-C result. Patients starting on BA+EZE with EZE in the 30 days pre-index were included in the BA cohort. LDL-C values were captured closest to 3 and 12 months post-index based on data availability.

RESULTS: Of 3,204 BA and 1,738 BA+EZE patients identified, 361 (11.3%) and 245 (14.1%) had diabetes with no history of ASCVD. Median age was 63 years for BA and 60 years for BA+EZE. Comorbid obesity and metabolic risk factors were common, including body mass index ≥ 30 kg/m² (58.4% and 59.2% for BA and BA+EZE, respectively) and hypertension (74.2% and 79.2%). Despite 31.9% and 38.4% of BA and BA+EZE patients receiving statin therapy in the 30 days pre-index, median (IQR) baseline LDL-C was 134 (107–163) mg/dL and 135 (104–166) mg/dL, respectively. Following index drug initiation, median LDL-C significantly decreased by 3 months

following BA (26.1% reduction) and BA+EZE (38.5% reduction) ($p < 0.0001$ for both cohorts at all time points); by 12 months, median LDL-C further reduced by 30.6% and 40.7%. By end of follow-up, median LDL-C was 93 (70-110) mg/dL and 80 (61-106) mg/dL for BA and BA+EZE patients with 63.4% and 74.6% of patients achieving LDL-C < 100 mg/dL.

CONCLUSIONS: These findings suggest that BA and BA+EZE were associated with meaningful LDL-C reductions in patients with diabetes without ASCVD, one-third of whom were receiving baseline statins. The observed LDL-C reductions were consistent with those seen in clinical trials.

SPONSORSHIP: Esperion Therapeutics, Inc.

Cell and Gene Therapies

53 Access, reimbursement, and risk management challenges for cell and gene therapies: U.S. payer perspectives

Pittos E¹, DePinto J²; Elias.Pittos@McKesson.com

¹McKesson; ²McKesson

BACKGROUND: Cell and gene therapies (CGTs) offer substantial clinical potential but present significant financial and risk management challenges for U.S. payers.

OBJECTIVE: To characterize payer perspectives on CGT access, reimbursement, contracting, and shared risk models.

METHODS: From February to March 2026, double-blinded qualitative interviews were conducted with payer decision makers. Semi-structured interviews (60 minutes) included quantitative Likert scale assessments and open-ended qualitative feedback. Findings were anonymized and analyzed to identify trends and consensus areas.

RESULTS: Thirty-five payers participated, including 11 national commercial, 9 regional commercial, 11 state Medicaid or managed care, 4 Medicare Advantage, and 1 from CMS. Eighteen held senior pharmacy leadership roles, 12 were medical officers or directors, and 5 held other leadership positions. Interviewed payer organizations represented approximately 295 million covered lives. Payers ranked prior authorization as the leading driver of access delays for both cell and gene therapies (mean score: 3.7/5 for each), followed by single case agreement (SCA) negotiation (cell: 3.5/5; gene: 3.6/5) and out-of-network contracting (cell: 3.4/5; gene: 3.5/5). Seventy-nine percent of payers reported using a Center of Excellence model for CGT delivery, prioritizing rate alignment, clinical experience, and accreditation status as top criteria for provider network inclusion. Across surveyed payers, 61% of CAR-T cases are managed under contracted global

case rates, 39% reimbursed via single case agreements. However, when CAR-T is delivered across multiple settings, 54% of payers rated current case rate strategies as challenging or poorly suited. For gene therapies, reimbursement is predominantly delivered via SCAs (75%). To demonstrate meaningful value, participants noted that cell therapies should deliver durable benefit for an average of 4.7 years, compared with 6.1 years for gene therapies. Participants moderately agreed that risk pools can address gene therapy financial unpredictability (mean 3.5/5); however, actuarial uncertainty and logistical complexity remain as top barriers. National standards for CGT outcomes data collection were ranked as the most impactful enabler of access, followed by federal reinsurance/stop loss and solutions to address member portability.

CONCLUSIONS: Payers continue to face operational and financial challenges in managing CGTs. Greater standardization, improved contracting efficiency, and scalable risk mitigation mechanisms are necessary to address ongoing barriers and ensure sustainable access to CGTs.

SPONSORSHIP: McKesson

Central Nervous System

61 Estimation of meaningful change scores for the EQ-5D Visual Analog Scale (EQ-VAS) in patients with tardive dyskinesia (TD)

Pickard A¹, Bron M², Mathias S³, Vanderhoeft D², Turner M³; pickard1@uic.edu; mbron@neurocrine.com

¹UIC College of Pharmacy; ²Neurocrine Biosciences, Inc.;

³Health Outcomes Solutions

BACKGROUND: TD is a potentially disabling involuntary movement disorder that can impact health-related quality of life. EQ-VAS, a component of EQ-5D-5L, is a patient-reported outcome measuring overall health today. To support interpretation of scores for EQ-VAS in patients with TD, it is necessary to estimate meaningful within patient change (MWPC) using benchmarking approaches.

OBJECTIVE: To estimate MWPC for EQ-VAS scores in adults with TD.

METHODS: Anchor- and distribution-based approaches were used to estimate MWPC for the EQ-VAS (range 0-100, higher scores indicate better health) using data from phase 4 studies (KINECT-PRO and TD4002). For the anchor-based (primary) approach, analyses included KINECT-PRO data (N = 59 participants with underlying psychiatric diagnosis and mild to severe TD), with participants categorized into clinically meaningful groups based on Patient Global Impression of Change

(PGI-C) and Clinical Global Impression of Change (CGI-C) (7-point Likert scales ranging from very much worse to very much improved) scores. For the distribution-based (supportive) approach, analyses included data from both KINECT-PRO and TD4002 (N=135 participants diagnosed with mood disorder or schizophrenia/schizoaffective disorder and moderate to severe neuroleptic-induced TD). Distribution-based benchmarks included approximately 0.33 standard deviation (SD) of the baseline score, representing a small-to-moderate effect, and approximately 0.50 SD, representing a moderate effect. MWPC was considered the smallest meaningful change from baseline in EQ-VAS at Week 8.

RESULTS: Baseline EQ-VAS scores in both studies were concentrated in the range of 50-90, with distribution skewed towards higher values. Floor and ceiling effects were not observed, with 6-8% of participants having EQ-VAS scores approaching 100; none had scores <10 at baseline. Participants and clinicians reporting minimal improvement (PGI-C = 3 and CGI-C = 3) had average EQ-VAS score improvements of 5 by Week 8. For KINECT-PRO, the baseline SD was 16.2, corresponding to distribution-based MWPC benchmarks of ~5.3 (0.33 SD) and ~8.1 (0.50 SD) points. Similar results were observed for TD4002, with a baseline SD of 18.4, corresponding to benchmarks of ~6 (0.33 SD) and ~9.2 (0.50 SD) points.

CONCLUSIONS: Results from these analyses support MWPC for EQ-VAS as 6 points in TD patients. This estimate can inform interpretation of EQ-VAS change scores in patients with TD, with MWPC thresholds supporting interpretation of treatment benefit. Clinicians can use the 6-point EQ-VAS change as a minimal threshold for response.

SPONSORSHIP: Neurocrine Biosciences, Inc.

62 Clinical and economic burden of sleep disorders in advanced Parkinson's disease: A real-world US claims database analysis

Jimenez-Shahed J¹, Lee J², Manthena S³, Parab A³, Wang S³, Gao Z³, Huang A⁴, Pan X⁴, Wu H⁴, Iyengar R³; reethi.iyengar@abbvie.com

¹Department of Neurology, Icahn School of Medicine at Mount Sinai; ²AbbVie Inc.; ³AbbVie Inc.; ⁴Tigermid-BDM

BACKGROUND: Although sleep disturbances negatively affect activities of daily living and quality of life for people with advanced Parkinson's disease (aPD), data quantifying the clinical and economic burden of sleep disorders in aPD are limited.

OBJECTIVE: To quantify healthcare resource utilization (HCRU) and direct costs among people with aPD with and without sleep disorders.

METHODS: This retrospective claims analysis utilized the Optum Clinformatics Data Mart from January 2016 to June

2024. The aPD cohort included adults with a Parkinson's disease (PD) diagnosis, ≥1 claim for PD treatment, a levodopa-equivalent daily dose (LEDD) ≥1000 mg for their PD medication(s) during any consecutive 30-day period, and continuous healthcare enrollment for ≥12 months pre- and post-index date (the first date of qualifying PD treatment). Patients with a diagnosed sleep disorder in the 12-month baseline period were included in the sleep disorders group and those remaining made up the group without sleep disorders. Propensity score matching (1:1) was performed to balance baseline characteristics between groups with and without sleep disorders. All-cause HCRU and direct costs (adjusted to 2024 USD) within the 12-month post-index period were presented on a per-patient-per-year basis.

RESULTS: Of the 9477 people with aPD, 3068 (32.4%) had a sleep disorder. Among matched groups with and without sleep disorders (both n = 2983), mean (SD) age was 73.9 (7.9) and 74.0 (8.0) years; LEDD at index was 1340.3 (339.0) mg and 1335.3 (358.9) mg; and the proportion of male patients was 60.9% and 60.3%, respectively. The mean (SD) number of all-cause inpatient visits (0.6 [1.3] vs 0.5 [2.7]), outpatient visits (45.7 [37.4] vs 35.4 [36.7]), emergency room (ER) visits (1.3 [2.7] vs 1.1 [3.6]), and office visits (24.9 [19.1] vs 19.4 [19.0]) were significantly higher for matched groups with vs without a sleep disorder (all P<.0001). Mean (SD) total costs (\$50,120 [\$73,825] vs \$37,060 [\$73,114]) and costs of inpatient admissions (\$15,867 [\$49,638] vs \$10,560 [\$45,310]), outpatient visits (\$23,409 [\$36,563] vs \$17,588 [\$43,563]), ER visits (\$2712 [\$5254] vs \$2220 [\$8643]), and office visits (\$13,200 [\$30,334] vs \$9437 [\$35,875]) were significantly higher for those with vs without sleep disorders (all P<.0001).

CONCLUSIONS: Sleep disorders are associated with higher clinical and economic burden (greater HCRU and direct costs) among people with aPD, underscoring the importance of timely diagnosis and initiation of optimal treatments to manage sleep in people with aPD.

SPONSORSHIP: AbbVie Inc.

63 Clinical burden, care needs, and healthcare resource utilization among 5-2-1-positive vs 5-2-1-negative people with Parkinson's disease: Evidence from a real-world survey in the US

Iyengar R¹, Gratie D², Homola J², Lee J³, Thomas A², Lee I², Mascia D⁴, Gillespie A⁴; reethi.iyengar@abbvie.com
¹AbbVie Inc.; ²AbbVie; ³AbbVie Inc.; ⁴Adelphi

BACKGROUND: The 5-2-1 criteria can be used as a screening tool to help identify people with Parkinson's disease (PwP) who may be experiencing suboptimal motor control on oral medication.

OBJECTIVE: To compare the clinical burden, care needs, and healthcare resource utilization (HCRU) in PwP screening positive vs negative for 5-2-1 criteria in the US, using physician-completed patient record forms.

METHODS: Interim data from the US were drawn from the Adelphi Real World Parkinson's Disease Wave X Disease Specific Programme, a multinational, retrospective, cross-sectional survey conducted between November 2025 and June 2026. Physician-provided data based on patient record forms were used for this study. Included PwP were receiving oral therapy and not treated with subcutaneous infusions or device-aided therapy. PwP were categorized as 5-2-1-positive if they met ≥ 1 of the 5-2-1 criteria: taking oral levodopa ≥ 5 times/day, having ≥ 2 hours of off-time/day, or experiencing troublesome dyskinesia ≥ 1 hour/day. Physician-reported measures of clinical burden, care needs, and HCRU were compared descriptively between patients screening 5-2-1-positive vs negative. T-tests and chi-square tests assessed group differences.

RESULTS: Data from 483 PwP were included (5-2-1-positive, $n=403$; 5-2-1-negative, $n=80$). A higher percentage of 5-2-1-positive-PwP had a modified Hoehn & Yahr score ≥ 2.5 than 5-2-1-negative-PwP (35% vs 18%, $P<.05$). In line with the group inclusion criteria, 5-2-1-positive-PwP had higher mean (standard deviation [SD]) hours of daily off-time (4.2 [3.2] vs 0.4 [0.5], $P<.05$), off-hours while trying to sleep (2.7 [2.7] vs 0.5 [1.4], $P<.05$), and on-time with dyskinesia (mean 3.3 [3.0] vs 0 [0], $P<.05$). Approximately one-third (34%) of 5-2-1-positive-PwP remained independent without additional support or care, whereas two-thirds (65%) of 5-2-1-negative-PwP did ($P<.05$). Higher HCRU was seen among 5-2-1-positive-PwP, with a greater percentage using mobility aids (62% vs 36%, $P<.05$) and receiving professional care support (22% vs 6%, $P<.05$) than 5-2-1-negative-PwP.

CONCLUSIONS: Complementary to previous research, this study found that PwP in the US who were 5-2-1-positive exhibited greater clinical burden, care needs, and HCRU than 5-2-1-negative-PwP. These findings highlight the need for timely consideration of optimal therapy to mitigate the worsening of symptoms in PwP and associated incremental HCRU.

SPONSORSHIP: AbbVie Inc.

64 The lifetime economic burden of Tourette syndrome: A model-based analysis of incremental costs compared with the US general population

Shafrin J¹, Wang S², Zhang S², King P³, Nguyen K³, Shenouda L³, Flatt J³, Karkanas G³; jason.shafrin@fticonsulting.com
¹FTI Consulting, Los Angeles, CA, USA; ²FTI Consulting, Washington, DC, USA; ³Emalex Biosciences, Inc., Chicago, IL, USA

BACKGROUND: Tourette syndrome (TS) is a neurodevelopmental disorder with symptoms commonly presenting between ages 3 and 8 years. Approximately 1.4 million US individuals have TS/persistent tic disorder. Clinical symptoms can adversely affect multiple aspects of functioning, including cognitive performance, academic attainment, and quality of life, with impact extending into adulthood. Nevertheless, the lifetime economic burden of TS remains poorly understood.

OBJECTIVE: To quantify the incremental lifetime societal US economic burden of TS.

METHODS: A prevalence-based, cohort-level lifetime state-transition economic burden model was developed using inputs derived from a targeted clinical and economic literature review. The model captured multiple life stages and estimated incremental health care costs, education outcomes, income loss, and premature mortality relative to age-specific US general population benchmarks. Outcomes were stratified by TS severity (mild; moderate/severe). Outcomes were discounted at 3% annually and reported in 2025 US dollars.

RESULTS: The lifetime undiscounted per-patient economic burden of TS was \$2.31M higher vs the general population (\$4.66M vs \$2.35M). The lifetime discounted per-patient economic burden of TS was \$0.64M higher vs the general population (\$1.55M vs \$0.91M). Key drivers of the increased incremental economic burden were employment income (\$0.36M; 56% of total incremental burden; 45% reduced employment income vs general population), premature mortality (\$0.2M; 30% of total incremental burden; 7.5 incremental life-years lost), and health care costs (\$53,112; 8% of total incremental burden). Burden differed by age: childhood (0-17 years) incremental burden was \$3924/alive year, driven by health care costs (65%) and caregiver burden (35%); working-age (18-65 years) incremental burden was \$29,328/alive year, dominated by lost earnings (80%). Among adults ≥ 70 years, annual per-person burden was elevated (\$32,755/alive year) due to higher medical costs, though the total burden in this group was driven predominantly by mortality, with 7.5 incremental life-years lost over a lifetime horizon.

CONCLUSIONS: TS imposes a substantial lifetime economic burden relative to the US general population, driven predominantly by employment loss and premature mortality, as well as moderate increases in direct health care costs. Notably, adult employment loss is partly attributable to impaired academic attainment in childhood, suggesting that early treatment intervention for TS may mitigate long-term economic consequences.

SPONSORSHIP: Emalex Biosciences, Inc.

65 Healthcare resource utilization and costs of multiple system atrophy in the United States: An observational claims database study

Wald Grossman S¹, Rieckmann A², Shah M¹, Mehta A²; MNHS@lundbeck.com

¹Lundbeck; ²H. Lundbeck A/S

BACKGROUND: Multiple system atrophy (MSA) is a rare, rapidly progressive neurodegenerative disorder characterized by relentless functional decline, severe disability, and premature mortality. There are no approved treatments for MSA. Treatment is currently limited to suboptimal symptomatic therapy.

OBJECTIVE: To evaluate direct healthcare costs and healthcare resource utilization (HCRU) associated with MSA among commercially insured individuals in the United States.

METHODS: Using a US administrative healthcare claims database (IQVIA PharMetrics Plus), we compared HCRU and direct healthcare costs between people with MSA (PwMSA, defined by ≥ 2 ICD-10 diagnoses of G23.2, G23.9, or G90.3 during the study period) and matched MSA-free controls (matched on age, sex, state of residence, and health insurance type). Outcomes were assessed over a 12-month follow-up period anchored to the first recorded MSA claim between October 2016 and June 2023. Costs were estimated using a linear mixed-effects model accounting for patient-level clustering and were expressed in Q2 2025 US dollars.

RESULTS: Mean (SE) total healthcare costs for PwMSA in the year after diagnosis were \$43,747 (927), comprising total medical costs of \$31,197 (727) [outpatient: \$12,391 (283); inpatient: \$18,016 (605); emergency room (ER): \$711 (36); urgent care: \$26 (2)], and pharmacy costs of \$12,261 (498). The mean out-of-pocket medical costs paid by PwMSA in the year after diagnosis were \$7,269 (337). Mean total healthcare costs for matched MSA-free controls were \$13,212 (415). Compared to matched MSA-free controls, PwMSA incurred \$30,535 [95% CI: \$28,546, 32,523] higher mean total costs in the year following diagnosis, driven by significantly higher medical (+\$23,116 [\$21,555, 24,676]), inpatient (+\$14,838 [\$13,539, 16,138]), outpatient (+\$7,691 [\$7,083, 8,298]), and pharmacy

(+\$7,072 [\$6,008, 8136]) costs (all $p < 0.01$). HCRU, including the mean frequency of outpatient visits, ER visits, and days spent in inpatient facilities in the year following diagnosis were also significantly higher among PwMSA compared to matched MSA-free controls (+22.6 visits, +1.0 visit, and +8.8 days, respectively, all $p < 0.01$).

CONCLUSIONS: The higher healthcare costs and HCRU observed among PwMSA compared with MSA-free controls highlight the substantial economic burden associated with the disease. Frequent inpatient, outpatient, and emergency visits reflect the intensive care needs of this rapidly progressive disorder and underscore the urgent unmet need for effective therapies.

SPONSORSHIP: Lundbeck

66 The impact of delaying subcutaneous device-aided therapy for patients with advanced Parkinson's disease

Surbhi S¹, Iyengar R², Lee J³, Boodhna T⁴, Homola J⁴, Ignacio T⁵, Van Den Puttelaar R⁵, Subramaniam D⁶; jaehyun.lee@abbvie.com

¹University of Tennessee Health Science Center; ²AbbVie Inc.;

³AbbVie Inc.; ⁴AbbVie; ⁵OpenHealth Group; ⁶Saint Louis University School of Medicine

BACKGROUND: As Parkinson's disease (PD) progresses, the effectiveness of current oral therapies often decreases, therefore requiring treatment options such as continuous subcutaneous (SC) device-aided therapies. Despite known clinical benefits, SC therapies are often initiated late, leaving people with Parkinson's (PwP) subjected to prolonged periods of uncontrolled symptoms.

OBJECTIVE: To evaluate the clinical, humanistic, economic, and societal impact of delayed SC therapy among PwP who are uncontrolled on orals based on currently available treatments.

METHODS: A Markov model was developed to quantify the impact of timely versus delayed initiation of SC therapy, comprising foslevodopa/foscarbidopa (LDp/CDp), and continuous SC apomorphine Infusion (CSAI), in PwP. PwP progress through the model according to OFF time levels. Two cohorts were defined as 1) starting SC therapy at baseline (timely initiation cohort) and 2) assuming delayed initiation of SC therapy by one year (delayed cohort) with outcomes assessed over 3 years. During the delay, patients received oral standard of care, reflecting suboptimal disease control. Efficacy of LDp/CDp and CSAI was sourced from a Phase 3 trials. Efficacy outcomes were based on inputs from Adelphi and literature. Outcomes were then annualized and reported on a

per-patient basis, including healthcare resource utilization (HCRU), costs, and health outcomes.

RESULTS: In the timely initiation cohort, mean OFF time decreased following initiation of SC therapy, whereas the delayed cohort experienced worsening OFF time before SC therapy was initiated at 1 year. Over 3 years, delayed treatment resulted in a mean of 2.3 additional OFF hours per patient per day. At year 3, the delayed cohort still experienced 0.9 more OFF hours per day vs the timely cohort. A 1-year delay was associated with a \$22,234 increase (+59.1%) in annual medical costs per patient, largely driven by increased emergency room visits, hospitalizations, and nursing home care. Reduced work productivity in the delayed cohort translated to a yearly monetary loss of \$2614 (-80.6%) per patient and their caregiver. Delayed treatment resulted in a net increase of \$21,187 per patient and their caregiver annually (+11.6%) in total costs encompassing direct and indirect costs.

CONCLUSIONS: A 1-year delay in initiating SC therapies results in worse health outcomes and greater HCRU compared with timely initiation. Relatively modest delays in optimal treatment initiation can have substantial downstream clinical, humanistic, economic, and societal consequences.

SPONSORSHIP: AbbVie

Clinical Trials/Drug Development

76 Zeleciment rostudirsen led to trends in long-term improvement in clinical outcomes including cardiopulmonary function

Alboustani M¹, Apkon S², DeWaele L³, Flanigan K⁴, McMillan H⁵, Pane M⁶, Shieh P⁷, Woodcock I⁸, Bansal P¹, Ray S¹, Wang D¹, Kerr D¹, Naylor M¹, Guglieri M⁹; mariam.alboustani@dyne-tx.com

¹Dyne Therapeutics; ²Children's Hospital Colorado; ³University Hospitals Leuven; ⁴Nationwide Children's Hospital; ⁵Children's Hospital of Eastern Ontario; ⁶Fondazione Policlinico Universitario A. Gemelli; ⁷University of California, Los Angeles; ⁸Murdoch Children's Research Institute, Parkville, Victoria and The Royal Children's Hospital, Melbourne; ⁹Royal Victoria Infirmary, Newcastle University

BACKGROUND: DMD is characterized by deficiency of dystrophin, a protein critical for structural integrity and signaling in muscle cells. Manifestations of DMD are multisystemic, impacting skeletal, smooth, and cardiac muscle. Affected individuals exhibit progressive muscle weakness and typically lose the ability to walk around age 12-13, with death occurring around age 30, most often due to cardiopulmonary failure. Zeleciment rostudirsen (z-rostudirsen, or DYNE-251)

leverages TfR1 to deliver an exon 51 skipping PMO to key tissues relevant to DMD such as skeletal, including pulmonary, smooth and cardiac muscle with the goal of producing near-full length functional dystrophin.

OBJECTIVE: To evaluate the safety and efficacy of z-rostudirsen in individuals with DMD aged 4-16 with mutations amenable to exon 51 skipping.

METHODS: In the multiple ascending dose (MAD) portion of the phase 1/2 DELIVER trial (NCT05524883), 54 participants received z-rostudirsen (one of 8 regimens) or placebo Q4W or Q8W for 6 months. MAD data informed selection of 20 mg/kg Q4W as the dose to be studied in a registrational expansion cohort (REC), in which 32 participants were randomized 3:1 to 20 mg/kg Q4W z-rostudirsen or placebo for 6 months. In MAD and REC, after 6 months, participants entered an OLE/LTE and switched to or continued active treatment at 20 mg/kg Q4W.

RESULTS: At 6 months, increase in dystrophin protein and improvement in functional outcomes were noted. Long-term analysis of muscle content-adjusted dystrophin from four optional biopsies in participants treated with 20 mg/kg Q4W z-rostudirsen for >12 months, showed dystrophin levels at 18.33% of normal. Additional long-term data from the MAD showed sustained improvement through 24 months in multiple clinical endpoints of muscle function. Trends in stabilization or improvement over 24 months were also noted in cardiac and pulmonary function based on data from a limited subset of participants who were randomized to z-rostudirsen at baseline and for whom FVC%p and cardiac MRI-based assessments were available. As of August 19, 2025, z-rostudirsen had a favorable safety and tolerability profile based on 86 participants followed in DELIVER for up to 36 months.

CONCLUSIONS: Long-term DELIVER data suggest potential for further increases in dystrophin with ongoing treatment beyond 6 months, and corresponding trends in improvement in muscle function and potential preservation of cardiopulmonary function through 24 months. Additional data are needed to confirm cardiopulmonary effects.

SPONSORSHIP: Dyne Therapeutics

Dermatology

86 AMCP Market Insights: Beyond skin deep on the role of managed care in moderate-to-severe atopic dermatitis

Wolff D¹, Lebwohl M², Abdo M³, Adeboye A⁴, Contreras Z⁵, Gandhi G⁶, Richardson T⁷; dwolff@amcp.org; terry.richardson@impactedu.net

¹AMCP; ²Icahn School of Medicine at Mount Sinai; ³Alignment Health; ⁴Emory Healthcare; ⁵Regional Health Plan in Southern CA; ⁶Agadia; ⁷Impact Education, LLC

BACKGROUND: Moderate-to-severe atopic dermatitis (AD) imposes substantial burden, including persistent pruritus, sleep disruption, and impaired quality of life. Although targeted systemic therapies have improved outcomes, many patients continue to experience residual disease.

OBJECTIVE: To assess payer perspectives on unmet needs, treatment gaps, and emerging therapies in moderate-to-severe AD and identify opportunities for managed care organizations (MCOs) to improve access and outcomes.

METHODS: An AMCP Market Insights program convened 8 stakeholders in November 2025, including health plan leaders, a dermatologist, specialty pharmacy representatives, and a patient advocate. Participants reviewed presentations on the patient journey, treatment landscape, and emerging therapies, followed by moderated discussions. Polling questions captured payer perspectives, and results were analyzed to identify themes relevant to managed care decision-making.

RESULTS: Baseline polling of payers identified system-level barriers as key drivers of delayed care. Limited access to dermatology specialists and delays in diagnosis or referral were each selected by ~25% of respondents as the greatest opportunities for MCOs to address. After reviewing the treatment landscape, 88% of respondents reported significant or some gaps in available treatment options. Panelists highlighted persistent itch, sleep disruption, and high treatment burden despite therapy. Emerging therapies targeting the OX40/OX40L pathway generated interest due to potential durability and less frequent dosing; 43% of respondents indicated these agents could be positioned alongside or as alternatives to current biologics pending further safety, efficacy, and economic data. Tele-dermatology was identified by 50% of respondents as the most effective strategy to improve equitable access. In a post-program survey, 42.9% reported plans to implement practice or administrative program changes, while 42.9% reported plans to reinforce current approaches.

CONCLUSIONS: Managed care stakeholders identified persistent gaps in moderate-to-severe AD, including delayed

diagnosis, limited specialist access, and ongoing disease burden despite therapy. Improving timely access, care coordination, and equitable care delivery, supported by tele-dermatology, may help address these challenges. Emerging OX40/OX40L agents may offer more durable disease control; however, payers emphasized the need for long-term and real-world evidence to inform coverage decisions. Intent to implement practice changes suggests multi-stakeholder dialogue may both reinforce and inform payer decision-making.

SPONSORSHIP: Sanofi

87 Characterizing prescription access challenges in atopic dermatitis: A survey of patients and caregivers

Loiselle A, Johnson J, Smith Begolka W; allison@nationaleczema.org; wendy@nationaleczema.org
National Eczema Association

BACKGROUND: Atopic dermatitis (AD), the most prevalent form of eczema, is a chronic disease with a relapsing-remitting nature. Insurance delays and prescription denials create treatment uncertainty and can negatively affect quality of life. However, a contemporary assessment of coverage issues that includes the spectrum of new AD treatments approved in recent years is needed.

OBJECTIVE: To assess the frequency of insurance coverage delays or denials for AD prescription treatments.

METHODS: Adult AD patients (18+ years) or caregivers of pediatric AD patients (0-17 years) were recruited to complete a survey (July-October 2025) examining experiences with prescription treatment access in the preceding 12 months.

RESULTS: A total of 533 respondents were included (86.3% adult AD patients and 13.7% caregivers); 60.6% (n = 323) reported moderate to severe AD symptoms over the past year. Among those with the same insurance for ≥12 months (n = 364), 32.6% (n = 119) experienced at least one AD prescription delay or denial during that period. Coverage issues were more frequent for those who changed insurance in the past year (51.9%, n = 69/133). Prior authorization was the most frequently cited coverage barrier, reported by more than half of affected respondents (56.0%; n = 106/188). Of prior authorizations that were ultimately approved, 43.6% (n = 17/39) took more than five weeks to resolve.

CONCLUSIONS: In this survey of AD patients and caregivers, one in three respondents with stable insurance coverage experienced a prescription delay or denial over 12 months, increasing to one in two for those who changed insurers. These findings underscore the need for policy reforms that streamline prior authorization, limit unnecessary delays,

and ensure timely access to guideline-recommended AD therapies, reducing avoidable burden on patients and families.

SPONSORSHIP: Funded by the National Eczema Association

88 Atopic dermatitis prescriptions in rural vs. urban areas in the United States: Analysis of claims data

Loiselle A¹, Smith Begolka W¹, Simpson E², Abuabara K³, Dosono B¹, Drucker A⁴, Eichenfield L⁵, Wallace Hood T¹, Silverberg J⁶, Takeshita J⁷; wendy@nationaleczema.org

¹National Eczema Association; ²Department of Dermatology, Oregon Health & Science University; ³Department of Dermatology, University of California, San Francisco;

⁴Department of Medicine, University of Toronto and Women's College Hospital; ⁵Rady Children's Hospital-San Diego and University of California San Diego School of Medicine;

⁶Department of Dermatology, The George Washington University School of Medicine and Health Sciences; ⁷University of Pennsylvania

BACKGROUND: Atopic dermatitis (AD) is a chronic, inflammatory skin disease associated with substantial disease burden. While treatment options have expanded in recent years, access to these treatments may vary by geography. Little is known about how rurality shapes real-world AD prescription patterns at a national level.

OBJECTIVE: To ascertain prescription use patterns for AD patients in rural and urban areas in the United States.

METHODS: Using U.S. administrative claims data, we identified commercially insured patients with ≥ 1 AD diagnosis code between January 1, 2022, and December 31, 2023. AD-related prescription fill rates per 1,000 members with diagnosed AD and the proportion with ≥ 1 AD-related fill were calculated and stratified by rurality using Rural Urban Commuting Area (RUCA) codes (urban: 1-3; rural: 4-10), with estimates adjusted for national age and gender distributions.

RESULTS: Data from 977,873 commercially insured individuals were included, with an adjusted AD prevalence of 2.2%. Overall, a slightly lower proportion of rural members with AD had at least one AD-related prescription fill compared to urban members with AD (46.0% vs. 48.9%). Fill rates for topical JAK inhibitors were approximately 50% lower in rural members (13.4 vs. 26.9 per 1,000), and topical calcineurin inhibitor fill rates were approximately 35% lower (73.1 vs. 98.6 per 1,000). In contrast, rural members had notably higher AD-related systemic corticosteroid (SCS) fill rates compared to urban members (70.6 vs. 57.0 per 1,000), with 5.0% of rural members filling at least one SCS prescription versus 3.9% of urban members. Dupilumab utilization was similar across settings (4.4% rural vs. 4.2% urban).

CONCLUSIONS: In this descriptive analysis of national claims data, commercially insured individuals in rural areas showed lower utilization of newer non-steroidal AD therapies and higher reliance on SCS compared to their urban counterparts. Understanding the drivers of these disparities, whether prescriber availability, formulary differences, or disease severity, may inform policy and payer strategies to promote more equitable access to guideline-recommended AD therapies.

SPONSORSHIP: This study was funded by a CDC grant

Digital Health and Technology

91 Real-world impact of proactive financial assistance automation on access, copay, adherence, and persistence among specialty pharmacy patients

Mathews K, LaPointe S, Watkins H, Purvis C, Dunn M; kelly.mathews@optum.com
OptumRx

BACKGROUND: The rising cost of specialty prescription medications has created sub-optimal adherence and impeded timely access to vital medications. This may increase disease complications and overall health care costs. Financial assistance (FA) support such as manufacturer copay cards, patient assistance programs and foundation grant programs may help offset patient out-of-pocket costs. Optum Specialty Pharmacy has implemented proactive FA automation to reduce patient out-of-pocket financial burdens and improve timely access to specialty medications.

OBJECTIVE: To evaluate FA utilization as well as patient \$0 out-of-pocket rate pre- and post-implementation of proactive FA automation. The secondary objectives were to measure patient persistence and adherence.

METHODS: This study compared patients who were proactively connected to FA (Participants) between January 1, 2024, and June 30, 2024, to a similar pre-implementation group (Control) between January 1, 2022, and June 30, 2022. The study included treatment-naïve patients with $> \$5$ copay before applying FA. A sub-analysis of oncology, neurology, and inflammatory conditions was conducted. Data was collected from the prescription dispensing platform at Optum. Adherence was measured through proportion of days covered (PDC) and % optimally adherent (PDC $\geq 80\%$). Persistence was measured through days on therapy (DOT) and persistence curve. Logistic regression and multivariate analysis of covariance (MANCOVA) were used for primary and secondary objectives analysis. Alpha was set to 0.05.

RESULTS: A total of 94,484 patients in the pre-period and 114,609 patients in the post-period were included. Baseline characteristics were controlled for using covariates. Participants had an 8.7% increase in FA utilization and had 46 times higher odds of having \$0 copay ($P < 0.0001$). Participants had 0.5% higher PDC ($P < 0.005$) and similar % optimal adherence ($P = 0.39$). Participants had an additional 5 days on therapy and 2.5% higher persistency at the 8th fill ($P < 0.0001$).

CONCLUSIONS: Post-implementation of proactive FA automation showed patients' copay per fill was significantly reduced and improved patient adherence and persistence outcomes. This research can justify continued development of automated tools to facilitate access to financial support programs. Research to evaluate total cost of care utilizing an automated FA platform can further show the value to health outcomes.

SPONSORSHIP: None

92 Budget impact of a prescription digital therapeutic for pediatric amblyopia: US commercial and Medicaid payer perspectives

Hancock S¹, Bohnsack B², Oke I³, Gaier E⁴; shelley@luminopia.com

¹Luminopia; ²Ann & Robert H Lurie Children's Hospital of Chicago; ³Boston Children's Hospital, Harvard Medical School; ⁴Picower Institute for Learning and Memory

BACKGROUND: Amblyopia, a neurodevelopmental visual disorder, affects ~2% of US children and is the leading cause of monocular vision loss. First-line treatment with refractive correction, patching, and/or atropine leaves a majority of treated children with persistent amblyopia. Luminopia is an FDA-cleared prescription digital therapeutic indicated for the improvement of visual acuity in amblyopia (anisometropic and/or mild strabismic) in patients ages 4-12 years.

OBJECTIVE: To estimate the 3-year budget impact of Luminopia from US commercial and Medicaid payer perspectives under two coverage scenarios: first-line (all indicated patients) and second-line (persistent amblyopia after failed first-line care).

METHODS: A 3-yr prevalence-based budget impact model was developed from US commercial and Medicaid perspectives. Pediatric ages 4-12 and amblyopia prevalence yielded a diagnosed population (75% diagnosis × 60% indicated subtypes), identifying the first-line eligible pool of ~1,009 commercial/~1,580 Medicaid patients/yr per 1M. Under second-line coverage, a sequential funnel of refractive correction and patching with payer-differentiated success rates (glasses 30%/25%; patching/atropine 60%/48% for commercial/Medicaid per IRIS-50 criteria, respectively) and a 6-month

step-edit narrowed the pool to ~216 commercial and ~419 Medicaid persistent-amblyopia patients/year. The new scenario added an 8-month Luminopia course at \$575/month, net of \$75 commercial copay or 23.1% Medicaid rebate. Cost growth reflects uptake ramp applied to a stable annual refractory pool. Outputs were PMPM across low (3/8/15%), base (10/20/30%), and high (12/25/40%) Y1/Y2/Y3 uptake scenarios.

RESULTS: Baseline plan cost for amblyopia was \$0.024 PMPM (commercial) and \$0.056 PMPM (Medicaid). Under base-case uptake, second-line coverage added Luminopia PMPM of \$0.0072 (commercial) and \$0.0123 (Medicaid) in yr 1, rising to \$0.0216 and \$0.0370 in yr 3; 3-yr average was \$0.0144 and \$0.0247. First-line coverage raised average 3 yr PMPM to \$0.0673 (commercial) and \$0.0931 (Medicaid). Per-patient net course plan cost was \$4,000 (commercial) and \$3,537 (Medicaid). Costs were most sensitive to first vs. second line positioning, uptake, and net course price.

CONCLUSIONS: Coverage criteria are the primary determinant of plan budget impact for Luminopia. Second-line coverage of persistent amblyopia keeps PMPM below \$0.05 in both commercial and Medicaid segments over 3 years; first-line remains affordable at under \$0.10 3-yr average PMPM. The model excludes downstream medical-cost offsets from improved visual outcomes.

SPONSORSHIP: Luminopia, Inc.

93 Payer engagement with pre-approval and evidence resources: A real-world analysis of engagement timing and patterns

Harkins S, Ruban C, Chang J; sydney.harkins@cencora.com; Jasper.Chang@cencora.com
Cencora

BACKGROUND: At the pre-approval stage, biopharma companies provide payers with evidence that describes investigational products and their potential place in therapy. These resources are intended to support early understanding and inform formulary decision-making. However, data on payer engagement with pre-approval resources over time were limited. Using engagement data from FormularyDecisions, a secure digital platform used by verified payers to access evidence supporting formulary decision-making, this study examined real-world engagement patterns with pre-approval resources to understand how materials are accessed throughout the decision-making process.

OBJECTIVE: To examine real-world engagement with pre-approval resources within FormularyDecisions to inform strategies for supporting formulary decision-making prior to product approval.

METHODS: A retrospective observational analysis was conducted using engagement data with pre-approval resources between June 1, 2018, and April 30, 2026. Metrics captured interactions with pre-approval resources over time, and materials were categorized by evidence type to assess patterns of access across the pre-approval period.

RESULTS: Across 32 pre-approval products, engagement with resources was generally sustained rather than only immediate. Median time to engagement was 149 days, with a mean time to engagement of ~249 days. Close to 37% of engagements occurred within 90 days following resource availability, while more than 60% occurred beyond 90 days, demonstrating a continuous pattern of engagement. Engagement varied by evidence type. Clinical trial data and pre-approval information exchange (PIE) presentations accounted for the highest engagement and were more likely to be accessed earlier relative to other resource types. In contrast, materials such as disease state resources and real-world evidence demonstrated slower uptake but sustained engagement over longer periods. Repeated engagement with the same resources was observed, indicating that payers revisited evidence as information needs evolved during the formulary decision-making process.

CONCLUSIONS: Payer engagement with resources was sustained over extended periods. These findings suggest that PIE is a meaningful contributor across a product's lifecycle in formulary decision-making, exceeding the impact of strategies focused solely on launch period dissemination.

SPONSORSHIP: Cencora

94 Comparative performance of general-purpose large language model-based approaches for title/abstract screening in literature reviews

Devani D, Fox G; darshdevani@openhealthgroup.com
OPEN Health

BACKGROUND: Artificial intelligence (AI) is increasingly being used in literature reviews; as such, it is imperative to understand the comparative performance of general-purpose large language model (LLM)-based screening approaches.

OBJECTIVE: To compare 2 general-purpose LLM-based methods, ChatGPT and Claude, in title/abstract screening against a human-reviewed reference standard.

METHODS: Two general-purpose LLM title/abstract screening approaches were evaluated in a cardiovascular literature review dataset of 992 references. Initially, a human reviewer identified includable references, which serve as the reference standard. ChatGPT (GPT-5.5) and Claude (Claude Sonnet 4.6) were then each evaluated independently, without iterative refinement, using the same predefined 5-question algo-

rithm encompassing cardiovascular population, adults aged ≥18 years, human studies, post-cardiovascular event outcomes or burden, and eligible observational study designs, with all 5 criteria required for inclusion. Sensitivity, specificity, accuracy, and precision were assessed against the human reference standard.

RESULTS: ChatGPT advanced 65 references and identified 14 of 98 references included by the human reviewer (sensitivity = 0.14), missing 84 human-included references. 927 of 992 references were excluded by ChatGPT indicating specificity of 0.94, accuracy 0.86, and precision 0.22. Claude advanced 492 references and identified 86 of 98 references included by the human reviewer (sensitivity = 0.88), missing only 12 human-included references. However, specificity was 0.55, accuracy 0.58, and precision 0.18.

CONCLUSIONS: The approaches applied to the same dataset produced markedly different results. ChatGPT achieved high specificity but critically low sensitivity, missing 86% of human-included references. This suggests overly strict criteria interpretation by the model. In title/abstract screening, sensitivity is the primary metric; missed references cannot be recovered, and high specificity or accuracy alone may reflect restrictive exclusion rather than effective screening. Claude demonstrated a more balanced profile with higher sensitivity. These results represent a first-pass evaluation without prompt refinement; iterative refinement may improve performance but adds resource costs that should be weighed against efficiency gains. For literature reviews supporting HTA submissions and other cases where completeness is essential, AI models with higher sensitivity should be prioritized.

SPONSORSHIP: OPEN Health

95 Governance and oversight of artificial intelligence (AI) in clinical decision-making at US health systems

Terrone C, Miller C; christopher.terrone@precisionaq.com
Precision AQ

BACKGROUND: As health systems increasingly deploy AI technologies for clinical decision-making, the pace of innovation requires agile governance. AI tools are already influencing diagnosis and treatment, which in turn impacts pharmaceutical product choices and overall utilization. Manufacturers must understand how health systems govern AI use in order to effectively engage and align products and strategies in this environment.

OBJECTIVE: To assess how health systems are governing AI implementation in clinical decision-making.

METHODS: Precision AQ conducted a survey of 25 health system decision-makers in Q2 2026. Participants were screened for those whose organizations are using AI in clinical decision-making, and who are involved in their organization's AI policy.

RESULTS: All respondents report AI governance at their system: 76% have formal AI governance, such as performance monitoring and accountability (24%), approval authority (40%), or advisory only (12%). Twenty-four percent indicate ad hoc governance. Governance bodies are multidisciplinary, most often including clinical informatics and decision support (72%), IT/AI implementation leads (72%), and clinical (68%) and pharmacy (68%) leadership. Governance is frequently aligned with external standards, with most respondents selecting Joint Commission/CHAI (72%) and NCQA standards (56%). Health systems are also implementing policies to guide clinician use of third-party tools such as OpenEvidence, with 96% reporting policies are already in place or in development. Prior to deploying AI tools, most health systems require validation, including usability testing in the EHR (80%), clinical expert review of AI outputs (72%), review of vendor documentation (68%), or testing against patient cases (32%). Health systems are open to collaborations with manufactures to improve AI-enabled clinical decision-making; 40% indicate they are very or somewhat likely to pursue partnerships, 28% were neutral, and 32% unlikely. Manufacturer capabilities that would most improve AI-driven drug selection were clinician education (56%) and machine-readable clinical and economic evidence (52%).

CONCLUSIONS: As AI deployment expands, health system decision-making around AI increasingly reflects multidisciplinary oversight, alignment to external standards, and validation of deployed tools. Manufacturers seeking to engage health systems must account for these governance frameworks, decision-makers, and processes when developing partnership and engagement strategies.

SPONSORSHIP: Precision AQ

96 The potential of wearables and portable smart devices to transform dementia managed care: A scoping review

Mazumder D¹, Gauni R², Loi S³, Rishabh R⁴, Sibal A²; dibyajyoti_mazumder@optum.com

¹Optum Tech, Noida, India; ²Optum Technology; ³Optum Rx PBM Operations; ⁴OptumRx

BACKGROUND: The potential of wearables in the overall care continuum of Alzheimer's disease and related disorders (ADRD) has been well studied. The recent guidelines for diagnostic evaluation, testing, counseling, and disclosure of ADRD (DETeCD-ADRD) have suggested that evidence on role of

digital health technologies biomarkers (e.g., wearables, self-administered remote computerized cognitive and behavioral testing) in managing ADRD is evolving.

OBJECTIVE: To assess the published evidence supporting the role of wearables and portable smart devices in a) diagnosis, b) treatment and c) monitoring of ADRD in the US.

METHODS: A targeted literature review was designed to identify observational studies or randomized controlled trials assessing the role of wearables in diagnosis, treatment, and/or monitoring of ADRD in the US. Studies published in the past 5 years were searched in PubMed. Studies were qualitatively assessed.

RESULTS: A total of 2144 studies were identified in the initial search, of which 42 qualified for the final analysis. Most were observational studies, except for one. Smartwatches, EEG headbands, GPS trackers, and accelerometers were the most widely studied devices (>80%, alone or in combination), while few studies also assessed smartphone-based applications (~12%) and smart ring (~5%). The primary objective of majority of studies was to evaluate the role of these devices in either diagnosis or monitoring of functional and/or cognitive health. Most widely studied outcomes (alone or in combination) were driving, physical activity, sleep, gait, and cognitive status. Only few studies (6) have aimed to establish digital markers (driving, sleep, speech) as surrogate for clinical outcomes. Two studies assessed portable digital devices for diagnosis and clinical phenotyping. Only one study reported therapeutic use of a smart tablet-based application for cognitive improvement. Overall, the quality of evidence is low, which is also highlighted by >90% studies.

CONCLUSIONS: The recent research assessing the role of wearables and portable smart devices in the management of ADRD in the US is limited. Although studies have shown meaningful association between digital markers from wearables/smart devices and clinical outcomes, the quality of evidence is low due to practical limitations associated with such studies. With advancement of large language models, pragmatic approach of chart reviews combined with wearables data might help establish the potential of these devices in managed care settings.

SPONSORSHIP: None

97 Can AI-generated evidence meet managed care standards? A rapid literature review of performance guidance for AI in systematic literature reviews

Martin S, Simon A, Fox G; stephanmartin@openhealthgroup.com

OPEN Health

BACKGROUND: With artificial intelligence (AI) increasingly utilized to accelerate systematic literature reviews (SLRs) for value assessments and formulary decisions, stakeholders must ensure the reliability of AI-generated evidence.

OBJECTIVE: To explore and synthesize guidance from industry organizations and health technology assessment (HTA) bodies on the performance metrics expected for AI in evidence synthesis.

METHODS: Using Claude in Web search mode, methodological standards published between 2023 and 2026 concerning AI in SLRs were identified and subsequently reviewed. Sources included reporting guidelines (PRISMA), methodological frameworks (RAISE), and position statements from industry organizations (AMCP, ISPOR) and HTA bodies (NICE, CDA, IQWiG). Data were extracted on performance metrics, acceptable thresholds, and validation requirements for AI use in title/abstract screening and full-text review.

RESULTS: Explicit numerical thresholds for AI performance metrics remain largely undefined, but strong consensus is emerging that AI must demonstrate very high sensitivity to prevent omission of pivotal evidence, as well as non-inferiority to dual-human review. IQWiG's 2023 General Methods permit validated machine learning classifiers in search and screening, citing the Cochrane RCT Classifier (~99% recall) as a benchmark. Precision is universally treated as secondary; modest precision is acceptable if it safeguards sensitivity. Although AI can meaningfully reduce screening workload, CDA's 2025 position statement emphasizes that efficiency gains must not come at the cost of missing evidence that could alter coverage or value decisions. In the absence of explicit thresholds, transparency becomes the proxy: RAISE recommendations and the PRISMA-trAIce checklist both call for comprehensive reporting of validation methodologies and performance metrics, echoed by ISPOR's ELEVATE-GenAI reporting guidelines alongside a human-in-the-loop expectation for title/abstract screening and full-text review. No formal AMCP guidance has been issued to date.

CONCLUSIONS: Although no specific numerical thresholds for AI performance metrics were identified, managed care professionals evaluating AI-generated SLRs should demand high-sensitivity models that prioritize capturing all relevant evidence over sheer precision. A semi-automated approach,

where AI conservatively excludes definitively irrelevant records while humans verify all potential inclusions, balances workflow efficiency with the rigorous evidentiary standards required for sound managed care policy decisions.

SPONSORSHIP: This project was funded by OPEN Health

98 Prior authorization process improvements and artificial intelligence-enabled solutions among United States health plans

Lokhandwala N, Terrone C, Cournoyer A; nikki.lokhandwala@precisionaq.com

Precision AQ

BACKGROUND: Prior authorization (PA) remains a key utilization management tool but continues to create administrative burden and delays in patient access. Health plans have increasingly implemented process improvements, including automation and artificial intelligence (AI), to improve efficiency. However, evidence of real-world impact on timelines and approval outcomes remains limited.

OBJECTIVE: To evaluate whether recent PA initiatives have improved efficiency and approval outcomes, identify tools and strategies used to streamline decision-making, and assess remaining challenges and optimization opportunities.

METHODS: Precision AQ conducted a survey of 27 United States healthcare decision-makers from national and regional health plans and pharmacy benefit managers (PBMs) (April-May 2026).

RESULTS: All respondents (N = 27) reported implementation of new processes to enhance PA approval, with ~90% indicating moderate to high levels of organizational activity. Despite these efforts, key operational challenges persist, most notably incomplete or incorrect submissions from provider offices (67%) and high PA request volume (52%). Adoption of automated tools was widespread as 81% of respondents reported implementing AI-enabled PA tools, and an equal proportion reported rules-based auto-approval systems. Among those who implemented AI systems, the most utilized tool was automated clinical criteria matching (68%). Adoption of these solutions improved decision timelines as the proportion of same-day approvals increased by 30% over 2 years; decisions within 3 business days increased by 6%, demonstrating steady approvals. Delays were most often attributed to the initial submission (44%), driven by incomplete submissions (85%). Provider education and improved submission quality were cited as key optimization opportunities for manufacturers to streamline the PA process.

CONCLUSIONS: PA process improvements through AI and automation have made measurable strides to improve efficiency and accelerated decision timelines; however, these

enhancements remain incremental rather than transformative as initial submission quality continues to limit performance. These findings emphasize the need to target root causes of delays, particularly at initial submission, where manufacturers can support improvements through provider education, clearer documentation, and alignment with payer requirements.

SPONSORSHIP: Precision AQ

Drug Pricing, Payment, and Reimbursement

106 Do prices and doses differ for initial and follow-on indications? An analysis of multi-indication orphan drugs

Lin C¹, Beinfeld M², Rucker J², Brennan C², Hughes T³, Phillips G³, Chambers J²; Ching-Hsuan.Lin@tuftsmedicine.org
¹Center for the Evaluation of Value and Risk in Health, Tufts Medical Center; ²The Center for the Evaluation of Value and Risk in Health, Institute for Clinical Research and Health Policy Studies, Tufts Medical Center; ³Argenx

BACKGROUND: The US pharmaceutical market typically relies on unit-based pricing, whereby a drug's price per unit (e.g., per tablet or per milligram) remains constant across indications. Therefore, when dosing differs across indications, unit-based pricing produces proportionally different treatment prices that may not reflect clinical value differences. For example, maralixibat's annual list price is higher for its follow-on indication: \$1,322,000 for progressive familial intrahepatic cholestasis (annual dose of 6,656 mg) versus \$578,000 for Alagille syndrome (annual dose of 2,913 mg). The prevalence and magnitude of such dose- and price-based variation remains poorly characterized, particularly among high-priced orphan drugs with multiple indications.

OBJECTIVE: To quantify dosing and pricing differences across indications for multi-indication orphan drugs.

METHODS: We identified novel orphan drugs with multiple FDA-approved orphan indications approved 2000 to 2024. We classified each indication as cancer or non-cancer and as pediatric or adult. We estimated annual dosing from FDA labeling, supplemented with clinical trial data and National Center for Health Statistics estimates for weight- or body surface area-based dosing. We estimated annual prices using July 2025 wholesale acquisition costs (Red Book). For each follow-on indication, we calculated dose and price ratios relative to the initial indication.

RESULTS: Among 565 drugs, 105 had multiple orphan indications (N=274 indications, 61% cancer; 23% pediatric). We excluded 18 drugs without follow-on indications, 43 with identical dosing across indications, and one without pricing information. The final sample included 43 drugs and 70 follow-on indications (46% cancer; 33% pediatric). Across follow-on indications, the mean (SD) and median (IQR) dose ratios (follow-on vs initial) were 4.4 (20.5) and 1.3 (0.7-2.0), respectively; corresponding price ratios were 2.3 (3.9) and 1.0 (0.9-2.0). Specifically, 56% (39/70) of follow-on indication required higher doses; of these, 77% (30/39) were associated with higher annual prices.

CONCLUSIONS: Follow-on indications for multi-indication orphan drugs frequently require higher dosing and are often associated with higher annual prices. Unit-based pricing ties reimbursement to dose intensity without accounting for clinical value. Rather than unit-based pricing, alternative approaches, such as indication-based or outcomes-based pricing, may better align reimbursement with clinical value across indications.

SPONSORSHIP: This study was supported by Argenx.

107 A 3-year actuarial budget impact model (BIM) for perfluorohexyloctane and lifitegrast for dry eye disease from a US commercial payer perspective

Nair A¹, Talwar A², Leier J³, Stokes N³, Warren G³; abhishek.nair@bausch.com

¹Bausch and Lomb Americas Inc.; ²Bausch & Lomb Americas Inc.; ³Axene Health Partners

BACKGROUND: Dry eye disease (DED) is a multifactorial disease of the tear film and ocular surface characterized by symptoms of discomfort, visual disturbance, tear film instability, with potential damage to the ocular surface leading to redness, inflammation, burning, stinging and irritation. Perfluorohexyloctane (PFHO) is a prescription eye drop that targets tear evaporation. Lifitegrast (LIF) is a prescription eye drop LFA-1 antagonist that reduces ocular surface inflammation.

OBJECTIVE: To estimate the 3-year actuarial budget impact of adding PFHO and LIF as co-preferred branded drugs to the formulary for treating dry eye disease from a US commercial payer perspective.

METHODS: Study utilized an excel-based actuarial BIM simulating a US commercial fully insured 1-million-member health plan to estimate the year-over-year (YoY) economic impact on the health plan. Study assumed total dry eye prescription rate of 5.2 prescriptions per 1000 plan members. Drug costs and utilization were derived from the MediSpan database

and MarketScan data, along with actuarial judgment and expertise. Base-case scenario assumed PFHO and LIF to be non-preferred branded drugs. Based on prior literature the study assumed the average member enrollment months to be 10.8 with a prescription utilization rate of 2.1%. The economic impact metrics included net plan cost per member per month (PMPM) and the total PMPM cost to position PFHO and LIF as co-preferred branded drugs to treat patients with DED.

RESULTS: Among 1-million-member commercial fully insured simulated health plan, the PFHO-LIF co-preferred branded formulary positioning compared to base-case PFHO-LIF non-preferred branded positioning yielded extensive YoY favorability on net plan cost PMPM (Year 1: \$0.20 vs. \$0.25, $\Delta = -\$0.05$; Year 2: \$0.20 vs. \$0.26, $\Delta = -\$0.06$; Year 3: \$0.19 vs. \$0.26, $\Delta = -\$0.07$). There was a nominal YoY increase in total PMPM cost, which includes payer, patient, and manufacturer liabilities (Year 1: \$0.47 vs. \$0.46, $\Delta = \$0.01$; Year 2: \$0.49 vs. \$0.48, $\Delta = \$0.01$; Year 3: \$0.52 vs. \$0.49, $\Delta = \$0.03$). Market share growth, rebate levels and introduction of newer drugs are key factors that influenced the actuarial budget impact model.

CONCLUSIONS: Co-preferred branded formulary positioning of PFHO-LIF for patients with DED generated significant payer savings of 20%, 23.1% and 26.9% YoY respectively compared to non-preferred formulary positioning with minimal impact on the total PMPM cost supporting the economic value proposition for fully insured managed care populations.

SPONSORSHIP: The study was funded by Bausch and Lomb Americas Inc.

108 Patient experience, medication delays and life impacts with copay maximizer programs

Slejko J¹, Poudel N¹, Gu X², Koulilianos K³, dosReis S¹, Wong W⁴, Majda T⁵; jslejko@rx.umaryland.edu

¹University of Maryland School of Pharmacy; ²University of Maryland, Baltimore; ³National Bleeding Disorders Foundation; ⁴Genentech; ⁵Genentech Inc.

BACKGROUND: Despite growth in copay maximizer programs (CMP), patients' experiences are not well characterized.

OBJECTIVE: To characterize patient experiences with enrollment, medication access, and program impacts.

METHODS: We used an iterative, multi-phased, and stakeholder-engaged approach to develop and pilot test our survey instrument. We recruited participants from January to April 2026 through Rare Patient Voice who had commercial insurance and specialty medication use and were able to identify their CMP. Key measures included CMP experience, medication access delays, and life impacts. Respondents' experiences

were categorized as positive or negative based on six Likert-scale questions about their feelings at time of enrollment, including whether they believed their out-of-pocket costs would decrease, had a clear understanding of the program, felt they had no other choice but to enroll, did not understand why they needed to enroll and/or had confusion about the program. Respondents self-reported delays in medication access. Life impacts included stress about obtaining medication, changing one's health plan or job due to CMP experiences. Descriptive statistics and univariate logistic regressions evaluated the association of experience and medication delays with life impacts.

RESULTS: Of 260 eligible respondents who identified a CMP, there were 205 complete, high-quality responses that constituted the analytic sample. Most ($n = 114$; 56%) reported a negative experience. Ninety-four (47%) reported stress about obtaining their specialty medication, and those with a negative experience had a 3.9 (95% CI: 2.3-6.6) higher odds of stress than those with a positive experience. Among those with a negative experience, 32 (28%) considered changing/changed their health plan, with a 3.4 (95% CI: 1.4-7.8) higher odds than those with positive experience; there was no association with job change. Sixty-nine (34%) reported medication access delays. Relative to those not reporting delays, those reporting delays had a higher odds of experiencing stress 12.0 (95% CI: 6.3-22.8), stopping/changing medication (OR: 2.7, 95% CI: 1.5-4.8), worsening condition/symptoms (OR: 9.9, 95% CI: 5.2-18.9), considering/changing health plans (OR: 2.9, 95% CI: 1.4-5.9), and considering/changing job (OR: 14.7, 95% CI: 3.2 - 67.5).

CONCLUSIONS: Over half of respondents enrolling in CMPs had negative experiences. Negative experiences correlated with life impacts on health plan or job changes. Medication delays correlated with health and life impacts.

SPONSORSHIP: Genentech Inc.

109 Expected impact of MFP on Part B Drugs in IPAY2028 on Medicare and Commercial lines of business

Borchardt M¹, Martin A¹, Terrone C²; molly.borchardt@precisionaq.com

¹PrecisionAQ; ²Precision AQ

BACKGROUND: HHS announced the list of 15 drugs, including several Medicare Part B drugs for the first time, selected for negotiation for MFP, taking effect in 2028.

OBJECTIVE: To understand how payers expect IRA-related Part B drug pricing to affect reimbursement and management of impacted brands and their competitors for Medicare and commercial plans.

METHODS: Precision AQ conducted a survey of health plan decision-makers from April to May 2026. Respondents were screened for those with knowledge of their organization's approach to managing provider-administered (buy-and-bill) drugs under the medical benefit in both commercial and Medicare lines of business. Eighteen respondents completed the survey.

RESULTS: Respondents were asked how access and reimbursement would change for the Medicare Part B drugs selected for negotiation in IPAY 2028 and their competitors across six management approaches: provider reimbursement, rebates, preferred positioning, step therapy, medical policy/PA, and site of care steerage. On the Medicare benefit, once MFP pricing takes effect, preferred positioning (67% of plans), step therapy (56%), and rebate strategy (56%) are the most likely levers to favor negotiated products. Seventy-two percent expect MFP to have a moderate-to-major spillover effect on commercial benefits, where preferred positioning (56%) and rebate strategy (56%) are the most likely approaches to favor negotiated products. Less than one quarter (22%) expect to use any management lever to favor competitor products. Currently 72% report using ASP as the pricing benchmark for reimbursing provider administered drugs on their commercial plans. For these respondents, 77% expect to shift to MFP as the reimbursement methodology if CMS stops publishing an ASP for selected Medicare part B drugs. When ranking potential negative impacts to avoid when selecting an ASP methodology replacement, 53% of respondents ranked shifts in utilization to higher cost competitor products as the top concern, and 31% selected negative net cost recovery.

CONCLUSIONS: Payers are likely to prefer part B drugs selected for MFP negotiation in IPAY 2028 for both their Medicare and commercial lines of business. Spillover onto the commercial lines of business is highly likely as a majority of payers surveyed utilize ASP-based reimbursement and may consider adjusting the methodology for selected products in the future. Stakeholders should consider the likely downstream impacts to both plans and providers given the potential shift in reimbursement methodology.

SPONSORSHIP: None

110 Patient voices in copay maximizer programs: Preferences, experiences, and tradeoffs

Poudel N¹, dosReis S¹, Gu X², Koulianos K³, Wong W⁴, Majda T⁵, Slejko J¹; npoudel@rx.umaryland.edu

¹University of Maryland School of Pharmacy; ²University of Maryland, Baltimore; ³National Bleeding Disorders Foundation; ⁴Genentech; ⁵Genentech Inc.

BACKGROUND: Evidence on patient preferences and experiences with copay maximizer programs (CMP) is limited.

OBJECTIVE: To elicit patient preferences for key attributes of CMP, and to assess the alignment between stated preferences and patient-reported real-world experiences.

METHODS: We administered a cross-sectional survey from January to April 2026. Eligible participants were commercially insured U.S. adults (≥ 18 years) using specialty medications who were required to enroll in or had enrolled in a CMP and could identify the program name. Participants were recruited via Rare Patient Voice. The literature and stakeholder input informed the attributes for the best-worst scaling (BWS) experiment. We assessed the relative importance of 9 CMP attributes using a balanced incomplete block design (12 tasks; 6 attributes per task). Each respondent completed 6 randomly assigned tasks, selecting the most and least important attribute in each task. Patient experiences, measured in 9 domains corresponding with each attribute, were dichotomized as a positive or negative experience. We estimated preferences using standardized best-worst scores and conditional logit (MaxDiff) models. Tradeoffs were calculated as a utility ratio. Univariate logistic regression examined associations between standardized best-worst scores and corresponding experience domains.

RESULTS: Of 260 eligible participants, we included 205 high-quality responses. All attributes compared to the reference, freedom to choose pharmacy, were significant ($p < 0.0001$). Low and predictable medication cost had the highest relative importance (44%), followed by access to medication without delay (22%) and no increase in other healthcare costs (14%). Patients were willing to trade higher medication costs to avoid delays in medication access ($\beta_{\text{access}}/\beta_{\text{cost}} = 0.81$) and increases in other healthcare costs ($\beta_{\text{other}}/\beta_{\text{cost}} = 0.69$). In contrast, patients were less willing to trade higher costs for ease of enrollment and reduced stress. Stronger preference for medication access without delay was associated with a higher odds of a negative experience (OR = 2.73; 95% CI: 1.28–5.82; $p = 0.009$). No significant associations were observed for other domains.

CONCLUSIONS: Patients exposed to CMPs place comparable value on minimizing medication costs with timely medication access and avoiding an increase in other healthcare costs. However, misalignment between preferences and experiences reveals a key barrier: delays in access are linked to negative experiences, suggesting that programs that reduce costs at the expense of access may have limited patient-perceived value.

SPONSORSHIP: Genentech Inc.

111 Cost-effectiveness of Yartemlea (narsoplimab) for transplant-associated thrombotic microangiopathy: US payer perspective

Arefin P, Zeng Z, Tatar M; PAREFIN@COUGARNET.UH.EDU
University of Houston

BACKGROUND: Transplant-associated thrombotic microangiopathy (TA-TMA) is a severe complication of allogeneic hematopoietic stem cell transplantation (allo-HSCT) associated with high mortality, major complications, multiorgan dysfunction, and substantial healthcare resource utilization. Yartemlea (narsoplimab) is the first-ever U.S. Food and Drug Administration–approved therapy for TA-TMA. The drug received expedited FDA approval based on phase II evidence from the OMS721-TMA-001 trial (NCT0222545) and supportive findings from the expanded access program (EAP). However, despite clinical potential, the economic value of narsoplimab remains uncertain, with no prior economic evaluation conducted.

OBJECTIVE: To evaluate the cost-effectiveness of narsoplimab plus supportive care compared with supportive care alone for adults with TA-TMA from a U.S. payer perspective.

METHODS: A Markov model was developed to simulate disease progression among adults with TA-TMA following allo-HSCT using phase II, expanded access program (EAP), and published data. The cohort included adults aged 22–68 years (median age, 48 years; 71% male). From a U.S. payer perspective, the model used a 1-year horizon with 12 monthly cycles to estimate costs, QALYs, and ICERs in 2026 U.S. dollars at a WTP threshold of \$150,000/QALY. Deterministic and probabilistic sensitivity analyses were conducted using TreeAge Pro.

RESULTS: At a WTP threshold of \$150,000/QALY, narsoplimab was estimated to be cost-effective compared with supportive care alone. Narsoplimab was associated with lower total costs (\$688,366 vs \$909,055) and greater effectiveness (0.60 vs 0.30 QALYs). Compared with supportive care, narsoplimab reduced costs by \$220,689 and increased QALYs by 0.30, resulting in an ICER of –\$735,629/QALY gained. Because narsoplimab was associated with both lower costs and greater effectiveness, it was considered economically dominant. Sensitivity analyses demonstrated that narsoplimab remained cost-effective across plausible parameter ranges. Probabilistic sensitivity analysis demonstrated a 100% probability of cost-effectiveness at the \$150,000/QALY threshold.

CONCLUSIONS: Narsoplimab plus supportive care was estimated to be cost-effective compared with supportive care alone for adults with TA-TMA. These findings suggest that using narsoplimab plus could reduce severe complications, ICU utilization, dialysis dependence, and mortality and may offset substantial drug acquisition costs in this population.

Narsoplimab may offer a promising treatment option with potential clinical and economic benefits in TA-TMA population and should be considered for use.

SPONSORSHIP: None

112 Quantifying the net financial impact of authorized generics for manufacturers and payers using three case studies

Yoo P, Quillen S; pyoo@ipdanalytics.com
IPD Analytics

BACKGROUND: An authorized generic (AG) is a brand-name drug that is approved under the original manufacturer's New Drug Application (NDA) and is marketed without the brand name on its label. In highly rebated therapeutic classes, AGs typically cost more per unit than their branded counterparts. Although payers commonly exclude AGs from their formularies for this reason, manufacturers may benefit financially by adopting an AG strategy.

OBJECTIVE: To compare the estimated net cost to payers of AGs relative to the originator product and to estimate the additional net revenue for manufacturers from an AG strategy.

METHODS: Analysis was performed for calendar year 2025. Drugs were included if they had a marketed AG, sufficient third-party sales data, and manufacturer-reported net sales. Gross sales were estimated by multiplying units dispensed by the wholesale acquisition cost (WAC) per unit. Total discount was estimated by comparing gross sales with net sales. In the hypothetical scenario where the manufacturer did not launch an AG, units of the AG were added to units of the branded product to estimate net sales of the branded product. Assumptions included a rebate of 0% and a total discount of 25% for the AGs and a manufacturer royalty of 85% for all AG net sales.

RESULTS: Flovent Diskus/HFA, Breo Ellipta, and Farxiga were identified for analysis. Prior to the discontinuation of the branded products, the net plan cost per box was \$105.05 after rebates for Flovent Diskus/HFA and \$170.79 for the AG. The net manufacturer revenue per box was \$57.78 for Flovent Diskus/HFA and \$108.88 for the AG. The AG strategy resulted in an estimated increase of \$273M in net sales for the manufacturer in 2025. The net plan cost per box was \$122.22 after rebates for Breo Ellipta and \$249.60 for the AG. The net manufacturer revenue per box was \$83.92 for Breo Ellipta and \$159.12 for the AG. The AG strategy resulted in an estimated increase of \$55M in net sales for the manufacturer in 2025. The net plan cost per tablet was \$6.00 after rebates for Farxiga and \$12.62 for the AG. The net manufacturer revenue per tablet was \$3.20 for Farxiga and \$8.05 for the AG. The AG

strategy resulted in an estimated increase of \$313M in net sales for the manufacturer in 2025

CONCLUSIONS: The net cost to plans is lower for highly rebated brand products compared with their AGs. Manufacturers may increase their net sales by adopting an AG strategy for their highly rebated branded products.

SPONSORSHIP: IPD Analytics

Endocrine and Metabolic

122 Healthcare resource utilization, costs, and characteristics of treatment-naïve and switch Fabry disease patients initiating pegunigalsidase alfa-iwxj in the US: A retrospective database analysis

Hovland S¹, Munsell M², Binka M³, Hollenberg B², Kunduri S¹; sara.hovland@chiesi.com

¹Chiesi USA; ²Norstell; ³Chiesi Canada Corp.

BACKGROUND: Enzyme replacement therapy for Fabry disease (FD) may impact clinical and economic outcomes. Changes in FD treatment can occur. Establishing baseline clinical characteristics and healthcare resource use (HCRU) for both treatment-naïve and patients who have switched FD therapies may provide a better understanding of subsequent clinical and economic outcomes. However, real-world data specific to pegunigalsidase alfa (PA) remain limited.

OBJECTIVE: To describe the clinical characteristics, HCRU and cost outcomes of treatment-naïve and switch FD patients who initiate PA treatment.

METHODS: Patients ≥18 years of age with an FD diagnosis and evidence of PA infusion from 5/9/2023 to 1/31/2026 (index = first infusion) were identified in the NorstellLinQ database. Patients with ≥12 months of continuous enrollment before and after index were included. Treatment-naïve patients had no FD treatment in their recorded history within the database prior to initiating PA (≥12 months). Clinical characteristics were described ≥12 months before index. Baseline HCRU and all-cause medical costs were analyzed in the 12 months before index.

RESULTS: Of the 44 patients who met the inclusion criteria, the mean age [SD] was 43.4 [13.45] years, 47.7% were female, and most had non-classic FD (63.6%). Patients who switched from a prior FD therapy (59.1%) vs naïve patients had a higher prevalence of gastrointestinal symptoms (61.5% vs 44.4%), proteinuria (38.5% vs. 22.2%) and stroke (15.4% vs. 11.1%) before index. At baseline, a larger proportion of switch patients had inpatient hospitalizations (34.6% vs 16.7%) and ER visits (30.8% vs 27.8%) than treatment-naïve patients.

Although a lower percentage of switch patients had outpatient encounters (96.2% vs 100%), on average [SD] they experienced a higher number of outpatient encounters (19.9 [15.3] vs 10.8 [10.5]). Among patients with available cost data (N = 15), the median (IQR) all-cause medical costs were \$13,674 (\$6,680-\$19,460) for switch patients (N = 8), compared with \$5,160 (\$2,972-\$13,261) for treatment-naïve patients (N = 7).

CONCLUSIONS: In this retrospective database analysis, patients with FD who switched from a prior FD therapy to pegunigalsidase alfa differed from treatment-naïve patients. Switch patients had a higher prevalence of several clinically relevant comorbidities and greater healthcare resource utilization at baseline than treatment-naïve patients, which may reflect underlying disease severity. These findings represent observed trends and require larger cohorts for confirmation.

SPONSORSHIP: Chiesi USA, Inc.

123 Managed care considerations in Barth syndrome: Insights from an AMCP Market Insights program on coverage decision-making for an ultra-rare disease

Kobernick M¹, Rahman F², Wescott S³, Contreras Z⁴, Cade T⁵, Wolff D⁶, Richardson T⁷; advocatesforhealth@comcast.net; terry.richardson@impactedu.net

¹Blue Cross of MI; ²AmeriHealth Caritas; ³Mayo Clinic;

⁴Regional Health Plan in Southern CA; ⁵Duke University;

⁶AMCP; ⁷Impact Education, LLC

BACKGROUND: Barth syndrome is an ultra-rare X-linked mitochondrial disorder caused by TFAZZIN mutations, leading to cardiolipin deficiency and multisystem effects, including cardiomyopathy and skeletal myopathy. Approximately 150 individuals are affected in the US, with 40% mortality by 1 year of age. Diagnosis is often delayed due to phenotypic variability and lack of newborn screening. The 2024 accelerated approval of elamipretide based on surrogate endpoints presents coverage challenges for health plans unfamiliar with the disease.

OBJECTIVE: To examine payer perspectives on clinical burden, evidence interpretation, and coverage considerations for therapies targeting Barth syndrome.

METHODS: An AMCP Market Insights program convened 9 participants, including pharmacy and medical directors from health plans, PBMs, and integrated delivery networks, along with clinical experts. Educational presentations and moderated discussions explored evidence interpretation, coverage criteria, and barriers.

RESULTS: Participants reported limited baseline familiarity with Barth syndrome. Pre-program polling on coverage priorities varied: skeletal myopathy with functional limitations

(38%) and cardiomyopathy (25%) were most selected. Post-program, skeletal myopathy priority increased to 50%, suggesting education influenced perspectives on functional outcomes. Clinical experts noted patients identify skeletal myopathy and fatigue as most burdensome. Regarding MOA, 83% identified targeting the underlying mitochondrial defect as most important for coverage evaluation. Payers acknowledged traditional RCT designs are not feasible and that alternative designs require additional payer education to interpret. Key unresolved challenges included lifelong treatment cost and lack of pediatric dosing guidance. Payers emphasized current elamipretide labeling (≥ 12 years, ≥ 30 kg) excludes the highest-mortality infant population. Collaboration opportunities identified included specialist peer-to-peer consultation, case management triggers, and registry-based evidence generation. Post-meeting, 69% reported intent to implement practice changes.

CONCLUSIONS: Payers identified knowledge gaps and evidence challenges in treating Barth syndrome. Focused education may influence payer coverage perspectives toward addressing functional outcomes. Lack of pediatric dosing guidance remains a critical barrier for the highest-risk population.

SPONSORSHIP: AMCP

124 GLP-1-RA documented reasons for discontinuation: Analysis of a national online survey

Peasah S¹, Estavillo A², Diaz-Castillo S³, Lee T⁴, Campbell V¹, Bellon J⁵, Good C¹; peasahsk@upmc.edu; ave7@pitt.edu
¹UPMC Health Plan; ²University of Pittsburgh; ³Evernorth, Cigna; ⁴Evernorth Research Institute; ⁵Evernorth Research Institute, Cigna

BACKGROUND: GLP-1 receptor agonists (GLP-1-RAs) are increasingly prescribed for obesity, type 2 diabetes mellitus (T2DM), and off-label indications such as substance use disorder. However, many patients discontinue these therapies, which may undermine clinical, economic, and formulary management goals. Because favorable economic analyses of GLP-1-RAs are often predicated on sustained use, understanding reasons for discontinuation is important for clinical practice and policy.

OBJECTIVE: To summarize reasons for discontinuing GLP-1-RA therapy by indication.

METHODS: This study examined responses from a national online survey fielded in August 2024 and commissioned by Evernorth Research Institute. The sample included 900 commercially insured U.S. adults aged 18-65 years with a GLP-1-RA prescription filled in the prior six months. The data were analyzed across four indications: weight loss, T2DM,

substance use disorder, and others. This descriptive analysis focused on weight loss, T2DM, and substance use disorder.

RESULTS: Weight loss was the most common indication for a GLP-1-RA prescription (58%), followed by T2DM (41%) and substance use disorder (14%). Side effects were the leading reason for discontinuation among patients with T2DM (55%). In contrast, reaching treatment goals was the leading reason for discontinuation among patients using these medications for weight loss (43%) and substance use disorder (48%). Across all indication groups, the most frequently reported discontinuation reasons were side effects and tolerability concerns, goal achievement or perceived improvement, high medication cost or loss of insurance coverage, difficulty with the method of administration such as injections, and recommendations from a healthcare provider to stop treatment. Patients with T2DM had the highest persistence (77%), compared to weight loss (59%) and substance use disorder (66%). Patients using GLP-1-RAs for weight loss had the highest fully out-of-pocket payment rate (8%), approximately four times that of T2DM users (2%).

CONCLUSIONS: Discontinuation of GLP-1-RAs is multifactorial and varies by clinical indication. While financial considerations appear to be a consistent barrier across patient groups, other factors, such as tolerability, perceived goal attainment, and clinical guidance, also play a substantial role. These findings may inform benefit design, support clinician-patient discussions, and contribute to efforts to promote access to GLP-1-RA therapies.

SPONSORSHIP: None

125 Uncovering barriers to therapy adoption by patient GLP-1 use status: A cross-sectional analysis using an AI-enabled patient priority tool

Wardwell E, Akki H, Okereke J;
erynn.wardwell@syneoshealth.com;
hannah.akki@syneoshealth.com
 Syneos Health

BACKGROUND: Real-world persistence with anti-obesity medications is low; ~20–50% discontinue within 1 year and weight regain after cessation is common. Beyond medication tolerability, psychosocial barriers (emotional distress, disrupted routines, stigma) limit initiation and continuation, while routine care focuses heavily on physical management, limiting identification of psychosocial barriers.

OBJECTIVE: To characterize patient-reported psychosocial barrier profiles across core domains of disease management using an AI-enabled patient priority tool and assess patterns by GLP-1 use status.

METHODS: In Q1 2026, adults with obesity completed a validated psychosocial assessment selecting and ranking their top 2 barriers and rating importance. Weighted unmet-need scores were calculated from selection frequency and importance, and summarized by domain, priority, and GLP-1 use status. Depressive symptoms were assessed using PHQ-2.

RESULTS: Cohorts included patients with current GLP-1 use (34%), prior GLP-1 use with discontinuation (39%), and GLP-1 interested patients with no prior use (27%) (N = 283). Psychological and therapy domains accounted for 75% of total weighted intensity. Psychological barriers dominated primary priorities (74%) and were highly concentrated in a small set of emotional statements (fear, overwhelm) representing 98% of psychological intensity. Therapy domains dominated secondary priorities (71%) and showed concentrated unmet-need intensity. Beyond the primary and secondary priority domains, social barriers were concentrated, with 83% of intensity captured within support gaps and stigma. Knowledge contributed <10% of total unmet-need intensity and was primarily focused on routine and skill-based execution challenges. GLP-1 interested respondents showed the highest overall unmet need concentration, while discontinued respondents shifted toward therapy as a primary priority. Mean PHQ-2 scores were highest in the cohort of interested in GLP-1 patients but with no prior use.

CONCLUSIONS: Barriers were highly concentrated around psychological and therapy needs across GLP-1 cohorts, rather than gaps in lack of knowledge. These findings highlight opportunities to personalize care plans, treatment, and communication by aligning support to patient-reported priorities and stage of treatment. A patient priority tool may help care teams better target support and improve adherence.

SPONSORSHIP: Syneos Health partnered with Spotlight AQ for deployment of the assessment used in this analysis. The patient priority tool incorporated AI enabled functionality; analyses were conducted on de identified survey data.

126 Impact of lomitapide on major adverse cardiovascular events plus (MACE+) and atherosclerotic cardiovascular disease (ASCVD) in patients with homozygous familial hypercholesterolemia (HoFH)

Hovland S¹, Chopra I², Achter E², Aweh G², Umeh E², Causse-Safar P³; sara.hovland@chiesi.com

¹Chiesi USA; ²STATinMED; ³Chiesi Pharmaceuticals, Bois-Colombes, France

BACKGROUND: Homozygous familial hypercholesterolemia (HoFH) is a rare genetic disorder estimated to affect 3 in 1 million individuals. HoFH is characterized by extremely high low-density lipoprotein cholesterol levels from conception

leading to premature atherosclerosis (ASCVD) and early death.

OBJECTIVE: To assess the real-world effectiveness of lomitapide on reduction in major adverse cardiovascular (MACE+) and ASCVD outcomes and their subsequent event medical costs in US HoFH patients.

METHODS: A retrospective claims analysis using the STATinMED RWD Insights database was conducted. The index date for cases was the earliest recoded date of lomitapide and the index date for controls was the earliest recorded date of evinacumab or apheresis. Lomitapide cases were required to have an ICD-10 code for familial hypercholesterolemia (FH) [no specific HoFH ICD-10 code at the time of analysis] and continuous capture of medical and/or pharmacy benefits for 12 months pre- and post-index. Controls were required to have an ICD-10 code for FH, no evidence of lomitapide during the study period, and continuous capture of medical and pharmacy benefits with no evidence of evinacumab or apheresis for 12 months pre-index. The 12-month clean period was used to compare controls to patients on lomitapide. Matched analyses via inverse probability of treatment weighting were used and comorbidities were adjusted.

RESULTS: There were 149 cases and 179 controls. Before matching, the lomitapide cohort was younger with a lower proportion of females. Cases also had lower rates of hypertension, smoking, coronary artery disease, obesity and dyslipidemia at baseline. After matching, characteristics were well balanced between groups. Patients on lomitapide had a significantly lower rate of any MACE+ (stroke, heart failure, revascularization, thromboembolic events) or ASCVD event (50.2% vs 63.9%, $p = 0.012$), non-fatal MI (2.3% vs 7.1%, $p = 0.043$), and coronary heart disease (44.3% vs 56.2%, $p = 0.031$). Follow-up median all-cause total medical costs were significantly lower for patients on lomitapide (\$2,494 vs \$7,988, $p < 0.0001$). Follow-up MACE+ and ASCVD-related medical costs were also significantly lower for patients on lomitapide (\$1,645 vs \$5,254, $p = 0.006$).

CONCLUSIONS: Despite looking at lifetime events, there was a significant reduction in lomitapide-treated patients of any MACE+/ASCVD event within 1 year of follow-up after receiving lomitapide leading to a ~70% reduction in total mean medical costs throughout this period.

SPONSORSHIP: Chiesi

127 Continuous glucose monitoring use is associated with improved glycemic status assessment performance in non-insulin-treated adults with type 2 diabetes

Nemlekar P¹, Taylor R², Forsberg A³, Norman G³;
poorva.nemlekar@dexcom.com

¹Dexcom; ²Dexcom Inc. – San Diego, CA; ³Dexcom, Inc.

BACKGROUND: An HbA1c >9% reflects poor glycemic control and adversely impacts performance on the HEDIS Glycemic Status Assessment for Patients with Diabetes (GSD) measure. For managed care organizations, reducing the proportion of members with glycemic status >9.0% is a measurable care gap and quality-improvement priority.

OBJECTIVE: To evaluate whether continuous glucose monitoring (CGM) use was associated with non-insulin-treated adults with type 2 diabetes (T2D) remaining with HbA1c >9%, overall and by payer type.

METHODS: This retrospective study used Optum's Market Clarity de-identified linked EHR and claims data. The cohort included CGM naïve adults aged 18–75 years with T2D who were receiving non-insulin therapy and had baseline HbA1c >9%. The index date was the first CGM claim between September 1, 2018, and December 1, 2024. Continuous health plan enrollment was required for 12 months before (baseline) and after (follow up) the index date, with ≥ 1 HbA1c laboratory value in each period. The primary outcome was HbA1c >9% during follow up, aligned with the HEDIS GSD measure. The secondary outcome was change in HbA1c. The analyses were stratified by payer type. Propensity score matching balanced baseline demographics, comorbidities, HbA1c, healthcare utilization, and costs.

RESULTS: A total of 25,783 propensity score-matched patients were identified, including 12,969 CGM users. Baseline characteristics were well balanced between cohorts: 44.5–44.6% female, mean (SD) age 56 (10.6) years, 68% commercially insured, 67.7% White, and 74.6% non-Hispanic. At follow-up, significantly fewer CGM users remained with HbA1c >9% versus non-CGM users (33.7% vs 44.2%; $p < 0.001$), with consistent findings across payer types. CGM use was also associated with greater HbA1c improvement, with a significant difference-in-differences of -0.6% ($p < 0.0001$). HbA1c reductions were directionally consistent across Commercial (-0.72%), Medicaid (-0.42%), and Medicare (-0.39%) populations.

CONCLUSIONS: CGM use among non-insulin-treated adults with T2D was associated with fewer members remaining with HbA1c >9%, indicating improved glycemic control and alignment with the HEDIS Glycemic Status >9% indicator. This suggests CGM may help guide strategies aimed at improving

GSD performance, supporting population risk management, and advancing system-level quality.

SPONSORSHIP: Dexcom Inc.

128 Payer coverage and management of anti-obesity medications (AOMs) on commercial formularies: Results from a 2026 US national payer survey

Yoshida S, Friedman M, Sequeira A;
shaila.yoshida@cencora.com; arvin.sequeira@cencora.com
Cencora

BACKGROUND: The prevalence of obesity among US adults is 40% (2021 to 2023). As of May 2026, there are 10 FDA-approved AOMs, including oral formulations Wegovy Pill and Foundayo (orforglipron), and higher dose Wegovy HD. The AOM market is expanding; however, challenges remain due to uneven commercial coverage, increasing demand, high drug costs, and evolving regulatory landscape.

OBJECTIVE: To investigate US payer coverage, management, and challenges related to AOMs on commercial formularies.

METHODS: An online survey was conducted among US payers from March 31 to April 23, 2026. 35 payers from health plans (54%), integrated delivery networks (23%), and pharmacy benefit managers (23%) completed the survey, representing over 200 million covered lives. The sample consisted of pharmacy (74%) and medical (26%) directors; 94% were voting members on their organization's P&T committee.

RESULTS: 37% of payers cover AOMs through rider policies; for 2026, half expect an increase in covered lives for AOM indications. In 2026, 66% cover Wegovy for all approved indications vs. 20% for obesity-adjacent only; 57% cover Zepbound for all vs. 29% for obesity-adjacent only; 60% cover Wegovy Pill for all vs. 29% for obesity-adjacent only. 77% ($n = 30$) prefer Wegovy and 73% ($n = 30$) prefer Zepbound; generic liraglutide preferred by 84% ($n = 25$) vs. Saxenda (50%, $n = 20$). Quantity limits (69%), reauthorization criteria (55%), and PA to label (54%) are top utilization tools. 89% include BMI thresholds in coverage policies: mean 28 kg/m² for patients with comorbidities, 31 kg/m² without. 91% identify high budget impact as top challenge in managing AOMs; other concerns include limited long-term data and patient discontinuation. 57% offer non-drug weight management programs, including virtual coaching and telehealth support. Payers track obesity outcomes, seeing positive results in weight loss (90%, $n = 21$) and BMI (85%, $n = 20$). At time of survey, payers show awareness of AOM pipeline including higher dose semaglutide (71%), CagriSema (69%), orforglipron (57%), and retatrutide (54%). Payers seek additional AOM

evidence such as medical cost offsets (77%) and comorbidity impact (69%).

CONCLUSIONS: Payer coverage of AOMs on commercial formularies continues to evolve with strong preference for GLP-1-based agents. Payers are tracking positive member outcomes including weight loss and BMI improvements; however, they face challenges due to high budget impact and limited long-term data. Payers are monitoring the AOM pipeline and continue to seek evidence such as medical cost offsets to inform formulary decisions.

SPONSORSHIP: Cencora

129 Payer perspectives on direct-to-patient (DTP) offerings for anti-obesity medications (AOMs): Results from a 2026 US national payer survey

Yoshida S, Friedman M, Sequeira A;
shaila.yoshida@cencora.com; arvin.sequeira@cencora.com
Cencora

BACKGROUND: The rapid growth of GLP-1 receptor agonist-based AOMs is reshaping obesity management. However, the AOM market is facing headwinds due to high drug costs and uneven insurance coverage, leading to patient access challenges. To address these gaps, AOM manufacturers and the current administration introduced DTP offerings: digital platforms where patients directly access medications. While the DTP channel may improve access for patients, it also raises implications for managed care stakeholders. This study examines payer perspectives on DTP pathways for AOMs and their impact on the managed care ecosystem.

OBJECTIVE: To understand payer perceptions of DTP offerings for AOMs and assess implications for current and future management strategies.

METHODS: An online survey was conducted among US payers from March 31 to April 23, 2026. A total of 35 payers from health plans (54%), integrated delivery networks (23%), and pharmacy benefit managers (23%) completed the survey, representing over 200 million covered lives. The sample consisted of pharmacy (74%) and medical (26%) directors; 94% were voting members on their organization's P&T committee.

RESULTS: 91% of payers are aware of leading AOM DTP offerings (LillyDirect, NovoCare); 54% are aware of specific details. 51% believe AOM DTP offerings are extremely/very impactful to rebate negotiations, 40% for pharmacy benefit costs. 49% have concerns including lack of full clinical visibility (82%, n=17) and benefit design implications (65%, n=17). Payers expect highest DTP growth in obesity (86%) and diabetes (51%). Organizations are actively evaluating DTP programs to assess downstream financial impacts (e.g., effects on pharmacy budgets, member utilization and costs), clinical

appropriateness, operational impact (directing members to the right channels), and exploring partnerships/data sharing opportunities. In response to TrumpRx, payers primarily view it as impactful on AOM net costs and contracting leverage, while also broadening access and strengthening the DTP channel.

CONCLUSIONS: US payers recognize the growing influence of the AOM DTP channel and are closely monitoring developments such as TrumpRx to assess financial, operational, and clinical impacts. However, they are concerned about lack of clinical visibility and impacts on benefit design. Payers expect the DTP channel to grow in obesity and diabetes. Consistently monitoring payer experiences with DTP will be critical to assess how these offerings reshape future managed care for AOMs.

SPONSORSHIP: Cencora

130 Early uptake of oral semaglutide for obesity (Wegovy pill)

Cartwright B, Vachon M, Holler E, Masters N, Farrar K;
briannac@truveta.com
Truveta, Inc

BACKGROUND: Injectable GLP-1-based therapies have demonstrated substantial benefits for weight loss and cardiometabolic risk reduction. Real-world uptake has been shaped by factors such as route of administration, access, tolerability, and insurance coverage. Oral formulations may lower barriers to initiation by offering a non-injectable option that can be prescribed and managed in a broader range of clinical settings.

OBJECTIVE: To characterize early recipients of oral semaglutide following FDA approval, including prescribing provider type and whether patients were GLP-1 therapy initiators or switchers.

METHODS: Using Truveta Data, we identified patients with a prescription order or pharmacy fill for oral semaglutide between December 22, 2025 (FDA approval date), and May 6, 2026. We describe population demographics. For a subset of patients with an encounter within the last year, we evaluated the proportion that had prior evidence of a GLP-1-based therapy. For a second subset of patients where provider data was available, we identified the prescribing practitioner.

RESULTS: We included 48,983 patients with evidence of a prescription or pharmacy fill for the oral formulation of semaglutide. Patients were predominantly female (74.6%), White (72.4%), non-Hispanic or Latino (77.5%), and living in urban areas (72.2%). The cohort skewed older, with 36.3% aged 45–59 years and 34.2% aged 60 years or older. Prior evidence of obesity was common (80.0%), and an additional 7.7% had

evidence of both obesity and type 2 diabetes. Most patients (90.0%) had an encounter within the prior year. Among patients with an encounter in the prior year, most had no prior evidence of GLP-1 therapy (60.2%), suggesting substantial uptake among new initiators rather than switches from injectable therapies. Prescribing provider data were available for 43.7% of patients; among these, 83.8% received oral semaglutide from a general practice provider.

CONCLUSIONS: Early uptake of oral semaglutide occurred primarily among patients without prior evidence of a GLP-1-based therapy, suggesting that oral formulations may expand access beyond patients already receiving GLP-1-based medications. Prescribing was most common among general practice providers, supporting the potential for broader adoption outside of specialty care settings. Continued tracking of oral GLP-1 formulations is important as new formulations enter the market, and data will be refreshed prior to the conference.

SPONSORSHIP: Truveta funded this study.

131 Real-world reduction in cirrhosis and liver-related hospitalizations with incretin-based obesity pharmacotherapy: Evidence to inform Medicare formulary decisions

Baser O¹, Sun Y², Rodchenko K², Yapar N², Zhu X², Wu L², Lu Y²; onur.baser@sph.cuny.edu

¹City University of New York (CUNY); ²Columbia Data Analytics

BACKGROUND: Metabolic dysfunction-associated steatotic liver disease (MASLD) affects >30% of adults globally; US prevalence is projected to reach 122 million by 2050. Older adults face disproportionate risk of cirrhosis, hepatic decompensation and liver-related mortality. Phase 3 trials of incretin-based therapies (GLP-1, dual GIP/GLP-1 receptor agonists) show meaningful metabolic dysfunction-associated steatohepatitis (MASH) and fibrosis improvement, yet evidence in the Medicare fee-for-service (FFS) population is sparse.

OBJECTIVE: To evaluate real-world impact of modern incretin-based obesity pharmacotherapy vs no obesity pharmacotherapy on noninvasive liver indices, incident cirrhosis and liver-related hospitalizations among older Medicare FFS beneficiaries diagnosed with obesity and MASLD/MASH.

METHODS: Retrospective active-comparator cohort study using the Medicare-Enhanced Lab & Demographics (MELD) database, which deterministically links 100% Medicare FFS claims with EMR and laboratory results. Beneficiaries aged ≥65 years with BMI ≥30 kg/m² and confirmed MASLD/MASH (ICD-10-CM:K76.0, K75.81) initiating incretin-based therapy or no obesity pharmacotherapy from 2021-2025 were included. Overlap weighting via propensity scores

balanced demographics, socioeconomic factors, Elixhauser comorbidities, BMI, and baseline labs. Weighted regression estimated adjusted changes in alanine aminotransferase, aspartate aminotransferase, gamma-glutamyl transferase and noninvasive Fibrosis-4 Index (FIB-4). Cox proportional hazards models estimated time-to-event clinical outcomes.

RESULTS: Of 191,769 eligible beneficiaries, 63,459 met inclusion criteria (5,544 treated; 57,915 untreated). The treated cohort had heavier cardiometabolic burden (type 2 diabetes 89.6% vs 54.7%; higher statin and SGLT2 use). After overlap weighting, the treated cohort achieved a significantly greater improvement in FIB-4 (adjusted difference -0.13; P = 0.005). Incretin-based therapy was associated with significantly lower risk of incident cirrhosis (aHR 0.68; 95% CI, 0.62-0.75; P<0.001) and liver-related hospitalizations including hepatic decompensation and hepatocellular carcinoma (aHR 0.72; 95% CI, 0.67-0.78; P<0.001).

CONCLUSIONS: Among Medicare patients with obesity and MASLD/MASH, modern incretin-based treatment was associated with improved noninvasive fibrosis indices and nearly 30% lower risk of cirrhosis and liver-related hospitalizations. The findings support the liver-related value of incretin-based therapies in routine Medicare care and may inform managed care formulary and utilization management decisions for high-risk older adults.

SPONSORSHIP: None

Gastrointestinal

145 Characterizing the real-world patient journey to advanced therapy in ulcerative colitis

Heard T, Lynch K, Herndon K, Gleboff A, Norman R; tom.heard@pfizer.com; kevin.lynch@pfizer.com
Pfizer

BACKGROUND: Ulcerative colitis (UC) has substantial clinical and economic burden. Real-world data show delayed escalation and prolonged steroid use, driving higher healthcare resource utilization (HCRU). Evaluating real-world treatment patterns can reveal gaps and inform payer strategies to support guideline-aligned UC care.

OBJECTIVE: To describe the patient journey to advanced therapy (AT) in newly diagnosed ulcerative colitis patients.

METHODS: This U.S. retrospective observational study used the IQVIA PharMetrics Plus, a closed health plan claims database composed of fully adjudicated medical and pharmacy claims. Data contributors to the database are a mix of commercial, managed Medicaid, and Medicare Advantage payer

types. Adults (≥ 18) newly diagnosed with UC (2018–2022) were identified by ≥ 2 ICD 10 UC codes ≥ 30 days apart, with no UC diagnosis or non-steroidal UC therapy in the prior year. Continuous enrollment (1-year pre, 3 years post) was required. Treatment patterns, time to therapy, provider specialty, demographics, comorbidities, and HCRU were assessed.

RESULTS: Among 11,024 newly diagnosed UC patients, 53% received conventional therapy (CT) only, 37% received no treatment, and only 10% progressed to AT. Treatment patterns were steroid dominated, with steroids alone (24.9%) and steroids plus 5-ASA (15.4%) most common, while biologics alone accounted for 1.3%. Mean time from diagnosis to CT was 214 days ($n = 6,796$) and mean time from CT to AT was 237 days ($n = 921$). Patients receiving AT had lower observed (unadjusted) all cause healthcare utilization, including fewer emergency department visits (2.27 vs 3.28), fewer inpatient admissions (1.15 vs 1.32), and shorter hospital length of stay (5.4 vs 6.0 days) than those receiving CT. Patients who ultimately progressed to AT experienced 4–5 $\times$ more steroid overlap days during 5-ASA therapy.

CONCLUSIONS: In this real-world analysis, most newly diagnosed UC patients did not receive AT and were on prolonged steroid use. Delayed escalation was common and with higher observed healthcare utilization, suggesting earlier guideline aligned advancement may improve outcomes and reduce acute care use. The statements, findings, conclusions, views, and opinions contained and expressed herein are not those of IQVIA Inc. or any of its affiliated or subsidiary entities. The statements, findings, conclusions, views, and opinions contained and expressed in this abstract are based in part on data obtained under license from the following IQVIA Inc. information service: IQVIA PharMetrics® Plus, January 2017 – December 2025, IQVIA Inc. All Rights Reserved.

SPONSORSHIP: Pfizer

146 Estimation of the treatment-eligible patients with compensated metabolic dysfunction-associated steatohepatitis cirrhosis in the United States

Kim Y¹, Atreja N¹, Goswami L², Hadker N², Parrinello C¹, O'Donnell J¹, ykim@madrigalpharma.com

¹Madrigal Pharmaceuticals; ²Trinity Life Sciences

BACKGROUND: Metabolic dysfunction-associated steatohepatitis (MASH) is associated with substantial clinical and economic burden, particularly among those with compensated MASH cirrhosis. Given that there are various drugs in the pipeline looking to treat compensated MASH cirrhosis, it is important to understand the potential size of the treatment-eligible population.

OBJECTIVE: To estimate the population size of those with compensated MASH cirrhosis in the United States (US) who may be treatment-eligible in the future.

METHODS: A systematic literature review (SLR) was conducted to assess the epidemiology of compensated MASH cirrhosis in the US. Following that, a dynamic population calculator was developed, using the literature from the SLR to provide a 1-year treatment-eligible population. A base case was developed using select literature published outputs of the SLR, and sensitivity analyses were conducted based on other available literature.

RESULTS: In the base case, a US MASH prevalence (F0-F4) of 6.8% was modeled, with 12.8% of those being F4 and 86% among F4 having compensated cirrhosis. A 12% diagnosis rate was applied to compensated MASH cirrhosis, resulting in 0.07% prevalence of diagnosed compensated MASH cirrhosis in the general US population. Sensitivity analyses were conducted to evaluate the impact of various assumptions in the US MASH prevalence, proportion of F4 rates, and diagnosis rates on the size of the estimated treatment-eligible population.

CONCLUSIONS: A population calculator was developed using inputs from an SLR and estimated the potential size of the treatment-eligible population with diagnosed compensated MASH cirrhosis to be approximately 246,000 adults within the first year of a given drug approval in the US. With no approved therapies to date, this analysis addresses a critical knowledge gap in quantifying the true prevalence of this underdiagnosed population.

SPONSORSHIP: Madrigal Pharmaceuticals

Genitourinary

150 Providers' perceptions of overactive bladder and urinary incontinence diagnosis and medication use in a long-term care survey

Han L¹, Sillman E¹, Harris D², Hoffert T³, Sheridan J³, Carrera A⁴, Lickert C⁴, Nesheim J⁴, Gravenstein S⁵, Davidson H¹, lhan@Inther.com

¹Insight Therapeutics, LLC; ²University of Delaware;

³CommuniCare Health Services; ⁴Sumitomo Pharma America, Inc.; ⁵Warren Alpert Medical School of Brown University

BACKGROUND: Overactive bladder (OAB) and urinary incontinence (UI) are common conditions among long-term care (LTC) residents that are often treated with anticholinergic medications despite risks. The uptake of alternative medications and prescribing practices for treating OAB/UI remain poorly characterized.

OBJECTIVE: To conduct a sequential quantitative and qualitative evaluation to understand how OAB/UI is managed in US LTC facilities.

METHODS: We conducted a serial cross-sectional study by quarter using electronic health records (EHRs) and minimum dataset assessments (MDS) from >7000 US LTC facilities (2014-2024) for quantitative insights. We then administered an anonymous, electronic survey to LTC clinicians in a nursing home chain of >130 facilities across 7 states to assess perspectives on our initial findings related to UI diagnoses, reported UI symptoms in the MDS, and prescribing practices.

RESULTS: Although 29% of 986,554 LTC residents (Quarter 37) were reported as “always incontinent” in MDS, only 81,422 (8%) had a formal UI-related diagnosis (including OAB). Of those with UI-related diagnoses, 30,446 (37%) received an OAB/UI medication. Of those treated, 14,662 received oxybutynin (48%) and 9185 received mirabegron (30%). Among 89 survey respondents, the most common roles were director of nursing (29%) and nurse practitioner (20%). Of respondents, 79% indicated that the reported UI-related diagnosis prevalence did not reflect their clinical experience, and 44% indicated it was lower than expected. The majority of respondents (81%) reported that OAB/UI medication prescribing rates reflected their experience. Anticholinergic burden was “always” considered by 24% of respondents, “usually” by 31%, and “sometimes” by 40% when prescribing OAB/UI medications.

CONCLUSIONS: Surveyed LTC providers confirmed a discrepancy between the extent of OAB/UI symptoms and documented diagnoses. Anticholinergic burden was only sometimes considered in prescribing OAB medications, underscoring the potential need for more specific guidelines and recommendations.

SPONSORSHIP: Sumitomo Pharma America, Inc.

has been proposed as a strategy to increase naloxone uptake among opioid users, but its implications for health equity are unclear.

OBJECTIVE: To evaluate the efficiency-equity tradeoffs of implementing an academic detailing program to increase naloxone distribution among opioid users on population health and health equity in the United States.

METHODS: An aggregate distributional cost-effectiveness analysis (DCEA) was conducted from the US healthcare payer perspective. Health outcomes and costs were derived from a hybrid decision tree-Markov model evaluating academic detailing to improve naloxone distribution, using a willingness-to-pay threshold of \$50,000 per quality-adjusted life year (QALY) gained. Health gains and opportunity costs were distributed across socioeconomic groups according to Centers for Disease Control and Prevention Social Vulnerability Index quintiles. Equally distributed equivalent (EDE) health was estimated using the Atkinson inequality aversion index, and tradeoffs between maximizing health and reducing inequality were assessed on the equity-efficiency plane. Sensitivity analyses varied the Atkinson inequality aversion index to evaluate its effect on inequality outcomes.

RESULTS: At a willingness-to-pay threshold of \$50,000 per QALY gained, implementation of academic detailing produced an incremental net health benefit of 0.08 QALYs gained per typical individual. For the total US population, incremental EDE health gained was 27,137,383 QALYs and incremental net health benefit was 27,797,555 QALYs. However, academic detailing implemented across the entire US population increased health inequality by -660,172 QALYs. Results were robust across a range of Atkinson inequality aversion indices.

CONCLUSIONS: Academic detailing to improve naloxone distribution among opioid users increases overall population health benefits but may worsen health inequality in the United States. These findings underscore the tradeoffs between maximizing health gains and promoting health equity.

SPONSORSHIP: None

Health Disparities/Equity

156 Health equity impact of academic detailing on naloxone distribution in the United States: An aggregate distributional cost-effectiveness analysis

Yip O¹, Yousif Z², Hendrix N³, Li M⁴, Sepassi A², Dong A¹, Bounthavong M²; oliviayipwc@gmail.com

¹UCSD; ²UCSD Skaggs School of Pharmacy and Pharmaceutical Sciences; ³American Board of Family Medicine; ⁴Center for the Evaluation of Value and Risk in Health

BACKGROUND: Opioid overdose remains a major public health crisis in the United States, and naloxone distribution programs can reduce overdose mortality. Academic detailing

157 Trends in AUD treatment and intensity by sex and behavioral health status among commercially insured adults, 2018–2024

Swart E¹, Lee T², Taylor B², Inneh A², Peasah S¹, Good C¹, Bellon J³, Tilstra S¹; swarte@upmc.edu

¹UPMC Health Plan; ²Evernorth Research Institute; ³Evernorth Research Institute, Cigna

BACKGROUND: Alcohol use disorder (AUD) is associated with substantial morbidity, mortality, and healthcare utilization in the United States. Although effective pharmacologic and behavioral treatments are available, treatment uptake remains low and patterns of care may vary by sex and co-occurring behavioral health (BH) conditions.

OBJECTIVE: To evaluate trends in AUD treatment receipt and treatment intensity from 2018–2024 by sex and BH diagnosis status among commercially insured adults with AUD.

METHODS: We conducted a retrospective analysis of commercially insured adults (≥18 years) with an AUD diagnosis using medical and pharmacy claims from a pharmacy benefit manager from 2018–2024. Within each year, treatment was classified as (1) any treatment (yes/no), defined as having pharmacotherapy and/or behavioral health (BH) services (e.g., therapy), and (2) treatment intensity, categorized as none, single modality (lower intensity), or combined medication and service treatment (higher intensity). Prescription medications included agents for AUD and other BH indications, and service-based treatment was identified using visits with a primary AUD or BH diagnosis. Population average generalized estimating equation (GEE) models were used to assess temporal trends overall and by BH diagnosis status and sex, with Poisson models for any treatment and ordinal models for treatment intensity.

RESULTS: From 2018 to 2024, treatment patterns showed modest changes. In adjusted models, the probability of receiving any treatment remained stable (RR = 1.00 per year, 95% CI, 0.98–1.01); temporal trends did not differ by sex or behavioral health (BH) diagnosis status. The odds of receiving higher intensity treatment declined modestly over time (OR = 0.98; 95% CI, 0.97–0.99). Temporal trends in treatment intensity did not differ by sex. BH comorbidity was strongly associated with greater treatment intensity; however, despite higher overall intensity, patients with a BH diagnosis experienced a decline in treatment intensity over time compared with those without BH comorbidity (OR = 0.96; 95% CI, 0.95–0.97).

CONCLUSIONS: From 2018 to 2024, AUD treatment patterns remained largely stable among commercially insured adults and did not differ substantially by sex. There were, however, significant impacts of comorbid BH diagnosis on treatment trends in each year and over time. These findings suggest that

despite increasing public awareness of AUD, treatment rates have not significantly improved and patients with an AUD only diagnosis are less likely to receive treatment than those with a comorbid BH diagnosis.

SPONSORSHIP: Evernorth/UPMC partnership

Health Policy

167 Evaluating price controls and patient affordability: Lessons from the historical PCSK9 price reductions and Medicare Part D formularies

Sheinson D, Wong W; sheinson.daniel@gene.com
Genentech

BACKGROUND: Drug price control policies have been proposed/enacted to curb U.S. healthcare spending; however, given their recency, there is little evidence on the impact of these policies on access to drugs subject to them. Historical list price changes of the PCSK9 drugs, which took an approximate 60% list price decrease in 2020, may offer insight into the impact of recently proposed/enacted drug price control policies.

OBJECTIVE: To assess changes in formularies and patient out-of-pocket (OOP) costs post-list price decreases for the PCSK9s as a case study for potential impacts of access following drug price control policies.

METHODS: Part D plan cost-sharing data (2019–2025) were obtained from the Medicare Part D formulary, pharmacy network, and pricing files from CMS. Trends in PCSK9 list prices, plan tiers, and out-of-pocket costs were summarized for each year. OOP costs per script were calculated from plan copay and coinsurance amounts, where the coinsurance rate was multiplied by the lowest WAC amount among covered PCSK9 drugs on the plan tier. Non-low-income-subsidy (LIS) OOP costs for each year were then calculated over all plans in that year via enrollment weighting of the non-LIS population. To evaluate the proportion of the increase in OOP costs attributable to benefit design vs. list price, non-LIS OOP costs were re-calculated with the list price for PCSK9 drugs fixed at their 2020 WAC.

RESULTS: Post-list price decrease, the majority of plans moved the PCSK9 drugs from specialty tiers to non-preferred tiers (60%), followed by switching to preferred tiers (78% in 2021 and >95% by 2023). The percent of enrollees with greater than \$100 OOP per PCSK9 script dropped from 36% in 2020 to 3% in 2022 but steadily rose to 45% in 2025, which was observed to be mostly attributable to benefit design changes. The percent of enrollees with coinsurance on non-preferred tiers was approximately 60% in 2020 and steadily declined to 9% in

2025 whereas, the percent of enrollees on preferred tiers with coinsurance has steadily risen, from 9% to 52% in the same time. By 2025, 60% of enrollees were seeing a year-over-year increase in their OOP cost per script.

CONCLUSIONS: Viewing historical price decreases as a proxy for recent price control policies, we observe that access issues may remain in both the short and long term due to formulary shifts and associated trends toward higher cost sharing. Addressing drug pricing may not improve affordability and policies addressing benefit design are needed to improve and sustain affordability for patients.

SPONSORSHIP: Genentech, Inc

168 Quantifying stakeholder oral comments and analytic engagement in ICER assessments: Implications for payers (2025–2026)

Naoko R, Paret K; nronquest@rti.org
RTI Health Solutions

BACKGROUND: United States payers frequently review assessments by the Institute of Clinical and Economic Review (ICER) to inform coverage, formulary, and utilization management decisions. Oral comments during ICER's assessment meetings provide critical input into deliberations, yet few published analyses characterize who participates, what issues are raised, and how comments relate to analytic engagement relevant to payer decision-making.

OBJECTIVE: To characterize stakeholder participation, themes, airtime, and reactions during the “Public comments and discussion” section across recent ICER public meetings.

METHODS: We reviewed transcripts from the oral comment sections of 7 ICER public meetings completed between March 2025 and March 2026. We abstracted speaker type and count, oral comment airtime, follow-up discussion duration, and issues raised over time. Comments were classified as testimonial, technical, or policy-focused.

RESULTS: Patient advocacy speakers were present in 5 of 7 reviews (71%), typically 1 to 3 organizations per assessment. Manufacturers participated in 5 of 7 reviews (71%), concentrated in competitive therapeutic areas. Patient advocacy speakers consistently raised disease burden and lived-experience themes (100%). In later assessments, model-related critiques (e.g., functional outcomes not captured, steroid toxicity, comparator choice) were raised by patient advocacy speakers in 4 of 5 reviews (80%), although those rarely prompted follow-up questions from ICER or review committee members. Manufacturer speakers raised model-specific critiques in all 5 assessments with manufacturer participation (100%), increasingly focused on model structure, extrapolation, comparators, and scenario analyses. When

manufacturers were present, they accounted for nearly all committee Q&A time. Combined, model-related critiques appeared in 4 of 7 assessments, with ICER typically citing data limitations in defense.

CONCLUSIONS: Oral public comments at ICER meetings increasingly reflect technical sophistication relevant to coverage and value decisions. Analytic deliberation remains disproportionately discussed during manufacturer participation, whereas patient and advocacy input, despite growing technical sophistication, primarily serves as contextual evidence. ICER's new modeling dialogue session introduced in late 2025 represents a promising mechanism to broaden technical engagement. Strengthening patient and advocacy familiarity with value assessment methodologies could further amplify their contributions.

SPONSORSHIP: None

169 Quantifying Medicaid coverage disruption under federal policy changes (H.R.1): A scalable claims-based framework for managed care decision-making

Leslie D¹, Hollenbeak C², Kotak S³;
dleslie@pennstatehealth.psu.edu

¹Department of Public Health Sciences, Penn State College of Medicine; ²The Pennsylvania State University; ³Yorker Health

BACKGROUND: Medicaid coverage stability has become a central concern for managed care organizations, particularly in the context of evolving federal policy proposals such as H.R.1, which may alter eligibility verification and redetermination processes. Coverage disruption, often referred to as “churn,” has been associated with interruptions in care, reduced medication adherence, and increased reliance on acute care services. Despite the recognized importance of this issue, stakeholders lack practical, scalable approaches to quantify the downstream impact of policy-driven coverage changes using real-world data.

OBJECTIVE: Develop an analytic framework to identify Medicaid populations at highest risk of coverage disruption using eligibility pathway, Federal Poverty Level (FPL), and Affordable Care Act (ACA) expansion status in order to evaluate the impact of coverage instability on adherence using proportion days covered (PDC), discontinuation, and acute care utilization.

METHODS: We developed a scalable, claims-based analytic framework to use with national, longitudinal Medicaid data to evaluate the downstream effects of Medicaid coverage instability (i.e., “churn”). Using longitudinal enrollment and utilization patterns, the framework simulated disruption scenarios and quantified associated changes in adherence (PDC),

discontinuation, acute care utilization, and payer-relevant cost metrics. Historical enrollment patterns were used as proxies for policy-driven instability. The analytical framework was developed to include Medicaid-eligibility pathways of disability, Supplemental Security Income (SSI), ACA expansion status and FPL, to more accurately identify populations at risk.

RESULTS: A cohort of 59 million beneficiaries was analyzed, including data from 12 non-expansion states and 38 expansion states. Approximately 51 million beneficiaries (87%) had income $\leq 133\%$ FPL; the majority were <40 years old, female, White, non-Hispanic, and in the South. Directional findings from ongoing analyses demonstrate measurable declines in adherence (PDC) associated with coverage gaps and increased acute care utilization following periods of enrollment disruption, with variation across populations stratified by eligibility pathway and income level.

CONCLUSIONS: We developed an empirical analytic framework that enables repeatable, cross-therapeutic evaluation of policy impact using real-world claims data, moving beyond descriptive analyses toward actionable, decision-relevant insights. This framework translates real-world evidence into payer-relevant metrics.

SPONSORSHIP: None

Hematologic

175 Real-world momelotinib treatment patterns and impact on transfusion burden in patients with myelofibrosis and anemia: Evidence from a US commercially insured population

Moore J¹, Derreumaux D², Vo B³, Kumari Singh W⁴, Zhang S¹, Liu T¹; julia.v.moore@gsk.com
¹GSK plc; ²GSK plc, Wavre, Walloon Region, Belgium; ³GSK plc, Philadelphia, PA, USA; ⁴GSK plc, Bengaluru, Karnataka, India

BACKGROUND: Momelotinib is a Janus kinase (JAK) inhibitor approved for patients with myelofibrosis and anemia. Due to its recent approval in 2023, there have been limited insights on real-world usage of momelotinib.

OBJECTIVE: To provide real-world evidence regarding momelotinib treatment duration and sequencing as well as changes in transfusion burden.

METHODS: This was a retrospective analysis using the Optum Clinformatics database of commercially insured US patients with myelofibrosis. Eligible patients were diagnosed with myelofibrosis between 1 January 2008 and 30 June 2025, with ≥ 1 pharmacy claim for momelotinib between 15 September 2023 and 31 March 2025. The index date was the first

momelotinib claim date (≥ 6 months of continuous enrollment before [baseline] and ≥ 3 months after [follow-up] required). Baseline characteristics, median time to discontinuation, and transfusion status and burden were analyzed descriptively.

RESULTS: Overall, 262 patients were eligible; 98 (37%) were JAK inhibitor naive and 164 (63%) were JAK inhibitor experienced. Overall, median age was 76 years and 8.4% were transfusion dependent (TD) at baseline. Among JAK inhibitor-experienced patients, 91% received prior ruxolitinib. Overall, 83% of patients started momelotinib at the full recommended dose (200 mg/day). Estimated Kaplan-Meier median time to momelotinib discontinuation was 10.6 months. Within 3 months of treatment initiation, 139/158 patients (88%) who were transfusion independent (TI) at baseline remained TI, 30/82 (37%) transfusion-requiring (TR) patients became TI, and 1/22 (4.5%) who were TD became TI. Among patients who were continuously enrolled through 6 months, no baseline TI patients ever became TD, and 4 additional patients who were TD at 3 months became TI by 6 months; mean transfusion rates improved among TD/TR patients from 1.25 to 0.84 per patients per month from 3 months pre-index to 6 months post index. Treatment patterns will also be presented.

CONCLUSIONS: Regardless of prior JAK inhibitor exposure, sustained momelotinib treatment duration was associated with anemia-related benefits. Most patients remained transfusion free within 3 months of starting treatment, further highlighting momelotinib's clinical benefits for improving anemia-related outcomes.

SPONSORSHIP: GSK (study 300182)

176 Advancing payer-provider alignment to improve access, outcomes, and value in bleeding disorders: Insights from a multi-regional managed care initiative

Dunn J¹, Pezalla E², Borrillo J³, Ding H⁴, Blocker A⁵, Richardson T⁶, Casebeer S⁶; jeffrey.d.dunn@comcast.net; terry.richardson@impactedu.net

¹Cooperative Benefits Group; ²Enlightenment Bioconsult, LLC; ³Hemophilia Alliance; ⁴University of California San Diego, Rady Children's Health; ⁵National Bleeding Disorders Foundation; ⁶Impact Education, LLC

BACKGROUND: The Comprehensive Care Sustainability Collaborative (CCSC) is a national initiative of the National Bleeding Disorders Foundation (NBDF) to evaluate and improve alignment between payers and Hemophilia Treatment Centers (HTCs). Misalignment in coverage policies, utilization management, and care coordination contributes to delayed access, administrative burden, and variability in care delivery for patients with bleeding disorders.

OBJECTIVE: To assess payer and provider perspectives on care barriers, evaluate alignment on key drivers of quality and cost, and identify actionable strategies to optimize coverage and care delivery.

METHODS: Four regional payer-provider roundtables (East, West, Midwest, South) were held in 2025, with 23 HTC providers and 17 payers. Structured polling and facilitated discussions captured quantitative and qualitative insights. Descriptive analyses identified cross-regional trends, alignment, and reported intent to implement changes.

RESULTS: Payers identified cost as the primary concern (76.5%), including catastrophic claims (35%) and non-factor and gene therapy costs (24%). HTCs identified prior authorization and utilization management as the most significant barrier (48%). Cross-regional findings showed consistent challenges, including misalignment between coverage policies and clinical practice, limited communication, and administrative burden. Alignment emerged on the value of HTC-based care (57%) and the importance of outcomes data (36%) in informing coverage decisions. Key opportunities included aligning policies with clinical expertise and improving coordination between payer care management and HTC teams. Participants reported improved understanding of opposing perspectives and intent to enhance collaboration.

CONCLUSIONS: Consistent cross-regional gaps exist between payers and HTCs, but shared opportunities were identified. Reducing administrative burden, strengthening communication, and incorporating HTC data into payer decision-making may improve access, outcomes, and total cost of care for patients with bleeding disorders.

SPONSORSHIP: Takeda, Bleeding & Clotting Disorders Institute, CSL Behring, Genentech, Inc., Gulf States Hemophilia and Thrombophilia Center, Hemophilia Alliance, Louisiana Center for Bleeding and Clotting Disorders, Mary M. Gooley Hemophilia Center, Sanofi, and Western New York BloodCare.

177 Economic burden of warm autoimmune hemolytic anemia among Medicare beneficiaries

Jackson L¹, Zhdanava M², Pesa J¹, Boonmak P², Chen G², Liu D², Pilon D³, Shah S⁴; ljacks16@its.jnj.com; jpresa@its.jnj.com

¹Johnson & Johnson; ²Analysis Group, Inc.; ³Analysis Group, Inc.;

⁴Mayo Clinic

BACKGROUND: Warm autoimmune hemolytic anemia (wAIHA) is a rare autoimmune disorder primarily affecting older adults. Treatment relies heavily on off-label medications and management can be challenging due to the complex nature of the disease and complications with current treatments. The economic burden of wAIHA remains poorly characterized.

OBJECTIVE: To characterize the economic burden of wAIHA among Medicare beneficiaries.

METHODS: Adults with wAIHA and without AIHA were identified from the 100% Medicare Fee-for-Service database (10/01/2019–12/31/2023). wAIHA was defined as 1) primary inpatient wAIHA diagnosis (*International Classification of Diseases, Tenth Revision, Clinical Modification* [ICD-10-CM]: D59.11; index: first diagnosis), 2) ≥ 2 any wAIHA diagnoses ≥ 30 days apart (index: second diagnosis), or 3) any wAIHA diagnosis preceded ≥ 30 days by an AIHA diagnosis (ICD-10-CM: D59.10, D59.19, D59.8, D59.9; index: first wAIHA diagnosis); patients with a diagnosis for cold or mixed-type AIHA (ICD-10-CM: D59.12, D59.13) during baseline (12 months pre-index) were excluded. The non-AIHA cohort had no diagnoses for AIHA during the study period (index: random visit date) and was matched 10:1 with the wAIHA cohort based on age on index date. Using overlap weighting, age-matched cohorts were further weighted on demographics and baseline comorbidities. Healthcare resource use (HRU) and costs per-patient-per-month (PPPM) during follow-up (index date until end of data/eligibility) were compared using weighted Poisson and ordinary least squares regressions with bootstrapping.

RESULTS: After weighting, the wAIHA cohort included 3,112 patients (mean age: 74.4 years; 56.1% female; 53.7% secondary wAIHA; mean follow-up: 17.2 months); the non-AIHA cohort included 31,120 patients (mean age: 74.6 years; 56.1% female; mean follow-up: 14.9 months). During follow-up, the wAIHA cohort had 2.32 times more intensive care admissions, 2.60 times more inpatient admissions, and 1.78 times more emergency visits vs the non-AIHA cohort (all $p < 0.05$). Mean total PPPM cost difference was \$6,224 (wAIHA: \$10,860 vs non-AIHA: \$4,636), driven mainly by mean differences in medical costs (86.8%), particularly inpatient costs (\$3,956; wAIHA: \$6,521 vs non-AIHA: \$2,565; all $p < 0.05$). wAIHA-related costs accounted for 64.1% of total costs in the wAIHA cohort.

CONCLUSIONS: Among Medicare patients, wAIHA was associated with significantly higher HRU and costs relative to the absence of AIHA. The economic burden was driven by inpatient care, highlighting the need for improved management strategies.

SPONSORSHIP: Johnson & Johnson

178 Clinical outcomes and economic burden among patients with severe hemophilia A and B in the United States: A real-world claims analysis

Chen J¹, Fridman M², Shy M², Waters E³; jgvc@novonordisk.com

¹Novo Nordisk Inc., Plainsboro, NJ, USA; ²AMF Consulting, Los Angeles, CA, USA; ³Novo Nordisk, Inc., Plainsboro, NJ, USA

BACKGROUND: Hemophilia is a rare bleeding disorder with substantial treatment costs. Despite advances in prophylactic therapy, some patients with severe hemophilia continue to experience breakthrough bleeding. Real-world data on clinical outcomes and economic burden among patients with severe hemophilia A (HA) or B (HB), including pediatric populations, are limited.

OBJECTIVE: To assess clinical outcomes and hemophilia-related costs among patients with severe HA (PwHA) or HB (PwHB) in the United States.

METHODS: This descriptive, retrospective cohort study used the Komodo Health claims database from January 2016 to December 2024. PwHA or PwHB with ≥ 2 hemophilia treatment pharmacy claims per follow-up year was included as a proxy for severe disease. The index date was the first claim; patients had to have ≥ 60 days of follow-up. PwHA with and without inhibitors were analyzed in total; results for PwHB with inhibitors ($n = 3$) are not presented due to the small sample size. Outcomes included mean annualized bleed rate (ABR) by treatment class (standard half-life [SHL], extended half-life [EHL], emicizumab [HA only]), proportion of patients by bleed frequency (0, >0 to <3 , ≥ 3 bleeds/year), and hemophilia-related total cost per patient per year (PPPY). Pediatric subgroups of PwHA (<12 and 12–17 years) were also evaluated.

RESULTS: Among 2,122 PwHA (mean follow-up 3.7 years), 78% ($n = 1,652$) received prophylaxis. Mean ABR was 0.97 overall; PwHA on prophylaxis, 1.00 (SHL factor [F] VIII), 0.96 (EHL FVIII), and 0.90 (emicizumab). By bleed frequency, 39% had 0, 53% had >0 to <3 , and 8% had ≥ 3 bleeds/year; among those on prophylaxis with ≥ 3 bleeds/year, mean ABR was 6.11. Among 738 pediatric PwHA, 80% aged <12 years ($n = 472$) and 79% aged 12–17 years ($n = 266$) received prophylaxis, with mean ABR of 0.76 and 0.81, respectively. Of pediatric patients on prophylaxis, 3% aged <12 and 4% aged 12–17 had ABR ≥ 3 during follow-up. Mean hemophilia-related cost was \$218,324 PPPY for PwHA overall and \$746,446 for those treated with emicizumab. Among 483 PwHB without inhibitors (mean follow-up 3.6 years), 59% received prophylaxis with a mean ABR of 1.45 (SHL FIX: 1.50; EHL FIX: 1.46); 11% experienced ≥ 3 bleeds. Mean hemophilia-related cost was \$93,176 PPPY.

CONCLUSIONS: Despite prophylaxis, some patients with severe hemophilia, particularly those with recurrent bleeding (≥ 3 bleeds/year), continue to experience significant

breakthrough bleeds and incur substantial hemophilia-related costs. These findings highlight unmet needs in severe hemophilia management and provide a real-world baseline for evaluating emerging therapies.

SPONSORSHIP: Novo Nordisk Inc.

Immunology

183 National and regional prevalence of primary biliary cholangitis among adults in the US

Wong R¹, Gish R², Jacobson I³, Leung G⁴, Rock M⁴, Kim C⁴; chong.kim9@gilead.com

¹Stanford University School of Medicine; ²Hepatitis B Foundation; ³New York University Grossman School of Medicine; ⁴Gilead Sciences, Inc.

BACKGROUND: Primary biliary cholangitis (PBC) is a chronic liver disease characterized by the progressive destruction of bile ducts.

OBJECTIVE: To evaluate national and regional prevalence and incidence of PBC among adults in the US.

METHODS: Adults (≥ 18 years) diagnosed with PBC (ICD-10-CM) from Jan 1, 2016, to Dec 31, 2024, were identified from the HealthVerity Database. Yearly and state-level prevalence of PBC were determined among all adults; incidence was calculated among adults with no PBC diagnoses prior to the date of their first PBC claim. Annual prevalence was calculated based on the lifetime prevalence approach; adults diagnosed on or before the year of assessment were included. Patient demographic and clinical characteristics were assessed among PBC-diagnosed patients with continuous enrollment for ≥ 12 months before first diagnosis and ≥ 1 inpatient claim or ≥ 2 outpatient claims, each ≥ 30 days apart.

RESULTS: Among 172,930,000 unique adults in the database between 2016 and 2024, 34,572 had PBC diagnosis, corresponding to a prevalence of 20.0 per 100,000. Yearly PBC prevalence among patients ranged from 20 to 44 per 100,000. Newly diagnosed PBC accounted for 31,324 cases, with an overall incidence of 18 per 100,000. The highest prevalence of PBC among adults was observed in Michigan (63.2 per 100,000) followed by New Mexico (57.2 per 100,000) and Idaho (53.4 per 100,000). Incidence was highest in Michigan (59.1 per 100,000), New Mexico (51.8 per 100,000), and Idaho (48.5 per 100,000). Among 8,897 patients assessed for patient characteristics, the mean (SD) age was 55.4 (14.5), 78.4% were female, 43.7% had commercial insurance, and had hypertension (76.6%), fatigue (65.5%), gastroesophageal reflux disease (63.3%), and pruritus (43.9%).

CONCLUSIONS: In a nationally representative US claims database, the PBC prevalence among adults was 20 per 100,000 and the incidence of PBC among all adults was 18 per 100,000 from 2016 to 2024. We observed significant regional differences in PBC prevalence and incidence, which was highest in Michigan. Evaluating PBC epidemiology will help guide healthcare resource planning and health policy as it relates to screening, diagnosis, and management of PBC.

SPONSORSHIP: Gilead Sciences, Inc.

Infectious Disease

188 Laboratory-confirmed RSV in Medicare beneficiaries aged ≥65 years: Baseline biomarker abnormalities and 30-day severity outcomes using linked lab-claims data, 2021–2025

Baser O¹, Zakeri M², Yapar N², Chen S²; onur.baser@sph.cuny.edu; nehir@cdanyc.com

¹City University of New York (CUNY); ²Columbia Data Analytics

BACKGROUND: Respiratory syncytial virus (RSV) drives substantial hospitalization, ICU use, and mortality in adults aged ≥75 years, yet claims-only data lack the clinical granularity needed to characterize severity in real-world managed-care populations.

OBJECTIVE: To describe baseline laboratory abnormalities and their association with 30-day severity outcomes among Medicare fee-for-service (FFS) beneficiaries aged ≥65 years with laboratory-confirmed RSV.

METHODS: Retrospective cohort of Medicare FFS beneficiaries aged ≥65 years with PCR/multiplex-confirmed RSV (1JAN2021–31DEC2025), drawn from the validated Medicare-Enhanced Labs and Demographics (MELD) dataset—100% Medicare claims deterministically linked to laboratory results and EMR. Baseline labs (–24 to +48 hours from index) included CBC, CRP, procalcitonin, albumin, troponin, and BNP/NT-proBNP. Multivariable logistic models estimated adjusted associations with 30-day all-cause mortality, ICU admission, and high-flow oxygen/mechanical ventilation, controlling for age, sex, and comorbidities.

RESULTS: Among 21,536 beneficiaries (mean age 78; 56% female; 32% heart failure, 38% diabetes), common abnormalities included lymphopenia (~45%), CRP >50 mg/L (~40%), elevated BNP/NT-proBNP (~40%), hypoalbuminemia (~35%), elevated troponin (~30%), and procalcitonin ≥0.5 ng/mL (~25%). Each was independently associated with worse 30-day outcomes; co-elevation of troponin and BNP/NT-proBNP carried the highest mortality risk (aOR 2.07, 95% CI 1.88–2.28).

CONCLUSIONS: Baseline inflammatory, cardiac, and nutritional lab abnormalities are common and prognostic in older adults with RSV. Lab-linked claims data can sharpen severity adjustment and risk stratification for managed-care outcomes and economic evaluations.

SPONSORSHIP: None

189 Real-world healthcare resource utilization and cost burden of COVID-19 in the US Medicare Advantage population

Mugwagwa T¹, Karanth S², Nham T², Goyal R², Esterberg E³, Sidhu G⁴, Yehoshua A⁵, Mokgokong R¹;

tendai.mugwagwa@pfizer.com

¹Pfizer Ltd.; ²RTI Health Solutions; ³RTI-HS; ⁴Pfizer, Inc.;

⁵Pfizer Inc

BACKGROUND: Medicare beneficiaries are at high risk for severe COVID-19 due to their age and prevalent comorbidities, and they incur significant healthcare resource use (HCRU) and costs.

OBJECTIVE: To examine real-world HCRU and cost burden among Medicare beneficiaries with a COVID-19 diagnosis during the omicron variant period, 2023–2024.

METHODS: This retrospective cohort study used TriNetX Linked data to assess US adults aged ≥65 years with Medicare Advantage and an incident COVID-19 diagnosis from July 2023 to June 2024 (index) who were at high risk of severe disease (per CDC criteria) and eligible for antiviral treatment. Follow-up was from diagnosis to disenrollment or December 31, 2024. All-cause HCRU and costs (in 2025 US dollars) associated with outpatient visits, emergency department (ED) visits, and inpatient (IP) admissions were assessed during acute (≤30 days from index) and post-acute phases. IP admissions were assigned to the highest level of care provided. Descriptive analyses were conducted.

RESULTS: The study included 6,219 patients (median age, 73 years; 61.3% female); median follow-up was 10 months. Comorbidity burden was high (96.4% had ≥1 high-risk condition; mean Charlson Comorbidity Index, 2.7), with prevalent hypertension (80.6%), heart condition (56.9%), and obesity/overweight (44.6%). Post-index, 29.0% received COVID-19 treatment. During follow-up, 27.5% had IP general ward admissions (2.3 admissions per patient, median length of stay [LOS] 3.6 days per admission). Intensive care unit (ICU) admissions without mechanical ventilation (MV) occurred in 3.7% (1.2 admissions per patient, median LOS 6 days), while ICU MV admissions occurred in 1.4% (1.1 admissions per patient, median LOS 9 days). ED visits occurred in 51.1% (2.9 visits per patient), and outpatient hospital visits occurred in 67.1% (7.8 visits per patient). Mean costs were \$4,776 per general

ward admission, \$16,287 per ICU admission without MV, \$33,389 per ICU admission with MV, \$700 per ED visit, and \$515 per outpatient hospital visit. Total mean cost per patient was \$23,565 (acute, \$3,832; post-acute, \$20,233).

CONCLUSIONS: Among high-risk Medicare Advantage beneficiaries, COVID-19 is associated with substantial HCRU and costs extending beyond the acute phase. Fewer than one-third received COVID-19 treatment, despite high risk at baseline. These findings highlight the ongoing clinical and economic burden of COVID-19 in older, high-risk adults and the potential value of optimizing treatment strategies.

SPONSORSHIP: Pfizer Inc.

190 Early real-world utilization of novel encounter for HIV pre-exposure prophylaxis diagnosis code: A retrospective analysis of US healthcare administrative claims

Ramirez-Ruiz L¹, Metzner A¹, Nguyen C², Martinez D¹, Herman G¹, Alinezhad F³, Banatwala A⁴, Young-Xu L⁵, DerSarkissian M⁴; leira.e.ramirez-ruiz@viivhealthcare.com; aimee.a.metzner@viivhealthcare.com

¹ViiV Healthcare; ²Analysis Group, Inc., Menlo Park, CA, USA;

³Analysis Group; ⁴Analysis Group, Inc.; ⁵Analysis Group, Inc., Boston, MA, USA

BACKGROUND: In July 2012, the United States Food and Drug Administration approved the first medication indicated for human immunodeficiency virus (HIV) pre-exposure prophylaxis (PrEP), a fixed dose combination of emtricitabine/tenofovir disoproxil fumarate. Cabotegravir long-acting (CAB LA) was approved for HIV PrEP in December 2021. A PrEP-specific ICD-10-CM code could enable more precise identification of PrEP encounters in healthcare administrative claims and provide an opportunity to better characterize real-world PrEP utilization patterns over time. On October 1, 2023, a PrEP-specific *International Classification of Diseases, Tenth Revision, Clinical Modification* (ICD-10-CM) code (Z29.81) became effective.

OBJECTIVE: To assess the uptake of the ICD-10-CM code for PrEP encounter (Z29.81) and describe utilization changes over time.

METHODS: PrEPFACTS was a retrospective US study using data from the Komodo Research Database. This analysis included all individuals with ≥ 1 injection of CAB LA or ≥ 1 prescription of oral PrEP from October 1, 2023, to September 30, 2024. ICD-10-CM code Z29.81 (encounter for HIV PrEP) was used to identify a PrEP encounter.

RESULTS: Among 445,376 individuals, 62,366 (14%) had at least one instance of ICD-10-CM code Z29.81 utilized between October 2023 and September 2024. Monthly utilization of

the PrEP ICD-10-CM code increased over time. Among individuals in the study population, the number with ≥ 1 HIV PrEP-related encounter (ICD-10-CM Z29.81) increased from 2,613 (4.2%) in October 2023 to 16,538 (26.5%) in September 2024.

CONCLUSIONS: Utilization of the PrEP ICD-10-CM diagnosis code increased over time between October 2023 and September 2024. Proper use of this code should be encouraged as it allows healthcare providers to avoid use of older, potentially inaccurate or stigmatizing codes such as “high-risk sexual behavior,” in addition to enabling more precise characterization of real-world PrEP use.

SPONSORSHIP: ViiV Healthcare

191 Value considerations for norovirus vaccination: Findings of a systematic review on costs and targeted literature review of cost-effectiveness models

Patterson B¹, Kodjamanova P², Ahn D³, Kim C⁴, Monaghan S⁴, Iqbal S⁴; brandon.patterson@modernatx.com

¹Moderna, Inc.; ²Amaris Consulting UK Ltd; ³Amaris consulting; ⁴Moderna

BACKGROUND: Vaccines for the prevention of norovirus acute gastroenteritis (AGE) are on the horizon. Considerations of value by NITAGs and other population-based decision makers will determine access for these vaccines and include measurements of disease costs and their inclusion in value assessment models.

OBJECTIVE: To describe literature on costs associated with norovirus AGE in adults and to examine how cost-effectiveness (CE) of hypothetical norovirus vaccines has been explored.

METHODS: A systematic literature review (SLR) focused on all costs for adults with norovirus AGE was conducted using electronic and hand searches in electronic databases and grey literature. Two independent reviewers screened studies against prespecified criteria, with standardized data extraction and verification. Findings were synthesized descriptively. Additionally, a targeted literature review (TLR) explored cost-effectiveness of hypothetical norovirus vaccine used in any age. Findings were synthesized descriptively, with stratification for population vaccinated and highlighting model features and findings.

RESULTS: Of 4,898 records identified in the SLR electronic search, 27 were included after duplicates and full text screening. Hand searches, including grey literature and extant reviews, added an additional 54. Of these, 16 reported overall costs, 5 reported productivity losses, 2 reported HRQoL, and 1 caregiver burden. While costs were heterogeneous across markets, a clear pattern emerged that norovirus AGE indirect

costs dominated direct costs across geographies. The TLR identified 7 manuscripts reporting CE analyses with various structures (ie. dynamic, Markov, decision tree). Two focused on military populations while a majority focused on vaccinating whole populations evenly split with adult, pediatric or all ages considered. All studies identified some vaccination strategies that could be cost-effective.

CONCLUSIONS: Norovirus AGE in adults causes substantial cost burden, albeit much is indirect and connected to productivity loss, caregiver effects, and opportunity costs. While several studies have demonstrated the cost-effectiveness of hypothetical vaccines, no consensus exists on modeling approach, included value elements or preferred vaccination strategy. As norovirus vaccines receive licenses, thoughtful development of cost-effectiveness frameworks capturing the full burden of disease, including direct and indirect costs, are needed to inform norovirus vaccine access decisions.

SPONSORSHIP: Moderna, Inc.

192 Economic burden of outpatient intravenous antibiotic use in patients with complicated urinary tract infection: A real-world claims-based study

Lodise T¹, Edgecomb A², Svedsater H³, Miller G⁴, Birch K⁴, Sunkari K⁴, Joshi K⁵; aguising01@gmail.com; henrik.x.svedsater@gsk.com

¹Albany College of Pharmacy and Health Sciences, 106 New Scotland Ave, Albany, 12208, NY, US; ²GSK, 1250 S Collegeville Rd, Collegeville, 19426, PA, US; ³GSK, 79 New Oxford Street, London, WC1A 1DG, UK; ⁴Inovalon, 4321 Collington Road, Bowie, 20716, MD, US; ⁵GSK, Collegeville, PA, USA

BACKGROUND: Complicated urinary tract infections (cUTIs) are common in community and hospital settings, with over 625,000 hospitalizations annually in the US. Intravenous (IV) antibiotics, including carbapenems and ceftriaxone, are often required due to multidrug-resistant uropathogens, but their use may be associated with substantial costs.

OBJECTIVE: To evaluate 30-day total healthcare costs, cUTI-related and outpatient IV prescription costs among patients with cUTI.

METHODS: This retrospective longitudinal study used de-identified claims data from the 100% Medicare Fee-For-Service database (1 Jan 2021–31 Dec 2023) and the Inovalon MORE2 Registry (1 Jan 2021–31 Dec 2024), including Managed Medicaid, Medicare Advantage and Commercial populations. Adults (≥18 years) with ≥1 medical claim for urinary tract infection (UTI) and a cUTI-defining condition within ±7 days were included. The index date was defined as the most recent date between the initial UTI diagnosis and the first cUTI-related claim. Patients received outpatient

IV carbapenem or ceftriaxone within ± 3 days of index and had continuous medical and pharmacy enrollment for ≥12 months pre- and ≥30 days post index. Patients hospitalized ± 7 days prior to the index date without a cUTI diagnosis were excluded. All-cause, cUTI-related and pharmacy costs were assessed over the 30-day follow-up.

RESULTS: A total of 327,370 patients were included. Mean (standard deviation [SD]) 30-day all-cause medical costs, excluding pharmacy, were \$6081 (\$12,810), driven by inpatient hospitalizations (\$2242 [\$8588]) and emergency department (ED) visits (\$1299 [\$1566]). Mean (SD) 30-day all-cause outpatient pharmacy prescription costs, excluding IV prescriptions, were \$537 (\$2482). Mean 30-day cUTI-related medical costs, excluding pharmacy costs, were \$3455 (\$7293), driven mainly by inpatient hospitalizations (\$1232 [\$5606]) and ED visits (\$1168 [\$1427]) and were higher among patients receiving carbapenems vs ceftriaxone. Mean 30-day cUTI-related IV antibiotic prescription costs were \$1174 (\$1598). Costs varied across payer types, with Medicare Advantage patients incurring the highest total 30-day cUTI-related medical costs (\$4577 [\$10,290]). Patients diagnosed in the inpatient setting had substantially higher 30-day cUTI-related 30-day costs (\$12,840 [\$16,284]) compared with other settings.

CONCLUSIONS: IV antibiotic treatment for cUTI is associated with substantial healthcare utilization and costs, largely driven by acute care services. There is a need for effective, less resource-intensive treatment strategies for patients with cUTI.

SPONSORSHIP: GSK (study 305460)

193 Characterization and treatment patterns of high-cost patients with uncomplicated urinary tract infections in the United States

Edgecomb A¹, San Martin P², Laliberté F³, Gao C⁴, Burdeau J⁴, Liu B⁴, Zhang K⁴, Mei H⁵, Joshi A⁶, Joshi K⁶; aguising01@gmail.com

¹GSK, 1250 S Collegeville Rd, Collegeville, 19426, PA, US; ²GSK, Wavre, Belgium; ³Groupe d'analyse SRI; ⁴Analysis Group Inc.; ⁵Global Real-World Evidence and Health Outcomes Research, GSK; ⁶GSK, Collegeville, PA, USA

BACKGROUND: Urinary tract infection (UTI) is one of the most common bacterial infections in the US, typically managed as low acuity. However, a subset of patients with uncomplicated UTI (uUTI) incurs disproportionately high healthcare costs, with limited real-world evidence describing this group.

OBJECTIVE: To characterize female patients with uUTI who incur high all-cause healthcare costs within 30 days of diagnosis.

METHODS: This retrospective cohort study used the IQVIA PharMetrics Plus Closed Health Plan Claims Database (May 2023–March 2025). Female patients ≥ 12 years with uUTI prescribed ≥ 1 oral antibiotic (ABX) within 5 days of diagnosis were included. High-cost patients were defined as those in the ≥ 80 th percentile of cumulative all-cause costs. Demographic and clinical characteristics were compared between high- and non-high-cost groups. All-cause and UTI-related healthcare resource utilization (HRU) were assessed during follow-up.

RESULTS: Among 101,367 patients (20,274 high-cost; 81,093 non-high-cost), mean (standard deviation [SD]) 30-day all-cause costs were substantially higher in the high-cost group (\$3904 [\$8271] vs \$347 [\$242]). High-cost patients were older (46.0 [19.7] vs 40.8 [18.9] years) and more likely to have Medicare coverage (17.1 vs 10.9%), reside in nursing homes (1.7 vs 0.8%), receive index treatment in emergency settings (22.1 vs 14.3%), and have higher comorbidity burden (Charlson Comorbidity Index score: 0.5 [1.1] vs 0.2 [0.7]). Compared to non-high-cost patients, high-cost patients had higher baseline HRU, more likely to receive >3 ABX during baseline (25.0 vs 19.0%; β -lactams 37.8 vs 34%) and have documented ABX allergy (3.0 vs 1.6%), and less likely to have no prior ABX use (37.0 vs 41.4%). During follow-up, high-cost patients had higher all-cause and UTI-related HRU across inpatient (IP; 11.0 vs 5.9%; 2.6 vs 0.9%), outpatient (OP; 97.1 vs 93.8%; 29.8 vs 25.7%), and emergency room (ER; 61.1 vs 53.8%; 17.1 vs 15.5%) settings. Mean (SD) all-cause OP visits per person per year were higher among high-cost patients (22.1 [35.9] vs 10.7 [14.2]). Adjusted analyses showed significantly higher all-cause IP (rate ratio [RR] 1.71), OP (RR 1.37), and ER visits (RR 1.20) (all $p < 0.001$). UTI-related IP (RR 1.96) and OP visits (RR 1.27) were also higher ($p < 0.001$), while ER use did not differ (RR 1.00; $p = 0.99$).

CONCLUSIONS: A small subset of patients with uUTI accounts for a high share of short-term HRU. Identifying characteristics and drivers of high-cost patients may inform targeted management strategies and reduce HRU.

SPONSORSHIP: GSK (study 300711)

194 Impact of extended antibiotic treatment duration on post-treatment healthcare utilization in patients with uncomplicated urinary tract infections in the United States

Bland C¹, Edgecomb A², Laliberté F³, Gao C⁴, Hayes J⁵, Burdeau J⁴, Ma S⁴, Liu B⁴, Joshi K⁶; cmbland@uga.edu; agusing01@gmail.com

¹The University of Georgia College of Pharmacy, Savannah, GA, US; ²GSK, 1250 S Collegeville Rd, Collegeville, 19426, PA, US;

³Groupe d'analyse SRI; ⁴Analysis Group Inc.; ⁵GSK, Durham, NC, US; ⁶GSK, Collegeville, PA, USA

BACKGROUND: Uncomplicated urinary tract infections (uUTIs) are a leading cause of antibiotic (ABX) prescribing in the US. Despite guideline recommendations for short treatment durations, extended courses remain common. There is limited data quantifying the association of extended duration of ABX on economic outcomes.

OBJECTIVE: To evaluate all-cause and treatment-related adverse event (TRAE)-related healthcare resource utilization (HRU) following extended vs appropriate durations of empiric oral ABX use in female patients with uUTI.

METHODS: This retrospective study used Optum Market Clarity electronic health record (EHR) data (May 2023–March 2025). Female patients (≥ 12 years) with symptomatic uUTI, an ABX prescription within 5 days of diagnosis, and ≥ 12 months of EHR activity prior to first ABX prescription post-diagnosis (index date) were included. Based on a 7-day post-index landmark period, patients were categorized as extended (≥ 8 days) or appropriate (5–7 days) users. HRU (outpatient [OP], inpatient [IP], and emergency department [ED] visits) was assessed over the 90 days post-landmark. Poisson regression with inverse probability of treatment weighting estimated rate ratios (RRs) comparing HRU between the two cohorts.

RESULTS: Among 57,448 patients, 17,867 (31.1%) received extended ABX treatment duration and 39,581 (68.9%) were appropriate users. Patients with extended ABX duration were older (mean $\pm$ standard deviation [SD] 55.1 $\pm$ 20.6 vs 52.3 $\pm$ 20.9 years) and had a higher Elixhauser comorbidity score (1.1 $\pm$ 4.8 vs 0.8 $\pm$ 4.2). Compared with appropriate users, a greater proportion of patients with extended ABX duration had ≥ 1 all-cause OP visit (72.5 vs 65.6%) and IP visit (3.0 vs 2.0%); ED visits were comparable (12.5 vs 12.9%). This pattern was consistent for TRAE-related HRU: OP (22.6 vs 17.3%) and IP (2.2 vs 1.4%) visits were higher, while ED visits were comparable (5.9 vs 5.2%). Extended ABX duration was associated with higher rates of all-cause OP (RR 1.03; 95% CI, 1.00–1.05; $p = 0.020$) and IP visits (RR 1.21; 95% CI, 1.05–1.40; $p = 0.007$). Similarly, extended ABX duration was associated with higher

rates of TRAE-related OP (RR 1.15; 95% CI, 1.10–1.21; $p < 0.001$) and IP visits (RR 1.22; 95% CI, 1.04–1.44; $p = 0.017$). TRAE-related ED visit rates did not differ significantly between cohorts (RR 1.08; 95% CI, 0.98–1.18; $p = 0.114$).

CONCLUSIONS: Extended ABX treatment duration was associated with increased all-cause and TRAE-related HRU compared with guideline-concordant duration. Adherence to recommended durations may reduce HRU and associated costs.

SPONSORSHIP: GSK (study 300328)

195 Budget impact of oral nirmatrelvir/ritonavir in adults at high risk for progression to severe COVID-19 from a United States commercial payer perspective

Mugwagwa T¹, Campbell D², Veenstra D², Mokgokong R¹, Migliaccio-Walle K²; tendai.mugwagwa@pfizer.com
¹Pfizer Ltd.; ²Curta

BACKGROUND: Nirmatrelvir/ritonavir (NMV/r) is indicated and authorized for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults who are at high risk for progression to severe COVID-19. As vaccination rates and the virus evolves, COVID-19 continues to impose a substantial clinical and economic burden on US health plans. Understanding the current budget impact of NMV/r is critical for US payer formulary decision-making.

OBJECTIVE: To estimate the annual budget impact of NMV/r for the treatment of mild-to-moderate COVID-19 in adults for a US commercial health plan in the current Omicron era.

METHODS: A budget impact model was developed to estimate the incremental healthcare cost impact of providing access to NMV/r to a hypothetical 1-million-member US commercial health plan over 1 year. Epidemiological, clinical, and cost inputs were sourced from published literature including a systematic review, and real-world evidence focusing on the current Omicron era. In the base case, we compared a situation without NMV/r on the formulary (supportive care, remdesivir, molnupiravir) and an alternative situation of adding NMV/r to the formulary. Antiviral treatment could reduce the risk of hospitalization or death, with no effect on disease severity among hospitalized patients. A scenario analysis assessed the potential impact of antiviral treatment on post-COVID conditions (PCC) using US real-world evidence of PCC incidence and costs for outpatient office visits, prescription drugs, and hospitalizations. Outcomes included number of hospitalizations averted, total costs, per member per month (PMPM) costs, and annual cost per treated member per year (PTMPY). Sensitivity and scenario analyses assessed how uncertain input parameters affect outcomes.

RESULTS: An estimated 8,085 adults within a 1-million-member commercial plan per year were eligible for COVID-19 antiviral therapy. Adding NMV/r to formulary resulted in 180 fewer hospitalizations and 9 fewer deaths annually within the plan. The total budget impact was \$4,071,996 (\$0.34 PMPM; \$504 PTMPY). Including PCC savings (~\$3,718,609), total budget impact was \$353,388 (\$0.03 PMPM). Key drivers were NMV/r market share, NMV/r effectiveness, and supportive care hospitalization rate.

CONCLUSIONS: NMV/r as a treatment option for COVID-19 is associated with minimal or near neutral budget impact for US payers, due to reductions in hospitalizations and potential cost savings when accounting for PCC, supporting the affordability and value of NMV/r from a US commercial payer perspective.

SPONSORSHIP: Pfizer Inc.

196 Exploration of real-world healthcare resource utilization (HCRU) following ibrexafungerp initiation in patients with vulvovaginal candidiasis (VVC)

Bell K¹, Deshpande C¹, Burns S¹, Chang R², Chen N³, Wang T³, Duh M², Boettner D¹, Azar M¹, Thompson G⁴; kelly.x.bell@gsk.com

¹GSK; ²Analysis Group, Inc., Boston, MA, USA; ³Analysis Group, Inc.; ⁴University of California-Davis Medical Center

BACKGROUND: Ibrexafungerp is a first-in-class oral triterpenoid antifungal for the treatment of VVC. Clinical trials (VANISH 303 [NCT03734991]/306 [NCT03987620] and CANDLE [NCT04029116]) demonstrated its effectiveness in patients with VVC and recurrent VVC (rVVC). However, real-world evidence on HCRU following ibrexafungerp initiation has not been evaluated to date.

OBJECTIVE: To explore HCRU in patients with VVC and rVVC initiating ibrexafungerp in a real-world setting.

METHODS: This retrospective cohort study leveraged US administrative claims from Inovalon's Closed Claims Real World Dataset (07/2020–09/2025). Women with ≥ 1 ibrexafungerp claim from 07/01/2021 to 12/31/2023 were included (index = first claim). Patients in the VVC cohort had ≥ 12 mo of continuous enrollment pre-index (baseline), evidence of VVC, and no evidence of pregnancy during baseline. A subset of the VVC cohort met criteria for rVVC (≥ 3 VVC diagnoses or ≥ 1 chronic VVC diagnosis during baseline or 10 d post-index). All-cause and VVC-related HCRU were assessed per person per month (PPPM) over the 6-mo pre-index and 6-mo post-index periods separately for the VVC and rVVC cohorts.

RESULTS: Of 954 patients treated with ibrexafungerp in the VVC cohort, 206 had rVVC. Mean (SD) age was 36.5 (11.2) y for patients with VVC and 34.6 (10.2) y for those with rVVC;

40.3% in both cohorts were White. Most patients were fluconazole-experienced (VVC, 87.1%; rVVC, 92.7%) and used antibiotics (VVC, 82.3%; rVVC, 83.0%) in baseline. 47.3% and 57.8% of patients with VVC and rVVC, respectively, used other antifungals in baseline. In the VVC cohort, total all-cause visits PPPM (95% CI) in the 6-mo pre-index and 6-mo post-index periods were 2.41 (2.37–2.45) and 2.15 (2.11–2.19), respectively. All-cause outpatient (OP) visits, a major driver of HCRU, were PPPM 1.70 (1.67–1.74) pre-index and 1.48 (1.45–1.52) post-index. This trend was consistent with VVC-related visits (0.24 [0.23–0.26] pre-index and 0.09 [0.08–0.10] post-index) and VVC-related OP visits (0.20 [0.19–0.21] pre-index and 0.08 [0.07–0.08] post-index). In the rVVC cohort, all-cause visits PPPM were 2.69 (2.60–2.78) pre-index and 2.49 (2.40–2.58) post-index, and all-cause OP visits PPPM were 2.04 (1.96–2.12) pre-index and 1.79 (1.71–1.87) post-index. The trend was similar with VVC-related visits (0.41 [0.37–0.44] pre-index and 0.16 [0.14–0.18] post-index) and VVC-related OP visits (0.34 [0.31–0.38] pre-index and 0.14 [0.12–0.16] post-index).

CONCLUSIONS: In patients with VVC and rVVC, low all-cause and VVC-related HCRU and numerically fewer visits were observed over the 6 mo post-ibrexafungerp initiation.

SPONSORSHIP: GSK

Managed Care Clinical Programs

203 Assessing the impact of clinical pharmacist intervention on improving the asthma medication ratio in a Medicaid population

Majev L, Meek M, Elame G; lhickman@jhph.org; gelame@jhph.org
Johns Hopkins Health Plans

BACKGROUND: The Pharmacy Quality Solutions team at Johns Hopkins Health Plans Priority Partners played a key role in enhancing the HEDIS measure, Asthma Medication Ratio (AMR), performance through a range of targeted outreach interventions, mostly refill support outreach to improve adherence to controller therapy. This pilot project, however, focused on a subgroup of members—those with a ratio of zero, indicating no recent controller medication and a potential gap in care.

OBJECTIVE: To describe the impact of clinical pharmacist intervention on the AMR, costs, and utilization among Medicaid members with persistent asthma, particularly those with an AMR of zero.

METHODS: In June of 2024, the team identified members in the measure denominator for measurement year 2024 (MY24)

AMR with a ratio of zero, indicating a gap in care—they either were not prescribed or were not filling an asthma controller medication. We also identified members who had a ratio of zero for measurement year 2023 (MY23). For those members who had a ratio of zero in both MY23 and MY24, a clinical pharmacist conducted a thorough chart review with member and provider outreach to close the care gap. In contrast, providers of members who only had a ratio of zero in MY24 received only a fax recommending initiation of controller therapy.

RESULTS: For the clinical pharmacist review group, at 12 months, 26% of members received and filled a prescription for a controller medication. For the fax only group, 30% of members received and filled a prescription for their controller medication. For all interventions groups, median asthma-related costs decreased at 12 months. There was also a decrease in ED visits for all intervention groups except those in the clinical pharmacist review group that received a controller prescription.

CONCLUSIONS: There was no clear advantage observed between the clinical pharmacist review group and fax only group. Median asthma-related medical costs decreased over the 12-month study period for all groups. Asthma-related ED visits also decreased for most intervention groups. Some limitations included data collection across two measurement years, plan membership attrition, and outliers in the clinical pharmacist review intervention group. Additionally, the rise in medical and pharmacist costs across the industry may have impacted some of the financial results. Intervention, whether it be clinical pharmacist review or fax only notification, resulted in a clinically favorable outcome—an increase in members with persistent asthma receiving a prescription for an asthma controller medication.

SPONSORSHIP: None

204 Optimizing secukinumab dispensing for cost containment: Results from a pharmacist-to-prescriber outreach program

Friedlander N¹, Bulochnik Y², Gleason P³; nicholas.friedlander@primetherapeutics.com
¹Prime Therapeutics; ²Prime Therapeutics; ³Prime Therapeutics, LLC

BACKGROUND: Autoimmune medication use has increased steadily in recent years and remains a significant contributor to rising prescription drug expenditures. Non-optimized medication use, defined as dispensing that does not achieve the lowest cost per unit for a given active ingredient, may unnecessarily increase overall autoimmune spend. To address one form of non-optimized medication use, logic was developed to identify instances of secukinumab (SEC)

dispensing that generated additional client costs, and the logic was implemented into a pharmacist-to-prescriber outreach program.

OBJECTIVE: To describe the SEC dispensing optimization opportunity identification logic. Quantify number of interventions, outcomes, and drug cost savings derived from associated managed care pharmacist (MCP) interventions.

METHODS: Pharmacy claims from 13.8 million commercially insured and 1.1 million Medicare members enrolled in the MCP outreach program, from January 2024 to April 2026 (28 months), were analyzed on a weekly basis. The SEC logic assessed pharmacy claims at a member level over the preceding 6 months to identify recent non-optimized dispensing of SEC, defined as member receiving two boxes each with a single 150 mg syringe per 300 mg dose, resulting in double the cost when a single box with two 150 mg syringes is available at the same cost. Cases were provided to MCPs via an integrated web tool; case details provided to MCPs included enrollment information, claims data, and estimated intervention drug cost savings. Total savings were calculated by subtracting the annualized post-intervention therapy drug cost from the pre-intervention annualized therapy drug cost, assuming 100% adherence.

RESULTS: A total of 127 unique cases of recent non-optimized SEC dispensing were identified across the enrolled population during the study period. MCP interventions were attempted for 80 cases, 56 (70.0%) of which were successful. This resulted in total annualized drug cost savings of \$4,739,523 (\$84,634 per case; \$1,788,567 Medicare, \$2,950,956 commercial); 17 (21.3%) of these cases are in progress at the time of abstract submission with estimated annualized savings of \$1,689,443. Interventions were unsuccessful for 7 (8.8%) cases.

CONCLUSIONS: Addition of targeted SEC package size dispensing optimization logic to a MCP outreach program resulted in total PMPM savings of \$0.011 (\$0.058 Medicare, \$0.008 commercial). These results demonstrate the large potential saving associated with optimization of SEC dispensing and the utility of a MCP outreach program in steering to the appropriate product based on prescribed dose.

SPONSORSHIP: Prime Therapeutics LLC

205 Impact of pharmacist-led diabetes reviews on A1c outcomes and provider engagement within a Program of All-Inclusive Care for the Elderly

Cobbinah A, Dhanraj M; acobbinah@centerlight.org;
MDhanraj@centerlight.org
 CenterLight Healthcare

BACKGROUND: Management of type 2 diabetes mellitus in medically complex older adults remains challenging, with multiple comorbidities, polypharmacy, and fragmented care contributing to poor glycemic control. Programs of All-Inclusive Care for the Elderly (PACE) provide an integrated payer-provider model where pharmacist-led diabetes reviews may improve A1c control; however, data in this setting remains limited.

OBJECTIVE: To evaluate impact of pharmacist-led diabetes reviews on operational and clinical outcomes in a PACE population.

METHODS: This retrospective evaluation was conducted on baseline reviews from an ongoing pharmacist-led diabetes program at a PACE organization completed between March 2023 and December 2025. Pharmacists assessed EMR data, medications, and preventive care gaps, such as ophthalmology/podiatry referrals and urine albumin-creatinine monitoring, to provide targeted recommendations to providers. Operational outcomes were assessed across all baseline reviews and included provider response, acceptance rate, and documented recommendation categories. Clinical outcomes were assessed among members with uncontrolled diabetes (baseline A1c >8% within 6 months pre-review) who had accepted recommendations and a follow-up A1c 3–6 months post-review; reviews with baseline A1c ≤8% or missing a follow-up A1c were excluded. The primary clinical outcome was mean change in A1c from baseline to follow-up. Secondary outcomes included proportions achieving a follow-up A1c <8% and a ≥1% A1c reduction. Paired t-test was used to compare baseline and follow-up A1c.

RESULTS: Among 440 baseline pharmacist-led diabetes reviews, recommendations were sent in 90.0% of cases (n = 396). Providers responded to 81.3% of sent reviews (n = 322), with recommendations accepted in 82.3% of responses (n = 265). Across all baseline reviews, the most common documented recommendation categories were preventative care gaps (34.9%), adherence (22.6%), and regimen intensification (19.9%). A total of 122 reviews met criteria for clinical outcomes analysis. Mean A1c changed from 10.4% at baseline to 9.0% at follow-up, representing a clinically significant mean A1c change of -1.34% (SD 2.02, 95% CI -1.70 to -0.97, p<0.001). At follow-up, 30.3% of members achieved A1c <8% (n = 37) and 60.7% achieved ≥1% A1c reduction (n = 74).

CONCLUSIONS: Pharmacist-led diabetes reviews in a PACE program were associated with high provider engagement and clinically meaningful A1c improvement, supporting pharmacist integration into diabetes management for medically complex older adults.

SPONSORSHIP: None

206 Beyond the price tag: Are high-cost rare disease drugs truly “high impact”? A decade in review

Tillman F, Ward M; ftillman@ipdanalytics.com

IPD Analytics

BACKGROUND: Rare diseases collectively affect more than 30 million Americans. Prior to 1983, less than 10 rare disease drugs were approved in the preceding decade. Passing of the Orphan Drug Act spurred the development of rare disease therapies. Due to high development costs and small patient populations, these drugs are typically very expensive and identified as “high impact” based on cost alone. Payers generally cover these therapies as treatment options are limited and often devote significant resources to implementing utilization management (UM) strategies to contain costs.

OBJECTIVE: To describe the volume, key attributes, and net revenue of non-oncology rare disease drugs approved over the past decade.

METHODS: Drugs approved between 2015 and 2024 with orphan drug designation or indications associated with rare disease were evaluated, excluding cell or gene therapies, products for acute use, and therapies used for oncology and infectious disease indications. Key attributes reviewed include annual therapy cost at launch, disease prevalence, novel therapies versus follow-on products, and key drivers for adoption. Product level annual U.S. net sales were evaluated beginning with the launch year through 2024.

RESULTS: Seven hundred eleven NDAs and BLAs approved between 2015 and 2024 were reviewed; 130 (18%) met study criteria for inclusion. Forty-five drugs were subsequently removed due to lack of U.S. net sales information or the product being no longer commercially available in the U.S. Of the 130 drugs identified, only 14 (10.8%) have reached blockbuster status (i.e., drugs generating over \$1 billion in annual U.S. net sales) and 6 (4.6%) are likely to achieve blockbuster status. Of the 14 blockbusters, 7 (50%) are novel therapies and/or only drug available for the condition at launch, and 7 (50%) are follow-on products with significant advantage(s) over available therapies at the time including decreased administration burden, lower risk of adverse events, and potentially increased efficacy and/or patient eligibility. Two drugs (14%)

achieved blockbuster status after the approval of additional indication(s).

CONCLUSIONS: Non-oncology rare disease drugs have accounted for fewer than 20% of all NDAs and BLAs approved over the past decade. Moreover, only about 15% of these therapies have achieved or are expected to achieve blockbuster status based on current data. Given that high per-patient costs do not necessarily translate into substantial overall budget impact, payers may consider streamlining utilization management programs to reduce the resources required for their development and maintenance.

SPONSORSHIP: None

Mental Health

215 Real-world clinical reasons patients with opioid use disorder initiate extended-release injectable buprenorphine (CAM2038)

Dawson B¹, Goulette D¹, Fox E¹, Cunningham C¹, Friedman A², Budilovsky-Kelley N², Kaempfer C², Cohen J²; briandawson@idealoption.net; dangoulette@idealoption.net

¹Ideal Option; ²Braeburn Inc

BACKGROUND: Buprenorphine is an effective, FDA-approved medication for the treatment of opioid use disorder (OUD), with multiple formulations available to support individualized care. While sublingual buprenorphine (SL-BUP) is widely used, daily dosing, risk of diversion and misuse, and stigma can present challenges for patients. Extended-release injectable buprenorphine (XR-BUP) may help address these concerns, offering an alternative delivery option that supports adherence, reduces diversion risk, and may simplify treatment logistics; however, real-world clinical reasons guiding its initiation are not well characterized.

OBJECTIVE: To assess clinician-documented reasons patients with OUD were initiated on Brixadi (CAM2038) in the outpatient setting.

METHODS: We conducted a retrospective analysis of adult patients with OUD who initiated CAM2038 in 2025 at Ideal Option, an outpatient network comprising approximately 85 addiction medicine clinics across 9 states. Clinician-documented reasons for CAM2038 initiation were collected via a standardized electronic medical record prompt allowing multiple selections. Patients without selected reasons for CAM2038 initiation were excluded. Descriptive statistics (counts and proportions) were used to summarize clinician-reported reasons for CAM2038 initiation.

RESULTS: A total of 855 patients were included. The most frequently selected reasons for initiating patients on CAM2038 involved complications with prior SL-BUP treatment (59.5%), including treatment failure (31.6%), non-adherence (27.3%), contraindications or clinically significant adverse effects (AEs; 26.7%), and prior diversion (3.2%). Intention to taper buprenorphine to discontinuation within 12 months was also selected for a notable proportion of patients (40.4%). Of patients with documented AEs from prior SL-BUP treatment ($n = 228$), the most frequently cited AE term was dental decay (80.3%), followed by oral lesions (14.5%), nausea/vomiting (9.2%), and headache (8.3%).

CONCLUSIONS: In this real-world outpatient setting, clinicians used CAM2038 for a variety of individualized reasons, including addressing challenges with prior SL-BUP treatment, such as non-adherence, clinically significant AEs, prior diversion, and treatment failure, as well as supporting broader patient-centered treatment goals. Among patients who switched to CAM2038 due to SL-BUP-related AEs, dental decay was the most frequently cited AE term. Despite limited evidence supporting discontinuation of medications for OUD, XR-BUP is used as a tool for tapering off buprenorphine in clinical practice settings.

SPONSORSHIP: Supported by Braeburn Inc

216 Budget impact model comparing treatment with sublingual vs extended-release injectable buprenorphine for individuals with opioid use disorder in the correctional setting

Halim N¹, Elliott Z¹, Fatula M², Friedman A², Budilovsky-Kelley N², DeMicco J³, Cohen J²; nader.halim@fingerprint.com; zachary.elliott@fingerprint.com

¹Fingerprint Market Access; ²Braeburn Inc; ³Braeburn Inc.

BACKGROUND: Providing daily sublingual buprenorphine (SL-BUP) in correctional facilities is often labor-intensive and may limit expanded access to medications for opioid use disorder (MOUD) in the criminal justice system. Extended-release injectable buprenorphine (XR-BUP), administered to patients weekly or monthly, is an alternative treatment option that may offer operational and clinical advantages in the correctional setting.

OBJECTIVE: To project, using a budget impact model, staff time, treatment-related costs, and post-release outcomes associated with providing Brixadi (XR-BUP) or SL-BUP to patients with moderate-to-severe OUD in the correctional setting.

METHODS: A budget impact model estimated the annual staff time and associated costs (in 2026 US dollars), from both a correctional facility and policymaker perspective, to treat

individuals with moderate-to-severe OUD using daily SL-BUP vs monthly XR-BUP in a hypothetical 700-inmate correctional facility. Inputs were based on published literature and supplemented with expert opinion. The time required for staff to provide each treatment was based on medication administration (groups of 10 patients per medication line), inmate movement, and diversion monitoring. Treatment-related costs (excluding drug costs) included those associated with medication administration, inmate movement, diversion monitoring, and supplies. The policymaker perspective additionally projected post-release recidivism and opioid-related fatalities and related societal costs.

RESULTS: An estimated 107 individuals with moderate-to-severe OUD were eligible and willing to receive MOUD. The estimated annual staff time required to provide daily SL-BUP to eligible individuals was 10,009 hours vs 177 hours for monthly XR-BUP, a difference of 9832 hours. The estimated annual treatment-related costs were \$585,547 for SL-BUP vs \$9931 for XR-BUP, a difference of \$575,616. Time and cost savings associated with XR-BUP were largely driven by medication administration and inmate movement. From a policymaker perspective, XR-BUP was associated with a 44% reduction in recidivism cases and 4% reduction in opioid-related fatalities, resulting in a total annual cost savings of \$1,404,517 compared to SL-BUP.

CONCLUSIONS: This budget impact model found that, compared to SL-BUP, use of XR-BUP in the correctional setting reduces staff hours and treatment-related costs, as well as recidivism and opioid-related deaths post-release. XR-BUP may enable more scalable treatment for moderate-to-severe OUD across the criminal justice system and provide additional societal value.

SPONSORSHIP: Funded by Braeburn Inc

217 Real-world suicidality outcomes in major depressive disorder: Comparative risks with brexpiprazole vs other adjunctive atypical antipsychotics

Zakeri M¹, Wagner S¹, Guo W¹, Baser O²; onur.baser@sph.cuny.edu

¹Columbia Data Analytics; ²City University of New York (CUNY)

BACKGROUND: Major depressive disorder (MDD) is one of the most prevalent mental health conditions in the United States and worldwide. Among the most serious complications of MDD is suicide, which is currently the 11th-leading cause of mortality in the United States. Suicidality encompasses a spectrum of behaviors, including suicidal ideation, characterized by thoughts or intentions of ending one's life, and self-harm, involving intentional self-injury or self-poisoning regardless of suicidal intent. Given the strong association between MDD severity and suicidality, early, sustained

treatment of MDD is a critical component of suicide prevention. However, there is limited real-world evidence regarding the effect of medications on suicidal ideation and self-harm among patients with MDD.

OBJECTIVE: To assess suicidal ideation, suicide attempt, and self-harm in MDD patients receiving brexpiprazole compared with those receiving other adjunctive oral AAPs.

METHODS: This retrospective cohort study used Kythera Labs commercial claims data. Adults initiating an oral atypical antipsychotic (AAP) (2021–2024) with ≥ 2 baseline MDD diagnoses and ≥ 90 days of overlapping antidepressant and AAP use were included. Suicidal ideation, suicide attempt, and self-harm were identified via *International Classification of Diseases, Tenth Revision* (ICD-10) codes. Adjusted Cox proportional hazards models accounted for demographics and baseline psychiatric severity.

RESULTS: The cohort included 10,998 brexpiprazole users and 152,697 users of other oral AAPs. After adjustment for age, sex, socioeconomic status, and region, brexpiprazole was associated with lower risk of suicidal ideation (hazard ratio [HR], 0.61; 95% confidence interval [CI], 0.51–0.72) and suicidal attempt or self-harm (HR, 0.56; 95% CI, 0.45–0.70). With additional adjustment for baseline psychiatric severity, brexpiprazole remained associated with reduced risk of suicidal ideation (HR, 0.82; 95% CI, 0.69–0.98) and suicidal attempt or self-harm (HR, 0.73; 95% CI, 0.58–0.91).

CONCLUSIONS: Brexpiprazole was associated with lower risks of suicidal ideation and suicidal attempt or self-harm compared with other adjunctive AAPs. These findings provide clinically meaningful real-world evidence to support adjunctive treatment decisions in MDD.

SPONSORSHIP: None

218 Managed care approaches to treatment-resistant depression: Payer perspectives on interventional therapies—Proceedings from an AMCP Market Insights roundtable

Haumschild R¹, Kobernick M², Shannon M³, Small G⁴, Richardson T⁵, Dragovich C⁶; rhaumschild@gmail.com; terry.richardson@impactedu.net

¹Emory University and Emory Health Plan; ²Blue Cross of MI; ³Ventegra; ⁴Hackensack Meridian Health; ⁵Impact Education, LLC; ⁶Stractical Solutions, LLC

BACKGROUND: Treatment-resistant depression (TRD) affects ~30% of patients with major depressive disorder and accounts for a disproportionate share of depression's \$43.8 billion annual US economic burden. Despite available interventional treatments, persistent infrastructure and access

gaps limit care. Advancing psilocybin clinical development introduces unique patient access considerations for payers.

OBJECTIVE: To assess the TRD treatment landscape, evaluate psilocybin evidence, and characterize payer perspectives on coverage, infrastructure for treatment and monitoring, and collaboration priorities.

METHODS: AMCP convened seven managed care decision-makers, pharmacy leaders, and a behavioral health expert for a Market Insights roundtable (March 31, 2026) using presentations, panel discussion, and real-time polling.

RESULTS: Top access barriers panelists identified were limited treatment centers (43%) and lack of provider awareness (29%) of interventional treatments. Panelists raised concerns about variability in provider qualifications and adequate oversight. Psilocybin showed rapid onset with 37% response and 29% remission rates (COMPASS trial, 25 mg); 33% of panelists considered this evidence compelling for coverage; 17% considered it promising, and 33% were uncertain due to trial design blinding integrity due to the psychoactive effects of the drug. Panelists unanimously identified a need for head-to-head comparative trials, and all reported benefit fragmentation as a moderate challenge. Panelists emphasized that evidence for cost offsets should focus on direct medical costs and noted that existing esketamine centers face long waits, and many operate outside insurance. Most payers would model new coverage policies after existing interventional treatment/REMS frameworks. Episodic treatment value was rated moderate (57%) or uncertain (43%), contingent on durability data. In the post-meeting survey, 66% of panelists reported their current approach was validated, 17% planned to implement changes, and 17% needed more information. Confidence to make change was mixed, and planned actions primarily focused on incorporating new evidence into drug evaluations and applying a collaborative care approach.

CONCLUSIONS: To advance appropriate access to interventional TRD therapies, payers would like head-to-head comparative trials and updated treatment guidelines. Payers identified provider network expansion and cross-benefit coordination as operational priorities for safe and equitable implementation.

SPONSORSHIP: Compass Pathways

219 Characteristics and timing of newly diagnosed mental health conditions following physical injury in a workers' compensation population: A descriptive analysis

Emptage T¹, Jhamb S², Patnala L³, Waters S¹, Kreidler M⁴;
Tron.Emptage@optum.com; sumit_jhamb@optum.com

¹Optum Workers' Comp and Auto No-Fault; ²Optum Global Solutions; ³Optum; ⁴OptumRx

BACKGROUND: Physical injuries are common among workers' compensation populations and can be followed by the development of mental health (MH) conditions. Characterizing the demographic, injury-related, and clinical profiles of injured members with and without subsequent MH conditions, and the timing of MH diagnosis, can inform early identification and intervention strategies.

OBJECTIVE: To describe the patterns and timing of newly diagnosed mental health conditions following physical injury in a workers' compensation population to inform early identification and screening strategies.

METHODS: A retrospective descriptive analysis was conducted among workers' compensation members with physical injury and no prior MH diagnosis. Members were followed for up to one year post injury to identify newly diagnosed MH conditions. MH diagnosis was categorized as early (≤ 90 days), mid (91–180 days), or late (181–365 days) following injury. Demographics, injury type, and baseline comorbidities were summarized overall and by MH diagnosis timing.

RESULTS: Among injured members, 5,170 (3.88%) developed a newly diagnosed MH condition within one year, while 128,162 (96.12%) did not. Of MH diagnoses, 51.9% occurred within 90 days, 21.8% between 91 and 180 days, and 26.3% between 181 and 365 days post injury. Across MH diagnosis groups, most members were aged ≥ 45 years, with those aged >55 years making up approximately 47–48% of cases. Gender distribution was consistent across timing groups, with approximately 53% male and 46% female members. Strains and sprains were the most common injury types among members with MH, accounting for 28–33% and 10–13% of cases across diagnosis groups, respectively, while fractures and contusions were less frequent. Musculoskeletal comorbidities were present in 47.8% of early diagnosis, 52.7% of mid diagnosis, and 52.6% of late diagnosis MH cases. Utilization of anticonvulsants was 37.3%, 46.0%, and 45.3% for early, mid, and late diagnosis groups, respectively.

CONCLUSIONS: In this analysis, a small but clinically meaningful proportion developed MH conditions within one year of injury, with over half diagnosed within the first 90 days. Injured members with newly diagnosed MH conditions were predominantly older and commonly had musculoskeletal and

other baseline comorbidities. These findings highlight the importance of early post-injury monitoring and may inform targeted screening strategies to identify members at elevated risk for subsequent MH conditions.

SPONSORSHIP: Optum

220 Stratifying risk for mental health diagnosis after injury: A multivariable competing risk model in workers' compensation

Jhamb S¹, Emptage T², Waters S², Kreidler M³; sumit_jhamb@optum.com; Tron.Emptage@optum.com

¹Optum Global Solutions; ²Optum Workers' Comp and Auto No-Fault; ³OptumRx

BACKGROUND: Mental health (MH) diagnosis after injury is a critical concern in a workers' compensation population. Understanding the timing and predictors of MH diagnosis enables targeted screening and intervention.

OBJECTIVE: To evaluate the timing and predictors of MH diagnosis after physical injury in a workers' compensation population using a competing risk Cox regression model.

METHODS: A Cox regression model with competing risk was developed on a workers' compensation cohort, categorizing MH diagnosis as early (0–90 days), mid (91–180 days), late (181–365 days), or no MH diagnosis within one year. Baseline demographics and clinical characteristics, including age group (reference: 25–34 years), gender (reference: male), and injury type (reference: contusion), were included as predictors.

RESULTS: Distinct predictors were identified for each diagnosis group compared to individuals with no MH diagnosis in one year. Anticonvulsant use was the strongest predictor across all diagnosis groups, with hazard ratios (HRs) and p values as follows: early diagnosis HR 4.38 (95% CI: 4.03–4.75, $p < 0.001$), mid diagnosis HR 5.90 (5.22–6.68, $p < 0.001$), and late diagnosis HR 5.43 (4.85–6.08, $p < 0.001$). Other comorbidities (musculoskeletal and dermatological) and corticosteroids use consistently increased risk, with HRs ranging from 1.29 to 1.86 depending on timing (all $p < 0.001$). Older age groups (≥ 35 years) were associated with increased risk, especially for late diagnosis (HRs up to 1.72 for ages 45–55 [$p < 0.001$] and 1.69 for ages >55 [$p < 0.001$]), while younger age (<25 years) was protective for mid and late diagnosis (HRs 0.56 [$p = 0.046$] and 0.46 [$p = 0.018$], respectively). Multiple injuries increased risk for early diagnosis (HR 1.31 [$p = 0.008$]), while dislocation was protective for early diagnosis (HR 0.65 [$p = 0.02$]) but increased risk for late diagnosis (HR 1.82 [$p < 0.001$]). Sprain and strain injuries were consistently protective across all timings (HRs 0.59–0.86, all $p \leq 0.038$).

Gender was not a significant predictor for any diagnosis period.

CONCLUSIONS: Baseline comorbidities and anticonvulsant use are the most powerful predictors of MH diagnosis after injury, regardless of timing. Older age and certain injury types (multiple injuries, dislocation) further stratify risk, while younger age and sprain/strain injuries are less problematic. These findings support targeted screening and intervention strategies, enabling early identification and management for high-risk individuals in a workers' compensation population.

SPONSORSHIP: Optum

221 Characterizing psychosocial distress of caregivers of children with ASD utilizing employee claims data

Nguyen J, Stitt K, Swart E, Peasah S, Rosenberg E, Good C;
nguyenj12@upmc.edu
UPMC Health Plan

BACKGROUND: Approximately 1 in 36 children are diagnosed with autism spectrum disorder (ASD). Caregivers of children with ASD face distinct challenges, as symptoms of ASD are seen across the lifespan. Additionally, as patients with ASD often have co-occurring diagnoses, caregivers can experience considerable quality-of-life strain. ASD treatment options can be multifaceted and complex, including intensive behavioral interventions and psychotropic medications. Managing dependent care requires persistence, time, and effort, which may lead to caregiver psychosocial distress.

OBJECTIVE: To characterize patterns of psychosocial distress and burden of employees of children with ASD, utilizing employee claims data.

METHODS: A retrospective cohort study of de-identified administrative claims from the WorkPartners Research Reference Database of employees and their dependents (aged 0-17 years old) with ASD. To classify binary complexity of ASD, dependents had to have had polypharmacy (>3 drug classes) and/or antipsychotic medication claims. Outcomes of interest were compared over 3 years and between 3 different groups. Descriptive statistics and comparisons were analyzed using chi-square or t-test where appropriate.

RESULTS: There were 3,430 employees in the analysis; 59% were male (n = 1,815). The cohort was split into three groups: n = 401 for complex ASD, n = 1,374 employees of children with non-complex ASD and on pharmacotherapy, and n = 1,655 employees of children with non-complex ASD and not on any ASD-relevant pharmacotherapy. Caregivers of those with complex ASD (z = 2.88, p = 0.004) and caregivers of non-complex ASD but medicated (z = 2.29, p = 0.022) had higher diagnoses of generalized anxiety disorder compared

to caregivers of unmedicated children with non-complex ASD. Similar trends were observed for depression, (complex ASD: z = 5.88, p < 0.001; non-complex, medicated: z = 4.04, p < 0.001) and opioid use disorder (complex ASD: z = 2.86, p = 0.004; non-complex, medicated: z = 2.51, p = 0.012.).

CONCLUSIONS: Caregivers of dependents with complex ASD and medicated, non-complex ASD had an elevated psychosocial burden, compared to caregivers of dependents with unmedicated, non-complex ASD. These results can inform clinicians and employers in identifying caregivers at risk and directing them toward appropriate supportive resources.

SPONSORSHIP: None

Oncology

247 Healthcare resource utilization in patients with newly diagnosed metastatic pancreatic adenocarcinoma in the US

Pant S¹, Meissner B², Parry R³, Ball P³, Barron J³, Korth T³, Bibeau W², Kent B², Lu E², Graham J²; spant@mdanderson.org; wbibeau@gmail.com

¹MD Anderson; ²Revolution Medicines; ³Carelon

BACKGROUND: In oncology, healthcare resource utilization (HCRU) is often substantial, due to intensive treatment, frequent monitoring, and management of disease and treatment-related complications. Metastatic pancreatic adenocarcinoma (mPDAC) is a particularly challenging disease with a 5-year survival of ~3%. Few studies have examined the burden of HCRU in patients with mPDAC in the US.

OBJECTIVE: To understand HCRU in patients with mPDAC who started first line (1L) treatment.

METHODS: Medical and pharmacy claims data from the Healthcare Integrated Research Database (HIRD) were used to identify patients with newly diagnosed mPDAC who were ≥18 years of age with Commercial, Medicare Advantage, or Supplemental Medicare insurance in the US. The index date was the first mPDAC diagnosis between 01/01/20 and 11/29/24. Patients were required to have ≥6 months of continuous enrollment before baseline, ≥1 month of follow-up after baseline (or ≥1 day of enrollment if death occurred within the first month of follow-up), and initiation of a chemotherapy regimen within 90 days of diagnosis. Study follow-up continued through end of enrollment, end of study period, or death, whichever occurred first. HCRU is reported in the inpatient, outpatient, and emergency department (ED) settings.

RESULTS: A total of 1,911 patients with newly diagnosed mPDAC initiated 1L treatment with chemotherapy (42.9% FOLFIRINOX,

25.9% gemcitabine + nab-paclitaxel). The median follow-up time was 6.2 months (IQR, 3.1-11.2). Patients' mean age was 64.7 years (SD, 10.4), 57.0% were male, and 67.8% were commercially insured. Most patients (88.9%) were followed until death. Regarding inpatient utilization, 83.6% of patients had ≥ 1 hospitalization, and patients averaged 0.4 (SD, 0.4) hospitalizations per person per month (PPPM). Among those with an inpatient hospitalization, the mean length of stay per hospitalization was 5.5 (SD, 4.6) days, and the mean cumulative number of hospitalization days per patient was 14.1 (SD, 14.7) days. For ED utilization, 50.8% of patients had ≥ 1 visit, and patients averaged 0.1 ED (SD, 0.2) visits PPPM. All patients had ≥ 1 outpatient visits and averaged 11.2 (SD, 4.8) outpatient visits PPPM, including an average 2.8 (SD, 1.9) visits for medications and related services PPPM.

CONCLUSIONS: Patients newly diagnosed with mPDAC experience high HCRU with frequent hospitalizations and ED visits, and high outpatient utilization. New therapeutic options with improved efficacy, better tolerability, and less burdensome requirements are needed.

SPONSORSHIP: Revolution Medicines

248 Managed care perspectives on precision medicine in ESR1-mutated advanced breast cancer: Insights from an AMCP Market Insights program

Evans J¹, Fleszar S², Gandhi G³, Hanna K⁴, Haumschild R⁵, O'Shea T⁶, Valbh T⁷, Tweed C⁸, Wolff D⁹, Richardson T¹⁰; jannacevans@gmail.com; terry.richardson@impactedu.net

¹Blue Cross and Blue Shield of Texas; ²Optum Whole Health Solutions; ³Agadia; ⁴Minnesota Oncology; ⁵Emory University and Emory Health Plan; ⁶Horizon BCBS; ⁷PharmaKonnnect; ⁸Maryland Oncology Hematology, Annapolis, MD; ⁹AMCP; ¹⁰Impact Education, LLC

BACKGROUND: Endocrine resistance drives progression in hormone receptor-positive (HR+)/HER2-negative advanced breast cancer (aBC). Mutations in the estrogen receptor alpha gene (ESR1) are rare at baseline (<5%) but emerge in ~40% of patients progressing on aromatase inhibitor plus CDK4/6 inhibitor therapy. Detection of ESR1 mutations using circulating tumor DNA (ctDNA) may occur a median of 6-7 months before radiologic disease progression, creating an opportunity for earlier treatment modification. Uncertainties remain regarding optimal testing intervals, clinical utility, and cost-effectiveness.

OBJECTIVE: To assess payer and patient perspectives on ESR1-mutated aBC, including ctDNA-guided monitoring and emerging therapies, and identify opportunities for managed care organizations to support precision medicine adoption.

METHODS: An AMCP Market Insights program convened 9 stakeholders in February 2026, including health plan leaders, oncology pharmacists, an oncologist, a patient advocate, and specialty pharmacy representatives. Participants reviewed the patient journey, evidence for ctDNA monitoring, and treatment strategies, followed by moderated discussion. Polling responses informed thematic analysis related to the patient journey and managed care decision-making.

RESULTS: Baseline polling identified key unmet needs affecting quality of life in HR+/HER2- aBC: strategies to address affordability (8/9), biomarker-guided treatment decisions (7/9), and guidance on treatment sequencing (6/9). Half of respondents felt evidence for routine ctDNA monitoring was sufficient for coverage decisions; one-quarter viewed the evidence as promising but evolving. Evidence linking earlier mutation detection with improved clinical outcomes was ranked most important (9/9), followed by comparative testing interval data (8/9) and cost-effectiveness data (7/9). Participants also noted the evolving role of next-generation selective estrogen receptor degraders (SERDs). In a post-meeting survey, most participants (5/8) planned to implement changes to practice or administrative programs, while about one-quarter said the discussion reinforced current approaches.

CONCLUSIONS: Managed care stakeholders recognize the potential value of ctDNA-guided treatment strategies in breast cancer. Patients want access to early mutation detection and targeted treatments. Findings highlight the need for testing guidance and evidence supporting clinical and economic value. Multistakeholder dialogue and emerging data may help support early integration of ctDNA-guided monitoring and next-generation SERDs into managed care decision-making.

SPONSORSHIP: AstraZeneca

249 Performance of a multi-cancer early detection (MCED) test in adults aged ≥65 years: Results from the PATHFINDER 2 study

Matrana M¹, Giridhar K², Kaltman R³, McDonnell III C⁴, Nabavizadeh N⁵, Kurbegov D⁶, Rybicki B⁷, Sternberg C⁸, Bole R⁹, Cancino R¹⁰, Jaboin J¹¹, Tung J¹², Vu T¹³, Guo D¹⁴, Shah S¹⁴, Fung E¹⁴, Colocci N¹⁵; mamatrana@ochsner.org;

Natalia.Colocci@sutterhealth.org

¹Ochsner Clinic Foundation; ²Mayo Clinic; ³Inova Fairfax Hospital; ⁴Sutter Institute for Medical Research; ⁵Oregon Health & Science University; ⁶HCA Healthcare Sarah Cannon Cancer Network; ⁷Henry Ford Health; ⁸Englander Institute for Precision Medicine, Weill Cornell Medicine; ⁹Cleveland Clinic; ¹⁰UT Health San Antonio; ¹¹University of Oklahoma College of Medicine; ¹²University of Pittsburgh; ¹³Kelsey-Seabold Clinic; ¹⁴Grail, Inc.; ¹⁵Palo Alto Medical Foundation

BACKGROUND: Cancer risk increases with age, and individuals eligible for Medicare, most of whom are ≥65 y, may benefit from screening with MCED tests. One available MCED test detects a shared cancer signal in cell-free DNA and predicts the cancer signal origin (CSO) to guide diagnostic evaluation.

OBJECTIVE: To describe performance of the MCED test in participants (ppts) aged ≥65 y.

METHODS: PATHFINDER 2 (NCT05155605) is a multicenter, prospective, interventional study that enrolled ppts aged ≥50 y. Key exclusion criteria were clinical suspicion of cancer, cancer diagnosis or cancer treatment ≤3 y prior to enrollment, or cancer diagnosis >3 y prior to enrollment without treatment. This analysis includes the first 12m of follow-up after the MCED test blood draw. For those with a positive (cancer signal detected) result, 1 or 2 CSO predictions were provided.

RESULTS: Of 35,878 enrolled ppts, 17,284 (48.2%) were analyzable and aged ≥65 y. In this subset, 53.4% were female, and 11.9% had a prior cancer history; 15,953 (92.3%) completed a 12-m cancer status assessment. MCED test positive rate was 1.28% (95% CI, 1.12-1.47%), cancer detection rate was 0.73% (0.61-0.87%), and the number needed to screen to detect 1 cancer was 138 (115-165). Positive predictive value (PPV) was 56.9% (50.0-63.5%), negative predictive value was 99.0% (98.8-99.1%), specificity was 99.44% (99.31-99.54%), and the false-positive rate was 0.56% (0.46-0.69%). 12-m episode sensitivity was 41.9% (36.2-47.8%) across all cancers and 71.9% (63.5-78.9%) in a subgroup of 12 cancers responsible for two-thirds of US cancer deaths. CSO1/2 prediction accuracy was 89.7% (82.8-94.0%). Of 116 ppts with MCED-detected cancers, 101 had new primary cancers and 16 had recurrences; 1 had both. Among the 101 ppts with new primaries, 51 (50.5%) were stage I-II and 70 (69.3%) stage I-III. Of

MCED-detected cancers, 79/116 (68.1%) were types without guideline-recommended screening (ie, types other than breast, cervix, colorectum, lung, and prostate).

CONCLUSIONS: In adults aged ≥65 y, MCED testing demonstrated clinically meaningful cancer detection with high specificity and PPV. CSO prediction accuracy was high, supporting its value in guiding diagnostic workups. These findings highlight the potential benefit of MCED testing as an addition to existing approaches to enable earlier detection of cancers, including cancers without guideline-recommended screening, in the ≥65-y, Medicare-eligible population.

SPONSORSHIP: GRAIL, Inc.

250 Barriers to measurable impact: Improving NSCLC care through payer-focused education

Kobernick M¹, Hoye-Simek A², Richardson T³, Tapan U⁴, Bhatt S⁵; terry.richardson@impactedu.net;

umit.tapan@bmc.org

¹Blue Cross of MI; ²Devoted Health; ³Impact Education, LLC;

⁴Section of Hematology & Medical Oncology, Boston University Chobanian & Avedisian School of Medicine, and Boston Medical Center; ⁵Boston Medical Center

BACKGROUND: Advances in non-small cell lung cancer (NSCLC) have increased reliance on biomarker-driven therapy, creating new challenges in coverage determination, prior authorization, and utilization management. Multistakeholder roundtables identified key barriers, delays in biomarker testing, misaligned coverage policies, and administrative burden that informed subsequent educational interventions.

OBJECTIVE: To describe payer and provider perspectives on access barriers in NSCLC and assess the impact of an educational initiative on knowledge, competence, and intended practice change.

METHODS: Qualitative insights were collected through two regional roundtables (oncologists, n = 5; managed care professionals, n = 9). Findings informed a multi-format education series (live symposium, webcast, and on demand) for a total of 386 learners who influence the care of more than 58,000 patients with NSCLC. Outcomes were evaluated using matched pre-/post-survey data (n = 219).

RESULTS: Roundtables highlighted delays in biomarker testing, inconsistent coverage, and fragmented workflows as key barriers. Outcomes from the education series improved significantly from pre- to post-assessment: correct identification of cost-effective biomarker testing strategies increased from 31% to 67% (P < .01); identification of value-based health plan strategies increased from 29% to 60% (P < .01); and identification of evidence-based formulary decision-making increased from 52% to 66% (P < .02). Directional

improvements were also observed in guideline-concordant biomarker coverage (+17%) and strategies addressing social determinants of health (+16%). Learner-reported behavioral impact was substantial: 82% of learners reported intent to change or validate practice, with >17,200 patients estimated to benefit.

CONCLUSIONS: This analysis links stakeholder-identified access barriers with measurable gains in payer-relevant knowledge and decision-making. Targeted education on NSCLC biomarker testing, coverage alignment, and utilization management may drive meaningful managed care practice changes, equipping health plan decision-makers and formulary committees with the evidence needed to support guideline-concordant care.

SPONSORSHIP: Regeneron Pharmaceuticals, Inc.

251 Economic Burden of Patients with Recurrent and Metastatic Head and Neck Squamous Cell Carcinoma in the US

Geiger J¹, Khadka S², DePriest A³, Wang Y⁴, Shi Q³, Xiang C⁴, Waters D⁵; geigerj@ccf.org; DWaters3@ITS.JNJ.com

¹Cleveland Clinic; ²Johnson & Johnson Innovative Medicine;

³Johnson & Johnson; ⁴Analysis Group, Inc.; ⁵Johnson and Johnson

BACKGROUND: Patients with recurrent/metastatic head and neck squamous cell carcinoma (R/M HNSCC) experience a significant disease burden, particularly in later lines.

OBJECTIVE: This study evaluates the health resource utilization (HRU) from first line (1L) to third line (3L) in R/M HNSCC.

METHODS: Adults with ≥ 2 HNSCC diagnoses were identified from the IQVIA PharMetrics® Plus with Mortality Closed Health Plan claims database (January 1, 2016-July 15, 2025). Among them, patients with recurrent HNSCC were identified if they had a ≥ 180 -day disease-free interval post initial HNSCC diagnosis, and those with metastatic HNSCC were identified based on metastatic diagnosis codes. The selected patients with R/M HNSCC were classified into the 1L, second line (2L), and 3L cohorts using a claims-based line-of-therapy algorithm. Eligible patients were required to have initiated 1L treatment $\geq$ July 2019 and ≥ 3 months of follow-up unless death. HRU was evaluated during baseline (12 months pre 1L) and each line of therapy (from initiation [index date] to next line or end of follow-up).

RESULTS: A total of 1,952 R/M HNSCC patients were included in the 1L cohort, with 23.1% (n = 450) in the 2L cohort and 5.8% (n = 114) in the 3L cohort (median follow-up [years]: 0.7 in 1L, 0.5 in 2L, and 0.6 in 3L). Among patients who did not progress to 2L, 25.1% had a death event; 68.6% did not initiate 2L before the end of the follow-up, among whom 46.2% received

analgesics and 14.0% received palliative care post 1L. In the 1L cohort, mean age was 65.7 years; 75.3% were male; 45.6% had oropharyngeal cancer; 40.8% had cervical lymph node involvement; 27.6% had lung metastases. Mean inpatient (IP) admissions rose from 0.6 at baseline to 1.8, 1.7, and 2.4 per-patient-per-year (PPPY) in 1L, 2L, and 3L, respectively. Average home care visits (9.0 at baseline vs. 18.5 in 1L, 22.7 in 2L, 31.8 in 3L) showed a similar trend. Mean emergency room (ER) visits (1.5 vs. 2.4, 3.0, 3.0) and outpatient (OP) visits (35.8 vs. 55.0, 53.8, 54.6) were similarly high across 1-3L relative to baseline. Supportive care also increased, with mean percutaneous endoscopic gastrostomy (PEG)-tube-related visits rising from 0.9 to 2.7, 2.4, and 3.0 and palliative care visits from 0.3 to 2.0, 2.5, and 4.6.

CONCLUSIONS: In the real world, patients with R/M HNSCC experienced significant HRU that intensifies across lines of therapy, indicating unmet needs for effective therapies after 1L failure. Increasing numbers of PEG-tube and palliative care visits highlight progressive functional decline and limited subsequent treatment options.

SPONSORSHIP: Johnson & Johnson Innovative Medicine

252 Real world clinical, utilization and economic burden of prostate cancer by disease stages in SEER Medicare

Lowentritt B¹, Patel C², Chen C³, Brown G⁴; blowentritt@chesuro.com; ychen342@its.jnj.com

¹Chesapeake Urology; ²Johnson & Johnson; ³Johnson & Johnson Innovative Medicine; ⁴New Jersey Urology

BACKGROUND: Prostate cancer is one of the most prevalent malignancies among U.S. men and represents a substantial source of healthcare utilization and costs, particularly within Medicare. Disease burden varies by clinical stage, with localized prostate cancer (LPC) accounting for a large proportion of patients requiring active management. For payers and healthcare decision-makers, understanding stage-specific patterns of resource use and costs is critical to inform decisions, care pathway design, and long-term budget planning.

OBJECTIVE: This study evaluated temporal trends in patient characteristics, healthcare resource utilization (HRU), and costs among Medicare beneficiaries diagnosed with LPC.

METHODS: A retrospective descriptive analysis was conducted using SEER-Medicare data. Adults aged ≥ 18 years with LPC on or after Jan 1, 2018 were identified using TNM staging, with the index date defined as the initial LPC diagnosis. Patient demographics, clinical, and socio-economic characteristics were assessed during the 12-month baseline period prior to index date. All-cause HRU and costs were evaluated during the calendar year of diagnosis.

RESULTS: The number of prostate cancer patients increased from 52,624 in 2018 to 61,727 in 2021, with LPC consistently representing approximately 50% of all prostate cancer cases across these years. Mean age at diagnosis was about 70 years and over 75% of patients were White. The proportion of patients with at least one inpatient admission declined from 20% in 2018 to 15% in 2021, while the proportion with at least one physician office visit increased from 57% in 2018 to 76% in 2021. Mean total all-cause costs declined modestly from \$19,042 in 2018 to \$18,135 in 2021. Outpatient services, including hospital outpatient services and physician office visits, accounted for about 70% of total costs across years.

CONCLUSIONS: LPC represented a substantial portion of prostate cancer cases within Medicare. Over time, while demographic and clinical characteristics remained stable, care delivery shifted toward outpatient management with declining inpatient utilization, accompanied by modest reductions in total costs. These findings highlight the importance of effective, stage-appropriate treatment strategies for LPC to address unmet clinical need while optimizing resource use.

SPONSORSHIP: Johnson & Johnson

253 A Budget Impact Analysis of Increasing Use of Radium-223 (Ra-223) plus Enzalutamide (Enza) for the treatment of Adult Patients with Metastatic Castration-Resistant Prostate Cancer (mCRPC) and Bone Metastases

Lee J¹, Appukkuttan S¹, Kalayeh B¹, Ngantung W², Saeedian M³; jean.lee.ext@bayer.com; msaeedian@bluepathsolutions.com

¹Bayer; ²BluePath Solutions; ³Blue Path Solutions

BACKGROUND: Prostate cancer is the most commonly diagnosed cancer among men, patients with advanced stages of prostate cancer such as mCRPC with bone metastases are at high risk of disease progression and mortality. Currently, there are many treatment options available for this patient population; notably, results from the PEACE-3 trial demonstrated that the combination of Ra-223+Enza has promising clinical outcomes for these patients.

OBJECTIVE: To calculate the 2-year budget impact to an integrated delivery network (IDN) of increasing use of Ra-223+Enza to treat adult patients with mCRPC with bone metastases initiating first-line therapies.

METHODS: A budget impact analysis was conducted for a hypothetical IDN with 1,000,000 covered lives to estimate the difference in costs for two scenarios: (1) the current treatment landscape reflecting existing usage of Ra-223+Enza; (2) a scenario with increased use of Ra-223+Enza with market share proportionally taken from Enza monotherapy, Ra-223 monotherapy, and Lutetium-177 Vipivotide Tetraxetan

monotherapy. The target population was estimated using an epidemiology funnel to quantify the annual number of incident mCRPC patients with bone metastases entering the model, who initiated therapies based on assumed market shares. Market shares were based on a manufacturer-conducted physician survey. Health states of the patients were tracked using a partitioned survival approach that was developed using radiographic progression-free survival (rPFS) and overall survival (OS) data from the PEACE-3, PSMAFore, and the ALSYMPCA studies. Costs were estimated based on the healthcare resource use associated with progression status or death. Cost inputs included drug acquisition, drug administration, monitoring, diagnostic tests, adverse events, post-progression, and terminal care. Cost inputs were sourced from published literature and publicly available data sources.

RESULTS: Over a 2-year horizon, increasing the market share of Ra-223+Enza by 13% resulted in a net difference in costs for an IDN system of \$733,916, which translates to \$0.03 per member per month. The budget impact was mainly driven by drug acquisition costs, which is primarily offset by post-progression care costs.

CONCLUSIONS: Increasing the market share of Ra-223+Enza resulted in a minimal budget impact for an IDN. These findings suggest that expanded use of Ra-223+Enza among patients with mCRPC and bone metastases remains affordable with limited financial burden.

SPONSORSHIP: Bayer

254 Real-World Procedure and Episode-of-Care Costs of CAR-T Therapies in Commercially Insured Patients

Kuester M, Naber J, Wicklund J, Kamran U; Melanie.Kuester@milliman.com; jessica.naber@milliman.com
Milliman

BACKGROUND: Chimeric antigen receptor T-cell (CAR-T) therapies offer durable clinical benefit in hematologic malignancies but present economic uncertainty for payers. Wholesale acquisition cost (WAC) is the list price, but it does not capture real-world discounts or mark-ups nor other ancillary costs associated with administration, support, and monitoring needs. Real-world cost variability associated with CAR-T therapy remains uncertain, which can present financial risks to insurers and plan sponsors.

OBJECTIVE: To evaluate real-world CAR-T therapy costs in relation to the WAC and episode-of-care costs 30, 60, and 90 days surrounding the index procedure among commercially insured patients.

METHODS: An observational claims-based analysis was conducted using commercial insurance claims between January 2022 to April 2025 from the Milliman Consolidated Health Cost Guidelines™ Sources Database. Six CAR-T therapies were in market and included in the study. Individuals receiving treatment were identified via procedure codes; results were presented across total cases. Descriptive statistics were used to evaluate CAR-T therapy costs and all costs (“episode-of-care”) within 30-, 60-, and 90-days before and after administration. Allowed cost distributions were evaluated using means, standard deviations, and percentile analyses. Threshold analyses estimated the proportion of cases exceeding 1.5x, 2x, 3x WAC.

RESULTS: There were 863 CAR-T cases where product costs were specifically attributable to the CAR-T claim line. Mean CAR-T therapy costs were \$608,280, exceeding the mean WAC of \$443,868. CAR-T therapy costs were highly variable (standard deviation: \$318,219), with the top 5% of claims exceeding \$1.3 million. CAR-T therapy costs exceeded 1.5x, 2x, 3x WAC approximately 23%, 15%, and 5% of the time, respectively. Total episode-of-care costs increased over time with mean costs of \$737,400, \$798,683, and \$851,714 at 30-, 60-, and 90-days, respectively. Cost distributions were right-skewed, with 95th percentile episode costs 2.3x higher than median costs for all three time periods. On average, therapy costs represented 71-82% of episode-of-care costs for the three periods.

CONCLUSIONS: In commercially insured populations, CAR-T therapy and episode-of-care costs are highly variable, largely driven by differences in CAR-T product costs. These findings highlight the importance of proactive reimbursement and risk-mitigation strategies, such as contracting, reinsurance, and alternative financing.

SPONSORSHIP: Milliman, Inc.

255 Cost per Complete Response and Total Cost of Care of Nadofaragene Firadenovec Versus Other FDA-Approved Bladder Sparing Therapies in BCG-Unresponsive High-Risk NMIBC: A US Payer Perspective Analysis

Myers A¹, Yang M², Chai X², Xu M², Moradi A³, Chauhan K³, Hollenack K³, Lotan Y⁴; amanda-myers@uiowa.edu; Kinsuk.Chauhan@ferring.com

¹University of Iowa Health Care; ²Analysis Group Inc.; ³Ferring Pharmaceuticals; ⁴UT Southwestern Medical Center

BACKGROUND: The treatment landscape for high-risk, BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) ± Ta/T1 is rapidly evolving, with bladder sparing therapies (BSTs) differing in dosing, durability, and cost.

OBJECTIVE: To compare the cost per complete response (CR) and total cost of care of nadofaragene firadenovec (NF) versus other FDA-approved BSTs in patients with BCG-unresponsive high-risk NMIBC from a US payer perspective.

METHODS: An economic model compared 1-year cost per CR and total cost of care for NF vs gemcitabine intravesical system (GIS/TAR-200), nogapendekin alfa inbakicept-pmln (NAI), and pembrolizumab (PEM), with 2-year scenario analyses. Patients remained on treatment while in CR. Costs included drug acquisition and administration, disease surveillance, recurrence, progression to muscle-invasive or metastatic disease, adverse events (AEs), and cystectomy. Cystectomy rates were assumed equal across treatments. To address shorter follow-up of TAR-200 and NAI, 2-year costs were estimated using observed counts (OC) or last observation carried forward (LOCF). OC counted only patients with observed CR at 2 years; LOCF carried forward the last response status.

RESULTS: NF demonstrated the lowest cost per CR at 1 year (\$732,475) vs PEM (\$770,177), TAR-200 (\$1,326,441), and NAI (\$1,053,289). Total costs of care per treated patient over 1-year were \$177,785 for NF, \$144,408 for PEM, \$608,836 for TAR-200, and \$475,265 for NAI. Total costs were lower for NF than TAR-200 and NAI despite higher 1-year CR rates for TAR-200 and NAI (NF: 24.3%, PEM: 18.8%, TAR-200: 45.9%, NAI: 45.1%). Cost savings vs TAR-200 and NAI were driven by lower drug acquisition and administration costs due to less intense dosing frequency (NF: \$139,736, TAR-200: \$576,987, NAI: \$439,032). Surveillance and disease-management costs were broadly comparable. TAR-200 had the highest AE cost among BSTs (NF: \$276, PEM: \$725, TAR-200: \$919, NAI: \$547). At 2 years, NF maintained a lower cost per CR versus comparators under both OC and LOCF methods. Total costs of care were directionally similar between BSTs at 2 years.

CONCLUSIONS: Among the assessed BSTs, NF is associated with a total cost similar to PEM while yielding a higher CR rate. Compared with TAR-200 and NAI, NF had a substantially lower total cost. Overall, NF delivered superior cost per CR at 1-year in BCG-unresponsive high-risk NMIBC, driven by fewer administrations and durable CR rates, with findings maintained at 2-years. These results support use of NF as a cost-efficient bladder-sparing treatment after BCG.

SPONSORSHIP: Ferring Pharmaceuticals Inc.

256 A structured literature review of the economic burden of disease recurrence or progression in prostate cancer

Kadri A¹, Nichols G², Barone F², Jenkins A¹, Norton D¹, Tak P², Dineen A¹; aksha.kadri@eversana.com; Deborah.Norton@Eversana.com

¹EVERSANA; ²Candel Therapeutics, Inc

BACKGROUND: Prostate cancer (PCa) is among the most common cancers in men in the US. Despite initial curative-intent treatment for localized PCa, ~30% of patients experience disease recurrence. Patients may also present with advanced castration-sensitive PCa (mCSPC), which can progress to castration-resistant PCa (mCRPC). Disease recurrence and progression greatly increase economic burden.

OBJECTIVE: Characterize the US economic burden associated with PCa recurrence and progression in recent literature.

METHODS: MEDLINE was searched for studies reporting comparative costs of PCa recurrence or progression for qualitative synthesis. Screening was performed in Nested Knowledge® by 1 human and 1 artificial intelligence (AI) reviewer, and bibliographies of relevant systematic reviews were hand-searched.

RESULTS: Of 1,312 identified records, 390 met date and indexing criteria (2020 onward; English; human studies), 30 underwent full-text review, and 7 met PICOS criteria. All included studies were retrospective claims or registry analyses of commercial or public databases. Costs consistently increased with disease progression (5 studies: non-metastatic [nm] to metastatic; 2 studies: pre-mCRPC to mCRPC). Three studies reported higher costs in mCSPC vs. nmCSPC populations. Ryan et al. (2021) reported mean total annual cost per patient per year (PPPY; 2019 USD) (commercial: \$108,767 vs. \$21,201; public: \$69,639 vs. \$16,819); Trinh et al. (2022) reported mean all-cause costs (commercial: \$127,374 vs. \$43,111; public \$100,331 vs. \$43,111; 2018 USD); Ko et al. (2022) reported \$113,725 PPPY greater costs for mCSPC vs. nmCSPC (2020 USD). Two studies reported higher costs in mCRPC vs. nmCRPC. Wu et al. (2020) found greater total healthcare cost PPPY (commercial: \$182,156 vs. \$29,192; public: \$139,847 vs. \$27,549; 2016 USD); Freedland et al. (2020) found up to 8.5-fold increases in inpatient, emergency room, outpatient, and pharmacy costs. Two studies demonstrated higher costs for CRPC vs. CSPC. Kaye et al. (2024) reported higher mean monthly total costs (\$9,717 mCRPC vs. \$4,424 mCSPC; 2022 USD); Freedland et al. (2023) reported higher mean PPPY costs (\$124,379 mCRPC vs. \$27,468 pre-mCRPC; 2019 USD). Across studies, hospitalization was the primary cost driver at earlier disease stages, whereas outpatient visits and pharmacy costs predominated at later stages.

CONCLUSIONS: Healthcare costs increase substantially with PCa progression, highlighting disease advancement as a major driver of economic burden and underscoring the importance of effective early intervention.

SPONSORSHIP: Candel Therapeutics, Inc.

257 Cost-Effectiveness of Ensartinib versus Crizotinib for Patients with Anaplastic Lymphoma Kinase-Positive Non-Small Cell Lung Cancer

Okonkwo M¹, Zeng Z², Nwogu I³, Thornton D², Tatar M²; mcokonkw@cougarnet.uh.edu

¹University of Houston, Texas; ²University of Houston;

³University of Washington

BACKGROUND: Ensartinib received FDA approval in December 2024 for treatment-naïve patients with locally advanced or metastatic ALK-positive non-small cell lung cancer (NSCLC), demonstrating superior progression-free survival and intracranial efficacy over crizotinib in the phase 3 eXalt3 trial. Despite this clinical advance, no U.S. cost-effectiveness evidence exists to guide formulary and reimbursement decisions.

OBJECTIVE: To assess the cost-effectiveness of ensartinib versus crizotinib as first-line therapy for advanced ALK-positive NSCLC from a U.S. healthcare perspective.

METHODS: A lifetime-horizon partitioned survival model was developed to compare ensartinib versus crizotinib in adults with previously untreated, locally advanced or metastatic ALK-positive NSCLC. Survival inputs were derived from parametric distributions fitted to digitized patient-level data reconstructed from published eXalt3 Kaplan-Meier curves. Costs, quality-adjusted life-years (QALYs), and incremental cost-effectiveness ratios (ICERs) were estimated against a willingness-to-pay (WTP) threshold of \$150,000 per QALY. Deterministic (one-way, two-way) and probabilistic sensitivity analyses were conducted to assess model uncertainty.

RESULTS: Ensartinib generated 3.07 QALYs at a lifetime total cost of \$1,945,392, versus 2.43 QALYs at \$1,765,052 for crizotinib, yielding an incremental gain of 0.64 QALYs at an incremental cost of \$180,340 and an ICER of \$280,484 per QALY, exceeding the \$150,000 WTP threshold, indicating that ensartinib was not cost-effective compared with crizotinib. The monthly drug acquisition cost of ensartinib was the primary driver of the unfavorable ICER. Probabilistic sensitivity analysis indicated a 45% probability of ensartinib being cost-effective at the \$150,000 threshold.

CONCLUSIONS: Although ensartinib demonstrated superior clinical efficacy compared with crizotinib, it was not cost-effective at its current U.S. price, with drug acquisition costs as the dominant barrier. These findings provide U.S. payers and

formulary decision-makers with the first cost-effectiveness evidence for ensartinib and identify price reduction as the most direct pathway to improving its economic value.

SPONSORSHIP: None

258 Safety profile of darolutamide + androgen deprivation therapy compared to enzalutamide, apalutamide, and abiraterone in metastatic castration-sensitive prostate cancer: Results from the first safety matching-adjusted indirect comparison

Kalayeh B¹, Shore N², Gallagher E³, Gaunt D⁴, Thom H⁴, Orishaba P⁴, Paracha N³, Morgans A⁵, bashir.kalayeh@bayer.com

¹Bayer; ²START Carolinas/Carolina Urologic Research Center; ³Bayer Pharmaceuticals; ⁴Clifton Insight; ⁵Dana Farber Cancer Institute

BACKGROUND: Indirect treatment comparisons in metastatic castration-sensitive prostate cancer (mCSPC) have predominantly focused on efficacy endpoints, with limited evaluation of safety outcomes or consideration of baseline imbalances. This analysis is the first matching-adjusted indirect comparison (MAIC) to evaluate the safety profile of darolutamide (DAR)+androgen deprivation therapy (ADT) versus other androgen receptor pathway inhibitors (ARPIs) in mCSPC.

OBJECTIVE: To compare the safety profile of DAR+ADT versus other ARPIs in mCSPC in the first MAIC.

METHODS: A MAIC was conducted using individual patient data from ARANOTE (DAR+ADT vs ADT) (n = 600) and published aggregate data from ARCHES (enzalutamide (ENZ)+ADT), TITAN (apalutamide (APA)+ADT), and LATITUDE (abiraterone acetate + prednisone (ABI)+ADT). Rates of adverse events (AEs) of special interest in ARANOTE were compared between studies after adjusting for baseline differences in age, Eastern Cooperative Oncology Group performance status (0 vs. 1+), Gleason score (<8 vs. 8+), disease volume, timing of metastatic disease, and presence of visceral metastases. Overall survival was used as an offset to account for varying study follow-up across trials.

RESULTS: DAR+ADT showed significantly lower rates of fatigue versus ENZ+ADT (RR 0.38, 95% CI 0.21-0.68; p = 0.0011) and APA+ADT (RR 0.48, 95% CI 0.27-0.85; p = 0.012), and significantly lower rash rates versus APA+ADT (RR 0.27, 95% CI 0.11-0.67; p = 0.0043). Numerical trends favored DAR+ADT versus ENZ+ADT and ABI+ADT for hypertension and fractures. Falls and vasodilation/hot flush rates were similar, while mental impairment favored DAR+ADT versus ENZ+ADT (RR 0.60, 95% CI 0.10-3.49; p = 0.57).

CONCLUSIONS: In this first safety MAIC in mCSPC, DAR + ADT demonstrated a favorable safety profile compared with other ARPIs. Significant reductions in fatigue and rash, together with numerically lower rates of other adverse events, support the tolerability and differentiated safety profile of DAR + ADT.

SPONSORSHIP: Bayer HealthCare Pharmaceuticals, Inc

259 Cost-effectiveness of novel androgen receptor inhibitors in metastatic castration-sensitive prostate cancer: A U.S. analysis incorporating two-way sensitivity assessment

Appukkuttan S¹, Padula W², Cohen B³, Steel P³, Kalayeh B¹, Rettig M⁴, Zemplenyi A³; sreevalsa.appukkuttan@bayer.com
¹Bayer; ²Stage Analytics; Univ. of Southern California, Los Angeles; ³Stage Analytics; ⁴UCLA

BACKGROUND: Comparative effectiveness of androgen receptor pathway inhibitor (ARPI) plus androgen deprivation therapy (ADT) doublets in metastatic castration-sensitive prostate cancer (mCSPC) remains uncertain, and long-term economic studies in the United States (U.S.) are limited even though these regimens are preferred first-line options. A cost-effectiveness analysis showed darolutamide plus ADT (DAR+ADT) was cost-effective against enzalutamide plus ADT (ENZ+ADT) (ICER: \$85,108) and dominated apalutamide plus ADT (APA+ADT) in progression-free mCSPC. This analysis extended these findings by evaluating cost-effectiveness under alternative assumptions for on-treatment and off-treatment health-state utilities in mCSPC.

OBJECTIVE: To evaluate the cost-effectiveness of novel ARPIs in metastatic castration-sensitive prostate cancer.

METHODS: A partitioned survival model was developed from a U.S. healthcare sector perspective over a lifetime horizon. Progression-free and overall survival informed health-state occupancy (mCSPC, progressed disease, death), with comparative outcomes derived from a network meta-analysis. Direct medical costs (2025 USD) and QALYs were discounted at 3% annually, and incremental cost-effectiveness ratios (ICERs) were assessed at a \$150,000/QALY threshold. Two-way sensitivity analyses explored the impact of assigning different utilities to the off-treatment mCSPC state while varying the relative baseline utilities of ENZ+ADT and APA+ADT compared with DAR+ADT.

RESULTS: DAR+ADT maintained cost-effectiveness across all plausible combinations of lower ENZ+ADT-treated utility values and increasing off-treatment disutility in the mCSPC state; under reasonable assumptions, the ICER fell as low as \$10,722. DAR+ADT dominated APA+ADT in all plausible scenarios that combined reduced utility while on APA with additional off-treatment disutility.

CONCLUSIONS: DAR+ADT is a cost-effective first-line ARPI doublet for mCSPC, particularly when health-state utilities are varied to reflect differences in tolerability, discontinuation, and adverse events, supporting its QALY advantage relative to ENZ+ADT and APA+ADT. These findings may also translate into reduced caregiver strain, preserved productivity, and improved overall well-being that are not fully captured in conventional cost-effectiveness metrics. Novel value frameworks (e.g., GRACE) may better capture this broader value for patients and could support reassessing willingness-to-pay thresholds in metastatic prostate cancer.

SPONSORSHIP: Bayer HealthCare Pharmaceuticals Inc.

260 Real-world evidence evaluating the association between the number of HPV vaccine doses and the incidence of cervical cancer

Dangpiaei S, Kamal K, Owens H; sd00087@mix.wvu.edu
West Virginia University

BACKGROUND: Cervical cancer is a major global health burden, with approximately 660,000 cases and 350,000 deaths reported in 2022, ranking fourth among cancers in women. Prophylactic HPV vaccines (bivalent, quadrivalent, and 9-valent) are highly effective in preventing persistent HPV infection and cervical precancer. Current guidelines in 2026 support a 2- or 3-dose series depending on age, with 2 doses recommended for those initiating vaccination before age 15 and 3 doses for those starting at ages 15–26, immunocompromised individuals, and adults aged 27–45 years based on shared clinical decision-making. Emerging evidence suggests that a single dose may provide sufficient protection; however, real-world evidence comparing dose effectiveness remains limited.

OBJECTIVE: To assess the efficacy of different numbers of HPV vaccine doses on the incidence of cervical cancer.

METHODS: A retrospective cohort study using TriNetX data included patients aged 9–45 years, representing the eligible population for HPV vaccination who received any of the three vaccine types (bivalent, quadrivalent, or nonavalent). Propensity score matching balanced baseline covariates. Cox proportional hazards models with clustering estimated hazard ratios for cancer across vaccine dose groups, and Kaplan–Meier curves assessed differences in cancer-free survival.

RESULTS: A total of 512 patients with cancer were matched to 512 without cancer from an initial cohort of 1,174 controls. Most participants were White (55.3% vs 58.2), and the majority received their first vaccine at ages 18–29 (61.3% vs 61.1%), followed by <18 years (12.3% vs 13.15) among those with cancer and without, respectively. After adjustment for the age at

index (first vaccine), race, prior malignancy, sexually transmitted infections, and nicotine dependence, receiving 2 doses versus 1 was associated with a lower cancer risk (HR = 0.68, 95% CI: 0.53–0.89, $p = 0.004$). Similarly, 3 versus 1 dose showed greater risk reduction (HR = 0.54, 95% CI: 0.42–0.68, $p < 0.001$). No significant difference was observed between 2 and 3 doses ($p = 0.053$). Moreover, older age at first HPV vaccination was associated with a higher risk of cervical cancer (HR = 1.06, 95% CI: 1.04–1.07, $p < 0.001$).

CONCLUSIONS: HPV vaccination was associated with a reduced risk of cancer, with greater protection observed with increasing number of doses and when administered at younger ages. These findings demonstrate the effectiveness of HPV vaccination, particularly with completion of at least two doses, supporting early vaccination and cost-reducing preventive strategies in managed care.

SPONSORSHIP: None

261 Real-world discontinuation rates among patients with metastatic castration-sensitive prostate cancer who initiated novel androgen receptor inhibitors: A US claims analysis

Perry E¹, McManus H², Appukkuttan S³, Liao N¹, Goel H⁴, Kalayeh B³, Arango-Hisijara I⁵; elizabeth.perry@bayer.com; hannah.mcmanus@duke.edu

¹Bayer Healthcare Pharmaceuticals, Inc.; ²Duke University Medical Center; ³Bayer; ⁴Bayer, Inc., Whippany, New Jersey, USA; ⁵Bayer HealthCare Pharmaceuticals, Inc.

BACKGROUND: Novel androgen receptor pathway inhibitors (ARPI) apalutamide (Apa), darolutamide (Daro), and enzalutamide (Enza) have been shown to be efficacious in clinical trials and are increasingly being utilized as first-line therapies in metastatic castration-sensitive prostate cancer (mCSPC). There is limited evidence available on ARPI utilization and duration of therapy (DOT) in the real-world setting.

OBJECTIVE: To determine real-world discontinuation rates in patients with mCSPC by assessing ARPI utilization and DOT.

METHODS: This retrospective cohort analysis used the IQVIA Real-World Data Adjudicated Claims, a US claims database. Patients diagnosed with mCSPC who initiated ARPI treatment as first treatment between January 1, 2020, and January 31, 2025, were included. Patients with concomitant docetaxel use were excluded. Discontinuation was defined as a gap of ≥ 60 days from the end of days supply. Inverse probability treatment weighting (IPTW) was used to minimize potential baseline confounders. Cox proportional hazards models were used to compare the time to discontinuation between patients initiated on Apa, Daro, and Enza.

RESULTS: 10,239 patients with mCSPC initiated ARPI (2340 Apa, 889 Daro, and 7010 Enza). Patient characteristics were well balanced after IPTW (mean age 69 yrs, 72% 65 and older, and 58% on Medicare). Patients receiving Daro had the lowest overall rate of discontinuation (52.5%) vs the Apa (61.2%) and Enza (64.9%) cohorts ($P < 0.0001$). This trend was consistent at 3, 6, and 12 months (Table 1). The median duration of treatment was also longest in the darolutamide cohort (437 days [IQR: 180–1057]) vs the apalutamide (364 days [IQR: 152–785]) and enzalutamide (346 days [IQR: 150–780]) cohorts. After weighting, patients initiating Daro had significantly lower risk of discontinuation compared with Apa (HR 0.87, 95% CI 0.73–0.96) and Enza (HR 0.87, 95% CI 0.82–0.96).

CONCLUSIONS: Real-world discontinuation is considered a treatment-based proxy of disease progression in oncology. In this large cohort, mCSPC patients treated with Daro had significantly lower risk of discontinuation and longer treatment durations vs those receiving Apa or Enza. Further research is warranted to confirm these benefits and explore the underlying reasons for reduced discontinuation and prolonged treatment duration.

SPONSORSHIP: Bayer HealthCare Pharmaceuticals Inc.

262 Darolutamide plus androgen deprivation therapy in metastatic hormone-sensitive prostate cancer: ARASEC—US prospective, open-label phase 2 study with an external control arm

Vazifdar T¹, McKay R², Ross A³, Preston M⁴, Gregg J⁵, Salami S⁶, Saad F⁷, Pieczonka C⁸, Tutrone R⁹, Hamilton J¹⁰, Littleton N¹¹, Constantinovici N¹², Srinivasan S¹³, Shore N¹⁴, Morris D¹⁵, Belkoff L¹⁶, Lance R¹⁷, Verholen F¹²; tasneem.vazifdar@bayer.com
¹Bayer HealthCare Pharmaceuticals Inc.; ²University of California San Diego; ³Northwestern University, Feinberg School of Medicine; ⁴Brigham and Women's Hospital; ⁵The University of Texas MD Anderson Cancer Center; ⁶University of Michigan; ⁷Centre Hospitalier de l'Université de Montréal (University of Montreal); ⁸Associated Medical Professionals of New York (an affiliate of US Urology Partners); ⁹Chesapeake Urology Research Associates; ¹⁰Urology Centers of Alabama; ¹¹Bayer Ltd; ¹²Bayer Consumer Care AG; ¹³Bayer HealthCare Pharmaceuticals, Inc.; ¹⁴START Carolinas/Carolina Urologic Research Center; ¹⁵Urology Associates of Nashville; ¹⁶MidLantic Urology; ¹⁷Spokane Urology

BACKGROUND: Darolutamide + androgen deprivation therapy (ADT) has FDA and EMA approval for metastatic hormone-sensitive prostate cancer (mHSPC) based on the phase 3 ARANOTE study, in which darolutamide significantly improved radiological progression-free survival (rPFS) vs placebo (hazard ratio [HR] 0.54; 95% CI 0.41–0.71; $P < 0.0001$) with favorable safety and tolerability.

OBJECTIVE: To compare darolutamide + ADT vs an external ADT control arm derived from CHAARTED using a novel, pragmatic design leveraging propensity score matching in a prospective investigational arm (ARASEC; NCT05059236).

METHODS: US patients with mHSPC received darolutamide 600 mg twice daily + ADT ($n=223$) and were matched 1:1 to patients in the CHAARTED ADT arm ($n=393$) using propensity scores based on prognostic characteristics: age, performance status, extent of disease, prior local therapy, Gleason score, and prostate-specific antigen (PSA). The primary endpoint was progression-free survival (PFS) defined per CHAARTED. Secondary endpoints included overall survival (OS), time to metastatic castration-resistant prostate cancer (mCRPC), rPFS, PSA < 0.2 ng/mL response rates, and safety. Sensitivity analyses applied inverse probability of treatment weighting to adjust for baseline differences between the ARASEC and CHAARTED match-eligible population and propensity score matching to compare the ARASEC darolutamide arm vs ARANOTE ADT arm.

RESULTS: Propensity score matching identified 160 patients/arm with similar baseline characteristics. At the primary data cutoff (median follow-up: darolutamide 26 months; ADT 28 months), darolutamide + ADT significantly improved PFS vs ADT (HR 0.29, 95% CI 0.20–0.40; $P < 0.001$), OS (HR 0.50, 0.30–0.82; $P=0.003$), time to mCRPC (0.26, 0.18–0.38; $P < 0.001$), and rPFS (0.30, 0.19–0.48; $P < 0.001$). PSA < 0.2 ng/mL response rates were 59% vs 23% at 6 months ($P < 0.001$) and 68% vs 33% at any time ($P < 0.001$) for darolutamide vs ADT arms. Sensitivity analysis PFS HRs: 0.28 (95% CI 0.23–0.33) and 0.30 (0.21–0.44). With darolutamide, treatment-emergent adverse events were mostly grade 1/2 (58%) and 8% discontinued.

CONCLUSIONS: In US patients with mHSPC, ARASEC demonstrates significantly improved efficacy with darolutamide + ADT vs ADT. To our knowledge, ARASEC is the first mHSPC study comparing a prospectively enrolled cohort with matched cohorts from previous and contemporary trials, demonstrating a feasible approach to accelerate enrollment, enhance operational efficiency, and expedite patient access to emerging therapies.

SPONSORSHIP: Bayer HealthCare Pharmaceuticals Inc.

263 Trends in utilization and spending for oral oncology medications in Medicare Part D, 2013–2023

Nubla J¹, Kogut S²; j.nubla1@gmail.com

¹New York Oncology Hematology; ²URI College of Pharmacy

BACKGROUND: Spending on oral oncology medications in Medicare Part D has increased substantially over the past decade, driven by the introduction of new therapies and indications.

OBJECTIVE: To evaluate trends in oral oncology medication utilization and spending among Medicare Part D beneficiaries from 2013 to 2023.

METHODS: A series of cross-sectional analyses were conducted using the Medicare Part D Prescribers: by Provider and Drug dataset, which includes drug-level measures of Part D utilization and spending. Oral oncology medications included targeted anticancer therapies, immunomodulatory agents, other oral antineoplastic therapies, and select hormonal, endocrine, and traditional cytotoxic medications available in oral formulations. Total claims volume, overall spending, and spending per 1,000 beneficiaries were examined between 2013 to 2023, overall and for each U.S. state. The top drugs by total expenditure in 2023 were further examined as drivers of spending, and growth in spending was determined from 2013 or the earliest year in which expenditures were reported. Descriptive statistics (N, %) were used to examine differences and prior costs were adjusted to 2023 dollars using CPI-U.

RESULTS: Oral oncology drug spending in Medicare Part D in 2023 totaled \$24.4b from 5.2 million total claims, while adjusted spending in 2013 totaled \$4.4 billion from 3.0 million total claims. In 2023, total annual Medicare Part D drug spending for several oral oncology medications exceeded \$1 billion, including lenalidomide (\$4.82b, +226% from 2013), enzalutamide (\$2.24b, +1233% from 2013), ibrutinib (\$2.06b, +1005% from 2014), palbociclib (\$1.69b, +730% from 2015), ruxolitinib (\$1.62b, +1604% from 2013), and pomalidomide (\$1.30b, +1933% from 2013). State variation in oncology drug spending in 2023 was observed, with per-1,000 beneficiary costs ranging from \$539,966 in New York and \$80,108 in Wyoming.

CONCLUSIONS: Analysis of Medicare Part D claims for oral oncology medications revealed substantial growth in both utilization and spending over the past decade. In 2023, a relatively small number of medications accounted for a substantial proportion of spending, with several products showing dramatic increases in both volume and spending. State-level variation in spending may reflect differences in beneficiary demographics, cancer prevalence, access to care, prescribing patterns, or other factors and warrants further research.

SPONSORSHIP: None

264 Modeling the managed-care value of personalized mRNA neoantigen vaccines in adjuvant oncology: A Medicare population scenario analysis of averted recurrences in high-risk resected solid tumors

Baser O¹, Sun Y², Nchekwube P², Wu L², Yapar N², Zhu X²; onur.baser@sph.cuny.edu; nehir@cdanyc.com

¹City University of New York (CUNY); ²Columbia Data Analytics

BACKGROUND: Cancer recurrence post curative-intent surgery is a principal driver of progression to metastatic, life-limiting disease among older adults. Personalized mRNA neoantigen vaccines, which encode patient-specific somatic mutations to elicit tumor-directed immunity, have demonstrated meaningful improvement in recurrence-free survival when added to adjuvant pembrolizumab in high-risk resected melanoma (KEYNOTE-942: 3-year HR 0.510; 74.8% vs 55.6% RFS).

OBJECTIVE: To estimate the reduction in 3-year cancer recurrences achievable among Medicare Fee-for-Service (FFS) beneficiaries with high-risk resected solid tumors if personalized mRNA neoantigen vaccine efficacy observed in melanoma were realized in clinical practice and extrapolated to other adjuvant settings.

METHODS: A deterministic scenario analysis was conducted projecting 3-year averted recurrences across 3 Medicare incident cohorts: high-risk resected melanoma (n = 15,000), stage II–III non-small cell lung cancer (NSCLC; n = 25,000), and stage II–III colorectal cancer (n = 30,000). Annual eligible population denominators approximated using validated Medicare-Enhanced Lab & Demographics (MELD) data (linked 100% Medicare FFS claims, EMR, patient-reported outcomes). Melanoma efficacy anchored to KEYNOTE-942. Conservative hypothetical HRs applied for NSCLC and colorectal cancer to reflect broader neoantigen literature and disease heterogeneity. A 50% base-case clinical uptake rate was assumed. Averted recurrences calculated as the difference between expected 3-year recurrences under standard care and modeled post-vaccine recurrences among treated patients. Two-way sensitivity analyses varied uptake and HR.

RESULTS: Under base-case assumptions, an effective personalized mRNA neoantigen vaccine strategy was projected to avert 4,750 cancer recurrences cumulatively over 3 years across the cohorts. Averted recurrences were broadly distributed: NSCLC: 1,750 events (36.8%), colorectal cancer 1,650 (34.7%), melanoma 1,350 (28.4%). Two-way sensitivity analyses confirmed robust population impact across all scenarios, from 1,860 averted recurrences under conservative

assumptions (30% uptake; HR 0.80) to 10,850 averted recurrences under highly optimistic conditions (70% uptake; HR 0.50).

CONCLUSIONS: For Medicare beneficiaries with high-risk resected solid tumors, translating the trial-level efficacy of personalized mRNA neoantigen vaccines into routine practice could substantially reduce the population-level recurrence burden, with magnitude scaling directly with uptake and real-world effectiveness.

SPONSORSHIP: None

265 Health and economic consequences of undertesting for ETV6-NTRK3 in pediatric infantile fibrosarcoma

Suh K¹, Kang A², Ramsey S³, Migliaccio-Walle K², Marian M⁴, Grossman J⁴, Pan X⁴, Johnson D⁵, Sullivan S⁶; kas551@pitt.edu
¹University of Pittsburgh; ²Curta; ³HICOR, Fred Hutch; ⁴Bayer Pharmaceuticals; ⁵Vanderbilt Ingram Cancer Center; ⁶University of Washington

BACKGROUND: Infantile fibrosarcoma (IFS) is a rare pediatric soft tissue sarcoma in which most tumors harbor the ETV6-NTRK3 fusion, and molecular testing is recommended using FISH or RT-PCR. For unresectable disease or when surgery would entail major morbidity, TRK inhibitors (e.g., larotrectinib) are an appropriate targeted therapy. Incomplete testing may result in use of non-targeted chemotherapy in patients who could otherwise receive targeted therapy.

OBJECTIVE: To estimate the clinical and economic harms of suboptimal NTRK fusion testing and treatment in pediatric IFS in the United States.

METHODS: We built a model comparing current practice with an optimal practice in which all eligible pediatric IFS patients undergo ETV6-NTRK3 testing and, when indicated, receive larotrectinib. Annual incident cases were estimated from U.S. birth statistics and published incidence rates. Testing pathways determined first-line systemic therapy: targeted therapy (larotrectinib) versus non-targeted chemotherapy (vincristine plus dactinomycin). Larotrectinib PFS/OS inputs were drawn from trial results (NCT02576431, NCT02637687) as of July 2024, and non-targeted survival inputs were taken from prior studies. We additionally modeled “mutilating surgery” as a major morbidity endpoint and applied cost estimates for extremity amputation and ongoing prosthetic-related costs. Outcomes were life-years lost (LYL), monetized LYL, economic harms of non-targeted therapy, incremental testing costs, and mutilating surgeries avoided with associated costs.

RESULTS: We estimated 23 incident pediatric IFS cases annually. Of these, 11 were projected to have an NTRK genomic

alteration and meet label-based eligibility for larotrectinib. Relative to optimal practice, current practice yielded 8 undertreated fusion-positive patients, resulting in 210 incremental LYL. Monetized harms of these LYL were \$127 million, and economic harms from non-targeted therapy attributable to undertesting were \$480,557. Expanding use of precision-matched targeted therapy was projected to avert 0.62 mutilating surgeries and \$140,381 in associated costs.

CONCLUSIONS: Suboptimal deployment of ETV6-NTRK3 testing and precision-matched therapy in pediatric IFS may lead to meaningful modeled survival losses and economic harms. Although few patients are affected, the large projected benefit of targeted therapy relative to non-targeted chemotherapy, and the potential to reduce mutilating surgery, supports policies and workflows that promote consistent upfront testing and appropriate treatment selection.

SPONSORSHIP: Bayer Pharmaceuticals

266 Healthcare resource utilization and costs among US patients with locally advanced head and neck squamous cell carcinoma: A real-world analysis using SEER-Medicare data

Ashton V¹, Geiger J², Ran T¹, Chen C¹, He J¹, Tejada Mordini J¹, Curran E¹, Adjei K³, Chioda M¹, Raza S¹, Waters D¹, Shen C⁴; vashton1@its.jnj.com; geigerj@ccf.org
¹Johnson & Johnson Innovative Medicine; ²Cleveland Clinic; ³Johnson & Johnson Scientific Affairs; ⁴University of North Carolina School of Medicine

BACKGROUND: Head and neck cancer is the seventh most common cancer globally. Locally advanced head and neck squamous cell carcinoma (LA-HNSCC) represents 50-60% of cases. It often requires multimodal therapy and is associated with high clinical and economic burdens. However, real-world data on healthcare resource utilization (HRU) and costs in patients with LA-HNSCC remain limited.

OBJECTIVE: To describe characteristics, HRU, and costs among US patients with LA-HNSCC receiving current standard of care (SOC).

METHODS: This retrospective cohort study used SEER-Medicare data. Patients aged ≥66 years with newly diagnosed stage III-IVB HNSCC (2010-2021) were included if they had ≥12 months of continuous Medicare fee-for-service coverage and received definitive radiotherapy (RT) ≤3 months from diagnosis, alone or with concurrent cisplatin, carboplatin, or cetuximab. Staging used AJCC 7th edition (diagnosis year 2015 and before), AJCC 8th (2018 and later), and a SEER-derived combined staging (2016-2017). Definitive RT was defined as ≥4 RT claims (20+ fractions) with no gap >21 days between sequential RT claims. The index date was the start of

definitive RT. All-cause HRU and costs (2022 USD) were assessed as per-patient-per-month (PPPM) during follow-up (RT start to earliest of data cutoff, death or plan switch) and cumulatively over the first year. All variables were summarized descriptively.

RESULTS: 2,132 patients met study criteria (mean age 73 years, 74% male, 88% White); 61% had stage IVA at diagnosis and most common tumor site was oropharynx (62%). Among patients with oropharynx cancer, 50% had documented HPV status (28% HPV-, 72% HPV+). RT+cisplatin was used in 50% of patients, followed by RT+cetuximab (24%), RT alone (14%), and RT+carboplatin (12%). Mean follow-up varied from 33 months (RT alone) to 51 months (RT+cisplatin). Mean outpatient visits PPPM ranged from 1.2 (RT alone) to 1.8 (RT+carboplatin and RT+cetuximab); office visits 1.1 (RT alone) to 1.9 (RT+carboplatin); inpatient and ED visits 0.1 (RT+cisplatin) to 0.2 for the other three treatment groups; length of stay from 1.1 days (RT+cisplatin) to 2.7 days (RT alone). Mean all-cause PPPM costs also varied across treatment groups, ranging from \$5,414 (RT+cisplatin) to \$10,103 (RT+cetuximab). Cumulative first-year total costs varied from \$62,665 (RT alone) to \$88,079 (RT+cetuximab).

CONCLUSIONS: LA-HNSCC patients had substantial HRU and costs across current SOC, driven predominantly by outpatient care and office visits, underscoring the ongoing health-care burden.

SPONSORSHIP: Johnson & Johnson

267 Comparison of oral oncology drugs excluded by large pharmacy benefit managers (PBMs)

Williams J, Norrell A, Wermerskirchen J, Merida K, Ercole S; jennifer.williams2@precisionvh.com; kirsten.merida@precisionaq.com
Precision AQ

BACKGROUND: Oncology has traditionally been treated as a protected therapeutic category by PBMs, with limited formulary management. Recent expansion of formulary exclusions into oncology reflects a shift toward more aggressive cost-containment strategies.

OBJECTIVE: To characterize oral oncology drugs selected for formulary exclusion and assess year-over-year trends across large PBMs.

METHODS: Publicly available 2026 formularies from CVS Health, Express Scripts, and OptumRx were reviewed to identify excluded oral oncolytics. Drugs were categorized by cancer type, mechanism of action, NCCN Category 1 recommendation, orphan designation, accelerated approval status, mutation targeting, and black box warnings. Exclusions were compared with 2025 to assess trends.

RESULTS: In 2026, 43 oral oncolytics were excluded by at least one PBM, up from 34 in 2025; 28 were excluded in both years. Sixteen products were excluded by two PBMs, and one product by all three. Single source brands without generic alternatives accounted for 67% (29/43) of excluded agents. Exclusions among single-source brands most frequently targeted drugs for common cancers, such as NSCLC, prostate cancer, and CLL, with each accounting for four exclusions. Of these drugs, kinase inhibitors made up 62%, and targeted therapies made up 58%. The majority had NCCN Category 1 recommendations (59%) and carried orphan designation (76%). In contrast, only 21% and 28% had a black box warning or at least one indication with an accelerated approval, respectively.

CONCLUSIONS: PBM formulary exclusions are increasing in oncology and disproportionately affect single-source agents, including products with strong guideline support and orphan designation. Limited overlap across PBMs suggests fragmented oncology management strategies. The low prevalence of exclusions with black box warnings and accelerated approvals, contrasted with the high percentage of NCCN category 1 recommendations, suggests that exclusions are driven primarily by cost considerations rather than efficacy or safety concerns.

SPONSORSHIP: Precision AQ

268 Treatment patterns and event-free survival among *Bacillus Calmette-Guérin*-unresponsive patients with high-risk non-muscle-invasive bladder cancer with carcinoma in situ

Richards K¹, Singhal M², Rossi C³, Emond B³, Hore E³, Liu S³, Pilon D³, Du S², Patel C²; richardsk@urology.wisc.edu; cpatel34@its.jnj.com

¹University of Wisconsin School of Medicine and Public Health; ²Johnson & Johnson; ³Analysis Group, Inc.

BACKGROUND: *Bacillus Calmette-Guérin* (BCG) is a standard of care for initial treatment of patients with high-risk non-muscle-invasive bladder cancer (HR-NMIBC); however, up to 40% of patients are BCG-unresponsive. Data are limited on clinical outcomes among patients with BCG-unresponsive HR-NMIBC with carcinoma in situ (CIS) ($\pm$ papillary carcinoma [PAP]).

OBJECTIVE: To describe real-world event-free survival (EFS) among patients with BCG-unresponsive HR-NMIBC with CIS receiving subsequent bladder-sparing therapy.

METHODS: A retrospective cohort study was conducted using the linked Precision Point Specialty Analytics (community-based urology practice electronic medical records) and Komodo Research Database (insurance claims; 1/1/2016-

10/31/2024). Patients with HR-NMIBC with CIS (as of the HR-NMIBC diagnosis date) were assessed for BCG discontinuation (last instillation before a gap of >180 days, following adequate induction [≥ 5 instillations in 70 days] and maintenance [≥ 2 instillations in 180 days]). BCG-unresponsive was defined as receiving subsequent guideline-recommended treatment (index date) within 365 days of BCG discontinuation. EFS (i.e., time without disease recurrence or progression) was defined based on codes for transurethral resection of bladder tumor, biopsy, systemic chemotherapy, non-index intravesical therapy, radiotherapy, radical cystectomy, pembrolizumab, diagnosis of muscle-invasive or metastatic bladder cancer, or death. EFS was described using Kaplan-Meier analyses among patients with bladder-sparing therapy after BCG discontinuation.

RESULTS: Overall, there were 130 patients with BCG-unresponsive HR-NMIBC with CIS $\pm$ PAP (mean age: 70 years; 77% male; 78% White). Among 108 patients initiating bladder-sparing therapies as next treatment, gemcitabine (52%), mitomycin (16%), pembrolizumab (15%), gemcitabine/docetaxel (14%), nadofaragene firadenovec-vncg (2%), docetaxel (1%), and doxorubicin (1%) were used. Among these patients, median EFS was 5.9 months (95% CI: 4.7, 12.1). The proportion of patients with recurrence, progression, or death was 28% at 3 months, 50% at 6 months, 59% at 12 months, 69% at 24 months and 74% at 36 months.

CONCLUSIONS: Treatment choice varied among patients with BCG-unresponsive HR-NMIBC with CIS. Despite radical cystectomy being recommended for BCG-unresponsive patients, most received bladder-sparing therapy, with 50% having disease recurrence, progression, or death within 6 months. These findings highlight a significant unmet need for more effective bladder-sparing therapies among BCG-unresponsive patients with HR-NMIBC with CIS $\pm$ PAP.

SPONSORSHIP: Johnson & Johnson

269 IMforte: Characterization of hospitalization and health care resource utilization with lurbinectedin + atezolizumab maintenance therapy for extensive-stage small cell lung cancer in a phase 3 randomized trial

Nguyen A¹, Paz-Ares L², Borghaei H³, Liu S⁴, Peters S⁵, Reck M⁶, Cuchelkar V⁷, Mohan S⁷, Lin Y⁷, Fuller D¹, Profant D⁸, Bhatt K¹, Herbst R⁹; amy.nguyen@jazzpharma.com

¹Jazz Pharmaceuticals, Philadelphia, PA, USA; ²Department of Medical Oncology, Hospital Universitario 12 de Octubre, H12O-CNIO Lung Cancer Unit, Universidad Complutense and Ciberonc, Madrid, Spain; ³Department of Hematology and Oncology, Fox Chase Cancer Center, Philadelphia, PA, USA; ⁴Department of Medical Oncology, Lombardi Comprehensive

Cancer Center, Georgetown University, Washington, DC, USA; ⁵Department of Oncology, Centre Hospitalier Universitaire Vaudois, Lausanne, Switzerland; ⁶LungenClinic, Airway Research Center North, German Center for Lung Research, Grosshansdorf, Germany; ⁷Genentech, Inc., South San Francisco, CA, USA; ⁸Jazz Pharmaceuticals, Carlsbad, CA, USA; ⁹Department of Medical Oncology and Hematology, Yale School of Medicine, New Haven, CT, USA

BACKGROUND: Extensive-stage small cell lung cancer (ES-SCLC) is an aggressive disease with poor prognosis. Among patients (pts) with ES-SCLC, rates of complications that drive health care resource utilization (HCRU) are high. The phase 3 IMforte (NCT05091567) trial demonstrated statistically significant and clinically meaningful improvements in progression-free and overall survival with lurbinectedin + atezolizumab (L+A) vs atezolizumab alone (A) for first-line maintenance treatment (1Lm) of ES-SCLC.

OBJECTIVE: To describe hospitalizations and HCRU from IMforte pts receiving 1Lm with L+A vs A.

METHODS: Eligible pts with ES-SCLC who were progression free after induction with atezolizumab, carboplatin, and etoposide were randomized 1:1 to receive 1Lm L+A or A every 3 weeks. Details of all-cause and treatment-related inpatient hospitalizations and supportive care during 1Lm were summarized descriptively.

RESULTS: As of February 12, 2025, the median treatment duration was 4.4 (L)/4.8 (A) and 2.1 months in the L+A and A arms. One or more treatment-related hospitalizations occurred in 25/242 (10%) pts in the L+A arm and 6/240 (3%) pts in the A arm. The median (quartile 1 [Q1]–Q3) number and total length of treatment-related hospitalizations were 1 (1–1) admission and 7 (4–14) days in the L+A arm and 1 (1–1) admission and 7 (2–13) days in the A arm, respectively. Regardless of relationship to study drug, 60/242 (25%) and 34/240 (14%) pts had an all-cause hospitalization in the L+A and A arms, respectively. The median (Q1–Q3) number and total length of all-cause hospitalizations were 1 (1–2) admission and 7 (5–14) days in the L+A arm and 1 (1–1) admission and 9 (4–17) days in the A arm, respectively. The most common preferred term used among all-cause hospitalizations was pneumonia (L+A, n=5 [2%]; A, n=6 [3%]). Most pts (215/242 [89%]) in the L+A arm used granulocyte colony-stimulating factor, compared to 28/240 (12%) in the A arm.

CONCLUSIONS: Consistent with the extended treatment duration, L+A appeared to be associated with a higher incidence of hospitalization than A. Nonetheless, the frequency remained low: 90% of all pts in the L+A arm did not experience a treatment-related hospitalization. Among pts who were hospitalized, the number of visits and lengths of stay were similar

between treatment arms, suggesting L+A did not increase inpatient burden on a per-event basis. Overall, L+A showed a manageable and predictable HCRU pattern, supporting its feasibility from clinical and health economic perspectives.

SPONSORSHIP: F. Hoffmann-La Roche Ltd and Jazz Pharmaceuticals

270 Patient perspectives on once-daily oral treatment regimens in myelofibrosis, polycythemia vera, and graft-versus-host disease: Qualitative interview findings

Verma S¹, Kissling A², McCaig E², King-Concialdi K², Parasuraman S¹; sverma@incyte.com

¹Incyte Corporation, Wilmington, DE, USA; ²Oracle Life Sciences, Austin, TX, USA

BACKGROUND: Understanding patient preferences for dosing regimens and what drives these preferences can inform treatment value, adherence, and downstream clinical and economic outcomes. Janus kinase (JAK) inhibitors were the focus of this research as they commonly treat myelofibrosis (MF), polycythemia vera (PV), and graft-versus-host disease (GVHD).

OBJECTIVE: To explore patient preferences for treatment dosing regimens, particularly a hypothetical once-daily (qd) option, and willingness to switch from twice-daily (bid) to qd, in patients with MF, PV, or GVHD.

METHODS: Telephone interviews were completed for patients with MF, PV, or GVHD. Interview transcripts were analyzed using inductive and deductive coding, supported by qualitative analysis software to identify emerging themes.

RESULTS: Thirty US adults (age 18+) with a self-reported diagnosis of MF (n=9), PV (n=12), or GVHD (n=9) were interviewed from February to March 2026. Mean ages were 61, 64, and 53 years for MF, PV, and GVHD, respectively; 70% were female. Across indications, healthcare providers (HCPs) were central to treatment decision making. Tolerability, particularly gastrointestinal adverse events (eg, nausea, diarrhea), was a key consideration among patients with PV and GVHD, whereas efficacy was more frequently emphasized among patients with MF. Patients consistently preferred oral therapies over injectables and qd over bid dosing, citing reduced treatment burden and easier integration into daily routines. Smaller, easy-to-swallow pills were also preferred. Patients expressed willingness to switch from a hypothetical bid to qd regimen if supported by their HCP and if efficacy and tolerability were maintained or improved. Patients perceiving greater disease severity prioritized adherence regardless of dosing frequency. Among those with higher pill burden,

perceived benefits of switching from bid to qd varied depending on overall pill burden and daily routines.

CONCLUSIONS: Treatment frequency, disease severity, and pill burden influence patient preference and anticipated adherence in MF, PV, and GVHD. Patients demonstrated a clear preference for qd regimens, which may support adherence through simplified treatment routines. Willingness to switch from bid to qd regimens was influenced by expectations of comparable or improved efficacy and tolerability as well as HCP support.

SPONSORSHIP: Incyte Corporation

271 The hidden healthcare resource utilization (HCRU) burden of melanoma recurrence in the US: A nationally representative matched cohort analysis

Samant S¹, Zhu Y², Engel-Nitz N², Ghatge S³, Grebennik D¹, Zhang S¹, Becker L², Sachdev A², Li S⁴, Tarhini A⁵;

salome.samant@merck.com; shujing.zhang@merck.com

¹Merck; ²Optum; ³Merck & Co Inc.; ⁴Optum Life Sciences;

⁵Moffitt Cancer Center

BACKGROUND: Resected stage IIB/C-III melanoma carries a high risk of recurrence, impacting prognosis. Updated evidence on the incremental healthcare resource utilization (HCRU) associated with locoregional (LR) and distant metastatic (DM) recurrence versus no recurrence (NR) is needed to inform the value of preventing recurrence.

OBJECTIVE: To conduct a retrospective matched-cohort analysis using a large U.S. claims database (Optum) linked to electronic health records.

METHODS: Adults diagnosed with stage IIB/C-III cutaneous melanoma (2019-2025) and resected within 4 months were observed until death or loss of follow-up. Patients (pts) with pregnancy, clinical trial participation, or other primary cancers were excluded. Recurrence events were identified algorithmically and categorized as LR or DM. Controls with NR were matched 1:1 using propensity scores and assigned an index date to allow equal time from resection to recurrence as their match. LR patients progressing to DM were included in both analyses but censored 30 days pre-DM in the LR HCRU. All-cause and melanoma-specific HCRU were reported per patient per month (PPPM) across all payers.

RESULTS: In year 1 post-recurrence, DM pts (491 pairs) had significantly higher incremental mean (SD) all-cause HCRU PPPM vs. NR: +1.92 (4.24) ambulatory visits (outpatient visits, office visits for therapy, etc.); +0.23 (0.52) emergency room (ER) visits; +0.12 (0.26) hospitalizations; +1.23 (4.12) pharmacy (Rx) fills; all p<0.001. Though more modest, LR pts (608 pairs) also had significantly higher HCRU PPPM vs. NR: +1.45 (3.96)

ambulatory visits; +0.05 (0.29) ER visits; +0.02 (0.13) hospitalizations; +0.67 (3.65) Rx fills; all $p < 0.001$. Melanoma-related incremental HCRU PPPM was also significantly higher for DM vs. NR by +1.25 (2.16) ambulatory visits; +0.04 (0.12) ER visits; +0.06 (0.14) hospitalizations; +0.12 (0.48) Rx fills; all $p < 0.001$. Melanoma-related HCRU PPPM for LR pts vs. NR was higher by +1.21 (2.16) ambulatory visits; +0.01 (0.11) ER visits; +0.01 (0.06) hospitalizations; +0.10 (0.54) Rx fills; all $p < 0.001$ except ER visits ($p < 0.01$). Year 2 showed a similar trend, but not all results were significant.

CONCLUSIONS: Resected stage IIB/C-III melanoma pts experiencing recurrence incur markedly higher HCRU compared with pts without recurrence, particularly following DM. Reducing the risk of recurrence offers payers and clinicians an opportunity to substantially reduce the healthcare burden.

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

272 Melanoma recurrence comes at a cost: Real-world economic burden in the US as assessed by a nationally representative matched cohort analysis

Tarhini A¹, Samant S², Zhu Y³, Engel-Nitz N³, Grebennik D², Zhang S², Becker L³, Sachdev A³, Li S⁴, Gbate S⁵; salome.samant@merck.com

¹Moffitt Cancer Center; ²Merck; ³Optum; ⁴Optum Life Sciences; ⁵Merck & Co Inc.

BACKGROUND: Resected stage IIB-C/III melanoma carries a substantial risk of disease recurrence, which remains a major determinant of long-term outcomes. Quantifying the incremental costs of locoregional (LR) and distant metastatic (DM) recurrence relative to no recurrence (NR) in the current treatment era among these patients (pts) is essential to fully characterize the value of preventing recurrence.

OBJECTIVE: To identify, using a nationally representative Optum claims database linked to electronic health record data, adults diagnosed with stage IIB/C-III cutaneous melanoma (2019-2025) who underwent resection ≤ 120 days of diagnosis.

METHODS: Pts with other primary cancers/pregnancy were excluded. LR and DM recurrences were defined using a pre-specified algorithm, and pts were propensity score matched 1:1 to NR controls with aligned index dates to ensure comparable time since resection. Follow-up continued until death, disenrollment, or study end; LR pts who later progressed to DM were censored at 30 days before DM onset. Incremental total all-cause and melanoma-related healthcare costs in years 1 and 2 post-recurrence were reported on a per-

patient-per-month (PPPM) basis in 2024 US dollars, standardized across all payer types.

RESULTS: In year 1 post-recurrence (1 month pre to 11 months post recurrence), mean all-cause healthcare costs were substantially higher (+\$16,747 PPPM, SD \$26,894) for DM vs. NR pts (\$24,607 vs \$7,860 PPPM; 491 matched pairs), with a more modest mean increase (+\$10,320 PPPM, SD \$23,566) reported for LR vs. NR pts (\$19,744 vs \$9,424; 608 pairs). In year 2, the cost differences persisted but attenuated, with increases of \$8,728 PPPM (SD \$18,016) for DM (\$11,589 vs \$2,860; 112 pairs) and \$4,473 PPPM (SD \$15,320) for LR (\$6,414 vs \$1,941; 155 pairs) reported versus NR. Melanoma-specific costs followed a similar trend with an incremental cost of +\$10,953 PPPM (SD \$21,209) for DM vs. NR pts (\$16,148 vs \$5,195 PPPM; 491 matched pairs), and +\$8,493 PPPM (SD \$20,072) for LR vs. NR pts (\$15,423 vs \$6,930; 608 pairs) in year 1. All results were statistically significant ($p < 0.001$).

CONCLUSIONS: In resected stage IIB-C/III melanoma, both LR and DM are associated with marked increases in healthcare costs compared with NR, with DM reflecting the greatest economic burden. Interventions that effectively reduce recurrence risk may offer not only clinical benefit but also meaningful economic value to payers.

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

273 Health and economic impact of pembrolizumab in advanced cancer among U.S. Medicare beneficiaries

Lai Y¹, Siddiqui A², Yi Y², Meiwald A², Fox A²; joyce.lai2@merck.com

¹Merck; ²Adelphi Values PROVE

BACKGROUND: Immunotherapy has revolutionized cancer care, with pembrolizumab becoming a key treatment that improves survival across multiple cancers. Its expanding indications raise questions about its long-term affordability for the Medicare program.

OBJECTIVE: To evaluate the health outcomes and budgetary impact of pembrolizumab for advanced cancer in the United States (US) Medicare population.

METHODS: A health impact projection model compared a hypothetical scenario without pembrolizumab to one with pembrolizumab reflecting current treatment landscape across 14 Food and Drug Administration approved advanced cancer settings in the US Medicare population from 2020 to 2024. The model structure was informed by partitioned survival and budget impact models for individual settings. Inputs were sourced from publicly available data, literature, and expert advice. Outcomes included life-years (LYs),

progression-free LYs, quality-adjusted life-years (QALYs), and associated costs, over a 5-year follow-up time horizon.

RESULTS: Across five years (2020 to 2024), an estimated 309,685 Medicare beneficiaries were treated with pembrolizumab for advanced cancers. The estimated gains in progression-free LYs, LYs, and QALYs were 150,667 (+28.26%), 120,197 (+9.61%) and 101,627 (+10.38%). The average budgetary increase was \$2.6 billion per year (+6.51%), which represented 0.37% of the total Medicare expenditure, or 6.15% of the Medicare expenditure on cancer care medicines in 2024.

CONCLUSIONS: Pembrolizumab provides improved survival and delayed progression to advanced cancer patients with a manageable economic impact. These findings underscore the importance of maintaining access to pembrolizumab for Medicare patients, as it is essential for enhancing the quality of cancer care and improving health outcomes in this population.

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

274 The economic burden of disease progression in extra-pulmonary neuroendocrine carcinoma (epNEC): A multimodal database analysis

Vijayvergia N¹, Liu N², Liu E³, Curran A³, Scherrer E³, Vrieze K², Christensen A², Ijioma S², Gay C⁴;

namrata.vijayvergia@fccc.edu; nicholas.g.liu@gmail.com

¹Fox Chase Cancer Center; ²Boehringer Ingelheim Pharmaceuticals, Inc.; ³Tempus AI; ⁴The University of Texas MD Anderson Cancer Center

BACKGROUND: Extra-pulmonary neuroendocrine carcinomas (epNEC) are rare and aggressive neoplasms with an incidence of ~1 per 100,000 individuals, characterized by rapid progression and poor prognosis. A recent analysis demonstrated that costs increase up to 58% from first-line to second-line therapy; however, the economic burden of disease progression remains uncharacterized.

OBJECTIVE: To describe the cost of progression in patients treated for epNEC by comparing progressors to non-progressors.

METHODS: A retrospective, longitudinal study of patients diagnosed with epNEC (August 2012-March 2025) was conducted using the Tempus de-identified multimodal dataset linked to Komodo Healthcare Map claims data. Costs were assessed as a per-patient per-month (PPPM) rate using standardized 2025 Medicare Fee Schedule reference costs. The index date was defined as the earliest of first progression or initiation of subsequent line of therapy. For non-progressors, the index date was randomly assigned based on the progressor cohort's time-to-progression distribution. Inverse

probability of treatment weighting (IPTW) was used to balance age, payer type, and Charlson Comorbidity Index (CCI) between progression cohorts. Cost ratios were estimated using a gamma regression model.

RESULTS: Among 105 patients (81 progressors; 24 non-progressors), the median age was 61 years, 42% were female, 87% had gastrointestinal primary tumors, and 66% had stage IV disease at initial diagnosis. Payers included commercial (52%), Medicare (32%), and Medicaid (13%), with a median CCI of 2.69. After IPTW balancing, progressors compared to non-progressors had a cost ratio of 2.69 ($p < 0.001$) times higher mean total all-cause (\$7,703 vs \$2,860, $p < 0.001$), 2.61 ($p = 0.006$) times higher mean total cancer-specific (\$4,969 vs \$1,902, $p = 0.011$), 2.20 ($p = 0.015$) times higher mean all-cause outpatient (\$3,949 vs \$1,795, $p = 0.016$), and 2.99 ($p = 0.020$) times higher mean all-cause pharmacy (\$310 vs \$104, $p = 0.044$) costs PPPM. Additionally, progressors had significantly higher all-cause hospitalization (\$2,836 vs \$525, $p = 0.017$), cancer-specific hospitalization (\$2,174 vs \$322, $p = 0.040$), and other cancer-specific (\$257 vs \$7, $p = 0.034$) costs PPPM.

CONCLUSIONS: Disease progression in epNEC imposes a substantial economic burden, with progressors consistently exhibiting more than twice the total all-cause, total cancer-specific, all-cause outpatient, and all-cause pharmacy costs compared with non-progressors, underscoring the need for therapies that delay or prevent progression and improve outcomes.

SPONSORSHIP: Boehringer Ingelheim Pharmaceuticals, Inc (BIPI)

275 Budget impact of relacorilant plus nab-paclitaxel in patients with platinum-resistant ovarian cancer: A US payer perspective

Bjerke A¹, Suri G², Patil D¹, Parthan A²;

annika.bjerke@lumanity.com; aparthan@corcept.com

¹Lumanity; ²Corcept Therapeutics

BACKGROUND: Patients with platinum-resistant ovarian cancer (PROC) have limited treatment options and short survival. Relacorilant + nab-paclitaxel has demonstrated improved clinical outcomes in this population. This study evaluated the budget impact of introducing this combination therapy.

OBJECTIVE: To estimate the budget impact of relacorilant + nab-paclitaxel for adult patients with PROC from a US payer perspective.

METHODS: A budget impact model was developed for a hypothetical US health plan with 1 million covered lives, with a 1-year commercial plan as base case. The eligible population

was estimated using epidemiology data and real-world treatment patterns. Current standard-of-care treatments, including chemotherapy and targeted therapies, were included in the model. Costs included drug acquisition, drug administration, diagnostic tests, and adverse event (AE) management. Drug costs were based on wholesale acquisition cost; AE costs were applied as one-time events. Costs were reported in 2026 US dollars. Infusion reimbursement varied by site of care. The base case used site-specific reimbursement rates, while a scenario assumed uniform reimbursement across settings. Incremental costs compared scenarios with/without relacorilant + nab-paclitaxel. One-way sensitivity analyses evaluated the impact of uncertainty in key model inputs on the budget impact results.

RESULTS: Approximately 30 patients per year were eligible for treatment. In Year 1, adding relacorilant + nab-paclitaxel had a minimal impact of \$0.0388 per member per month (PMPM). Total PMPM costs increased from \$0.3762 in a scenario without relacorilant to \$0.4150 with relacorilant. This increase was mainly due to higher pharmacy costs and partially offset by lower medical costs. In a scenario without site-of-care variation in reimbursement rates for IV infusions, budget impact remained low (PMPM \$0.0436) and consistent with the base case. One-way sensitivity analyses showed that the results were most affected by assumptions about relacorilant uptake, drug acquisition cost, patient weight, the proportion of treated patients, and ovarian cancer incidence. However, the overall budget impact remained low in all scenarios. Similar results were observed over a 3-year time horizon.

CONCLUSIONS: Relacorilant + nab-paclitaxel is associated with minimal budget impact for US payers while addressing a high unmet need in PROC. The relatively small eligible population and low PMPM impact indicate that adoption of this regimen is financially manageable at the health plan level.

SPONSORSHIP: Corcept Therapeutics

276 Infusion chair time and clinic visits as drivers of healthcare resource utilization in platinum-resistant ovarian cancer

Arn C¹, Shahin M², Weisdack S³, Frankenthal R⁴, Parthan A³; courtney.arn@osumc.edu; mshahin@pennstatehealth.psu.edu

¹James Cancer Center, The Ohio State University; ²Penn State Health Milton S. Hershey Medical Center; ³Corcept Therapeutics; ⁴Department of Obstetrics and Gynecology, University of California, Los Angeles

BACKGROUND: Patients with platinum-resistant ovarian cancer (PROC) typically require ongoing systemic therapy, making treatment burden a key consideration along with clinical outcomes. Treatment burden, including visit frequency and infusion chair time, affects patient quality of

life, healthcare resource utilization, and clinic capacity. Comparative data on these aspects across recently approved or targeted PROC regimens over a defined interval are limited.

OBJECTIVE: To compare treatment burden across selected systemic therapies in PROC, with clinic visit frequency and infusion chair time as key drivers of patient burden and healthcare resource utilization.

METHODS: Descriptive analyses estimated treatment burden over 12 weeks for 3 regimens: relacorilant (150 mg orally the day before, of, and after nab-paclitaxel) + nab-paclitaxel (80 mg/m² IV on day 1, 8, 15 of each 28-day cycle), mirvetuximab (6 mg/kg IV Q3W), and a pembrolizumab (200 mg IV Q3W or 400 mg IV Q6W) regimen with paclitaxel (80 mg/m² IV on day 1, 8, 15 of each 3-week treatment cycle), with or without bevacizumab (10 mg/kg on day 1 Q2W). Visit frequency was defined as the number of clinic infusion visits over 12 weeks. Infusion chair time was based on label recommendations with estimates of lower and higher time assumptions, reflecting variability in infusion and administration requirements. Premedication with diphenhydramine and dexamethasone (30–60 min) was included in pembrolizumab and mirvetuximab calculations. Mirvetuximab infusion times may vary by infusion rate titration, dose, and infusion tolerability. This analysis excluded visits for adverse event management, which may further increase overall treatment burden.

RESULTS: Over 12 weeks, clinic visits were 4 for mirvetuximab, 9 for relacorilant + nab-paclitaxel, and 12 for the pembrolizumab regimen. Estimated chair time was 4–7 hours for relacorilant + nab-paclitaxel, 8–16 hours for mirvetuximab, and 21–28 hours for the pembrolizumab regimen. In the pembrolizumab regimen, paclitaxel administration was the primary driver of increased chair time, and subcutaneous administration of pembrolizumab was not associated with a meaningful reduction in total infusion time.

CONCLUSIONS: Substantial differences in treatment burden were observed across PROC regimens. Regimens that require fewer clinic visits and lower infusion chair time may reduce patient burden and ease demands on infusion clinic capacity. Incorporating treatment-burden metrics and clinical outcomes into decision making supports more patient-centered care and efficient use of healthcare resources in PROC management.

SPONSORSHIP: Corcept Therapeutics

277 Real-world clinical outcomes among treatment-naïve patients (pts) with HER2-mutant advanced (unresectable/metastatic) non-small cell lung cancer (NSCLC) treated with platinum-based chemotherapy and immunotherapy (PBC + IO)

McCarthy T¹, Cheng W², Bhanegaonkar A³, Klein A³, Wang Y⁴, Espirito J⁵, Alam S⁵, Aguilar K⁵, O'Brien M⁶, Paulus J⁵, Reid R⁵; timothy.mccarthy@usoncology.com;

wendy.cheng@boehringer-ingelheim.com

¹Affiliation Virginia Cancer Specialists; ²Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT, USA; ³Boehringer Ingelheim Pharmaceuticals, Inc.; ⁴Ontada, McKesson; ⁵Ontada; ⁶Ontada/McKesson

BACKGROUND: PBC + IO is a guideline-recommended first-line (1L) regimen for pts with HER2-mutant advanced NSCLC; however, real-world evidence for this rare genomic cohort remains limited.

OBJECTIVE: To evaluate characteristics, treatment patterns, and outcomes of pts receiving 1L PBC + IO in the US community oncology setting.

METHODS: This retrospective cohort study utilized the iKnowMed electronic health record to identify adults with HER2-mutant advanced NSCLC who initiated 1L PBC + IO between 08/01/2022 and 07/31/2024. Follow-up concluded 01/31/2025. Endpoints included real-world overall response rate (rwORR; clinician-assessed complete or partial response), time to treatment discontinuation (TTD), overall survival (OS), and adverse events (AEs). TTD and OS were analyzed using Kaplan-Meier methods.

RESULTS: Among the 64 eligible pts, the median age was 68 years, 53.1% were female, 82.8% presented with stage IV metastatic disease, 89.1% had an Eastern Cooperative Oncology Group performance status score of 0 or 1, and 82.8% had adenocarcinoma. OncoKB classification of HER2 mutations was oncogenic/likely oncogenic in 50.0% of patients, variant of uncertain significance (VUS) in 46.9%, likely neutral in 1.6%, and undocumented in 1.6%. With a median follow-up duration of 9.4 months (interquartile range [IQR]: 7.0, 16.8), the median time from diagnosis to the start of 1L PBC+IO was 1.3 months (IQR: 0.8, 1.6). Before the end of follow-up, 78.1% discontinued 1L PBC + IO treatment with a median time on treatment of 3.0 months (IQR: 2.1, 7.6). Among pts who discontinued treatment (n = 50), 38.0% did not receive subsequent treatment (n = 19). The most common reasons for discontinuation were progression (34.0%), clinician-documented completion of planned treatment (32.0%), death/hospice (20.0%), and toxicity (16.0%). The rwORR was 57.8%. Median (95% confidence interval) TTD and OS were 3.5 (2.1, 5.7) and 17.2 (9.0, not reached)

months, respectively. Adverse events were documented for 90.6% of pts, with fatigue (73.4%), nausea/vomiting (50.0%), diarrhea (28.1%), neuropathy/numbness (25.0%), and rash (21.9%) being the most common.

CONCLUSIONS: Although PBC + IO is the guideline-recommended 1L standard of care for HER2-mutant advanced NSCLC, many pts in this community oncology setting discontinued within a short period of time due to progression or toxicity. These findings suggested that there is an unmet need for more effective and tolerable 1L therapies for pts with HER2-mutant advanced NSCLC.

SPONSORSHIP: Boehringer Ingelheim Pharmaceuticals, Inc.

278 Real-world healthcare resource utilization and costs among patients with small cell lung cancer receiving second-line and third-line therapy in the US

Fan X¹, Nguyen A², Betts K³, Wang Y³, Wang S³, Ma T³, Wang L³, Fuller D², Profant D⁴, Rengarajan B⁵;

xiaozhou.fan@jazzpharma.com; amy.nguyen@jazzpharma.com

¹Jazz Pharmaceuticals; ²Jazz Pharmaceuticals, Philadelphia, PA, USA; ³Analysis Group, Inc.; ⁴Jazz Pharmaceuticals, Carlsbad, CA, USA; ⁵Jazz

BACKGROUND: N/A

OBJECTIVE: To describe real-world healthcare resource utilization (HCRU) and costs in patients with small cell lung cancer (SCLC) receiving lurbinectedin or tarlatamab in the second-line (2L) and third-line (3L) settings in the US.

METHODS: This retrospective cohort study included adults with SCLC who initiated lurbinectedin or tarlatamab on or after June 2020 in the 2L or 3L setting, identified from the Komodo Research Database between January 1, 2016, and August 31, 2025. Patients were required to have ≥1 month of follow-up after treatment initiation (index date) unless death occurred within 1 month. All-cause HCRU and healthcare costs were assessed from index through the end of the respective line of therapy and reported per patient per month (PPPM) among the lurbinectedin and tarlatamab cohorts separately in 2L and 3L. Safety outcomes and treatment patterns were assessed and will be reported in the poster.

RESULTS: In the 2L setting, 1,511 patients received lurbinectedin monotherapy, and 77 received tarlatamab monotherapy, with a median follow-up of 2.7 and 2.5 months, respectively. Mean age was similar between cohorts (67.3 years for lurbinectedin and 68.0 years for tarlatamab), with comparable sex distribution (51% and 47% female) and predominantly White populations (72% and 64%). Mean (SD) Elixhauser comorbidity index was 29.1 (11.0) and 30.8 (11.7), respectively. Both cohorts had comparable total costs in the first-line

setting (\$18,337 and \$18,857, respectively). Mean (SD) PPPM total all-cause costs were \$31,870 (\$21,631) for lurbinectedin and \$40,945 (\$39,137) for tarlatamab, primarily driven by out-patient (OP) costs (\$23,081 [\$11,682] and \$28,610 [\$26,371], respectively). Mean (SD) PPPM inpatient (IP) costs were \$5,975 (\$14,112) for lurbinectedin and \$8,367 (\$15,943) for tarlatamab. Mean (SD) PPPM OP visits and IP admissions were 6.08 (3.80) and 0.26 (0.48), respectively, for lurbinectedin and 6.50 (2.93) and 0.34 (0.62) for tarlatamab. Mean (SD) PPPM emergency room visits were 0.27 (0.55) and 0.21 (0.59), respectively. In the 3L setting, 515 patients received lurbinectedin, and 64 received tarlatamab, with HCRU and cost patterns consistent with findings in 2L. Mean (SD) PPPM total all-cause costs were \$32,917 (\$24,540) for lurbinectedin and \$39,660 (\$37,063) for tarlatamab, primarily driven by OP costs (\$22,533 [\$11,811] and \$27,484 [\$27,568], respectively).

CONCLUSIONS: Lurbinectedin was associated with descriptively lower all-cause healthcare costs compared with tarlatamab in both 2L and 3L real-world settings for the treatment of SCLC.

SPONSORSHIP: Jazz Pharmaceuticals

279 Economic burden and evidence gaps in ES-SCLC: A systematic literature review of healthcare resource use (HCRU), costs, and utilities

Puri S¹, Kakehi S², Aouchiche B², Piron C³, Yu X³, Martin P³, Mukherjee V²; sonam.puri@moffitt.org

¹University of South Florida; ²AbbVie; ³Medical Decision Modeling Inc.

BACKGROUND: Extensive-stage small cell lung cancer (ES-SCLC) is associated with poor prognosis and substantial HCRU. While the economic burden of 1L treatment has been increasingly studied, less is known about costs and HCRU in later-line (≥ 2 L) settings, particularly as new therapies enter clinical practice.

OBJECTIVE: To characterize the economic burden of ES-SCLC and identify evidence gaps across HCRU, costs, economic evaluations, and utilities, with emphasis on ≥ 2 L settings and evolving treatment patterns.

METHODS: An economic systematic literature review following PRISMA guidelines identified publications in SCLC (Jan 2015–Oct 2025). ES-SCLC publications were prioritized, with ≥ 2 L SCLC studies included where ES-SCLC data were limited. Subsequent targeted updates supplemented US evidence. Findings were qualitatively synthesized.

RESULTS: A total of 3,593 records were initially screened. Of 157 SCLC economic publications, 23 reported ES-SCLC HCRU/costs (13 US-based); 68 were models specific to

ES-SCLC, primarily evaluating 1L therapies; and 10 were utility publications reporting ES-SCLC data. Few studies reported ≥ 2 L data specific to ES-SCLC; however, available evidence indicates a high economic burden across lines of therapy. Newer evidence points to shifting cost considerations in ≥ 2 L settings. Total cost of care for older ≥ 2 L therapies (approved pre-2020) had substantial economic burden from hematologic adverse event risk mitigation and management. With newer therapies, higher pharmacy costs and shifts in resource use patterns are emerging. For example, lurbinectedin has shown reduced hematologic burden but higher drug acquisition costs. Tarlatamab analyses suggest extended time on treatment and improved survival, but with higher total drug costs and increased HCRU concentrated in early treatment cycles, driven by immune-mediated toxicity monitoring. Utility data were limited and variably stratified, with a reported range of 0.53 to 0.84 for US studies/value sets across health states. Most ≥ 2 L SCLC models relied on utility estimates based on non-small cell lung cancer populations, which may not reflect the symptom burden of modeled SCLC patients.

CONCLUSIONS: ES-SCLC is associated with high economic burden. Recent changes in the ≥ 2 L treatment landscape are likely to alter this burden, but these shifts are not yet fully captured in the current evidence base. Key gaps persist, including limited reporting specific to ≥ 2 L ES-SCLC, reliance on non-ES-SCLC utility estimates, limited indirect cost data, and heterogeneity in reporting.

SPONSORSHIP: AbbVie Inc.

280 Medicare reimbursement implications of subcutaneous versus intravenous oncology biologics across sites of care

Liang X¹, Tan C², Sarocco P³, Theuer C⁴, Desai A⁵, Asche C⁶; xi.liang@utah.edu

¹University of Utah; ²College of Pharmacy, University of Utah; ³Halozyne, Inc.; ⁴Halozyne Inc; ⁵O'Neal Comprehensive Cancer Center, The University of Alabama at Birmingham, Birmingham, AL, USA; ⁶University of Utah College of Pharmacy

BACKGROUND: Subcutaneous (SC) oncology biologics reduce administration burden relative to intravenous (IV) formulations, but comparative reimbursement implications across sites of care are not well characterized.

OBJECTIVE: To compare Medicare fee-for-service reimbursement for SC versus IV oncology biologics across sites of care and assess implications for payer decision-making.

METHODS: A descriptive micro-costing analysis evaluated six biologics with approved SC and IV formulations (daratumumab, trastuzumab, pertuzumab-trastuzumab, atezolizumab,

nivolumab, rituximab) using 2026 CMS Part B Average Sales Price files and Medicare outpatient and physician fee schedules. Annual acquisition, administration, and total reimbursement were estimated using labeled dosing schedules, standard weight-based dosing assumptions, and applicable acquisition and administration codes. Analyses were conducted separately for hospital outpatient department (HOPD) and physician office settings and included IV biosimilar comparators where available.

RESULTS: In the HOPD, SC drug acquisition costs were 3-7% higher than IV while SC administration costs were 83-90% lower, yielding mean annual savings of \$12,431 (7.6%) for SC vs. branded IV. Atezolizumab SC and nivolumab SC had modestly higher total costs than IV; daratumumab SC, trastuzumab SC alone and rituximab SC had slightly lower total costs than branded IV; pertuzumab-trastuzumab SC was 36% lower than the branded IV antibodies and remained lower (22%) when compared to IV biosimilars, primarily due to lower drug acquisition cost for the SC combination product. In the physician office, SC administration costs were 46-67% lower than branded IV, resulting in smaller mean annual savings of \$5,378 (3.4%) than branded IV. In both settings, IV biosimilars yielded the lowest total reimbursement in the case of trastuzumab and rituximab. The larger HOPD savings for SC administration reflected separate reimbursement allowed for the facility and physician with IV administration.

CONCLUSIONS: Medicare reimbursement for oncology biologics varies meaningfully by route of administration and site of care, with SC formulations often reducing annual reimbursement relative to IV in the HOPD and physician office. Payer strategies aligning product selection with lower-cost sites of care may improve efficiency while supporting patient-centered care.

SPONSORSHIP: Halozyme, Inc.

Ophthalmic

285 Managed care provider perceptions and experiences with anti-VEGF and anti-VEGF/Ang-2 therapies for retinal vascular diseases

Sternberger A¹, Stinchon M², Khanani A³, Holmes B¹, Zyborowicz E¹, Heggen C¹, Carter J¹, Anderson C¹; a.sternberger@primeinc.org; michaelstinchon@gmail.com

¹PRIME Education; ²Optum Rx; ³Sierra Eye Associates

BACKGROUND: Recent advances in intravitreal therapies targeting vascular endothelial growth factor (VEGF) and angiopoietin-2 (Ang-2) offer effective, durable treatments

for retinal vascular diseases (RVDs), including neovascular age-related macular degeneration (nAMD), diabetic macular edema (DME), and retinal vein occlusion (RVO). Managed care decision-makers have a pivotal role in shaping evidence-based adoption and integration of these therapies in clinical care.

OBJECTIVE: To assess managed care decision-makers' perspectives on key barriers and potential solutions related to the integration of anti-VEGF and anti-VEGF/Ang-2 therapies for RVDs.

METHODS: From February to March 2025, 128 managed care decision-makers completed surveys distributed in partnership with the AMCP Foundation. Quantitative data were analyzed using descriptive statistics.

RESULTS: Respondents (N=128) primarily worked at health systems (32%), health plans (20%), and employers (16%), with the most common roles including clinical programs (38%), other (e.g., HEDIS coordinator, pharmacy director, physician) (16%), case management (12%), and prior authorization (9%). Only 34% reported feeling knowledgeable/very knowledgeable (4/5 on a 5-point Likert scale) with new and emerging therapies for RVDs, yet 67% agreed/strongly agreed (4/5 Likert) that anti-VEGF and anti-VEGF/Ang-2 therapies greatly improve clinical outcomes and quality of life for patients with RVDs. Key barriers to evidence-based integration included determining the optimal place in formulary (30%), developing appropriate eligibility criteria (22%), cost (14%), limited real-world evidence (13%), and lack of documentation supporting patient eligibility (13%). Evidence-based guidelines were cited as the most valued resource when developing utilization management criteria (51%). However, current therapeutic guidelines for RVDs lack consensus, are outdated relative to emerging data, and provide limited guidance on therapy switching. Proposed solutions to support evidence-based integration included standardized authorization forms/criteria, increased real-world and cost-effectiveness data, and improved collaboration between payers and retinal specialists.

CONCLUSIONS: These findings underscore real-world barriers and highlight managed care-driven strategies to enable evidence-based integration of anti-VEGF and anti-VEGF/Ang-2 therapies, ultimately improving quality of care and outcomes for eligible patients with RVDs.

SPONSORSHIP: Genentech, a member of the Roche Group

286 Healthcare resource utilization and costs associated with teprotumumab in moderate-to-severe thyroid eye disease

Ko S¹, Patel A¹, Bonine N¹, Ahmed A¹, Tamhankar M²; ko.stella@gene.com

¹Genentech, Inc.; ²Scheie Eye Institute, University of Pennsylvania

BACKGROUND: Thyroid eye disease (TED) is a rare but debilitating autoimmune condition commonly associated with Graves' disease. A targeted therapy, teprotumumab (TEP), has become the standard of care for moderate-to-severe TED; however, its economic impact including healthcare resource utilization (HRU) and related costs (HC) is not well documented.

OBJECTIVE: To quantify HRU and HC associated with TEP initiation in adults with moderate-to-severe TED.

METHODS: Adults initiating TEP between Jan 2021 and Sep 2024 were retrospectively identified from the IQVIA PharMetrics Plus closed health plan claims database. Patients were required to have a diagnosis of Graves' disease and TED based on ICD codes and to have ≥ 12 months of continuous enrollment pre-/post-index (index defined as TEP initiation). Patients with evidence of TED-specific surgery, orbital radiotherapy, or dry eye-related procedures within 6 months prior to index were excluded. All-cause and TED-related HRU and HC were assessed during the 12-month follow-up period, along with HRU associated with relapse or adverse event management following TEP initiation.

RESULTS: Among 925 eligible patients (mean age, 53.1 years; 77.5% female), mean total HC during the 12-month baseline was \$17,878 (SD \$32,283); 92.5% had no inpatient visits; mean 26.5 outpatient visits. High-dose corticosteroid use (IV or oral) was observed in 43.8% of patients at baseline. During the 12-month follow-up, 93.4% of patients had no inpatient visits and mean 32.4 outpatient visits. Mean total HC during follow-up was \$468,507 (SD \$260,250), primarily driven by outpatient costs (\$434,285, SD \$267,725), with the majority of outpatient spending from the high cost of TEP (\$385,149, SD \$239,767). Overall, 27.1% of patients had a proxy indicator of relapse following TEP, 20.1% experienced ≥ 1 hearing-related adverse event encounter, and 9.0% underwent TED-related surgery, with a mean cost of \$5,746 (SD \$5,351).

CONCLUSIONS: Initiation of TEP was associated with substantially higher HC during the 12-month follow-up compared with baseline, largely driven by outpatient care. While TEP represents an important advancement for patients with moderate-to-severe TED, a notable proportion of patients experienced relapse and adverse events, including hearing-related complications. These findings highlight the economic

burden associated with TEP in real-world settings and emphasize the need for further evaluation of long-term clinical outcomes and potential cost offsets.

SPONSORSHIP: Genentech, Inc.

287 Real-world use of aflibercept 8 mg in eyes with nAMD or DME: Analysis from the Veterans Health Administration

Sherman S¹, Yapar N², Baser O³, Murdock D¹; steven.sherman@regeneron.com

¹Regeneron Pharmaceuticals, Inc.; ²Columbia Data Analytics;

³Graduate School of Public Health, The City University of New York

BACKGROUND: Treatment (tx) patterns of aflibercept (AFL) 8 mg among patients who receive care through the Veterans Health Administration (VHA) are currently unknown.

OBJECTIVE: To describe tx patterns among tx-naïve and previously treated (switcher) eyes in the VHA initiating AFL 8 mg for neovascular age-related macular degeneration (nAMD) or diabetic macular edema (DME).

METHODS: Eligible eyes had nAMD or DME, were tx-naïve (no prior anti-VEGF, intravitreal steroids, photodynamic, or laser therapy), or were switching to AFL 8 mg from treatment with another anti-VEGF. Eyes receiving an AFL 8-mg injection between Aug 18, 2023, and Apr 30, 2025, with >12 months (M) baseline, ≥ 6 M follow-up, and ≥ 1 AFL 8-mg injection after the initial dosing phase (first 90 days or 3 injections) were included. Dosing intervals after the initial monthly doses and the last observed interval were determined. For switchers, pre-switch intervals were described.

RESULTS: Most eligible patients with nAMD or DME were male, White, and non-Hispanic. Median follow-up was 10.7 and 13.4 M for tx-naïve (n=466) and switchers (n=1644) with nAMD, respectively, and 10.1 and 12.5 M for tx-naïve (n=173) and switchers (n=532) with DME, respectively. Mean age for tx-naïve/switchers was 80.5/81.7 years among nAMD patients and 71.5/70.2 years for DME. Bilateral nAMD was present in 20% of tx-naïve and 35% of switchers, respectively, and bilateral DME was present in 61% of tx-naïve and 68% of switchers. The last observed interval of AFL 8-mg after the initial monthly doses was on average (median [Q1, Q3]) 10.0 (8.3, 12.3) and 10.9 (8.0, 13.3) weeks (W) in tx-naïve and switchers with nAMD and 11.0 (8.4, 14.0) and 10.9 (8.0, 13.0) W with DME. The proportion of tx-naïve and switcher eyes with last dosing interval <7 W was 7.9% and 6.0% (nAMD) and 5.2% and 4.0% (DME). The proportion of tx-naïve and switcher eyes with any interval <7 W after the initial monthly doses was 12.2% and 8.0% (nAMD) and 7.5% and 6.2% (DME). Among switchers, the last observed injection interval after

AFL 8 mg increased by median (Q1, Q3) 2.9 (1.0, 5.7) W (nAMD) and 3.0 (1.1, 5.9) W (DME) versus pre-switch.

CONCLUSIONS: VHA real-world treatment patterns suggest <10% of eyes initiated on AFL 8 mg required dosing intervals of <7 W at the last observed tx interval, and only 8-12% (nAMD) and 6-7% (DME) of eyes required AFL 8-mg dosing intervals of <7 W at any time after the initial monthly dosing phase. Eyes switching from prior anti-VEGF therapy were able to extend their dosing intervals by a median of ~3 weeks over their previous anti-VEGF regimen.

SPONSORSHIP: Regeneron Pharmaceuticals, Inc.

Quality and Safety Programs

294 A Bayesian approach to predicting non-adherence using monthly proportion of days covered (PDC) patterns in Medicare Part D plans

Chamberlain J¹, Tidmore L², Keast S³, Hendricks J⁴, Patel B³; james.chamberlain@medimpact.com

¹MedImpact Healthcare Systems, Inc.; ²MedImpact Healthcare Systems, Inc.; ³MedImpact; ⁴MedImpact Healthcare Systems

BACKGROUND: Star ratings cut points have increased in recent years, necessitating the development of actionable predictive programs. Pharmacy benefit managers play a key role in supporting this initiative through the tracking and analysis of proportion of days covered (PDC). Historical adherence patterns play a vital role in developing algorithms to predict which members are at risk of nonadherence.

OBJECTIVE: To demonstrate improved identification of Part D members with increased risk of nonadherence (defined as PDC less than 80%) in three medication classes (diabetes, hypertension, and statins) using Bayesian analysis of proprietary scoring methods.

METHODS: This study analyzed 2023 data from eight Medicare Part D plans (n=60,201 members). Each class was evaluated separately, and members who were nonadherent at the end of the measurement year were excluded. A proprietary nonadherence score was assigned to each member's monthly year-to-date (YTD) PDC report based on claims history with higher scores indicating a higher risk of year-end nonadherence. This adherent population's mean score was modeled with a gamma distribution and served as the prior probability benchmark. To evaluate the utility of this benchmark distribution to identify nonadherent members, data from a ninth client (n = 3,536) was used. Bayesian updates with each member's data obtained posterior probability estimates of their individual performance. Each member's posterior distribution was compared against the benchmark, and members were

identified as potentially nonadherent if there was >90% probability that their monthly nonadherence scores were higher than adherent population mean.

RESULTS: This Bayesian comparison identified more truly non-adherent members than using monthly PDC values alone. On average, the Bayesian model identified 34%, 41%, and 27% more nonadherent hypertension, statin and diabetes utilizers, respectively. The most dramatic difference between using monthly PDC values was observed in February, March, and April where identification of nonadherent members is most useful.

CONCLUSIONS: By combining proprietary nonadherence risk scoring with probabilistic modeling, this approach identifies members at-risk before PDC falls below 80%, enabling risk-stratified outreach with member-level probabilities. Future work will extend this framework through integration with machine learning algorithms to further improve predictive accuracy.

SPONSORSHIP: MedImpact Healthcare Systems, Inc.

295 Predicting Medicare Part D Star Rating cut points: Capturing industry momentum and policy changes through time-series vs. linear analysis

Tidmore L¹, Keast S², Chamberlain J³, Vu H³, Hendricks J⁴, Patel B²; Laura.Tidmore@MedImpact.com

¹MedImpact Healthcare Systems, Inc.; ²MedImpact; ³MedImpact Healthcare Systems, Inc.; ⁴MedImpact Healthcare Systems

BACKGROUND: Medicare Part D Star Rating cut points for medication adherence measures have demonstrated sustained upward trajectory, reflecting ongoing industry-wide quality improvement. Accurate forecasting is essential for plans to maintain or increase their Star Rating. Regulatory changes, including implementation of Tukey Outlier Deletion and the 5% guardrail policy, have introduced new structural volatility. Whether linear or autoregressive methods better characterize these trends has not been formally examined, representing a gap with direct implications for plan-level quality strategy.

OBJECTIVE: To compare predictive accuracy of linear regression versus time-series models in forecasting future Star Rating cut points across 2- to 5-star thresholds for Part D medication adherence measures.

METHODS: Historical Centers for Medicare and Medicaid (CMS) Star Rating cut point data (2017-2026) for diabetes, renin angiotensin system (RAS) antagonist, and statin adherence measures among MA PD plans were analyzed. Linear regression and time series forecasting models were applied to estimate future cut points across 2- through 5-star thresholds. Forecasted 2026 cut points, generated using pre 2026

data, were compared with actual CMS published 2026 values. Predictive accuracy was assessed using mean absolute percentage error (MAPE) and model fit was evaluated using coefficients of determination (R^2).

RESULTS: For RAS antagonists, time-series models demonstrated superior predictive performance, with 3.6%–17.8% lower MAPE across all star thresholds. For diabetes, time-series models showed slightly higher error at 5-star threshold (1.5%) but achieved 1.1%–14.4% lower MAPE across all other thresholds. For statins, no improvement was observed at 2-star level and a modest decrease in accuracy occurred at 5-star level (1.1%). However, substantial improvements were observed at 3-star (12.8%) and 4-star (28.6%) thresholds. Across all measures, time-series models demonstrated comparable or modestly improved goodness-of-fit (0%–5% increase in R^2).

CONCLUSIONS: While gains in overall model fit were modest, time series forecasting consistently reduced cut point prediction error for key pharmacy quality thresholds. These findings suggest moving beyond traditional linear benchmarks can help MA PD plans more accurately anticipate cut point shifts, establish realistic quality targets, and allocate clinical resources effectively in evolving regulatory environments. Future analyses should incorporate emerging Social Risk (SDS) adjustment methodologies, expected to further influence cut point dynamics.

SPONSORSHIP: MedImpact Healthcare Systems, Inc.

296 Health plan quality improvement strategies to strengthen diabetes care through continuous glucose monitoring: A mixed-methods study

Richardson T¹, Dunn J², Casebeer S¹, Richardson H³; terry.richardson@impactedu.net

¹Impact Education, LLC; ²Cooperative Benefits Group;

³University of Washington

BACKGROUND: Continuous glucose monitoring (CGM) is associated with improved glycemic control and reduced complications for individuals with diabetes. Adoption and implementation approaches vary across health plans, reflecting differences in coverage policies, administrative processes, and integration into care models. As diabetes quality measures evolve, understanding how health plans are implementing CGM-related quality improvement (QI) strategies is increasingly important.

OBJECTIVE: To identify, characterize, and evaluate health plan-driven QI interventions that support CGM implementation and improve clinical outcomes.

METHODS: The sequential mixed-method design included a structured literature review, in-depth interviews (IDIs), and

a national survey. Sixty-three abstracts and 26 supplementary publications were screened, yielding 19 full-text sources describing CGM-related QI models. Seven IDIs with endocrinologists, QI leaders, and payer medical directors explored real-world strategies and operational considerations. These themes informed a 10-item survey distributed to stakeholders across managed care, integrated delivery systems, and academic settings, generating 53 complete responses, surpassing the planned sample size.

RESULTS: The literature review identified few published examples specific to health plan-led CGM QI initiatives. IDI findings highlighted interest in streamlined coverage workflows, coverage of CGM under the pharmacy benefit, data-driven high-risk patient identification, and expanded provider education. Survey respondents most frequently cited broader eligibility criteria (74%) and simplified prior authorization requirements (62%) as high-impact strategies. Common barriers included cost and coverage constraints (77%), patient-level engagement challenges (57%), and electronic health record interoperability (40%). Interdisciplinary teams were viewed as essential or major contributors to QI efforts by 81% of respondents.

CONCLUSIONS: This mixed-method study outlines QI strategies that health plans may consider to strengthen diabetes management through appropriate CGM implementation, including optimizing coverage processes, applying data-informed patient identification, and supporting provider education and interdisciplinary care models. These strategies may help health plans align CGM QI efforts with NCQA and HEDIS diabetes quality measures.

SPONSORSHIP: Dexcom Inc. Medical Affairs

Real-World Evidence

310 Real-world adherence trajectories of cabotegravir long-acting and oral PrEP in the United States: A latent class growth analysis from the PrEPFACTS study using healthcare administrative claims data

Metzner A¹, Nguyen C², Alinezhad F³, Herman G¹, Martinez D¹, Banatwala A⁴, Young-Xu L⁵, Ramirez-Ruiz L¹, DerSarkissian M⁴; aimee.a.metzner@viivhealthcare.com; leira.e.ramirez-ruiz@viivhealthcare.com

¹ViiV Healthcare; ²Analysis Group, Inc., Menlo Park, CA, USA;

³Analysis Group; ⁴Analysis Group, Inc.; ⁵Analysis Group, Inc., Boston, MA, USA

BACKGROUND: Understanding real-world adherence to HIV pre-exposure prophylaxis (PrEP) is critical for evaluating the

value of modalities in clinical practice. Summary adherence measures are informative but may obscure heterogeneity in longitudinal adherence behavior. Limited real-world data has characterized how adherence patterns over time compare between cabotegravir long-acting injectable PrEP (CAB LA) and daily oral PrEP.

OBJECTIVE: To compare real-world PrEP adherence trajectories over the first year among individuals initiating CAB LA versus oral PrEP overall and versus emtricitabine/tenofovir alafenamide (FTC/TAF) using latent class growth analysis (LCGA).

METHODS: PrEPFACTS was a retrospective US cohort study using data from the Komodo Research Database (01/12/2020–30/09/2024). Individuals ≥ 12 years old with ≥ 1 CAB LA injection or oral PrEP fill (with the first claim defining the index date), and ≥ 12 months of continuous insurance eligibility before (baseline) and after index were included. Adherence was described using proportion of days covered (PDC) across consecutive 2-month intervals during the first year. LCGA identified distinct adherence trajectory groups, and multinomial regression with standardized mortality ratio (SMR) weighting was used to compare trajectory group membership for CAB LA versus oral PrEP overall and vs FTC/TAF.

RESULTS: Four distinct PrEP adherence trajectory groups were identified: rapid decline, delayed decline, steady moderate, and sustained high. After SMR weighting, individuals using CAB LA were significantly less likely to follow a rapid decline trajectory compared with those initiating oral PrEP overall (probability ratio (PR) 0.80; 95% confidence interval (CI) 0.67–0.95; P-value 0.01) and FTC/TAF (PR 0.76; CI 0.64–0.90; P-value < 0.01). Membership in the steady moderate trajectory was also less common among users of CAB LA vs oral PrEP overall (PR 0.53; CI 0.37–0.77; P-value < 0.01) and vs FTC/TAF (PR 0.63; CI 0.44–0.91; P-value 0.01). Those on CAB LA were significantly more likely to follow a sustained high trajectory vs oral PrEP overall (PR 1.51; CI 1.23–1.85; P-value < 0.01) and vs FTC/TAF (PR 1.51; CI 1.23–1.85; P-value < 0.01).

CONCLUSIONS: CAB LA was associated with a greater probability of sustained high adherence and a reduced probability of rapidly declining or steady moderate adherence compared with oral PrEP overall and vs FTC/TAF in real-world practice. These findings support CAB LA's role in addressing real-world adherence challenges over time by highlighting that CAB LA may allow more individuals to maintain sustained high adherence.

SPONSORSHIP: ViiV Healthcare

311 Real-world dosing patterns of narcolepsy-indicated therapies among adults with narcolepsy type 1 in the United States: A retrospective claims-based study

Crawford S, Tormey Hudzik A, Li L, Ulbricht C, Duhig A;
anthony.tormey-hudzik@takeda.com
Takeda

BACKGROUND: Narcolepsy type 1 (NT1) is a rare neurologic disorder often requiring pharmacologic therapy. Although US labeling specifies recommended doses, real-world dosing patterns are poorly characterized.

OBJECTIVE: To characterize real-world daily doses of narcolepsy-indicated therapies among US adults with NT1, including use below, within, or above label-recommended doses.

METHODS: This retrospective cohort study used US medical and pharmacy claims from the NorstellLinQ closed claims database (January 2019–September 2025). Diagnosed adults with NT1 (identified using ICD codes) initiating narcolepsy-indicated therapy were followed for 12 months. Therapies included modafinil, armodafinil, pitolisant, solriamfetol, sodium oxybate twice nightly (2N; brand/generic), 2N low-sodium oxybate, and sodium oxybate once nightly (1N). Daily dose was derived from dispensed quantity, strength, and days' supply and summarized per therapy and without censoring at switch or discontinuation. Dosing was analyzed descriptively across follow-up and within anchor quarters relative to initiation (Q1–Q4). Mean daily dose over follow-up was estimated at the cohort level by dividing total dispensed dose across all patients by total dispensed days across all patients.

RESULTS: Among treated adults (N=3774), 73% were female, and median (IQR) age was 38 (28–48) years. Over the follow-up, sample sizes were 1783 for modafinil, 1055 for armodafinil, 541 for pitolisant, 529 for solriamfetol, 793 for 2N sodium oxybate (brand), 52 for 2N generic, 419 for 2N low-sodium oxybate, and 29 for 1N sodium oxybate. During follow-up (median 12 months), the mean daily dose on days dispensed was 275.4 mg for modafinil, 220.2 mg for armodafinil, 28.0 mg for pitolisant, 133.7 mg for solriamfetol, 8.0 g for 2N sodium oxybate (brand), 8.5 g for 2N generic, 7.9 g for 2N low-sodium oxybate, and 7.4 g for 1N sodium oxybate. In Q4, proportion of adults receiving the maximum dose was 38% for modafinil (317/829), 58% for armodafinil (267/458), 68% for pitolisant (90/133), 86% for solriamfetol (152/176), 53% for 2N sodium oxybate (brand; 254/478), 57% for 2N generic (8/14), 61% for 2N low-sodium oxybate (74/121), and 20% for 1N sodium oxybate (1/5).

CONCLUSIONS: Among adults with NT1 receiving narcolepsy-indicated therapies, average dose during dispensed days was

generally near the upper end of labeled recommendations, with frequent use of the maximum labeled dose in Q4 follow-up treatment initiation. Incorporating real-world dosing, rather than nominal label doses, is important for payer estimates of utilization and costs.

SPONSORSHIP: Takeda Development Center Americas

312 Demographic and clinical characteristics of adults with elevated lipoprotein(a) without prior ASCVD events: Implications for managed care

Mody R¹, Beyene T², Carlsen C¹, Crocker K², Grabner M², Wong N³; mody_reema@lilly.com

¹Eli Lilly and Company; ²Carelon Research; ³University of California, Irvine

BACKGROUND: Lipoprotein(a) [Lp(a)] is a genetically determined, independent risk factor for atherosclerotic cardiovascular disease (ASCVD). ACC/AHA 2026 guidelines recommend measuring Lp(a) at least once in adulthood, yet testing remains underutilized. Mendelian randomization studies demonstrate that lower Lp(a) levels sustained over longer periods produce greater reductions in cardiovascular (CV) risk, reinforcing the importance of early identification. Characterizing patients with elevated Lp(a) is important to optimize management of modifiable CV risk factors while preparing for emerging treatments.

OBJECTIVE: To compare demographic and clinical characteristics between adults without prior ASCVD events with normal (<125 nmol/L) vs elevated (≥125 nmol/L) Lp(a) in a commercially insured US population.

METHODS: This retrospective cohort study used claims and laboratory data from the Healthcare Integrated Research Database (HIRD). Adults (≥18 y) with ≥1 Lp(a) result (nmol/L) from Jan 2017 to Oct 2024 (first Lp(a)=index), ≥12 months' enrollment pre/post index, and no prior ASCVD events were included. Demographics, CV risk factors, lipid profile, and medications were compared between the cohorts stratified by their Lp(a) level.

RESULTS: Among 66,531 patients (mean Lp(a): 81.6 [SD 87.1] nmol/L), 24.1% had elevated Lp(a). Most Lp(a) tests (90.3%) accompanied a routine lipid panel; 50.6% of Lp(a) tests had a plan-paid amount of \$0, suggesting the patient paid out of pocket. Non-Hispanic Black patients made up 9.5% of the elevated Lp(a) vs 4.9% of the normal Lp(a) cohort ($p < 0.001$). The mean Lp(a) levels were higher in Black vs White patients (120.5 vs 80.5 nmol/L) with Black female patients having the highest mean Lp(a) (128.3 nmol/L). Elevated Lp(a) cohort had modestly higher prevalence of dyslipidemia (72.2 vs 66.1%), hypertension (35.4 vs 32.3%), CAD (22.4 vs 19.6%), and CHF (2.3 vs 1.7%; all $p < 0.01$) compared to normal Lp(a) cohort.

Among the elevated Lp(a) cohort, 28.2% had LDL-C < 100 mg/dL; 34.1% were on lipid-lowering therapy; 13.3% on high-intensity statins; 1.3% on PCSK9i.

CONCLUSIONS: This analysis among adults without a prior ASCVD event confirms a high prevalence of elevated Lp(a). Despite a higher CV risk burden, significant gaps in lipid management were evident—over two-thirds had LDL-C levels above recommended levels, yet only one-third received any lipid-lowering therapy. Broader Lp(a) testing in those without prior ASCVD event can enable early identification of high CV risk, prompting intensified CV risk management until dedicated Lp(a)-lowering therapies are evaluated for CV risk reduction.

SPONSORSHIP: Eli Lilly and Company

313 Real-world impact of prior treatment duration on response to an FDA-cleared dichoptic digital therapeutic for pediatric amblyopia

Hancock S¹, Gold R², Indaram M³, Bohnsack B⁴; shelley@luminopia.com; rsgeye@gmail.com

¹Luminopia; ²Eye Physicians of Central Florida, Maitland and Orlando, FL-retired; ³University of California San Francisco;

⁴Ann & Robert H Lurie Children's Hospital of Chicago

BACKGROUND: Amblyopia, a neurodevelopmental visual disorder, affects ~2% of children, causing permanent visual impairment if untreated/undertreated. First-line refractive correction, patching, or atropine leaves 40-50% of treated children with persistent amblyopia. First-line patching or atropine produces most of its benefit within 6 months, with minimal gains thereafter; continued therapy beyond this plateau drives ongoing resource utilization (visits, supplies) without further gains. Luminopia is an FDA-cleared prescription digital therapeutic indicated for the improvement of visual acuity in amblyopia (anisometropic and/or mild strabismic, with or without prior treatment) in patients ages 4-12 years.

OBJECTIVE: To evaluate whether duration of prior amblyopia therapy is associated with visual acuity outcomes following transition to Luminopia, using retrospective real-world data from the PUPiL Registry (NCT06429280).

METHODS: Registry was queried for children ages 4-12 years with unilateral amblyopia consistent with the FDA-cleared indication. Subgroups were formed based on a 6-month cut point of cumulative prior treatment (investigator-reported patching + atropine). Primary outcome was the change in amblyopic-eye BCVA (lines) from start of treatment to most recent follow-up. Maintenance of vision gains, defined as <2 line reduction after treatment conclusion, was evaluated among patients with off-treatment follow-up. ANCOVA adjusted for baseline acuity.

RESULTS: N = 351 children qualified for analysis. Baseline acuity and Luminopia usage (~156 hours) were balanced across groups. Children with ≤6 months of prior conventional therapy (n = 129) gained 1.70 adjusted lines versus 1.00 (95% CI 0.78-1.21) for those with >6 months of prior therapy (n = 222); adjusted difference 0.71 lines (95% CI 0.36-1.06; p < 0.01). Post-treatment follow-up (n = 157; mean 6.6 months off treatment) showed durable gains with 95.5% of children maintaining gains.

CONCLUSIONS: Children with ≤6 months of prior amblyopia treatment showed significantly greater visual acuity gains on Luminopia than those with longer prior treatment exposure despite equivalent Luminopia usage. First-line treatment durations >6 months may jeopardize Luminopia treatment response while continuing to use health care resources for payers and families that do not significantly improve vision. Patients with extensive prior treatment still showed clinically meaningful gains, supporting Luminopia access for persistent amblyopia regardless of prior treatment duration. Durable post-treatment gains reduce re-authorization and re-treatment risk.

SPONSORSHIP: Luminopia, Inc.

314 Real-world dosing trends over time and projections for valbenazine and deutetrabenazine XR in the US

Borrelli E¹, Copley K², Swaminathan N², Kruger E³, Perez-Rodriguez M⁴, Cyriac R¹, Nedzesky J¹;
eborrelli@neurocrine.com; rcyriac@neurocrine.com

¹Neurocrine Biosciences, Inc.; ²IQVIA; ³Verida Advisory Pty Ltd; ⁴Icahn School of Medicine at Mount Sinai

BACKGROUND: Tardive dyskinesia (TD) and Huntington's disease chorea (HDC) are neurological movement disorders treated first-line with VMAT2 inhibitors. Prior longitudinal research has shown dose increases following treatment initiation and differences in therapeutic dose attainment; however, dosing trends over time and projected future dosing remain less characterized.

OBJECTIVE: To evaluate real-world dosing trends for valbenazine (VBZ) and deutetrabenazine extended release (dTBZ XR) and projected future mean daily doses.

METHODS: This retrospective observational study used a repeated cross-sectional time-series design with linked, de-identified US administrative claims data from IQVIA longitudinal prescription (LRx), professional fee (Dx), and long-term care (MHA) databases. Adults ≥18 years receiving VBZ or dTBZ XR from January to December 2025 with a diagnosis of TD or HDC were identified and analyzed separately. Mean daily dose was estimated monthly and standardized to the

nearest labeled strength; dose distributions were assessed descriptively and stratified by payer type. Future mean daily doses were projected to January 2029 using linear extrapolation and a tier-based approach accounting for labeled dose ceilings (primary analysis). Projections were limited to subgroups with sufficient sample size.

RESULTS: Monthly patient counts increased from January to December 2025 for VBZ (TD: 7,832-9,029; HDC: 321-454) and for dTBZ XR (TD: 3,298-4,542; HDC: 331-447). VBZ dosing remained stable over time, with minimal change in mean dose (TD: -0.7%, 64.0-63.5 mg; HDC: +0.9%, 62.8-63.3 mg). In contrast, dTBZ XR dosing increased consistently, with mean dose rising 6.5% in TD (30.0-31.9 mg) and 7.4% in HDC (31.2-33.6 mg); mean dose in HDC was modestly higher than in TD (+5.3%). Stratified analyses showed similar trends across payer types. Among Medicare Part D patients, dTBZ XR mean dose increased 7.0% in TD (30.1-32.2 mg) and 8.4% in HDC (30.5-33.0 mg), with tier-based projections to January 2029 suggesting continued dTBZ XR dose escalation to 36.0 mg (linear: 37.9 mg) in TD and 37.3 mg (linear: 39.1 mg) in HDC.

CONCLUSIONS: Real-world data shows stable dosing for VBZ versus progressive dose escalation for dTBZ XR across TD and HDC populations and payer types. As dTBZ XR costs increase with higher doses, these trends suggest rising per-patient treatment costs over time, with potential implications for payer budgets and utilization management. Further research is needed to understand factors underlying VMAT2 inhibitor dosing trends and their potential clinical implications.

SPONSORSHIP: Neurocrine Biosciences, Inc.

315 GLP1 anti-obesity medication real-world one-year adherence among a commercially insured population in a cardiometabolic care management program

Marshall L¹, Gleason P¹, Urick B², Cooperman T², Saliba C²;
london.marshall@primetherapeutics.com

¹Prime Therapeutics, LLC; ²Prime Therapeutics

BACKGROUND: Obesity is a chronic, relapsing disease requiring long-term, individualized management. Anti-obesity medicines (AOMs) such as glucagon-like peptide-1 receptor agonist and dual GIP/GLP1 co-agonists (GLP1 AOMs) have demonstrated meaningful, sustained weight loss in pivotal trials with cardiometabolic management. However, real-world evidence on the impact of cardiometabolic management programs on GLP1 AOMs adherence remains limited.

OBJECTIVE: To evaluate 1-year, GLP1 AOMs adherence among commercially insured groups in a cardiometabolic care management program using intent-to-treat (ITT) and per-protocol (PP) approaches.

METHODS: Prime Therapeutics pharmacy claims and data from the KeepWell cardiometabolic care management program were used to identify groups implementing the program on 1/1/2025. The study population was limited to members with program enrollment between 1/1/2025 and 4/30/2025, with a subsequent newly initiated GLP1 AOM paid claim on or before 4/30/2025 with 365 days continuous health plan enrollment from new GLP1 AOM initiation date. Newly initiated GLP1 AOM was defined as no GLP1 AOM paid claim in 2025 prior to program enrollment. Adherence was assessed among members initiating a GLP1 AOM using proportion of days covered (PDC) over a 1-year period, with adherence defined as PDC $\geq 80\%$. Two analytic approaches were applied: (1) intent-to-treat (ITT), including all eligible GLP1 AOM program initiators regardless of program enrollment duration, and (2) per-protocol (PP), restricted to members with ≥ 365 days of continuous program enrollment following GLP1 AOM index date. All outcomes were summarized using descriptive statistics.

RESULTS: The study included 44,679 commercially insured adults with at least one eligible month in 2025, of whom 2,983 (6.7%) enrolled in the program. In the ITT cohort ($n = 401$), mean GLP1 AOM PDC was 78.5% (SD = 26.1%), with 63.8% of members meeting the adherence threshold (PDC $\geq 80\%$). In the PP cohort ($n = 226$), mean PDC was higher at 85.1% (SD = 22.9 %), with 78.3% of members adherent.

CONCLUSIONS: Adherence to GLP1 AOM therapy was notably higher among members with sustained engagement in the cardiometabolic care management program and other real-world adherence estimates by more than 20 percentage points among members persisting for 1 year in the program, this equates to an additional 1 in 5 members adherent. In the ITT cohort, we found an additional 1 in 13 members adherent. These findings highlight the importance of a cardiometabolic care management program to facilitate GLP1 AOM adherence.

SPONSORSHIP: Prime Therapeutics, LLC

316 Anticholinergic polypharmacy among Medicare beneficiaries ≥ 65 years with and without tardive dyskinesia

Borrelli E¹, Mohan A², Vanderhoef D¹, Clark S², Kogut S³, Nedzesky J¹; eborrelli@neurocrine.com

¹Neurocrine Biosciences, Inc.; ²Medicus Economics, LLC;

³University of Rhode Island College of Pharmacy

BACKGROUND: Anticholinergic medication (ACH) use in adults ≥ 65 years is associated with adverse outcomes, including blurred vision, delirium, falls, and impaired cognition. The Centers for Medicare & Medicaid Services introduced a new quality measure for the 2027 Medicare Star Ratings (MSR) assessing ACH polypharmacy (POLY-ACH) among

beneficiaries ≥ 65 . ACH use is common in patients with tardive dyskinesia (TD), despite evidence that certain agents (e.g., benztrapine) may worsen TD symptoms.

OBJECTIVE: To assess POLY-ACH among Medicare beneficiaries ≥ 65 with and without TD.

METHODS: A cross-sectional analysis of 2023 Medicare claims was conducted among beneficiaries ≥ 65 . Beneficiaries were categorized into 3 groups: with TD (≥ 1 ICD-10 code G24.01), without TD with serious mental illness (SMI), and without TD or SMI. Beneficiaries with TD were captured from the full Medicare dataset, while those without TD were captured from a random 5% sample. The primary outcome was POLY-ACH (≥ 2 unique ACH used concurrently for ≥ 30 cumulative days), assessed using 1) the MSR definition (denominator: beneficiaries with ≥ 2 claims for the same ACH on different dates of service) and 2) a population definition (denominator: all beneficiaries). Secondary outcomes included chronic POLY-ACH (≥ 90 days concurrent ACH) for both POLY-ACH definitions and benztrapine use. Descriptive statistics were calculated to assess differences between groups.

RESULTS: The analysis included beneficiaries with TD ($n = 47,532$), without TD with SMI ($n = 342,123$), and without TD or SMI ($n = 1,818,947$). The TD group had higher rates of MSR POLY-ACH (24.2% [95% CI: 23.8–24.7%]) compared to those without TD with SMI (12.3% [95% CI: 12.1–12.5%]) and without TD or SMI (6.0% [95% CI: 5.9–6.1%]). Similar patterns were seen for the population definition (TD: 10.8% [95% CI: 10.5–11.1%]; without TD with SMI: 2.7% [95% CI: 2.7–2.8%]; without TD or SMI: 0.5% [95% CI: 0.5–0.5%]). Chronic POLY-ACH was also more common in the TD group (MSR: 17.9%; population: 8.0%) compared to those without TD with SMI (8.5%; 1.9%) and without TD or SMI (3.8%; 0.3%). Benztrapine use was higher in the TD group (13.3%) compared to those without TD with SMI (0.7%) and without TD or SMI ($< 0.1\%$).

CONCLUSIONS: Among Medicare beneficiaries with TD aged ≥ 65 , 11% received multiple ACH concurrently and nearly one-quarter met the MSR POLY-ACH criteria. POLY-ACH rates were substantially higher among beneficiaries with TD than those without TD, highlighting greater exposure to potentially harmful ACH combinations and risk of adverse outcomes in this population.

SPONSORSHIP: Neurocrine Biosciences, Inc.

317 Major adverse cardiovascular events following initiation of GLP-1 receptor agonists to treat obesity among commercially insured members without diabetes: A three-year real-world assessment

Tran J¹, Urick B¹, Marshall L², Farley J³, McCann M¹, Gleason P²; jacinda.tran@primetherapeutics.com

¹Prime Therapeutics; ²Prime Therapeutics, LLC; ³University of Minnesota College of Pharmacy

BACKGROUND: While clinical trial evidence has shown that glucagon-like peptide-1 receptor agonist (GLP1) products may reduce the risk of major adverse cardiovascular events (MACE), real-world evidence establishing this relationship is lacking.

OBJECTIVE: To assess MACE outcomes in the year before versus three years after GLP1 obesity treatment initiation among commercially insured members without diabetes compared to matched controls.

METHODS: Using Prime Therapeutics' integrated pharmacy and medical claims data from 2020 to 2025, the study population consisted of new initiators of an obesity treatment GLP1 ("treatment") or a chronic medication ("control") between 1/1/2021 and 3/31/2022. We required continuous enrollment 1 year before ("pre-period") and 1 year after ("post-period") index, a pre-period obesity diagnosis, age 19+, and no prior evidence of GLP1 use or diabetes pre-index. Members were matched 3:1 on a range of demographic and clinical characteristics. The composite of all-cause MACE outcomes included acute myocardial infarction, coronary artery bypass grafting, percutaneous coronary intervention, stroke, and transient ischemic attack and was assessed each year for up to 3 years after index. Difference-in-differences (DID) regression was used to compare outcomes trends before and after initiation between the treatment and control groups. Subanalyses of treatment-adherent members were conducted using the same matching and statistical approach for treatment members with proportion of days covered $\geq 80\%$ for the entire post-period.

RESULTS: 22,998 controls were matched to 7,922 treatment members; 80.4% were female and mean age was 45.8 years old. Prevalence of all-cause MACE events in the pre-period was 11.0 per 1,000 person-years (PY) and 12.5, 13.4, and 12.9 per 1,000 PY in post-period years 1 to 3 for the treatment group. For controls, pre-period prevalence was 12.8 and increased to 15.9, 16.3, and 16.9 per 1,000 PY in years 1 to 3, respectively. For year 3 versus pre-period, the DID was -2.2 (95% confidence interval [CI]: -6.6 to 2.3; $p=0.34$) events in the treatment group compared to matched controls. The treatment-adherent subanalysis (609 treatment; 1,751

matched controls) did not find any significant year 3 differences (DID 0.0, 95% CI: -12.7 to 12.7; $p=1$).

CONCLUSIONS: This study finds a 3-year trend towards lower all-cause MACE event rates among GLP1 obesity treatment initiators. Although these findings are not statistically significant, future studies evaluating MACE events in a larger sample of GLP-1 users without diabetes, over a longer period, may be warranted.

SPONSORSHIP: Prime Therapeutics, LLC

318 Gastrointestinal adverse effects following initiation of glucagon-like peptide-1 receptor agonists to treat obesity among commercially insured members without diabetes: A three-year real-world assessment

Tran J¹, Urick B¹, Marshall L², Farley J³, McCann M¹, Gleason P²; jacinda.tran@primetherapeutics.com

¹Prime Therapeutics; ²Prime Therapeutics, LLC; ³University of Minnesota College of Pharmacy

BACKGROUND: Gastrointestinal (GI) events are the most frequently reported adverse effects (AE) associated with glucagon-like peptide-1 (GLP1) receptor agonists. While some GI AE such as nausea and vomiting are mild and often self-limiting, severe AE, including acute pancreatitis, cholecystitis, and intestinal obstruction, can create substantial healthcare burdens.

OBJECTIVE: To describe severe GI AEs prevalence in the year before versus three years after GLP1 obesity treatment initiation among commercially insured members without diabetes compared to matched controls.

METHODS: Using Prime Therapeutics' integrated pharmacy and medical claims data from 2020 to 2025, the study population consisted of new initiators of obesity treatment GLP1 ("treatment") or a chronic medication ("control") between 1/1/2021 and 3/31/2022. We required continuous enrollment 1 year before ("pre-period") and 1 year after ("post-period") index, a pre-period obesity diagnosis, age 19+, and no prior evidence of GLP1 use or diabetes pre-index. Members were matched 3:1 on a range of demographic and clinical characteristics. The prevalence of any severe GI AE (intestinal obstruction, acute pancreatitis, cholecystectomy) was assessed in the pre-period and each post-period year. Difference-in-differences (DID) regression was used to compare outcomes trends before and after initiation between the treatment and control groups.

RESULTS: 22,998 controls were matched to 7,922 treatment members; 80.4% were female and mean age was 45.8 years old. Prevalence of any severe GI AE event among treatment

members was 11.6 per 1,000 person-years (PY) in the pre-period and 19.8, 19.0, and 17.1 in post-period years 1-3. For controls, prevalence was 13.9 in the pre-period and 15.7, 14.9, and 13.0 across post-period years 1-3. Events across both groups were highest in year 1, with a DID of 6.4 (95% confidence interval [CI]: 2 to 10.8; $p = 0.01$) and remained elevated for the treatment group throughout the post-period for a year 3 DID of 6.3 (95% CI: 1.3 to 11.2; $p = 0.01$). Year 1 DID estimates were highest for acute pancreatitis (2.7 [95% CI: 0.8 to 4.6; $p = 0.005$]) and intestinal obstruction (1.7 [95% CI: -0.6 to 3.9; $p = 0.145$]). Cholecystectomy had the highest DID estimate in year 3 (5.4 [95% CI: 1.5 to 9.2; $p = 0.006$]).

CONCLUSIONS: The results of this work suggest that GLP1 obesity treatment can increase rates of severe GI AEs, emphasizing the need for early and ongoing cardiometabolic care management. Further research into the impact of these events is essential to understand cost trends following GLP1 obesity treatment initiation.

SPONSORSHIP: Prime Therapeutics, LLC

319 Antiemetic utilization following initiation of glucagon-like peptide-1 receptor agonists to treat obesity among commercially insured members without diabetes: A three-year real-world assessment

Tran J¹, Urick B¹, Marshall L², Farley J³, McCann M¹, Gleason P²; jacinda.tran@primetherapeutics.com

¹Prime Therapeutics; ²Prime Therapeutics, LLC; ³University of Minnesota College of Pharmacy

BACKGROUND: Nausea and vomiting are among the most common side effects of glucagon-like peptide-1 (GLP1) receptor agonists. While antiemetic drugs early in GLP1 treatment has been recommended, long-term use is less understood.

OBJECTIVE: To assess antiemetic utilization in the year before and three years after GLP1 obesity treatment initiation among commercially insured members without diabetes compared to matched controls.

METHODS: Using Prime Therapeutics' integrated pharmacy and medical claims data from 2020 to 2025, the study population consisted of new initiators of an obesity treatment GLP1 ("treatment") or a chronic medication ("control") between 1/1/2021 and 3/31/2022. We required continuous enrollment 1 year before ("pre-period") and 1 year after ("post-period") index, a pre-period obesity diagnosis, age 19+, and no prior evidence of GLP1 use or diabetes pre-index. Members were matched 3:1 on a range of demographic and clinical characteristics. Prevalence of antiemetic use was assessed in the pre-period and each post-period year, and difference-in-differences (DID) regressions were used to compare outcomes trends before and after index between the treatment

and control groups. An additional subanalysis of antiemetic use requiring GLP1 treatment adherence (proportion of days covered $\geq 80\%$) was also conducted.

RESULTS: 22,998 controls were matched to 7,922 treatment members; 80.4% were female and mean age was 45.8 years old. Prevalence of antiemetic use was 14.4% in the pre-period and 22.2%, 21.4%, and 21.9% in years 1 to 3 for the treatment group. Prevalence ranged from 12.1% in the pre-period to 14.7%, 14.8% and 15.2% in years 1 to 3 in the control group. The DID estimate for year 1 vs. pre-period (5.2% [95% CI: 4.0 to 6.3%; $p < 0.01$]) shows an immediate increase in use of antiemetic drugs early in GLP1 treatment which persists throughout the post-period for a year 3 DID estimate of 4.3% (95% CI: 2.9 to 5.8%; $p < 0.01$) for treatment compared to controls. Similar trends were observed for the treatment-adherent group.

CONCLUSIONS: Antiemetic use increased significantly immediately following obesity GLP1 treatment initiation and remained elevated throughout 3 years among all treatment members as well as the treatment adherent sub-analysis. The persistent more than 1 in 5 members with antiemetic use indicates some members continue to use antiemetics to maintain GLP-1 therapy through three years. These findings highlight the role of cardiometabolic case management in supporting ongoing side effect management for members using GLP1 products.

SPONSORSHIP: Prime Therapeutics, LLC

320 Real-world uptake and characteristics of commercially insured initiators of oral glucagon-like peptide-1 receptor agonists for obesity treatment

Tran J¹, Urick B¹, Marshall L², Farley J³, McCann M¹, Gleason P²; jacinda.tran@primetherapeutics.com

¹Prime Therapeutics; ²Prime Therapeutics, LLC; ³University of Minnesota College of Pharmacy

BACKGROUND: Oral glucagon-like peptide-1 (GLP1) receptor agonists for obesity treatment have expanded treatment options for patients. Real-world uptake and characterization of early initiators remain limited.

OBJECTIVE: To describe utilization and demographic and clinical characteristics of commercially insured members who initiated an oral or injectable GLP1 from 1/1/2026 to 5/4/2026.

METHODS: Using Prime Therapeutics' integrated pharmacy and medical claims data from 7/1/2025 to 5/4/2026, the study population consisted of members who filled an obesity-indicated oral or injectable GLP1 in 2026. Index dates were identified as the first fill in calendar year 2026. We required continuous enrollment 180 days before index ("pre-period")

and age 19+. Descriptive statistics compared oral and injectable users across a range of demographic and clinical characteristics, including prior use which was defined as presence of a GLP1 product claim during the pre-period.

RESULTS: 3,253 members started an obesity-indicated oral GLP1 and 134,331 filled at least one obesity-indicated injectable GLP1 prescription during the study period; 2,696 (2.3%) oral and 115,482 (97.7%) injectable initiators met inclusion and exclusion criteria. Compared to injectable users, oral GLP1 users were older (mean 48.5 years old vs 46.7; $p < 0.01$) with no differences in gender (70.5% female vs 70.5%; $p = 0.93$). Comorbidity burden was similar (mean Charlson Comorbidity Index [CCI] score of 0.46 vs 0.43; $p = 0.18$). Oral users had a higher percentage of diabetes (6.0% vs 4.5%; $p < 0.01$) but lower prevalence of severe obesity (15.1% vs 17.7%; $p < 0.01$) and sleep apnea (11.9% vs 18.6%; $p < 0.01$). Assessing prior GLP1 use among oral GLP1 users, 31.8% ($N = 856$) had prior injectable GLP1 use. Of these users, 90.6% ($N = 776$) were previously exposed to an obesity-indicated product.

CONCLUSIONS: In the initial months of availability, on-benefit use of oral GLP1s has grown but remains a small share, at 1 in 50 utilizers of an obesity-indicated GLP1. Results should be interpreted in the context of potentially high off-benefit use, which is not captured in claims data. Most oral users did not have previous experience with GLP1 products, with more than two-thirds appearing to be new to GLP1 therapy. Among oral GLP1 users with prior injectable GLP1 use, use of diabetes-indicated products was rare, with less than 10% of oral GLP1 users using a prior diabetes-indicated GLP1 product. Future studies should continue monitoring oral GLP1 utilization trends and assess treatment persistence.

SPONSORSHIP: Prime Therapeutics, LLC

321 “Hitting the mark”: A spotlight on adherence and medication usage patterns among individuals receiving cabotegravir long-acting for HIV-1 pre-exposure prophylaxis in the United States from the real-world observational CAPTIVATE cohort

Cole K¹, Garbinsky D², Rab S¹, Boyle K³, Reynolds M², Sherif B⁴, Richardson D², Morris R¹, Swygard H⁵, Sullivan M¹, Zografos L², Metzner A¹; kelli.a.cole@viihealthcare.com

¹ViiV Healthcare; ²RTI Health Solutions; ³RTI Health Solutions LLC; ⁴RTI International; ⁵Medical Affairs

BACKGROUND: Efficacy of oral pre-exposure prophylaxis (PrEP) is highly correlated with adherence, and populations disproportionately impacted by HIV may face obstacles with this. Therefore, alternative forms of PrEP have been developed, including every-2-month injectable cabotegravir

long-acting (CAB LA), to help address unmet needs for people who could benefit from PrEP.

OBJECTIVE: To describe adherence and utilization patterns of those using CAB LA in routine clinical practice.

METHODS: CAPTIVATE is a study of PrEP users with CAB LA experience from 18 sites across the US with data collected via retrospective case report forms (CRF) and cross-sectional PrEP-user surveys between Nov 2024 and Apr 2025. Participants were ≥ 18 years old and had ≥ 6 months of follow-up after CAB LA initiation. Missed injections were described and defined as an injection that was due but not given within 1 month of target injection date.

RESULTS: Among 241 individuals, 235 (98%) continued CAB LA at study enrollment with a mean of 10.3 injections per participant (standard deviation [SD], 4.20; range, 3-19) according to CRF. Of 238 second initiation and 1,997 continuation injections, 92% and 83% were given during the target dosing window (± 7 days surrounding target injection date). CAB LA was initiated on the same day as screening for PrEP (i.e., “same day start”) for 9% of participants with the optional lead-in of oral cabotegravir prescribed for 10%. Overall, 85% of participants did not miss any CAB LA continuation injections; among the 36 individuals who did have a missed injection, a total of 66 (3%) continuation injections were missed. In those with missed doses, the median number of missed injections per individual was 1 (range, 1-6) and the mean (SD) was 1.8 (1.38). Of 6 discontinuations, 4 had documented reasons (citing primarily side effects, excluding injection site reactions [$n=1$], not wanting to receive an injection [$n=1$], or other reasons [$n=2$]). No HIV diagnoses were reported during the study period.

CONCLUSIONS: This study reported high rates of adherence in a real-world setting with zero HIV diagnoses on CAB LA for PrEP. While most participants did not miss any continuation injections, missed doses occurred among a small subset of individuals and accounted for a low proportion of injections overall, suggesting this modality offers another option for PrEP users that may help address some of the barriers associated with oral PrEP adherence.

SPONSORSHIP: ViiV Healthcare

322 Impact of formulary-related rejections of initial Auvelity (dextromethorphan-bupropion [45 mg/105 mg]) claims on healthcare resource utilization and costs among patients with major depressive disorder

Stoner S¹, Zeni C², Alter S², Cong J³, Zhang Y³, DePue R², Bessonova L⁴, Zhao Y²; stoners@umkc.edu

¹University of Missouri-Kansas City, Kansas City, MO, USA;

²Axsome Therapeutics Inc., New York, NY, USA; ³KMK

Consulting, LLC, Morris Plains, NJ; ⁴Axsome Therapeutics Inc

BACKGROUND: Major depressive disorder (MDD) is a leading cause of disability in the US, associated with substantial healthcare resource utilization (HCRU) and economic burden. Formulary restrictions may delay or prevent access to recently approved therapies, with potential downstream clinical and economic consequences. Auvelity (dextromethorphan-bupropion [45 mg/105 mg]) is a first-in-class oral therapy approved for the treatment of MDD in adults.

OBJECTIVE: To evaluate the impact of formulary-related rejections of initial dextromethorphan-bupropion claims on subsequent HCRU and costs among patients with MDD.

METHODS: Using Symphony Health Integrated Dataverse data, commercially insured adults with MDD (ICD-10-CM: F32.xx and F33.xx) with an initial dextromethorphan-bupropion claim between March 2024 and October 2025 were identified and stratified by formulary-related rejection vs approval. Rejected patients were required to receive subsequent MDD-related treatment. All patients had ≥ 6 months of continuous pre-index activity. All-cause HCRU during follow-up was assessed using multivariate regressions adjusting for age, sex, and baseline HCRU; incidence rate ratios (IRR) with 95% confidence intervals (CIs) were reported. Excess annual costs attributable to claim rejection were estimated.

RESULTS: The rejected and approved cohorts included 1,963 patients and 28,329 patients, respectively, with similar baseline demographics, comorbidities, and MDD-related medication use. Compared with approved patients, rejected patients had significantly higher adjusted rates of emergency room (ER) visits (0.211 vs 0.261 visits per patient-year [PPY]; IRR 1.22, 95% CI 1.02-1.45, $P < 0.05$) and inpatient admissions (0.095 vs 0.130 admissions PPY; IRR 1.30, 95% CI 1.01-1.66; $P < 0.05$). Excess annual healthcare costs associated with initial dextromethorphan-bupropion rejection were estimated at \$1,749,745, driven by inpatient and ER utilization.

CONCLUSIONS: Formulary-related rejection of initial dextromethorphan-bupropion claims among patients with MDD was associated with significantly greater numbers of ER visits and inpatient admissions resulting in substantial excess healthcare costs. These findings highlight the potential

economic impact of formulary barriers and the importance of timely access to effective therapies in MDD management.

SPONSORSHIP: Axsome Therapeutics, Inc.

323 Real-world hospitalization outcomes in patients with idiopathic pulmonary fibrosis (IPF) in a Commercial and Medicare Advantage population

Mathai S¹, Lin M², Wu B², Rutter C², Morland K², Blackstock E³; susan.mathai@bswhealth.org; mclin@unither.com

¹Baylor University Medical Center; ²United Therapeutics Corporation; ³Intermountain Medical Center

BACKGROUND: IPF is a progressive fibrotic lung disease with poor prognosis. Inpatient care is frequently required during acute worsening; however, the clinical and economic impact of IPF-related hospitalizations remains poorly characterized.

OBJECTIVE: To evaluate real-world outcomes of IPF-related hospitalizations.

METHODS: A retrospective cohort study was conducted using the Optum de-identified Clinformatics Data Mart Database. Adult patients were identified by a diagnosis of IPF between January 1, 2017, and September 30, 2025. The index date was defined as the first hospitalization with an IPF diagnosis code (J84.112) in the primary or secondary position. Patients were required to have 6 months of continuous enrollment prior to the index date. Key outcomes included all-cause 30-day mortality, length of stay (LOS), intensive care unit (ICU) utilization, and hospitalization-related all cause medical costs. Additionally, subsequent IPF-related hospitalizations were characterized and compared to the index event. Patients were followed until the earliest occurrence of death, disenrollment, or the end of the study period.

RESULTS: A total of 4,059 patients met the inclusion criteria. The cohort's mean (SD) age at index IPF-related hospitalization was 75 (8) years; 59% were male and 74% were White, and 91% had Medicare Advantage coverage (9% Commercial). At baseline, the mean (SD) Quan-Charlson Comorbidity Index was 3 (2). For the index hospitalization, 57% of patients required ICU-level care, and all-cause 30-day mortality was 19%. Mean (SD) LOS was 10 (16) days, with a median cost of \$31,942. Among Medicare patients, the median medical cost was \$31,764 and mean (SD) LOS was 9 (13) days; among commercially insured patients, the median medical cost was \$33,835 and mean (SD) LOS was 18 (30) days. Following the index hospitalization, patients had a mean follow-up of 13 (18) months. During follow-up, 17% of patients experienced at least one IPF-related hospitalization, with a median time to readmission of 69 days; 34% of readmissions occurred within 30 days. Between the first and subsequent IPF-related

hospitalizations, mean LOS more than doubled (6 vs. 14 days; $p < 0.0001$) and median total medical costs increased from \$29,891 to \$34,479.

CONCLUSIONS: IPF-related hospitalizations impose a substantial clinical and economic burden among patients with IPF, as reflected by high 30-day mortality, frequent ICU utilization, and considerable inpatient costs.

SPONSORSHIP: United Therapeutics Corporation

324 Validation of a composite mortality variable among patients with integrated electronic health records in a large multimodal database

Kapilivsky J¹, Islam F¹, Dow J¹, Tucker M¹, Scherrer E², Hyun S¹, Sangli C¹; joshuah.kapilivsky@tempus.com; emilie.scherrer@tempus.com

¹Tempus AI, Inc.; ²Tempus AI

BACKGROUND: Real-world data (RWD) from electronic health records (EHRs) are important for evaluating treatment effectiveness and overall survival in oncology. Accurate mortality data are essential in studying treatment effectiveness; however, EHR data have known limitations in completeness that can be mitigated by combining with other data sources.

OBJECTIVE: To evaluate the performance of a composite mortality variable that integrates structured and unstructured data sources, including EHRs, with an external mortality data source and claims data by benchmarking against the National Death Index (NDI).

METHODS: We evaluated deidentified clinical and molecular data from a cohort of 17,597 patients diagnosed with advanced solid tumors from 2016 to 2020 from the Tempus real-world multimodal database. Cancer types included non-small cell lung cancer (NSCLC), breast (BC), ovarian (OC), pancreatic (Panc), prostate (PC), and colorectal cancer (CRC). All data were linked with third-party mortality and claims datasets using deterministic tokenization, and performance metrics were calculated using NDI data as ground truth. Date agreement was assessed at 0-, ± 15 -, and ± 30 -day tolerances. All analyses were restricted to patients with ongoing direct EHR integrations ($n = 4,795$).

RESULTS: The sensitivity of mortality data in the EHR was 56.7%. Adding third-party data increased to 84.3%, and adding claims on top brought the final sensitivity to 86.6%. This composite mortality variable demonstrated a specificity of 96.2% when benchmarked against the NDI. All cancer types had at least 84% sensitivity: BC 84.1%, CRC 84.4%, NSCLC 88.0%, OC 90.2%, Panc 87.4%, PC 87.6%; Sensitivity was stable by sex: 86.7% male, 86.5% female. Sensitivity was generally stable by age at diagnosis but was highest for older populations (age < 35 : 84.4%; age 35-49: 86.3%; age 50-64: 85.7%;

age 65-74: 85.4%; age ≥ 75 : 91.2%). Overall, the positive predictive value (PPV) was 96.7% and the negative predictive value (NPV) was 84.7%. Exact date agreement with the NDI database was 74.6%; this increased to 91.8% with a ± 15 -day tolerance, and to 96.1% with a ± 30 -day tolerance. Exact date agreement was highest for mortality dates directly from the EHR (81.1%) but was similar to the composite for ± 30 -day tolerance (96.4%).

CONCLUSIONS: The composite mortality variable demonstrated robust performance and high sensitivity (86.6%) and specificity (96.2%) in the EHR-integrated population. These findings suggest that the composite mortality variable is a reliable endpoint for real-world evidence analyses.

SPONSORSHIP: Tempus AI

325 Healthcare resource utilization associated with delay in progression in US patients with newly diagnosed diffuse large B-cell lymphoma treated with first-line rituximab + cyclophosphamide, doxorubicin, vincristine, and prednisone

Sorial M¹, Branchcomb T², Wang T², Zhang G², Wang A³, Alshreef A³, Atiya M², Atiya B², Patel V²; Marksorial@outlook.com; tybr@genmab.com

¹Dana-Farber Cancer Institute; ²Genmab US, Inc.; ³AbbVie

BACKGROUND: About 30-40% of newly diagnosed diffuse large B-cell lymphoma (DLBCL) patients (pts) treated with the first-line (1L) standard-of-care regimen rituximab plus cyclophosphamide, doxorubicin, vincristine, and prednisone (R-CHOP) relapse or are refractory within 24 mo. Novel therapies such as epcoritamab+R-CHOP (NCT04663347) may potentially delay progression. Healthcare resource utilization (HCRU) and economic burden may be reduced with delayed progression; the real-world impact of progression timing on HCRU is not well characterized.

OBJECTIVE: To evaluate HCRU by progression status and timing of progression in newly diagnosed DLBCL pts treated with R-CHOP.

METHODS: This retrospective study used electronic health records linked to claims data (COTA Healthcare and Komodo Health: Oct 2015-Feb 2026) to identify adults with newly diagnosed DLBCL initiating 1L R-CHOP. Pts were followed up to 24 mo from treatment initiation (index date). HCRU was compared without/with progression within 24 mo/by progression timing: ≤ 6 , $> 6-12$, $> 12-18$, $> 18-24$ mo. All-cause/DLBCL-related HCRU was assessed per pt per year (PPPY): inpatient (IP), outpatient (OP), emergency room (ER), pharmacy visits, and IP length of stay (days). HCRU was adjusted for baseline demographics, disease severity, and comorbidities. Kaplan-Meier analyses estimated overall

survival (OS) and progression-free survival (PFS; unadjusted). Subgroup analyses were conducted in patients with/without subsequent chimeric antigen receptor T-cell therapy and pre/post its regulatory approval.

RESULTS: Of 3321 pts treated with R-CHOP, 28% progressed/died within 24 mo. Median time-to-event was 8.7 y for OS and 7.7 y for PFS. Pts with progression had higher adjusted all-cause HCRU vs pts without progression across IP, ER, OP, pharmacy visits, and IP days (PPPY: 3.7 vs 1.3, 2.5 vs 1.2, 32.2 vs 20.8, 6.4 vs 4.4, and 29.3 vs 10.0, respectively; all $P \leq 0.01$). Earlier progression was associated with higher IP visits, with the highest burden among patients progressing ≤ 6 months (PPPY for ≤ 6 vs $>6-12$ vs $>12-18$ vs $>18-24$ mo: 4.4 vs 2.8 vs 1.6 vs 1.2, respectively; $P \leq 0.01$). Consistent reductions in HCRU were seen across all categories with increased time-to-progression. DLBCL-related HCRU followed similar patterns to all-cause HCRU.

CONCLUSIONS: Early progression in pts with newly diagnosed DLBCL treated with R-CHOP was associated with significantly increased HCRU. Interventions that delay progression may reduce healthcare burden, supporting their potential value from a healthcare system perspective.

SPONSORSHIP: Genmab A/S, AbbVie

326 Real-world health care burden of idiopathic pulmonary fibrosis in the first year following diagnosis

Blackstock E¹, Rutter C², Wu B², Lin M², Morland K², Mathai S³; erin.blackstock@imail.org; crutter@unither.com

¹Intermountain Medical Center; ²United Therapeutics Corporation; ³Baylor University Medical Center

BACKGROUND: Idiopathic pulmonary fibrosis (IPF) is progressive with high morbidity and mortality.

OBJECTIVE: To quantify changes in health care resource utilization (HCRU) before and after initial IPF diagnosis.

METHODS: This is a longitudinal analysis of patients with incident IPF diagnosed between 1/1/2017 and 09/30/2025. Data were extracted from the Optum's de-identified Clinformatics Data Mart Database. Patients were included if their index IPF diagnosis (J84.112) occurred in the study period, had 6 months of continuous enrollment prior to index, were ≥ 40 years of age at index, and had no claims for IPF in the 6 months prior to index. Patients were followed until loss of coverage, 365 days after IPF diagnosis, or end of study period. Primary outcome was all-cause hospitalization and was analyzed in the pre- and post-IPF period with per-member per-month (PMPM) rates and incidence rate ratios (IRR). Mixed-effects Poisson regression modeling was performed to estimate hospitalization rates. Length of stay for inpatient utilization and

ICU admissions were also analyzed. Patient survival was explored with Kaplan-Meier methods.

RESULTS: 27,045 patients were included with a mean (SD) follow-up time after IPF diagnosis of 266 (127) days, 53% with 1 year of follow-up. Patients were on average 76 years old (SD 8), were primarily White (92%) and male (55%), and had Medicare Advantage insurance (92%). The cohort had multiple comorbidities, with 48% having a Quan Charlson Comorbidity Index ≥ 4 . Antifibrotic use was present in 19% of patients (7% initiated pre-IPF and 12% initiated post-IPF). Hospitalizations increased from 31% to 45% of patients pre- and post-IPF diagnosis. PMPM hospitalization rate increased from 0.04 admissions/month pre-IPF to 0.09 admissions/month post-IPF (IRR [95% CI] = 2.06 [2.02-2.1]; $p < 0.001$). In a mixed-effects Poisson regression model controlling for comorbidity, insurance coverage, race, geography, age, and gender, PMPM hospitalization rate was 160% higher in the post-IPF period (adjusted IRR = 2.6; 95% CI 2.54-2.66; $p < 0.001$). ICU visits occurred in 17% and 28% of patients pre- and post-IPF diagnosis, respectively; PMPM ICU admission rates also increased from 0.02 admissions/month to 0.05 admission/month from pre- to post-IPF periods (IRR [95% CI] = 2.36 [2.29-2.43]; $p < 0.001$). Median length of stay increased from 6 to 8 days ($p < 0.001$). Median survival was 33.9 months post-IPF diagnosis.

CONCLUSIONS: HCRU in the period after initial IPF diagnosis was significantly elevated.

SPONSORSHIP: United Therapeutics Corporation

327 Patient heterogeneity in physician preference studies: Insights from a systematic literature review

Dieyi C¹, Ramachandran N², Quaipe M², Jiongco A², Webb E², Samuelson A³, Thomas C², Ashaye A¹; christopher.dieyi@takeda.com

¹Takeda Development Center Americas, Inc.; ²Evidera; ³Thermo Fisher Scientific, Inc.

BACKGROUND: Physicians treat heterogeneous patient populations and must balance treatment benefits, risks, and patient characteristics when making decisions. Discrete choice experiments (DCEs) are widely used to quantify preferences, but it is unclear whether and how patient heterogeneity is considered in study design and whether this affects physicians' decision-making. Although prior systematic literature reviews (SLRs) have included physician DCEs, this aspect has not been specifically explored.

OBJECTIVE: To characterize physician preference studies, with a focus on whether and how patient heterogeneity is considered and if this affects physicians' decision-making.

METHODS: An SLR of English-language DCEs published 2015–2025 was conducted using Embase and MEDLINE. Eligible studies assessed physicians' preferences for pharmacological treatment of patients. Two researchers independently screened studies and extracted data on study characteristics, DCE design, and approaches to incorporating patient heterogeneity; discrepancies were resolved by a third researcher.

RESULTS: A total of 121 studies were included. Annual publications increased from 9 in 2015 to 22 in 2025. Studies spanned 32 countries, most commonly in the United States ($n = 47$; 39%), and multiple therapeutic areas, especially oncology ($n = 54$; 45%), with hematologic malignancies most frequent ($n = 15/54$; 28%). Most studies also included other stakeholders ($n = 85$; 70%), usually patients ($n = 74$; 61%). Differences between physicians' and other stakeholders' preferences were often identified ($n = 73/79$; 92%), with few ($n = 6/79$; 8%) studies finding similar preferences. Most studies ($n = 84$; 69%) did not consider patient heterogeneity in the presented tasks. Among those that did ($n = 37$; 31%), age ($n = 17/37$; 46%), disease severity ($n = 15/37$; 41%), and ECOG performance status ($n = 10/37$; 27%) were the most common characteristics included. Of the studies that evaluated the impact of patient characteristics on physicians' preferences ($n = 27$; 73%), the majority identified differences ($n = 23/27$; 85%). However, this was not consistently assessed and/or reported in 27% ($n = 10/37$) of studies despite the design accounting for patient heterogeneity.

CONCLUSIONS: Physician DCEs often overlook patient heterogeneity despite evidence that it influences treatment preferences, potentially limiting clinical relevance. Incorporating varied patient profiles better reflects real-world decision-making and has the potential to improve understanding of expected treatment patterns across patient subgroups.

SPONSORSHIP: Takeda Development Center Americas, Inc

328 Quantifying pharmacy claim denial rates, demographic disparities, and outcomes associated with prescription abandonment in the U.S.

Tkacz J, Cheng J; joseph.tkacz@veradigm.com
Veradigm

BACKGROUND: Formulary restrictions are designed to minimize use of inappropriate therapies and reduce healthcare costs without compromising clinical care, though evidence has demonstrated that these policies may have adverse downstream effects for select patient cohorts. As comprehensive pharmacy denial data are not widely available, it is critical to understand specific therapeutic denial rates and associated outcomes.

OBJECTIVE: To assess the most commonly denied pharmaceuticals within the U.S., along with associated patient characteristics, rates of abandonment, and subsequent hospitalizations.

METHODS: This was a retrospective analysis of the Veradigm Network EHR database linked with Komodo claims. Pharmacy claims with an NCPDP Reject Code of 70 (Product not Covered) or 75 (Prior Authorization Required) were assessed in 2024. Demographics were compared between patients with and without a denial; patients with a denial and ≥ 12 months of continuous enrollment were assessed for prescription abandonment at the class level and compared on subsequent hospitalization rates. Chi-square and independent t-tests were used to determine statistically significant differences between cohorts.

RESULTS: Among 106,031,055 total patients, 14,945,951 (14.1%) presented a pharmacy claim with a rejection code of interest. Semaglutide (7.4% of denials), tirzepatide (5.5%), and albuterol (5.2%) accounted for the most denied claims; tetracycline for acne presented the highest individual denial rate (87.9%). Compared to patients without a denial, patients with a denial were older (53.8 ± 19.5 vs. 48.3 ± 22.8), and more likely to be female (61.3% vs. 56.3%), non-Hispanic (63.0% vs. 54.7%) and a Medicare beneficiary (37.7% vs. 29.3%; p values < 0.01). In total, 44.2% of patients abandoned the denied therapy. Across a variety of medication classes, patients who abandoned therapy presented higher hospitalization rates compared to those who eventually received the initially denied therapy: BTK inhibitors (34.5% vs. 25.6%), DMARDs (19.0% vs. 12.9%), antipsychotics (23.3% vs. 19.7%; p values < 0.01).

CONCLUSIONS: Nearly half of U.S. patients who presented a policy-based prescription denial abandoned therapy in 2024, which was associated with significantly greater rates of subsequent hospitalization across a variety of chronic diseases. GLP-1 agonists remain the most denied pharmaceutical in the U.S., and disparities were observed between patients with and without a denial. Patient-centered pharmacy benefit designs that prioritize access are critical to mitigating avoidable clinical decline and also addressing potential disparities in healthcare delivery.

SPONSORSHIP: None

329 Payer-related differences in time to CAR-T infusion among patients with DLBCL: A real-world claims analysis

Rodriguez-Silva J¹, Mudumby P², Barhoush Y², Fisher M², Maughn K²; PMudumby@statinmed.com
¹STATinMED, LLC; ²STATinMED

BACKGROUND: Chimeric antigen receptor T-cell (CAR-T) therapy is an effective treatment option for patients with relapsed/refractory diffuse large B-cell lymphoma (DLBCL). Timely transition to CAR-T is critical; however, delays may reflect barriers in treatment access, payer approval, or care coordination.

OBJECTIVE: To evaluate whether insurance type is associated with time from last anti-cancer therapy to CAR-T infusion.

METHODS: A retrospective analysis was conducted using the STATinMED RWD Insights database, an all-payer medical and pharmacy claims source. Adult patients with DLBCL who received CAR-T therapy between January 1, 2019, and December 31, 2023, were identified. Time from last DLBCL-directed therapy to CAR-T infusion was categorized as urgent (0–15 days), standard (16–26 days), or delayed (≥ 27 days). Multivariable logistic regression models were performed in a complete-case cohort with non-missing socioeconomic covariates (N = 694) to evaluate predictors of each timing category. Covariates included payer type, race, income, sex, age, and Charlson Comorbidity Index (CCI).

RESULTS: Among 694 patients, 31.1% received CAR-T within 0–15 days, 16.0% within 16–26 days, and 52.9% after ≥ 27 days. In descriptive analyses, Medicaid patients had the lowest proportion of urgent treatment (24.7%) and the highest proportion of delayed treatment (60.7%), compared with commercially insured patients (38.0% urgent; 46.2% delayed). In adjusted analyses, Medicaid patients had significantly lower odds of receiving CAR-T within 0–15 days (OR 0.54; 95% CI 0.30–0.97; $p = 0.043$) and significantly higher odds of delayed treatment (OR 1.91; 95% CI 1.12–3.31; $p = 0.018$) compared with commercially insured patients. Medicare patients showed similar directional trends but did not reach statistical significance. Higher CCI was associated with increased odds of standard timing (OR 1.08; 95% CI 1.02–1.14; $p = 0.010$). Patients with household income \$75,001–\$100,000 had higher odds of delayed treatment compared with those with income $< \$25,000$ (OR 1.66; 95% CI 1.02–2.70; $p = 0.041$).

CONCLUSIONS: In this real-world claim analysis, Medicaid coverage was associated with lower likelihood of rapid transition to CAR-T therapy and higher likelihood of delayed treatment versus commercial insurance. These findings suggest potential payer-related differences in timely access to

CAR-T therapy and highlight opportunities to improve care coordination and streamline access across insurance types.

SPONSORSHIP: STATinMED, LLC

330 Real-world impact of semaglutide (Wegovy) initiation on healthcare resource utilization and costs in non-diabetic adults with overweight or obesity and cardiovascular disease

Osundolire S¹, Maglaque D², Durand C², Inneh A², Bellon J³; seun.osundolire@evernorth.com
¹Evernorth Health Services; ²Evernorth Research Institute; ³Evernorth Research Institute, Cigna

BACKGROUND: Wegovy (semaglutide) has demonstrated reduced risk of major adverse cardiovascular events (MACE) in non-diabetic adults with overweight or obesity and established cardiovascular disease (CVD) in clinical trials, with mixed real-world evidence. As use of glucagon-like peptide-1 receptor agonists (GLP-1RAs) expands, understanding real-world economic impact is critical; however, data on healthcare resource utilization (HCRU) and costs remain limited.

OBJECTIVE: To assess the real-world association between semaglutide initiation and HCRU and costs among adults with overweight or obesity and established CVD without diabetes.

METHODS: Pharmacy and medical claims were used to identify adults aged ≥ 45 years without diabetes initiating semaglutide between June 2021 and December 2024, with BMI ≥ 27 kg/m², established CVD, and ≥ 12 months of continuous enrollment prior to initiation. Users were matched 1:1 to non-users on age group, sex, race, type of insurance coverage, and region. All-cause HCRU (inpatient, outpatient hospital, office and emergency department (ED) visits) and costs were assessed over 12, 18, 24, and 36 months post-initiation. Poisson models estimated incidence rate ratios (IRR) for HCRU, while generalized linear models were used for costs. Subgroups included obese, overweight, and adherent populations. Adherence was defined as proportion of days covered $\geq 80\%$.

RESULTS: A total of 1,489 semaglutide users were matched to 1,489 non-users. Baseline characteristics were well balanced; participants were predominantly commercially insured (92.4%), female (61.8%), and non-Hispanic White (85.5%). No statistically significant differences in HCRU were observed (12-month ED IRR: 1.17; 95% CI: 0.91–1.51), with consistent findings across settings and subgroups. Pharmacy costs were significantly higher among semaglutide users (12-month mean: \$17,889 vs \$4,204), while total medical costs were not significantly different (IRR: 1.13; 95% CI: 0.96–1.33). ED visit costs were higher (IRR: 1.42; 95% CI: 1.10–1.82), while office visit costs were lower (IRR: 0.78; 95% CI: 0.67–0.89) and

remained lower at 18 months and in obese and adherent subgroups. Adherence declined over time (39.8% at 12 months to 18.2% at 36 months).

CONCLUSIONS: Semaglutide initiation was not associated with differences in overall HCRU but was associated with higher pharmacy and ED costs and lower office visit costs. Findings suggest increased pharmacy-driven spending without clear reductions in utilization, informing payer decision-making for GLP-1RAs in this population.

SPONSORSHIP: None

331 Zilucoplan utilization in patients with generalized myasthenia gravis in the US: A retrospective, longitudinal, observational study

Sanchez J¹, Öhagen P¹, Yi J², Park M², Smith D¹;
jasie.sanchez@ucb.com

¹UCB; ²Alira Health

BACKGROUND: Generalized myasthenia gravis (gMG) is an autoimmune disease characterized by muscle weakness. Zilucoplan (ZLP), the only C5 inhibitor approved in the US for acetylcholine receptor (AChR) autoantibody-positive gMG that can be self-administered, became commercially available from January 2024.

OBJECTIVE: To describe ZLP utilization patterns and patient characteristics in a real-world setting.

METHODS: This was an observational, retrospective, longitudinal cohort study of adults with gMG treated with ZLP between January 3, 2024, and October 31, 2025. Data were obtained from the ONWARD patient support program (PSP) and PANTHERx specialty pharmacy (SP). Index date was start of ZLP treatment (a day after first ZLP shipment date). Baseline period was the date of entry into the PSP/SP to the index date. Follow-up began the day after index and ended at the earliest date of data cutoff, death or PSP/SP deregistration.

RESULTS: Overall, 697 patients were included. Mean (standard deviation [SD]) follow-up was 257.7 (167.1) days. Mean (SD) age was 60.0 (16.2) years, and 52.7% were female. Overall, 72.7% were >77 kg, 23.1% were 56–77 kg and 4.2% were ≤56 kg. US geographic distribution was South (42.3%), Midwest (23.8%), West (21.1%) and Northeast (12.7%). Payers included Medicare (52.4%), Commercial (34.2%), Medicaid (5.9%), Dual (3.4%), Government (2.4%) and Other (1.8%). Most patients were MGFA Class III (51.2% [189/369]) or II (30.9% [114/369]); mean (SD) MG-ADL (506/697) score was 8.2 (4.15), and 95.4% (349/366 with autoantibody status) were AChR positive. Prior biologics included eculizumab (21.9%; 152/694) and ravulizumab (17.3%; 120/694). Most prescriptions were written by a neurologist (91.3%). At first prescription, 71.4%

(498/697), 24.7% (172/697) and 3.9% (27/697) received 32.4 mg, 23.0 mg and 16.6 mg doses, respectively. In total, 83.5% (582/697) had a fixed medication possession ratio (FMPR) of >80%, with a mean FMPR of 87% (SD 21%). Mean (SD) number of days to zilucoplan discontinuation or end of follow-up if no discontinuation was observed was 258.05 (166.9). Discontinuation was recorded in 25.7% (179/697) of patients, with a probability of discontinuing ZLP by Day 100 of 10.8%. Among patients with ≥1 treatment gap of >28 days, 19.2% (42/219) reinitiated therapy during follow-up.

CONCLUSIONS: US patients initiating ZLP were an average of 60 years old, mostly on Medicare or Commercial insurance and mostly MGFA Class II or III, and their starting dose was aligned with weight. High levels of adherence and persistence were observed.

SPONSORSHIP: UCB

332 Real-world healthcare resource utilization associated with repeated administration of capsaicin 8%, guideline-directed, or non-guideline-directed treatment in patients with diabetic peripheral neuropathy: A US retrospective claims cohort study

Fishman J¹, Allen S¹, McMullen S², Fakhraei R², Caisip C², Gulas I²; jesse.fishman@averitaspharma.com

¹Averitas Pharmaceuticals; ²Broadstreet HEOR

BACKGROUND: Oral treatments for diabetic peripheral neuropathic (DPN) pain are often discontinued due to systemic adverse effects or inadequate pain control. Capsaicin 8% high concentration topical system (HCCTS) offers a non-systemic treatment for DPN-related foot pain. However, no claims studies have assessed long-term HCCTS use on healthcare resource utilization (HCRU) versus oral treatments.

OBJECTIVE: To compare HCRU over 12 months among DPN patients receiving 1–3 doses of HCCTS vs patients receiving oral DPN treatments.

METHODS: A retrospective cohort study was conducted using HealthVerity medical and pharmacy claims (January 2021–January 2025) to identify adults with a DPN treatment and an ICD-coded DPN diagnosis between 2021 and 2023. Patients were assigned hierarchically to cohorts based on their earliest claim for HCCTS, a guideline-directed treatment (GT [e.g., duloxetine, pregabalin]), or a non-guideline-directed treatment (NGT [e.g., opioids]). HCCTS was categorized by number of claims occurring 3 months apart during 12 months of follow-up. HCRU outcomes included the number of inpatient stays, emergency department (ED) visits, and outpatient visits, assessed quarterly and over 12 months of follow-up.

RESULTS: A total of 259 patients were in the HCCTS ≥ 3 -dose cohort (other cohorts not reported here), 885 in the GT cohort, and 446 in the NGT cohort. At baseline, age and sex were similar across cohorts (44.2–52.1% female; mean age 64.4–67.6 years). Compared with the GT and NGT cohorts, HCCTS ≥ 3 -dose cohort had higher comorbidity burden (97.7% vs 92.4% in GT [standardized mean differences (SMD): 0.24] and 95.7% in NGT [SMD: 0.11]), more DPN-related pain (60.2% vs 38.9% in GT [SMD 0.44] and 36.1 in NGT [SMD 0.50]) and more prior opioid use (47.1% vs. 33.7% in GT [SMD: 0.28]). Descriptively, the HCCTS ≥ 3 -dose cohort had fewer mean inpatient visits in Q1 of follow-up (0.5 vs. 1.2 GT, 1.1 NGT), and over 12 months (2.0 vs. 3.6 GT, 2.9 NGT; 29.0% with ≥ 1 stay vs. 31.6% GT, 32.1% NGT). ED use was lower over 12 months in the HCCTS group (48.3% with ≥ 1 visit vs. 50.5% GT, 51.1% NGT). Outpatient visits were higher in the HCCTS ≥ 3 -dose cohort during follow-up (mean use 36.7 [includes HCCTS application] vs. 25.0 GT, 27.4 NGT; proportion with ≥ 1 visit 99.2% vs. 97.4% GT, 98.2% NGT).

CONCLUSIONS: Despite having higher-risk characteristics, patients with DPN who received ≥ 3 doses of HCCTS ≥ 90 days apart had lower inpatient and ED use than the GT and NGT cohorts. These descriptive findings suggest that sustained HCCTS use may reduce annual high-acuity resource use in DPN.

SPONSORSHIP: Averitas Pharmaceuticals

333 Disease burden and severity characterization of atopic dermatitis using real-world data from NorstellinQ: EMR and open claims with AI-extracted clinical insights

Patel S, Friedman S, Hollenberg B, Behm I, Perry A;
shefali.patel@norstella.com
Norstella

BACKGROUND: Atopic dermatitis affects ~7–10% of U.S. adults and is characterized by chronic pruritus, sleep disruption, and impaired quality of life. Structured severity instruments are hard to capture in traditional claims data, limiting payers' ability to assess disease burden for formulary, prior authorization, and step therapy decisions. AI-enabled extraction from unstructured clinical notes offers a scalable path to filling this gap.

OBJECTIVE: To characterize real-world AD severity using NorstellinQ EMR and open claims with LLM-extracted itch scores, Fitzpatrick skin type, and sleep disturbance, to inform managed care formulary and authorization decisions.

METHODS: Retrospective observational study used NorstellinQ EMR and open claims data. Adults (≥ 18 years) with ≥ 1 AD diagnosis (ICD-10: L20) identified across sources

between January 2017 and May 2026 and ≥ 12 months of data availability were included (N=112,852). An LLM pipeline extracted itch severity, Fitzpatrick skin score, BSA, IGA, EASI, SCORAD, and sleep disturbance mentions with negation correction from free-text clinical notes. A composite algorithm stratified severity as mild, moderate, or severe.

RESULTS: Mean age 46.8 years; 64% female; 60% White, 15% Black, 15% Asian, 3% Hispanic. Of 112,852 patients, 92% lacked assessable severity data, indicating a systemic gap with direct payer consequences. Among 9,958 assessable patients (8.8%): 16.6% mild, 21.8% moderate, 61.6% severe. Non-BSA scores documented in 42.4% of severe versus 3.2% of mild/moderate patients ($p < 0.001$), validating LLM-derived stratification. Mean BSA: 2.3% (mild), 7.0% (moderate), 38.8% (severe); EASI: 17.5 to 29.7; NRS: 5.1 to 8.3 across moderate to severe. Sleep disturbance: 0% mild, 59.3% moderate, 73.4% severe ($p < 0.001$). Fitzpatrick V–VI trended toward higher severity vs. I–II (93.2% vs. 87.6%; $p = 0.16$).

CONCLUSIONS: This study highlights a significant real-world evidence gap in AD, where the majority of patients lack structured severity documentation traditionally relied upon in managed care decision-making. At the same time, structured severity instruments were substantially more likely to be documented among patients with more severe disease burden, supporting the clinical relevance and concordance of the AI-enabled severity characterization approach. The findings demonstrate how AI-enabled RWD approaches can surface clinically meaningful indicators not consistently captured in structured fields alone, with important implications for formulary strategy, utilization management, patient identification, and equitable access considerations in managed care environments.

SPONSORSHIP: None

334 Enhancing real-world evidence generation using AI-driven analytics on Medicare Enhanced Laboratory Data (MELD)

Baser O¹, Yapar N²; onur.baser@sph.cuny.edu;
nehir@cdanyc.com

¹City University of New York (CUNY); ²Columbia Data Analytics

BACKGROUND: AI-enabled MELD analytics can improve formulary management, optimize targeting of care interventions, and support more effective allocation of healthcare resources, aligning with AMCP priorities in real-world evidence and value-based care.

OBJECTIVE: To assess the added value of integrating Medicare Enhanced Laboratory Data (MELD) with Medicare Fee-for-Service (FFS) claims using artificial intelligence (AI) models

to improve risk prediction and inform value-based care strategies.

METHODS: We conducted a retrospective cohort study of 145,786 Medicare FFS beneficiaries with type 2 diabetes between January 2021 and December 2025 using MELD-linked claims and electronic medical record (EMR) laboratory data. Key variables included HbA1c, LDL-C, and estimated glomerular filtration rate (eGFR), alongside claims-based measures of medication adherence, comorbidities, and healthcare utilization. Machine learning models, including gradient boosting and deep neural networks, were developed to predict 12-month hospitalization and total cost of care. Model performance using MELD-enhanced data was compared to claims-only models using area under the curve (AUC) and mean absolute error (MAE).

RESULTS: AI models incorporating MELD data outperformed claims-only models in predicting hospitalization risk (AUC: 0.823 vs. 0.712; relative improvement: 15.6%). Inclusion of laboratory values improved identification of high-risk patients by 24.3%, particularly among individuals with HbA1c levels greater than 9.2%, who experienced a 1.74-fold higher risk of hospitalization despite comparable adherence rates. Cost prediction models showed a 13.8% reduction in MAE when MELD variables were included. AI-driven stratification identified a high-risk subgroup comprising 17.6% of the population that accounted for 41.3% of total healthcare expenditures over the follow-up period.

CONCLUSIONS: The integration of MELD with AI-driven analytics significantly enhances the precision of real-world evidence and risk stratification in Medicare populations. These findings demonstrate the value of combining laboratory and claims data to better identify unmet clinical needs and support data-driven decision-making in managed care.

SPONSORSHIP: None

335 Health care resource utilization with cariprazine versus lumateperone among patients with major depressive disorder

Clayton A¹, Ripley S², Zanardo E³, Ma S⁴, Laliberté F⁵, Khairnar R⁶; AHC8V@uvahealth.org; rahul.khairnar@abbvie.com

¹University of Virginia School of Medicine; ²Groupe d'analyse SRI; ³Analysis Group; ⁴Analysis Group Inc.; ⁵Groupe d'analyse SRI; ⁶AbbVie Inc.

BACKGROUND: Cariprazine and lumateperone are atypical antipsychotics approved as adjunctive therapy with antidepressants for the management of major depressive disorder (MDD). Despite their clinical utility, limited real-world

evidence exists on differences in health care resource utilization (HCRU) between the two treatments.

OBJECTIVE: To evaluate comparative HCRU outcomes among patients with MDD receiving either adjunctive cariprazine or lumateperone.

METHODS: Claims from the Komodo Research Database (between 1/1/2016 and 07/31/2025, the most recent date of data availability) were used to identify adults with MDD who had ≥ 2 pharmacy claims for adjunctive cariprazine or adjunctive lumateperone on or after 12/20/2021; the first fill date served as the index date. Patients were required to have ≥ 12 months of continuous eligibility before index (baseline period), ≥ 3 months after index, and ≥ 1 anti-depressant therapy 90 days before index with a ≥ 30 -day overlap with either adjunctive cariprazine or lumateperone during 90 days after index. Cohorts were weighted using inverse probability of treatment weighting based on the propensity score. All-cause HCRU included inpatient hospitalizations, emergency room (ER) visits, and outpatient (OP) visits. Mental health (MH)-related HCRU included inpatient hospitalizations and ER visits with a primary MH diagnosis and OP visits with an MH diagnosis as the primary or secondary condition. HCRU rates per person-year were assessed during the on-treatment period and compared between weighted cohorts using Poisson regression to estimate rate ratios (RR).

RESULTS: The analysis included 24,270 patients who received cariprazine and 1787 patients who received lumateperone during the period of interest. Baseline characteristics were balanced in the weighted cohorts. Patients who received cariprazine had significantly lower all-cause (22% lower; RR [95% CI] 0.78 [0.69, 0.88], $P < 0.001$) and MH-related (22% lower; RR [95% CI]: 0.78 [0.66, 0.93], $P = 0.005$) ER utilization and significantly fewer all-cause OP visits (RR [95% CI]: 0.94 [0.89, 1.00], $P = 0.038$) vs those who received lumateperone. Comparable outcomes were seen for cariprazine vs lumateperone for all-cause (RR [95% CI]: 1.00 [0.81, 1.24], $P = 0.993$) and MH-related (RR [95% CI]: 0.88 [0.69, 1.13]; $P = 0.324$) hospitalizations and MH-related OP visits (RR [95% CI]: 0.96 [0.89, 1.03]; $P = 0.267$).

CONCLUSIONS: Real-world evidence shows that adjunctive cariprazine was associated with significantly fewer all-cause ER and OP visits and MH-related ER visits compared with adjunctive lumateperone.

SPONSORSHIP: AbbVie

336 Persistence with adjunctive cariprazine versus adjunctive lumateperone among patients with major depressive disorder

Cutler A¹, Ripley S², Zanzardo E³, Ma S⁴, Laliberté F⁵, Khairnar R⁶; acutler@ajcmd.com; rahul.khairnar@abbvie.com

¹Department of Psychiatry, SUNY Upstate Medical University, Syracuse, NY; Neuroscience Education Institute, Lakewood Ranch, FL; ²Groupe d'analyse SRI; ³Analysis Group; ⁴Analysis Group Inc.; ⁵Groupe d'analyse SRI; ⁶AbbVie Inc.

BACKGROUND: Cariprazine and lumateperone are atypical antipsychotics (AAP) indicated as adjunctive therapy with antidepressants for major depressive disorder (MDD). Comparative evidence on treatment persistence among patients treated with adjunctive AAP therapy is limited.

OBJECTIVE: To evaluate real-world persistence with adjunctive cariprazine versus adjunctive lumateperone in patients with MDD.

METHODS: Claims data from the Komodo Research Database (1/1/2016–7/31/2025) were used to identify commercially insured adults with MDD who had ≥ 2 pharmacy claims for either adjunctive cariprazine or lumateperone on or after December 16, 2022. Index date was the first fill date. Eligible patients had ≥ 12 months of continuous insurance coverage before index (baseline period), ≥ 3 months after index, and ≥ 1 anti-depressant therapy 90 days before index with a ≥ 30 day overlap with either adjunctive cariprazine or lumateperone during 90 days after index. Baseline characteristics were weighted between cohorts using inverse probability of treatment weighting based on propensity scores. Treatment persistence was evaluated using Kaplan–Meier analyses and was defined as the time on therapy without discontinuation, where discontinuation was identified by a >60 -day gap between the end of days' supply and a subsequent fill or the end of follow-up. Persistence between weighted cohorts was compared using Cox proportional hazards models. Results are reported as hazard ratios (HRs).

RESULTS: The analysis included 12,440 patients who initiated adjunctive cariprazine and 768 who initiated adjunctive lumateperone. At 6 months, the proportion of patients persistent on cariprazine vs lumateperone was 58.2% and 53.8%, respectively. At 12 months, the proportion of patients persistent on cariprazine vs lumateperone was 40.2% and 37.6%, respectively. The median persistence duration for cariprazine vs lumateperone was 247 days and 214 days, respectively. Compared with patients initiating lumateperone, patients initiating cariprazine were 21% more likely to be persistent at 6 months (HR [95% CI] = 1.21 [1.09, 1.35], $P < 0.001$ and 15% more likely to be persistent at 12 months (1.15 [1.05, 1.27], $P = 0.004$).

CONCLUSIONS: This real-world study found that patients with MDD initiating adjunctive use of cariprazine had significantly greater persistence than patients initiating adjunctive lumateperone.

SPONSORSHIP: AbbVie

337 Healthcare resource use among people newly diagnosed with narcolepsy type 1 in the United States

Crawford S¹, Calingaert B², Meyers J², Sinclair L³, Duhig A¹, Candrilli S², Ulbricht C¹; stephen.crawford@takeda.com; christine.ulbricht@takeda.com

¹Takeda; ²RTI Health Solutions; ³Real-World Data & Analytics

BACKGROUND: Narcolepsy type 1 (NT1) is a rare, chronic neurological disorder associated with substantial burden due to reduced functioning and disability. Given approvals of narcolepsy-indicated medications in the past few years, this study provides an update to the published data on healthcare resource utilization (HCRU).

OBJECTIVE: To evaluate the burden of NT1 by assessing HCRU and costs among individuals newly diagnosed with NT1.

METHODS: This retrospective observational study used the Merative MarketScan Commercial Claims and Encounters and Medicare Supplemental and Coordination of Benefits databases (January 2017–January 2025) to identify adults newly diagnosed with NT1. Individuals with NT1 were matched 1:2 to controls based on age (± 2 years), sex, and insurance type. Objectives included assessing real-world adjusted all-cause HCRU and associated costs among individuals with NT1 vs controls over 365 days following diagnosis. Results were derived from generalized linear models that were adjusted for age, Charlson Comorbidity Index score, index year, health plan type, and geographic region.

RESULTS: Overall, 580 individuals with NT1 and 1160 controls (females: 71.7% in each group) met the inclusion criteria. Median (IQR) age was 33 (23–45) and 34 (23–47) years for NT1 vs controls. Comorbidities were higher in NT1 vs controls: anxiety disorders (45.7% vs 16.6%), depression (34.5% vs 11.6%), sleep apnea (34.3% vs 4.1%), obstructive sleep apnea (30.5% vs 3.6%), obesity (23.4% vs 10.2%), and cardiovascular disease (18.3% vs 7.7%). Adjusted all-cause HCRU in the year following diagnosis was significantly greater in NT1 vs controls (all $P < 0.001$): mean outpatient hospital visits were 4.14 vs 1.25; emergency department (ED) visits, 0.46 vs 0.22; and office visits, 18.52 vs 6.95. Inpatient stays were infrequent in both groups. Outpatient visit costs were 3.7-fold greater; ED visit costs, 2.1-fold; office visit costs, 3.0-fold; total medical costs, 3.0-fold; pharmacy costs 9.8-fold; and total costs

(medical + pharmacy) were 5.5-fold greater for individuals with NT1 vs controls.

CONCLUSIONS: Individuals newly diagnosed with NT1 incur 2- to 5-fold higher HRCU and costs than matched controls despite treatment availability, indicating that current management does not adequately address disease burden. The pronounced excess utilization in the first year following diagnosis highlights a substantial and persistent unmet need in NT1, with clear relevance for clinical and policy decision-making.

SPONSORSHIP: Study: Takeda Development Center America Inc USA (TDCA); Medical writing: Takeda Pharmaceutical Inc USA and TDCA

338 Association of hospitalization history prior to long-acting injectable antipsychotic initiation and subsequent hospitalizations and costs in young dual-eligibles with schizophrenia: The CRITICAL PERIOD study

Li P¹, Geng Z¹, Benson C², Doshi J¹; penli@pennmedicine.upenn.edu; CBenson5@its.jnj.com

¹University of Pennsylvania, Philadelphia, PA, USA; ²Johnson & Johnson, Titusville, NJ, USA

BACKGROUND: Early intervention can substantially influence the long-term course of psychosis and can potentially reduce overall health care costs.

OBJECTIVE: To assess whether schizophrenia (SCZ)-related hospitalization history prior to first long-acting injectable antipsychotic (LAI) initiation is associated with subsequent hospitalizations and healthcare costs among young dual-eligible adults in the United States.

METHODS: Using 2006–2021 Medicare and Medicaid claims, we identified dual-eligible beneficiaries diagnosed with SCZ at ages ≤ 25 who initiated an LAI between 07/01/2009 and 12/31/2020 (index date = first LAI fill). Patients were stratified by the number of pre-index SCZ-related hospitalizations (0, 1, 2–5, ≥ 6). Outcomes during the 12-month post-index period included all-cause costs and all-cause, mental health-related, and SCZ-related hospitalizations. Ordinary least squares (OLS) models estimated associations between pre-index hospitalization history and post-index utilization and costs, adjusting for demographic and clinical characteristics.

RESULTS: Among 3,447 LAI initiators, the median time from SCZ diagnosis to LAI initiation was 11 months, ranging from 5 months for patients with 0 pre-index hospitalizations to 42 months for those with ≥ 6 pre-index hospitalizations. Greater pre-index hospitalization burden was associated with higher post-index all-cause (0.6–2.9), mental health-related (0.5–2.8), and SCZ-related (0.4–2.4) hospitalizations and

higher all-cause costs (\$31,527–\$59,066). OLS regressions confirmed these associations.

CONCLUSIONS: Young dual-eligible adults with more SCZ-related hospitalizations before LAI initiation had higher hospitalization rates and costs after initiation. These findings highlight the potential clinical and economic implications of delayed LAI treatment and support efforts to promote earlier initiation to help reduce potentially preventable utilization and downstream spending.

SPONSORSHIP: Johnson & Johnson Innovative Medicine

Respiratory

359 Economic burden of refractory chronic cough and unexplained chronic cough among older patients (≥ 65 years of age): Results from two databases of Medicare beneficiaries

Bunniran S¹, Parikh B¹, Henning C², Joshi K¹, Nguyen C³, Zhang A⁴, Young-Xu L⁴, Long T⁴, Chang R⁴, Duh M⁴, Sundar K⁵; Su.x.bunniran@gsk.com

¹GSK, Collegeville, PA, USA; ²GSK, Durham, NC, USA; ³Analysis Group, Inc., Menlo Park, CA, USA; ⁴Analysis Group, Inc., Boston, MA, USA; ⁵University of California Davis, Sacramento, CA, USA

BACKGROUND: Refractory chronic cough (RCC) is identified in patients (pts) experiencing chronic cough (CC; >8 weeks) despite adequate treatment for known cough-related etiologies. Unexplained chronic cough (UCC) describes CC with no known underlying cause. Persistent CC, RCC, and UCC may be identified using the ICD-10 symptom code R05.3; however, no specific ICD-10 disease code for RCC/UCC exists. The Clear-CC algorithm was developed to identify pts with RCC/UCC in real-world claims data.

OBJECTIVE: To identify older pts with RCC/UCC and estimate associated healthcare resource utilization (HCRU) and costs, we applied the Clear-CC algorithm to real-world data from two US claims databases: Medicare Advantage prescription drug (MAPD) pt data (from Optum's de-identified Clinformatics Data Mart) and 100% Medicare Fee-For-Service (FFS).

METHODS: MAPD and FFS data from 01/01/2016 to 12/31/2023 were used. Pts aged ≥ 65 years with ≥ 2 years of continuous enrollment pre-RCC/UCC identification (index date) were included. HCRU and costs (2024 USD, standardized) were described per person per year (PPPY) at baseline (BL; 2-year pre-index period) and follow-up (from index to earliest death/end of continuous eligibility/data availability).

RESULTS: In MAPD and FFS data, respectively, 38,995 pts (mean [standard deviation (SD)] age: 75.6 [6.6] years; 69.1% female; mean [SD] follow-up: 2.1 [1.5] years) and 362,773 pts (mean [SD] age: 77.5 [7.9] years; 67.3% female; mean [SD] follow-up 2.4 [1.6] years) with RCC/UCC were identified. HCRU was mostly driven by outpatient (OP) visits and diagnostics. Mean (SD) number of OP visits at BL and follow-up were high (MAPD: 14.9 [16.9] and 16.2 [22.0] PPPY; FFS: 16.6 [10.4] and 16.6 [11.9] PPPY). From BL to follow-up, the overall mean (SD) number of diagnostic tests increased from 2.4 (2.6) to 3.4 (8.7) PPPY (+42%; MAPD), and 3.3 (3.6) to 4.6 (7.7) PPPY (+39%; FFS). From BL to follow-up, mean (SD) total all-cause costs increased by 53% in MAPD (\$18,531 [\$39,086] to \$28,429 [\$100,941]) and FFS (\$17,291 [\$28,724] to \$26,507 [\$57,041]); mean costs for diagnostic tests at BL and follow-up, respectively, were \$1193 and \$2069 PPPY (MAPD) and \$1696 and \$2273 PPPY (FFS).

CONCLUSIONS: Older pts experienced persistently high HCRU and increasing costs following RCC/UCC identification, primarily driven by repeat OP visits and frequent diagnostic tests. This pattern suggests ongoing HCRU associated with unresolved symptoms, contributing to persistent costs. This highlights the economic burden of RCC/UCC in older pts, suggesting a need for improved diagnoses and treatments.

SPONSORSHIP: GSK (study 223232)

360 Patient journey from symptom onset to treatment of idiopathic pulmonary fibrosis (IPF): Data from the Mayo Clinic

Gallagher S¹, Fairbanks J¹, Baldwin M², Khan S², Fan Y², Kanakapura M², Limper A³; Gallagher.Shannon@mayo.edu
¹Mayo Clinic Platform, Mayo Clinic, Rochester, MN, USA;
²Boehringer Ingelheim International GmbH, Ingelheim am Rhein, Germany; ³Division of Pulmonary and Critical Care, Mayo Clinic, Rochester, MN, USA

BACKGROUND: IPF is associated with poor outcomes including high mortality. Timely diagnosis and treatment are important to preserve lung function.

OBJECTIVE: To characterize the patient journey from symptom onset to treatment of IPF to enable system improvement.

METHODS: Electronic health records from Mayo Clinic, a healthcare delivery network in Minnesota, Florida, Arizona, Iowa, and Wisconsin, were analyzed. Patients with IPF were identified based on ≥ 2 outpatient visits with an ICD-9-CM or ICD-10-CM diagnosis code for IPF ≥ 1 to 365 days apart, or ≥ 1 inpatient visit with an ICD-9-CM or ICD-10-CM diagnosis code for IPF, between 1 October 2017 and 31 December 2024. Patients needed to have 36 months of data before the first diagnosis code for IPF. We evaluated prescription of anti-fibrotic therapies (nintedanib or pirfenidone) from 36 months

before the first diagnosis code for IPF until the end of follow-up (death, last encounter, or 31 December 2024).

RESULTS: Among 1133 patients, at time of the first IPF diagnosis code, mean age was 74 years; 72.0% were male. In the prior 36 months, 70.1% of patients had ≥ 1 comorbidity, most commonly hyperlipidemia (42.7%), arterial hypertension (42.0%) or essential hypertension (36.2%), while 61.7% of patients had ≥ 1 symptom potentially related to IPF (cough, dyspnea, fatigue, sleep disorder). Among these patients, the median (Q1, Q3) time from first symptom to first IPF diagnosis code was 20 (6, 31) months; time from first symptom to first diagnosis code for IPF was >6 months in 74.4% of patients. From 36 months before first IPF diagnosis code to end of follow-up (median 22 months), 42.3% patients were prescribed nintedanib or pirfenidone. 36.1% of patients had ≥ 1 prescription at the time of or after the first IPF diagnosis code. The median time to prescription was longer for patients with FVC ≥ 80 than ≥ 50 to $<80\%$ predicted at time of first diagnosis code for IPF.

CONCLUSIONS: This analysis of data collected during routine clinical care at Mayo clinic showed that patients with IPF experienced delays both in receiving a diagnosis and in receiving treatment. A high comorbidity burden may have contributed to these delays. Patients with preserved lung function at diagnosis waited longer to be prescribed anti-fibrotic therapy than patients with moderate lung function impairment, suggesting that some clinicians took a “wait and watch” approach before starting therapy. A structured approach to addressing systemic delays in diagnosis and treatment is needed to improve outcomes for patients with IPF.

SPONSORSHIP: Boehringer Ingelheim

361 Healthcare resource utilization in people with bronchiectasis by baseline pulmonary exacerbation frequency: A real-world data analysis

Brown C¹, Mingora C², Iglay K³, Patel B¹, Lavalley M¹, VanTieghem M⁴, Mountford W¹, Shetty S⁵, Flume P⁶; carolyn.brown@boehringer-ingelheim.com
¹Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT, United States of America; ²Medical University of South Carolina, Charleston, SC, United States of America; ³CERObS Consulting LLC, Asheville, NC, United States of America; ⁴Genesis Research Group, Hoboken, NJ, United States of America; ⁵Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT, USA; ⁶Medical University of South Carolina, Charleston, SC, United States of America.

BACKGROUND: Bronchiectasis (BE) is the third most common chronic lung disease, and despite increasing incidence of BE in the United States (US), real-world data remain limited.

OBJECTIVE: To bridge this gap by evaluating healthcare resource utilization (HCRU) in people newly diagnosed with BE in a large, US-based cohort.

METHODS: This non-interventional study used healthcare claims data from Optum Clinformatics Data Mart. Data were analyzed from individuals with an incident BE diagnosis (2017–2022) who were continuously enrolled for 365 days prior to the index date, defined as the date on which the case criteria were fully met during the index period. Individuals were grouped by baseline pulmonary exacerbation (PEX) frequency (0, 1, 2, ≥ 3) and followed for a maximum of 7 years and 9 months. Data from the 365 days prior to index BE diagnosis were used to determine the number of baseline PEXs. PEXs were defined as an emergency department visit, hospitalization with a primary or secondary diagnosis code for a respiratory disease, or an outpatient visit with a diagnosis code for a respiratory disease followed by a prescription for specific antibiotics, including macrolides, within 7 days. HCRU outcomes assessed included healthcare visits, days in hospital, intensive care unit (ICU) stays, and pharmacy claims.

RESULTS: Data from 75,731 individuals with BE were included (mean age: 74.2 years). The proportion of people with baseline PEXs was 32.3% with 0, 39.1% with 1, 16.1% with 2, and 12.4% with ≥ 3 . The mean (standard deviation) yearly rate of any respiratory-related healthcare visits increased with baseline PEXs: 0 PEXs, 6.8 (11.8); 1 PEX, 11.0 (16.6); 2 PEXs, 16.5 (20.3); ≥ 3 PEXs, 26.0 (26.7). In those with 0, 1, 2, and ≥ 3 PEXs, mean yearly rates of all-cause healthcare visits were 31.9 (27.1), 36.1 (31.3), 41.9 (33.8), and 50.8 (38.1); respiratory-related emergency department visits were 0.1 (0.5), 0.2 (0.8), 0.4 (1.1), and 0.8 (1.9); all-cause days in hospital were 5.0 (15.5), 21.1 (49.5), 24.0 (51.2), and 30.8 (53.7); and mean yearly pharmacy claims were 38.1 (40.3), 46.5 (51.0), 58.3 (56.0), and 74.9 (65.9), respectively. Thirty percent of respiratory hospitalizations and 25% of all-cause hospitalizations included an ICU stay.

CONCLUSIONS: HCRU typically increased with number of baseline PEXs. These findings highlight the critical importance of assessing PEX risk early and proactively managing BE to potentially modify disease trajectory, reduce healthcare burden, and improve long-term outcomes.

SPONSORSHIP: Boehringer Ingelheim International GmbH

362 Treatment patterns and exacerbations among patients with chronic obstructive pulmonary disease by payer type: Findings from the DUALITY patient journey study

Siddharthan T¹, Germack H², DeMartino J², Carstens D³, Baudy P³, Holder M³, Willshaw L⁴, Spy A³, Satija A⁵, Smith J⁵, Jiang F⁵, Arscott H⁵, Gauthier-Loiselle M⁵, Naddaf H⁶; tsiddhar@miami.edu; hayley.germack@astrazeneca.com

¹University of Miami, Miller School of Medicine; ²US Medical Evidence, BioPharmaceuticals Medical, AstraZeneca;

³US Medical-Respiratory, BioPharmaceuticals Medical, AstraZeneca; ⁴US Payer Medical, BioPharmaceuticals Medical, AstraZeneca; ⁵Analysis Group; ⁶The Toledo Clinic

BACKGROUND: Inhaled maintenance therapy, including individual or combination therapy with long-acting beta agonists (LABA), long-acting muscarinic antagonists (LAMA), and inhaled corticosteroids (ICS), is a mainstay of chronic obstructive pulmonary disease (COPD) management.

OBJECTIVE: To characterize contemporary COPD treatment patterns and exacerbations among patients with Medicare (Advantage/Fee-for-Service) or commercial insurance.

METHODS: Retrospective data (01/2016–06/2024) were obtained from Komodo Research Data (KRD+) for patients with COPD aged ≥ 40 years. The index date was the latest of the first COPD diagnosis or 01/01/2022. Eligible patients had continuous health plan enrollment for ≥ 12 months pre-index (i.e., baseline) and ≥ 6 months post-index (i.e., follow-up), unless death occurred. Inhaled maintenance therapy and exacerbations per person-year (PPY) were described during the follow-up period by payer type.

RESULTS: In total, 727,747 and 347,609 patients had Medicare and commercial insurance, respectively (female: 51% and 49%; mean age: 75 and 60 years; mean Charlson Comorbidity Index [excluding COPD]: 2.2 and 1.1; long-term care residence: 16% and 3%). Over a mean follow-up of 25 and 23 months, 47% and 50% of Medicare and commercially insured patients received any inhaled maintenance therapy (dual: 29% and 31%; triple: 21% and 23%). Among untreated patients, exacerbation rates were 2.3 and 1.9 PPY for Medicare and commercially insured patients. Among treated patients, these rates were 3.4 and 2.8 PPY for monotherapy, 3.3 and 2.7 PPY for dual therapy, and 4.1 and 3.4 PPY for triple therapy. Following a hospitalized exacerbation, nearly 1 in 4 Medicare and 1 in 6 commercially insured patients were readmitted within 30 days (untreated: 23% and 17%; monotherapy: 26% and 17%; dual: 24% and 16%; triple: 23% and 16%, respectively). Following an exacerbation, 6% and 9% of untreated patients with Medicare and commercial insurance were

escalated to triple therapy, while these proportions were 17% and 18% among those treated with monotherapy or dual therapy.

CONCLUSIONS: Despite having a high clinical burden and experiencing high rates of exacerbations and 30-day readmission, most patients insured with Medicare did not receive any maintenance therapy or escalate to triple therapy following an exacerbation. Similar findings, though less pronounced, were found among commercially insured patients. Taken together, these results highlight gaps in treatment optimization and underscore opportunities to improve disease management in COPD, particularly among Medicare beneficiaries.

SPONSORSHIP: AstraZeneca

363 Cost offset calculator for budesonide/glycopyrrolate/formoterol (BUD/GLY/FORM) compared to fluticasone furoate/umeclidinium/vilanterol (FF/UMEC/VI) in uncontrolled asthma from a US perspective

Parsekar K¹, Edmonds C², Germack H³, Walpole K⁴, Bentley A⁵; krishnali.parsekar@astrazeneca.com;

hayley.germack@astrazeneca.com

¹BioPharmaceutical Business Unit, Global Market Access & Pricing, AstraZeneca; ²Global Price and Market Access, AstraZeneca; ³US Medical Evidence, BioPharmaceuticals Medical, AstraZeneca; ⁴BioPharmaceutical Marketing and Access Strategy, AstraZeneca; ⁵Petauri Evidence

BACKGROUND: Asthma remains a substantial public health burden in the US, affecting 26.8 million people (8.2% of overall US population) and projected to cost \$48 billion in 2038. Treatment with ICS/LABA therapy is the mainstay for patients with moderate-to-severe asthma; however, this is suboptimal as more than 50% of patients continue to experience symptoms and/or exacerbations leading to increased costs. Single inhaler triple therapies have been evaluated in Phase III programs (budesonide/glycopyrrolate/formoterol [BUD/GLY/FORM] in KALOS/LOGOS; fluticasone furoate/umeclidinium/vilanterol [FF/UMEC/VI] in CAPTAIN). However, comparative budget impact and potential cost offsets between single-inhaler triple therapies remain unexplored.

OBJECTIVE: To estimate the potential cost offset of using BUD/GLY/FORM compared with FF/UMEC/VI among patients with uncontrolled asthma on medium- or high-dose ICS/LABA from a US perspective.

METHODS: A cost offset analysis from a payer perspective using a 1-year time horizon in a hypothetical cohort of 1,000,000 patients uncontrolled on medium/high-dose

ICS/LABA therapy was conducted. Two scenarios were compared: 1) FF/UMEC/VI with 43% of patients receiving 100/62.5/25 µg and 57% receiving 200/62.5/25 µg based on 2025 market shares; 2) 100% of patients were treated with BUD/GLY/FORM 320/36/9.6 µg. Annualized severe exacerbation rates for FF/UMEC/VI were sourced from the CAPTAIN trial; rates for BUD/GLY/FORM were informed by a network meta-analysis (NMA) comparing BUD/GLY/FORM with single-inhaler triple therapies. Exacerbation distributions through emergency room visits, hospitalizations, and corticosteroid use were included with health care resource utilization (HCRU), treatment, and exacerbation costs being derived from published literature.

RESULTS: The model estimated that treating 1,000,000 patients with BUD/GLY/FORM instead of FF/UMEC/VI could avoid 15,000 severe exacerbations leading to 1020 fewer ER visits, 1035 fewer hospitalizations, and 4347 fewer inpatient days. The analysis suggests that compared to FF/UMEC/VI, BUD/GLY/FORM could reduce total healthcare costs by \$176 million, equating to \$155 million savings in drug costs and \$21 million savings in exacerbation-related costs per year.

CONCLUSIONS: In patients with uncontrolled asthma, treatment with BUD/GLY/FORM can reduce severe exacerbations and HCRU compared to FF/UMEC/VI, resulting in substantial cost savings.

SPONSORSHIP: AstraZeneca

Specialty Pharmacy

368 Variation in step therapy for commercial plan coverage of rheumatoid arthritis therapies

Brennan C, Chambers J; Claire.Brennan@tuftsmedicine.org
The Center for the Evaluation of Value and Risk in Health,
Institute for Clinical Research and Health Policy Studies,
Tufts Medical Center

BACKGROUND: The treatment landscape for rheumatoid arthritis (RA) is evolving, with increasing biosimilar approvals, new drug classes, and greater use of combination therapies. While these therapies expand treatment options, variation in payer step therapy protocols may lead to differences in patient access.

OBJECTIVE: To compare step therapy protocols for RA therapies across commercial health plan coverage policies and drugs.

METHODS: We used the Tufts Medical Center Specialty Drug Evidence and Coverage (SPEC) Database, which contains specialty drug coverage policies from 18 large US commer-

cial health plans. We identified active coverage policies for 32 RA therapies as of August 2025 and reviewed policies for step therapy requirements, including the required line of therapy, use of non-biologic disease-modifying anti-rheumatic drugs (DMARDs) as first-line therapy, and the number of first-line biologic treatment options available to patients. Analyses compared variation across health plans and drugs.

RESULTS: Among 466 active policies, 85% required step therapy beyond the FDA-labeled line of therapy. Among policies with step therapy, 41% required one prior step, 24% two, 19% three, 11% four, and 3% five or more. Step therapy requirements varied substantially across health plans. Three plans imposed step therapy beyond the FDA label in 100% of policies, while the remaining plans ranged from 64% to 94%. The average required line of therapy ranged from 2.1 to 3.6 across plans, and the proportion of policies covering drugs as fourth-line or later ranged from 0% to 59%. First-line treatment choice varied. In 85% of policies, methotrexate or another non-biologic DMARD was required as first-line therapy. When non-biologic DMARDs were not required first-line, plans offered between one and five first-line treatment options. Among these policies, 18% offered one option, 61% two, 2% three, 12% four, and 7% five. Step therapy requirements also varied across drugs. Fifteen drugs had step therapy beyond the FDA label in 100% of policies, while the remaining drugs range from 40% to 94%. The average required line of therapy ranged from 1.9 to 4.6 across drugs, and the proportion of policies covering drugs as fourth-line or later ranged from 7% to 33%.

CONCLUSIONS: Step therapy protocols for RA therapies vary substantially across health plans and drugs and may contribute to differences in patient access. Patients also experience varying degrees of choice in first-line therapy. As the RA treatment landscape continues to expand, understanding payer coverage decisions will remain important for evaluating patient access.

SPONSORSHIP: None

369 Estimating the cost-effectiveness of sparsentan relative to real-world standard of care for focal segmental glomerulosclerosis: a patient-level microsimulation

Alizadeh E¹, Rava R¹, Incerti D², Ruderian A², Bensink M³; elmar.alizadeh1@gmail.com

¹EntityRisk; ²EntityRisk, Inc.; ³Traverse Therapeutics, Inc.

BACKGROUND: Focal segmental glomerulosclerosis (FSGS) is a rare chronic kidney disorder with unmet treatment need. FILSPARI (sparsentan) is a novel dual endothelin angiotensin

receptor antagonist (DEARA) demonstrated to reduce proteinuria, the strongest modifiable prognostic factor in FSGS.

OBJECTIVE: To estimate the cost-effectiveness of sparsentan relative to a real-world renin-angiotensin system inhibitor (RASi) standard of care (SoC) for reducing proteinuria in adult and pediatric patients aged 8 years and older with FSGS without nephrotic syndrome.

METHODS: A patient-level microsimulation was parametrized using Phase 3 DUPLEX study data for patients without nephrotic syndrome at baseline. The base case reflected a 60-year time horizon, societal perspective, and 3% discount rate. Patients transitioned across nine mutually exclusive health states (CKD1-4, Kidney Failure without and with Dialysis, Post-kidney transplant, FSGS recurrence, and Death). At model start, a urine protein creatinine ratio (UPCR) and estimated glomerular filtrate rate (eGFR) were sampled via bootstrapping. Post-treatment reduction in UPCR was also sampled via bootstrapping and applied to baseline UPCR after the first model cycle with RASi SoC modeled as no treatment effect. UPCR was then utilized to assign an eGFR slope for each patient based on published real-world evidence. eGFR was then calculated at each model cycle and a corresponding health state assigned. Digitized curves and estimates from literature informed all other state transitions and model parameters. Costs included treatment acquisition, clinical events, adverse events, health state, and indirect (i.e., labor, time, non-medical consumption). Total costs and quality-adjusted life-years (QALYs) were estimated and the incremental cost-effectiveness ratio (ICER) calculated utilizing generalized cost-effectiveness analysis (GCEA) with generalized risk- and severity-adjusted (GRASA) QALYs, annual stacked cohorts, and dynamic pricing for sparsentan acquisition cost. Probabilistic sensitivity analyses were also conducted.

RESULTS: Sparsentan's incremental costs and QALYs relative to real-world RASi SoC were \$12,928 and 0.52, respectively, yielding an ICER of \$24,930. Sensitivity analyses demonstrated this result was robust at a willingness to pay of \$150,000/QALY.

CONCLUSIONS: Sparsentan, as a treatment to reduce proteinuria in adult and pediatric patients aged 8 years and older with FSGS without nephrotic syndrome, is cost-effective relative to real-world RASi SoC and is a valuable addition to the sparse FSGS treatment landscape.

SPONSORSHIP: Traverse Therapeutics

370 Estimating the cost-effectiveness of garadacimab as a long-term prophylaxis therapy for hereditary angioedema

Alizadeh E¹, Rashid B¹, Huang J¹, Incerti D², Jursca R³; elmar.alizadeh1@gmail.com

¹EntityRisk; ²EntityRisk, Inc.; ³CSL Employee

BACKGROUND: Hereditary angioedema (HAE) is a rare genetic condition that involves recurrent attacks of swelling in various parts of the body. Andembry (garadacimab) is approved by the FDA for the long-term prophylaxis (LTP) treatment of HAE.

OBJECTIVE: To estimate the cost-effectiveness of garadacimab as an LTP therapy relative to multiple LTP comparators.

METHODS: The Markov cohort model had a base case with a 25-year horizon, payer perspective, 3% discount rate, and monthly cycles. Patients transitioned across three health states (Full Attack Freedom, Prone to Attack, and Death). LTP comparator treatments were Takhzyro (lanadelumab), Dawnzera (donidalorsen), Orladeyo (berotralstat), Haegarda, and Cinryze (both C1 esterase inhibitors). Published indirect treatment comparisons parametrized the probability of full attack freedom and HAE attack rates across LTP therapies. All other state transitions and model parameters were informed by the literature. HAE attacks that occurred despite LTP therapy were assumed to be treated with a basket of branded and generic on-demand HAE therapies, including the recently FDA-approved Ekterly (sebetralstat). Costs included

LTP and on-demand treatment acquisition, LTP administration, and attack-related healthcare utilization. Total costs and quality-adjusted life-years (QALYs) were estimated for each comparator, and the incremental cost-effectiveness ratios (ICERs) of garadacimab relative to each LTP comparator were calculated. The annual value-based price (i.e., the price at which the value generated by the intervention equals its cost) of garadacimab was also estimated. Scenario, one-way, and probabilistic sensitivity analyses were conducted. A generalized cost-effectiveness analysis scenario was estimated, with stacked cohorts and dynamic pricing for all LTP comparator acquisition costs.

RESULTS: Garadacimab dominates all other LTP therapies, which is primarily driven by sustaining full attack freedom, with cost savings and QALYs gains per patient relative to lanadelumab of \$380,614 and 0.36, respectively. The estimated annual value-based price of garadacimab is \$711,298. Sensitivity and scenario analyses demonstrate that garadacimab dominance relative to other LTP therapies is robust.

CONCLUSIONS: This analysis assesses the cost-effectiveness of garadacimab as a LTP therapy for HAE. Out of all LTP comparators, garadacimab provides the greatest QALY benefit for HAE patients at the lowest cost. This result is largely influenced by garadacimab's ability to achieve and maintain full attack freedom relative to other comparators.

SPONSORSHIP: CSL Behring

Student Abstract Titles

Analgesics/Pain

8 Geographic variation in opioid and non-opioid pain therapy utilization in the United States, 2010–2025: A scoping review

Ambattu P¹; pambattu@ufl.edu

¹University of Florida

Benefit Design and Management

17 Access barriers to GLP-1 receptor agonists in U.S. managed care: A scoping review of patients with type 2 diabetes and cardiovascular risk

Antoniak K¹; kantoniak@umaryland.edu

¹University of Maryland School of Pharmacy

18 Impact of prior authorization on patient access, clinical outcomes, and cost of care since 2000: A scoping review

Gilmour J¹, Yu J¹, Pawloski P², Lockhart C³; jgilmour@uw.edu; tszy@uw.edu

¹University of Washington; ²AMCP Research Institute; ³AMCP Research Institute

19 Landscape analysis of trends in patient cost-sharing and benefit design

Le A¹; aaron.le.1372@gmail.com

¹University of Washington

Biosimilars

30 Shifting routes: Real-world utilization, costs and site of care (SOC) of intravenous (IV) and subcutaneous (SC) oncology (ONC) biologics

Brill A¹, Kim A², Shah K¹, Wilson A¹; alexabrill@icloud.com

¹Prime Therapeutics; ²Washington State University

Cardiovascular

43 Evaluating the cost-effectiveness of novel oral anticoagulants compared to vitamin K Antagonists in patients with atrial fibrillation: A systematic review

Liu G¹; liu01139@umn.edu

¹University of Minnesota

44 On-site blood pressure screening as a recruitment engagement strategy in a community-based hypertension study

Owino J¹, Bosire A¹; jowino37@gmail.com; bosirealex@gmail.com

¹Texas Southern University

45 Estimating Medicare costs of quadruple guideline-directed medical therapy for heart failure

Chanpura M¹; mohin.chanpura@rutgers.edu

¹University of Southern California

46 Cardiovascular and venous thromboembolic safety of JAK inhibitors versus TNF inhibitors

McGovern M¹, Kim D¹, Park C²; michael.mcgovern@bswhealth.org

¹Baylor Scott & White Health; ²UT Austin

47 Early feasibility of dissolving hyaluronic acid microneedles for cardiovascular drug delivery: A formulation and permeation study

Sangha N¹, Alsabbagh S¹, Ferguson J¹, Stinchcomb A²; nsangha@umaryland.edu; sana.alsabbagh@umaryland.edu

¹University of Maryland School of Pharmacy; ²Principal Investigator

48 Identifying and addressing recruitment barriers to improve enrollment in a community-based hypertension study

Owino J¹, Bosire A¹; jowino37@gmail.com; bosirealex@gmail.com

¹Texas Southern University

49 Risk factors of bleeding among atrial fibrillation patients discharged with oral anticoagulation medications

Trieu S¹, Fuerte B¹, Chen L¹, Reynolds T¹; sunnytrieu@gmail.com
¹Baylor Scott & White Health

50 Bridging the gap following venous thromboembolism: A real-world analysis of anticoagulation treatment patterns, adherence, and readmissions in a large integrated health care system

Colon Carreras D¹, Camden P²; dcoloncarreras@ufl.edu
¹UPMC; ²UPMC Health Plan

Central Nervous System

67 Current and emerging therapeutic strategies for Parkinson's disease: From symptomatic management to disease modification

Nadi A¹, Sethi R²; angelinanady24@gmail.com
¹Rutgers University, Ernest Mario School of Pharmacy; ²Rutgers University - Ernest Mario School of Pharmacy

Clinical Trials/Drug Development

77 From accelerated approval to real world outcomes: A systematic literature review of post-market evidence

Twining C¹, Bishop T², Pawloski P³, Lockhart C⁴; tuj63052@temple.edu; bish@unc.edu
¹Temple University School of Pharmacy; ²UNC School of Pharmacy; ³AMCP Research Institute; ⁴AMCP Research Institute

78 From IRB approval to implementation: Evaluating medication therapy management (MTM) services on medication adherence in children with special healthcare needs (CSHN)

Sconiers J¹; justicesconiers@gmail.com
¹PCOM

79 Analyzing the trends and utility of matching adjusted indirect comparisons (MAICs) since 2010: A targeted literature review

Kim K¹, Akpan I¹, Tam I²; katjkim325@gmail.com
¹University of California, San Francisco; ²Iris Tam, LLC

Digital Health and Technology

99 Digital fatigue and technostress in managed care pharmacy training: Implications for workforce readiness

Ike U¹, White A², Ndiulor M³, Powell C⁴, Andrade Lara C⁵, Thompson H⁶, Nwaogu E², Duah A¹, Pingle M⁷; ugochinyeremike@my.unthsc.edu
¹UNT Health College of Pharmacy and Health Professions; ²University of North Texas Health College of Pharmacy and Health Professions; ³UNT Health College of Pharmacy and Health Professions; ⁴n/a; ⁵UNT Health College of Pharmacy and Health Professions; ⁶UNT College of Pharmacy and Health Professions; ⁷UNT Health Fort Worth

100 Effectiveness of artificial intelligence and machine learning methods for detecting adverse drug events using electronic health records and claims data: A systematic review

Majeed A¹, White A¹; amunmajeed@gmail.com
¹University of North Texas Health College of Pharmacy and Health Professions

101 Current trends in artificial intelligence use in managed care

McClain A¹, Baker L¹, Hikmat Z¹, Noonan K², Yoshida S¹, Zheng C³; alec.mcclain@cencora.com
¹Cencora; ²LEO Pharma; ³Sobi

Drug Pricing, Payment, and Reimbursement

113 Coverage criteria of anti-obesity medications in employer-sponsored pharmacy benefits: Clinical value, durability, and affordability implications

Mikhail A¹, Mikhail P¹; amikhail@rxtalents.com
¹RxTalents

114 The widening value gap: A genotype-stratified Markov cost-effectiveness analysis of elexacaftor/tezacaftor/ivacaftor in cystic fibrosis

Lim G¹, La Mantia A²; changseim@gmail.com; asl184@scarletmail.rutgers.edu
¹Rutger's Ernest Mario School of Pharmacy; ²Rutgers University Ernest Mario School of Pharmacy

115 Budget impact of introducing bepirovirsen for chronic hepatitis B in a mixed commercial and Medicare health plan: A five-year budget impact model

Zhou Z¹, Vu H², Keast S¹, Tidmore L³; zyzhou@health.ucsd.edu
¹MedImpact; ²MedImpact Healthcare Systems, Inc.; ³Medimpact Healthcare Systems, Inc.

Endocrine and Metabolic

132 Alignment between clinical value and economic drivers of formulary decision-making for GLP-1 receptor agonists: A systematic review

Bell B¹, White A², Opara C³; bobbybell@my.unthsc.edu
¹UNT Health; ²University of North Texas Health College of Pharmacy and Health Professions; ³N/A

134 Sex-dependent modulation of hippocampal CA1 angiotensin II signaling in aged rats

Mohammed A¹, J. Gardner J¹, Armstrong T¹, Farmer G¹, L. Bradshaw J¹, Wilson E¹, L. Cunningham R¹; aburahmoha@gmail.com; Rebecca.Cunningham@unthsc.edu
¹University of North Texas Health at Fort Worth

135 Optimizing GLP-1 receptor agonist adherence in managed care: Impact of financial incentive strategies

Binu L¹, White A², Henderson C³; LeemaBinu@my.unthsc.edu
¹UNT Health College of Pharmacy and Health Professions; ²University of North Texas Health College of Pharmacy and Health Professions; ³Dyne Therapeutics

136 Baseline barriers and post-session practice commitments in obesity care: Interim results from a national population health roundtable series

Lakshminarayanan S¹, McCluskey M², Seung A²; slakshminarayanan@mjlifesciences.com
¹Rutgers Institute for Pharmaceutical Industry Fellowships; ²MJH Life Sciences

137 Changes in glucose-lowering treatments among GLP-1 RA users by medication adherence trajectory

Paik J¹, Wind H², Rastegar J³, Poonawalla I⁴, Hames A³, Shrestha N⁵, Diaz M¹; jpaik25@uw.edu
¹Humana; ²Humana, Inc.; ³Humana Healthcare Research; ⁴Humana Healthcare Research, Inc.; ⁵N/A

Gastrointestinal

147 Real-world time to guselkumab initiation in inflammatory bowel disease (IBD): A single-center retrospective analysis

Flores J¹, Magboo J¹, Mathew A², Rubin D², Choi D²; jflor115@uic.edu
¹UIC Retzky College of Pharmacy, University of Chicago Medicine; ²University of Chicago Medicine Inflammatory Bowel Disease Center, Chicago, IL, USA

Genitourinary

151 Value assessment of oral gonadotropin-releasing hormone antagonists for symptomatic uterine fibroids in the United States

Zhou Z¹, Bounthavong M²; zyzhou@health.ucsd.edu
¹UC San Diego, Skaggs School of Pharmacy and Pharmaceutical Sciences; ²University of California, San Diego Skaggs School of Pharmacy and Pharmaceutical Sciences

Health Disparities/Equity

158 Do published cost-effectiveness analyses reflect real-world burden? Comparing economic evaluations of SCT/CAR-T with access barriers in multiple myeloma

Zhang R¹, Gu X², Slejko J¹; rzhang1@umaryland.edu
¹University of Maryland School of Pharmacy; ²University of Maryland, Baltimore

159 Food insecurity and diabetes care among U.S. adults with diabetes: A cross-sectional analysis of the 2022 Medical Expenditure Panel Survey

Hicks V¹, Koomoa-Lange D¹, Stewart R¹; vh621046@wne.edu
¹Western New England University

160 From prescription to patient: Navigating current barriers to medication access

Persaud V¹, Wertheimer A²; vpersaud6@student.touro.edu
¹Touro College of Pharmacy; ²Touro College of Pharmacy, Department of Social, Behavioral and Administrative Sciences

161 Geographic and social vulnerability drivers of pharmacy access in Oregon: A statewide census-tract analysis to inform Medicaid managed care strategy

San B¹; bran@pacificu.edu

¹Pacific University School of Pharmacy & University of Illinois, Chicago

162 Social determinants of health as predictors of cognitive limitation among adults in the United States of America: A machine learning analysis

Nguyen J¹, Zhou B¹, Sambamoorthi U², Hellersli V²; herbbirham@gmail.com

¹UNT Health College of Pharmacy; ²Temple University School of Pharmacy

163 Leveraging virtual education to improve hypertension health literacy in young adults

Mercado D¹; daniela.e.mercado2@gmail.com

¹The University of Texas at Austin College of Pharmacy

164 Assessing health disparities in adherence and persistence to oral targeted therapies among patients with advanced or metastatic non-small cell lung cancer in a specialty pharmacy setting

Arefin P¹, Mathews K², Ogale S³, Good M⁴, Marthone C⁵, Purvis C², Clay E⁶, LaPointe S², Sansgiry S¹; PAREFIN@COUGARNET.UH.EDU

¹University of Houston; ²OptumRx; ³Genentech; ⁴Healthcare Analytics & HEOR Executive; ⁵Optum; ⁶AMCP Foundation

Health Policy

170 The impact of summary of information for patients (SIPs) on patient advocacy organization engagement in health technology assessment: A literature review

Mouawad K¹, Durisala D¹; km42531@uga.edu

¹AbbVie Inc

Infectious Disease

197 Exploring factors affecting antiretroviral therapy adherence among people with HIV in Texas: A qualitative study

Brown C¹, Sakthisivabalan L¹, Showers P², Prata Menezes N², Duggal A², Christoph M², Bogart M², Zachry W², Baffoe J¹, Allison T¹; cmbrown@austin.utexas.edu; lakshya.sakthisivabalan@austin.utexas.edu

¹University of Texas at Austin; ²Gilead Sciences

198 Real-world evaluation of SVR4 frequency and opportunities in HCV treatment

Nelson E¹, Hynicka L¹; emma.nelson@rx.umaryland.edu

¹University of Maryland School of Pharmacy

Managed Care Clinical Programs

207 Immunization practices, barriers, and attitudes in cancer care: A multispecialty provider survey in North Carolina

Yu J¹; tszy@uw.edu

¹BCBSNC

Mental Health

222 Adjunctive L-methylfolate in major depressive disorder: Clinical outcomes, healthcare utilization, and formulary considerations for managed care

Morton B¹, White A²; bradymorton@my.unthsc.edu

¹University of North Texas Health - Fort Worth; ²University of North Texas Health College of Pharmacy and Health Professions

Oncology

231 Real-world assessment of associations between comorbidity burden and respiratory vaccine uptake among patients with solid tumors (2023–2025)

Hasan A¹, Coladonato C¹, Brisco Fields M¹; adil.syed.hasan@gmail.com

¹VytOne

281 Who gets tested? HER2 testing rates and patient characteristics in metastatic gastric cancer within an integrated delivery network

Lebada L¹, Fuerte B², Reynolds T³, Chen L³;

lel3977@bswhealth.org

¹Student; ²Baylor Scott and White Health; ³Baylor Scott & White Health

282 Appraising the safety profile of tarlatamab-dlle (Imdelltra) compared to lurbinectedin and topotecan as a second-line agent for ES-SCLC

Choi J¹, Williams J¹, Sevillano G¹;

jc2931@scarletmail.rutgers.edu;

jnw69@scarletmail.rutgers.edu; gps70@scarletmail.rutgers.edu

¹Rutgers University

283 Real-world utilization patterns among new users of CDK 4/6 inhibitors for HR+/HER2-breast cancer: A retrospective U.S. commercial claims analysis

Aguilera A¹, Siwak A², Wickizer M, Francis S³; aereyes1024@gmail.com

¹AMCP Foundation/Pfizer/Navitus; ²Navitus Health Solutions LLC - Madison; ³Pfizer

284 Real-world genomic profiling patterns among patients with metastatic prostate cancer: A retrospective managed care claims analysis

Wanza J¹, O'Shea T², Boyd B, Prestipino B; jw3020@mynsu.nova.edu

¹Horizon Blue; ²Horizon BCBS

Ophthalmic

288 Estimating the real-world United States prevalence, prevalence trends and age distribution at diagnosis of individuals with neovascular age-related macular degeneration

Zhang Y¹, Ye M¹, Sheth S¹, Manthena S², Hallak J¹; yiyaoz@umd.edu
¹AbbVie; ²AbbVie Inc.

Quality and Safety Programs

297 Impact of polypharmacy on health-related quality of life among adults with chronic conditions: Evidence to inform medication optimization in managed care

Vallejo V¹, White A¹; vanessavallejo@my.unthsc.edu

¹University of North Texas Health College of Pharmacy and Health Professions

Real-World Evidence

339 Reporting of patient out-of-pocket costs in real-world evidence studies: A review of published literature

Kamaliza A¹, Davis S¹, Allen M¹, Patel P¹; adelinekamaliza@gmail.com

¹University of Toledo

340 Comparison of inclisiran and monoclonal antibody PCSK9 inhibitors in patients with atherosclerotic cardiovascular disease

Mittal S¹, George L², Landi T¹; sm2961@scarletmail.rutgers.edu; ldg80@scarletmail.rutgers.edu; tal142@scarletmail.rutgers.edu

¹Ernest Mario School of Pharmacy at Rutgers University;

²Ernest Mario School of Pharmacy

341 Appropriate prescribing of antipsychotics among Mississippi Medicaid beneficiaries in long-term care

Ghodke O¹, Prajapati P¹, Qi J¹, Pittman E¹, Smith D², Kirby T², Ha A², Bhattacharya K¹; oghodke@go.olemiss.edu

¹University of Mississippi; ²Mississippi Division of Medicaid

342 An RWE-informed cost-utility analysis of oral orforglipron versus injectable GLP-1 receptor agonists in adults with T2DM

Ki N¹, Lee Y¹, Kim M²; nathan.ki@rutgers.edu; yl1754@scarletmail.rutgers.edu;

mk1986@scarletmail.rutgers.edu

¹Rutgers University; ²Rutgers

343 Evaluation of suzetrigine utilization across the Mayo Clinic enterprise: Impact on opioid prescribing following acute surgical procedures

Yang A¹, Bedford A¹, Jensen C², Smith N¹; avinayang@outlook.com; Smith.Nathan5@mayo.edu

¹Mayo Clinic; ²Mayo Clinic

344 The impact of medication adherence on clinical and economic outcomes: A scoping review of real-world evidence

Evanik H¹, Mendelsohn A², Pawloski P³, Bishop T⁴, Keast S⁵, Lockhart C⁶; tui18681@temple.edu

¹Temple University School of Pharmacy; ²AMCP; ³AMCP

Research Institute; ⁴UNC School of Pharmacy; ⁵MedImpact;

⁶AMCP, BBCIC

345 Comparative effectiveness of sodium-glucose cotransporter-2 inhibitors versus glucagon-like peptide-1 receptor agonists in adults with type 2 diabetes

Walle B¹, Johal P²; bew1998@outlook.com;

p.johal1542@student.tsu.edu

¹Texas Southern University; ²Texas Southern College of Pharmacy and Health Sciences

346 Real world evaluation of GLP-1 receptor agonist safety in individuals with opioid use disorder: A retrospective cohort study

Ramon R¹, Hussain T², Hasan M², Faysal J², Kotecha P², Wang Y², Guo S²; rramon1@ufl.edu

¹University of Florida College of Pharmacy; ²University of Florida

348 Healthcare resource utilization trends for patients with inflammatory bowel disease and iron deficiency anemia: A real-world claims analysis

Madsen C¹, Diehl C², Geisler E³, Bender J³, Tutino A²; cody.madsen@comcast.net

¹Excellus; ²Excellus BCBS; ³Lifetime Healthcare Companies

Respiratory

364 Time to initiation of inhaled triple therapy after COPD exacerbation: A real-world analysis by blood eosinophil count and exacerbation history

Kim D¹, Reynolds T¹, Chen L¹, Sanchez J¹, Campbell C², Chang K², Dicharry L², Godley P¹; dak1878@BSWHealth.org; Caresse.Campbell@sanofi.com

¹Baylor Scott & White Health; ²Sanofi

365 Real-world treatment patterns and healthcare resource utilization following moderate or severe exacerbations in chronic obstructive pulmonary disease

Kim D¹, Reynolds T¹, Chen L¹, Sanchez J¹, Campbell C², Chang K², Dicharry L², Godley P¹; dak1878@BSWHealth.org;

Tim.Reynolds@BSWHealth.org

¹Baylor Scott & White Health; ²Sanofi

Specialty Pharmacy

371 Utilization patterns and factors associated with immunoglobulin route selection in a specialty pharmacy

Kim J¹, Moshtahedian M², Jeong A³; hana.kim@csprx.com; morvari.moshtahedian@westernu.edu

¹California Specialty Pharmacy and Western university;

²Western University of Health Sciences; ³California Specialty Pharmacy

372 Exploring factors influencing primary non-adherence to asthma biologics among asthma patients in a California specialty pharmacy

Kim J¹, Jeong A², Le Q³; hana.kim@csprx.com

¹California Specialty Pharmacy and Western university;

²California Specialty Pharmacy; ³Western University of Health Sciences

Encore Abstract Titles

Analgesics/Pain

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

Ailani J¹, Graham C², Erbe A², Grinnell T³, Sikder A³, Zhao Y⁴; Jessica.Ailani@gunet.georgetown.edu; asikder@axsome.com

¹Department of Neurology, Medstar Georgetown University Hospital; ²RTI Health Solutions; ³Axsome Therapeutics, Inc.;

⁴Axsome Therapeutics Inc., New York, NY, USA

2 Real-world suzetrigine administration and prescribing for postoperative pain among older adults in the U.S. health systems

Dasa V¹, Rasouliyan L², Mehta J³, Rava J³, Menzie A³; vdasas@lsuhsc.edu; juliana_rava@vrtx.com

¹Department of Orthopedic Surgery, Louisiana State University Health Sciences Center; ²OMNY Health; ³Vertex

Pharmaceuticals Incorporated

3 Suzetrigine prescribing patterns in the 12 months following approval: An analysis of the Walgreens Retail Pharmacy Database

Mathew P¹, Keating S², Rosen M², Mehta J², Patel K³, Chavers S³, Syed S³, Menzie A²; paige.mathew@gmail.com; Scott_Keating@vrtx.com

¹Veteran's Healthcare Administration; ²Vertex Pharmaceuticals Incorporated; ³Walgreens

Biosimilars

22 Impact of a virtual pharmacy service on biosimilar conversion, total cost of care, and the provider experience

Lynton J¹, Vircks J¹, Allsup K², Hayden A²; jessica.lynton@optum.com

¹Optum; ²Optum Specialty Pharmacy

26 The current state of biosimilar coverage and formulary management in the United States: Results from a 2026 payer survey

Hydery T, Yoshida S, Biehn B, Nelson D; tasmina.hydery@cencora.com

Cencora

28 Trends in biosimilar formulary and contracting strategy from 2021 to 2026

Hydery T, Yoshida S, Nelson D, Biehn B; hyderyt@gmail.com

Cencora

Cardiovascular

32 Safety and efficacy of aficamten in patients with nonobstructive hypertrophic cardiomyopathy: A 96-week analysis from FOREST-HCM

Masri A¹, Sherrid M², Choudhury L³, Garcia-Pavia P⁴, Kramer C⁵, Barriaes-Villa R⁶, Maron M⁷, Owens A⁸, Solomon S⁹, Tower-Rader A¹⁰, Heitner S¹¹, Jacoby D¹¹, Simkins T¹¹, Wei J¹¹, Saberi S¹², Cavaliere K¹³; masria@ohsu.edu; martin.maron@lahey.org; kcavaliere@cytokinetics.com

¹Oregon Health and Science University; ²NYU Langone Health;

³Northwestern University Feinberg School of Medicine;

⁴Hospital Universitario Puerta de Hierro Majadahonda, IDIPHISA, CIBERCV, and Centro Nacional de Investigaciones

Cardiovasculares (CNIC); ⁵University of Virginia Health

System; ⁶Complejo Hospitalario Universitario de A Coruña;

⁷Lahey Hospital and Medical Center, Burlington, MA, USA;

⁸University of Pennsylvania, Philadelphia, PA, USA; ⁹Brigham

and Women's Hospital, Harvard Medical School, Boston, MA,

USA; ¹⁰Massachusetts General Hospital, Boston, MA, USA;

¹¹Cytokinetics Incorporated, South San Francisco, CA, USA;

¹²University of Michigan Medical Center, Ann Arbor, MI, USA;

¹³Cytokinetics, Incorporated, South San Francisco, CA, USA

33 Aficamten versus metoprolol as monotherapy for symptomatic obstructive hypertrophic cardiomyopathy: Results from MAPLE-HCM

Garcia-Pavia P¹, Fifer M², Sommers M³; pablogpavia@yahoo.es; fifer.michael@mgh.harvard.edu; msommers@cytokinetics.com
¹Hospital Universitario Puerta de Hierro Majadahonda, IDIPHISA, CIBERCV, and Centro Nacional de Investigaciones Cardiovasculares (CNIC); ²Massachusetts General Hospital and Harvard Medical School, Boston, Massachusetts, USA; ³Cytokinetics, Incorporated, South San Francisco, CA, USA

34 Polypharmacy and potential for drug–drug interactions among patients with transthyretin amyloidosis with cardiomyopathy initiating treatment with tafamidis

DiDomenico R¹, Patel A², Kauf T²; rddom1@uic.edu; tkauf@alnylam.com
¹Center for Pharmacoepidemiology and Pharmacoeconomic Research; ²Alnylam Pharmaceuticals Inc

35 Real world adherence and persistence with vutrisiran, an RNA interference therapeutic for the treatment of transthyretin amyloidosis

Heffernan M¹, Patel A², Kauf T²; heffernan.cdn@gmail.com; ankatpatel@alnylam.com
¹Oakville Cardiologists Inc.; ²Alnylam Pharmaceuticals Inc

36 Effect of evolocumab in patients at high cardiovascular risk without prior myocardial infarction or stroke: Primary results of the VESALIUS-CV trial

Bohula E¹, Marston N¹, Bhatia A², De Ferrari G³, Leiter L⁴, Nicolau J⁵, Park J¹, Murphy S¹, Walsh E², Wang H², Cyrille M², Paiva da Silva Lima G², Giugliano R¹, Sabatine M¹; ebohula@bwh.harvard.edu; abhati04@amgen.com
¹TIMI Study Group, Brigham and Women's Hospital, Harvard Medical School, Boston, MA; ²Amgen Inc., Thousand Oaks, CA; ³University of Turin, Turin, Italy; ⁴St. Michael's Hospital, University of Toronto, Toronto, ON, Canada; ⁵Instituto do Coracao, Hospital das Clinicas da Faculdade de Medicina da Universidade de São Paulo, Universidade de São Paulo, São Paulo

Cell and Gene Therapies

52 Addressing data gaps and early engagement preferences among healthcare decision-makers for cell and gene therapies

Hydery T¹, Cicchini L¹, Yoshida S¹, Dale J¹; tasmina.hydery@cencora.com; louis.cicchini@cencora.com
¹Cencora

Central Nervous System

54 Long-term safety and effect of ecopipam, a selective dopamine D1 receptor antagonist, in children, adolescents, and adults with Tourette syndrome

Gilbert D¹, Black K², Kompoliti K³, Rice P⁴, Flatt J⁴, Karkanas G⁴, Wanaski S⁵, Cunniff T⁵, Tomczak K⁶; Donald.Gilbert@cchmc.org
¹Division of Neurology, Cincinnati Children's Hospital Medical Center, Cincinnati, OH, USA; Department of Pediatrics, University of Cincinnati College of Medicine, Cincinnati, OH, USA; ²Departments of Psychiatry, Neurology, Radiology, and Neuroscience, Washington University School of Medicine, St. Louis, MO, USA; ³Rush University Medical Center, Chicago, IL, USA; ⁴Emalex Biosciences, Inc., Chicago, IL, USA; ⁵Paragon Biosciences, LLC, Chicago, IL, USA; ⁶Tic Disorders and Tourette Syndrome Program, Department of Neurology, Boston Children's Hospital, Harvard Medical School, Boston, MA, USA

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

Thorpy M¹, Krahn L², Bogan R³, Corser B⁴, Shapiro C⁵, Chhabra A⁶, Leary E⁷, Abraham T⁶, Tabuteau H⁶; michael.thorpy@einsteinmed.edu; tabraham@axsome.com
¹Albert Einstein College of Medicine; ²Mayo Clinic College of Medicine and Science; ³University of South Carolina School of Medicine; ⁴Intrepid Research; ⁵University of Toronto; ⁶Axsome Therapeutics, Inc.; ⁷Formerly of Axsome Therapeutics, Inc.

56 Real-world clinical outcomes of patients switching to treatment with Auvelity (dextromethorphan-bupropion [45 mg/105 mg])

Young J¹, Zeni C², Alter S², Zheng Z³, Qin Q³, Mehta J⁴, Zhao Y²; jyoung@rcbm.net; jmehta@axsome.com
¹Rochester Center for Behavioral Medicine; ²Axsome Therapeutics Inc., New York, NY, USA; ³KMK Consulting, Inc.; ⁴Axsome Therapeutics, Inc.

57 Real-world healthcare resource utilization and economic burden of narcolepsy type 1 in the United States

Plante D¹, Floam S², Wang W³, Cong J⁴, Shah D², Bessonova L²; dplante@wisc.edu; dshah@axsome.com

¹Department of Psychiatry, University of Wisconsin-Madison;

²Axsome Therapeutics Inc; ³KMK Consulting, LLC; ⁴KMK Consulting, LLC, Morris Plains, NJ

58 Symbravo (meloxicam and rizatriptan) for the acute treatment of migraine: Post-hoc composite efficacy and safety endpoint analysis of INTERCEPT and MOMENTUM

Cohen F¹, Eglit G², Loucks C³, Chhabra A⁴, Grinnell T⁴, Knudsen K³, Tepper S⁵; fredcohenmd@gmail.com; kknudsen@axsome.com

¹Department of Medicine, Icahn School of Medicine at Mount Sinai, New York, NY; ²Axsome Therapeutics Inc., New York, NY, USA; ³Axsome Therapeutics Inc; ⁴Axsome Therapeutics, Inc.;

⁵Department of Neurology, Icahn School of Medicine at Mount Sinai, New York, NY

59 Improvements in nighttime sleep quality and daytime sleepiness are associated with better quality of life in narcolepsy: Findings from LYRICAL

Drachenberg C¹, Farrell M², D'Souza J², Kim E², Hayes C², Zhang D², Lawrence M², Graham C², Whalen M¹, Alexander J¹, Beaty S¹, Markt S¹, Herpel L³;

Caroleen.Drachenberg@jazzpharma.com

¹Jazz Pharmaceuticals; ²IQVIA; ³Medical University of South Carolina

60 Daytime and nighttime symptom improvements are associated with better quality of life in idiopathic hypersomnia: Findings from LYRICAL

Drachenberg C¹, Farrell M², D'Souza J², Kim E², Hayes C², Zhang D², Lawrence M², Graham C², Whalen M¹, Alexander J¹, Beaty S¹, Markt S¹, Herpel L³;

Caroleen.Drachenberg@jazzpharma.com

¹Jazz Pharmaceuticals; ²IQVIA; ³Medical University of South Carolina

Clinical Trials/Drug Development

70 Olezarsen for managing severe hypertriglyceridemia and pancreatitis risk

Marston N¹, Bergmark B², Alexander V³, Prohaska T³, Kang Y², Moura F², Zimmerman A², Waldman E³, Weinland J³, Murphy S¹, Goodrich E², Zhang S², Xia S³, Li D⁴, Goldberg A⁵, Tsimikas S³, Giugliano R¹, Sabatine M¹; nmarston@bwh.harvard.edu; VAlexander@ionis.com

¹TIMI Study Group, Brigham and Women's Hospital, Harvard Medical School, Boston, MA; ²TIMI Study Group, Division of Cardiovascular Medicine, Brigham and Women's Hospital, Boston, MA, USA; ³Ionis, Carlsbad, CA, USA; ⁴Ionis Pharmaceuticals, Inc., Carlsbad, CA, USA; ⁵Division of Endocrinology, Metabolism, and Lipid Research, Washington University, St. Louis, MO, USA

71 Long-term safety and efficacy of oral deucritibant for prophylaxis in hereditary angioedema: Final results of the phase 2 CHAPTER-1 open-label extension study

Anderson J¹, Manning M², Wedner H³, Katbeh U⁴, Riedl M⁵, Stein S⁶; JAnderson@allervie.com; Steven.Stein@pharvaris.com

¹AllerVie Health, Clinical Research Center of Alabama, Birmingham, AL, United States of America; ²Allergy, Asthma and Immunology Associates, Ltd., Scottsdale, AZ, United States of America; ³Washington University School of Medicine, Division of Allergy and Immunology, Department of Medicine, St. Louis, Missouri, United States of America; ⁴Pharvaris GmbH, Zug, Switzerland; ⁵University of California San Diego, Division of Allergy and Immunology, La Jolla, California, United States of America; ⁶Pharvaris Inc., Lexington, Massachusetts, United States of America

72 On-demand treatment of hereditary angioedema attacks with oral deucricitbant immediate-release capsule: Efficacy and safety results of the phase 3 RAPiDe-3 trial

Jacobs J¹, Lumry W², Soteres D³, Li H⁴, Tachdjian R⁵, Anderson J⁶, Craig T⁷, Sitz K⁸, Wedner H⁹, Zaragoza-Urdaz R¹⁰, Baptist A¹¹, Hong D¹², Manning M¹³, Ramos C¹⁴, Giannattasio G¹⁵, Riedl M¹⁶, Pfister B¹⁷; jsjacobsmd@sbcglobal.net; brian.pfister@pharvaris.com

¹Allergy and Asthma Clinical Research, Walnut Creek, California, United States of America; ²AARA Research Center, Dallas, Texas, United States of America; ³Colorado Allergy and Asthma Society; University CO Health Sciences Center; Asthma & Allergy Associates and Research Center, P.C., Colorado Springs, Colorado, United States of America; ⁴Institute for Asthma and Allergy, Chevy Chase, Maryland, United States of America; ⁵University of California at Los Angeles, Division of Allergy, Immunology, and Rheumatology, Los Angeles, California, United States of America; ⁶AllerVie Health, Clinical Research Center of Alabama, Birmingham, AL, United States of America; ⁷Penn State University, Departments of Medicine, Pediatrics, MFM/OG/GYN, and Biomedical Sciences, Hershey, Pennsylvania, United States of America; Vinmec-VinUni Institute of Immunology, Vinmec Hospital, Times City, Vietnam, and Vin University, Hanoi, Vietnam; ⁸Acuro Research, Inc, Little Rock, Arkansas, United States of America; ⁹Washington University School of Medicine, Division of Allergy and Immunology, Department of Medicine, St. Louis, Missouri, United States of America; ¹⁰University Pediatric Hospital, Medical Sciences Campus, San Juan, Puerto Rico; ¹¹Henry Ford Health System, Detroit, Michigan, United States of America; ¹²Harvard Medical School and Brigham and Women's Hospital, Division of Allergy and Clinical Immunology, Boston, Massachusetts, United States of America; ¹³Allergy, Asthma and Immunology Associates, Ltd., Scottsdale, AZ, United States of America; ¹⁴FDI Clinical Research, San Juan, Puerto Rico; ¹⁵Pharvaris GmbH, Zug, Switzerland; ¹⁶University of California San Diego, Division of Allergy and Immunology, La Jolla, California, United States of America; ¹⁷Pharvaris Inc., Lexington, Massachusetts, United States of America

73 Efficacy of elinzanetant for the treatment of vasomotor symptoms in women with breast cancer: Subgroup analysis of the OASIS-4 trial by type of endocrine therapy

Cardoso F¹, Wilke D², Brennan D³, Simoncini T⁴, Wahyudi L⁵, Laapas K⁶, Seitz C⁷; fcardoso@abcglobalalliance.org; donna.wilke@bayer.com

¹Champalimaud Clinical Center/Champalimaud Foundation; ABC Global Alliance; ²Bayer; ³UCD School of Medicine; Mater Misericordiae University Hospital; ⁴University of Pisa; ⁵Bayer Consumer Care AG; ⁶Bayer Oy; ⁷Bayer AG, Pharmaceuticals Division, Berlin, Germany Affiliation: Bayer AG, Berlin, Germany, and Charité University, Institute of Clinical Pharmacology and Toxicology, Berlin, Germany

74 Elinzanetant improves sleep disturbance in menopausal women partially independently of reductions in vasomotor symptoms: Post hoc analysis from clinical trials

Maki P¹, Wilke D², Trigg A³, Nappi R⁴, Panay N⁵, Simon J⁶, Thurston R⁷, Soares C⁸, Caetano C⁹, Seitz C¹⁰; pmaki1@uic.edu; donna.wilke@bayer.com

¹University of Illinois at Chicago, Chicago, Illinois, USA; ²Bayer; ³Bayer plc, Reading, UK; ⁴University of Pavia, Pavia, Italy and San Matteo Hospital, Pavia, Italy; ⁵Imperial College London, Queen Charlotte's Hospital London; ⁶George Washington University, IntimMedicine Specialists, Washington, DC, US; ⁷University of Pittsburgh, Pennsylvania, US; ⁸Queen's University, Kingston, Ontario, Canada; ⁹Bayer Consumer Care, Basel, Switzerland; ¹⁰Bayer AG, Pharmaceuticals Division, Berlin, Germany Affiliation: Bayer AG, Berlin, Germany, and Charité University, Institute of Clinical Pharmacology and Toxicology, Berlin, Germany

75 INTEGUMENT-INFANT: Once-daily roflumilast cream 0.05% in infants aged 3 to <24 months with atopic dermatitis

Eichenfield L¹, Gonzalez M², Hebert A³, Prajapati V⁴, Krupa D⁵, Kato S⁵, Snyder S⁵, Hanna D⁵, Seal M⁵, Berk D⁵; leichenfield@gmail.com; mseal@arcutis.com

¹Rady Children's Hospital-San Diego and University of California San Diego School of Medicine; ²Pediatric Skin Research, LLC; ³UTHealth McGovern Medical School; ⁴Dermatology Research Institute, Skin Health & Wellness Centre, University of Calgary, and Probit Medical Research; ⁵Arcutis Biotherapeutics, Inc.

Dermatology

82 Patients with more extensive and/or progressive vitiligo enrolled in TRuE-V1/TRuE-V2 achieved high repigmentation thresholds with ruxolitinib cream

Desai S¹, Sturm D², McMichael A³, Diaz X², Ren H², Rosmarin D⁴; seemald@yahoo.com

¹Clinical Associate Professor, Department of Dermatology, The University of Texas Southwestern Medical Center; ²Incyte Corporation, Wilmington, DE, USA; ³Wake Forest University School of Medicine, Winston-Salem, NC, USA; ⁴Indiana University School of Medicine, Indianapolis, IN, USA

83 Identifying predictors of high-cost care in generalized pustular psoriasis: Insights from U.S. real-world data

Garg A¹, Nili M², Rasouliyan L³; amgarg@northwell.edu; monii@leo-pharma.com

¹Northwell Health, New Hyde Park, NY, USA; ²Leo Pharma; ³OMNY Health

84 Mortality and adverse outcomes in patients with pyoderma gangrenosum (PG) in the US

Mostaghimi A¹, Hall C², Bohn R³, Chiu G⁴, Londhe A⁴, Ng C⁴, Nili M⁵, Dini V⁶; amostaghimi@bwh.harvard.edu; monii@leo-pharma.com

¹Department of Dermatology, Brigham and Women's Hospital, Harvard Medical School, Boston, MA, USA; ²Bohn Epidemiology, LLC, Boston, MA; ³Bohn Epidemiology, LLC, Boston, MA, USA; ⁴Boehringer Ingelheim, Ridgefield, CT, USA; ⁵Leo Pharma; ⁶Department of Dermatology, University of Pisa, Pisa, Italy

85 Durable repigmentation with ruxolitinib cream in patients with progressive vitiligo: Pooled subgroup analysis from the 104-week TRuE-V phase 3 studies

Rosmarin D¹, Sebastian M², Lynde C³, Sturm D⁴, Diaz X⁴, Ren H⁴, Desai S⁵; rosmarin@gmail.com

¹Indiana University School of Medicine, Indianapolis, IN, USA; ²Dermatologie Mahlow, Blankenfelde-Mahlow, Germany; ³Division of Dermatology, Temerty Faculty of Medicine, University of Toronto, Toronto, ON, Canada; The Lynde Institute for Dermatology & Lynderm Research Inc., Markham, ON, Canada; Probit Medical Research Inc., Markham, ON, Canada; ⁴Incyte Corporation, Wilmington, DE, USA; ⁵Clinical Associate Professor, Department of Dermatology, The University of Texas Southwestern Medical Center

Drug Pricing, Payment, and Reimbursement

104 Cost per complete responder for epcoritamab + lenalidomide and rituximab (R2) versus tafasitamab + R2 in relapsed or refractory follicular lymphoma: A US Medicare perspective

Wang T¹, Wang T¹, Gao W¹, Bains Chawla S², Branchcomb T², Ding Z², Jun M², Marques Goncalves F², Tybor D³, Alshreef A³, Swallow E¹, Moore D⁴; taiji.wang@analysisgroup.com; tybr@genmab.com

¹Analysis Group, Inc.; ²Genmab US, Inc.; ³AbbVie; ⁴Atrium Health Levine Cancer Institute

105 Tirzepatide persistence and adherence post supply shortage by payer type among individuals with obesity/overweight and without diabetes

Upadhyay N¹, Bonakdar A², Subedi K², Hunter Gible T³, Banerjee S³; navneet.upadhyay@lilly.com

¹Eli Lilly And Company; ²Cencora; ³Eli Lilly and Company

Endocrine and Metabolic

117 Medication adherence in Wilson disease patients treated with trientine tetrahydrochloride supplied by a single-source specialty pharmacy

Tomor V¹, Heise J¹, Dockery C¹, Manamley N¹, DiVito M², Youschak F², Sherback J², Askari F³; veronica.tomor@orphalan.com; Jamieheise@orphalan.com

¹Orphalan; ²PantheRx Rare; ³University of Michigan, Ann Arbor Michigan

118 Glucagon-like peptide-1 receptor agonist discontinuation in people with obesity: Real-world insights across disease burden subgroups

Almandoz J¹, Saydam S², Sartini C², Eng S³, Howe C³, Tabatabaepour N³, Schattenberg J⁴; Jaime.Almandoz@UTSouthwestern.edu

¹Department of Internal Medicine, Division of Endocrinology, University of Texas Southwestern Medical Center; ²Boehringer Ingelheim International GmbH; ³Truveta Inc, Bellevue, Washington; ⁴Department of Internal Medicine II, Saarland University Medical Center; Faculty of Medicine, Saarland University, Saarbrücken

119 Transforming the burden of hyperphagia in Bardet-Biedl syndrome: 6-Month real-world outcomes from the RESTORE study

Pomeroy J¹, Huber C², Haqq A³, Yang M⁴, Mallya U², Zhang S⁵, Liu J⁵, Sweeney B⁶; pomeroy.jeremy@marshfieldresearch.org; chuber@rhythmtx.com

¹Marshfield Clinic Research Institute; ²Rhythm Pharmaceuticals; ³University of Alberta; ⁴Analysis Group Inc.; ⁵Analysis Group; ⁶University of Missouri–Kansas City School of Medicine

120 Real-world weight and healthcare utilization outcomes with setmelanotide in US patients with Bardet-Biedl syndrome

Kumar S¹, Nguyen A², Longoni M³, Amirpour S², Huber C³; Kumar.Seema@mayo.edu; chuber@rhythmtx.com

¹Mayo Clinic; ²Precision AQ; ³Rhythm Pharmaceuticals

Gastrointestinal

139 Optimizing ulcerative colitis maintenance treatment: Indirect comparison on number needed to treat among interleukin-23p19 inhibitors highlights mirikizumab's efficacy

Peyrin-Biroulet L¹, Dignass A², Hoque S³, Jairath V⁴, Kwapisz I⁵, Redondo I⁶, Mendiola M⁷, Duan Y⁷, Zhu B⁷, Maier S⁷, Regueiro M⁸, Luy I⁷; peyrinbiroulet@gmail.com; irene.luy@lilly.com

¹Hopitaux De Brabois, Department of Gastroenterology and Inserm U954; ²Agaplesion Markus Hospital, Department of Medicine I, Frankfurt/Main; ³Whipps Cross University Hospital, Department of Gastroenterology; ⁴Western University, Department of Medicine; ⁵Gastro Health, Gastroenterology; ⁶Eli Lilly and Company, Lisbon; ⁷Eli Lilly and Company; ⁸Department of Gastroenterology, Hepatology and Nutrition, Cleveland Clinic, Cleveland, OH, USA

140 Healthcare resource utilization among patients receiving olezarsen versus placebo for severe hypertriglyceridemia in CORE/CORE2 clinical trials

Sikora Kessler A¹, Vera Llonch M², Alexander V³, Prohaska T³, Xia S³, Li D⁴, Hunt O⁵, Salyakina D⁵, Weycker D⁵, Falk A⁶, Gouni-Berthold I⁷, Shapiro M⁸, Stroes E⁹, Verges B¹⁰, Wyne, K¹¹, Tsimikas S³; ASikoraKessler@ionis.com

¹Ionis; ²Ionis Pharmaceuticals; ³Ionis, Carlsbad, CA, USA; ⁴Ionis Pharmaceuticals, Inc., Carlsbad, CA, USA; ⁵Avalere Health; ⁶Sobi – Swedish Orphan Biovitrum Ab (publ); ⁷University of Cologne; ⁸Wake Forest University School of Medicine; ⁹AmsterdamUMC; ¹⁰University Bourgogne-Europe; ¹¹The Ohio State University

141 Impact of up to 3 years of continuous etrasimod treatment: Long-term efficacy results from the ELEVATE UC open-label extension

Sands B¹, Dubinsky M², Armuzzi A³, Ma C⁴, Blumenstein I⁵, Afzali A⁶, Smolinski P⁷, Goetsch M⁸, Lazin K⁸, Keating M⁹, Kudela M¹⁰, Zang C¹¹, Segovia M¹², Branquinho D¹², Woolcott J¹¹, Danese S¹³, Rubin D¹⁴; bruce.sands@mssm.edu; Michelle.SegoviaMedina@pfizer.com

¹Dr. Henry D. Janowitz Division of Gastroenterology, Icahn School of Medicine at Mount Sinai, New York, NY, USA; ²Susan and Leonard Feinstein IBD Center, Icahn School of Medicine at Mount Sinai, New York, NY, USA; ³IBD Unit, IRCCS Humanitas Research Hospital, Rozzano, Milan, Italy; Department of Biomedical Sciences, Humanitas University, Pieve Emanuele, Milan, Italy; ⁴Division of Gastroenterology and Hepatology, University of Calgary, Calgary, AB, Canada; Department of Community Health Sciences, University of Calgary, Calgary, AB, Canada; ⁵Goethe University Frankfurt, Frankfurt University Hospital, Medical Clinic 1, 60596 Frankfurt am Main, Germany; ⁶Department of Internal Medicine, Division of Digestive Diseases, University of Cincinnati College of Medicine, Cincinnati, Ohio, USA; ⁷Penta Hospitals Przychodnie, Wrocław Wejherowskam, Poland; ⁸Pfizer AG, Zürich, Switzerland; ⁹Formerly Pfizer Inc, New York, NY, USA; ¹⁰Pfizer Inc, Cambridge, MA, USA; ¹¹Pfizer Inc, Collegeville, PA, USA; ¹²Pfizer Inc, New York, NY, USA; ¹³Division of Gastroenterology and Endoscopy, IRCCS San Raffaele Hospital and Vita Salute San Raffaele University, Milan, Italy; ¹⁴University of Chicago Medicine Inflammatory Bowel Disease Center, Chicago, IL, USA

142 Etrasimod for the treatment of ulcerative colitis: Up to 5 years of safety data from the global clinical program

Rubin D¹, Regueiro M², Takeuchi K³, Walsh A⁴, Kotze P⁵, Charabaty A⁶, Caldera F⁷, Lazin K⁸, Goetsch M⁸, Zang C⁹, Tsamos G¹⁰, Branquinho D¹¹, Segovia M¹¹, Danese S¹²; drubin@bsd.uchicago.edu; Michelle.SegoviaMedina@pfizer.com
¹University of Chicago Medicine Inflammatory Bowel Disease Center, Chicago, IL, USA; ²Department of Gastroenterology, Hepatology and Nutrition, Cleveland Clinic, Cleveland, OH, USA; ³Department of Gastroenterology, IBD Center, Tsujinaka Hospital Kashiwanoha, Chiba, Japan; ⁴Translational Gastroenterology and Liver Unit, Oxford University Hospital, Oxford, UK; ⁵IBD Outpatient Clinics, Colorectal Surgery Unit, Pontificia Universidade Católica do Paraná (PUCPR), Curitiba, Brazil; ⁶Division of Gastroenterology and Hepatology, University of Maryland, Baltimore, MD, USA; ⁷Division of Gastroenterology and Hepatology, Department of Medicine, University of Wisconsin-Madison, School of Medicine & Public Health, Madison, WI, USA; ⁸Pfizer AG, Zürich, Switzerland; ⁹Pfizer Inc, Collegeville, PA, USA; ¹⁰Pfizer, Thessaloniki, Central Macedonia, Greece; ¹¹Pfizer Inc, New York, NY, USA; ¹²Division of Gastroenterology and Endoscopy, IRCCS San Raffaele Hospital and Vita Salute San Raffaele University, Milan, Italy

143 Indirect comparison of treatment effects of afimkibart and adalimumab using data from patients with ulcerative colitis in the TUSCANY-2 and HIBISCUS Trials

Levitte S¹, Xu Q², Manickam V³, Li Y¹, Rihani R¹, Zhang J¹, Banerjee A⁴, Chandra D⁴, Peeva E⁴, Neelakantan S⁴, Vincent M⁴, Park K¹; levitte.steven@gene.com; qixiang.xu@yale.edu; rihani.rami@gene.com
¹Genentech, Inc.; ²Yale University; ³Georgia Institute of Technology; ⁴Pfizer Inc.

144 Treatment patterns in routine US clinical practice for patients with moderate to severe ulcerative colitis

Shapouri S¹, Patel A¹, Schuldt R¹, Fehlmann T², Kostiuik B², Win N¹, Reilly N¹, Zurek O¹; shapouri.sheila@gene.com
¹Genentech, Inc.; ²Crohn's & Colitis Foundation

Health Disparities/Equity

155 Driving patient outcomes with the implementation of a social determinants of health (SDOH) network in an imbedded community pharmacy setting

Mathews K¹, Gress D², McKinney R¹, LaPointe S¹, Purvis C¹, Loftus S²; kelly.mathews@optum.com
¹OptumRx; ²Genoa Healthcare

Health Policy

166 Concentration of 340B Program expansion among hospitals of varying sizes: A retrospective analysis, 2017-2023

Masia N¹, Neumann U², Martin S³; neal@healthcapitalgroup.com; uneuman1@its.jnj.com
¹Health Capital Group & Columbia University (Department of Economics and Columbia Business School); ²Center for U.S. Healthcare Policy Research, Johnson & Johnson Scientific Affairs; ³Center for U.S. Healthcare Policy Research Johnson & Johnson Scientific Affairs

Hematologic

173 Real-world experience with imetelstat in lower-risk myelodysplastic syndromes: Insights from United States claims data

Sweet B¹, Thomas J¹, Felber G¹, Papademetriou E², Tyagi R², Eid J¹; bsweet@geron.com
¹Geron Corporation; ²Inizio Ignite Putnam

174 Evaluating the cost per month of response for olutasidenib versus ivosidenib for patients with relapsed/refractory mutant IDH1 acute myeloid leukemia

Shallis R¹, Thomassen A², Smare C³, Pepper A³, Sheppard A²; rory.shallis@moffitt.org
¹Moffitt Cancer Center; ²Rigel Pharmaceuticals; ³Precision AQ

Immunology

181 RSV vaccine uptake among US older adults enrolled in Medicare Advantage: Across two RSV seasons—July 2023 to December 2024

Saundankar V¹, Sato R², Ford K², Casey E³, Moucka R³, Smith P³, Barger C⁴, Sheer R⁵, Suehs B⁵, Vsaundankar1@humana.com

¹Humana Healthcare Research, Inc.; ²Pfizer, Inc.; ³Pfizer, Inc.;

⁴Humana, Inc.; ⁵Humana Healthcare Research

182 Dupilumab improved work productivity in patients with CRSwNP: Results from the Global AROMA Registry

Mims J¹, Buchheit K², Cornet M³, Xia C⁴, Gandhi A⁵, Corbett M⁵, Nash S⁶, Thomas R⁴, Jang D⁷; wmims@wakehealth.edu;

ryan.thomas@regeneron.com

¹Wake Forest School of Medicine, Winston-Salem, NC, USA;

²AERD Center, Division of Allergy and Clinical Immunology,

Brigham and Women's Hospital, Harvard Medical School,

Boston, MA, USA; ³Department of Otorhinolaryngology,

Alrijne Hospital, Leiderdorp, The Netherlands; ⁴Regeneron

Pharmaceuticals Inc., Tarrytown, NY, USA; ⁵Sanofi,

Morristown, NJ, USA; ⁶Regeneron Pharmaceuticals Inc;

⁷Department of Head and Neck Surgery, Duke University, Durham, NC, USA

Infectious Disease

186 Up to 36 months' durability of functional cure in response to bepirovirsen therapy in B-Clear On-NA responders: Results from the B-Sure study

Pippin J¹, Lim S², Hezareh M¹; joey.j.pippin@gsk.com;

mdclimsg@nus.edu.sg

¹GSK; ²National University Hospital; National University of Singapore

187 Clinically meaningful rates of functional cure in virologically suppressed patients with chronic hepatitis B infection treated with bepirovirsen: B-Well phase 3 trials

Franklin-Thompson B¹, Hou J², Elston R¹;

beverly.x.franklin-thompson@gsk.com; jlhoumu@163.com

¹GSK; ²Nanfang Hospital, Southern Medical University

Managed Care Clinical Programs

201 Impact of targeted clinical pharmacist interventions on high-risk patients with heart failure and/or chronic obstructive pulmonary disease

Thacker R¹, Furman A¹, Chaus N¹, Salamunovich S¹, Chau J¹, roxanne.thacker@optum.com

¹Optum Health

202 A centralized utilization management model's impact on medication access

Vircks J¹, Lynton J¹, Bhatia A¹, Mathews K², Fisackerly D³; janelle.vircks@optum.com

¹Optum; ²OptumRx; ³Optum Pharmacy

Mental Health

209 Real-world utilization trends of weekly and monthly injectable buprenorphine (CAM2038) in the United States during the era of high-potency synthetic opioids

Lofwall M¹, Frost M², Budilovsky-Kelley N³, Friedman A³, Kaempfer C³, Cohen J³; michelle.lofwall@uky.edu; nbudilovsky@braeburnrx.com

¹University of KY College of Medicine, Center on Drug and Alcohol Research; ²Wayspring; ³Braeburn Inc

210 First dose treatment effects with injectable weekly and monthly buprenorphine (CAM2038) and the relationship between buprenorphine plasma concentrations and withdrawal suppression in participants with opioid use disorder

Frost M¹, Nunes E², Lofwall M³, Walsh S⁴, Bailey G⁵, Dawson B⁶, Budilovsky-Kelley N⁷, Friedman A⁷, Kaempfer C⁷, Cohen J⁷; drfrost@verizon.net; nbudilovsky@braeburnrx.com

¹Wayspring; ²Columbia University Irving Medical Center;

³University of KY College of Medicine, Center on Drug and

Alcohol Research; ⁴University of Kentucky; ⁵Stanley Street

Treatment and Resources & Brown University; ⁶Ideal Option;

⁷Braeburn Inc

211 Office-based treatment retention among patients with opioid use disorder and recent fentanyl use: Extended-release injectable buprenorphine (CAM2038) vs sublingual buprenorphine

Dawson B¹, Goulette D¹, Fox E¹, Cunningham C¹, Friedman A², Kaempfer C², Budilovsky-Kelley N², Cohen J²;

briaandawson@idealoption.net; dangoulette@idealoption.net

¹Ideal Option; ²Braeburn Inc

212 Reimagining schizophrenia management: Outcomes of a community pharmacy-integrated LAI program

Mathews K¹, Shoemaker B², Gress D², Holguin A³, McKinney R¹, Purvis C¹, LaPointe S¹, Lynton J⁴; cshoemaker@genoahealthcare.com

¹OptumRx; ²Genoa Healthcare; ³Optum Specialty Pharmacy; ⁴Optum

213 Real-world comparison of olanzapine/samidorphan vs olanzapine: Assessment of treatment patterns and acute care events in patients with schizophrenia or bipolar I disorder

Panchmatia H¹, Jain R², Hughes A³, Doane M¹, Chepke C⁴, Cutler A⁵; hemangi.parekh@gmail.com

¹Alkermes, Inc.; ²Department of Psychiatry, Texas Tech University School of Medicine-Permian Basin, Midland, TX; ³Optum, Inc.; ⁴Excel Psychiatric Associates, P.A., Huntersville, NC; Atrium Health, Charlotte, NC; ⁵Department of Psychiatry, SUNY Upstate Medical University, Syracuse, NY; Neuroscience Education Institute, Lakewood Ranch, FL

214 Real-world persistence on olanzapine/samidorphan versus other oral second-generation antipsychotics in patients with schizophrenia

Cutler A¹, Correll C², Jain R³, Chepke C⁴, Oyediji H⁵, Hughes A⁶, Webb N⁷, Doane M⁸, Panchmatia H⁸; acutler@ajcmd.com; hemangi.parekh@gmail.com

¹Department of Psychiatry, SUNY Upstate Medical University, Syracuse, NY; Neuroscience Education Institute, Lakewood Ranch, FL; ²Department of Psychiatry, Zucker Hillside Hospital, Northwell Health, Glen Oaks, NY, USA; Department of Psychiatry and Molecular Medicine, Donald and Barbara Zucker School of Medicine at Hofstra/Northwell, Hempstead, NY, USA; Center for Psychiatric Neuroscience, The Feinstein Institute for Medical Research, Northwell Health, New Hyde Park, NY, USA; Department of Child and Adolescent Psychiatry, Charité Universitätsmedizin Berlin, Berlin, Germany; German Center for Mental Health (DZPG), partner site Berlin, Berlin, Germany; ³Department of Psychiatry, Texas Tech University School of Medicine-Permian Basin, Midland, TX; ⁴Excel Psychiatric Associates, P.A., Huntersville, NC; Atrium Health, Charlotte, NC; ⁵Fortitude Behavioral Health, Baltimore, MD, USA; ⁶Optum, Inc.; ⁷Optum; ⁸Alkermes, Inc.

Musculoskeletal

225 Delandistrogene moxeparvovec in Duchenne muscular dystrophy: Functional and safety outcomes up to 3 years post-infusion in the EMBARK study

Mendell J¹, Muntoni F², McDonald C³, Mercuri E⁴, Ciafaloni E⁵, Komaki H⁶, Leon-Astudillo C⁷, Nascimento A⁸, Proud C⁹, Schara-Schmidt U¹⁰, Veerapandiyani A¹¹, Zaidman C¹², Furgerson M¹, Vivien M¹, Asher D¹, Murphy A¹³, Gerber M¹⁴, Torre C¹³, Manfredini M¹⁴, Rodino-Klapac L¹; JMendell@sarepta.com

¹Sarepta Therapeutics, Inc., Cambridge, MA, USA; ²Dubowitz Neuromuscular Centre, NIHR Great Ormond Street Hospital Biomedical Research Centre, Great Ormond Street Institute of Child Health and Institute of Neurology, University College London and Great Ormond Street Hospital Trust, London, UK; ³UC Davis Health, Sacramento, CA, USA; ⁴Pediatric Neurology Institute, Catholic University and Nemo Pediatrico, Fondazione Policlinico Gemelli IRCCS, Rome, Italy; ⁵University of Rochester Medical Center, Rochester, NY, USA; ⁶Translational Medical Center, National Center of Neurology and Psychiatry, Kodaira, Tokyo, Japan; ⁷Department of Pediatrics, University of Florida, Gainesville, FL, USA; ⁸Neuromuscular Unit, Neuropaediatrics Department, Hospital Sant Joan de Déu, Fundacion Sant Joan de Déu, CIBERER – ISC III, Barcelona, Spain; ⁹Children's Hospital of the King's Daughters, Norfolk, VA, USA; ¹⁰University Hospital Essen, Centre for Neuromuscular Disorders in Children and Adolescents; ¹¹Department of Pediatrics, Division of Neurology, University of Arkansas for Medical Sciences, Arkansas Children's Hospital, Little Rock, AR, USA; ¹²Department of Neurology, Washington University in St Louis, St Louis, MO, USA; ¹³Roche Products Ltd, Welwyn Garden City, UK; ¹⁴F. Hoffmann-La Roche Ltd, Basel, Switzerland

226 Delandistrogene moxeparvovec micro-dystrophin expression and safety in 2- to 3-year-olds with Duchenne muscular dystrophy in ENDEAVOR and ENVOL studies

McDonald C¹, Muntoni F², Gangfuss A³, Proud C⁴, Zaidman C⁵, Servais L⁶, Connolly A⁷, Thrasher P⁸, Vivien M⁸, Haile A⁸, Thomas-Ahner J⁸, Meng J⁸, Murphy A⁹, Zhang B¹⁰, Karasek E¹¹, Pordeli P¹⁰, Rodino-Klapac L⁸; cmmcdonald@ucdavis.edu
¹UC Davis Health, Sacramento, CA, USA; ²Dubowitz Neuromuscular Centre, NIHR Great Ormond Street Hospital Biomedical Research Centre, Great Ormond Street Institute of Child Health and Institute of Neurology, University College London and Great Ormond Street Hospital Trust, London, UK; ³Department of Paediatric Neurology, Center for Neuromuscular Disorders in Children and Adolescents, University Hospital Essen, University of Duisburg-Essen, Essen, Germany; ⁴Children's Hospital of the King's Daughters, Norfolk, VA, USA; ⁵Department of Neurology, Washington University in St Louis, St Louis, MO, USA; ⁶MDUK Oxford Neuromuscular Centre, Department of Paediatrics, University of Oxford, Oxford, UK; Division of Child Neurology, Centre de Références des Maladies Neuromusculaires, Department of Paediatrics, University Hospital Liège and University of Liège, Liège, Belgium; ⁷Division of Neurology, Nationwide Children's Hospital, Columbus, OH, USA; ⁸Sarepta Therapeutics, Inc., Cambridge, MA, USA; ⁹Roche Products Ltd, Welwyn Garden City, UK; ¹⁰F. Hoffmann-La Roche Ltd, Mississauga, ON, Canada; ¹¹F. Hoffmann-La Roche Ltd, Basel, Switzerland

227 Pooled safety analysis from phase 1 to phase 3 clinical trials of delandistrogene moxeparvovec in Duchenne muscular dystrophy

Proud C¹, McDonald C², Mercuri E³, Muntoni F⁴, Zaidman C⁵, Pizzo V⁶, Furgerson M⁶, Jin J⁶, Murphy A⁷, Vivien M⁶, Gerber M⁸, Mendell J⁶; crystal.proud@chkd.org
¹Children's Hospital of the King's Daughters, Norfolk, VA, USA; ²UC Davis Health, Sacramento, CA, USA; ³Pediatric Neurology Institute, Catholic University and Nemo Pediatrico, Fondazione Policlinico Gemelli IRCCS, Rome, Italy; ⁴Dubowitz Neuromuscular Centre, NIHR Great Ormond Street Hospital Biomedical Research Centre, Great Ormond Street Institute of Child Health and Institute of Neurology, University College London and Great Ormond Street Hospital Trust, London, UK; ⁵Department of Neurology, Washington University in St Louis, St Louis, MO, USA; ⁶Sarepta Therapeutics, Inc., Cambridge, MA, USA; ⁷Roche Products Ltd, Welwyn Garden City, UK; ⁸F. Hoffmann-La Roche Ltd, Basel, Switzerland

228 Characterizing the patients with fibromyalgia: A US real-world claims analysis

Gould E¹, Clark M²; errol.gould@tonixpharma.com; matthew.clark@tonixpharma.com
¹Tonix Medicines, Inc.; ²Tonix Medicines

229 Opioid use in patients with fibromyalgia: A retrospective claims analysis

Gould E¹, Clark M²; errol.gould@tonixpharma.com; matthew.clark@tonixpharma.com
¹Tonix Medicines, Inc.; ²Tonix Medicines

Oncology

232 Overall survival with anti-BCMA therapies: Indirect comparison of belantamab mafodotin/bortezomib/dexamethasone (BVD) vs teclistamab/daratumumab (tec-dara) in relapsed/refractory multiple myeloma (RRMM)

Richter J¹, Kapetanakis V², Meader N³, Kumar S², Truscott J², Dobi B², Purser M³, Ladhani O³, Levy M⁴, Sborov D⁵, Banerjee R⁶, Ballew N³; molly.x.purser@gsk.com
¹Department of Medical Oncology and Hematology, Mount Sinai Hospital; ²Evidera, a business unit of PPD, part of Thermo Fisher Scientific; ³GSK; ⁴Department of Hematology and Medical Oncology, Baylor University Medical Center; ⁵Huntsman Cancer Institute, University of Utah School of Medicine; ⁶Fred Hutchinson Cancer Center

233 Budget impact model (BIM) of belantamab mafodotin (belamaf) in combination with bortezomib and dexamethasone (BVD) in patients with relapsed/refractory multiple myeloma (RRMM) in the United States (US)

Boytssov N¹, Purser M¹, Zur R², Samyshkin Y¹, Niehoff N¹, Palumbo T¹, Batts T¹, Kamdar M¹, Osborne J¹, Ferrufino C²; natalie.n.boytssov@gsk.com
¹GSK; ²IQVIA

234 Total cost of care for third-line or later treatment among patients with relapsed/refractory multiple myeloma: Comparison of standard-of-care triplets and B-cell maturation antigen-targeting therapies

Boytssov N¹, Purser M¹, Zur R², Samyshkin Y¹, Palumbo T¹, Batts T¹, Kamdar M¹, Osborne J¹, Ferrufino C²; natalie.n.boytssov@gsk.com
¹GSK; ²IQVIA

235 Efficacy and safety of ivonescimab (ivo) vs placebo (pbo) plus chemotherapy (chemo) in epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI)-resistant, EGFR-mutated non-small cell lung cancer (NSCLC) in the phase 3 HARMONi study

Le X¹, Passaro A², Laskin J³, Rodriguez Abreu D⁴, Calles A⁵, Bazhenova L⁶, Lo Russo G⁷, Leighl N⁸, Cappuzzo F⁹, Girard N¹⁰, Popat S¹¹, Fang W¹², Luo Y¹³, Yang R¹⁴, West H¹⁵, Li J¹⁵, Goldman J¹⁶, Zhang L¹⁷, Bikkina M¹⁸; xle1@mdanderson.org; sanjay.popat@rmh.nhs.uk; mohan.bikkina@smmttx.com

¹The University of Texas MD Anderson Cancer Center; ²IEO (European Institute of Oncology); ³BC Cancer and University of British Columbia; ⁴Hospital Universitario insular de Gran Canaria; ⁵Hospital General Universitario Gregorio Marañón; ⁶UCSD; ⁷Fondazione IRCCS Istituto Nazionale dei Tumori di Milano; ⁸Princess Margaret Cancer Centre; ⁹National Cancer Institute IRCCS Regina Elena, Roma, Italy; ¹⁰Institut Curie, Institut du Thorax Curie-Montsouris, Paris; Paris-Saclay University, Université de Versailles Saint-Quentin-en-Yvelines, Versailles, France; ¹¹The Royal Marsden Hospital; ¹²Department of Medical Oncology, Sun Yat-sen University Cancer Center; ¹³Department of Thoracic Medicine I, Hunan Cancer Hospital; ¹⁴Yunnan Cancer Hospital; ¹⁵Summit Therapeutics; ¹⁶UCLA; ¹⁷Sun Yat-Sen University Cancer Center; ¹⁸Summit Therapeutics

238 Comparative Medicare cost-consequence analysis of NAI plus BCG versus TAR-200 for BCG-unresponsive NMIBC CIS: Evidence from QUILT-3.032 and SunRISe-1 trials

Talwar R¹, Flanders S², Matthews E³, Dolph M³, Ly C³, Jangra V³; ruchika.talwar@vumc.org; scott.flinders@immunitybio.com

¹Department of Urology, Vanderbilt University Medical Center, Nashville, TN; ²ImmunityBio, Inc.; ³Cytel, Inc.

239 Zongertinib in treatment-naïve patients with HER2-mutant NSCLC, including those with active brain metastases: Beamion LUNG-1

Heymach J¹, Yamamoto N², Girard N³, Ruiter G⁴, Smit E⁵, Planchard D⁶, Nadal E⁷, Wu Y⁸, Zugazagoitia J⁹, Tu H⁸, Baik C¹⁰, Yoh K¹¹, Soo R¹², Zhao Y¹³, Sabari J¹⁴, Wermke M¹⁵, Scheffler M¹⁶, Ahn M¹⁷, Sadrolhefazi B¹⁸, Popat S¹⁹; jheymach@mdanderson.org

¹Department of Thoracic/Head and Neck Medical Oncology, The University of Texas MD Anderson Cancer Center, Houston, TX, USA; ²Department of Experimental Therapeutics, National Cancer Center Hospital, Tokyo, Japan; ³Institut Curie, Institut du Thorax Curie-Montsouris, Paris; Paris-Saclay University, Université de Versailles Saint-Quentin-en-Yvelines, Versailles, France; ⁴Netherlands Cancer Institute, Amsterdam, Netherlands; ⁵Department of Pulmonary Diseases, Leiden University Medical Center, Leiden; Department of Thoracic Oncology, Netherlands Cancer Institute, Amsterdam, The Netherlands; ⁶Department of Medical Oncology, Institut Gustave Roussy, Thoracic Group and International Centre for Thoracic Cancers, Villejuif; Faculty of Medicine, Paris-Saclay University, Paris, France; ⁷Catalan Institute of Oncology (ICO), Barcelona, Spain; ⁸Guangdong Lung Cancer Institute, Guangdong Provincial People's Hospital (Guangdong Academy of Medical Sciences), Southern Medical University, Guangzhou, China; ⁹Department of Medical Oncology, 12 de Octubre Hospital, Madrid, Spain; ¹⁰Thoracic, Head and Neck Medical Oncology, Fred Hutchinson Cancer Center, University of Washington, Seattle, WA, USA; ¹¹Department of Thoracic Oncology, National Cancer Center Hospital East; ¹²Department of Hematology-Oncology, National University Cancer Institute, Singapore, Singapore; ¹³Department of Medical Oncology, The Affiliated Cancer Hospital of Zhengzhou University and Henan Cancer Hospital, Zhengzhou, China; ¹⁴Perlmutter Cancer Center, New York University Langone Health; ¹⁵National Center for Tumor Diseases/University Cancer Center Early Clinical Trial Unit, Technische Universität Dresden, Dresden, Germany; ¹⁶Department I of Internal Medicine, University of Cologne, Faculty of Medicine and University Hospital Cologne, Cologne, Germany; ¹⁷Department of Hematology and Oncology, Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, Republic of Korea; ¹⁸Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT; ¹⁹The Royal Marsden Hospital

240 Cost-effectiveness of Orca-T vs allogeneic hematopoietic cell transplantation with conventional graft-versus-host disease prophylaxis for the treatment of advanced hematologic malignancies in the United States

Faramand R¹, McClellan S², Pavlova A², Manghani R², Blank A², Yadav S³, Saeedian M³, Perales M⁴;

rocio.manghani@orcabio.com

¹Moffitt Cancer Center; ²Orca Bio; ³Blue Path Solutions;

⁴Memorial Sloan Kettering Cancer Center

241 The budget impact of introducing zongertinib into the formulary for treatment-naïve and pretreated HER2-mutant advanced NSCLC in the United States

Patel R¹, Cheng W¹, Basarir H², Clemmet T³, Zettl H⁴;

ravi.patel@boehringer-ingelheim.com; hbasarir@rti.org

¹Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT, USA;

²RTI Health Solutions, Manchester, United Kingdom;

³University of Manchester, Manchester, United Kingdom;

⁴Boehringer Ingelheim International GmbH, Ingelheim, Germany

242 Patient-reported outcome (PRO) results from the Beamion LUNG-1 trial in treatment-naïve patients (pts) with HER2-mutant advanced NSCLC

Sabari J¹, Ruiter G², Nadal E³, Hendriks L⁴, Goto Y⁵,

Fairbanks H⁶, Zettl H⁷, Lauer A⁸, Sadrolhefazi B⁹;

joshua.sabari@nyulangone.org

¹Perlmutter Cancer Center, New York University Langone Health;

²Netherlands Cancer Institute, Amsterdam, Netherlands;

³Catalan Institute of Oncology (ICO), Barcelona, Spain;

⁴Maastricht University Medical Center, Netherlands;

⁵National Cancer Center Hospital East City, Japan;

⁶Adelphi Mill, Bollington, Cheshire, UK;

⁷Boehringer Ingelheim International GmbH, Ingelheim, Germany;

⁸Boehringer Ingelheim Pharma GmbH & Co. KG, Germany;

⁹Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT

243 Characterization and management of sevabertinib-induced diarrhea in the SOHO-01 study

Selim J¹, Girard N², Kim T³, Loong H⁴, Prelaj A⁵, Li L⁶, Fang Y⁷, Lu S⁸, Dong X⁹, Wu L¹⁰, Shinno Y¹¹, Daniele G¹², Yang T¹³, Kim H¹⁴, Aris V¹, Ghadessi M¹, Grassi P¹⁵, Bernard-Gauthier V¹⁶, Le X¹⁷;

julie.selim@bayer.com; nicolas.girard2@curie.fr

¹Bayer HealthCare Pharmaceuticals, Inc., Whippany, NJ, USA;

²Institut Curie, Institut du Thorax Curie-Montsouris, Paris;

Paris-Saclay University, Université de Versailles Saint-

Quentin-en-Yvelines, Versailles, France;

³Seoul National University Hospital, Seoul, South Korea;

⁴The Chinese University of Hong Kong, Hong Kong SAR, China;

⁵Oncologia Medica Toracica Dept., Fondazione IRCCS - Istituto Nazionale dei Tumori, Milan, Italy;

⁶Department of Medical Oncology, Beijing Hospital, National Center of Gerontology, Institute of Geriatric Medicine, Chinese Academy of Medical Sciences,

Beijing, China;

⁷Sir Run Run Shaw Hospital, Zhejiang University School of Medicine, Hangzhou, China;

⁸Shanghai Chest Hospital, School of Medicine, Shanghai Jiao Tong University, Shanghai, China;

⁹Union Hospital of Tongji Medical College, Huazhong University of Science and Technology, Wuhan, China;

¹⁰Department of Thoracic Medical Oncology, Hunan Cancer Hospital, The Affiliated Cancer Hospital of Xiangya School of Medicine, Central South University, Changsha, China;

¹¹National Cancer Center Hospital, Chuo-ku, Tokyo, Japan;

¹²Phase 1 Unit, Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Rome, Italy;

¹³Department of Chest Medicine, Taichung Veterans General Hospital, Taichung, Taiwan;

¹⁴Yonsei Cancer Center, Seoul, South Korea;

¹⁵Bayer S.p.A., Milan, Italy;

¹⁶Bayer Pharmaceuticals Inc., Mississauga, ON, Canada;

¹⁷The University of Texas MD Anderson Cancer Center

244 Major adverse cardiovascular events in androgen receptor signaling inhibitor-treated patients with metastatic castration sensitive prostate cancer (MACE-ARMS)

Huhmann L¹, Burgess E², La J³, Dulberger K³, Schoen M⁴, Appukkuttan S⁵, Goel H⁶, Kalayeh B⁵, Lee J⁷, Paller C⁸, Fillmore N³; kushali.patel.ext@bayer.com; eric.burgess@bayer.com

¹US Department of Veterans Affairs; ²Bayer Healthcare Pharmaceuticals Inc.; ³Massachusetts Veterans Epidemiology Research and Information Center, Department of Veterans Affairs Healthcare System; ⁴Division of Hematology and Medical Oncology, Department of Internal Medicine, Saint Louis University School of Medicine; ⁵Bayer; ⁶Bayer, Inc., Whippany, New Jersey, USA; ⁷Bayer HealthCare Pharmaceuticals, Inc.; ⁸Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins University School of Medicine

245 Health-related quality of life in patients previously treated with an EGFR-TKI from HARMONi: A phase 3 trial of ivonescimab vs placebo plus chemotherapy

Popat S¹, Girard N², Le X³, Passaro A⁴, Laskin J⁵, Rodriguez Abreu D⁶, Calles A⁷, Bazhenova L⁸, Lo Russo G⁹, Cappuzzo F¹⁰, Fang W¹¹, Luo Y¹², Yang R¹³, Ladeluca L¹⁴, West H¹⁴, Clow F¹⁵, Goldman J¹⁶, Zhang L¹⁷, Leighl N¹⁸; sanjay.popat@rmh.nhs.uk; Laura.ladeluca@smmmttx.com

¹The Royal Marsden Hospital; ²Institut Curie, Institut du Thorax Curie-Montsouris, Paris; Paris-Saclay University, Université de Versailles Saint-Quentin-en-Yvelines, Versailles, France; ³The University of Texas MD Anderson Cancer Center; ⁴IEO (European Institute of Oncology); ⁵BC Cancer and University of British Columbia; ⁶Hospital Universitario insular de Gran Canaria; ⁷Hospital General Universitario Gregorio Marañón; ⁸UCSD; ⁹Fondazione IRCCS Istituto Nazionale dei Tumori di Milano; ¹⁰National Cancer Institute IRCCS Regina Elena, Roma, Italy; ¹¹Department of Medical Oncology, Sun Yat-sen University Cancer Center; ¹²Department of Thoracic Medicine I, Hunan Cancer Hospital; ¹³Yunnan Cancer Hospital; ¹⁴Summit Therapeutics; ¹⁵Dr; ¹⁶UCLA; ¹⁷Sun Yat-Sen University Cancer Center; ¹⁸Princess Margaret Cancer Centre

246 Budget impact of sevabertinib for HER2-mutated locally advanced or metastatic non-squamous NSCLC from a United States payer perspective

Grossman J¹, Dayer V², Campbell D², Ramsey S², Kalayeh B³, Lee J⁴, Appukkuttan S³; jamie.grossman@bayer.com
¹Bayer Pharmaceuticals; ²Curta; ³Bayer; ⁴Bayer HealthCare Pharmaceuticals, Inc.

Precision Medicine

291 The economic case for next-generation sequencing (NGS) in early-stage lung cancer: A forward-looking analysis

Malin J¹, Ma Q², Ye W³, White J², Sheffield K², Aminnejad N³, Zou D³, Brechtelsbauer E²; erich.brechtelsbauer@lilly.com

¹Health & Care Insights and Innovation Consulting, LLC, Santa Monica, CA, USA; ²Eli Lilly and Company; ³PPD™ Evidera™ Health Economics & Market Access, Thermo Fisher Scientific

Real-World Evidence

300 Characteristics associated with disease progression in patients with transthyretin amyloid cardiomyopathy treated with tafamidis

Li W¹, Semwal M¹, Goss A¹, Asmar M¹, Uzoigwe C¹, Wang Y², Chao A³, Song Y³, Wolf Khachatourian K¹, Gaggin H⁴; weilongli9392@gmail.com; qkhc@novonordisk.com

¹Novo Nordisk, Inc., Plainsboro, NJ, USA; ²Analysis Group, Inc.; ³Analysis Group; ⁴Massachusetts General Hospital/Harvard Medical School, Boston, MA, USA

301 12-Month real-world weight loss with tirzepatide among individuals with obesity/overweight who switched from semaglutide

Upadhyay N¹, Bonakdar A², Subedi K², Hunter Gible T³, Banerjee S³; navneet.upadhyay@lilly.com

¹Eli Lilly And Company; ²Cencora; ³Eli Lilly and Company

302 Real-world characteristics and treatment patterns among patients with chronic inflammatory demyelinating polyradiculoneuropathy initiating subcutaneous efgartigimod in the United States

Karkare S¹, Zaveri N², Mahajerin A¹, Yachendra C³, Zou W³, Sato M³, Blein C¹; skarkare@argenx.com

¹argenx; ²Argenx; ³ZS Associates

303 Real-world disease progression in patients with transthyretin amyloid cardiomyopathy treated with tafamidis

Li W¹, Semwal M¹, Goss A¹, Asmar M¹, Uzoigwe C¹, Wang Y², Chao A³, Song Y³, Wolf Khachatourian K¹, Gaggin H⁴; weilongli9392@gmail.com; qkhc@novonordisk.com

¹Novo Nordisk, Inc., Plainsboro, NJ, USA; ²Analysis Group, Inc.; ³Analysis Group; ⁴Massachusetts General Hospital/Harvard Medical School, Boston, MA, USA

304 Human immunodeficiency virus (HIV) testing and evidence of HIV among real-world long-acting pre-exposure prophylaxis (PrEP) users in a United States claims database: Updated results from the PrEPFACTS study

Martinez D¹, Ramirez-Ruiz L¹, Nguyen C², Herman G¹, Alinezhad F³, Banatwala A⁴, Young-Xu L⁵, Metzner A¹, DerSarkissian M⁴, Oglesby A¹; dora.a.martinez@viivhealthcare.com; alan.k.oglesby@viivhealthcare.com

¹ViV Healthcare; ²Analysis Group, Inc., Menlo Park, CA, USA;

³Analysis Group; ⁴Analysis Group, Inc.; ⁵Analysis Group, Inc., Boston, MA, USA

306 What can social drivers of health data tell us about health plan members in large real-world databases?

Johnson M¹, Avula R¹, Sponholtz T¹, Price A¹, Silver C¹, Grabner M¹, Stephenson J¹; martha.johnson@carelon.com

¹Carelon Research

307 Real-world assessment of once-a-month dosing of lebrikizumab in commercial claims

Chovatiya R¹, McCann W², Aldredge L³, Gou R⁴, Tran J⁴, Wallem A⁴, Pierce E⁴, DeLuca Carter L⁴, Pandya S⁵, Chi-Chang C⁵, Doshi R⁵, Chen C⁶, Zhou M⁵, Armstrong A⁷; Raj.chovatiya@gmail.com; ray.gou@lilly.com

¹Chicago Medical School, Rosalind Franklin University of Medicine and Science; Center for Medical Dermatology + Immunology Research; ²Allergy Partners, Asheville; ³VA Portland Healthcare System, Portland; ⁴Eli Lilly and Company; ⁵IQVIA, Rockledge, PA; ⁶IQVIA Inc, Wayne, PA; ⁷Division of Dermatology, Department of Medicine, David Geffen School of Medicine at the University of California, Los Angeles

309 Costs associated with adjunctive atypical antipsychotic-related weight gain among patients with major depressive disorder (MDD): An economic model using numbers needed to harm

Citrome L¹, Nabulsi N², Guo H², Waraich S², Zanardo E³, Ripley S⁴, Laliberté F⁵, Parikh M², Khairnar R⁶; nntman@gmail.com; rahul.khairnar@abbvie.com

¹New York Medical College; ²AbbVie; ³Analysis Group; ⁴Groupe d'analyse SRI; ⁵Groupe d'analyse SRI; ⁶AbbVie Inc.

Respiratory

349 Brensocatib in patients with non-cystic fibrosis bronchiectasis (NCFB) and history of nontuberculous mycobacteria (NTM) infection: A post-hoc analysis of the ASPEN trial

Winthrop K¹, Tolle J², Chalmers J³, Loebinger M⁴, Namkoong H⁵, Wei X⁶, Lauterio M⁶, Teper A⁶; winthrop@ohsu.edu; melanie.lauterio@insmed.com

¹School of Public Health, OHSU-PSU School of Public Health, Portland, Oregon, USA; ²Department of Medicine, Vanderbilt University, Nashville, Tennessee, USA; ³Radcliffe Department of Medicine, University of Oxford, Oxford, UK; ⁴Royal Brompton Hospital and National Heart and Lung Institute, Imperial College, London, UK; ⁵Department of Infectious Diseases, Keio University School of Medicine, Tokyo, Japan; ⁶Insmed Incorporated, Bridgewater, NJ, USA

350 Relation between airway damage and disease activity and the effect of dupilumab on exacerbations and lung function in chronic obstructive pulmonary disease: BOREAS and NOTUS

Couillard S¹, Petousi N², Ramakrishnan S³, Buhl R⁴, Roche N⁵, Chen R⁶, Sugiura H⁷, Xia C⁸, Cunoosamy D⁹, Soliman M¹⁰, Pavord I¹¹, Schindler E¹²; s.couillard@usherbrooke.ca; erik.schindler@sanofi.com

¹Integrated Health and Social Services Center of Bas-Saint-Laurent; ²Oxford University Hospitals NHS Foundation Trust (Department of Respiratory Medicine); ³Sir Charles Gairdner Hospital (Department of Respiratory Medicine); ⁴University Medical Center of the Johannes Gutenberg University Mainz (Department of Pulmonology); ⁵Hospitals of Paris - Cochin - Port-Royal Hospital (Pulmonology Services); ⁶Shenzhen People's Hospital (Department of Respiratory and Critical Care Medicine); ⁷Tohoku University Hospital (Department of Respiratory Medicine); ⁸Regeneron Pharmaceuticals Inc., Tarrytown, NY, USA; ⁹Sanofi Genzyme; ¹⁰Regeneron Pharmaceuticals; ¹¹Westongrove Partnership - Oxford University Hospitals NHS Foundation Trust (Department of Respiratory Medicine); ¹²Medical Value and Outcomes at Sanofi - North America and Asia

351 Dupilumab improves lung function and disease burden vs omalizumab in patients with severe chronic rhinosinusitis with nasal polyps and coexistent asthma with highly elevated type 2 inflammatory biomarkers

Sumner L¹, Wechsler M², Couillard S³, Pavord I⁴, Petousi N⁵, Heffler E⁶, Wagenmann M², Altincatal A⁷, Nash S⁸, Corbett M⁷, Gall R⁸, Moraco A⁷, Ramakrishnan S⁹;

Lauren.Sumner@sanofi.com; wechslerm@njhealth.org

¹Sanofi Genzyme Corporation; ²National Jewish Health, Denver, CO, USA; ³Integrated Health and Social Services Center of

Bas-Saint-Laurent; ⁴Westongrove Partnership - Oxford University Hospitals NHS Foundation Trust (Department of Respiratory Medicine); ⁵Oxford University Hospitals NHS

Foundation Trust (Department of Respiratory Medicine);

⁶Humanitas University; ⁷Sanofi, Morristown, NJ, USA;

⁸Regeneron Pharmaceuticals Inc.; ⁹Sir Charles Gairdner Hospital (Department of Respiratory Medicine)

352 Predicting long-term survival benefit of nerandomilast in patients with pulmonary fibrosis

Maher T¹, Pimple P², Aronson K³, Kanakapura M⁴, Patel D², Shetty S², Shukla P⁵, Swigris J⁶, Nagy E⁵, Weidlich D⁴, Wijzenbeek M⁷; Toby.Maher@med.usc.edu;

sharashchandra.shetty@boehringer-engelheim.com

¹Department of Pulmonary, Critical Care and Sleep Medicine, Keck School of Medicine, University of Southern California,

Los Angeles, CA, USA; ²Boehringer Ingelheim Pharmaceuticals, Inc, Ridgefield, CT, USA; ³Division of Pulmonary and Critical

Care Medicine, Weill Cornell Medicine, New York, NY, USA;

⁴Boehringer Ingelheim International GmbH, Ingelheim am Rhein, Germany; ⁵Evidera, a business unit of PPD, part of

Thermo Fisher Scientific, Montreal, QC, Canada; ⁶Center for Interstitial Lung Disease, National Jewish Health, Denver, CO,

USA; ⁷Center of Expertise for Interstitial Lung Diseases, Department of Respiratory Medicine, Erasmus MC, University

Medical Centre, Rotterdam, The Netherlands

353 Clinical predictors and outcomes of hospitalizations among patients with systemic autoimmune rheumatic disease-associated interstitial lung diseases (SARD-ILDs) in the ILD-PRO Registry

Callahan S¹, Astrike-Davis E¹, Neely M², Wojdyla D³, Snyder L², Swaminathan A², Bracken S⁴, Chauffe A⁵, Antao V⁶, Kinder B¹; Sean_Callahan@med.unc.edu

¹UNC School of Medicine, The University of North Carolina at Chapel Hill, Chapel Hill, North Carolina, USA; ²Duke Clinical

Research Institute, Durham, North Carolina, USA, and Duke University Medical Center, Durham, North Carolina, USA;

³Duke Clinical Research Institute, Durham, North Carolina, USA; ⁴Duke University Medical Center, Durham, North

Carolina, USA; ⁵Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, Connecticut, USA; ⁶Boehringer Ingelheim

Pharmaceuticals, Inc., Ridgefield, CT, USA

354 Effects of nerandomilast in US patients with idiopathic pulmonary fibrosis (IPF) and progressive pulmonary fibrosis (PPF)

Flaherty K¹, Zoz D², Wachtlin D³, Orsatti L², Glassberg M⁴; flaherty@med.umich.edu

¹Department of Medicine, University of Michigan, Ann Arbor, MI, USA; ²Boehringer Ingelheim Pharmaceuticals, Inc,

Ridgefield, CT, USA; ³Boehringer Ingelheim Pharma GmbH & Co. KG, Ingelheim am Rhein, Germany; ⁴Division of Pulmonary and

Critical Care, Department of Medicine, Loyola Stritch School of Medicine, Maywood, IL, USA

355 Characterization of diarrhea adverse events in the FIBRONEER trials of nerandomilast in patients with idiopathic pulmonary fibrosis (IPF) and progressive pulmonary fibrosis (PPF)

Kim H¹, Kondoh Y², Hamblin M³, Han Q⁴, Antao V⁵, Hofmann P⁶, Ritter I⁶, Wachtlin D⁷, Kreuter M⁸; kimxx015@umn.edu

¹Department of Medicine, Division of Pulmonary, Allergy, Critical Care and Sleep, University of Minnesota, Minneapolis,

MN, USA; ²Department of Respiratory Medicine and Allergy, Tosei General Hospital, Seto, Aichi, Japan and Department of

Respiratory Medicine and Allergology, Aichi Medical University, Nagakute, Japan; ³Division of Pulmonary, Critical

Care and Sleep Medicine, University of Kansas School of Medicine, Kansas City, KS, USA; ⁴The First Affiliated Hospital of

Guangzhou Medical University, Guangzhou, Guangdong, China; ⁵Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield,

CT, USA; ⁶Boehringer Ingelheim International GmbH, Ingelheim am Rhein, Germany; ⁷Boehringer Ingelheim Pharma

GmbH & Co. KG, Ingelheim am Rhein, Germany; ⁸Center for Pulmonary Medicine, Department of Pneumology, Mainz

University Medical Center and Pulmonary, Critical Care & Sleep Medicine, Marienhaus Clinic Mainz, Mainz, Germany

356 Causal mediation analysis describes the proportion of dupilumab effect on patient-reported outcomes linked to exacerbation reduction, lung function improvements, or decline in FeNO: BOREAS and NOTUS

Sumner L¹, Bhatt S², Brusselle G³, Puggioni F⁴, Bhutani M⁵, Roche N⁶, Kilpelainen M⁷, Xuan A⁸, Wen F⁹, Zhang M¹⁰, Soliman M¹¹, Cunoosamy D¹², Singh D¹³;
Lauren.Sumner@sanofi.com; sbhatt@uabmc.edu
¹Sanofi Genzyme Corporation; ²UAB Hospital - The Kirklin Clinic of UAB Hospital - Pulmonary Medicine Services; ³Ghent University Hospital (Pulmonary Diseases Team); ⁴IRCCS Humanitas Clinical Institute - Humanitas Research Hospital (Personalized Medicine Center: Asthma and Allergology); ⁵University of Alberta (Alberta Respiratory Centre); ⁶Hospitals of Paris - Cochin - Port-Royal Hospital (Pulmonology Services); ⁷Turku University Hospital (Division of Medicine, General Medicine and Emergency Services - Department of Lung Diseases); ⁸Public Assistance Hospitals of Paris - Cochin - Port-Royal Hospital (Physiology-Functional Explorations Service); ⁹West China Hospital of Sichuan University (Department of Respiratory Medicine); ¹⁰Sanofi US Services Inc.; ¹¹Regeneron Pharmaceuticals; ¹²Sanofi Genzyme; ¹³NHS England - NHS England — North West - Greater Manchester Integrated Care Partnership - Manchester University NHS Foundation Trust - Wythenshawe Hospital (Respiratory and Allergy Services - North West Lung Centre)

357 Treatment burden over time in people with bronchiectasis by baseline pulmonary exacerbation frequency

Flume P¹, Mingora C², Brown C³, Mountford W³, Patel B³, Lavallee M³, VanTieghem M⁴, Iglay K⁵; flumepa@muscc.edu
¹Medical University of South Carolina, Charleston, SC, United States of America.; ²Medical University of South Carolina, Charleston, SC, United States of America; ³Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT, United States of America; ⁴Genesis Research Group, Hoboken, NJ, United States of America; ⁵CEROb Consulting LLC, Asheville, NC, United States of America

358 Mepolizumab reduces the burden of chronic obstructive pulmonary disease exacerbations in a wide spectrum of patients: Pooled results from phase 3 randomized controlled trials

Criner G¹, Watz H², Schamroth J³, Gould S⁴, Biswas A⁵, Martinez F⁶; Gerard.Criner@tuhs.temple.edu; steven.d.gould@gsk.com
¹Department of Thoracic Medicine and Surgery, Lewis Katz School of Medicine, Temple University; ²Velocity Clinical Research Germany GmbH; ³Respiratory & Immunology Research Unit, Global Clinical Sciences, GSK; ⁴Global Medical Affairs, Specialty Care, GSK; ⁵Biostatistics, GSK; ⁶University of Massachusetts Chan Medical School

SUPPLEMENT

JMCP
JOURNAL OF
Managed Care +
Specialty Pharmacy

jmcp.org