2026 Launch Price and Access Report

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AUTHORS:

Foluso Agboola, MBBS, MPH
Senior Vice President of Research
Institute for Clinical and Economic Review

Abigail Wright, PhD, MSc
Director, Evidence Synthesis
Institute for Clinical and Economic Review

Woojung Lee, PharmD, PhD
Director of Health Economics and Decision Modeling
Institute for Clinical and Economic Review

Marie Phillips, BA
Senior Health Economics Research Assistant
Institute for Clinical and Economic Review

Grace A. Lin, MD
Medical Director for Health Technology Assessment
Institute for Clinical and Economic Review

Max Lee, PharmD
Associate Director of Pharmaceutical Intelligence
Institute for Clinical and Economic Review

Sarah K. Emond, MPP
President and Chief Executive Officer
Institute for Clinical and Economic Review

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As an organization, we value transparency and hold ourselves, and our collaborators, to high standards for conducting our work. Our full policy to manage potential conflicts of interest can be found here. You can find ICER's Code of Ethics here.

The figures in this report were refined using Claude Design (Opus 5) by Anthropic Labs; authors checked all figures for accuracy. Claude (Sonnet 5), an AI assistant created by Anthropic, was used to abstract the data from the coverage policies and the FDA label for all drugs. A human reviewer also abstracted the same data. The two abstracted sheets were manually cross-checked.

Data Partners

We'd like to thank our data partners, including:

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Working Group Members

This report benefited from extensive input from the members of our multi-stakeholder Working Group, drawing on people with life sciences, health plan, purchases, patient and consumer advocacy, and clinical expertise:

- **Jennifer Day**, PharmD, Drug Intelligence and Strategy Lead, Kaiser Permanente
- **Omar Escontrias**, DrPH, MPH, Senior Vice President, Equity, Research and Programs, National Health Council
- **Mary Gens**, MPP, Senior Research Associate, Health Policy, West Health
- **Clifford Hudis**, MD, FACP, FASCO, CEO, American Society of Clinical Oncology
- **Julie Kueppers**, PhD, FNP, RN, Vice President of Clinical Client Engagement, Quantum Health
- **Andreas Kuznik**, PhD, Executive Director, Health Economics and Outcomes Research, Regeneron Pharmaceuticals, Inc.
- **Julia Logan**, MD, MPH, Chief Medical Officer, Clinical and Programs Division, CalPERS
- **Landon Marshall,** PharmD, Principal Health Outcomes Researcher, Prime Therapeutics
- **Jennifer Martin**, PharmD, Consultant, Remund Group, LLC
- **Joe Nadglowski,** President/CEO, Obesity Action Coalition
- **Carl Schmid**, MBA, Executive Director, HIV+Hepatitis Policy Institute
- **Silke Schoch,** MA, Director, Research & Programs, National Health Council
- **Amir Abbas Tahami Monfared**, MD, PhD, Head, Societal Value Platform and Evidence Development, Eisai, Inc.
- **Namrata Uberoi,** PhD, MPH, Executive Director, Health Care Cost and Affordability, West Health
- **Melea Ward,** PhD, Sr. Director, Financial and Market Insights, IPD Analytics
- **Heidi C. Waters**, PhD, MBA, Principal Advisor, Blue Persimmon Group

No member of the Working Group, nor of any of the data partners, is responsible for the final contents of this report, nor should it be assumed they support any part of it.

About ICER

The Institute for Clinical and Economic Review (ICER) is an independent, non-profit research institute that conducts evidence-based reviews of health care interventions, including prescription drugs, other treatments, and diagnostic tests. In collaboration with patients, clinical experts, and other key stakeholders, ICER analyzes the available evidence on the benefits and risks of these interventions to measure their value and suggest fair prices. ICER also regularly reports on the barriers to care for patients and recommends solutions to ensure fair access to prescription drugs. For more information about ICER, please visit www.icer.org.

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About West Health

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List of Acronyms and Abbreviations Used in this Report

APOE	apolipoprotein E
ASP	average sales price
ATTR-CM	transthyretin amyloid cardiomyopathy
ARIA	amyloid-related imaging abnormalities
AUR	appropriate use recommendations
CBER	Center for Biologics Evaluation and Research
CDER	Center for Drug Evaluation and Research
CI	confidence interval
CMS	Centers for Medicare and Medicaid Services
evLY	equal value life year
FDA	United States Food and Drug Administration
FSS	Federal Supply Schedule
HBPB	Health Benefit Price Benchmark
ICER	Institute for Clinical and Economic Review
IQR	interquartile range
IRA	Inflation Reduction Act
LAAD	IQVIA's Longitudinal Access and Adjudication Data
MFN	Most-Favored-Nation
MRI	magnetic resonance imaging
N	number
OOP	out of pocket
PA	prior authorization
PET	positron emission tomography
QALY	quality-adjusted life year
ST	step therapy
US	United States
VIF	Variance Inflation Factor
WAC	Wholesale Acquisition Cost

Executive Summary

Background

The growth in prescription drug spending is contributing to an increase in overall health spending,[1] and is one of the major drivers of health insurance premium increases.[2,3] High launch prices for new drugs significantly contribute to this trend, with many new medications entering the market at prices exceeding $200,000 annually.[4,5] This has sparked ongoing discussions about whether these high launch prices are justified and if they correspond to the clinical benefits provided to patients.[6-8] A critical aspect of the launch price debate is the impact of launch prices on patient access to new therapies. Coverage delays or exclusions for newly launched drugs have become common. While policymakers, researchers, and other stakeholders have not always agreed on how to tackle these issues, improving drug affordability and patient access remains one of the few areas of bipartisan consensus in the United States (US). To contribute to this ongoing policy discussion, we have developed an annual report that evaluates the year-to-year trend in launch prices of new Food and Drug Administration (FDA)-approved drugs and patient access to these therapies.

Launch Prices

Key Takeaways:

- The median annual net launch price rose 35% from 2022 to 2025 after inflation adjustment, driven mostly by a sharp rise in 2022–2023. However, it declined by 2% from 2024 to 2025.
- In 2025, the median net launch price was about $257,000, with nearly 25% of new drugs launching above $500,000 and another 34% between $200,000 and $500,000.
- Among drugs previously reviewed by ICER, two-thirds exceeded ICER's Health Benefit Price Benchmark (HBPB). ICER's HBPB is the price range that aligns fairly with the overall health benefits the treatment provides patients over their lifetime.

In this year's report, we analyzed launch price trends of novel agents approved by the US FDA Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) over a four-year period, from 2022 to 2025. Our analysis showed a 24% increase in the median annual launch price (list price) in that time period, after adjusting for inflation. There was a larger 35% increase in the median annual net launch price (i.e., the actual transaction amount after rebates, discounts, and other price reductions). The most substantial increase occurred between 2022 and 2023. From 2023 onward, launch prices remained relatively stable, with a slight decrease observed in 2025. Despite the slight decline, the median annual net launch price in 2025 was about $257,000 (list price: $293,000). Approximately one in four drugs introduced in 2025 had an annual net price greater than $500,000, with two drugs exceeding $2 million. An additional 34% were launched at net prices between $200,000 and $500,000.

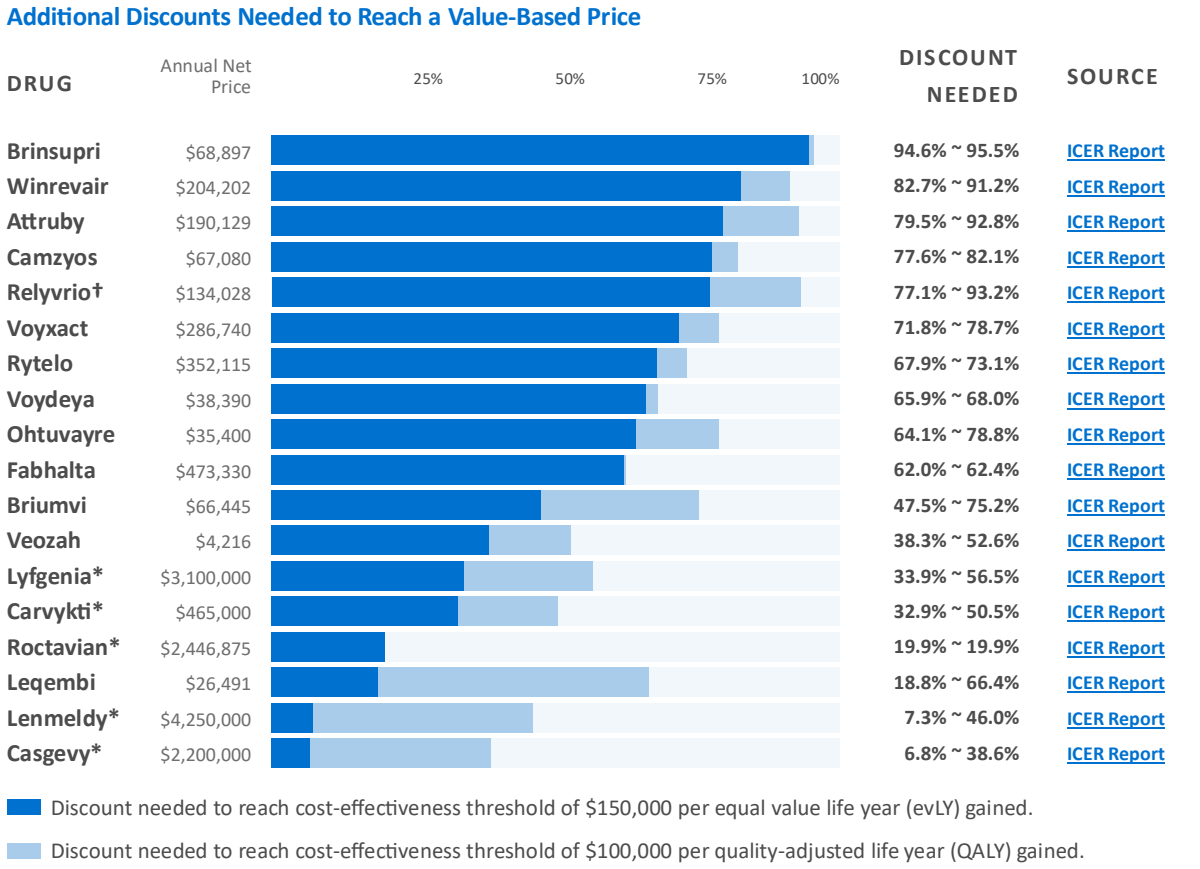
Compared from 2022 to 2024, a smaller share of drugs approved in 2025 fell into categories generally linked to higher launch prices, including gene and cell therapies (9% vs. 10-13%), biologics (40% vs. 50-58%), orphan products (55% vs. 60%), and ultra-rare drugs (11% vs. 18-25%). Given differences in the mix of drugs approved each year, we used a multiple linear regression model to adjust for drug characteristics that may affect launch prices, including product type, therapeutic class, and orphan or ultra-rare status. After accounting for drug characteristics, the median annual net launch price increased by 18% per year. Although not statistically significant, this suggests that launch prices may still be drifting upward when drug characteristics are held constant across years.

Importantly, trends in launch prices, whether overall or within specific sub-categories, may reflect the relative therapeutic value of new drugs introduced in a given year. Independent assessments of the value of each drug are therefore essential for evaluating launch price trends. As such, for drugs approved by the FDA between 2022 and 2025 that have been previously reviewed by the Institute for Clinical and Economic Review (ICER), we assessed their net price in relation to ICER's Health Benefit Price Benchmark (HBPB) to determine if they are fairly priced. ICER's HBPB suggests a price range, net of any discounts and rebates, that aligns fairly with the overall health benefits the treatment provides for patients over their lifetime, based on the data available at the time of drug approval. When drugs are priced at or below these thresholds, it helps ensure that the health benefits gained by patients using new treatments are not outweighed by health losses due to long-term cost pressures that lead individuals to delay care, abandon care, or lose health insurance.

Consistent with last year's findings,[9] our analysis showed that only about one in three of the 26 newly approved drugs previously reviewed by ICER in our scope are priced at or below the HBPB, with the remainder exceeding their estimated value based on evidence available at launch (See Figure ES1). In our previous report, we estimated excess drug spending of over $1 billion during the first year after approval for approximately 15% of drugs approved between 2022 and 2024 alone. As shown in Figure ES1, the majority of these drugs require steep discounts, ranging from 7% to over 90% off the net launch price, to be priced in line with value.

One area of uncertainty is the net price estimates used. We relied on the best available sources to estimate the net price; however, actual net pricing data are not transparent and can vary substantially among payers depending on negotiating leverage, formulary tier placement, and rebate structure. Additionally, we focused on net drug prices paid by the health system rather than net revenue manufacturers receive. We planned to conduct a scenario analysis using the manufacturer's net price estimates. However, no net price data submissions were received from manufacturers in response to the open input call for net price estimates in our research protocol. Instead, we conducted a scenario analysis using Federal Supply Schedule (FSS) prices, as these are generally considered the lower bound of drug pricing because they reflect direct purchasing by a select set of government agencies. Our trend analysis using FSS prices was consistent with the primary analysis results.

Figure ES1. ICER-Reviewed Drugs with Annual Net Prices Exceeding ICER's Upper-Bound HBPB



Bar length shows how far a drug's price sits above ICER's Health Benefit Price Benchmark (HBPB).
ICER's HBPB: price range that aligns fairly with the overall health benefits the treatment provides patients over their lifetime.

*One-time administered gene or cell therapies.

†We acknowledge that Relyvrio was withdrawn from the market in 2024 based on negative Phase III results. As our focus was on price at launch, we included this drug in our analysis because it was on the market for over a year.

Patient Access

Key Takeaways:

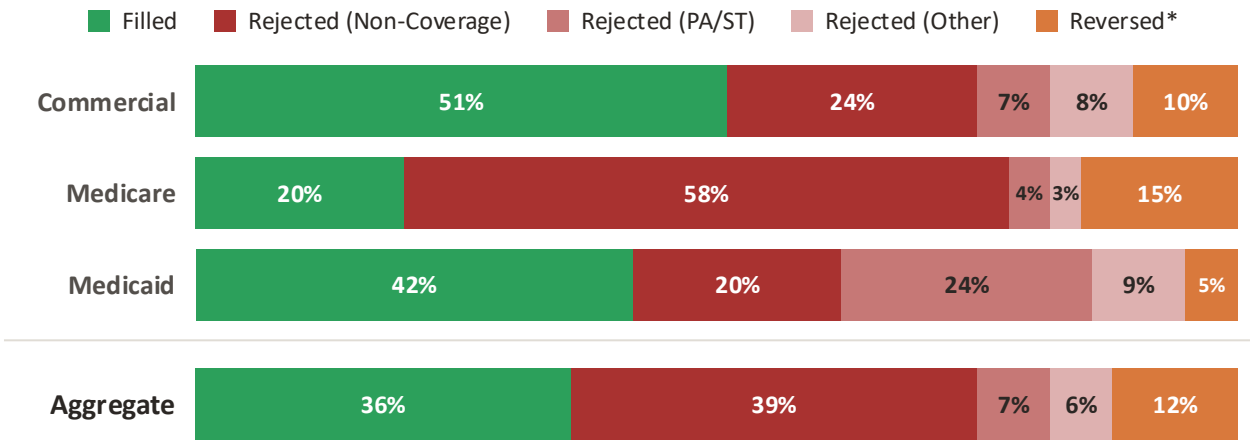
- Only one in three outpatient prescriptions for drugs launched between July 2024 and June 2025 were filled within 30 days of the first prescription, while nearly 40% were rejected due to non-coverage.
- Our data also showed significant variation in out-of-pocket costs by payer; Medicare recipients had the highest mean out-of-pocket costs and Medicaid the lowest for the majority of drugs in scope.

To evaluate the patient access barriers to newly launched drugs, ICER focused on the novel drugs approved from the second half of 2024 (2H2024, July 1-December 31, 2024) to the first half of 2025 (1H2025, January 1-June 30, 2025). This timeframe was chosen to ensure one full year of data post-

approval for each newly approved drug. We obtained IQVIA's Longitudinal Access and Adjudication Data (LAAD) database, which contains de-identified prescription data, including claim adjudication decisions (e.g., prescription fill rates, prescription rejection rates) for outpatient prescription drugs and out-of-pocket costs for both outpatient and physician-administered drugs.

Our analysis showed that rejection appears to be the norm in the first year post-approval for outpatient prescription drugs, with only about one-third of prescriptions ultimately filled within 30 days of attempting to fill them, although these varied across drugs and by payer type. As shown in Figure ES2, outpatient pharmacy prescriptions billed to commercial insurers and Medicaid were more likely to be approved than those billed to Medicare within 30 days of attempting to fill them. The majority of rejected prescriptions were due to non-coverage, likely because of new-to-market blocks. ICER's own Fair Access criteria call on payers to have coverage policies available for newly approved drugs within three months of approval, and immediately following FDA approval for treatments of rapidly progressive and/or fatal conditions for which there is no alternative approved therapy.[10]

Figure ES2. Summary of Adjudication for New-to-Brand Outpatient Pharmacy Prescriptions



PA: prior authorization, ST: step therapy
*The proportion of prescription claims that were approved by insurance and dispensed by the pharmacy but the patient did not pick up the prescription from the pharmacy.

Rejection due to prior authorization and step therapy was observed in about 7% of outpatient prescriptions overall. Although rejection due to prior authorization and step therapy is not an inherently adverse outcome if applied appropriately, our data indicate that having clinically appropriate coverage policies is not sufficient to guarantee appropriate access to newly launched drugs. In many cases, in practice, implementation of utilization management strategies is complex for patients and providers and may pose additional barriers to access and burdens on the health care system. For example, our data showed that most drugs required multiple submission attempts before being filled, suggesting that opportunities exist to streamline utilization management by leveraging technology to aid in data collection and data sharing.

To understand this more, we evaluated the appropriateness of coverage policies for eight of the drugs in our cohort (Attruby, Cobenfy, Journavx, Ebglyss, Nemluvio, Aqneursa, Miplyffa, and Kisunla). For each drug, we compared the coverage policies of the top five US health plans by covered lives with ICER's Fair Access criteria. Our analysis showed high concordance with ICER's Fair Access criteria on clinical eligibility, step therapy, and prescriber restriction for most policies evaluated (87.5%). However, our analysis could not capture the real-world burden of prior authorization on patients or other complexities in our health care system.

Finally, our data showed variation in out-of-pocket costs by payer. For the majority of drugs in our scope, Medicare recipients had the highest mean out-of-pocket costs and Medicaid the lowest. One likely reason for this is the use of manufacturer copay cards, since Medicare recipients are not eligible for such discounts. Our study also covered a time period where there was no out-of-pocket maximum for Medicare Part D enrollees (2H2024), which may explain some of the data. An out-of-pocket maximum was instituted for Medicare Part D enrollees as of January 1, 2025, and so out-of-pocket costs may represent less of a barrier moving forward.

Conclusion

This report contributes to the critical decisions facing the US health care system. With an average launch net price of over $250,000, and many drugs priced out of line with value, new-to-market blocks to delay coverage pending clinical and economic review and prior authorizations have become routine. While these measures are intended to help keep insurance premiums more affordable for patients and all health plan members, they also risk delaying care or creating other barriers to effective care for many patients. Even with these measures, health insurance premiums are rising at unsustainable rates, and the number of uninsured individuals is projected to increase significantly.[11,12]

An objective analysis of launch price trends and patient access challenges serves as a call to action to those with the power to improve affordability and access. Moving away from a system that allows prices out of line with value, cost-sharing based on list price instead of net price, and access restrictions not based on objective notions of fair access requires urgent action. Choosing prices aligned with benefits should lead to better access for patients. Manufacturers have the opportunity to use ICER's independent assessments of value to inform their prices, while health insurers and pharmacy benefit managers have the opportunity to build coverage policies that align with our Fair Access criteria. Those choices, in turn, will translate into a more affordable and accessible health care system. A voluntary de-escalation of the status quo is likely to ensure affordable access for all patients while preserving incentives for future innovation.

1. Introduction

1.1. Background

The growth in prescription drug spending is contributing to an increase in overall health spending,[1] and is one of the major drivers of health insurance premium increases.[2,3] High launch prices for new drugs significantly contribute to this trend, with many new medications entering the market at prices exceeding $200,000 annually.[4,5] This has sparked ongoing discussions about whether these high launch prices are justified and if they correspond to the clinical benefits provided to patients.[6-8] For example, one analysis of net launch prices of cancer drugs from 2008 to 2022 did not find that higher prices were associated with better clinical efficacy.[13] Manufacturers often cite the substantial costs of innovation as a reason for these prices; however, studies have shown no significant correlation between how much a company spends on research and development and the price of the drugs.[14,15] Further complicating these discussions is the fact that the net price of a drug (i.e., the actual transaction amount after rebates, discounts, and other price reductions) often differs from the list price. Determining the overall net price is complex because net prices are proprietary and discrepancies exist between manufacturer and payer net prices. Additionally, net prices vary significantly among payers due to market conditions and statutory requirements.

The impact of the Medicare drug price negotiation provision of the Inflation Reduction Act (IRA), introduced in 2022, which lets the federal government directly negotiate maximum prices for some of the highest-spending drugs covered under Medicare at least nine years after approval, on launch prices remains unclear. Some predict that Medicare drug price negotiation could lead to further increases in launch prices as the industry responds to potential future price reductions.[16,17] Separately, in 2025, the federal government began pursuing most-favored-nation (MFN) pricing to close the gap between United States (US) drug prices and those in peer countries.[18] Unlike IRA negotiations, MFN agreements can be implemented at launch; however, the current MFN rollout is voluntary and, therefore, not standardized. Some experts have also argued that MFN could inadvertently delay access to medicines in other countries while not substantially lowering US launch prices.[19-21] The net effect of these overlapping drug pricing policies on future launch prices remains to be seen.

A critical aspect of the launch price debate is patient access to these new therapies. Coverage delays or exclusions for newly launched drugs have become common.[22] Even when these drugs are covered, utilization management strategies (e.g., prior authorization, step therapy) can create barriers to access and delay care, and high copays and deductibles can create financial burdens for patients. An online survey of nearly 3,000 US adults with chronic health conditions conducted in 2025 found that prescription medication access and affordability have declined over the past year.[23] Almost half of the respondents reported difficulties accessing prescription medications through

their health plans, mainly due to coverage issues (18%), high out-of-pocket costs (18%), prior authorization (16%), and high deductibles (13%). Prior authorization delays can have substantial consequences on patients receiving adequate care, with approximately 25% of patients reporting delayed care and an additional 28% abandoning treatment. In addition, over 20% of patients reported difficulties paying for prescriptions, and approximately the same proportion indicated they could not obtain necessary prescriptions due to cost, putting their health at risk. The ongoing tension between the high costs of treatments and the standard methods payers use to manage these costs may hinder patients from receiving appropriate, evidence-based, and patient-centered care. Many studies have indicated that although the US spends more on health care and prescription drugs than other high-income countries, Americans experience worse health outcomes and access to care.[8,24]

Improving drug affordability and patient access remains one of the few areas of bipartisan consensus in the US; however, policymakers, researchers, and other stakeholders have not always agreed on how to tackle these issues. To contribute to this ongoing policy discussion, the Institute for Clinical and Economic Review (ICER) publishes this annual report to evaluate the launch prices of new Food and Drug Administration (FDA)-approved drugs and patient access to those therapies.

2. Scope of Work and Approach

In April 2026, we organized a multi-stakeholder working group to provide input into the approach and methods for this report. The working group was comprised of representatives from patient and consumer advocacy groups, pharmaceutical companies, clinical experts, purchasers, and insurers. Working with this group, we developed a Launch Price and Access Protocol that was previously published. Below we present a summary of our approach; see Appendix A and B for detailed methodology.

2.1. Launch Price Evaluation

We analyzed launch price trends over four years (2022 to 2025), as well as the impact of various relevant drug characteristics, such as drug type, therapeutic area, and population size, on list and net prices (i.e., the actual transaction amount after rebates, discounts, and other reductions) at launch. Our scope included all novel agents approved by the US FDA Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) from January 2022 to December 2025. Novel agents are new drugs that have never been approved or marketed in the US and therefore do not include generics, biosimilars, or drugs previously approved for other indications. From the list of novel agents, we excluded vaccines, blood- or plasma-based products, and imaging or diagnostic agents due to differences in pricing strategies and market dynamics.

For drugs in scope that have been previously reviewed by ICER (see ICER's Topic Selection Process), we assessed their net price in relation to ICER's Health Benefit Price Benchmark (HBPB) to determine if they are fairly priced. ICER's HBPB suggests a price range, net of any discounts and rebates, that aligns fairly with the overall health benefits the treatment provides for patients over their lifetime, based on the data available at the time of drug approval. Prices at or below these thresholds help ensure that the health benefits gained by patients using new treatments are not outweighed by health losses due to long-term cost pressures that lead individuals to delay care, abandon care, or lose health insurance. For this year's report, we did not conduct a health system impact analysis for drugs priced above ICER's HBPB due to the limited sample size of reviewed drugs since the previous report.

Determination of List and Net Prices

Data on the manufacturer's list price (Wholesale Acquisition Cost [WAC]) at launch was obtained from Redbook. We converted unit WAC prices to annual WAC prices using the dosage information available on the FDA label. For drugs that required assumptions or placeholders to determine annual WAC estimates, we have outlined the inputs we used in Table A1.3 of the Appendix.

Given the complexities and lack of transparency around net prices, we relied on multiple data sources to generate the best net price estimates for our analyses (see Figure A1.1 in Appendix). For this year's report, we focused on estimating net price from the health system perspective for the primary analysis. For provider-administered drugs, we prioritized Average Sales Price (ASP) data when available through the Centers for Medicare and Medicaid Services (CMS) ASP files, and removed the 6% markup that is included in the CMS payment allowance.[25] We prioritized ASP as a net price estimate for provider-administered drugs because it is manufacturer-reported and based on sales to most purchasers. When ASP was not available for a provider-administered drug in scope, we used WAC as a placeholder. This is in accordance with the CMS policy for drug reimbursement, which states that drugs will be reimbursed at a rate of WAC with a 3% markup in the time between launch and before an ASP price is available. We did not include the 3% markup in our calculations. This approach was further supported by our analysis, which found that among the 50 provider-administered drugs with an ASP available, the first available ASP price was generally similar to the WAC price at launch. The median percentage difference between WAC and ASP was 0.6%, and the mean was 3.3%. ASP was within 1% of WAC at launch for more than half of these provider-administered drugs in our scope (27 of 50 drugs).

For outpatient pharmacy prescription drugs, we used gross-to-net discount estimates from multiple sources (Rebate Benchmark and Estimated Total Discounts from the IPD Analytics Rebate Monitor, forecasted discounts from the IPD Analytics Market & Financial Insights, and gross-to-net discount rates from SSR Health) to calculate net price. Detailed information about these sources is available in the Appendix. When more than one of these sources had data for a drug in scope, we calculated the median of all available discount data. If data were not available from any of these sources, we used the Federal Supply Schedule (FSS) price closest to the time of launch, given its fully-public status. If FSS data were also not available, we estimated the gross-to-net discount rate from the median discount among all other outpatient drugs in scope approved in 2025, which was 23%.

After collecting net prices from all sources, we adjusted our net price estimates to exclude the share of discounts that were administered through the 340B program. This was done to support our use of a health system perspective for price analyses, as 340B covered entities receive these discounts but do not pass them on to the payers who ultimately reimburse for the drugs. Since some of our net price data sources incorporated 340B discounts (IPD Analytics, SSR Health) and some did not (WAC, ASP, FSS), we adjusted our estimates accordingly and standardized the exclusion of 340B discounts. For net price estimates sourced from SSR Health or IPD Analytics, we adjusted the overall gross-to-net discounts to account for the share of discounts that were attributable to the 340B program, resulting in slight increases in net price.

To execute this 340B adjustment, we identified the share of total sales that were administered through 340B eligible providers and pharmacists according to drug class,[26] and the estimated 340B-specific discount from WAC (sourced from IPD Analytics).[27] We used these inputs for each drug where the net price was sourced from SSR Health or IPD Analytics, and recalculated the net price.

See Appendix A for additional details. Apart from the 340B adjustments described, we did not update any net price data that was previously calculated for drugs approved between 2022 and 2024 that were included in our 2025 Launch Price and Access report.[9]

We also included an open input survey in our research protocol to allow manufacturers of any drug in scope to submit their net prices. Our goal was to conduct a secondary analysis using the net price estimates from the manufacturer's perspective. However, we did not receive any net price data submissions from any manufacturer. Instead, we conducted a scenario analysis using FSS prices, as this represents a fully public and routinely updated dataset and generally (but not always) is considered to be the lower bound of drug pricing since it is reflective of direct purchasing by a select set of government agencies.

2.2. Patient Access Evaluation

Our objective was to evaluate potential barriers to patient access for newly approved drugs from the second half of 2024 (2H2024, July 1-December 31, 2024) to the first half of 2025 (1H2025, January 1-June 30, 2025). We chose this timeframe to ensure one full year of data post-approval for each drug to allow for robust analysis.

The journey from obtaining a prescription to a patient taking a medication has multiple steps, and with each step there are potential barriers to access. As such, we sought to examine access to newly approved drugs in multiple ways, including: (1) real-world access at point of care (prescription fill rates, prior authorization burden); (2) health plan coverage policies; (3) patient out-of-pocket costs; and (4) first-hand patient experience.

Methods

To accomplish our objectives, we obtained data from the following sources:

- IQVIA's Longitudinal Access and Adjudication Data (LAAD) database, which contains de-identified data on outpatient pharmacy prescriptions and provider-administered drugs, including claim adjudication decisions, payer type, and out-of-pocket costs.
- Publicly available coverage policies from the top five US health plans by covered lives.
- Survey of patients who have obtained a prescription for or have been treated with a subset of drugs of interest.

From the IQVIA LAAD database, we obtained one-year post-approval data for each drug in scope stratified by payer type (commercial, Medicare, Medicaid). Data represents claims written and/or dispensed in the US.

For drugs where a pharmacy claim was submitted (i.e., outpatient prescription drugs picked up at a retail or specialty pharmacy), prescription volumes reflect outpatient prescriptions from participating pharmacies (93% retail coverage, 85% mail order and 74% long-term care coverage) that were routed to payers for adjudication. We obtained volumes of new-to-brand written prescriptions and new-to-brand dispensed prescriptions. New-to-brand prescriptions are defined as the first written prescription for the drug for a specific patient. We obtained summary adjudication metrics for new-to-brand prescriptions for each drug during a 30-day look-forward period, including: 1) proportion of prescriptions filled (claim where payer has approved and script was filled); 2) rejection (claim where payer has rejected claim); and 3) reversal (payer approved claim and prescription was dispensed by pharmacy, but not picked up by patient and returned to pharmacy stock). Furthermore, for each rejected claim, we obtained summary metrics on the reason for rejection, including non-coverage, need for prior authorization or step therapy, or other (e.g., administrative errors), and whether there were single or multiple attempts to fill the prescription. Finally, we were able to obtain patient out-of-pocket costs in ranges. Out-of-pocket costs represent the amount paid by the patient directly to the pharmacy or facility (for an infused drug). Outpatient drugs that had fewer than 10 claims were excluded from the analysis.

For drugs where a medical claim was submitted (i.e., provider-administered drugs given in a clinical setting like a doctor's office or hospital), the database draws from adjudicated office and institutional medical claims from participating payers and health care providers. Medical claims do not provide adjudication metrics parallel to those for pharmacy claims; however, we obtained dispensed claim volume and out-of-pocket costs. Provider-administered drugs that had fewer than 10 claims were excluded from the analysis.

For coverage policies, we evaluated the top five US health plans by covered lives (Centene Corporation, CVS Health/Aetna, Elevance Health, Health Care Service Corporation [HCSC], and UnitedHealth Group) for select drugs in scope. We obtained coverage policies through manual keyword searches on Google and the selected health plans' publicly facing websites. If after searching a health plan's website we did not find a policy, we reached out to the health plan directly. All policies obtained were the most recent policies dated prior to June 18, 2026. All policies were compared to ICER's Cornerstones of Fair Access criteria for clinical eligibility, step therapy, and prescriber restrictions, and judged to be concordant with the criteria or not by two independent reviewers. To compare the policies to the Fair Access criteria, data were abstracted from the coverage policies on clinical eligibility details, step therapy details (number of steps required and criteria for each step), and prescriber requirements. Data were also abstracted from the FDA label, including approved indication and information on the clinical studies (National Clinical Trial [NCT] number, key eligibility criteria, dosing, and endpoints). Claude (Sonnet 5), an artificial intelligence (AI) assistant created by Anthropic, was used to abstract the data from the coverage policies and the FDA label for all drugs. A human reviewer also abstracted the same data. The two abstracted sheets were manually cross-checked. Relevant clinical guidelines for the indications of the selected

drugs were also identified and used to judge the policies against the Fair Access criteria. See Appendix Section B2.

Finally, we sought to characterize patient access experience, including awareness of drug availability, prior authorization burden, and affordability for selected drugs in scope. To do this, we developed a patient survey in collaboration with the National Health Council (NHC). Two patient advocacy organizations and one patient reviewed the survey, and their feedback was incorporated into the final version. NHC deployed the finalized survey and partnered with relevant patient organizations to share it through newsletters, social media, websites, and other community channels. All survey responses were anonymous. See Appendix B2 for additional details.

3. Launch Prices

Table 3.1 summarizes the annual launch prices, including the list price and the best net price estimate, for each drug in scope approved in 2025. The annual launch prices for each drug in scope across all years (2022-2025) can be found in the Appendix. The table is sorted by net price from highest to lowest.

Table 3.1. 2025 Launch Prices: Annual List and Net Prices

Drug Name [Brand Name (generic name)]	Annual List Price	Best Annual Net Price Estimate
2025 Approvals		
Zevaskyn® (prademagene zamikeracel)	$3,147,000.00	$3,147,000.00†
Itvisma® (onasemnogene abeparvovec-brve)	$2,586,629.70	$2,586,629.70†
Qfitlia® (fitusiran)	$968,400.00	$938,349.00*
Modeyso™ (dordaviprone)	$834,285.71	$735,339.43#
Forzinity™ (elamipretide)	$795,739.11	$694,083.44#
Lynozyfic™ (linvoseltamab-gcpt)	$585,620.00	$581,993.00*
Dawnzera™ (donidalorsen)	$689,544.00	$578,355.03#
Avmapki Fakzynja Co-Pack® (avutometinib and defactinib)	$632,232.14	$557,249.41#
Sephience™ (sepiapterin)	$766,500.00	$550,193.70#
Kygevvi® (doxecitine and doxribtimine)	$600,005.25	$528,844.63#
Andembry® (garadacimab-gxii)	$618,583.33	$518,836.77#
Encelto™ (revakinagene taroretcel-lwey)	$500,000.00	$500,000.00†
Komzifti™ (ziftomenib)	$590,083.33	$490,595.28#
Emrelis™ (telisotuzumab vedotin-tllv)	$484,756.90	$477,177.46*
Papzimeos™ (zopapogene imadenovec-drba)	$460,000.00	$460,000.00†
Datroway® (datopotamab deruxtecan-dlnk)	$415,740.93	$413,437.00*
Gomekli® (mirdametinib)	$450,450.00	$359,053.70#
Ibtrozi® (taletrectinib)	$358,770.66	$319,036.81#
Imaavy® (nipocalimab-aahu)	$305,760.00	$302,718.30*
Yartemlea® (narsoplimab-wuug)	$294,440.00	$294,440.00†
Voyxact® (sibeprenlimab-szsi)	$360,000.00	$286,740.00#
Romvimza™ (vimseltinib)	$340,597.14	$273,522.19¤
Inluriyo™ (imlunestrant)	$293,303.57	$273,182.94#
Hyrnuo® (sevabertinib)	$292,000.00	$257,368.80#
Palsonify® (paltusotine)	$294,007.50	$233,653.39¤
Hernexeos® (zongertinib)	$263,615.29	$232,350.51#
Keytruda Qlex™ (pembrolizumab and berahyaluronidase alfa-pmph)	$209,116.50	$203,534.00*
Ekterly® (sebetralstat)	$200,640.00	$172,751.04#
Wayrilz™ (rilzabrutinib)	$212,916.67	$164,073.59#
Jascayd® (nerandomilast)	$197,339.44	$152,385.52#
Vanrafia® (atrasentan)	$162,499.97	$123,158.73#
Myqorzo™ (aficamten)	$108,400.01	$77,180.81#
Brinsupri® (brensocatib)	$89,222.18	$68,897.37#

Drug Name [Brand Name (generic name)]	Annual List Price	Best Annual Net Price Estimate
Redemplo® (plozasiran)	$60,000.00	$52,425.00#
Exdensur™ (depemokimab-ulaa)	$52,000.00	$52,000.00†
Rhapsido® (remibrutinib)	$55,005.50	$34,427.94#
Grafapex™ (treosulfan)	$31,110.00	$31,110.00*
Anzupgo® (delgocitinib)	$24,163.00	$13,763.24#
Cardamyst™ (etripamil)	$11,130.75	$5,810.25#
Lynkuet® (elinzanetant)	$7,604.17	$5,190.23#
Lerochol® (lerodalcibep-liga)	$4,500.00	$3,550.50‡‡
Tryptyr® (acoltremon)	$10,706.67	$3,509.65#
Blujepa™ (gepotidacin)	$1,900.00	$1,745.72#
Nereus™ (tradipitant)	$1,785.00	$1,433.36‡‡
Vizz™ (aceclidine)	$1,095.00	$884.54‡‡
Enflonsia™ (clesrovimab-cfor)	$556.00	$556.00†
Journavx® (suzetrigine)	$232.50	$101.22#

Net price sources: *ASP (Note that ASP is occasionally higher than WAC); †WAC; ‡Median of multiple sources; §SSR Health; #IPD Analytics; ¤FSS; ‡‡Placeholder discount (23%)

3.1. Drugs Approved in 2025

The median annual list price of drugs approved in 2025 was $293,304 (range: $233-$3,147,000), while the median annual net price was $257,369 (range: $101-$3,147,000).

Of the 47 drugs included in our analysis, over half (55%) were orphan drugs (i.e., intended to treat a condition affecting fewer than 200,000 people), 11% were ultra-rare drugs (i.e., intended to treat a condition affecting fewer than 10,000 people and not approved for oncology indication; see Appendix Section A1), 40% were biologics, 30% were oncology drugs, 9% were gene and cell therapies, and 83% were first approved in the US.

Compared to prior years, the proportion of ultra-rare drugs decreased (11% compared to 18-25%), as did biologics (40% compared to 50-58%), and gene and cell therapies (9% compared to 10-13%). However, a higher percentage of drugs were first approved in the US in 2025 (83%) compared to previous years (65%). See Table 3.2. See Table A1.1 for all characteristics.

Table 3.2. Proportion of Drug Characteristics in Each Year (2022-2025)

Various Drug Characteristics	2025 (n=47)	2024 (n=54)	2023 (n=61)	2022 (n=40)
Biologic	40%	50%	51%	58%
Gene/Cell Therapy	9%	11%	10%	13%
Orphan Drug Designation	55%	61%	59%	60%
Ultra-Rare Drug	11%	22%	25%	18%
Oncology	30%	31%	25%	33%
First in US	83%	65%	64%	65%

n: number, US: United States

3.2. Trend Analysis

We conducted analyses examining trends in launch prices (list and net prices) over a four-year period (2022-2025), independent of various drug characteristics. We examined year-over-year changes, as well as the total change over the four years. A total of 202 drugs were included in our trend analysis.

Because the data were highly skewed by some extremely high launch prices, we report the annual median list and net prices. The median annual list and net prices are presented in Table 3.3. To account for inflation, the list and net prices for drugs approved from 2022 to 2024 were adjusted to 2025 values.[28]

List and Net Price Changes

Overall, there was a 24% increase ($56,155) in the inflation-adjusted median annual list price of newly launched drugs from 2022 to 2025. Specifically, from 2022 to 2023, the median annual list price increased by 29%. However, from 2023 to 2024, prices remained relatively stable, with only a small 2% decrease from $306,832 to $299,630. From 2024 to 2025, there was another 2% decrease to $293,304 (Table 3.3, Figure 3.1).

Similarly, the inflation-adjusted median annual net price of newly launched drugs increased by 35% ($66,816) from 2022 to 2025. From 2022 to 2023, prices increased by 32% from $190,553 to $252,296, while from 2023 to 2024, prices remained relatively stable, with only a small increase of 4% from $252,296 to $261,368. From 2024 to 2025, there was a decrease of 2% to $257,369 (Table 3.3, Figure 3.1).

Table 3.3. Launch Price: Median Annual List and Net Price*

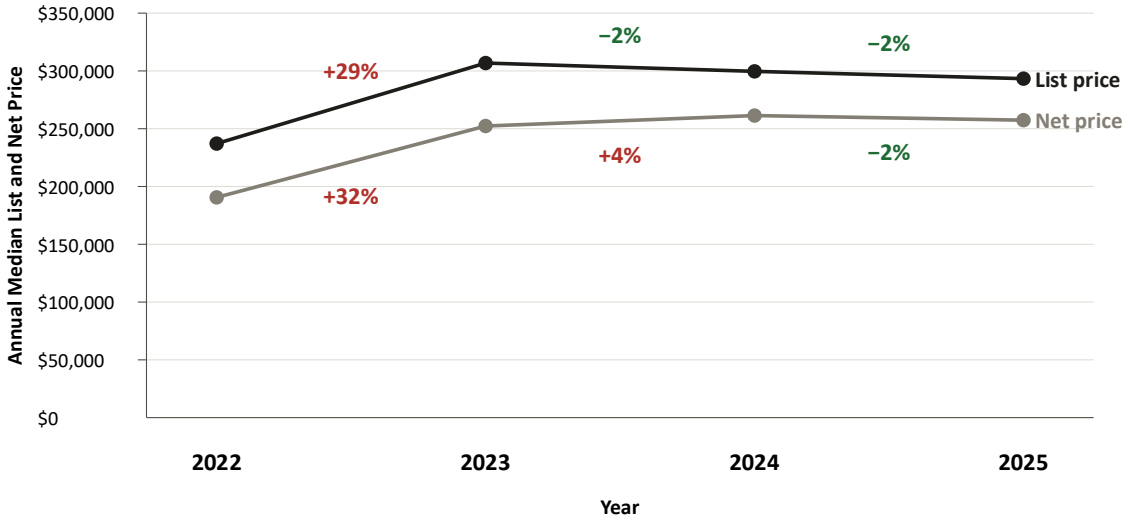
	Annual List Price		Annual Net Price	
Year	**Median Launch (Range)***	**Median Launch (Range) Adjusted to 2025†**	**Median Launch (Range)***	**Median Launch (Range) Adjusted to 2025†**
2022, n=40	$215,575 ($350-$3,500,000)	$237,149 ($385-$3,850,270)	$173,218 ($278-$3,000,000)	$190,553 ($306-$3,300,321)
2023, n=61	$290,400 ($475-$3,200,000)	$306,832 ($501-$3,381,072)	$238,784 ($406-$3,200,000)	$252,296 ($429-$3,381,072)
2024, n=54	$291,948 ($660-$4,250,000)	$299,630 ($677-$4,361,830)	$254,667 ($660-$4,250,000)	$261,368 ($677-$4,361,830)
2025, n=47	$293,304 ($233-$3,147,000)	$293,304 ($233-$3,147,000)	$257,369 ($101-$3,147,000)	$257,369 ($101-$3,147,000)

n: number of drugs

*There are slight changes to the trends reported in our previous analysis of approvals from 2022 to 2024.[9] These changes are due to the addition of six drugs (one in 2022, three in 2023, and two in 2024), which were included either because of expanded inclusion criteria, such as the addition of antibiotics, updated net price estimates, or because previously unavailable launch price data became available.

†List and net price for drugs approved in 2022-2024 were adjusted for inflation to 2025 values.[28]

Figure 3.1. Annual Median List and Net Price with Year-on-Year Change



Adjusted List and Net Price Changes

Given the differences in the mix of drugs approved each year (Table 3.2), we fitted a multiple linear regression model to adjust for various drug characteristics that may impact the launch prices. Regression models provide estimations of which drug characteristics have the highest correlation with the outcome (i.e., list or net price).

Drug characteristics associated with significantly higher launch prices included gene and cell therapies, ultra-rare therapies, and therapeutic areas, specifically oncology and hematology drugs. We accounted for drug characteristics in our regression model to examine the underlying trend in launch price. This means that we evaluated the impact of year on list and net price while holding all the drug characteristics equal. After accounting for drug characteristics in the model, the annual list price increased by 16% per year (95% CI: -6% to 43%), while the annual net price increased by 18% per year (95% CI: -5% to 46%) between 2022 and 2025, although increases were not statistically significant. See Table 3.4.

Table 3.4. Adjusted Change in List and Net Price

	List Price Change	Net Price Change
2022 to 2025, n=202	+16% per year (95% CI: -6% to 43%; p=0.16)	+18% per year (95% CI: -5% to 46%; p=0.13)

CI: confidence interval, n: number of drugs

Scenario Analyses

We conducted three scenario analyses. We evaluated whether a quadratic regression might better fit the pricing trend compared to the linear regression. The quadratic regression did not provide a better fit to the data than the linear regression, so we report the linear regression results as our primary analysis. See Table A1.12. Next, we evaluated differences in trend analysis results using FSS prices as a conservative proxy for net prices, since FSS prices represent a lower bound of net prices. Results were consistent with the primary analysis. See Table A1.14. Third, we evaluated whether orphan drug designation, instead of ultra-rare, may explain more variance in price (replication of approach in 2025 Launch Price and Access Trend Analysis). Replacing ultra-rare with orphan drug did not meaningfully change the model results. See Table A1.16. Full details are reported in the Appendix.

Trends By Drug Characteristics

In Figures 3.2 and 3.3 and Tables 3.5 and 3.6 below, we present the trends in launch prices (list and net) by various drug characteristics, including orphan drug designation, non-orphan drugs, biologics, small molecules, gene and cell therapies, and by the largest therapeutic class (oncology), over the four-year period. The median annual launch price for the typically higher-cost categories— orphan drugs, gene and cell therapies, oncology therapies, and biologics—remained stable or declined from 2024 to 2025. In contrast, the median annual launch price of small-molecule therapies, non-orphan drugs, and non-oncology therapies increased during the same period. Small-molecule therapies showed a consistent year-over-year increase from 2022, while non-orphan drugs saw a 58% increase in list price from 2024 to 2025 but only an 8% increase in net price. Given that the distribution of characteristics varies across years, the adjusted result presented in Table 3.4 above better reflects the overall trend in launch prices when characteristics are held constant.

Figure 3.2. Median List Price Across Drug Characteristics

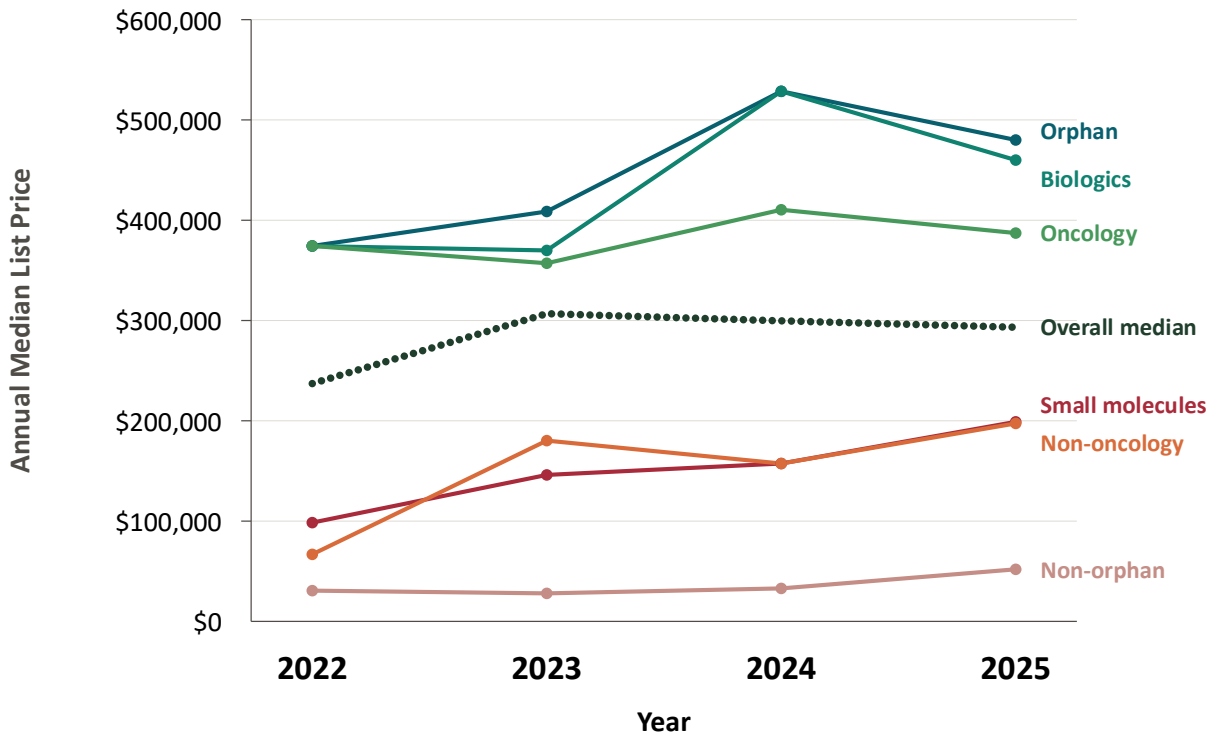


Table 3.5. Annual List Price by Drug Characteristics and Approval Year

	2022	2023	2024	2025	2024→2025 % Change	2022→2025 % Change
Overall Median List Price, n=202*	$237,149	$306,832	$299,630	$293,304	-2%	+24%
Orphan Drugs, n=119	$374,354	$408,750	$528,551	$480,000	-9%	+28%
Non-Orphan Drugs, n=83†	$30,653	$28,000	$32,842	$52,000	+58%	+70%
Biologics, n=100	$374,246	$369,804	$528,551	$460,000	-13%	+23%
Small Molecules, n=102	$98,457	$146,066	$157,409	$198,990	+26%	+102%
Oncology Therapies, n=59	$374,462	$357,126	$410,598	$387,256	-6%	+3%
Non-Oncology Therapies, n=143	$66,885	$180,231	$157,409	$197,339	+25%	+195%
Gene/Cell Therapies, n=21‡	$3,080,216	$2,454,909	$2,169,113	$1,543,315	-29%	-50%

n: number

*List prices for drugs approved in 2022-2024 were adjusted for inflation to 2025 values.[28]

†We included ultra-rare drugs in our regression analysis, a small subset of the drugs in the orphan drugs category (N=39). Ultra-rare drugs showed a steady increase over time.

‡Because of the high price and small sample size, we did not include gene and cell therapies in the graph.

Figure 3.3. Median Net Price Across Drug Characteristics

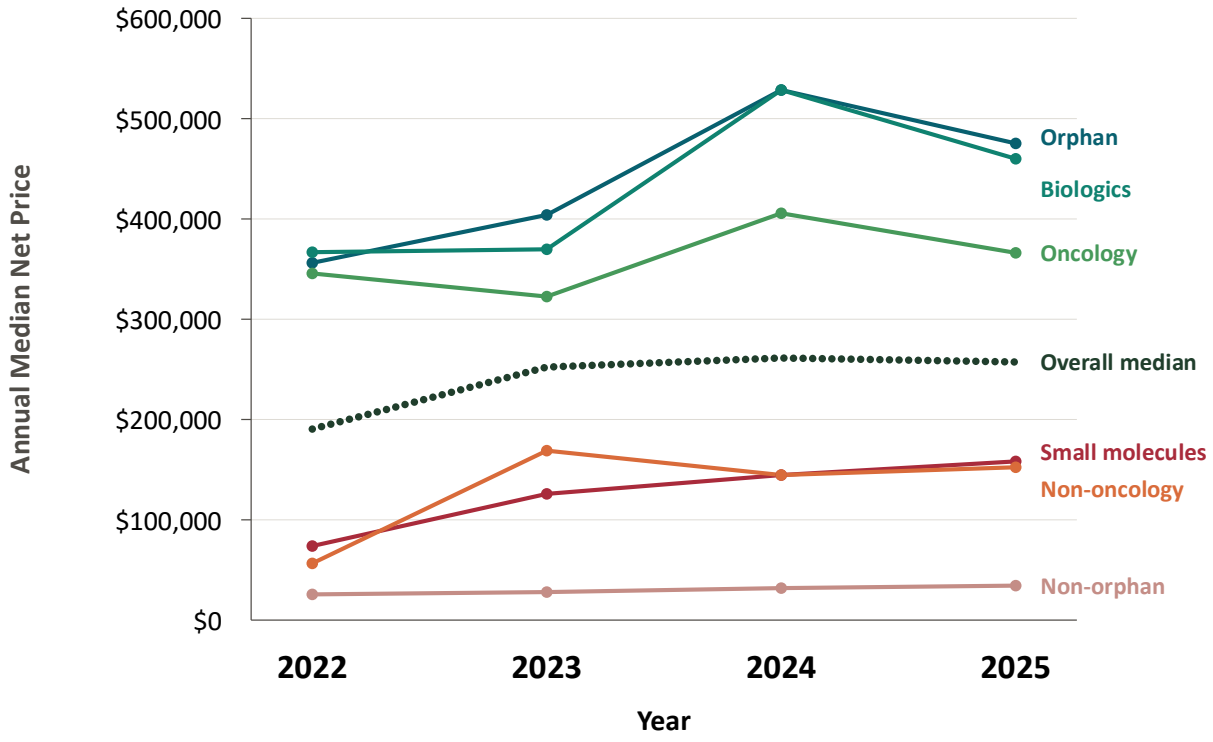


Table 3.6. Net Price by Drug Characteristics and Approval Year*

	2022	2023	2024	2025	2024→2025 % Change	2022→2025 % Change
Overall Median Net Price, n=202*	$190,553	$252,296	$261,368	$257,369	-2%	+35%
Orphan Drugs, n=119	$356,271	$404,002	$528,551	$475,298	-10%	+33%
Non-Orphan Drugs, n=83†	$25,564	$27,990	$31,909	$34,428	+8%	+35%
Biologics, n=100	$366,901	$369,791	$528,551	$460,000	-13%	+25%
Small Molecules, n=102	$73,793	$125,848	$144,659	$158,230	+9%	+114%
Oncology Therapies, n=59	$345,641	$322,634	$405,610	$366,237	-10%	+6%
Non-Oncology Therapies, n=143	$56,580	$168,918	$144,659	$152,386	+5%	+169%
Gene/Cell Therapies, n=21‡	$2,352,727	$2,454,909	$2,169,113	$1,523,315	-30%	-35%

n: number

*Net prices for drugs approved in 2022-2024 were adjusted for inflation to 2025 values.[28]

†We included ultra-rare drugs in our regression analysis, a small subset of the drugs in the orphan drugs category (N=39). Ultra-rare drugs showed a steady increase over time.

‡Because of the high price and small sample size, we did not include gene and cell therapies in the graph.

3.3. Launch Price Versus Health Benefit Price Benchmark

To assess the extent to which drugs approved by the US FDA are priced in accordance with their value, we compared launch prices, with a focus on net estimates, to ICER's Health Benefit Price Benchmark (HBPB). ICER's HBPB suggests a price range, net of any discounts and rebates, that aligns fairly with the overall health benefits the treatment provides for patients over their lifetime, based on the data available at the time of drug approval. Prices at or below these thresholds help ensure that the health benefits patients gain from new treatments are not outweighed by health losses resulting from long-term cost pressures that leave individuals underinsured or uninsured.

Out of 202 novel drugs approved by the US FDA between 2022 and 2025 included in our trend analysis, 26 have been previously reviewed by ICER and have corresponding HBPBs available. Of these 26 drugs, only 31% (8 out of 26) were considered fairly priced at launch, meaning their launch prices were within or below the ICER HBPB range. Table 3.7 presents the additional discount required for the remaining drugs to be considered fairly priced. For those priced above the ICER HBPB range, a median additional discount of 63% (interquartile range [IQR]: 33% to 75%) off the net launch price is needed to reach the $150,000 equal value life year (evLY) threshold, while a median additional reduction of 71% (IQR: 53% to 81%) is needed to reach the $100,000 per quality-adjusted life year (QALY) threshold.

Table 3.7. ICER-Reviewed Drugs Between 2022 and 2025 (N=26)

Drug Name	Condition	Annual Net Price (Best Estimate)	Is this Fairly Priced Based on ICER HBPB*	Additional Discount Needed to be Considered Fairly Priced†	Source/ICER Report
Approved in 2022					
Adstiladrin	Bladder Cancer	$239,643	Yes	--	ICER Report[29]
Briumvi	Relapsing Forms of Multiple Sclerosis	$66,445	No	47.5% ~ 75.2%	ICER Report[30]
Camzyos	Hypertrophic Cardiomyopathy	$67,080	No	77.6% ~ 82.1%	ICER Report[31]
Carvykti	Multiple Myeloma	$465,000‡	No	32.9% ~ 50.5%	ICER Report[32]
Cibinqo	Atopic Dermatitis	$36,153	Yes	--	ICER Report[33]
Hemgenix	Hemophilia B	$2,646,633‡	Yes	--	ICER Report[34]
Mounjaro	Type 2 Diabetes	$5,293	Yes	--	ICER Report[35]
Relyvrio	Amyotrophic Lateral Sclerosis	$134,028	No	77.1% ~ 93.2%	ICER Report[36]
Zynteglo	Beta Thalassemia	$2,138,693‡	Yes	--	ICER Report[37]
Approved in 2023					
Casgevy	Sickle Cell Disease	$2,200,000‡	No	6.8% ~ 38.6%	ICER Report[38]
Fabhalta	Paroxysmal Nocturnal Hemoglobinuria	$473,330	No	62.0% ~ 62.4%	ICER Report[39]
Leqembi	Early Alzheimer's Disease	$26,491	No	18.8% ~ 66.4%	ICER Report[40]
Lyfgenia	Sickle Cell Disease	$3,100,000‡	No	33.9% ~ 56.5%	ICER Report[38]
Roctavian	Hemophilia A	$2,446,875‡	No	19.9% ~ 19.9%	ICER Report[41]
Veozah	Vasomotor Symptoms from Menopause	$4,216	No	38.3% ~ 52.6%	ICER Report[42]
Approved in 2024					
Attruby	Transthyretin Amyloid Cardiomyopathy	$190,129	No	79.5% ~ 92.8%	ICER Report[43]
Cobenfy	Schizophrenia	$18,398	Yes	--	ICER Report[44]
Lenmeldy	Metachromatic Leukodystrophy	$4,250,000‡	No	7.3% ~ 46.0%	ICER Report[45]
Ohtuvayre	Chronic Obstructive Pulmonary Disease	$35,400	No	64.1% ~ 78.8%	ICER Report[46]
Rezdiffra	Metabolic Dysfunction-Associated Steatohepatitis (Non-Alcoholic Steatohepatitis)	$44,858	Yes	--	ICER Report[47]

Drug Name	Condition	Annual Net Price (Best Estimate)	Is this Fairly Priced Based on ICER HBPB*	Additional Discount Needed to be Considered Fairly Priced†	Source/ICER Report
Rytelo	Anemia in Myelodysplastic Syndrome	$352,115	No	67.9% ~ 73.1%	ICER Report[48]
Voydeya	Paroxysmal Nocturnal Hemoglobinuria	$38,390	No	65.9% ~ 68.0%	ICER Report[39]
Winrevair	Pulmonary Arterial Hypertension	$204,202	No	82.7% ~ 91.2%	ICER Report[49]
Approved in 2025					
Brinsupri	Non-cystic Fibrosis Bronchiectasis	$68,897	No	94.6% ~ 95.5%	ICER Report[50]
Journavx	Acute Pain	$101[§]	Yes	--	ICER Report[51]
Voyxact	Immunoglobulin A Nephropathy	$286,740	No	71.8% ~ 78.7%	ICER Report[52]

HBPB: Health Benefit Price Benchmark, ICER: Institute for Clinical and Economic Review

*A drug is considered fairly priced if its launch net price is within or below the ICER HBPB.

†Percentage discounts needed to reach ICER HBPB at cost-effectiveness thresholds of $100,000 per quality-adjusted life year (QALY) gained and $150,000 per equal value life year (evLY) gained were calculated.

‡This is a one-time treatment; therefore, this price represents the total cost of a single treatment.

§Journavx is a one-week treatment; therefore, this price represents the total cost of one week of treatment.

3.4. Discussion

The aim of this report is to inform current policy conversations that address launch prices and highlight opportunities to enhance affordability and access. Recent reports indicate stabilization or decline in the net prices of brand-name drugs,[53] but these analyses generally include all drugs rather than focusing on newly launched products, and rarely assess prices at the individual drug level. The lack of granular data has impeded efforts to fully understand and address launch pricing. Our evaluation of launch prices for newly approved drugs over the past four years seeks to fill this gap and contribute to this important policy question.

Our analyses indicated that from 2022 to 2025, the inflation-adjusted median annual list price of newly launched drugs increased by 24%, while the median annual net price rose by 35%. The most substantial increase occurred between 2022 and 2023. From 2023 onward, launch prices remained relatively stable, with a slight decrease observed in 2025. Given that certain drug classes are typically associated with higher launch prices, we examined whether the decline from 2024 to 2025 was due to fewer approvals of these drugs or due to an actual reduction in launch prices. Compared to previous years, a smaller share of drugs fell into categories generally linked to higher launch prices, such as gene and cell therapies (9% vs. 10-13%), biologics (40% vs. 50-58%), orphan products (55% vs. approximately 60%), and ultra-rare drugs (11% vs. 18-25%). This pattern suggests that the

flattening in the overall trend may be attributable to a lower proportion of typically higher-priced drugs approved in 2025. Accordingly, we adjusted for characteristics associated with higher launch prices, including gene and cell therapies, ultra-rare therapies, and therapeutic areas, specifically oncology and hematology drugs. After adjustment, regression analyses showed an increase in drug pricing over the years, with inflation-adjusted list prices rising 16% per year and net prices 18% per year between 2022 and 2025, although these increases were not statistically significant. This represents a smaller increase than observed between 2022 and 2024,[9] indicating that the most recent year's launch price growth was smaller than the trend predicted by the prior three years.

To further explore these trends, specific drug categories were analyzed. Our analysis showed that the median annual launch price for typically higher-cost groups—including orphan products, oncology therapies, and biologics—declined from 2024 to 2025. Although these categories overlap for certain drugs, this finding suggests that, in addition to a lower proportion of typically higher-priced drugs approved in 2025, the decline in annual launch price for drugs in these categories in 2025 also likely contributed to the flattening of the overall trend.

Interestingly, the median annual launch price for small-molecule therapies, non-orphan drugs, and non-oncology therapies increased from 2024 to 2025. The steady rise in the median annual launch price of non-orphan drugs could have a large impact on overall health care spending, given the large populations typically eligible for these therapies. For small-molecule drugs, the median annual launch price increased by more than 100% over four years. This change may be due to anticipatory IRA negotiation. The IRA has a differential price negotiation strategy for small-molecule drugs, occurring seven years after launch, compared to eleven years for biologics. This four-year difference, often referred to as the "pill penalty" or the "biologics bonus," has raised concerns about its potential impact on investment behaviors, with some projections indicating reduced investment in small molecule therapies.[54] However, our analysis indicates a modest increase in the proportion of small-molecule drug approvals from 2022 to 2025, accompanied by a steady rise in median launch prices. These findings suggest a behavioral shift toward higher launch prices, potentially intended to offset anticipated future losses from negotiations, rather than a reduction in investment. Future analyses will examine whether this trend persists and will continue to assess the potential impact of Medicare price negotiation on launch prices.

While our analysis, which showed a median annual net price of $257,000 in 2025, indicates a slower-than-expected growth in annual median launch prices compared to previous years, about one in four drugs introduced in 2025 still had an annual net price greater than $500,000, with two exceeding $2 million. An additional 34% were launched at prices between $200,000 and $500,000. High launch prices without anchoring to how well those drugs actually work drive up overall health care costs and lead directly to reduced access and higher out-of-pocket expenses for all patients. To promote genuine innovation, higher prices should be reserved for treatments that offer clear benefits over existing options, while lower prices should be assigned to those that do not. However, pricing to value at launch, or ensuring that the launch price is tied to the benefit it provides to

patients based on available evidence, is often missing from many US drug price choices. This is the goal of ICER's individual drug assessments. ICER's HBPB is a price range, net of any discounts and rebates, that aligns fairly with the overall health benefits the treatment provides for patients over their lifetime, based on the data available at the time of drug approval. Prices at or below these thresholds help ensure that the health benefits patients gain from new treatments are not outweighed by health losses resulting from long-term cost pressures that leave other individuals underinsured or uninsured. Consistent with last year's findings, we found that only about one in three newly approved drugs previously reviewed by ICER are priced at or below the HBPB, with the remainder exceeding their estimated value. In our previous report, we estimated excess drug spending of over $1 billion during the first year after approval for approximately 15% of drugs approved between 2022 and 2024. Excess spending analysis was not conducted this year due to the limited sample size of the drugs reviewed since the previous report.

The concern around the significant price differential between the US and comparable countries has led to the implementation of the MFN drug pricing approach, intended to lower US prescription drug costs by aligning prices with those in similarly developed nations. Under the voluntary MFN framework, manufacturers are expected to offer all new drugs launched in the US to Medicaid at prices comparable to those in other high-income countries. Apart from its reliance on foreign benchmarks that may not reflect the financial considerations and societal values of the US population, one operational challenge for a prospective MFN framework is that many drugs are typically launched first in the US, with an average lag of one year before introduction in other countries.[55] Many experts have suggested that MFN could further delay launches in other countries, potentially resulting in unchanged or even higher prices in the US. Our analysis showed an uptick in the proportion of drugs first approved in the US in 2025 (83%) compared with previous years (65%). Further research is needed to evaluate the lag time between these approvals and subsequent launches in other countries.

There are important limitations to consider in our analysis. One area of uncertainty is the net price estimates used. While we relied on the best available sources to estimate the net price paid by the health system, actual net pricing data are not transparent and can vary substantially among payers depending on negotiating leverage, formulary tier placement, volume, and rebate structure. Our net price estimates are also likely to differ from the manufacturer's net price, as they do not include 340B discounts. We chose not to include 340B discounts because our primary goal was to evaluate trends in net drug prices paid by the health system, rather than net revenue received by manufacturers. We planned to conduct a scenario analysis using the manufacturer's net price estimates. However, no net price data submissions were received from manufacturers in response to the open input call for net price estimates in our research protocol. Instead, we conducted a scenario analysis using FSS prices, as this represents a fully public and routinely updated dataset and is generally considered to be the lower bound of drug pricing since it reflects direct purchasing by a select set of government agencies. Results using FSS prices were consistent with the primary

analysis. Additionally, ICER's HBPB is based on the available evidence on the drug at the time of launch. New data may become available post-launch, potentially changing the fair price benchmark. Finally, trends in launch prices, whether overall or within specific sub-categories, may reflect the relative therapeutic value of new drugs introduced in a given year. Independent assessments of the value of each drug are therefore essential for evaluating launch price trends.

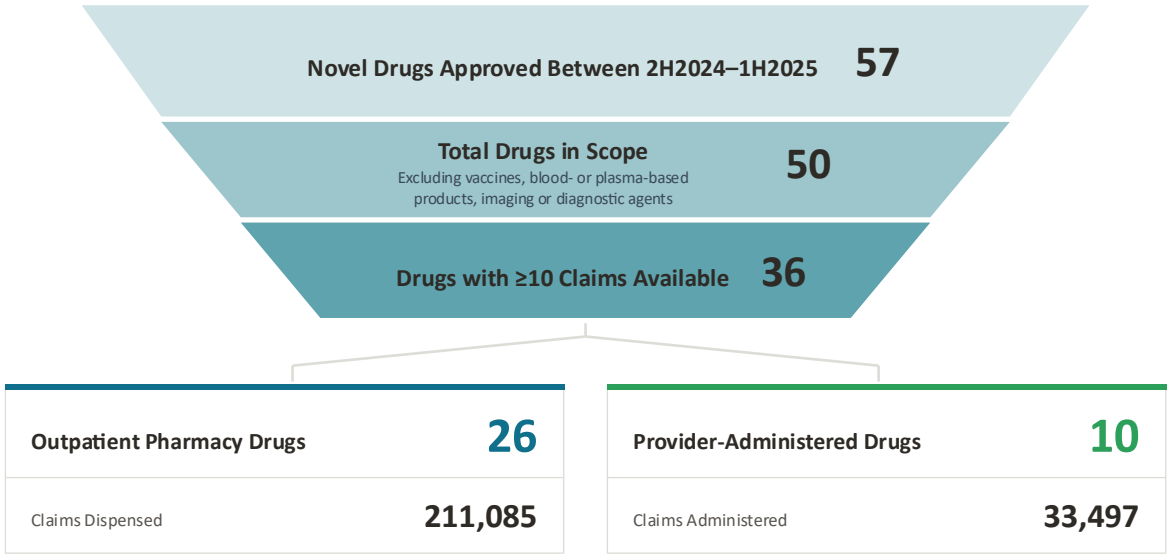
4. Patient Access

4.1. Overview of Drugs in Scope

Our initial list of drugs included all drugs approved between July 1, 2024 (2H2024) and June 30, 2025 (1H2025) (See Appendix Table B1.1). We chose this time frame so that we would have one full year of data post-approval for analysis. Of the 57 initial drugs approved in this timeframe, we excluded seven drugs that were vaccines, blood- or plasma-based products, or imaging or diagnostic agents. The remaining 50 drugs in scope covered 31 different conditions. Eighteen treated cancer or complications from cancer, 30 had an orphan drug designation, 23 were considered biologics, and 25 were first-in-class medications.

For the 50 drugs in scope, we obtained claims data to evaluate real-world access from the IQVIA LAAD database, which contains longitudinal patient data. For outpatient prescription drugs, the database includes information on adjudicated outcomes (e.g., prescription fill rates, prescription rejection rates), while for provider-administered drugs (injections and infusions administered in a hospital or outpatient setting) it includes information only on finalized claims (i.e., drugs already approved by the health plan). We excluded drugs with fewer than 10 claims from our analyses, which led to a final cohort of 26 outpatient pharmacy drugs and 10 provider-administered drugs. Figure 4.1 shows the full drug cohort selection process.

Figure 4.1. Drug Cohort Selection and Claims Availability



2H2024: 2nd half of 2024, defined as July 1–December 31, 2024; 1H2025: 1st half of 2025, defined as January 1–June 30, 2025

4.2. Real-World Access

Based on the information from the IQVIA LAAD database, we evaluated the following outcomes on the final cohort of drugs:

(a) Prescription Volume: We obtained total written and dispensed prescription volumes, as well as total new-to-brand prescriptions written and dispensed for each drug. New-to-brand indicates the first prescription written for a specific drug for a specific patient. For provider-administered drugs, we had information only on finalized, submitted claims.

(b) Prescription Adjudication: The prescription adjudication outcomes were reported only for outpatient prescription drugs.
   - Prescription fill rates: Proportion of new-to-brand prescriptions that were approved by payers during the 30-day period after the first claim was filed and filled by patients. We obtained data for single, multiple, and all attempts. For a drug that is approved by the health plan on the first try, this would be counted as a single attempt. For a drug that is first rejected, and other attempt(s) are made to fill, if approved, it will be counted as multiple attempts.
   - Rejection rates: Proportion of new-to-brand prescriptions that were rejected by payers during the 30-day period after the first claim was filed. Rejection rates were broken down into three rejection reasons: non-coverage (the drug is not covered under the plan), need for prior authorization or step therapy, or administrative errors. We obtained data for single, multiple, and all attempts.
   - Reversal rates: Once a drug is filled by the pharmacy, the final step is for the patient to pick up the drug at the pharmacy (also called “dispensed”). Reversal rate is the proportion of prescriptions that were filled by the pharmacy but not picked up by the patient within the 30-day period after the first claim was filed (i.e., the claim was “reversed”).

(c) Out-of-pocket costs: The actual amount the patient paid for a prescription or infused drug. Reported for both outpatient and provider-administered drugs.

All data, for both prescription and provider-administered drugs, were stratified by payer type (commercial, Medicare, and Medicaid). Data for each drug were aggregated over one-year post-FDA approval. Therefore, we could not ascertain whether fill rates changed over time based on changes in health plan coverage policies.

Prescription Volume

Tables 4.1 and 4.2 show the final cohort of outpatient prescription drugs (i.e., filled at outpatient pharmacies) and provider-administered drugs, across commercial, Medicare, and Medicaid claims for each drug one-year post approval. For the 26 outpatient pharmacy drugs, the volume of new-to-brand written prescriptions in the first year after approval varied widely, ranging from 31 (Alhemo for treatment of Hemophilia) to more than 200,000 (Journavx, a non-opioid pain medication). The proportion of prescriptions dispensed (prescriptions filled and picked up by the patient within 30 days) also varied, from 1% for Crenessity (for the treatment of classic Congenital Adrenal Hyperplasia) and Tryngolza (for the treatment of familial chylomicronemia syndrome) to 78% for Alyftrek (for the treatment of cystic fibrosis). There was wide variation even within drug class – for example, the proportion of prescriptions dispensed ranged from 21% to 73% for oncology drugs, and between 1% and 78% for orphan drugs.

For provider-administered drugs (n=10), Table 4.2 shows the number of new-to-brand prescriptions dispensed in the first year after approval. Kisunla, for the treatment of Alzheimer's disease, was the most commonly dispensed provider-administered drug with more than 16,000 prescriptions dispensed in the first year after approval.

Table 4.1. Drugs in Scope with Available Data, Outpatient Pharmacy Drugs

Drug Name	Indication	Total New-to-Brand Written Prescriptions*	Proportion of Prescriptions Dispensed†
Journavx (suzetrigine)	Acute Pain	251,696	55%
Tryptyr (acoltremon)	Dry Eye Disease	94,944	28%
Nemluvio (nemolizumab-ilto)	Atopic Dermatitis	22,210	57%
Cobenfy (xanomeline and trospium chloride)	Schizophrenia	21,286	73%
Ebglyss (lebrikizumab-lbkz)	Atopic Dermatitis	12,409	58%
Livdelzi (seladelpar)	Primary Biliary Cholangitis	3,602	56%
Alyftrek (vanzacaftor, tezacaftor, and deutivacaftor)	Cystic Fibrosis	2,597	78%
Attruby (acoramidis)	ATTR-CM	2,462	54%
Voranigo (vorasidenib)	Brain Cancer	1,874	72%
Itovebi (inavolisib)	Breast Cancer	789	73%
Lazcluze (lazertinib)	Non-Small Cell Lung Cancer	770	59%
Blujepa (gepotidacin)	Urinary Tract Infection	574	41%
Yorvipath (palopegteriparatide)	Hypoparathyroidism	503	42%
Revuforj (revumenib)	Leukemia	401	59%
Ibtrozi (taletrectinib)	Non-Small Cell Lung Cancer	370	72%
Andembry (garadacimab-gxii)	Hereditary Angioedema	339	63%
Gomekli (mirdametinib)	Neurofibromatosis Type 1	274	63%
Aqneursa (levacetylleucine)	Niemann-Pick Disease Type C	250	68%
Miplyffa (arimoclomol)	Niemann-Pick Disease Type C	146	35%
Crenessity (crinecerfont)	Congenital Adrenal Hyperplasia	142	1%
Avmapki Fakzynja Co-Pack (avutometinib and defactinib)	Low-Grade Serous Ovarian Cancer	136	21%
Tryngolza (olezarsen)	Familial Chylomicronemia Syndrome	136	1%
Romvimza (vimseltinib)	Tenosynovial Giant Cell Tumor	120	35%
Vanrafia (atrasentan)	IgA Nephropathy	89	6%
Hympavzi (marstacimab-hncq)	Hemophilia A & B	35	49%
Alhemo (concizumab-mtci)	Hemophilia A & B	31	55%

ATTR-CM: transthyretin amyloid cardiomyopathy

New-to-brand: the first prescription written for a patient.

*Volume is the total number of prescriptions written in the one-year post-approval for each drug, based on FDA approval date, across all payers in scope (commercial, Medicare, Medicaid).

†Prescriptions dispensed are prescriptions that were filled by the pharmacy and picked up by the patient within 30 days after the first claim was filed.

Table 4.2. Drugs in Scope with Available Data, Provider-Administered Drugs

Drug Name	Indication	Provider-Administered Prescriptions Dispensed*
Kisunla (donanemab-azbt)	Alzheimer's Disease	16,223
Enflonsia (clesrovimab-cfor)	Respiratory Syncytial Virus	8,346
Datroway (datopotamab deruxtecan-dlnk)	HR+/HER2- Breast Cancer	2,305
Vyloy (zolbetuximab-clzb)	Stomach Cancer	2,063
Imaavy (nipocalimab-aahu)	Myasthenia Gravis	1,912
Niktimvo (axatilimab-csfr)	Graft vs. Host Disease	1,363
Emrelis (telisotuzumab vedotin-tllv)	Non-Small Cell Lung Cancer	1,016
Ziihera (zanidatamab-hrii)	Biliary Tract Cancer	202
Encelto (revakinagene taroretcel-lwey)	Idiopathic Macular Telangiectasia Type 2	51
Ryoncil (remestemcel-L-rknd)	Graft vs. Host Disease	16

HR+/HER2-: hormone receptor positive/human epidermal growth factor receptor 2 negative

*For provider-administered drugs, the LAAD database does not contain information on number of prescriptions written, only number dispensed (i.e., patient received the injection or infusion). This number is the total number of prescriptions dispensed in the first-year post-approval, based on FDA approval date.

Prescription Adjudication

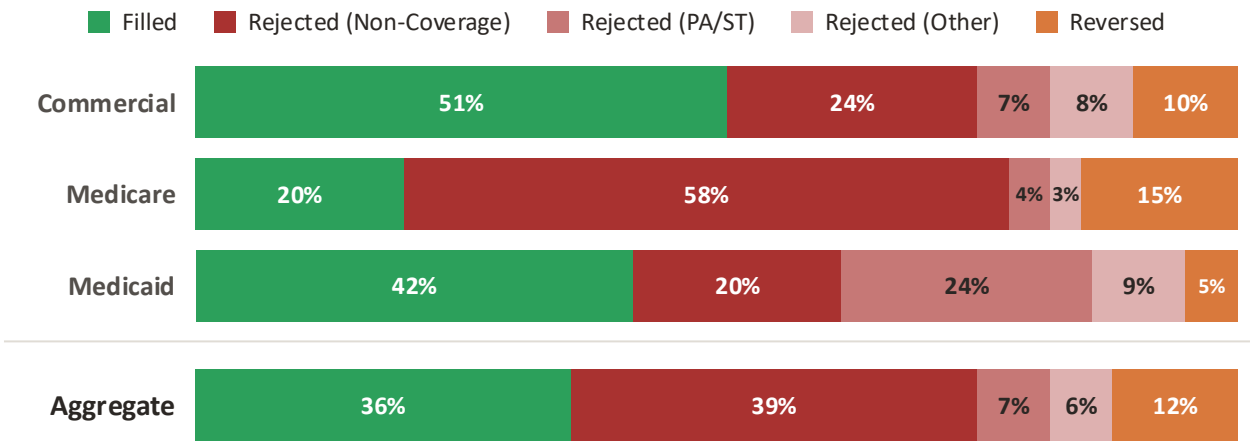
Prescription adjudication outcomes and potential prior authorization burden are described below for outpatient pharmacy prescription drugs. As noted above, medical claims for provider-administered drugs do not contain comparable adjudication metrics, so we cannot determine whether prior authorization was a barrier to patients obtaining these treatments.

Prescription Adjudication Outcomes for Outpatient Pharmacy Prescription Drugs

Overall, for the 26 outpatient pharmacy drugs with sufficient data for analysis, we found that a little more than one-third of new-to-brand prescriptions were ultimately filled within a 30-day period, and just over half of all prior authorization requests were rejected (Figure 4.2). Fill rates varied by payer type, with prescriptions billed to commercial insurers and Medicaid more likely to be approved than those billed to Medicare. Almost two-thirds of prescriptions billed to Medicare were rejected within 30 days of the initial claim being filed (Figure 4.2), most frequently due to non-coverage or prior authorization requirements not met in that timeframe. One of the most common reasons for non-coverage after a drug's initial approval is a new-to-market block, where a health plan does not issue a coverage policy for a period of time after approval (typically 6-12 months) in order to evaluate the drug, write a coverage policy, and decide on formulary placement. With aggregated data, we were not able to understand whether rates of rejection for non-coverage varied over the one-year period – i.e., whether the observed high rejection rates occurred in the

first six months when new-to-market blocks may have been present, and then if rejection rates shifted with coverage policy changes.

Figure 4.2. Summary of Adjudication for New-to-Brand Outpatient Pharmacy Prescriptions



PA: prior authorization, ST: step therapy

When examining prescription fill rates drug-by-drug across all payers (Table 4.3), overall fill rates varied widely from 1% to 66% in the 30-day timeframe after the first claim was filed. If a prescription was not filled, we obtained data on reasons for non-fill, including rejection for non-coverage, prior authorization or step therapy requirements, or administrative reasons (e.g., prior authorization form incorrectly filled out). Prescription claims that were initially rejected could be resubmitted multiple times if needed before final adjudication. Rejection of a prescription can be a marker for how difficult it is to fill, and rejection rates varied across drugs. Almost all prescriptions (around 90%) were rejected for Tryngolza and Crenessity during the 30-day timeframe, likely due to the fact that there are inexpensive generic alternative treatments available for these conditions. On the other hand, rejection rates were much lower (mainly in the 20-35% range) for oncology drugs, where alternatives may or may not be available, and where utilization management is less common.

Finally, prescription reversals (prescriptions that are written, submitted to the payer and approved, but not picked up from the pharmacy) indicate potential barriers beyond prior authorization – for example, out-of-pocket costs that are not affordable to the patient or difficulty getting to the pharmacy and picking up a prescription. Prescription reversal rates were ≥20% for almost half of the 26 drugs in scope (n=11) and ≥10% for more than half the drugs (n=19). Overall, 12% of prescriptions were reversed, meaning that despite payer approval and the pharmacy dispensing the drug, about one in eight patients did not receive the prescribed treatment within 30 days of the initial prescription. This is indicative that there may be barriers to access beyond payer coverage.

Table 4.3. 30-Day Drug-by-Drug Prescription Adjudication, Sorted by Fill Rates, Across All Payers

Drug Name	Indication	Total New-to-Brand Prescriptions Attempted	Filled	Rejected	Reversed*
Ibtrozi (taletrectinib)	Non-Small Cell Lung Cancer	212	66%	16%	18%
Itovebi (inavolisib)	Breast Cancer	405	59%	22%	19%
Cobenfy (xanomeline and trospium chloride)	Schizophrenia	14,938	58%	34%	8%
Alyftrek (vanzacaftor, tezacaftor, and deutivacaftor)	Cystic Fibrosis	1,217	52%	39%	9%
Livdelzi (seladelpar)	Primary Biliary Cholangitis	2,129	51%	27%	22%
Lazcluze (lazertinib)	Non-Small Cell Lung Cancer	473	49%	29%	23%
Gomekli (mirdametinib)	Neurofibromatosis Type 1	134	48%	31%	21%
Voranigo (vorasidenib)	Brain Cancer	932	43%	27%	30%
Revuforj (revumenib)	Leukemia	219	43%	34%	23%
Attruby (acoramidis)	ATTR-CM	1,302	42%	36%	22%
Journavx (suzetrigine)	Acute Pain	175,475	39%	52%	7%
Alhemo (concizumab-mtci)	Hemophilia A & B	19	37%	58%	5%
Yorvipath (palopegteriparatide)	Hypoparathyroidism	367	36%	42%	22%
Ebglyss (lebrikizumab-lbkz)	Atopic Dermatitis	5,562	32%	52%	16%
Romvimza (vimseltinib)	Tenosynovial Giant Cell Tumor	67	31%	34%	34%
Blujepa (gepotidacin)	Urinary Tract Infection	456	30%	51%	19%
Nemluvio (nemolizumab-ilto)	Atopic Dermatitis	11,078	28%	53%	19%
Andembry (garadacimab-gxii)	Hereditary Angioedema	131	27%	61%	12%
Hympavzi (marstacimab-hncq)	Hemophilia A & B	13	23%	69%	8%
Tryptyr (acoltremon)	Dry Eye Disease	56,731	22%	52%	26%
Aqneursa (levacetylleucine)	Niemann-Pick Disease Type C	131	19%	78%	3%
Avmapki Fakzynja Co-Pack (avutometinib and defactinib)	Low-Grade Serous Ovarian Cancer	107	17%	42%	41%
Miplyffa (arimoclomol)	Niemann-Pick Disease Type C	66	14%	53%	33%
Vanrafia (atrasentan)	IgA Nephropathy	52	4%	83%	13%
Crenessity (crinecerfont)	Congenital Adrenal Hyperplasia	91	2%	88%	10%

Tryngolza (olezarsen)	Familial Chylomicronemia Syndrome	95	1%	91%	8%

ATTR-CM: transthyretin amyloid cardiomyopathy

*Reversed is the proportion of prescription claims that were approved by insurance and dispensed by the pharmacy but the patient did not pick up the prescription from the pharmacy. The intensity of the color corresponds to relative proportion of prescription claims – darker shading indicates higher proportion of prescriptions claims

Prescription Adjudication Attempts for Outpatient Pharmacy Prescription Drugs

The majority of drugs required multiple submission attempts to a payer before final adjudication. Figure 4.3a presents prescription fill success rate relative to prior authorization burden. A relatively high prescription fill rate with a lower proportion of multiple fill attempts suggests less administrative burden and easier access - these drugs reside in the upper left quadrant of the scatterplot. Drugs in the lower right quadrant show a relatively low prescription fill rate with a high proportion of multiple fill attempts, suggesting that there may be barriers to obtaining the treatment. When looking by payer type (Figure 4.3b-d), we saw similar patterns of most drugs requiring multiple attempts before a successful fill for claims sent to commercial plans or Medicare; fewer drug claims sent to Medicaid appeared to require multiple attempts prior to a successful fill, which may correspond to better access for plan-covered drugs.

As a class, oncology drugs had a high rate of requiring prior authorization, with rates of requiring multiple fill attempts in the 70-82% range for all oncology drugs. Both Hemophilia A & B drugs had high rates of successful fills on the first attempt, likely because these drugs are considered first-line therapy for bleeding prophylaxis, and thus restrictions on use are less likely. In disease areas where there are multiple treatment choices, including generic drugs (e.g., atopic dermatitis, schizophrenia, pain, dry eye disease), prior authorization burden appeared to be higher and successful fill rates were lower (20-40% range). This was also true of treatments for rare diseases such as Tryngolza, Andembry, Gomekli, Aqneursa, and Miplyffa, where prior authorization appeared to be the norm, and overall fill rates were less than 50%. In particular, 91% of prescriptions for Tryngolza for familial chylomicronemia were rejected, mainly due to non-coverage.

Adjudication decisions also varied by payer. For example, for Tryptyr for dry eye disease, fill rates for Medicare were much lower than for either commercial payers or Medicaid (14% Medicare vs. 29% commercial and 32% Medicaid), with non-coverage being the most common reason for a rejected claim for Medicare recipients. Of note, these are aggregate data over one year; coverage policies may change throughout the year and access may have increased or decreased throughout the year with coverage policy changes.

Figure 4.3a. Prescription Fill Rate vs. Prior Authorization Burden, Aggregate

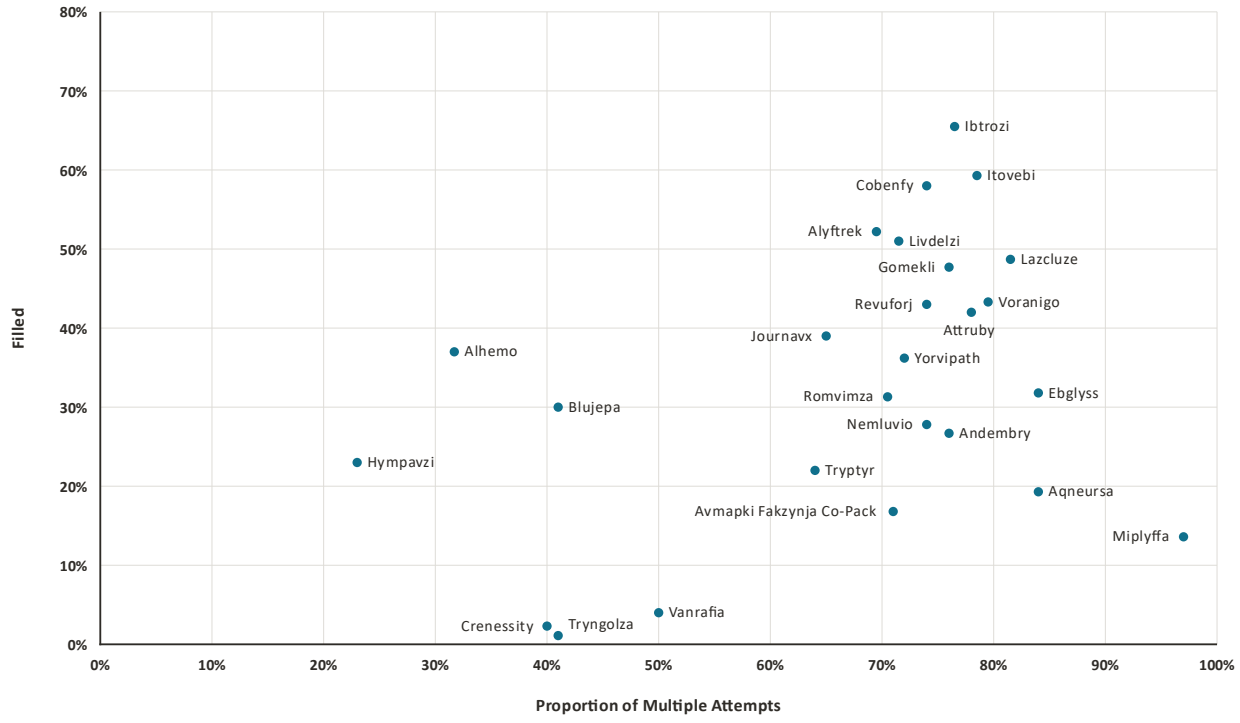


Figure 4.3b. Prescription Fill Rate vs. Prior Authorization Burden, Commercial Payers

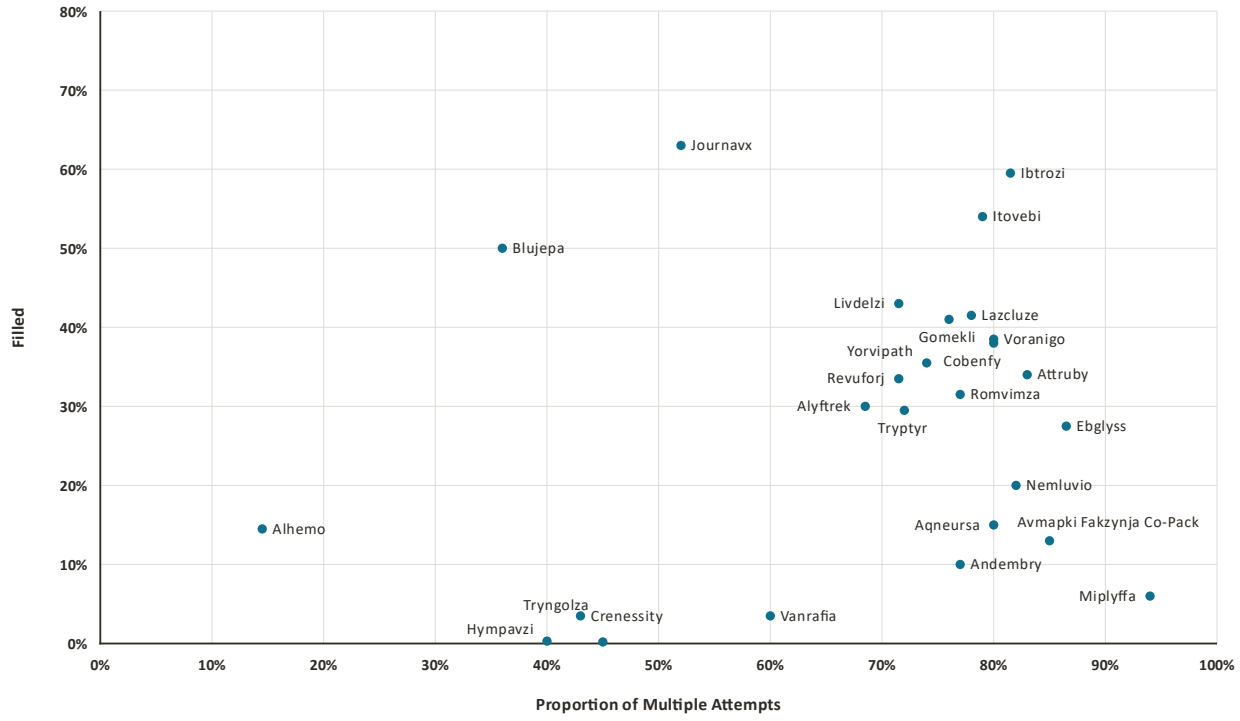


Figure 4.3c. Prescription Fill Rate vs. Prior Authorization Burden, Medicare

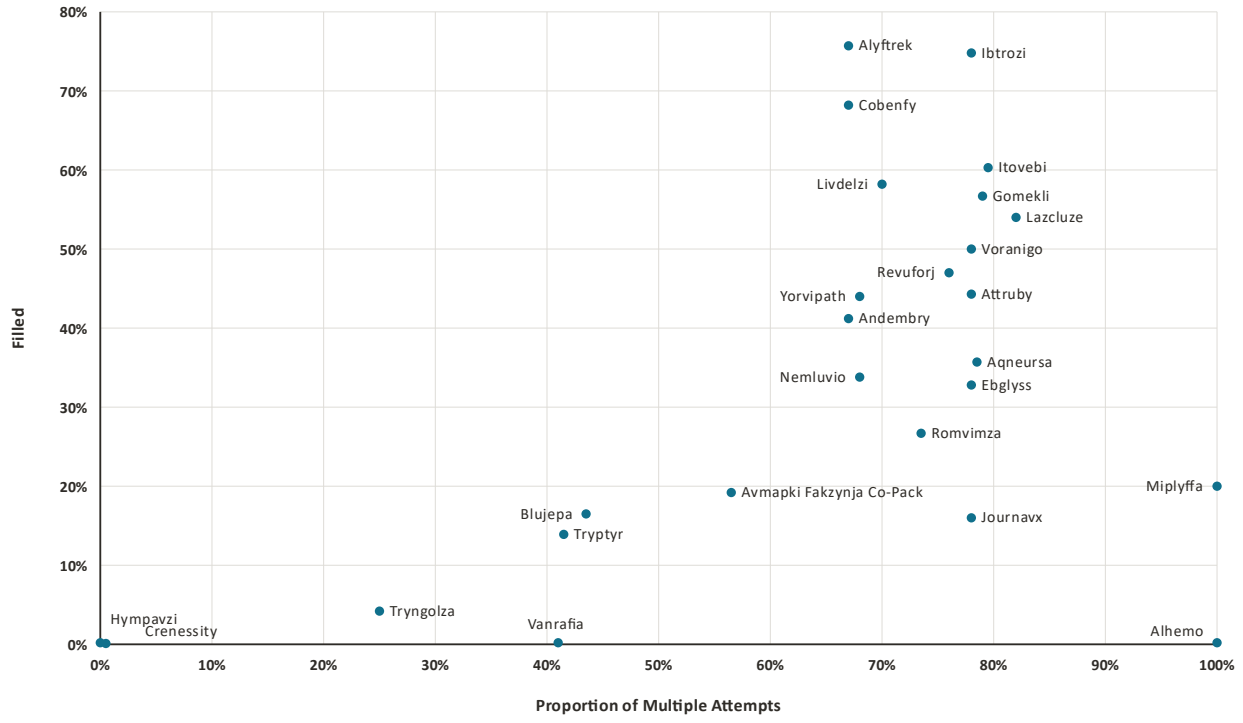
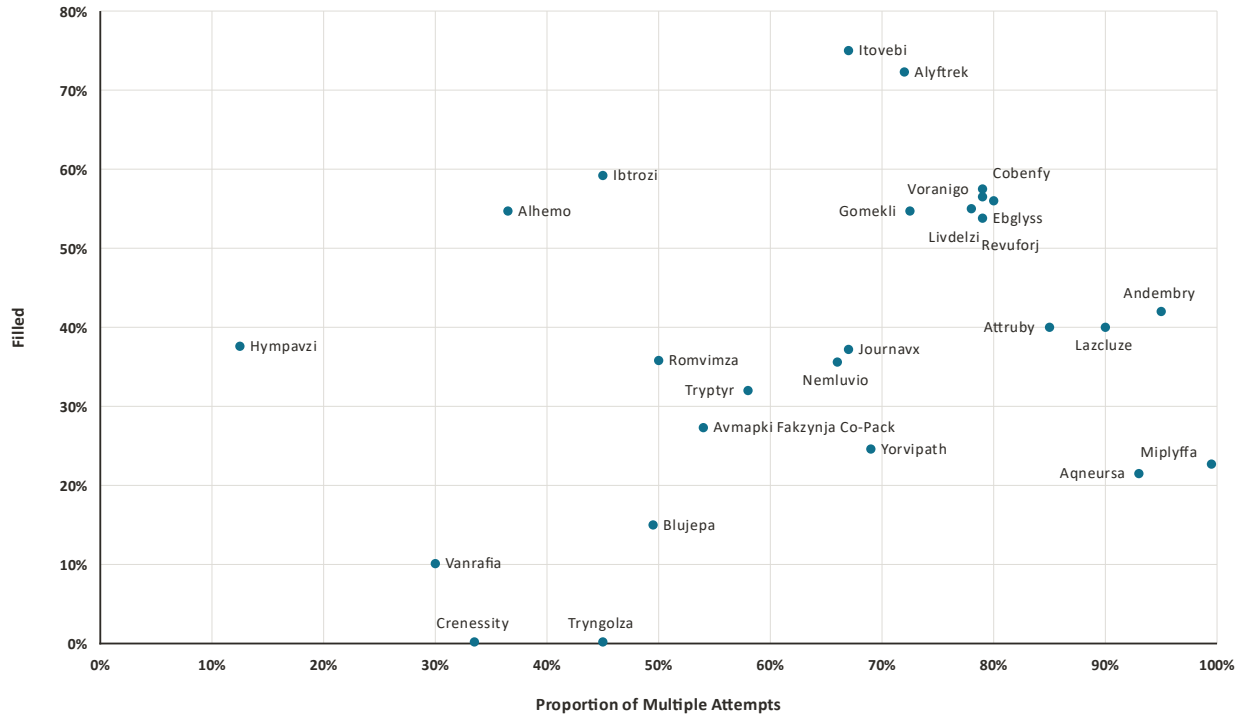


Figure 4.3d. Prescription Fill Rate vs. Prior Authorization Burden, Medicaid



Patient Out-of-Pocket Costs

We obtained patient out-of-pocket costs, in ranges and by payer, for each drug (Appendix Tables B2.4-B2.7). From those data, we calculated a monthly weighted average of patient out-of-pocket costs for each drug, by payer type (Tables 4.4 and 4.5). For most outpatient pharmacy drugs, Medicaid-paid claims generated the lowest out-of-pocket costs, often costing the patient less than $1 per month, consistent with statutory limitations on cost-sharing in Medicaid. Claims paid by Medicare generally had higher out-of-pocket costs for most drugs, often two to five times those for claims paid by commercial health plans. There are several possible explanations for this difference. This may reflect, in part, the prohibition of patient assistance programs such as copay cards for those with Medicare. For example, for Avmapki, out-of-pocket costs for claims paid by Medicare were more than five times higher than claims paid by commercial plans ($614.50 vs. $122.38).

A breakdown of out-of-pocket costs for outpatient pharmacy drugs reveals that 71% of claims paid by commercial plans had a $0 out-of-pocket cost compared with 48% for claims paid by Medicare. Another reason for higher Medicare out-of-pocket costs could be that prior to January 1, 2025, there was no cap on out-of-pocket costs for Medicare Part D; these data reflect a mix of the period before the out-of-pocket cap (2H2024) and the period after it (1H2025). This may be one reason why 28% of claims paid by Medicare generated more than $1,500 in out-of-pocket costs, compared with 5% for commercial claims. Finally, with aggregated data, we were unable to determine whether or not a patient had met their deductible and maximum out-of-pocket cost limits at the time the prescription was written. This may explain some of the variation in out-of-pocket costs seen within each drug (Appendix Tables B2.4-B2.7).

Table 4.4. Monthly Weighted Average of Out-of-Pocket Costs, Outpatient Pharmacy

Drug	Indication	Commercial	Medicare	Medicaid
Alhemo (concizumab-mtci)	Hemophilia A & B	$4.65	$0.00	$1.40
Alyftrek (vanzacaftor, tezacaftor, and deutivacaftor)	Cystic Fibrosis	$17.48	$0.00	$0.15
Andembry (garadacimab-gxii)	Hereditary Angioedema	$148.58	$120.25	$0.65
Aqneursa (levacetylleucine)	Niemann-Pick Disease Type C	$22.03	$79.41	$0.05
Attruby (acoramidis)	ATTR-CM	$126.05	$125.83	$1.05
Avmapki Fakzynja Co-Pack (avutometinib and defactinib)	Low-Grade Serous Ovarian Cancer	$122.38	$614.50	$1.55
Blujepa (gepotidacin)	Urinary Tract Infection	$86.35	$267.78	$1.65
Cobenfy (xanomeline and trospium chloride)	Schizophrenia	$84.80	$20.10	$0.60
Crenessity (crinecerfont)*	Congenital Adrenal Hyperplasia	-	-	-
Ebglyss (lebrikizumab-lbkz)	Atopic Dermatitis	$320.18	$370.40	$0.75

Drug	Indication	Commercial	Medicare	Medicaid
Gomekli (mirdametinib)	Neurofibromatosis Type 1	$68.05	$71.81	$0.15
Hympavzi (marstacimab-hncq)	Hemophilia A & B	-	-	-
Ibtrozi (taletrectinib)	Non-Small Cell Lung Cancer	$81.05	$182.80	$0.75
Itovebi (inavolisib)	Breast Cancer	$49.58	$58.28	$1.55
Journavx (suzetrigine)	Acute Pain	$50.43	$77.28	$2.25
Lazcluze (lazertinib)	Non-Small Cell Lung Cancer	$55.40	$239.57	$0.90
Livdelzi (seladelpar)	Primary Biliary Cholangitis	$92.03	$102.48	$1.25
Miplyffa (arimoclomol)	Niemann-Pick Disease Type C	$223.33	$0.20	$0.00
Nemluvio (nemolizumab-ilto)	Atopic Dermatitis	$98.38	$363.74	$20.66
Revuforj (revumenib)	Leukemia	$30.35	$64.68	$0.55
Romvimza (vimseltinib)	Tenosynovial Giant Cell Tumor	$124.58	$485.25	$0.35
Tryngolza (olezarsen)*	Familial Chylomicronemia Syndrome	-	-	-
Tryptyr (acoltremon)	Dry Eye Disease	$72.28	$252.00	$0.80
Vanrafia (atrasentan)*	IgA Nephropathy	-	-	-
Voranigo (vorasidenib)	Brain Cancer	$60.45	$284.25	$0.50
Yorvipath (palopegteriparatide)	Hypoparathyroidism	$84.90	$174.98	$1.50

Note: Out-of-pocket cost data were not available for drugs indicated by a dash.

Provider-administered drugs are most likely administered in a hospital setting or an outpatient infusion center, which increases the cost of administration and may account for the high out-of-pocket costs observed with some of these drugs (Table 4.5). Patients with traditional Medicare are subject to co-insurance under Medicare Part B (which is not subject to an out-of-pocket maximum), and thus pay a percentage of drug costs rather than a flat copay. For high-cost infusions, this can result in high out-of-pocket costs. Interestingly, for two drugs, Datroway and Kisunla, Medicaid patients had higher out-of-pocket costs than the other two forms of insurance. This could be due to cost-sharing rules that allow states to charge up to 20% of the cost of a non-preferred drug for people whose income is above 150% of federal poverty level.[56]

Table 4.5. Monthly Weighted Average of Out-of-Pocket Costs, Provider-Administered Drugs

Drug	Indication	Commercial	Medicare	Medicaid
Datroway® (datopotamab deruxtecan-dlnk)	HR+/HER2- Breast Cancer	$15.07	$48.00	$165.18
Emrelis™ (telisotuzumab vedotin-tllv)	Non-Small Cell Lung Cancer	$83.82	$225.62	$0.00
Encelto® (revakinagene taroretcel-lwey)	Idiopathic Macular Telangiectasia Type 2	$505.00	-	-
Enflonsia™ (clesrovimab-cfor)	Respiratory Syncytial Virus	$182.47	-	-
Imaavy™ (nipocalimab-aahu)	Myasthenia Gravis	$355.03	$320.11	$0.00
Kisunla™ (donanemab-azbt)	Alzheimer's Disease	$16.33	$135.96	$297.76
Niktimvo™ (axatilimab-csfr)	Graft vs. Host Disease	$68.67	$208.53	$0.00
Ryoncil® (remestemcel-L-rknd)	Graft vs. Host Disease	-	-	-
Vyloy® (zolbetuximab-clzb)	Stomach Cancer	-	$149.25	$1.28
Ziihera® (zanidatamab-hrii)	Biliary Tract Cancer	-	$1,317.07	-

HR+/HER2-: hormone receptor positive/human epidermal growth factor receptor 2 negative
Note: Out-of-pocket costs were not available for some drugs or some payers.

4.3. Potential Barriers to Access

To examine potential barriers to access in more detail, we selected eight of the drugs in our cohort, including three previously ICER-reviewed drugs (Attruby, Cobenfy, and Journavx), four outpatient pharmacy prescription drugs with a high burden of multiple fill attempts and low prescription fill rates (Ebglyss, Nemluvio, Aqneursa, and Miplyffa), and the most commonly dispensed provider-administered drug (Kisunla) (Table 4.6). For each drug, in addition to evaluating real-world access and out-of-pocket costs, we evaluated the concordance of the coverage policies of the top five US health plans (see Section 2) with ICER's Fair Access criteria.

ICER's Cornerstones of Fair Access criteria evaluate four areas of payer coverage policies: clinical eligibility, step therapy, provider restriction, and cost-sharing to patients (see Appendix B2 for detailed criteria). For each of the eight drugs, we analyzed coverage policies and judged whether: (1) clinical eligibility criteria matched the FDA label or were appropriately narrowed; (2) step therapy was clinically appropriate and had fewer than three steps; and (3) provider restrictions, if any, were appropriate. We were not able to judge the fourth main criteria, whether cost-sharing was appropriate, because we lacked specific formulary placement information. Concordance with Fair Access criteria should indicate a coverage policy and utilization management program that results in evidence-based, clinically appropriate, and timely care for patients. By correlating coverage policy analysis with real-world prescription data, we can get a sense of the impact of the implementation of coverage policies on access to treatment.

We also attempted, in partnership with the National Health Council, to survey patients who received a prescription for one of the eight drugs of interest to ascertain experiences with and barriers to obtaining one of the eight drugs. However, the survey response rate was low, and we were unable to reliably distinguish responses from real patients from survey bots. Therefore, we have not included any survey data in this report.

Table 4.6. Drugs in Scope for Potential Barriers to Access Analyses

Drug	Indication
Attruby (acoramidis)	ATTR-CM
Cobenfy (xanomeline and trospium chloride)	Schizophrenia
Journavx (suzetrigine)	Acute Pain
Kisunla (donanemab-azbt)	Alzheimer's Disease
Ebglyss (lebrikizumab-lbkz)	Atopic Dermatitis
Nemluvio (nemolizumab-ilto)	Atopic Dermatitis
Aqneursa (levacetylleucine)	Niemann-Pick Disease Type C
Miplyffa (arimoclomol)	Niemann-Pick Disease Type C

ATTR-CM: Transthyretin Amyloid Cardiomyopathy

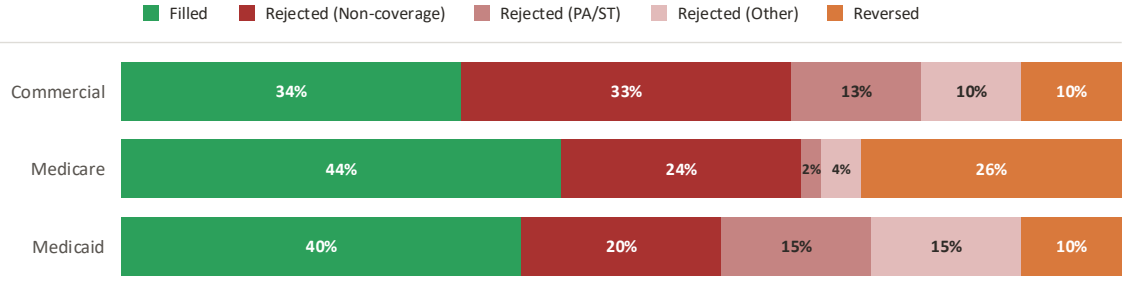
Attruby for ATTR-CM

Attruby was approved by the FDA in November 2024 for transthyretin amyloid cardiomyopathy (ATTR-CM) and was the subject of an ICER review in September 2024. ICER rated Attruby as having at least a small net health benefit compared to no treatment, and insufficient evidence to distinguish it from other available treatments for the same condition. Based on the evidence at launch and the net price of approximately $190,000 annually, ICER estimated it would require substantial discounts of 80-92% to be considered fairly priced (see Table 3.7). When considering real-world outpatient pharmacy claims in the first year after launch, prescriptions for Attruby were filled 42% of the time within 30 days, across all payers, with prescriptions sent to Medicare and Medicaid more likely to be filled compared with prescriptions sent to commercial payers (Figure 4.4).

We evaluated coverage policies from the top five payers by covered lives, and found that for Attruby, coverage policies from all payers were concordant with ICER's Fair Access criteria for clinical eligibility rules, step therapy, and prescriber restrictions. However, even though coverage policies appeared to be consistent with fair access, adjudication data from payers (Figure 4.4) show that more than half of prescriptions were rejected. The majority of rejections were due to non-coverage. This may be a reflection of new-to-market blocks that many payers employ immediately post-FDA approval. Because our data are aggregated over one year, we are not able to pinpoint whether coverage improved over time, which may be suggested by a manufacturer study that noted that more than 90% of Medicare Part D plans covered Attruby by August 2025, nine months after approval.[57] However, ICER's Fair Access criteria call for formal coverage to be instituted within three months of approval,[10] so a nine-month delay would be considered excessive and a barrier to timely access to the drug.

Figure 4.4. Prescription Adjudication and Coverage Policy Concordance for Attruby

A. Real-World Adjudication Outcomes by Payer Type



B. Coverage Policy Concordance with ICER's Fair Access Criteria

Drug	Clinical Eligibility	Step Therapy	Prescriber Restriction
Attruby (acoramidis)	(5/5) 100%	(5/5) 100%	(5/5) 100%

C. Real-World Patient Out-of-Pocket Cost (Copay/Co-insurance) by Payer Type

Payer Type	$0	$1–$50	$51–$250	$251–$1,500	$1,500+	Weighted Average
Commercial	59%	7%	28%	1%	5%	**$126.05**
Medicare	87%	2%	2%	4%	4%	**$125.83**
Medicaid	79%	21%	0%	0%	0%	**$1.05**

PA: prior authorization, ST: step therapy

Adjudication outcomes and patient out-of-pocket costs are based on real-world pharmacy claims data from IQVIA's LAAD database, from 2H2024 and 1H2025.

Coverage policy concordance is based on ICER's analysis of coverage policies from the top five US payers by covered lives.

Another common reason for rejection was step therapy, impacting between 2-15% of prescriptions depending on payer type. This is likely because there are older, more established drugs available to treat ATTR-CM. Given that ICER's review of Attruby indicated that there was insufficient evidence to distinguish net health benefits between Attruby and two older drugs,[43] requiring step therapy through one of the older drugs as a broader evidence-based approach to negotiate lower prices is not unreasonable. As our evaluation of coverage policies indicates, this is being done in a way that meets the Fair Access criteria. Finally, between 10-20% of prescriptions were reversed, meaning that a payer approved the drug but the pharmacy never dispensed the drug. While there may be several reasons for reversal, high out-of-pocket costs can make the drug unaffordable even with insurance coverage. From the patient out-of-pocket cost data, we observed an average cost to those with commercial insurance and Medicare of around $125. Furthermore, 28% of patients covered by commercial insurance had an out-of-pocket cost between $51 and $250, and 5% of patients with commercial insurance and 4% of patients with Medicare had out-of-pocket costs of $1,500 or more. However, even with very little cost sharing for Medicaid patients, 10% of prescriptions were reversed, indicating there may be other reasons for reversal that require further investigation.

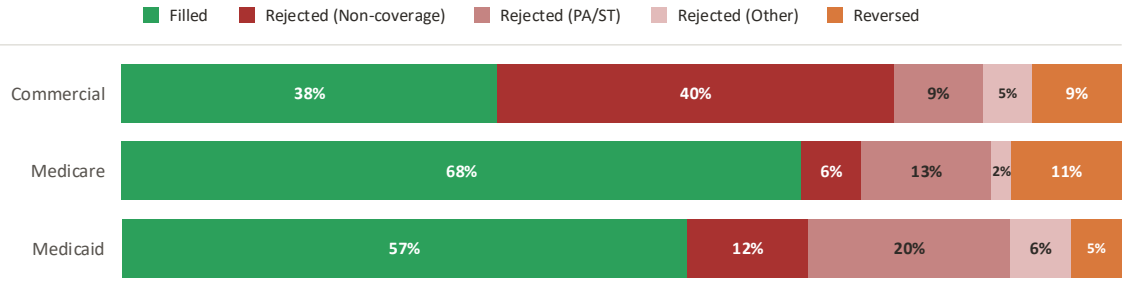
Cobenfy for Schizophrenia

Cobenfy was approved by the FDA in September 2024 and was the subject of an ICER review in February 2024. Based on clinical evidence at launch, ICER concluded that the net health benefit of Cobenfy was promising but inconclusive against no treatment and older antipsychotics, and inconclusive compared to aripiprazole. At an annual launch net price of about $18,400, Cobenfy was considered to be fairly priced. Our evaluation of coverage policies at least one year post-approval showed that the five payers evaluated achieved concordance with ICER's Fair Access criteria. Real-world one-year post-approval data showed substantial variation in fill rates in the 30 days after the first prescription claim was filed; more than half of prescriptions adjudicated by Medicaid and two-thirds of prescriptions adjudicated by Medicare were ultimately filled, and less than 10% of prescriptions were rejected due to non-coverage (4% for Medicare, 9% for Medicaid). However, the majority of Cobenfy outpatient pharmacy prescriptions (54%) sent to commercial health plans for adjudication were rejected (Figure 4.5). Of those rejections, the majority (40%) were due to non-coverage. We are not able to assess rejections due to non-coverage over time, so it may be that many of the rejections came early after launch, when many payers have a new-to-market block. Almost 10% of rejections for commercial plans were due to step therapy. We found that some policies required failure, contraindication, or intolerance to at least three atypical antipsychotics prior to approval of Cobenfy. Although this technically meets the Fair Access criteria of three or fewer steps, patient groups stated during the ICER review that there are substantial barriers to finding care and staying on medication, so needing to try multiple medications may delay access.[44]

For Cobenfy, reversal rates were lowest for people with Medicaid, and higher for people with Medicare and commercial insurance. This could in part be explained by differences in out-of-pocket costs – patients with commercial insurance paid, on average, more than four times the amount that Medicare patients did, and more than 100 times the amount charged to Medicaid patients. Only 66% of patients with commercial insurance paid $20 or less for Cobenfy, while 97% of patients with Medicare and 100% of patients with Medicaid paid $20 or less per prescription. ICER's Fair Access criteria state that for a fairly priced drug, insurance plans should place at least one drug in the class on the lowest relevant cost-sharing tier.[10] Since Cobenfy is a first-in-class medication and fairly priced, it should be placed on the lowest tier for a branded drug, minimizing out-of-pocket costs. While $20 per month may not seem like a high amount, many people living with schizophrenia earn less than $50,000 a year despite working full-time,[58] or have housing instability or are unemployed and therefore unable to afford medication that costs more than a few dollars.[9] Thus, even a modest out-of-pocket cost could be challenging to meet.

Figure 4.5. Prescription Adjudication and Coverage Policy Concordance for Cobenfy

A. Real-World Adjudication Outcomes by Payer Type



B. Coverage Policy Concordance with ICER's Fair Access Criteria

Drug	Clinical Eligibility	Step Therapy	Prescriber Restriction
Cobenfy (xanomeline and trospium chloride)	(5/5) 100%	(5/5) 100%	(5/5) 100%

C. Real-World Patient Out-of-Pocket Cost (Copay/Co-insurance) by Payer Type

Payer Type	$0	$1–$50	$51–$250	$251–$1,500	$1,500+	Weighted Average
Commercial	63%	10%	22%	4%	2%	**$84.80**
Medicare	80%	17%	1%	3%	0%	**$20.10**
Medicaid	88%	12%	0%	0%	0%	**$0.60**

PA: prior authorization, ST: step therapy

Adjudication outcomes and patient out-of-pocket costs are based on real-world pharmacy claims data from IQVIA's LAAD database, from 2H2024 and 1H2025.

Coverage policy concordance is based on ICER's analysis of coverage policies from the top five US payers by covered lives.

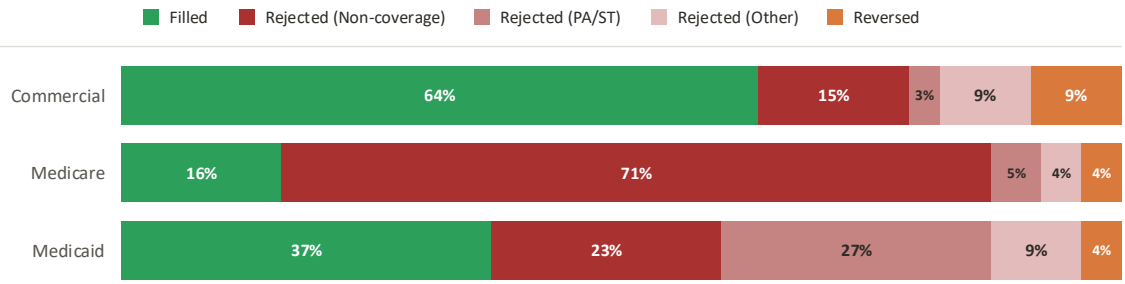
Journavx for Acute Pain

Journavx was approved by the FDA in January 2025 as a non-opioid medication for acute pain. It was the subject of an ICER review in March 2025. Based on clinical evidence at launch, ICER concluded that the net health benefit of Journavx was promising but inconclusive against other non-opioid and opioid treatments and that, based on the evidence at launch, the estimated net price would be cost-saving compared with opioids when used for acute pain (See Table 3.7). In examining the most current coverage policies, we found that all five plans met ICER's criteria for Fair Access in terms of clinical eligibility, step therapy, and prescriber restrictions (Figure 4.6). However, when evaluating prescription adjudication outcomes for Journavx during the one-year post-approval period, we found that commercial payers were more likely to approve Journavx prescriptions in the 30 days after the first claim was filed than Medicare and Medicaid (63% commercial vs. 16% Medicare and 37% Medicaid) (Figure 4.6). The majority (71%) of prescriptions to Medicare were rejected due to non-coverage, likely reflecting the limited coverage by Medicare plans at launch. We do not know if Medicare plans started to implement policies within three months of approval, which would be a reasonable time frame. However, the high number of rejections for non-coverage suggest that this is not the case. Thus, even if some policies suggest fair access to a drug but only a few plans have coverage, the barriers to obtaining the drug may remain high.

For those with insurance coverage, out-of-pocket costs for Journavx were relatively modest. The majority of patients with any kind of insurance coverage paid $40 or less monthly, with weighted average out-of-pocket costs between $2 and $77. Although a little more than half of Medicare recipients with coverage had $0 out-of-pocket cost for Journavx (52%), for the remaining 48%, out-of-pocket costs were higher than either commercial insurance or Medicaid. Finally, of all outpatient pharmacy drugs in scope, Journavx had the greatest number of cash pay prescriptions over the first year, with nearly two thousand new-to-brand prescriptions dispensed during the year. The majority (87%) of people paying cash for Journavx paid $250 or more for treatment, with 72% paying more than $500 for treatment (Appendix Table B2.7). This may reflect a mismatch between prescriber adoption of a new, effective therapy and payer policies that lag behind clinical practice.

Figure 4.6. Prescription Adjudication and Coverage Policy Concordance for Journavx

A. Real-World Adjudication Outcomes by Payer Type



B. Coverage Policy Concordance with ICER's Fair Access Criteria

Drug	Clinical Eligibility	Step Therapy	Prescriber Restriction
Journavx (suzetrigine)	(5/5) 100%	(5/5) 100%	(5/5) 100%

C. Real-World Patient Out-of-Pocket Cost (Copay/Co-insurance) by Payer Type

Payer Type	$0	$1–$50	$51–$250	$251–$1,500	$1,500+	Weighted Average
Commercial	13%	76%	8%	3%	0%	**$50.43**
Medicare	52%	20%	17%	11%	0%	**$77.28**
Medicaid	71%	29%	0%	0%	0%	**$2.25**

PA: prior authorization, ST: step therapy

Adjudication outcomes and patient out-of-pocket costs are based on real-world pharmacy claims data from IQVIA's LAAD database, from 2H2024 and 1H2025.

Coverage policy concordance is based on ICER's analysis of coverage policies from the top five US payers by covered lives.

Ebglyss and Nemluvio for Atopic Dermatitis

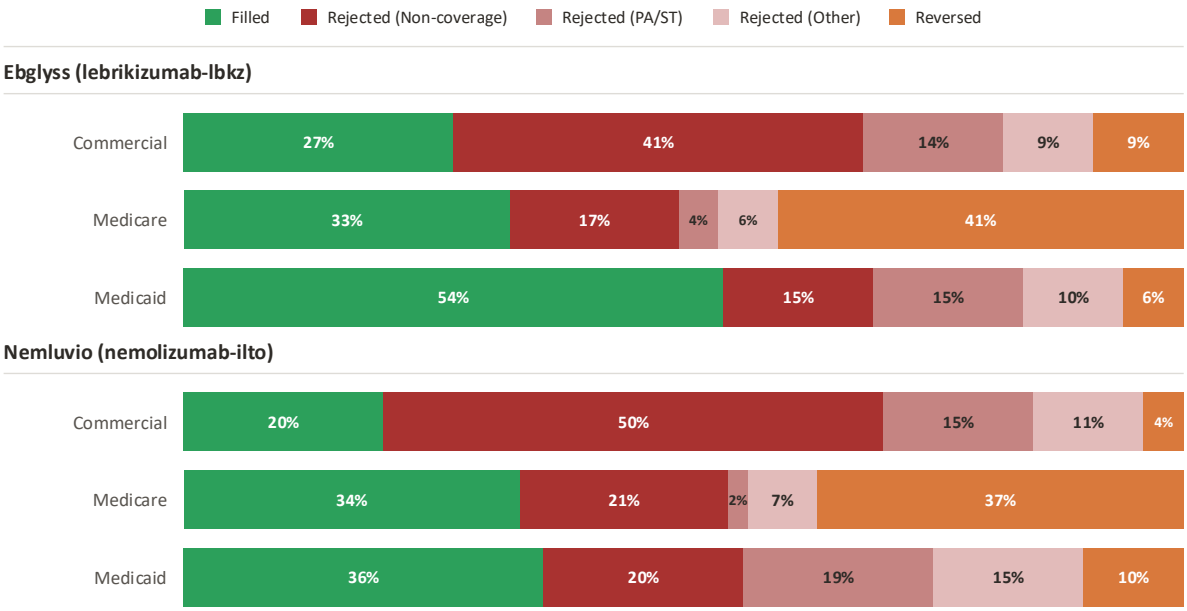
Both Ebglyss and Nemluvio are monoclonal antibody therapies for the treatment of moderate-to-severe eczema, approved in the fall of 2024. The annual net price at launch was $41,622 for Ebglyss and $37,255 for Nemluvio. ICER has not previously reviewed the clinical and cost-effectiveness of these two therapies, although it has previously done a class review of several treatments for atopic dermatitis.[33]

Real-world prescription adjudication data showed variation in fill rates by payer in the 30 days after the first claim was filed. For example, twice as many prescriptions for Ebglyss sent to Medicaid for adjudication were filled compared with commercial payers (54% vs. 27%). Most rejections from commercial payers were due to non-coverage; this may be a reflection of the numerous existing treatments for atopic dermatitis in addition to new-to-market blocks that are commonly employed by payers. Step therapy was also relatively common for commercial and Medicaid plans (14-19% rejections due to step therapy). Evaluation of coverage policies showed that only three out of five plans met ICER's Fair Access criteria for step therapy (Figure 4.7), with those failing to meet criteria either requiring failure of more than three drugs or step therapy that is not consistent with clinical practice guidelines (e.g., requiring step through a drug that is not required by guidelines such as dupilumab, or requiring a trial of at least two topical corticosteroids). Additionally, requiring failure of multiple drugs can cause substantial delays in treatment, affecting disease control.

For people with Medicare, there were very high rates of reversal (prescription filled but was not dispensed to the patient). We also observed that out-of-pocket costs were high for prescriptions covered by Medicare, with a weighted average out-of-pocket cost of more than $350 per prescription for each drug. More than 20% of patients paid $500 or more for either drug, and around 15% paid over $1,500 per month. This may be in part because Medicare recipients are not typically eligible for manufacturer-provided assistance such as copay cards. For many Medicare recipients, who are older and may be on fixed incomes, these high out-of-pocket costs may not be affordable, causing the filled prescriptions not to be picked up at the pharmacy. The Medicare out-of-pocket maximum cap for outpatient prescription drugs covered by Part D went into effect on January 1, 2025, so our data reflect both a period of time prior to the cap (2H2024) and after the cap went into effect (1H2025), although we are not able to distinguish those effects in the current dataset.

Figure 4.7. Prescription Adjudication and Coverage Policy Concordance for Ebglyss and Nemluvio

A. Real-World Adjudication Outcomes by Payer Type



B. Coverage Policy Concordance with ICER's Fair Access Criteria

Drug	Clinical Eligibility	Step Therapy	Prescriber Restriction
Ebglyss (lebrikizumab-lbkz)	(5/5) 100%	(5/5) 100%	(5/5) 100%
Nemluvio (nemolizumab-ilto)	(5/5) 100%	**(3/5) 60%**	(5/5) 100%

C. Real-World Patient Out-of-Pocket Cost (Copay/Co-insurance) by Payer Type

Drug	Payer Type	$0	$1–$50	$51–$250	$251–$1,500	$1,500+	Weighted Average
Ebglyss (lebrikizumab-lbkz)	**Commercial**	23%	53%	5%	7%	12%	**$320.18**
	Medicare	70%	5%	4%	6%	15%	**$370.40**
	Medicaid	91%	9%	0%	0%	0%	**$0.75**
Nemluvio (nemolizumab-ilto)	**Commercial**	62%	30%	3%	1%	4%	**$98.38**
	Medicare	68%	6%	4%	8%	14%	**$363.74**
	Medicaid	89%	10%	0%	0%	1%	**$20.66**

PA: prior authorization, ST: step therapy

Adjudication outcomes and patient out-of-pocket costs are based on real-world pharmacy claims data from IQVIA's LAAD database, from 2H2024 and 1H2025.

Coverage policy concordance is based on ICER's analysis of coverage policies from the top five US payers by covered lives.

Aqneursa and Miplyffa for Niemann-Pick Type C Disease

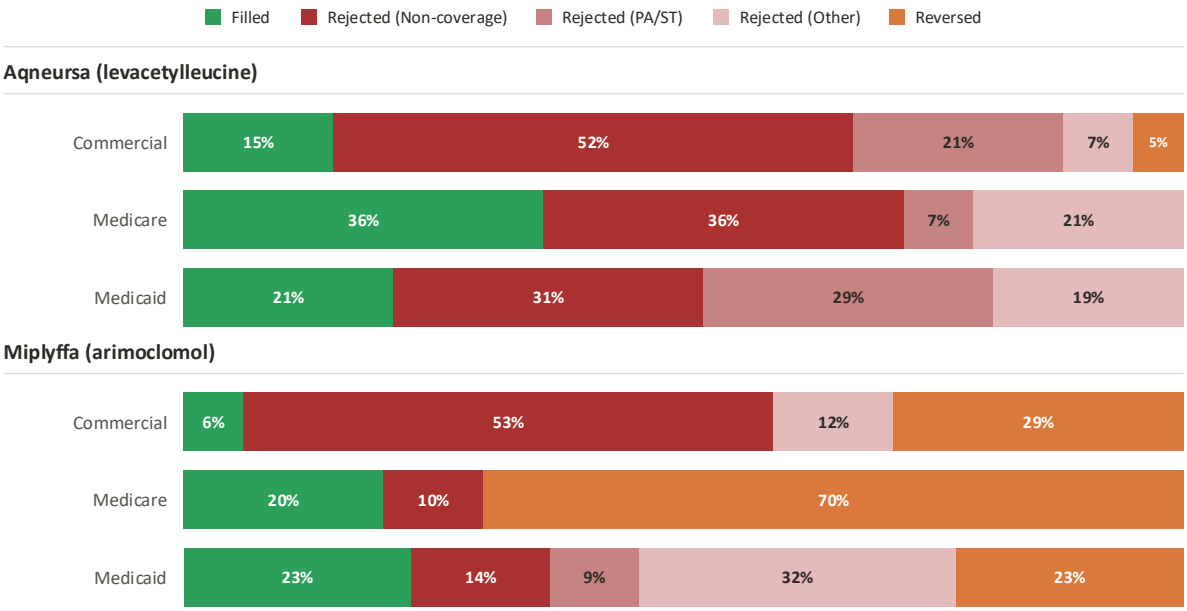
Aqneursa and Miplyffa were approved for the treatment of Niemann-Pick Type C disease in September 2024. The annual net price at launch was $576,661 for Aqneursa and $940,586 for Miplyffa. ICER has not previously reviewed the clinical effectiveness and cost-effectiveness of Aqneursa and Miplyffa.

Prescription adjudication data showed low fill rates within 30 days for these drugs among all payers (Figure 4.8). For Aqneursa, both commercial payers and Medicaid rejected approximately 80% of prescriptions. Although Medicare had 1.5 to 2 times the approval rate compared with commercial payers and Medicaid, two-thirds of prescriptions were still rejected. For Miplyffa, 55%-65% of prescriptions were rejected by commercial payers and Medicaid. This appears mainly due to non-coverage, but some plans also employed step therapy or placed age restrictions on use, both of which are not consistent with current clinical practice guidelines or the pivotal trials, and one of five plans did not meet criteria consistent with Fair Access for either clinical eligibility or step therapy. Thus, lengthy delays due to the prior authorization process may contribute to the high rejection rate, as very few prescriptions for either Aqneursa or Miplyffa were filled on the first attempt.

Medicare has a very high rate of reversals for Miplyffa (70%). Our data do not permit us to understand the reasons behind the high rate of reversals. One possibility is that Miplyffa may be covered under either the medical benefit (Part B) or the pharmacy benefit (Part D), depending on the circumstances. If billed under Part B, Medicare recipients are usually responsible for 20% of the cost – Miplyffa costs about $1 million per year, so a 20% co-insurance cost could be out of reach for Medicare recipients without Medicare Advantage or Medigap insurance. However, this is likely not the only reason, as 100% of patients with Medicaid had $0 out-of-pocket costs but still around 20% of prescription claims to Medicaid were reversed.

Figure 4.8. Prescription Adjudication and Coverage Policy Concordance for Aqneursa and Miplyffa

A. Real-World Adjudication Outcomes by Payer Type



B. Coverage Policy Concordance with ICER's Fair Access Criteria

Drug	Clinical Eligibility	Step Therapy	Prescriber Restriction
Aqneursa (levacetylleucine)	**(4/5) 80%**	(5/5) 100%	(5/5) 100%
Miplyffa (arimoclomol)	(5/5) 100%	**(4/5) 80%**	(5/5) 100%

C. Real-World Patient Out-of-Pocket Cost (Copay/Co-insurance) by Payer Type

Drug	Payer Type	$0	$1–$50	$51–$250	$251–$1,500	$1,500+	Weighted Average
Aqneursa (levacetylleucine)	**Commercial**	93%	4%	1%	0%	1%	**$22.03**
	Medicare	95%	1%	0%	0%	4%	**$79.41**
	Medicaid	99%	1%	0%	0%	0%	**$0.05**
Miplyffa (arimoclomol)	**Commercial**	54%	8%	23%	10%	6%	**$223.33**
	Medicare	98%	2%	0%	0%	0%	**$0.20**
	Medicaid	100%	0%	0%	0%	0%	**$0.00**

PA: prior authorization, ST: step therapy

Adjudication outcomes and patient out-of-pocket costs are based on real-world pharmacy claims data from IQVIA's LAAD database, from 2H2024 and 1H2025.

Coverage policy concordance is based on ICER's analysis of coverage policies from the top five US payers by covered lives.

Kisunla for Alzheimer's Disease

Kisunla is an infusion that was approved in July 2024 for the treatment of mild cognitive impairment (MCI) and mild Alzheimer's disease. It has not previously been reviewed by ICER, although ICER did review similar medications (aducanumab and lecanemab) for the treatment of MCI and mild Alzheimer's disease. The launch price of Kisunla was around $32,000.

Coverage policies do not appear to be overly restrictive, with most plans not more restrictive than clinical trial eligibility criteria and concordant with Fair Access criteria for step therapy and prescriber restrictions. In fact, some plans were less restrictive than clinical trial criteria, allowing treatment of patients starting at age 50. Data obtained from IQVIA does not include written prescriptions of Kisunla, only infusions that were billed to the payer. We therefore do not have any direct knowledge of the proportion of people who were offered the infusion but did not go through with it for insurance coverage issues, among other reasons.

The number of infusion orders for Kisunla appears to be relatively modest in the first year. There may be several reasons for this, including the ongoing debate about the benefit-risk profile of anti-amyloid therapies, other access barriers such as a lack of specialist providers and infusion centers, prior authorization barriers, and cost. IQVIA data for provider-administered drugs does not include adjudication metrics such as rejections due to non-coverage or prior authorization, and thus we are unable to characterize how large those barriers were. We learned during our previous assessments of treatments for Alzheimer's disease that a lack of health care infrastructure may be a substantial barrier to utilization.[59] For example, there is a shortage of physicians who can diagnose Alzheimer's disease, refer a patient for treatment before the disease becomes too advanced, and conduct the intense magnetic resonance imaging (MRI) monitoring that is required for safely administering the drug. Kisunla is an infused drug and therefore patients need to live near enough to a clinic or infusion center to be able to receive treatment every two weeks. Thus, although many people may qualify for treatment, only a modest number of people are able to access that treatment, regardless of how straightforward coverage policies appear to be. Out-of-pocket costs may play a role as well – Kisunla can be administered both in a hospital setting and in an outpatient setting, with facility fees higher in a hospital setting. The setting may impact affordability, as almost 50% of Medicare recipients who have infusions in a hospital setting pay from $125 to upwards of $1,500 per month. Finally, surprisingly, Medicaid patients have a relatively high out-of-pocket cost, which in some cases may be due to states imposing cost-sharing for up to 20% of the cost of the drug for those who have an income higher than the 150% of the federal poverty level.[56]

Figure 4.9. Coverage Policy Concordance for Kisunla

A. Real-World Adjudication Outcomes by Payer Type

Prior authorization adjudication data are not reported for medical claims.

B. Coverage Policy Concordance with ICER's Fair Access Criteria

Drug	Clinical Eligibility	Step Therapy	Prescriber Restriction
Kisunla (donanemab-azbt)	**(4/5) 80%**	(5/5) 100%	(5/5) 100%

C. Real-World Patient Out-of-Pocket Cost (Copay/Co-insurance) by Payer Type

Payer Type	$0	$1–$50	$51–$250	$251–$1,500	$1,500+	Weighted Average
Commercial	38%	7%	11%	37%	6%	**$16.33**
Medicare	71%	0%	3%	25%	0%	**$135.96**
Medicaid	45%	0%	6%	50%	0%	**$297.76**

PA: prior authorization, ST: step therapy

Adjudication outcomes and patient out-of-pocket costs are based on real-world pharmacy claims data from IQVIA's LAAD database, from 2H2024 and 1H2025.

Coverage policy concordance is based on ICER's analysis of coverage policies from the top five US payers by covered lives.

4.4. Discussion

In this second annual Launch Price and Access report, one of our objectives was to ascertain both utilization of new drugs in the first year after approval and potential barriers to access. We found that, for new drugs in the first year after approval, around one-third of prescriptions were filled within 30 days of attempting to fill the prescription. As indicated in our data, reasons for this likely include providers prescribing drugs not covered by the health plans in the early months after approval or not in line with prior authorization or step therapy criteria without pre-approval, or high out-of-pocket costs that render the treatment unaffordable to patients. Furthermore, a limitation of our data is that it only looks forward for 30 days from the first claim submission, so prior authorization attempts that took longer than 30 days to resolve will be recorded as a rejection, even if the prescription was ultimately approved. We found that even when prescriptions were approved, it often took multiple attempts, potentially indicating a large administrative burden on clinicians and delays in care for patients, although written coverage policies were concordant with fair access principles. Finally, we found that out-of-pocket costs varied greatly by drug and by payer. Taken together, these data suggest that access to newly approved drugs could be improved, but understanding the nuances and barriers is important for creating effective solutions.

Our data show that the most common reason for prescription rejection was non-coverage. This is most likely a reflection of the impact of new-to-market blocks, which can typically be in place for the first six to 12 months of a drug's launch, and affect as many as 56% of covered lives in the US.[60]

New-to-market blocks can cause delays in care, as clinicians and patients then need to appeal to health plans for coverage, which can take weeks to months. ICER's Fair Access criteria encourages payers to have coverage policies available within three months of approval, and immediately after approval for newly approved drugs that address rapidly progressive and/or fatal conditions with no other treatments available.[61] Of note, we were only able to obtain aggregate data over one year and thus cannot distinguish whether prescription fill rates changed over time as new-to-market blocks were replaced by coverage policies; however, the fact that for many drugs, rejections due to non-coverage were a large percentage of rejections over the year suggests that new-to-market blocks may be lasting longer than three months for most drugs.

Rejection due to prior authorization and step therapy was observed in about 7% of prescriptions overall, although this varied significantly across payers and by drugs. By pairing IQVIA data on the patient experience at the pharmacy counter with an independent assessment of the fairness of coverage criteria from the five largest health plans for eight of the drugs in scope, we were able to identify that most coverage policies we evaluated were consistent with ICER's Fair Access criteria. Utilization management through prior authorization and step therapy is designed to encourage appropriate, evidence-based use of drugs and help manage resources across populations. Therefore, rejection due to prior authorization and step therapy is not an inherently wrong outcome if applied appropriately. However, our data indicate that having clinically appropriate coverage policies is not sufficient to guarantee appropriate access to newly launched drugs, as in many cases, in practice, implementation of utilization management strategies is complex for patients and providers and may pose additional barriers to access and burdens on the health care system. For example, our data showed that most drugs required multiple submission attempts before being filled, suggesting that in many cases the health plan may have denied a drug that should have been approved, creating additional burden for patients and clinicians. Additionally, even if prescriptions were ultimately filled after the initial 30-day timeframe, these delays in care can be associated with adverse patient outcomes.[62]

New to this year's report, we were able to obtain data stratified by three payer groups: commercial plans, Medicare, and Medicaid. Our analyses, not surprisingly, found substantial variation in prescription adjudication by drug and by payer type. For most drugs, rejection or reversal is still the norm during the first year, regardless of payer. There were a few notable exceptions – for Journavx, for example, prescriptions were almost four times more likely to be filled by a commercial payer than Medicare, likely reflecting low coverage amongst Medicare Part D plans compared to commercial plans. An external study found that Journavx was covered for 10.7% of Medicare enrollees compared with 62.3% for enrollees in commercial plans.[63] The opposite was true for Cobenfy, where those with Medicare and Medicaid were more likely to have the prescription filled than those with commercial insurance, reflecting almost 100% coverage across Medicare and Medicaid plans, compared with around 70% for commercial plans.[63]

We also saw variation in out-of-pocket costs by drug and by payer. For the majority of drugs in our scope, Medicare recipients had the highest average out-of-pocket costs and Medicaid the lowest. For many drugs, particularly amongst people with commercial insurance, out-of-pocket costs were $0 to $25. One likely reason for this discrepancy is the use of manufacturer copay cards, since Medicare recipients are not eligible for such discounts. Our study also covered a time period where there was no out-of-pocket maximum for Medicare Part D enrollees (2H2024), which may lead to very high out-of-pocket costs and unfilled prescriptions. This was most prominently seen in our data in reversal rates for drugs such as Ebglyss and Nemluvio for atopic dermatitis, where there were much higher rates of reversal for Medicare compared to other payers. An out-of-pocket maximum was instituted for Medicare Part D enrollees as of January 1, 2025 and so out-of-pocket may represent less of a barrier after this date. However, capping out-of-pocket costs may have other unintended consequences such as higher deductibles and more limited formularies, though there may have been other changes required by the Inflation Reduction Act of 2022 that prompted these changes.[64,65] Finally, we had only aggregate data on out-of-pocket costs paid at the pharmacy or to a facility for infused drugs for first new-to-brand prescriptions, so we are unable to account for changes in out-of-pocket costs over time (e.g., lower out-of-pocket costs once deductibles have been met, other patient assistance programs such as grants from non-profit organizations, or copay assistance programs that are time-limited).

Also new to this year's report were data on provider-administered drugs, though data were limited to volume of prescriptions dispensed and out-of-pocket costs. In general, out-of-pocket costs were quite high for provider-administered drugs, regardless of payer. This is most likely due to the fact that co-insurance, where the patient pays a percentage of the drug's cost (often list price) rather than a flat copay, is standard practice for provider-administered drugs, which can cost thousands of dollars per dose. However, without prescription adjudication data for provider-administered drugs, we were unable to assess the proportion of prescriptions filled and other access barriers.

There were several limitations to our analyses. First, we were only able to obtain information on prescription adjudication for a 30-day period after the first claim was filed. Thus, there may be claims that were initially rejected but then, after appeal, subsequently got approved after the 30-day window. This would result in artificially low fill rates. Secondly, the data for provider-administered drugs in the IQVIA LAAD database, although large and comprehensive, does not contain every medical claim in the US. Additionally, it represents health care services reimbursed under the medical benefit and does not include adjudication information. Finally, we were not able to achieve our goal of understanding more comprehensive facets of the patient access experience with a direct patient survey due to a very low response rate.

Patient access to medications is complex – there are potentially many areas, starting from trying to obtain a prescription to picking it up at the pharmacy or receiving an infusion, where barriers may exist. Our data covered only prescription adjudication, coverage policies, and out-of-pocket patient costs. However, there continue to be gaps in understanding the other potential barriers and

facilitators to patient access, including patient and clinician awareness of new treatments, accessing a prescribing provider, the time burden of prior authorization, sources of assistance, affordability to patients, the impact of high prescription drug costs on lifestyle, health disparities, and the impact of care delays in patient and caregiver health and lives. These types of barriers can not necessarily be characterized through prescription fill data; future work is needed to help fill information gaps and identify other points in the care ecosystem that can impact access.

5. Conclusion

This is ICER's second Launch Price and Access report. In Section 3 of this report, we evaluated trends in launch prices for new FDA-approved drugs from 2022 to 2025. Our analyses showed a substantial increase in inflation-adjusted median annual launch prices during this period, rising from a median net price of approximately $190,000 (inflation-adjusted) in 2022 to $257,000 in 2025. However, the most significant increase occurred between 2022 and 2023; a slight decline was observed in 2025. After adjusting for variations in drug categories approved each year, our analysis indicates that launch prices continue to rise annually, although the rate of increase is smaller than that observed in the previous report.[9] This suggests that the most recent year's launch price growth was smaller than the trend predicted by the prior three years (2022 to 2024). Still, a launch price of over $200,000 is the norm in 2025. About one in four drugs introduced in 2025 had an annual net price exceeding $500,000, while an additional 34% were launched at prices between $200,000 and $500,000. Consistent with last year's findings,[9] we found that only about one in three of the 26 newly approved drugs previously reviewed by ICER in our scope are priced at or below the HBPB, with the remainder exceeding their estimated value. High launch prices that are not aligned with how well the drugs actually work drive up overall health care costs and directly reduce patient access and increase out-of-pocket expenses for all patients.

Our evaluation of patient access in Section 4, although limited, underscores the numerous barriers patients face in accessing new drugs. Our data showed the complexity of patient access during the first year post-approval. Rejection appears to be the norm in the first-year post-approval, with fewer than one-third of prescriptions ultimately filled within 30 days of attempting to fill them. A significant proportion of prescriptions were rejected due to non-coverage, likely due to new-to-market blocks. ICER's own Fair Access criteria call on payers to have coverage policies available for newly-approved drugs within three months of approval, and immediately following FDA approval for treatments of rapidly progressive and/or fatal conditions for which there is no alternative approved therapy.[10] Although our coverage policy evaluation for a select number of drugs showed high concordance with ICER's Fair Access criteria on clinical eligibility, step therapy, and prescriber restriction, we could not evaluate when these drugs were added to coverage or fully capture patient and clinician lived experiences with aspects of coverage such as the real-world burden of cost sharing and prior authorization on patients and other complexities in our health care system. To fill these gaps, we developed and deployed a patient survey to attempt to characterize patient access experiences, including awareness of drug availability, prior authorization burden, and affordability for selected drugs in scope. However, due to a low response rate, we did not analyze the patient survey data. Therefore, our ability to see through the complexity and opacity of these systems remains limited.

Finally, our analyses do not fully account for the impact of high launch prices on access or the trade-offs plan sponsors may make between providing optimal coverage and keeping costs affordable for all beneficiaries. With an average launch net price of over $250,000, and many drugs priced out of line with value, new-to-market blocks to temporarily delay coverage pending clinical and economic review and utilization strategies to ensure that only patients for whom a treatment is clinically appropriate receive insurance coverage have become routine. While these measures are intended to help keep insurance premiums more affordable for patients and all health plan members, they also risk delaying care or creating other barriers to effective care for certain patients. Even with these measures, health insurance premiums are rising at unsustainable rates, and the number of uninsured individuals is projected to increase significantly.[11,12] Employers identify escalating prescription drug costs as one of the major drivers of premium increases. For example, in the span of 24 hours between August 25 and 26, 2026, the Business Group on Health released its annual employer survey warning that health care costs for employers were projected to increase at a median rate of 9.2% in 2027,[66] while Revolution Medicines announced an annual price for its new pancreatic cancer drug of just under $480,000 per year.[67] Compared to the launch price of Gleevec, considered a transformational cancer medicine when it was approved in May 2001, of about $26,000[68] (~$50,000 in today's dollars),[69] the Revolution Medicines product, Rasonque™, is priced 10 times higher, after adjusting for inflation. This level of acceleration in price is directly contributing to the unaffordability of our health care system. And that unaffordability impacts patient access today.

An objective analysis of launch price trends and patient access challenges serves as a call to action to those with the power to improve affordability and access. Moving away from a system that allows prices out of line with value, cost-sharing based on list price instead of net price, and access restrictions not based on objective notions of fair access requires urgent action. Choosing prices aligned with benefits should lead to better access for patients. Manufacturers have the opportunity to use ICER's independent assessments of value to inform their prices, while health insurers and pharmacy benefit managers have the opportunity to build coverage policies that align with our Fair Access criteria. Those choices, in turn, will translate into a more affordable and accessible health care system. A voluntary de-escalation of the status quo is likely to ensure affordable access for all patients while preserving incentives for future innovation.

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APPENDIX

A. Launch Price: Detailed Methodology

A1. Trend Analysis

Data Sources

Drug Characteristics

We abstracted drug characteristics for each drug included in this report from the FDA's New Drug Therapy Approvals reports for drugs approved by CDER. Information was sourced manually from official review documents in Drugs@FDA for products regulated by CBER. Drug characteristics of interest included approval pathway (e.g., accelerated approval), special designations awarded (e.g., ultra-rare [intended to treat a condition affecting fewer than 10,000 people and not approved for oncology indication], breakthrough), therapeutic area (e.g., oncology, cardiovascular, hematology), drug type (biologic vs. small molecule), gene and cell therapy, first-in-class mechanism, and first approved in the US. We examined the proportion of various drug characteristics across the four years. See Table A1.1.

Table A1.1. Drug Characteristics for Each Year (2022, 2023, 2024, 2025)

Drug Characteristics		2022 (n=40)	2023 (n=61)	2024 (n=54)	2025 (n=47)
Indication*	Oncology	33%	25%	31%	30%
	Endocrine/Metabolic	15%	13%	11%	13%
	Dermatology	15%	7%	9%	6%
	Hematology	10%	10%	11%	6%
Drug Type	Biologic	58%	51%	50%	40%
	Small Molecule	43%	49%	50%	60%
Type of Therapy	Gene/Cell Therapy	13%	10%	11%	9%
Mechanism	First-in-Class	60%	41%	54%	45%
Population Size	Orphan Drug	60%	59%	61%	55%
	Ultra-Rare Drug	18%	25%	22%	11%
FDA Designation	Breakthrough	45%	18%	37%	34%
Approval Pathway	Accelerated	18%	16%	19%	21%
First Approved in US	First in US	65%	64%	65%	83%

FDA: US Food and Drug Administration, n: number, US: United States

*Therapeutic areas that had at least 10 drugs in the category and were significantly associated with price were included in the analysis.

Ultra-Rare Drugs

In our 2025 Launch Price and Access Report, we included "orphan drug" as a drug characteristic in the model that we wanted to adjust for in our analysis. Orphan drugs are considered by the FDA as a drug or biological product to prevent, diagnose, or treat a rare disease or condition, defined as fewer than 200,000 people. However, over 50% of drugs were considered orphan drugs in our 2025 report, which may not appropriately represent "rare" conditions. Instead, we took the approach of estimating the population size for each of the drugs included in the scope of our review to categorize the drugs into "ultra-rare" (i.e., intended to treat <10,000 patients) or "not ultra-rare" (i.e., intended to treat ≥10,000 patients).

To obtain the population size, we identified estimates as close to the condition described in the FDA label as possible. We identified prevalence estimates from the following sources: IPD Analytics Market & Financial Insights, Datamonitor, and targeted literature review for the condition of interest. Based on the estimated population size, we categorized the drugs into "ultra-rare" or "not ultra-rare." We excluded oncology drugs from the ultra-rare list as these drugs tend to be approved based on one indication but soon after approved for use across many oncology indications, broadening the potential pool of patients who could receive this therapy. In this year's report, we decided a priori to replace "orphan drug" with "ultra-rare" as a covariate in the trend analysis (regression model).

Price Estimates

Table A1.2 summarizes the launch prices, including list price and the best net price estimate, for all drugs in scope.

Table A1.2. 2022-2025 Launch Prices: List and Net Prices

Drug Name [Brand Name (generic name)]	Annual List Price	Best Annual Net Price Estimate
2022 Approvals		
Skysona® (elivaldogene autotemcel)	$3,000,000.00	$3,000,000.00†
Hemgenix® (etranacogene dezaparvovec-drlb)	$3,500,000.00	$2,646,633.00††
Zynteglo® (betibeglogene autotemcel)	$2,800,000.00	$2,138,693.47¤
Kimmtrak® (tebentafusp-tebn)	$1,294,440.00	$1,294,440.00*
Xenpozyme™ (olipudase alfa-rpcp)	$871,324.00	$871,324.00*
Carvykti® (ciltacabtagene autoleucel)	$465,000.00	$465,000.00*
Amvuttra™ (vutrisiran)	$463,500.00	$459,986.23*
Elahere™ (mirvetuximab soravtansine-gynx)	$431,253.25	$430,402.94*
Tecvayli™ (teclistamab-cqyv)	$369,930.00	$365,966.89*
Opdualag™ (nivolumab and relatlimab-rmbw)	$356,049.00	$354,467.32*
Lunsumio™ (mosunetuzumab-axgb)	$340,395.98	$340,396.06*
Enjaymo™ (sutimlimab-jome)	$340,200.08	$333,522.59*
Rezlidhia™ (olutasidenib)	$391,766.69	$314,196.89§
Pyrukind® (mitapivat)	$335,800.00	$292,851.18‡
Pluvicto™ (lutetium Lu 177 vipivotide tetraxetan)	$255,000.00	$255,000.00†

Drug Name [Brand Name (generic name)]	Annual List Price	Best Annual Net Price Estimate
Adstiladrin® (nadofaragene firadenovec)	$240,000.00	$239,643.04**
Ztalmy® (ganaxolone)	$289,677.87	$239,476.70[#]
Lytgobi® (futibatinib)	$304,253.60	$232,394.46[¤]
Vonjo™ (pacritinib)	$237,250.00	$207,925.90[#]
Krazati™ (adagrasib)	$240,291.62	$183,006.10[‡]
Tzield™ (teplizumab-mzwv)	$193,900.00	$163,430.19*
Relyvrio® (sodium phenylbutyrate and taurursodiol)	$163,001.70	$134,028.15[‡‡]
Camzyos™ (mavacamten)	$89,499.93	$67,080.20[‡]
Briumvi™ (ublituximab-xiiy)	$98,333.30	$66,445.19*
Terlivaz® (terlipressin)	$60,800.00	$60,800.00†
Rolvedon™ (eflapegrastim-xnst)	$58,500.00	$51,433.05*
Spevigo® (spesolimab-sbzo)	$51,133.00	$51,132.74*
Imjudo® (tremelimumab-actl)	$48,750.00	$48,311.32*
Sotyktu™ (deucravacitinib)	$74,999.94	$44,111.22[‡§§]
Sunlenca® (lenacapavir)	$43,062.50	$43,062.50†
Cibinqo™ (abrocitinib)	$59,787.00	$36,153.20[‡]
Vabysmo™ (faricimab-svoa)	$11,680.00	$10,323.69*
Mounjaro™ (tirzepatide)	$12,666.29	$5,292.61[‡]
Nexobrid® (anacaulase-bcdb)	$3,150.00	$3,150.00†
Quviviq® (daridorexant)	$5,560.05	$2,085.02[‡]
Vivjoa™ (oteseconazole)	$2,700.00	$2,021.07[¤]
Vtama® (tapinarof)	$3,975.00	$1,329.64‡[##]
Daxxify™ (daxibotulinumtoxinA-lanm)	$840.00	$564.53*
Voquenza Triple Pak™ (vonoprazan, amoxicillin, clarithromycin)	$812.00	$453.50[#]
Omlonti® (omidenepag isopropyl)	$350.00	$278.01[‡‡]
2023 Approvals		
Elevidys® (delandistrogene moxeparvovec-rokl)	$3,200,000.00	$3,200,000.00†
Lyfgenia® (lovotibeglogene autotemcel)	$3,100,000.00	$3,100,000.00†
Roctavian® (valoctocogene roxaparvovec-rvox)	$2,446,875.00	$2,446,875.00†
Casgevy® (exagamglogene autotemcel [exa-cel])	$2,200,000.00	$2,200,000.00†
Lamzede® (velmanase alfa-tycv)	$1,456,000.00	$1,513,718.04*
Vyjuvek® (beremagene geperpavec-svdt)	$1,261,000.00	$1,235,780.00*
Veopoz™ (pozelimab-bbfg)	$1,168,269.00	$1,168,269.00†
Rivfloza™ (nedosiran)	$754,560.00	$743,184.72[¤]
Pombiliti™ (cipaglucosidase alfa-atga)	$618,799.85	$605,345.58*
Sohonos™ (palovarotene)	$624,150.00	$565,074.20[#]
Joenja® (leniolisib)	$547,500.00	$533,853.75[¤]
Daybue™ (trofinetide)	$616,120.00	$518,896.26[‡]
Elrexfio™ (elranatamab-bcmm)	$490,432.32	$490,432.32†
Fabhalta® (iptacopan)	$550,000.03	$473,330.03[#]
Zilbrysq® (zilucoplan)	$524,840.40	$454,879.17[#]
Elfabrio® (pegunigalsidase alfa-iwxj)	$430,051.44	$438,658.26*
Filsuvez® (birch triterpenes)	$583,200.17	$433,278.72[¤]
Wainua™ (eplontersen)	$498,999.94	$426,794.65[‡§§]
Vanflyta® (quizartinib)	$398,580.00	$398,580.00†
Epkinly® (epcoritamab-bysp)	$396,170.11	$396,169.23*
Talvey™ (talquetamab-tgvs)	$371,121.00	$366,151.91*
Columvi™ (glofitamab-gxbm)	$349,999.38	$349,986.93*

Drug Name [Brand Name (generic name)]	Annual List Price	Best Annual Net Price Estimate
Omisirge® (omidubicel-onlv)	$338,000.00	$338,000.00†
Augtyro™ (repotrectinib)	$363,412.25	$320,893.02#
Ojjaara® (momelotinib)	$327,283.35	$305,355.36#
Lantidra™ (donislecel-jujn)	$300,000.00	$300,000.00†
Skyclarys™ (omaveloxolone)	$375,138.90	$297,203.79#
Ogsiveo™ (nirogacestat)	$352,837.69	$293,913.79#
Rystiggo® (rozanolixizumab-noli)	$290,400.00	$289,733.43*
Orserdu™ (elacestrant)	$259,880.00	$245,898.46#
Adzynma™ (ADAMTS13, recombinant-krhn)	$238,784.00	$238,784.00†
Fruzaqla™ (fruquintinib)	$327,600.00	$223,750.80#
Qalsody™ (tofersen)	$213,450.01	$214,517.25*
Jaypirca™ (pirtobutinib)	$255,500.00	$198,906.75‡
Truqap™ (capivasertib)	$297,986.04	$186,658.46#
Zynyz™ (retifanlimab-dlwr)	$185,120.00	$182,944.34*
Loqtorzi® (toripalimab-tpzi)	$154,128.52	$154,124.07*
Agamree® (vamorolone)	$156,037.50	$136,798.08#
Filspari™ (sparsentan)	$120,450.00	$101,418.90#
Omvoh™ (mirkizumab-mrkz)	$150,229.00	$95,051.60*
Ngenla™ (somatrogon-ghla)	$99,699.60	$85,165.00¤
Bimzelx® (bimekizumab-bkzx)	$66,387.60	$66,387.60†
Velsipity™ (etrasimod)	$74,999.94	$57,824.96‡§§
Izervay™ (avacincaptad pegol)	$50,400.00	$50,400.00*
Defencath® (taurolidine, heparin)	$38,998.44	$38,998.44†
Litfulo™ (ritlecitinib)	$49,134.62	$34,806.97‡§§
Leqembi® (lecanemab-irmb)	$26,500.24	$26,490.57*
Ryzneuta® (efbemalenograstim alfa-vuxw)	$18,400.00	$18,400.00†
Exxua™ (gepirone)	$22,167.67	$17,204.33#
Aphexda™ (motixafortide)	$11,800.00	$11,800.12*
Zurzuvae™ (zuranolone)	$15,900.00	$11,226.99#
Jesduvroq® (daprodustat)	$11,417.20	$8,375.29¤
Zavzpret™ (zavagepant)	$17,600.00	$7,099.84#
Rezzayo™ (rezafungin)	$5,850.00	$5,729.43*
Xacduro® (sulbactam, durlobactam)	$4,433.24	$4,433.24†
Veozah™ (fezolinetant)	$6,691.65	$4,216.08‡
Inpefa™ (sotagliflozin)	$7,275.65	$3,681.48‡
Miebo™ (perfluorhexyloctane)	$9,252.00	$2,963.42‡§§
Xdemvy™ (lotilaner)	$1,850.00	$1,025.45#
Beyfortus™ (nirsevimab-alip)	$495.00	$495.00†
Brenzavvy™ (bexagliflozin)	$474.50	$406.22‡‡
2024 Approvals		
Lenmeldy™ (atidarsagene autotemcel)	$4,250,000.00	$4,250,000.00†
Kebilidi™ (eladocagene exuparvovec-tneq)	$3,950,000.00	$3,950,000.00†
Beqvez™ (elaparvovec-dzkt)	$3,500,000.00	$3,500,000.00†
Ryoncil® (remestemcel-L-rknd)	$1,552,000.00	$1,552,000.00†
Miplyffa™ (arimoclomol)	$967,432.50	$940,586.25#
Alhemo® (concizumab-mtci)	$888,552.00	$773,573.37#
Revuforj® (revumenib)	$810,984.37	$756,648.42#
Tecelra® (afamitresgene autoleucel)	$727,000.00	$727,000.00*

Drug Name [Brand Name (generic name)]	Annual List Price	Best Annual Net Price Estimate
Hympavzi™ (marstacimab-hncq)	$795,600.00	$692,649.36[#]
Bizengri® (zenocutuzumab-zbco)	$617,500.00	$617,500.00†
Duvyzat® (givinostat)	$675,032.21	$588,796.85[#]
Aqneursa™ (levacetylleucine)	$701,321.42	$576,661.54[#]
Tryngolza™ (olezarsen)	$595,008.00	$576,562.75[#]
Ziihera® (zanidatamab-hrii)	$554,580.00	$553,652.83*
Piasky® (crovalimab-akkz)	$551,839.55	$551,839.55†
Anktiva® (nogapendekin alfa inbakicept-pmln)	$537,000.00	$537,000.00*
Aucatzyl® (obecabtagene autoleucel)	$525,000.00	$525,000.00†
Amtagvi® (lifileucel)	$515,000.00	$515,000.00†
Xolremdi™ (mavorixafor)	$496,400.00	$469,842.60[#]
Crenessity™ (crinecerfont)	$466,384.83	$464,041.05[¤]
Voranigo® (vorasidenib)	$485,218.83	$428,448.23[#]
Imdelltra™ (tarlatamab-dlle)	$400,071.00	$395,210.40*
Rytelo™ (imetelstat)	$354,780.69	$352,114.71*
Niktimvo™ (axatilimab-csfr)	$319,410.00	$319,410.00†
Ojemda™ (tovorafenib)	$330,720.00	$308,561.76[#]
Alyftrek® (vanzacaftor, tezacaftor, and deutivacaftor)	$370,269.29	$304,435.41[#]
Itovebi™ (inavolisib)	$298,087.68	$259,038.19[#]
Yorvipath® (palopegteriparatide)	$285,808.04	$250,296.39[#]
Unloxcyt™ (cosibelimab-ipdl)	$224,900.00	$224,900.00†
Ensacove™ (ensartinib)	$255,014.55	$210,744.02[#]
Winrevair® (sotatercept-csrk)	$245,140.00	$204,201.62[#]
Lazcluze™ (lazertinib)	$221,409.00	$194,042.85[#]
Attruby® (acoramidis)	$244,538.52	$190,128.70[#]
Tevimbra® (tislelizumab-jsgr)	$180,405.33	$187,099.61*
Vyloy® (zolbetuximab-clzb)	$175,968.00	$174,084.85*
Livdelzi® (seladelpar)	$153,373.00	$140,949.79[#]
Iqirvo® (elafibranor)	$139,430.00	$130,889.91[#]
Leqselvi™ (deuruxolitinib)	$55,525.14	$45,447.32[‡‡]
Rezdiffra™ (resmetirom)	$48,058.35	$44,857.66[‡§§]
Ebglyss™ (lebrikizumab-lbkz)	$66,500.00	$41,622.35[#]
Voydeya™ (danicopan)	$50,260.50	$38,389.97[¤]
Nemluvio® (nemolizumab-ilto)	$55,120.00	$37,255.61[#]
Ohtuvayre™ (ensifentrine)	$35,400.01	$35,400.23*
Kisunla™ (donanemab-azbt)	$31,999.90	$31,091.23*
Symvess™ (acellular tissue engineered vessel-tyod)	$29,500.00	$29,500.00†
Cobenfy™ (xanomeline and trospium chloride)	$22,508.31	$18,398.29[#]
Vafseo® (vadadustat)	$15,549.00	$14,843.33[¤]
Rapiblyk™ (landiolol)	$12,950.00	$12,950.00†
Sofdra™ (sofpironium)	$8,784.51	$6,539.19[#]
Tryvio™ (aprocitentan)	$9,429.17	$5,926.23[#]
Zevtera® (ceftobiprole medocaril sodium)	$4,935.00	$4,935.00†
Orlynvah™ (sulopenem etzadroxil, probenecid)	$2,975.00	$2,732.84[#]
Zelsuvmi™ (berdazimer)	$1,950.00	$1,596.08[‡‡]
Letybo® (letibotulinumtoxinA-wlbg)	$660.00	$660.00†

Drug Name [Brand Name (generic name)]	Annual List Price	Best Annual Net Price Estimate
2025 Approvals		
Zevaskyn® (prademagene zamikeracel)	$3,147,000.00	$3,147,000.00†
Itvisma® (onasemnogene abeparvovec-brve)	$2,586,629.70	$2,586,629.70†
Qfitlia® (fitusiran)	$968,400.00	$938,349.00*
Modeyso™ (dordaviprone)	$834,285.71	$735,339.43#
Forzinity™ (elamipretide)	$795,739.11	$694,083.44#
Lynozyfic™ (linvoseltamab-gcpt)	$585,620.00	$581,993.00*
Dawnzera™ (donidalorsen)	$689,544.00	$578,355.03#
Avmapki Fakzynja Co-Pack® (avutometinib and defactinib)	$632,232.14	$557,249.41#
Sephience™ (sepiapterin)	$766,500.00	$550,193.70#
Kygevvi® (doxecitine and doxribtimine)	$600,005.25	$528,844.63#
Andembry® (garadacimab-gxii)	$618,583.33	$518,836.77#
Encelto™ (revakinagene taroretcel-lwey)	$500,000.00	$500,000.00†
Komzifti™ (ziftomenib)	$590,083.33	$490,595.28#
Emrelis™ (telisotuzumab vedotin-tllv)	$484,756.90	$477,177.46*
Papzimeos™ (zopapogene imadenovec-drba)	$460,000.00	$460,000.00†
Datroway® (datopotamab deruxtecan-dlnk)	$415,740.93	$413,437.00*
Gomekli® (mirdametinib)	$450,450.00	$359,053.70#
Ibtrozi® (taletrectinib)	$358,770.66	$319,036.81#
Imaavy® (nipocalimab-aahu)	$305,760.00	$302,718.30*
Yartemlea® (narsoplimab-wuug)	$294,440.00	$294,440.00†
Voyxact® (sibeprenlimab-szsi)	$360,000.00	$286,740.00#
Romvimza™ (vimseltinib)	$340,597.14	$273,522.19¤
Inluriyo™ (imlunestrant)	$293,303.57	$273,182.94#
Hyrnuo® (sevabertinib)	$292,000.00	$257,368.80#
Palsonify® (paltusotine)	$294,007.50	$233,653.39¤
Hernexeos® (zongertinib)	$263,615.29	$232,350.51#
Keytruda Qlex™ (pembrolizumab and berahyaluronidase alfa-pmph)	$209,116.50	$203,534.00*
Ekterly® (sebetralstat)	$200,640.00	$172,751.04#
Wayrilz™ (rilzabrutinib)	$212,916.67	$164,073.59#
Jascayd® (nerandomilast)	$197,339.44	$152,385.52#
Vanrafia® (atrasentan)	$162,499.97	$123,158.73#
Myqorzo™ (aficamten)	$108,400.01	$77,180.81#
Brinsupri® (brensocatib)	$89,222.18	$68,897.37#
Redemplo® (plozasiran)	$60,000.00	$52,425.00#
Exdensur™ (depemokimab-ulaa)	$52,000.00	$52,000.00†
Rhapsido® (remibrutinib)	$55,005.50	$34,427.94#
Grafapex™ (treosulfan)	$31,110.00	$31,110.00*
Anzupgo® (delgocitinib)	$24,163.00	$13,763.24#
Cardamyst™ (etripamil)	$11,130.75	$5,810.25#
Lynkuet® (elinzanetant)	$7,604.17	$5,190.23#
Lerochol® (lerodalcibep-liga)	$4,500.00	$3,550.50‡‡
Tryptyr® (acoltremon)	$10,706.67	$3,509.65#
Blujepa™ (gepotidacin)	$1,900.00	$1,745.72#
Nereus™ (tradipitant)	$1,785.00	$1,433.36‡‡
Vizz™ (aceclidine)	$1,095.00	$884.54‡‡
Enflonsia™ (clesrovimab-cfor)	$556.00	$556.00†
Journavx® (suzetrigine)	$232.50	$101.22#

Net price sources: *ASP (Note that ASP is occasionally higher than WAC); †WAC; ‡Median of multiple sources; §SSR Health; #IPD Analytics; ¤FSS; **Manufacturer data submission based on ASP; ††Manufacturer data submission based on FSS pricing; ‡‡Placeholder discount (20%). §§IPD Analytics uses the value of Non-Supply Chain Discount as a placeholder for drugs that do not yet have Rebate Benchmark data available. ##Annual conversion updated from previous Launch Price & Access Report based on manufacturer data submission.

List Price

For all drugs in scope, we obtained the list price or Wholesale Acquisition Cost (WAC) from Redbook at the time of launch (or closest to the time of launch). We used the unit WAC from Redbook and calculated the annual WAC based on dosing information from the FDA label. For drugs with multiple doses, we used the median dose. For weight-based dosing, we used a placeholder body weight based on the indicated population when available, or data from the clinical trial population. For drugs with dosing based on other variables (e.g., body surface area, number of chemotherapy cycles), we used clinical trial data to inform placeholder inputs for the dosing calculations. Table A1.3 lists the assumptions and placeholder inputs we used for annual calculations.

Table A1.3. Assumptions and Inputs Used in Annual Price Calculations

Drug	Assumptions and Inputs
Adzynma	We used a placeholder body weight of 70 kg.
Agamree	We used a placeholder body weight of 30 kg.
Alhemo	We used a placeholder body weight of 70 kg.
Alyftrek	We used the dosing regimen for patients aged 12 years and older.
Anzupgo	We estimated annual costs assuming patients apply 0.5 g of cream per application.
Aphexda	We included only one dose in our calculation, assuming only a minority of patients use the optional second dose.
Aqneursa	We used the dosing regimen for patients weighing 35 kg or more.
Cardamyst	We used a placeholder of 13.5 episodes per year. We included a single 70 mg dose per episode in our annual calculation.
Crenessity	We used the dosing regimen for the adult population.
Datroway	We included 5 units per dose and 17 doses per year in our annual calculation.
Daxxify	We included two treatment sessions within our annual cost estimate.
Daybue	We used the dosing regimen for patients weighing 20 kg to 35 kg.
Defencath	We used a placeholder frequency of hemodialysis sessions of 3 times per week.
Duvyzat	We used a median of the weight-based dosing regimens included in the FDA label.
Ekterly	We used a placeholder number of Hereditary Angioedema attacks of 12. We did not include the optional second 600 mg dosage in our calculation.
Elahere	We used a placeholder body weight of 60 kg.
Elfabrio	We used a placeholder body weight of 80 kg.
Emrelis	We used a placeholder body weight of 70 kg.
Encelto	We included two implants in our calculation of annual cost (one per eye).
Enjaymo	We used a placeholder body weight of 80 kg.
Filsuvez	We assumed a month's supply is 27 tubes.

Drug	Assumptions and Inputs
Grafapex	We used a placeholder BSA of 1.7 m^2.
Hernexeos	We used the dosage for patients weighing less than 90 kg.
Imaavy	We used a placeholder body weight of 70 kg.
Imjudo	We used a placeholder body weight of 80 kg.
Izervay	We assumed both eyes were treated in our calculations.
Journavx	We included an initial dose of 100 mg, followed by 50 mg every 12 hours for one week.
Kygevvi	We included 3 individual packets per day in our annual calculation.
Lamzede	We used a placeholder body weight of 70 kg.
Lantidra	We assumed one infusion bag would be used.
Leqembi	We used a placeholder body weight of 80 kg.
Letybo	We included 3 treatments in our annual estimate.
Miebo	We assumed one package is one month's supply.
Miplyffa	We used the dosing regimen for patients weighing 30 kg to 55 kg.
Modeyso	We estimated annual costs using the recommended dosage for adults.
Nemluvio	We used the dosing regimen for patients weighing less than 90 kg.
Nereus	We included 7 doses in our annual calculation.
NexoBrid	We included one package in our annual cost.
Ngenla	We used a placeholder body weight of 35 kg.
Niktimvo	We used a placeholder body weight of 70 kg.
Ojemda	We used the 375 mg weekly dose in our calculations.
Omlonti	We included one 2.5 ml package in our estimate of annual price.
Pombiliti	We used a placeholder body weight of 70 kg.
Rapiblyk	We used a placeholder body weight of 70 kg and calculated the median of the minimum and maximum dosages listed in the FDA label.
Revuforj	We used the dosing regimen for patients weighing 40 kg or more.
Rezdiffra	We used the dosing regimen for patients weighing less than 100 kg.
Rivfloza	We used the dosing regimen for patients weighing 50 kg or more.
Roctavian	We used a placeholder body weight of 70 kg.
Rolvedon	We assumed the chemotherapy cycle to be 28 days, for a total of 13 cycles per year.
Rystiggo	We used a placeholder of 4 cycles per year.
Rytelo	We used a placeholder body weight of 70 kg.
Ryzneuta	We used a placeholder of 4 cycles per year.
Sephience	We estimated annual costs using the 60 mg/kg dosage, which is recommended for patients 2 years and older. We used a placeholder body weight of 70 kg.
Sofdra	We estimated annual cost based on one pump per day.
Sohonos	We used the dosing regimen for patients 14 years and older.
Talvey	We used a placeholder body weight of 70 kg.
Veopoz	We used a placeholder body weight of 25 kg.
Vizz	We estimated annual costs assuming Vizz is used daily.
Voquezna Triple Pak	We included one kit in our calculation of annual cost.

Drug	Assumptions and Inputs
Vtama	We included 2.4 tubes in our calculation of annual cost. *(Note: This conversion was updated since the previous Launch Price and Access Report due to new utilization data submitted by the manufacturer.)*
Xacduro	We included 7 days of injections every 6 hours in our estimate of annual cost.
Xenpozyme	We used a placeholder body weight of 50 kg.
Xolremdi	We used the dosing regimen for patients weighing 50 kg or more.
Yartemlea	We used a placeholder duration of treatment of 8 weeks, and a placeholder body weight of 50 kg or more.
Zevtera	We included 7 days of injections every 8 hours in our estimate of annual cost.
Ziihera	We used a placeholder weight of 70 kg.
Ztalmy	We used the dosing regimen for patients weighing more than 28 kg.

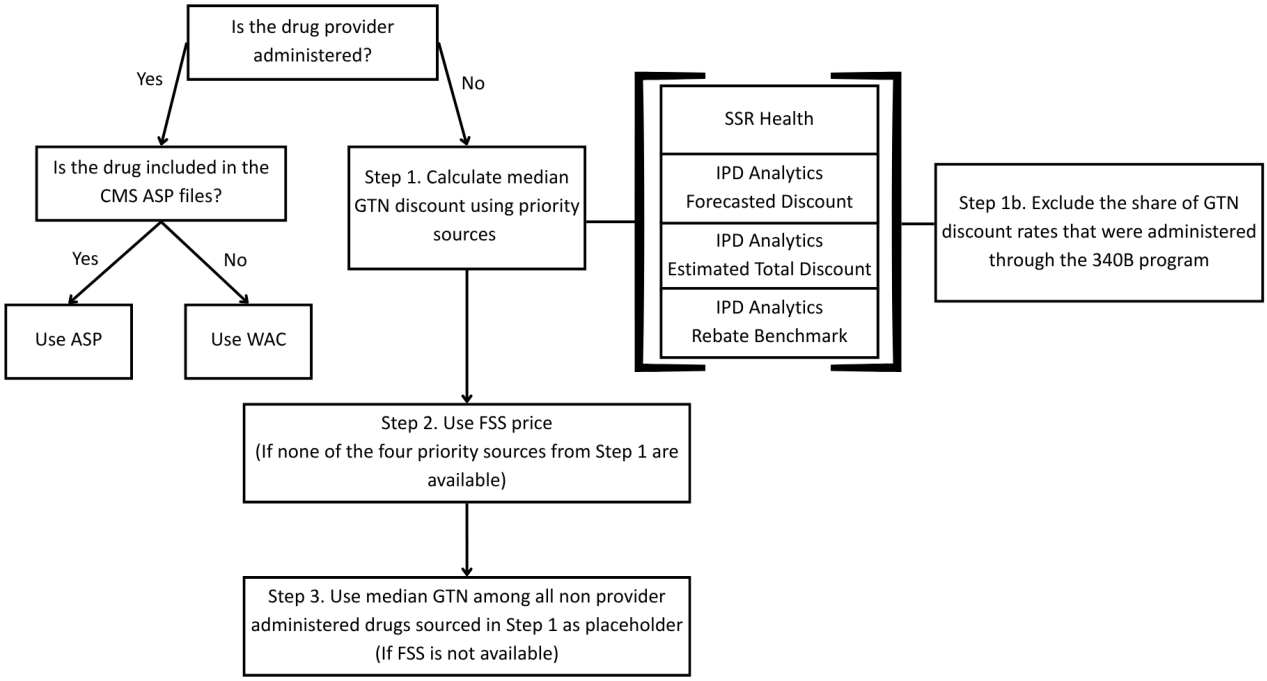
BSA: body surface area, FDA: Food and Drug Administration, g: gram, kg: kilogram, m: meter, mg: milligram, ml: milliliter

Net Price

We used multiple data sources to estimate the net price at the time of launch for drugs in scope (see Figure A1.1). We developed two separate approaches for provider-administered versus non-provider-administered drugs. For provider-administered drugs, we used ASP to represent net price. We sourced ASP from the CMS pricing files and removed the 6% markup included in the CMS payment allowance. For provider-administered drugs in scope that did not have pricing data available from CMS, we used WAC as a placeholder for net price. This approach was informed by the CMS reimbursement policy, which states that CMS reimburses Part B (provider-administered) drugs at the WAC price plus a 3% markup in the quarters before ASP becomes available.[70]

For outpatient pharmacy prescription drugs, we used gross-to-net discount rates from multiple sources to calculate the net price. We prioritized data from the Rebate Benchmark and Estimated Total Discounts from the IPD Analytics Rebate Monitor, forecasted discounts from the IPD Analytics Market & Financial Insights, and gross-to-net discount rates from SSR Health. When more than one of these sources had data for a drug in scope, we calculated the median of all discount data available. If data was not available from any of these sources for a drug in scope, we used the FSS price closest to the time of launch. If FSS data were also not available, we used a placeholder gross-to-net discount rate calculated as the median discount among all other outpatient drugs in scope approved in 2025, which was 23%.

Figure A1.1. Prioritization of Net Price Data Sources Flowchart



ASP: Average Sales Price, CMS: Centers for Medicare and Medicaid Services, FSS: Federal Supply Schedule, GTN: gross-to-net, WAC: Wholesale Acquisition Cost

After collecting net prices from all sources, we adjusted our net price estimates to exclude the share of gross-to-net discount rates that were administered through the 340B program. Since some of our net price data sources incorporated 340B discounts (IPD Analytics, SSR Health) and some did not incorporate 340B discounts (WAC, ASP, FSS), we adjusted our estimates accordingly and standardized the exclusion of 340B discounts. We chose to exclude the share of discounts that were attributable to the 340B program because the goal of our analysis was to evaluate trends in net drug prices paid by the health system, as opposed to net revenue received by manufacturers. 340B discounts decrease the net price paid to manufacturers, but because these savings are realized by facilities and other covered entities but are not passed on to payers, they do not decrease the net price paid by the health system. Therefore, in net price estimates sourced from SSR Health or IPD Analytics, we adjusted the overall gross-to-net discounts to account for the share of discounts that were attributable to the 340B program, resulting in slight increases in net price.

To execute this 340B adjustment, we identified the share of total sales that were administered through 340B eligible providers and pharmacists according to drug class,[26] and the estimated 340B-specific discount from WAC (sourced from IPD Analytics).[27] We used these inputs for each drug where net price was sourced from SSR Health or IPD Analytics and recalculated net price using the following formulas:

Non 340B Net Cost [final estimate] *= WAC * (1 - Non 340B Total Discount)*

Non 340B Total Discount = Non 340B Supply Chain Discount + Non Supply Chain Discount

*Non Supply Chain Discount = Overall Gross-to-Net Discount Rate – (Non 340B share of sales * Non 340B Supply Chain Discount) – (340B share of sales * 340B supply chain discount)*

We then used the Non 340B Net Cost as our final net price estimate, which is intended to be reflective only of discounts to the prices paid by the health system, and not inclusive of any discounts in revenue realized by the manufacturer (i.e., 340B discounts).

As part of our net price estimation methods for this report, we administered a survey that allowed manufacturers of any drug in our scope to submit their annual WAC and net prices. Through this survey, we received one submission from a manufacturer that corrected the conversion from unit to annual price for a drug, Vtama, that was included in our 2025 Launch Price and Access Report.[9] We updated our annual conversion based on the feedback received from this manufacturer. Aside from this update, and the 340B adjustments previously described, we did not update any net price data that was previously calculated for drugs approved between 2022 and 2024 that were included in our previous Launch Price and Access Report.

Data Analysis

List and Net Price

As noted in the main report, the list and net price data were heavily skewed due to some extremely expensive launch prices; therefore, we report the median prices in the unadjusted analysis. The list and net prices for drugs approved in 2022, 2023, and 2024 were inflation-adjusted to 2025 values.[28]

As also noted in the main report, we conducted trend analyses to examine changes in list and net prices at launch from 2022-2025, while controlling for drug characteristics listed above in Table A1.1. This is the adjusted analysis.

Therapeutic area (e.g., oncology, cardiovascular, hematology, etc.) was one of the drug characteristics of interest. To ensure robust adjustment for therapeutic area as a covariate, we only included therapeutic areas that had at least ten drugs in the category and were significantly associated with launch price.

We conducted ordinary least squares regression analyses with log-transformed list or net price as the dependent variable and year approved as the independent variable. We included drug characteristics as covariates in the model. Due to a heavy skew, we log-transformed list and net price (outcome variable). We also conducted the regression analysis with log-transformed list or net price as the dependent variable, year approved as the independent variable, and drug characteristics and their interaction with year (the effect of one variable on the dependent variable

depends on the level of another variable; e.g., year approved impacts list or net price only when the population is rare) as covariates in the model. In these models, we were able to identify drug characteristics that are associated with list and net price over time.

All categorical covariates were converted into dummy variables for inclusion in the regression analyses. As independent variables may be correlated (multicollinearity), we assessed the correlation between the independent variables in the model. For continuous variables, we examined the correlation coefficients; for categorical variables, we examined chi-square tests of independence for each pair of variables; for mixed, we examined Wilcoxon signed rank tests. We also examined Variance Inflation Factors (VIFs) post-model estimation. All analyses were conducted in R.

Additional Results

We report a summary of the key findings in the main report. In this Appendix, we report the detailed multiple regression analyses and scenario analyses.

Launch Price by Drug Characteristics

In Tables A1.4 and A1.5 we provide median list and net price by drug characteristics and approval year.

Table A1.4. Median List Price by Drug Characteristics and Year

	All Years	N	2022	N	2023	N	2024	N	2025
Gene/Cell Therapies	$2,585,331	5	$3,080,216	6	$2,454,909	6	$2,169,113	4	$1,543,315
Non-Gene/Cell Therapies	$230,818	35	$108,174	55	$252,296	48	$251,282	43	$263,615
Ultra-Rare Therapies	$650,983	7	$509,886	15	$616,201	12	$732,952	5	$795,739
Non-Ultra-Rare Therapies	$197,339	33	$98,457	46	$163,858	42	$229,026	42	$238,266
Orphan Drugs	$450,450	24	$374,354	36	$408,750	33	$528,551	26	$480,000
Non-Orphan Drugs	$32,842	16	$30,653	25	$28,000	21	$32,842	21	$52,000
Biologics	$391,901	23	$374,246	31	$369,804	27	$528,551	19	$460,000

	All Years	N	2022	N	2023	N	2024	N	2025
Small Molecules	$163,683	17	$98,457	30	$146,066	27	$157,409	28	$198,990
Oncology Therapies	$369,804	13	$374,462	15	$357,126	17	$410,598	14	$387,256
Non-Oncology Therapies	$157,409	27	$66,885	46	$180,231	37	$157,409	33	$197,339
Hematology Therapies	$581,122	4	$1,727,231	6	$1,452,804	6	$691,447	3	$294,440
Non-Hematology Therapies	$264,019	36	$196,310	55	$274,585	48	$277,527	44	$292,652
Dermatology	$56,410	6	$30,312	4	$343,172	5	$56,570	3	$55,006
Non-Dermatology Therapies	$300,100	34	$272,429	57	$306,832	49	$339,422	44	$293,656

N: number

Table A1.5. Median Net Price by Drug Characteristics and Year

	All years	N	2022	N	2023	N	2024	N	2025
Gene/Cell Therapies	$2,352,728	5	$2,352,727	6	$2,454,909	6	$2,169,113	4	$1,543,315
Non-Gene/Cell Therapies	$201,321	35	$73,793	55	$210,162	48	$212,932	43	$232,351
Ultra-Rare Therapies	$591,734	7	$506,020	15	$548,258	12	$668,982	5	$694,083
Non-Ultra-Rare Therapies	$178,666	33	$73,095	46	$153,692	42	$197,140	42	$217,942
Orphan Drugs	$421,134	24	$356,271	36	$404,002	33	$528,551	26	$475,298
Non-Orphan Drugs	$31,909	16	$25,564	25	$27,990	21	$31,909	21	$34,428
Biologics	$388,406	23	$366,901	31	$369,791	27	$528,551	19	$460,000
Small Molecules	$144,599	17	$73,793	30	$125,848	27	$144,659	28	$158,230
Oncology Therapies	$345,641	13	$345,641	15	$322,634	17	$405,610	14	$366,237

	All years	N	2022	N	2023	N	2024	N	2025
Non-Oncology Therapies	$123,159	27	$56,580	46	$168,918	37	$144,659	33	$152,386
Hematology Therapies	$566,360	4	$1,359,814	6	$1,412,300	6	$638,618	3	$294,440
Non-Hematology Therapies	$228,735	36	$163,614	55	$226,656	48	$243,850	44	$245,511
Dermatology	$39,004	6	$21,618	4	$263,970	5	$38,236	3	$34,428
Non-Dermatology Therapies	$263,534	34	$259,547	57	$252,296	49	$316,681	44	$265,276

N: number

Multiple Regression Results

List Price

We fitted a multiple regression model with year predicting the list price (log-transformed list price) while controlling for all drug characteristics. List prices increased over the four years, independent of drug characteristics, but the increase was not statistically significant (β=0.15, p=0.16). See Figure A1.2 visually displaying the predicted launch price across the four years, adjusting for drug characteristics. In this model, 49% of the variance was explained by the predictors (p<0.001). Oncology drugs, hematology drugs, gene and cell therapy, and ultra-rare products were significant covariates and associated with higher list prices. There was no evidence of multicollinearity. See Table A1.6 for the percentage change in list price by each drug characteristic. See Table A1.8 for Beta estimates of the drug characteristics.

Next, we fitted a multiple regression model with year predicting list price (log-transformed list price) while controlling for all drug characteristics and their interaction with approval year. After controlling for drug characteristics and their interaction with year, list price increased each year, but the increase was not statistically significant (β=0.30, p=0.28). In this model, 49% of the variance was explained by year and the covariates (p<0.001). In this model, there were no significant interaction terms. See Table A1.9 for Beta estimates of the drug characteristics and their interactions.

Figure A1.2. Predicted Launch Price by Approval Year, Adjusted for Drug Characteristics

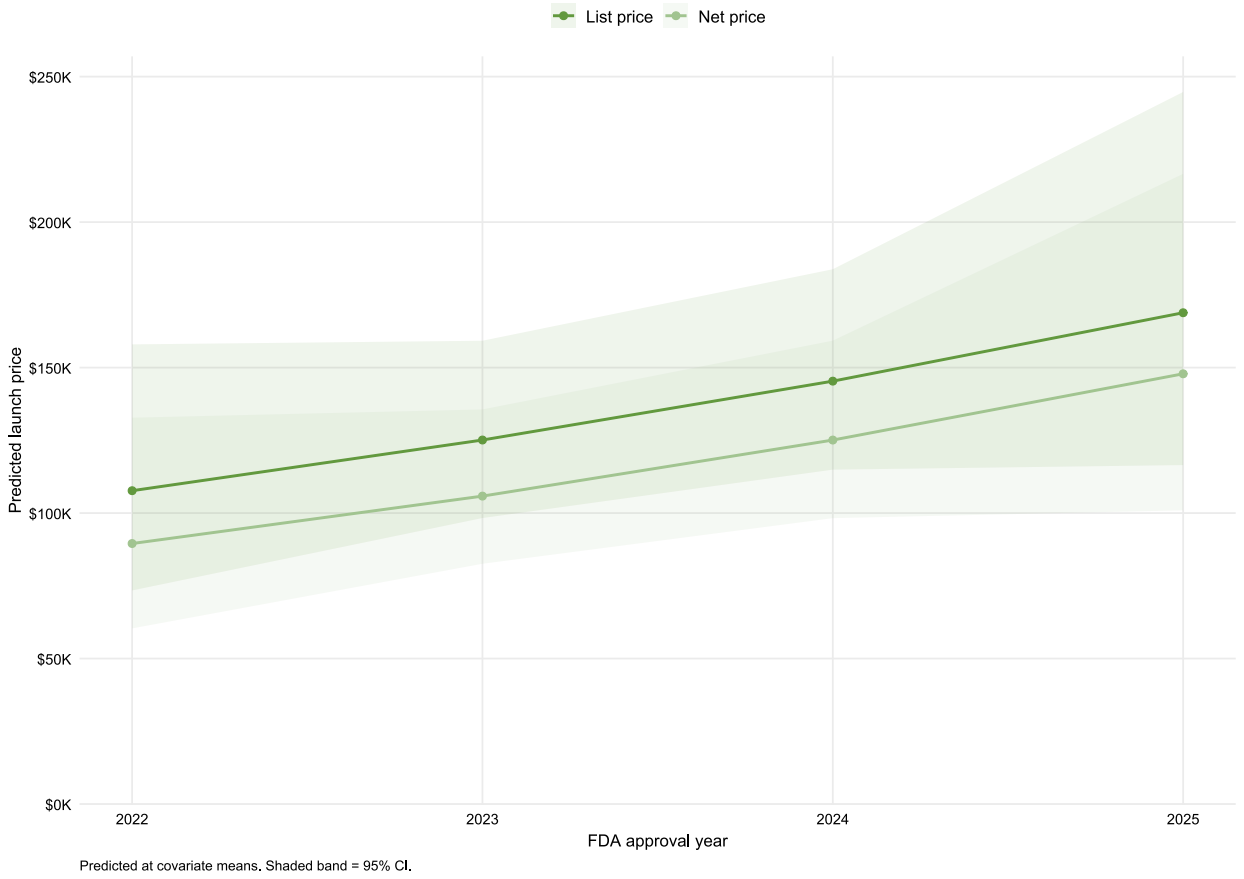


Table A1.6. Multiple Log-Linear Regression Reporting Change in List Price by Year and Drug Characteristics

Drug Characteristics		List Price			
		Median List Price Annual Price	Relative Change (Unadjusted)	Percentage Change (Unadjusted)	Percentage Change (Adjusted)*
All Drugs (N=202)		$277,552 ($233-$4,361,830)	-	-	-
Year†	**2022, n=40**	$237,149 ($385-$3,850,270)	Reference	Reference	Reference
	2023, n=61	$306,832 ($501-$3,381,072)	+$69,683	+29%	+16%
	2024, n=54	$299,630 ($677-$4,361,830)	+$62,481	+26%	
	2025, n=47	$293,304 ($233-$3,147,000)	+$56,155	+24%	
Indication‡§	**Oncology, n=59**	$369,804 ($12,468-$1,423,984)	+$212,395	+135%	**+504%**
	Hematology, n=19	$581,122 ($12,063-$3,850,270)	+$317,104	+120%	**+231%**
	Dermatology, n=18	$56,410 ($677-$3,147,000)	-$243,690	-81%	-23%
	Endocrine/Metabolic, n=26	$518,561 ($501-$4,361,830)	+$261,917	+102%	+101%
Drug Type	**Biologic, n=100**	$391,901 ($523-$4,361,830)	+$228,218	+139%	+49%
	Small Molecule, n=102	$163,683 ($233-$992,889)	Reference	Reference	Reference
Type of Therapy	**Gene/Cell Therapy, n=21**	$2,585,331 ($264,019-$4,361,830)	+$2,354,514	+1020%	**+333%**
	Not Gene/Cell Therapy, n=181	$230,818 ($233-$1,592,838)	Reference	Reference	Reference

Drug Characteristics		List Price			
		Median List Price Annual Price	Relative Change (Unadjusted)	Percentage Change (Unadjusted)	Percentage Change (Adjusted)*
Mechanism	**First-in-Class, n=99**	$392,121 ($385-$4,361,830)	+$212,807	+119%	+43%
	Not First-in-Class, n=103	$179,314 ($233-$3,592,096)	Reference	Reference	Reference
Population Size	**Ultra-Rare, n=39**	$650,983 ($51,583-$4,361,830)	$453,644	+230%	**+585%**
	Not Ultra-Rare, n=163	$197,339 ($233-$3,850,270)	Reference	Reference	Reference
FDA Designation	**Breakthrough, n=65**	$374,246 ($233-$3,850,270)	+$165,129	+79%	+27%
	Not Breakthrough, n=137	$209,117 ($385-$4,361,830)	Reference	Reference	Reference
Approval Pathway	**Accelerated, n=37**	$374,462 ($28,000-$4,053,936)	+$123,489	+49%	+64%
	Not Accelerated, n=165	$250,973 ($233-$4,361,830)	Reference	Reference	Reference
First Approved in US	**First in US, n=139**	$305,760 ($233-$3,850,270)	+$126,446	+71%	+17%
	Not First in US, n=63	$179,314 ($385-$4,361,830)	Reference	Reference	Reference

CI: confidence interval, FDA: Food and Drug Administration, N: total number of drugs, n: number, US: United States
Bold signifies significant independent variables in the model.
*We exponentiated log-transformed list price to provide percentage change
†Year was included as a linear factor in the adjusted analysis
‡All therapeutic areas that had at least ten drugs in the category and were significantly associated with price were included in the analysis.
§Each indication is compared to all other drugs for relative and percentage change, e.g., oncology vs. non-oncology drugs.

Net Price

We fitted a multiple regression model with year predicting net price (log-transformed net price) while controlling for all drug characteristics. Net prices increased over the four years, but the increase was not statistically significant, independent of drug characteristics (β=0.17, p=0.13). See Figure A1.2 visually displaying the predicted launch price across the four years, adjusting for drug characteristics. In this model, 51% of the variance was explained by the predictors (p<0.001).

Oncology drugs, hematology drugs, biologics, gene and cell therapy, and ultra-rare drugs were significant covariates and associated with higher net prices. There was no evidence of multicollinearity. See Table A1.7 for the percentage change in net price by each drug characteristic. See Table A1.8 for Beta estimates of the drug characteristics.

Next, we fitted a multiple regression model with year predicting net price (log-transformed net price) while controlling for all drug characteristics and their interaction with approval year. After controlling for drug characteristics and their interaction with year, net price increased each year, but the increase was not statistically significant (β=0.33, p=0.25). In this model, 51% of the variance was explained by year and the covariates ($p<0.001$). In this model, there were no significant interaction terms. See Table A1.9 for Beta estimates of the drug characteristics and their interactions.

Table A1.7. Multiple Log-Linear Regression Reporting Change in Net Price by Year and Drug Characteristics

Drug Characteristics		Net Price			
		Median Net Price Annual Price	Relative Change (Unadjusted)	Percentage Change (Unadjusted)	Percentage Change (Adjusted)*
All Drugs (N=202)		$244,354 ($101-$4,361,830)	-	-	-
Year†	**2022, n=40**	$190,553 ($306-$3,300,231)	Reference	Reference	Reference
	2023, n=61	$252,296 ($429-$3,381,072)	+$61,743	+32%	+18%
	2024, n=54	$261,368 ($677-$4,361,830)	+$70,815	+37%	
	2025, n=47	$257,369 ($101-$3,147,000)	+$66,816	+35%	
Indication‡§	**Oncology, n=59**	$345,641 ($12,468-$1,423,984)	+$222,482	+181%	**+572%**
	Hematology, n=19	$566,361 ($8,849-$3,592,096)	+$337,627	+148%	**+232%**
	Dermatology, n=18	$39,004 ($621-$3,147,000)	-$224,531	-85%	-32%
	Endocrine/Metabolic, n=26	$491,136 ($429-$4,361,830)	+$277,910	+130%	+96%

Drug Characteristics		List Price			
		Median List Price Annual Price	Relative Change (Unadjusted)	Percentage Change (Unadjusted)	Percentage Change (Adjusted)*
Drug Type	**Biologic, n=100**	$388,406 ($523-$4,361,830)	+$243,807	+169%	**+77%**
	Small Molecule, n=102	$144,599 ($101-$965,336)	Reference	Reference	Reference
Type of Therapy	**Gene/Cell Therapy, n=21**	$2,352,728 ($263,626-$4,361,830)	+$2,151,407	+1069%	**+348%**
	Not Gene/Cell Therapy, n=181	$201,321 ($101-$1,599,372)	Reference	Reference	Reference
Mechanism	**First-in-Class, n=99**	$386,871 ($101-$4,361,830)	+$224,026	+138%	+35%
	Not First-in-Class, n=103	$162,845 ($306-$3,592,096)	Reference	Reference	Reference
Population Size	**Ultra-Rare, n=39**	$591,734 ($39,400-$4,361,830)	+$413,068	+231%	**+683%**
	Not Ultra-Rare, n=163	$178,666 ($101-$3,381,072)	Reference	Reference	Reference
FDA Designation	**Breakthrough, n=65**	$366,901 ($101-$3,592,096)	+$173,605	+90%	+31%
	Not Breakthrough, n=137	$193,296 ($306-$4,361,830)	Reference	Reference	Reference
Approval Pathway	**Accelerated, n=37**	$374,462 ($27,990-$4,053,936)	+$175,313	+88%	+67%
	Not Accelerated, n=165	$199,149 ($101-$4,361,830)	Reference	Reference	Reference
First Approved in US	**First in US, n=139**	$265,854 ($101-$3,381,072)	+$103,009	+63%	+18%
	Not First in US, n=63	$162,845 ($306-$4,361,830)	Reference	Reference	Reference

CI: confidence interval, FDA: Food and Drug Administration, N: total number of drugs, n: number, US: United States
All analyses were conducted in R.
*We exponentiated log-transformed net price to provide percentage change.
†Year was included as a linear factor in the adjusted analysis.
‡All therapeutic areas that had at least ten drugs in the category and were significantly associated with price were included in the analysis.
§Each indication is compared to all other drugs for relative and percentage change, e.g., oncology versus non-oncology drugs.

Table A1.8. Multiple Log-Linear Regression Predictors for List and Net Price

Predictor/Covariate	List Price Estimate	p-Value	Net Price Estimate	p-Value	VIF
Intercept (Baseline Price)	9.94	-	9.66	-	-
Year	0.15	0.16	0.17	0.13	1.04
Oncology	1.80	<0.001	1.91	<0.001	1.51
Hematology	1.20	0.006	1.20	0.008	1.35
Dermatology	-0.26	0.53	-0.38	0.37	1.18
Endocrine/Metabolic	0.70	0.07	0.67	0.09	1.41
Drug type: Biologic vs. Small Molecule	0.40	0.11	0.57	0.02	1.26
Gene/Cell Therapy	1.47	<0.001	1.50	<0.001	1.23
First-in-Class	0.36	0.14	0.30	0.24	1.23
Ultra-Rare Drug	1.93	<0.001	2.06	<0.001	1.39
Breakthrough Designation	0.24	0.37	0.27	0.31	1.25
Accelerated Approval	0.49	0.12	0.52	0.12	1.26
First Approved in US	0.16	0.54	0.16	0.54	1.18

US: United States, VIF: Variance Inflation Factor

Table A1.9. Multiple Log-Linear Regression Predictors (and Interactions) for List and Net Price

Predictor/Covariate	List Price Estimate	p-Value	Net Price Estimate	p-Value	VIF†
Intercept (Baseline price)	9.95	<0.001	9.67	<0.001	—
Year	0.30	0.28	0.33	0.25	6.84
Oncology	1.76	<0.001	1.86	<0.001	1.55
Hematology	1.14	0.01	1.15	0.02	1.43
Dermatology	-0.21	0.64	-0.33	0.47	1.26
Endocrine/Metabolic	0.65	0.11	0.62	0.14	1.46

Predictor/Covariate	List Price Estimate	p-Value	Net Price Estimate	p-Value	VIF†
Drug Type: Biologic vs. Small Molecule	0.41	0.11	0.58	0.03	1.30
Gene/Cell Therapy	1.50	<0.001	1.55	<0.001	1.39
First-in-Class	0.34	0.18	0.28	0.29	1.30
Ultra-rare Drugs	1.93	<0.001	2.06	<0.001	1.52
Breakthrough Designation	0.28	0.31	0.32	0.26	1.31
Accelerated Approval	0.51	0.12	0.53	0.12	1.29
First Approved in US	0.16	0.56	0.17	0.55	1.29
Year * Oncology	-0.01	0.98	0.004	0.99	2.54
Year * Hematology	0.12	0.79	0.20	0.67	1.60
Year * Dermatology	0.19	0.63	0.21	0.60	1.40
Year * Endocrine/Metabolic	0.29	0.45	0.34	0.39	1.81
Year * Drug Type: Biologic vs. Small Molecule	0.02	0.93	-0.002	0.995	2.56
Year * Gene/Cell Therapy	-0.02	0.95	0.02	0.97	1.65
Year * First-in-Class	-0.01	0.98	-0.01	0.97	2.66
Year * Ultra-rare Drug	-0.27	0.48	-0.31	0.43	1.99
Year * Breakthrough Designation	-0.21	0.41	-0.25	0.34	2.23
Year * Accelerated Approval	0.01	0.96	0.02	0.96	1.71
Year * First Approved in US	-0.14	0.59	-0.15	0.58	4.32

US: United States, VIF: Variance Inflation Factor

Denotes an interaction (e.g., year oncology = whether the effect of year changes for oncology versus non-oncology drugs).

†As these predictors include interaction terms, VIF was higher than what was deemed normal.

Scenario Analyses

1.0 Stepwise Regression

While the primary analysis, which includes all covariates, provides a comprehensive assessment of their impact, a more parsimonious model can help identify the most relevant predictors and reduce potential overfitting. We conducted scenario analyses that only included the most relevant variables that predicted list price or net price and assessed the robustness of the primary analysis results.[71] We conducted regression models using variable selection techniques: stepwise regression analyses. In the stepwise analyses, year was included first in the null model as a predictor of list or net price, and all drug characteristics were then added as possible predictors.

List Price

We conducted a stepwise regression analysis with year and all drug characteristics predicting list price (log-transformed list price). List price increased (β=0.16, p=0.12), independent of gene and cell therapies, ultra-rare drugs, oncology drugs, hematology drugs, endocrine drugs, biologics, accelerated approval, and first-in-class drugs. The model accounts for 48% of the variance in list price (p<0.001). See Table A1.10 for Beta values. The scenario analysis results are consistent with the base-case multiple regression described above.

Table A1.10. Stepwise Regression Predictors for List Price

Predictor/Covariate	List Price Estimate	p-Value
Intercept	10.01	-
Year	0.16	0.12
Gene/Cell Therapy	1.48	<0.001
Ultra-Rare Drugs	1.92	<0.001
Oncology Drugs	1.91	<0.001
Hematology Drugs	1.27	0.002
Biologics	0.37	0.013
Accelerated Approval	0.58	0.06
Endocrine/Metabolic Drugs	0.78	0.04
First-in-Class	0.44	0.06

Net Price

We conducted a stepwise regression analysis with year and all drug characteristics predicting net price (log-transformed net price). Net prices increased (β=0.18, p=0.08), independent of covariates: gene and cell therapy, ultra-rare drugs, oncology drugs, biologics, hematology drugs, endocrine/metabolic drugs, accelerated approval, and first-in-class. The model accounts for 50% of the variance in net price (p<0.001). See Table A1.11 for Beta values. The scenario analysis results are consistent with the base-case multiple regression described above.

Table A1.11. Stepwise Regression Predictors for Net Price

Predictor/Covariate	Net Price Estimate	p-Value
Intercept	9.71	-
Year	0.18	0.08
Gene/Cell Therapy	1.51	<0.001
Ultra-Rare Drugs	2.05	<0.001
Oncology Drugs	2.05	<0.001
Biologics	0.53	0.03
Hematology Drugs	1.30	0.002
Accelerated Approval	0.62	0.05
Endocrine/Metabolic Drugs	0.79	0.04
First-in-Class	0.40	0.10

1.1 Quadratic Regression

As noted in the main report, we also fitted a quadratic regression model to examine whether it provided a better fit to the price trend than the linear model. As shown in Table A1.12, linear year had a positive coefficient, whereas quadratic year had a negative coefficient. However, because the quadratic term was not statistically significant, the model did not support a nonlinear relationship between year and list or net price. Thus, we report the linear regression results as our primary analysis. We also conducted a stepwise regression including both linear and quadratic year in the full model to identify which term should be retained. In this model, only linear year remained as a predictor of list or net price.

Table A1.12. Regression Analysis with Linear and Quadratic Term for Approval Year

Predictor/Covariate	List Price Estimate	p-Value	Net Price Estimate	p-Value
Intercept	10.06	-	9.81	-
Year (Linear)	0.14	0.19	0.15	0.16
Year (Quadratic)	-0.13	0.24	-0.17	0.14
Oncology	1.80	<0.001	1.90	<0.001
Hematology	1.20	0.006	1.21	0.007
Dermatology	-0.22	0.59	-0.33	0.44
Endocrine/Metabolic	0.74	0.06	0.72	0.07
Drug type: Biologic vs. Small Molecule	0.39	0.11	0.56	0.03
Gene/Cell Therapy	1.47	<0.001	1.50	<0.001
First-in-Class	0.37	0.13	0.31	0.21
Ultra-Rare Drug	1.87	<0.001	1.99	<0.001
Breakthrough Designation	0.27	0.31	0.31	0.24
Accelerated Approval	0.49	0.12	0.51	0.12
First Approved in US	0.18	0.48	0.20	0.46

1.2 Conservative Pricing (FSS)

We conducted a scenario analysis to evaluate differences in trend analysis results using a conservative net pricing approach (i.e., FSS pricing). See Net Price Section A1 above. To provide the most appropriate comparison in estimates, we only included drugs that had complete data for list, net, and FSS pricing. There was a total of 184 drugs included in this scenario analysis. We were unable to determine whether the excluded drugs were missing at random. Drugs approved in the most recent years were more likely to be excluded. Thus, this should be considered when interpreting the data.

Table A1.13 presents the median annual prices for list, net, and FSS pricing. Consistent with our assumption, FSS had a lower median annual price compared to our net price estimates.

Table A1.13. Launch Price: Median Annual List, Net, FSS Price*

	Annual List Price		Annual Net Price		Annual FSS Price	
Year	**Median (Range)**	**Median (Range) Adjusted to 2025***	**Median (Range)**	**Median (Range) Adjusted to 2025***	**Median (Range)**	**Median (Range) Adjusted to 2025***
2022, n=38	$238,625 ($812-$3,500,000)	$262,506 ($893-$3,850,270)	$195,466 ($454-$3,000,000)	$215,028 ($499-$3,300,231)	$180,454 ($561-$2,894,755)	$198,513 ($617-$3,184,453)
2023, n=58	$275,140 ($495-$3,200,000)	$290,709 ($523-$3,381,072)	$231,267 ($495-$3,200,000)	$244,354 ($523-$3,381,072)	$210,196 ($371-$3,183,920)	$222,090 ($391-$3,364,082)
2024, n=47	$298,088 ($1,950-$4,250,000)	$305,931 ($2,001-$4,361,830)	$259,038 ($1,596-$4,250,000)	$265,854 ($1,638-$4,361,830)	$227,685 ($1,460-$3,246,231)	$233,676 ($1,498-$3,331,649)
2025, n=41	$294,008 ($233-$3,147,000)	$294,008 ($233-$3,147,000)	$273,183 ($101-$3,147,000)	$273,183 ($101-$3,147,000)	$221,830 ($174-$2,547,635)	$221,830 ($174-$2,547,635)

n: number of drugs

*Prices for drugs approved in 2022-2024 were adjusted for inflation to 2025 values.[28]

Adjusted FSS Price Changes

After accounting for drug characteristics in the model, the annual FSS price increased by 14% per year (95% CI: -8% to 40%), although this was not statistically significant (β=0.13, p=0.23). The results were consistent with the changes in list and net price. The results of the regression analysis are reported in Table A1.15.

Table A1.14. Adjusted Change in List, Net, and FSS Price

	List Price Change	Net Price Change	FSS Price Change
2022 to 2025, n=184	+14% per year (95% CI: −7% to +40%, p=0.20)	+16% per year (95% CI: −6% to +44%, p=0.16)	+14% per year (95% CI: −8% to +40%, p=0.23)

n: number of drugs

Table A1.15. Multiple Log-Linear Regression Predictors for List and Net Price

Predictor/Covariate	List Price Estimate	p-Value	Net Price Estimate	p-Value	FSS Price Estimate	p-Value	VIF
Intercept (Baseline Price)	10.25	-	9.95	-	9.95	-	-
Year	0.13	0.20	0.15	0.16	0.13	0.23	1.04
Oncology	1.67	<0.001	1.78	<0.001	1.67	<0.001	1.49
Hematology	1.07	0.01	1.09	0.01	1.08	0.01	1.33
Dermatology	-0.13	0.77	-0.27	0.55	-0.15	0.74	1.17
Endocrine/Metabolic	0.74	0.07	0.71	0.09	0.75	0.07	1.48
Drug type: Biologic vs. Small Molecule	0.37	0.12	0.54	0.03	0.39	0.10	1.23
Gene/Cell Therapy	1.61	<0.001	1.64	<0.001	1.63	<0.001	1.20
First-in-Class	0.21	0.38	0.15	0.55	0.21	0.39	1.22
Ultra-Rare Drug	1.76	<0.001	1.90	<0.001	1.76	<0.001	1.42
Breakthrough Designation	0.21	0.40	0.26	0.32	0.24	0.35	1.26
Accelerated Approval	0.45	0.14	0.47	0.14	0.47	0.13	1.28
First Approved in US	0.07	0.77	0.08	0.76	0.08	0.77	1.17

FSS: Federal Supply Schedule, US: United States, VIF: Variance Inflation Factor

1.3 Is Ultra-Rare Drug or Orphan Drug a Better Predictor of Price?

To ensure direct comparison to last year's results, we conducted a scenario analysis where we included orphan drug instead of ultra-rare drug, as we did last year. The results are provided below, and inclusion of an orphan drug instead of an ultra-rare drug did not change the model results. See Table A1.16.

List Price

In this scenario analysis, we re-fitted the multiple regression model with year predicting the list price (log-transformed list price) while controlling for all drug characteristics, replacing ultra-rare with orphan designation in the model. After adjustment, approval year was associated with a 14% higher list price per additional year (95% CI: −6% to 39%; β=0.13, p=0.17), although this was not statistically significant. The model explained 56% of the variation in list price (p<0.001), comparable

to the primary model. There was no evidence of multicollinearity. See Table A1.16 for Beta estimates of the drug characteristics.

To confirm which predictor best fits the model, we also conducted a stepwise regression including both orphan drug and ultra-rare drug in the full model. In this model, only ultra-rare drug remained as a significant predictor of list price (as well as the other significant drug characteristics as noted above).

Net Price

In this scenario analysis, we re-fitted the multiple regression model with year predicting the net price (log-transformed net price) while controlling for all drug characteristics, replacing ultra-rare with orphan designation in the model. After adjustment, approval year was associated with a 16% higher net price per additional year (95% CI: −4% to 41%; β=0.15, p=0.13), although this was not statistically significant. The model explained 59% of the variation in net price (p<0.001), comparable to the primary model. There was no evidence of multicollinearity. See Table A1.16 for Beta estimates of the drug characteristics.

To confirm which predictor best fits the model, we also conducted a stepwise regression including both orphan drug and ultra-rare drug in the full model. In this model, only ultra-rare drug remained as a significant predictor of net price (as well as the other significant drug characteristics as noted above).

Table A1.16. Multiple Log-Linear Regression Predictors for List and Net Price

Predictor/Covariate	List Price Estimate	p-Value	Net Price Estimate	p-Value	VIF
Intercept (Baseline Price)	9.55	-	9.25	-	-
Year	0.13	0.17	0.15	0.13	1.04
Oncology	1.17	<0.001	1.24	<0.001	1.50
Hematology	0.98	0.02	0.97	0.02	1.36
Dermatology	0.08	0.84	-0.02	0.96	1.19
Endocrine/Metabolic	0.87	0.01	0.86	0.02	1.31
Drug type: Biologic vs. Small Molecule	0.27	0.23	0.43	0.06	1.26
Gene/Cell Therapy	1.29	<0.001	1.31	<0.001	1.24
First-in-Class	0.34	0.12	0.28	0.21	1.21

Predictor/Covariate	List Price Estimate	p-Value	Net Price Estimate	p-Value	VIF
Orphan Drug	1.29	<0.001	2.15	<0.001	1.29
Breakthrough Designation	0.11	0.66	0.13	0.59	1.25
Accelerated Approval	0.35	0.24	0.36	0.23	1.27
First Approved in US	-0.02	0.93	-0.03	0.91	1.18

US: United States, VIF: Variance Inflation Factor

A2. Clinical Trial Evidence

Methods

As secondary research objectives, we evaluated the quantity and characteristics of clinical trial evidence supporting newly approved drugs and the timing of the publication of those trials in relation to FDA approval. We identified the pivotal trials supporting FDA approval for drugs approved between July 2024 and June 2025. We abstracted data on the number and phase of pivotal clinical trials included in the FDA submission, the number of participants enrolled in the pivotal trials, trial design (e.g., randomized trial, single-arm trial), and publication date of the primary peer-reviewed manuscript(s) reporting trial results. Data were collected from the FDA Drug Trial Snapshots, FDA labels, clinicaltrials.gov, and published manuscripts.

Analysis

We provided descriptive statistics (e.g., mean, median) for the number of pivotal trials supporting FDA approval for drugs approved between July 2024 and June 2025. We assessed the proportion of drugs that had a publication of peer-reviewed manuscript(s) of the pivotal clinical trial(s) published before FDA approval. In those that did not have a publication before FDA approval, we evaluated the time between publication of peer-reviewed manuscript and FDA approval of the drug.

Results

For 50 drugs approved between July 2024 and June 2025, 68% of drugs were approved based on evidence from one pivotal clinical trial. The mean number of pivotal trials that were included in the FDA approval package was 1.4 (median: 1, interquartile range [IQR]: 1 to 2), with a mean number of participants of 625 (median: 228, IQR: 82 to 732). Overall, 70% of drugs were approved based on evidence from one or more RCT, while 30% were approved based on single-arm trials only. A total of 16% of drugs received accelerated approval.

To assess the availability of clinical evidence at the time of FDA approval, we examined whether the pivotal trial results had been published in a peer-reviewed journal before or after FDA approval. For those published after FDA approval, we examined the time from FDA approval to publication.

A total of 34% of drugs did not have a pivotal trial published in a peer-reviewed manuscript before FDA approval. The median time from FDA approval to publication was 75 days (IQR: 54 to 119), with a mean of 119 days (SD: 113.8). Three drugs had pivotal trials published more than 300 days after approval: Hympavzi (356 days), penpulimab-kcqx (350 days), and Tryptyr (338 days). All drugs included the clinical trial results in the FDA submission package and had clinical trials that were completed before peer-reviewed publication. In the case of Tryptyr, the primary completion date reported on ClinicalTrials.gov was up to 730 days before peer-reviewed publication was available.

We further compared the characteristics of drugs whose pivotal trials were published after FDA approval with those whose trials were published before approval. Those drugs with pivotal trials published after FDA approval were more likely to have been approved based on single-arm trials compared to drugs with pivotal trials published before FDA approval (41% vs. 24%). They were more likely to be a dermatology drug (12% vs. 6%), hematology drug (12% vs. 3%), a biologic drug (65% vs. 45%), gene and cell therapy (24% vs. 3%), first-in-class drug (65% vs. 42%), or drug approved first in the US (88% vs. 64%). We conducted chi-squared analyses to compare these characteristics, but none of the differences were statistically significant. There were also no differences between the groups for other therapeutic areas (e.g., oncology), fast track or breakthrough designations, or accelerated approval.

B. Access: Detailed Methodology

B1. Drug Cohort Selection

We evaluated patient access to drugs approved in the second half of 2024 (2H2024) and first half of 2025 (1H2025). We chose this time frame so that we would have one full year of data for each drug approved. We obtained a list of drugs approved by the FDA between July 1, 2024 and June 30, 2025 (n=57). From the list of 57 drugs, we then excluded products that were classified as vaccines, blood- or plasma-based products, or imaging or diagnostic agents (n=7). A total of 50 drugs comprised our initial cohort (Table B1.1). Subsequently, all drugs having fewer than 10 claims were excluded from our analyses.

Table B1.1. Initial Drug Cohort, Drugs Approved Between 2H2024 and 1H2025

Drug Name	Indication	Approval Date	Excluded (Y/N)	Fewer Than 10 Claims Available (Y/N/NA)	Drug Classification	First-In-Class	Oncology
Kisunla (donanemab-azbt)	Alzheimer's Disease	7/2/2024	N	N	Biologic	N	N
Leqselvi (deuruxolitinib)	Alopecia Areata	7/25/2024	N	Y	Small molecule	N	N
Tecelra (afamitresgene autoleucel)	Synovial Sarcoma	8/1/2024	N	Y	Biologic	Y	Y
Voranigo (vorasidenib)	Brain Cancer	8/6/2024	N	N	Small molecule	N	Y
Yorvipath (palopegteriparatide)	Hypoparathyroidism	8/9/2024	N	N	Peptide	N	N
Nemluvio (nemolizumab-ilto)	Prurigo Nodularis	8/12/2024	N	N	Biologic	Y	N
Livdelzi (seladelpar)	Primary Biliary Cholangitis	8/14/2024	N	N	Small molecule	N	N
Niktimvo (axatilimab-csfr)	Graft vs. Host Disease	8/14/2024	N	N	Biologic	Y	N
Lazcluze (lazertinib)	Non-Small Cell Lung Cancer	8/19/2024	N	N	Small molecule	N	Y
Ebglyss (lebrikizumab-lbkz)	Atopic Dermatitis	9/13/2024	N	N	Biologic	N	N
Miplyffa (arimoclomol)	Niemann-Pick Disease Type C	9/20/2024	N	N	Small molecule	Y	N
Aqneursa (levacetylleucine)	Niemann-Pick Disease Type C	9/24/2024	N	N	Small molecule	Y	N

Drug Name	Indication	Approval Date	Excluded (Y/N)	Fewer Than 10 Claims Available (Y/N/NA)	Drug Classification	First-In-Class	Oncology
Cobenfy (xanomeline and trospium chloride)	Schizophrenia	9/26/2024	N	N	Small molecule	Y	N
Flyrcado (flurpiridaz F 18)	Myocardial Infarction	9/27/2024	Y	NA	Small molecule	N	N
Itovebi (inavolisib)	Breast Cancer	10/10/2024	N	N	Small molecule	N	Y
Hympavzi (marstacimab-hncq)	Hemophilia A & B	10/11/2024	N	N	Biologic	Y	N
Vyloy (zolbetuximab-clzb)	Stomach Cancer	10/18/2024	N	N	Biologic	Y	Y
Orlynvah (sulopenem etzadroxil, probenecid)	Urinary Tract Infection	10/25/2024	N	Y	Small molecule	N	N
Aucatzyl (obecabtagene autoleucel)	Acute Lymphoblastic Leukemia	11/8/2024	N	Y	Biologic	N	Y
Kebilidi (eladocagene exuparvovec-tneq)	Aromatic L-Amino Acid Decarboxylase Deficiency	11/13/2024	N	Y	Biologic	Y	N
Revuforj (revumenib)	Leukemia	11/15/2024	N	N	Small molecule	Y	Y
Ziihera (zanidatamab-hrii)	Biliary Tract Cancer	11/20/2024	N	N	Biologic	Y	Y
Attruby (acoramidis)	ATTR-CM	11/22/2024	N	N	Small molecule	N	N
Rapiblyk (landiolol)	Supraventricular Tachycardia	11/22/2024	N	Y	Small molecule	N	N
Iomervu (iomeprol)	Radiographic Contrast Agent	11/27/2024	Y	NA	Small molecule	N	N
Bizengri (zenocutuzumab-zbco)	Non-Small Cell Lung Cancer	12/4/2024	N	Y	Biologic	Y	Y
Crenessity (crinecerfont)	Congenital Adrenal Hyperplasia	12/13/2024	N	N	Small molecule	Y	N
Unloxcyt (cosibelimab-ipdl)	Skin Cancer	12/13/2024	N	Y	Biologic	N	Y
Ensacove (ensartinib)	Non-Small Cell Lung Cancer	12/18/2024	N	Y	Small molecule	N	Y
Ryoncil (remestemcel-L-rknd)	Graft vs. Host Disease	12/18/2024	N	N	Biologic	Y	N
Symvess (acellular tissue engineered vessel-tyod)	Vascular Trauma	12/19/2024	N	Y	Biologic	Y	N
Tryngolza (olezarsen)	Familial Chylomicronemia Syndrome	12/19/2024	N	N	Other	Y	N

Drug Name	Indication	Approval Date	Excluded (Y/N)	Fewer Than 10 Claims Available (Y/N/NA)	Drug Classification	First-In-Class	Oncology
Alhemo (concizumab-mtci)	Hemophilia A & B	12/20/2024	N	N	Biologic	N	N
Alyftrek (vanzacaftor, tezacaftor, and deutivacaftor)	Cystic Fibrosis	12/20/2024	N	N	Small molecule	N	N
Automated C3d Plate (Anti-Human Globulin [Murine Monoclonal])	Diagnostic Reagent	1/8/2025	Y	NA	Biologic	N	N
Datroway (datopotamab deruxtecan-dlnk)	Breast Cancer	1/17/2025	N	N	Biologic	N	Y
Grafapex (treosulfan)	Acute Myeloid Leukemia	1/21/2025	N	Y	Small molecule	N	Y
Journavx (suzetrigine)	Acute Pain	1/30/2025	N	N	Small molecule	Y	N
Gomekli (mirdametinib)	Neurofibromatosis	2/11/2025	N	N	Small molecule	N	Y
Penmenvy (Meningococcal Groups A, B, C, W, and Y Vaccine)	Meningococcal Disease	2/14/2025	Y	NA	Biologic	N	N
Romvimza (vimseltinib)	Tenosynovial Giant Cell Tumor	2/14/2025	N	N	Small molecule	N	N
Vimkunya (Chikungunya Vaccine, Recombinant)	Chikungunya Virus	2/14/2025	Y	NA	Biologic	Y	N
Encelto (revakinagene taroretcel-lwey)	Idiopathic Macular Telangiectasia Type 2	3/5/2025	N	N	Biologic	Y	N
Blujepa (gepotidacin)	Urinary Tract Infection	3/25/2025	N	N	Small molecule	Y	N
Qfitlia (fitusiran)	Hemophilia A & B	3/28/2025	N	Y	Other	Y	N
Vanrafia (atrasentan)	IgA Nephropathy	4/2/2025	N	N	Small molecule	N	N
Penpulimab-kcqx (penpulimab-kcqx)	Nasopharyngeal Cancer	4/23/2025	N	Y	Biologic	N	Y
Zevaskyn (prademagene zamikeracel)	Epidermolysis Bullosa	4/28/2025	N	Y	Biologic	Y	N
Imaavy (nipocalimab-aahu)	Myasthenia Gravis	4/29/2025	N	N	Biologic	N	N
Avmapki Fakzynja Co-Pack (avutometinib and defactinib)	Ovarian Cancer	5/8/2025	N	N	Small molecule	Y	Y

Drug Name	Indication	Approval Date	Excluded (Y/N)	Fewer Than 10 Claims Available (Y/N/NA)	Drug Classification	First-In-Class	Oncology
Emrelis (telisotuzumab vedotin-tllv)	Non-Small Cell Lung Cancer	5/14/2025	N	N	Biologic	Y	Y
Nuvaxovid (Covid-19 Vaccine, Adjuvanted)	Covid-19	5/16/2025	Y	NA	Biologic	N	N
Tryptyr (acoltremon)	Dry Eye Disease	5/28/2025	N	N	Small molecule	Y	N
mNEXSPIKE (Covid-19 Vaccine, mRNA)	Covid-19	5/30/2025	Y	NA	Biologic	N	N
Enflonsia (clesrovimab-cfor)	Respiratory Syncytial Virus	6/9/2025	N	N	Biologic	N	N
Ibtrozi (taletrectinib)	Non-Small Cell Lung Cancer	6/11/2025	N	N	Small molecule	N	Y
Andembry (garadacimab-gxii)	Hereditary Angioedema	6/16/2025	N	N	Biologic	Y	N

ATTR-CM: transthyretin amyloid cardiomyopathy, mRNA: messenger ribonucleic acid, N: no, NA: not applicable, Y: yes

B2. Data Sources and Analysis

In order to evaluate access to newly approved drugs, we obtained data from IQVIA, publicly available coverage policies from the top five US health plans by covered lives, and a survey of patients in collaboration with the National Health Council to collect patient experiences accessing newly launched drugs.

Real-World Access Data

We obtained data on real-world access from IQVIA, a leading health care data analytics provider. They provide measures on consumer access of prescription drugs through their Longitudinal Access and Adjudication Data (LAAD) database, which contains de-identified data from outpatient pharmacy prescriptions (pharmacy claims), provider-administered drugs (medical claims), and out-of-pocket costs from almost all pharmacies in the US. For outpatient pharmacy prescription drugs, we obtained data on total number of prescriptions written, number of prescriptions dispensed, number of new-to-brand written prescription volumes, and number of written prescriptions dispensed. New-to-brand claims represent a patient's first prescription of a drug. We also obtained prescription adjudication decisions in the 30 days after initial prescription, including proportion of prescriptions filled (prescription dispensed to patient), rejected (prescription denied by payer), and reversed (prescription filled but not dispensed), from single attempts, multiple attempts, and overall. Reasons for rejection included non-coverage, prior authorization, step therapy, and administrative errors or other. We also obtained out-of-pocket costs in ranges ($0, $0-$10, $11-20, $21-30, $31-40, $41-50, $51-75, $76-125, $126-250, $251-500, $500-750, $750-1,000, $1,000-1,250, $1,250-1,500, and $1,500+). We also calculated weighted averages of out-of-pocket costs. All data were stratified by attempts (single, multiple, all) and payer (commercial, Medicare, Medicaid).

For provider-administered drugs, claims only appear in the database when the drug is billed when approved. Since provider-administered drugs are only dispensed once approved, there is no information in the database on number of prescriptions written or adjudication decisions. Therefore, for all provider-administered drugs, we were only able to obtain number of prescriptions dispensed and out-of-pocket costs in the same ranges as for outpatient prescription drugs, as well as calculate weighted averages of out-of-pocket costs.

Table B2.1. 30-Day Drug-by-Drug Prescription Adjudication (Commercial)

Drug Name	Indication	Total New-to-Brand Written Prescriptions*	Proportion of Prescriptions Dispensed†	Filled All Attempts	Rejected All Attempts	Reversed All Attempts
Alyftrek (vanzacaftor, tezacaftor, and deutivacaftor)	Cystic Fibrosis	1359	67%	30%	62%	9%
Andembry (garadacimab-gxii)	Hereditary Angioedema	162	56%	10%	77%	13%
Aqneursa (levacetylleucine)	Niemann-Pick Disease Type C	142	86%	15%	80%	5%
Attruby (acoramidis)	ATTR-CM	537	44%	34%	56%	10%
Avmapki Fakzynja Co-Pack (avutometinib and defactinib)	Ovarian Cancer	67	18%	13%	48%	39%
Blujepa (gepotidacin)	Urinary Tract Infection	254	64%	50%	26%	23%
Cobenfy (xanomeline and trospium chloride)	Schizophrenia	4088	61%	38%	54%	9%
Crenessity (crinecerfont)	Congenital Adrenal Hyperplasia	107	2%	3%	92%	5%
Ebglyss (lebrikizumab-lbkz)	Atopic Dermatitis	8387	54%	27%	64%	9%
Gomekli (mirdametinib)	Neurofibromatosis	150	58%	41%	45%	14%
Ibtrozi (taletrectinib)	Non-Small Cell Lung Cancer	191	70%	59%	24%	17%
Itovebi (inavolisib)	Breast Cancer	352	73%	54%	39%	7%
Journavx (suzetrigine)	Acute Pain	132702	90%	63%	28%	9%
Lazcluze (lazertinib)	Non-Small Cell Lung Cancer	291	53%	41%	44%	14%
Livdelzi (seladelpar)	Primary Biliary Cholangitis	1711	45%	43%	41%	16%
Miplyffa (arimoclomol)	Niemann-Pick Disease Type C	76	34%	6%	65%	29%
Nemluvio (nemolizumab-ilto)	Atopic Dermatitis	10893	53%	20%	76%	4%
Revuforj (revumenib)	Leukemia	187	56%	33%	46%	20%
Romvimza (vimseltinib)	Tenosynovial Giant Cell Tumor	75	32%	32%	47%	21%
Tryngolza (olezarsen)	Familial Chylomicronemia Syndrome	83	0%	0%	96%	4%
Tryptyr (acoltremon)	Dry Eye Disease	53067	35%	29%	56%	14%
Vanrafia (atrasentan)	IgA Nephropathy	55	2%	3%	87%	10%
Voranigo (vorasidenib)	Brain Cancer	1308	73%	38%	33%	29%
Yorvipath (palopegteriparatide)	Hypoparathyroidism	284	43%	35%	47%	18%

ATTR-CM: transthyretin amyloid cardiomyopathy

*Volume is the total number of prescriptions written in the one year post-approval for each drug, based on FDA approval date.

†Prescriptions dispensed are prescriptions that were filled by the pharmacy and picked up by the patient. New-to-brand: the first prescription written for a patient.
Note: Shading indicates relative rate of prescription fills, rejections, and reversals. Darker shading indicates a higher rate.

Table B2.2. 30-Day Drug-by-Drug Prescription Adjudication (Medicare)

Drug Name	Indication	Total New-to-Brand Written Prescriptions*	Proportion of Prescriptions Dispensed†	Filled All Attempts	Rejected All Attempts	Reversed All Attempts
Alyftrek (vanzacaftor, tezacaftor, and deutivacaftor)	Cystic Fibrosis	394	91%	76%	14%	10%
Andembry (garadacimab-gxii)	Hereditary Angioedema	119	67%	41%	47%	12%
Aqneursa (levacetylleucine)	Niemann-Pick Disease Type C	28	57%	36%	64%	0%
Attruby (acoramidis)	ATTR-CM	1885	57%	44%	30%	26%
Avmapki Fakzynja Co-Pack (avutometinib and defactinib)	Low-Grade Serous Ovarian Cancer	58	23%	19%	33%	48%
Blujepa (gepotidacin)	Urinary Tract Infection	267	25%	16%	64%	19%
Cobenfy (xanomeline and trospium chloride)	Schizophrenia	8404	81%	68%	21%	11%
Ebglyss (lebrikizumab-lbkz)	Atopic Dermatitis	2635	60%	33%	27%	41%
Gomekli (mirdametinib)	Neurofibromatosis Type 1	52	62%	57%	10%	33%
Ibtrozi (taletrectinib)	Non-Small Cell Lung Cancer	149	78%	75%	2%	23%
Itovebi (inavolisib)	Breast Cancer	359	70%	60%	11%	28%
Journavx (suzetrigine)	Acute Pain	97139	11%	16%	80%	4%
Lazcluze (lazertinib)	Non-Small Cell Lung Cancer	436	63%	54%	18%	28%
Livdelzi (seladelpar)	Primary Biliary Cholangitis	1513	66%	58%	13%	29%
Miplyffa (arimoclomol)	Niemann-Pick Disease Type C	21	62%	20%	10%	70%
Nemluvio (nemolizumab-ilto)	Atopic Dermatitis	9177	59%	34%	29%	37%
Revuforj (revumenib)	Leukemia	143	61%	47%	27%	26%
Romvimza (vimseltinib)	Tenosynovial Giant Cell Tumor	25	36%	27%	7%	67%
Tryngolza (olezarsen)	Familial Chylomicronemia Syndrome	32	3%	4%	79%	17%
Tryptyr (acoltremon)	Dry Eye Disease	38366	18%	14%	46%	40%
Vanrafia (atrasentan)	IgA Nephropathy	17	6%	0%	75%	25%
Voranigo (vorasidenib)	Brain Cancer	322	68%	50%	10%	40%
Yorvipath (palopegteriparatide)	Hypoparathyroidism	137	46%	44%	25%	30%

ATTR-CM: transthyretin amyloid cardiomyopathy
*Volume is the total number of prescriptions written in the one year post-approval for each drug, based on FDA approval date.
†Prescriptions dispensed are prescriptions that were filled by the pharmacy and picked up by the patient. New-to-brand: the first prescription written for a patient.
Note: Shading indicates relative rate of prescription fills, rejections, and reversals. Darker shading indicates a higher rate.

Table B2.3. 30-Day Drug-by-Drug Prescription Adjudication (Medicaid)

Drug Name	Indication	Total New-to-Brand Written Prescriptions*	Proportion of Prescriptions Dispensed†	Filled All Attempts	Rejected All Attempts	Reversed All Attempts
Alyftrek (vanzacaftor, tezacaftor, and deutivacaftor)	Cystic Fibrosis	844	91%	72%	20%	8%
Andembry (garadacimab-gxii)	Hereditary Angioedema	58	72%	42%	47%	11%
Aqneursa (levacetylleucine)	Niemann-Pick Disease Type C	80	40%	21%	79%	0%
Attruby (acoramidis)	ATTR-CM	41	41%	40%	50%	10%
Avmapki Fakzynja Co-Pack (avutometinib and defactinib)	Low-Grade Serous Ovarian Cancer	11	27%	27%	45%	27%
Blujepa (gepotidacin)	Urinary Tract Infection	53	15%	15%	81%	2%
Cobenfy (xanomeline and trospium chloride)	Schizophrenia	8794	72%	56%	38%	5%
Crenessity (crinecerfont)	Congenital Adrenal Hyperplasia	32	0%	0%	78%	22%
Ebglyss (lebrikizumab-lbkz)	Atopic Dermatitis	1387	73%	54%	40%	6%
Gomekli (mirdametinib)	Neurofibromatosis Type 1	73	72%	55%	21%	24%
Ibtrozi (taletrectinib)	Non-Small Cell Lung Cancer	30	67%	59%	32%	9%
Itovebi (inavolisib)	Breast Cancer	78	90%	75%	10%	15%
Journavx (suzetrigine)	Acute Pain	21856	47%	37%	59%	4%
Lazcluze (lazertinib)	Non-Small Cell Lung Cancer	43	60%	40%	40%	20%
Livdelzi (seladelpar)	Primary Biliary Cholangitis	378	61%	56%	29%	15%
Miplyffa (arimoclomol)	Niemann-Pick Disease Type C	49	24%	23%	55%	23%
Nemluvio (nemolizumab-ilto)	Atopic Dermatitis	2140	64%	36%	54%	10%
Revuforj (revumenib)	Leukemia	71	66%	55%	23%	23%
Romvimza (vimseltinib)	Tenosynovial Giant Cell Tumor	20	45%	36%	29%	36%
Tryngolza (olezarsen)	Familial Chylomicronemia Syndrome	21	0%	0%	89%	11%

Drug Name	Indication	Total New-to-Brand Written Prescriptions*	Proportion of Prescriptions Dispensed†	Filled All Attempts	Rejected All Attempts	Reversed All Attempts
Tryptyr (acoltremon)	Dry Eye Disease	3,511	36%	32%	62%	6%
Vanrafia (atrasentan)	IgA Nephropathy	17	18%	10%	80%	10%
Voranigo (vorasidenib)	Brain Cancer	245	76%	58%	25%	18%
Yorvipath (palopegteriparatide)	Hypoparathyroidism	83	31%	25%	52%	23%

ATTR-CM: transthyretin amyloid cardiomyopathy

*Volume is the total number of prescriptions written in the one year post-approval for each drug, based on FDA approval date.

†Prescriptions dispensed are prescriptions that were filled by the pharmacy and picked up by the patient. New-to-brand: the first prescription written for a patient.

Note: Shading indicates relative rate of prescription fills, rejections, and reversals. Darker shading indicates a higher rate.

Table B2.4. Patient Out-of-Pocket Costs for Drugs In Scope (Commercial)

Drug Name	Indication	Patient OOP Cost (Copay/Co-insurance)					
		$0	$1-$50	$51-$250	$251-$1500	$1500+	Weighted Average
Outpatient Pharmacy Drugs							
Alhemo (concizumab-mtci)	Hemophilia A & B	7%	93%	0%	0%	0%	$4.65
Alyftrek (vanzacaftor, tezacaftor, and deutivacaftor)	Cystic Fibrosis	89%	4%	6%	0%	1%	$17.48
Andembry (garadacimab-gxii)	Hereditary Angioedema	66%	13%	13%	2%	6%	$148.58
Aqneursa (levacetylleucine)	Niemann-Pick Disease Type C	93%	4%	1%	0%	1%	$22.03
Attruby (acoramidis)	ATTR-CM	59%	7%	28%	1%	5%	$126.05
Avmapki Fakzynja Co-Pack (avutometinib and defactinib)	Low-Grade Serous Ovarian Cancer	71%	3%	19%	1%	5%	$122.38
Blujepa (gepotidacin)	Urinary Tract Infection	2%	73%	18%	6%	1%	$86.35
Cobenfy (xanomeline and trospium chloride)	Schizophrenia	63%	10%	22%	4%	2%	$84.80
Crenessity (crinecerfont)	Congenital Adrenal Hyperplasia	-	-	-	-	-	-
Ebglyss (lebrikizumab-lbkz)	Atopic Dermatitis	23%	53%	5%	7%	12%	$320.18
Gomekli (mirdametinib)	Neurofibromatosis Type 1	79%	12%	6%	0%	3%	$68.05

Drug Name	Indication	Patient OOP Cost (Copay/Co-insurance)					
		$0	$1-$50	$51-$250	$251-$1500	$1500+	Weighted Average
Hympavzi (marstacimab-hncq)	Hemophilia A & B	-	-	-	-	-	-
Ibtrozi (taletrectinib)	Non-Small Cell Lung Cancer	81%	4%	11%	2%	3%	$81.05
Itovebi (inavolisib)	Breast Cancer	81%	4%	11%	2%	2%	$49.58
Journavx (suzetrigine)	Acute Pain	13%	76%	8%	3%	0%	$50.43
Lazcluze (lazertinib)	Non-Small Cell Lung Cancer	77%	11%	9%	1%	2%	$55.40
Livdelzi (seladelpar)	Primary Biliary Cholangitis	72%	11%	12%	2%	4%	$92.03
Miplyffa (arimoclomol)	Niemann-Pick Disease Type C	54%	8%	23%	10%	6%	$223.33
Nemluvio (nemolizumab-ilto)	Atopic Dermatitis	62%	30%	3%	1%	4%	$98.38
Revuforj (revumenib)	Leukemia	82%	8%	8%	1%	1%	$30.35
Romvimza (vimseltinib)	Tenosynovial Giant Cell Tumor	75%	7%	11%	2%	5%	$124.58
Tryngolza (olezarsen)*	Familial Chylomicronemia Syndrome	-	-	-	-	-	-
Tryptyr (acoltremon)	Dry Eye Disease	78%	6%	7%	9%	0%	$72.28
Vanrafia (atrasentan)*	IgA Nephropathy	-	-	-	-	-	-
Voranigo (vorasidenib)	Brain Cancer	56%	34%	7%	1%	2%	$60.45
Yorvipath (palopegteriparatide)	Hypoparathyroidism	27%	64%	5%	1%	3%	$84.90
Provider-Administered Drugs							
Datroway® (datopotamab deruxtecan-dlnk)	HR+/HER2- Breast Cancer	98%	1%	1%	1%	0%	$15.07
Emrelis™ (telisotuzumab vedotin-tllv)	Non-Small Cell Lung Cancer	89%	0%	5%	2%	4%	$83.82
Encelto® (revakinagene taroretcel-lwey)	Idiopathic Macular Telangiectasia Type 2	58%	0%	8%	17%	17%	$505.00
Enflonsia™ (clesrovimab-cfor)	Respiratory Syncytial Virus	-	-	-	-	-	-
Imaavy™ (nipocalimab-aahu)	Myasthenia Gravis	81%	5%	5%	1%	9%	$182.47
Kisunla™ (donanemab-azbt)	Alzheimer's Disease	38%	7%	11%	37%	6%	$355.03
Niktimvo™ (axatilimab-csfr)	Graft vs. Host Disease	99%	0%	0%	0%	1%	$16.33
Ryoncil® (remestemcel-L-rknd)	Graft vs. Host Disease	-	-	-	-	-	-
Vyloy® (zolbetuximab-clzb)	Stomach Cancer	95%	0%	1%	0%	3%	$68.67
Ziihera® (zanidatamab-hrii)	Biliary Tract Cancer	-	-	-	-	-	-

OOP: out-of-pocket

Note: Shading indicates relative proportion of prescriptions within an out-of-pocket cost range. Darker shading indicates a higher proportion of prescriptions.

Table B2.5. Patient Out-of-Pocket Costs for Drugs In Scope (Medicare)

Drug Name	Indication	Patient OOP Cost (Copay/Co-insurance)					
		$0	$1-$50	$51-$250	$251-$1500	$1500+	Weighted Average
Outpatient Pharmacy Drugs							
Alhemo (concizumab-mtci)	Hemophilia A & B	100%	0%	0%	0%	0%	$0.00
Alyftrek (vanzacaftor, tezacaftor, and deutivacaftor)	Cystic Fibrosis	98%	1%	0%	0%	0%	$0.00
Andembry (garadacimab-gxii)	Hereditary Angioedema	91%	3%	0%	0%	6%	$120.25
Aqneursa (levacetylleucine)	Niemann-Pick Disease Type C	95%	1%	0%	0%	4%	$79.41
Attruby (acoramidis)	ATTR-CM	87%	2%	2%	4%	4%	$125.83
Avmapki Fakzynja Co-Pack (avutometinib and defactinib)	Low-Grade Serous Ovarian Cancer	48%	12%	4%	7%	28%	$614.50
Blujepa (gepotidacin)	Urinary Tract Infection	28%	22%	17%	31%	2%	$267.78
Cobenfy (xanomeline and trospium chloride)	Schizophrenia	80%	17%	1%	3%	0%	$20.10
Crenessity (crinecerfont)*	Congenital Adrenal Hyperplasia	-	-	-	-	-	-
Ebglyss (lebrikizumab-lbkz)	Atopic Dermatitis	70%	5%	4%	6%	15%	$370.40
Gomekli (mirdametinib)	Neurofibromatosis Type 1	82%	12%	2%	3%	2%	$71.81
Hympavzi (marstacimab-hncq)	Hemophilia A & B	-	-	-	-	-	-
Ibtrozi (taletrectinib)	Non-Small Cell Lung Cancer	83%	5%	2%	3%	8%	$182.80
Itovebi (inavolisib)	Breast Cancer	92%	2%	0%	1%	4%	$58.28
Journavx (suzetrigine)	Acute Pain	52%	20%	17%	11%	0%	$77.28
Lazcluze (11azertinib)	Non-Small Cell Lung Cancer	78%	5%	3%	4%	10%	$239.57
Livdelzi (seladelpar)	Primary Biliary Cholangitis	87%	5%	2%	2%	4%	$102.48
Miplyffa (arimoclomol)	Niemann-Pick Disease Type C	98%	2%	0%	0%	0%	$0.20
Nemluvio (nemolizumab-ilto)	Atopic Dermatitis	68%	6%	4%	8%	14%	$363.74
Revuforj (revumenib)	Leukemia	93%	2%	1%	2%	2%	$64.68

Drug Name	Indication	Patient OOP Cost (Copay/Co-insurance)					
		$0	$1-$50	$51-$250	$251-$1500	$1500+	Weighted Average
Romvimza (vimseltinib)	Tenosynovial Giant Cell Tumor	66%	4%	4%	2%	23%	$485.25
Tryngolza (olezarsen)*	Familial Chylomicronemia Syndrome	-	-	-	-	-	-
Tryptyr (acoltremon)	Dry Eye Disease	31%	15%	13%	42%	0%	$252.00
Vanrafia (atrasentan)*	IgA Nephropathy	-	-	-	-	-	-
Voranigo (vorasidenib)	Brain Cancer	75%	7%	2%	2%	13%	$284.25
Yorvipath (palopegteriparatide)	Hypoparathyroidism	82%	6%	1%	5%	6%	$174.98
Provider-Administered Drugs							
Datroway® (datopotamab deruxtecan-dlnk)	HR+/HER2- Breast Cancer	96%	0%	1%	1%	2%	$48.00
Emrelis™ (telisotuzumab vedotin-tllv)	Non-Small Cell Lung Cancer	86%	0%	1%	3%	10%	$225.62
Encelto® (revakinagene taroretcel-lwey)	Idiopathic Macular Telangiectasia Type 2	-	-	-	-	-	-
Enflonsia™ (clesrovimab-cfor)	Respiratory Syncytial Virus	-	-	-	-	-	-
Imaavy™ (nipocalimab-aahu)	Myasthenia Gravis	80%	0%	1%	5%	14%	$320.11
Kisunla™ (donanemab-azbt)	Alzheimer's Disease	71%	0%	3%	25%	0%	$135.96
Niktimvo™ (axatilimab-csfr)	Graft vs. Host Disease	73%	0%	7%	12%	8%	$208.53
Ryoncil® (remestemcel-L-rknd)	Graft vs. Host Disease	-	-	-	-	-	-
Vyloy® (zolbetuximab-clzb)	Stomach Cancer	88%	0%	2%	4%	6%	$149.25
Ziihera® (zanidatamab-hrii)	Biliary Tract Cancer	34%	0%	0%	0%	66%	$1,317.07

OOP: out-of-pocket

Note: Shading indicates relative proportion of prescriptions within an out-of-pocket cost range. Darker shading indicates a higher proportion of prescriptions.

Table B2.6. Patient Out-of-Pocket Costs for Drugs In Scope (Medicaid)

Drug Name	Indication	Patient OOP Cost (Copay/Co-insurance)					
		$0	$1-$50	$51-$250	$251-$1500	$1500+	Weighted Average
Outpatient Pharmacy Drugs							
Alhemo (concizumab-mtci)	Hemophilia A & B	72%	28%	0%	0%	0%	$1.40
Alyftrek (vanzacaftor, tezacaftor, and deutivacaftor)	Cystic Fibrosis	97%	3%	0%	0%	0%	$0.15
Andembry (garadacimab-gxii)	Hereditary Angioedema	87%	13%	0%	0%	0%	$0.65
Aqneursa (levacetylleucine)	Niemann-Pick Disease Type C	99%	1%	0%	0%	0%	$0.05
Attruby (acoramidis)	ATTR-CM	79%	21%	0%	0%	0%	$1.05
Avmapki Fakzynja Co-Pack (avutometinib and defactinib)	Low-Grade Serous Ovarian Cancer	69%	31%	0%	0%	0%	$1.55
Blujepa (gepotidacin)	Urinary Tract Infection	67%	33%	0%	0%	0%	$1.65
Cobenfy (xanomeline and trospium chloride)	Schizophrenia	88%	12%	0%	0%	0%	$0.60
Crenessity (crinecerfont)*	Congenital Adrenal Hyperplasia	-	-	-	-	-	-
Ebglyss (lebrikizumab-lbkz)	Atopic Dermatitis	91%	9%	0%	0%	0%	$0.75
Gomekli (mirdametinib)	Neurofibromatosis Type 1	97%	3%	0%	0%	0%	$0.15
Hympavzi (marstacimab-hncq)	Hemophilia A & B	-	-	-	-	-	-
Ibtrozi (taletrectinib)	Non-Small Cell Lung Cancer	85%	15%	0%	0%	0%	$0.75
Itovebi (inavolisib)	Breast Cancer	73%	27%	0%	0%	0%	$1.55
Journavx (suzetrigine)	Acute Pain	71%	29%	0%	0%	0%	$2.25

Drug Name	Indication	Patient OOP Cost (Copay/Co-insurance)					
		$0	$1-$50	$51-$250	$251-$1500	$1500+	Weighted Average
Lazcluze (lazertinib)	Non-Small Cell Lung Cancer	82%	18%	0%	0%	0%	$0.90
Livdelzi (seladelpar)	Primary Biliary Cholangitis	85%	15%	0%	0%	0%	$1.25
Miplyffa (arimoclomol)	Niemann-Pick Disease Type C	100%	0%	0%	0%	0%	$0.00
Nemluvio (nemolizumab-ilto)	Atopic Dermatitis	89%	10%	0%	0%	1%	$20.66
Revuforj (revumenib)	Leukemia	89%	11%	0%	0%	0%	$0.55
Romvimza (vimseltinib)	Tenosynovial Giant Cell Tumor	93%	7%	0%	0%	0%	$0.35
Tryngolza (olezarsen)*	Familial Chylomicronemia Syndrome	-	-	-	-	-	-
Tryptyr (acoltremon)	Dry Eye Disease	90%	10%	0%	0%	0%	$0.80
Vanrafia (atrasentan)*	IgA Nephropathy	-	-	-	-	-	-
Voranigo (vorasidenib)	Brain Cancer	90%	10%	0%	0%	0%	$0.50
Yorvipath (palopegteriparatide)	Hypoparathyroidism	70%	30%	0%	0%	0%	$1.50
Provider-Administered Drugs							
Datroway® (datopotamab deruxtecan-dlnk)	HR+/HER2- Breast Cancer	86%	0%	0%	7%	7%	$165.18
Emrelis™ (telisotuzumab vedotin-tllv)	Non-Small Cell Lung Cancer	100%	0%	0%	0%	0%	$0.00
Encelto® (revakinagene taroretcel-lwey)	Idiopathic Macular Telangiectasia Type 2	-	-	-	-	-	-
Enflonsia™ (clesrovimab-cfor)	Respiratory Syncytial Virus	-	-	-	-	-	-
Imaavy™ (nipocalimab-aahu)	Myasthenia Gravis	100%	0%	0%	0%	0%	$0.00
Kisunla™ (donanemab-azbt)	Alzheimer's Disease	45%	0%	6%	50%	0%	$297.76
Niktimvo™ (axatilimab-csfr)	Graft vs. Host Disease	100%	0%	0%	0%	0%	$0.00
Ryoncil® (remestemcel-L-rknd)	Graft vs. Host Disease	-	-	-	-	-	-
Vyloy® (zolbetuximab-clzb)	Stomach Cancer	98%	0%	2%	0%	0%	$1.28
Ziihera® (zanidatamab-hrii)	Biliary Tract Cancer	-	-	-	-	-	-

OOP: out-of-pocket

Note: Shading indicates relative proportion of prescriptions within an out-of-pocket cost range. Darker shading indicates a higher proportion of prescriptions.

Table B2.7. Patient Out-of-Pocket Costs for Drugs In Scope (Cash Pay)

Drug Name	Indication	Patient OOP Cost (Copay/Co-insurance)				
		$0	$1-$50	$51-$250	$251-$1500	$1500+
Outpatient Pharmacy Drugs						
Alhemo (concizumab-mtci)	Hemophilia A & B	0%	0%	0%	0%	100%
Alyftrek (vanzacaftor, tezacaftor, and deutivacaftor)	Cystic Fibrosis	0%	0%	0%	0%	100%
Andembry (garadacimab-gxii)	Hereditary Angioedema	0%	0%	0%	0%	100%
Aqneursa (levacetylleucine)	Niemann-Pick Disease Type C	0%	0%	0%	0%	100%
Attruby (acoramidis)	ATTR-CM	0%	0%	0%	0%	100%
Avmapki Fakzynja Co-Pack (avutometinib and defactinib)	Low-Grade Serous Ovarian Cancer	0%	0%	0%	0%	100%
Blujepa (gepotidacin)	Urinary Tract Infection	0%	0%	0%	0%	100%
Cobenfy (xanomeline and trospium chloride)	Schizophrenia	15%	0%	9%	34%	42%
Crenessity (crinecerfont)*	Congenital Adrenal Hyperplasia	-	-	-	-	-
Ebglyss (lebrikizumab-lbkz)	Atopic Dermatitis	0%	3%	0%	0%	97%
Gomekli (mirdametinib)	Neurofibromatosis Type 1	-	-	-	-	-
Hympavzi (marstacimab-hncq)	Hemophilia A & B	-	-	-	-	-
Ibtrozi (taletrectinib)	Non-Small Cell Lung Cancer	0%	0%	0%	0%	100%
Itovebi (inavolisib)	Breast Cancer	0%	0%	0%	0%	100%
Journavx (suzetrigine)	Acute Pain	1%	1%	11%	87%	0%
Lazcluze (lazertinib)	Non-Small Cell Lung Cancer	20%	0%	0%	0%	80%
Livdelzi (seladelpar)	Primary Biliary Cholangitis	0%	0%	0%	0%	100%
Miplyffa (arimoclomol)	Niemann-Pick Disease Type C	-	-	-	-	-
Nemluvio (nemolizumab-ilto)	Atopic Dermatitis	7%	0%	0%	0%	93%
Revuforj (revumenib)	Leukemia	0%	0%	0%	0%	100%
Romvimza (vimseltinib)	Tenosynovial Giant Cell Tumor	0%	0%	0%	0%	100%
Tryngolza (olezarsen)*	Familial Chylomicronemia Syndrome	-	-	-	-	-
Tryptyr (acoltremon)	Dry Eye Disease	0%	1%	0%	98%	1%

Drug Name	Indication	Patient OOP Cost (Copay/Co-insurance)				
		$0	$1-$50	$51-$250	$251-$1500	$1500+
Vanrafia (atrasentan)*	IgA Nephropathy	-	-	-	-	-
Voranigo (vorasidenib)	Brain Cancer	0%	0%	0%	0%	100%
Yorvipath (palopegteriparatide)	Hypoparathyroidism	0%	0%	0%	0%	100%
Provider-Administered Drugs*						
Datroway® (datopotamab deruxtecan-dlnk)	HR+/HER2- Breast Cancer	-	-	-	-	-
Emrelis™ (telisotuzumab vedotin-tllv)	Non-Small Cell Lung Cancer	-	-	-	-	-
Encelto® (revakinagene taroretcel-lwey)	Idiopathic Macular Telangiectasia Type 2	-	-	-	-	-
Enflonsia™ (clesrovimab-cfor)	Respiratory Syncytial Virus	-	-	-	-	-
Imaavy™ (nipocalimab-aahu)	Myasthenia Gravis	-	-	-	-	-
Kisunla™ (donanemab-azbt)	Alzheimer's Disease	-	-	-	-	-
Niktimvo™ (axatilimab-csfr)	Graft vs. Host Disease	-	-	-	-	-
Ryoncil® (remestemcel-L-rknd)	Graft vs. Host Disease	-	-	-	-	-
Vyloy® (zolbetuximab-clzb)	Stomach Cancer	-	-	-	-	-
Ziihera® (zanidatamab-hrii)	Biliary Tract Cancer	-	-	-	-	-

OOP: out-of-pocket

*Medical-benefit drugs administered by a provider in the clinic or hospital are typically billed to the payer so no cash claims exist in this dataset.

Note: Shading indicates relative proportion of prescriptions within an out-of-pocket cost range. Darker shading indicates a higher proportion of prescriptions.

Table B2.8. Definitions/Data Fields from IQVIA Consumer Access Report

Category	Definition
Market Share / Volume (Unprojected)	**Medical Claims*:** Claims paid by third-party payers.
	Written Prescriptions: Prescriptions written by a prescriber (includes Rx's that have been filled, rejected, or reversed). The claim samples included are claims that have been normalized to a 30-day supply.
	Dispensed (Paid) Prescriptions: Prescriptions filled. The claim samples included are claims that have been normalized to a 30-day supply.
	New-to-Brand Prescriptions (NBRx): New-to-Brand claims represents a patient's first prescription of a drug. Claims have been normalized to a 30-day supply.
Claim Adjudication (Calculated on Normalized New-to-Brand)	**Claim Status**: The outcome of the patient's attempt to fill a prescription in the 30 days after the initial claim is filed. Patients that were rejected or reversed a script on their initial claim might have ultimately filled by the end of the look forward period. Prescriptions filled after the 30-day period will not be recorded in this number.
	Look-forward Period: A period in which a patient associated with a claim is monitored and their prescription activity is tracked following a rejection or reversed claims.
	Attempts: Number of attempts patient submitted prescription for approval.
	Filled %: The claims where payer has approved and script was filled.
	Rejection - Not Covered %: The claims where payer has indication product in Not Covered divided by the sum of the NBRx claims.
	Rejection - Prior Auth/Step %: The rejected claims where payer indicated that product requires physician to submit a prior authorization request to payer or payer requires another product(s) must be tried/failed prior to coverage divided by the sum of the NBRx claims. Step Edit is a common way for a payer to dictate use of a particular medication or medications in a particular order. Failing to prescribe in the correct order can cause a rejection.
	Rejection - Other %: The rejected claims due to other reasons such as plan/refill limits, distribution limitations or administrative errors, divided by the sum of the NBRx Claims.
	Rejection - Reversal %: The claims that were approved by the payer but not picked up by the patient divided by the sum of the NBRx claims.
	Single Attempt: Only one attempt is made to receive approval and/or fill a written prescription.
	Multiple Attempts: More than one attempt is made to fill a written prescription. Attempts are made to receive approval beyond the initial attempt.
	All Attempts: Single Attempts and Multiple Attempts are, between them, mutually exclusive and collectively exhaustive. The All Attempts rates are weighted averages of the two.
Patient Out-of-Pocket (OOP)	**Final Cost**: The actual amount the patient pays in order to fill the product after any discounts (e.g., manufacturer copay card).
	Patient OOP Categories: Range of patient cost exposure for final cost.

NBRx: new-to-brand prescriptions, OOP: out-of-pocket, Rx: prescription

*Pharmacy adjudication claim metrics noted in table are not captured for claims paid under medical benefits.

Payer Coverage Policies

We identified the top five US payers by all covered lives using data from MMIT. We then identified eight drugs (three ICER-reviewed, five chosen by the project team based on having high attempts and low fill rates from IQVIA data). We then conducted key word searches on web search engines (e.g., Google) and payer websites for each of the eight drugs and downloaded the most recent coverage policy of the drug of interest dated on or before June 18, 2026. We abstracted data from each coverage policy including coverage/non-coverage, clinical eligibility, step therapy protocols, and prescriber restrictions. We also abstracted from the FDA label, including approved indication and information on the clinical studies (National Clinical Trial [NCT] number, key eligibility criteria, dosing, and endpoints). We identified relevant clinical guidelines for the indications of the selected drugs and used them to judge the policies against the Fair Access criteria. See descriptions of the clinical guidelines identified below.

We then attempted to assess, based on data availability, whether the coverage policies are consistent with ICER's Fair Access criteria (Table B2.9a-c).[10] For each of the eight drugs, ICER staff discussed each policy and judged whether: (1) clinical eligibility in line with clinical trial inclusion/exclusion criteria and/or clinical practice; (2) whether step therapy was clinically appropriate and had fewer than three steps; and (3) whether provider restrictions, if any, were appropriate. We were not able to judge the fourth main criteria, whether cost-sharing was appropriate, because we lacked specific formulary placement information.

Table B2.9a. Clinical Eligibility Fair Design Criteria

Clinical Eligibility

For all drugs: Clinical eligibility criteria that complement the FDA label language may be used to:
• Set standards for diagnosis; and/or
• Define indeterminate clinical terms in the FDA label (e. g., "moderate-to-severe") with explicit reference to clinical guidelines or other standards; and/or
• Triage patients by clinical acuity when the payer explicitly documents that triage is both reasonable and necessary because:
  • The size of the population included within the FDA label is extremely large, and there is a reasonable likelihood that many patients would seek treatment in the short term; AND
  • The clinical infrastructure is not adequate to treat all patients seeking care and/or broad coverage would create such substantial increases in short-term insurance premiums or other financial strain that patients would be harmed through loss of affordable insurance; AND
  • Acuity can be determined on objective clinical grounds and waiting for treatment will not cause significant irremediable harm.

For drugs with prices that have been deemed reasonable: Except for the three purposes outlined above, clinical eligibility criteria should not deviate from the FDA label language in a manner that would narrow coverage.

Clinical Eligibility
For drugs with prices that have been deemed reasonable: Documentation that patients meet clinical eligibility criteria should represent a light administrative burden, including acceptance of clinician attestation in lieu of more formal medical record documentation unless documentation is critical to ensure patient safety.
For drugs with prices that have been deemed unreasonable: Clinical eligibility criteria may narrow coverage by applying specific eligibility criteria from the pivotal trials used to generate evidence for FDA approval if implemented with reasonable flexibility and supported by robust appeals procedures as described in the implementation criteria.

Table B2.9b. Step Therapy Fair Design Criteria

Step Therapy
• The first-step therapy is clinically appropriate for all or nearly all patients and does not pose a greater risk of any significant side effect or harm. • Patients will have a reasonable chance to meet their clinical goals with first-step therapy. • Failure of the first-step drug and the resulting delay in beginning the second-step agent will not lead to long-term harm for patients. • Patients are not required to retry a first-line drug with which they have previously had adverse side effects or an inadequate response at a reasonable dose and duration. • The number of steps do not exceed 3 even if all include appropriate first-line therapies.

Table B2.9c. Provider Qualifications Fair Design Criteria

Provider Qualifications
Restrictions of coverage to specialty prescribers are reasonable with one or more of the following justifications: • Accurate diagnosis and prescription require specialist training, with the risk that non-specialist clinicians would prescribe the medication for patients who may suffer harm or be unlikely to benefit. • Determination of the risks and benefits of treatment for individual patients requires specialist training due to potential for serious side effects of therapy. • Dosing, monitoring for side effects, and overall care coordination require specialist training to ensure safe and effective use of the medication.
Requiring that non-specialist clinicians attest they are caring for the patient in consultation with a relevant specialist is a reasonable option when the condition is frequently treated in primary care settings but some elements of dosing, monitoring for side effects, and/or overall coordination of care would benefit from specialist input for many patients.

Identified Clinical Guidelines Used to Assess Fair Access Criteria

US Food and Drug Administration (FDA) labels and relevant clinical guidelines for the indications of the eight drugs were identified and used to judge the policies against the Fair Access criteria for the eight drugs described in the Patient Access Section. We have described and cited the clinical guidelines below.

Attruby (acoramidis)

Attruby is a transthyretin (TTR) stabilizer that is FDA-approved for adults with wild-type or variant TTR-mediated amyloid cardiomyopathy (ATTR-CM) to reduce cardiovascular death and cardiovascular-related hospitalization.[72]

The 2025 American College of Cardiology (ACC) Concise Clinical Guidance for ATTR-CM incorporates the current disease-modifying therapies: the TTR stabilizers tafamidis and acoramidis, as well as the TTR silencer vutrisiran.[73] The guidance notes that stabilizers and silencers should be started without delay in appropriate patients to slow disease progression, while current data are insufficient to recommend routine combination therapy or switching solely to mitigate progression.[73] Earlier guidance primarily informs diagnosis.[74,75]

Cobenfy (xanomeline/trospium chloride)

Cobenfy is an FDA-approved therapy for schizophrenia and represents the first approved antipsychotic with a primarily muscarinic rather than direct dopamine D_2 receptor mechanism.[76,77] It combines one drug (xanomeline) that targets central nervous system (CNS) muscarinic receptors (M1 and M4 receptor agonists) with a second drug (trospium) that reduces the peripheral side effects of muscarinic receptor activation.[44]

Current major schizophrenia guidelines largely predate Cobenfy's approval. The 2025 INTEGRATE international schizophrenia guideline acknowledges xanomeline/trospium as a newly approved nondopaminergic therapy but notes that its position within treatment algorithms requires further appraisal.[78] The APA Practice Guideline for Schizophrenia recommends antipsychotic treatment with monitoring for effectiveness and adverse effects, reserves clozapine for treatment-resistant schizophrenia or persistent substantial suicide risk, and supports long-acting injectable antipsychotics when preferred or when adherence is poor or uncertain.[79]

Ebglyss (lebrikizumab) and Nemluvio (nemolizumab)

Ebglyss (lebrikizumab) and Nemluvio (nemolizumab) are two FDA-approved treatments for atopic dermatitis. Ebglyss (lebrikizumab) is FDA-approved for adults and pediatric patients aged ≥12 years weighing ≥40 kg with moderate-to-severe atopic dermatitis that is inadequately controlled with topical prescription therapies or when such therapies are not advisable.[80] It may be used with or

without topical corticosteroids. Nemluvio (nemolizumab) is FDA-approved for adults and pediatric patients aged ≥12 years with moderate-to-severe atopic dermatitis inadequately controlled with topical prescription therapies and is used in combination with topical corticosteroids and/or topical calcineurin inhibitors.[81]

American Academy of Dermatology (AAD) guidelines support topical corticosteroids, topical calcineurin inhibitors, topical PDE-4 inhibitors, and topical JAK inhibitors as evidence-based topical therapies. The 2025 AAD focused update strongly recommends lebrikizumab and nemolizumab with concomitant topical therapy for adults with moderate-to-severe atopic dermatitis.[82] The British Association of Dermatologists has also supported access to newer biologic therapies for moderate-to-severe atopic dermatitis, specifically noting that nemolizumab provides an important additional treatment option for patients who have inadequate response to or cannot tolerate existing biologic or JAK inhibitor therapies.[83]

Journavx (suzetrigine)

Journavx is a first-in-class, non-opioid selective NaV1.8 sodium-channel inhibitor FDA-approved in 2025 for the treatment of moderate-to-severe acute pain.[84] Treatment should be used for the shortest duration appropriate to the patient; use beyond 14 days has not been studied.

As of this review, major acute-pain clinical practice guidelines have not yet incorporated suzetrigine into a specific treatment algorithm. The 2022 CDC Clinical Practice Guideline for Prescribing Opioids for Pain, which predates Journavx, recommends maximizing non-opioid pharmacologic and nonpharmacologic therapies for acute pain and considering opioids when anticipated benefits outweigh risks.[85] For nonsurgical acute musculoskeletal pain, the ACP/AAFP guideline recommends topical nonsteroidal anti-inflammatory drugs (NSAIDs) as first-line treatment, with oral NSAIDs or acetaminophen as additional options, and suggests against opioids, including tramadol, except in selected circumstances such as severe injury or intolerance of first-line therapies.[86]

Kisunla (donanemab-azbt)

Kisunla is an amyloid beta-directed monoclonal antibody FDA-approved for the treatment of Alzheimer's disease. Treatment should be initiated in patients with mild cognitive impairment or mild dementia due to Alzheimer's disease, consistent with the population studied in clinical trials.[87] Amyloid beta pathology must be confirmed before treatment. The FDA labeling recommends a recent baseline brain MRI, apolipoprotein E (APOE) ε4 genotyping to inform amyloid-related imaging abnormalities (ARIA) risk, and surveillance MRI before the 2nd, 3rd, 4th, and 7th infusions.[87]

The 2025 Donanemab Appropriate Use Recommendations (AUR) similarly support treatment in patients with early symptomatic Alzheimer's disease with biomarker confirmation by amyloid positron emission tomography (PET) or cerebralspinal fluid (CSF). The AUR recommend APOE

genotyping, a pretreatment MRI, and scheduled MRI surveillance for ARIA, with careful patient selection based on individual risk factors.[88] The 2025 Alzheimer's Association DETeCD-ADRD clinical practice guideline supports biomarker-based diagnostic confirmation when disease-modifying therapy is being considered, including use of amyloid PET to establish amyloid pathology and help determine eligibility for anti-amyloid treatment.[89]

Patient Survey

We developed a patient survey to identify barriers to access that may not be identified by IQVIA data or payer coverage policies for the same eight drugs of interest chosen for the payer coverage analysis. Topics covered in the survey included questions about patient awareness of the new treatment, insurance coverage restrictions, experiences with prior authorization, out-of-pocket costs, drug affordability, and impact of treatment on quality of life (Table B2.10). We also collected demographic data, including data on social determinants of health (e.g., housing status, employment status, primary insurance, etc.).

Table B2.10. Survey Domains and Specific Areas Assessed

Survey Domain	Specific Areas Assessed
Screening and Respondent Role	Source of survey awareness, patient community affiliation, medication familiarity, and whether the respondent was a patient or caregiver.
Medication Awareness and Information Sources	Sources through which patients or caregivers learned about the medication, including clinicians, advocacy organizations, other patients, family/friends, social media, and advertising.
Medication Use and Prescribing	Whether the medication was prescribed or received, and reasons for not being prescribed or treated.
Insurance and Access Barriers	Insurance status, coverage exclusions, prior authorization, step therapy, appeals, specialist requirements, difficulty locating prescribers, pharmacies, or treatment centers.
Time to Treatment/Access	Time between prescription and receipt of the medication or, for Kisunla, time to first infusion.
Health Impact of Delayed Access	Perceived effects of delays on health, including worsening health, emergency department visits, and hospitalization.
Out-of-Pocket Costs	Estimated annual out-of-pocket medication costs following insurance or other financial assistance.
Medication Affordability	Whether the respondent or care recipient considered the medication affordable.

Survey Domain	Specific Areas Assessed
Financial Assistance	Use of manufacturer copay coupons, manufacturer assistance programs, discount programs, non-profit assistance, and assistance from family/friends.
Financial and Treatment-Related Consequences	Effects of medication costs on ability to pay for necessities and health care, medical debt/borrowing, lifestyle changes, and ability to take medication as prescribed.
Patient/Caregiver Experience—Open-Ended	Qualitative perspectives on barriers to accessing and affording the medication and factors that facilitated affordability.
Patient Demographics	Age, gender, household composition, household income, urbanicity, Hispanic/Latino ethnicity, race, employment status, and health insurance.
Patient-Reported Health Status	Overall self-rated health.

We partnered with the National Health Council (NHC) in developing and disseminating the survey to relevant patient groups. In order to preserve the anonymity of survey respondents, the survey was deployed in SurveyMonkey through links shared by the NHC and their member organizations. Survey respondents were given the opportunity to enter a drawing for a $50 gift card separately. The survey was open from July 6 through August 21, 2026.

We received 371 responses in total. In reviewing the responses early on after survey deployment, it became apparent that the majority of responses were consistent with survey bots, and not actual humans, answering the questions. Thus, we instituted screening questions to try to help separate out bot responses from real patient responses. Two ICER staff members then reviewed all responses after the screening questions were implemented to exclude those which did not fit the inclusion and exclusion criteria or appeared to be generated by a survey bot. The two staff members looked for inconsistencies in survey responses (e.g., drug chosen was X, but free text responses referenced drug Y; inconsistency of answer about relevant patient community and drug chosen; inconsistency between patient age and condition/drug chosen; writing patterns and language used in free text responses that are characteristic of AI-generated responses, etc.). We also looked at multiple submissions that were submitted close in time, or that did not spend an appropriate amount of time answering the survey. For the responses to be included in our report, at least two ICER staff members independently reviewed the survey responses and agreed that a response was most likely human (primarily free-text responses). No responses met these criteria and thus no results from the survey were included in the report.