



# **Launch Price and Access Report**

**Research Protocol**

**MAY 4, 2026**

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# 1. Background

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## 1.1. Background

The launch prices of drugs in the United States (US) have been rising significantly over the past few decades, with many new medications entering the market at prices exceeding \$200,000 annually.<sup>1,2</sup> This trend has sparked ongoing discussions about whether these high launch prices are justified and if they correspond to the clinical benefits provided to patients.<sup>3-5</sup> However, an analysis of net launch prices of cancer drugs from 2008 to 2022 did not support the idea that higher prices were associated with better clinical efficacy.<sup>6</sup> 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.<sup>7,8</sup> Complicating these discussions is the fact that the price paid for a drug (i.e., the net price [the actual amount the manufacturer receives after rebates, discounts, and other reductions]) often differs from the list price. However, determining the actual net price can be complex, as it varies significantly among different payers due to market conditions and statutory requirements. Additionally, the impact of government regulations—such as the Medicare drug price negotiation provision of the Inflation Reduction Act—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 price reductions in the future.<sup>9,10</sup>

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.<sup>11</sup> 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 co-pays 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.<sup>12</sup> 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.<sup>5,13</sup>

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 an annual "Launch Price and Access Report" to evaluate the launch prices of new Food and Drug Administration (FDA)-approved drugs and patient access to those therapies.

## 2. Scope of Drugs and Research Objectives

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### 2.1. Scope of Drugs

For this year’s report, we will evaluate new drugs approved in the timeframe outlined by research objectives in Table 2.1. For each indicated timeframe, we will include novel drugs approved by the US FDA Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). Novel drugs are drugs that have never been approved or marketed in the US and therefore will not include generics, biosimilars, or drugs previously approved for other indications. From this list, we will exclude vaccines, blood- or plasma-based products, and imaging or diagnostic agents due to differences in pricing strategies and market dynamics.

**Table 2.1. Drug Approval Timeframe for Research Objectives**

	<b>New Drug Approval Timeframe</b>
<b>Research Objectives 1 &amp; 2</b>	2022 to 2025
<b>Research Objectives 3 to 6</b>	July 2024 to June 2025

### 2.2. Research Objectives

**On launch prices, we will:**

1. Evaluate the median annual launch price (list and net) for newly approved drugs, overall and stratified by drug characteristics (orphan vs. non-orphan designation, gene/cell therapy vs. other, biologic vs. small molecule, and therapeutic area, including oncology and endocrine/metabolic).
2. Evaluate the year-to-year change in annual launch prices (list and net) of new drugs, independent of inflation and key drug characteristics.

*Starting from research objective 3, newly approved drugs refer to drugs approved between July 2024 and June 2025 (See Table 2.1). This timeframe was chosen to ensure one full year of data post-approval to allow for robust analysis.*

3. Evaluate the proportion of newly approved drugs that have been assessed by ICER that have net prices that exceed ICER's Health Benefit Price Benchmark (HBPB) at launch. For drugs priced above the ICER HBPB, we will estimate excess spending attributable to above-benchmark pricing in the first year post-approval.

**On patient access, we will:**

4. Evaluate the real-world patient access experience at the point of care, as measured by drug-specific data on filled prescription rates, denial rates, prescription abandonment, and out-of-pocket costs for newly approved drugs.
5. Evaluate the proportion of payer coverage policies that meet ICER's fair access criteria and which specific criteria are most commonly unmet, for newly approved drugs previously assessed by ICER and a selected subset of drugs with identified coverage barriers based on real-world access data.
6. Evaluate the patient-reported access experience (e.g., awareness of drug availability, prior authorization burden, affordability), as measured by direct patient survey, for newly approved drugs previously assessed by ICER, and a selected subset of drugs with identified coverage barriers based on real-world access data.

### 3. Role of the Working Group

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To help provide important guidance on this project, the Launch Price and Access Report benefits from ongoing input from a multi-stakeholder Working Group, drawing on people with life sciences, health plan, purchaser, patient, and consumer advocacy, and clinical expertise. The Working Group advises ICER on the approach and positioning of the report. None of the Working Group members should be assumed to agree with any of the specific methods, findings, or perspectives presented in this report.

The Working Group members are:

- **Jennifer Day**, PharmD, Drug Intelligence and Strategy Lead, Kaiser Permanente
- **Omar Escontrias**, DrPH, MPH, Senior Vice President, Equity, Research and Programs, National Health Council
- **Clifford Hudis**, MD, FACP, FASCO, CEO, American Society of Clinical Oncology
- **Julie Kueppers**, PhD, FNP, RN, Vice President of Clinical Analytics and Advocacy, Alera Group
- **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.
- **Melea Ward**, PhD, Sr. Director, Financial and Market Insights, IPD Analytics
- **Heidi C. Waters**, PhD, MBA, Principal Advisor, Blue Persimmon Group

## 4. Launch Price Evaluation

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We will identify the drug characteristics for each drug included in this report. Drug characteristics of interest include approval pathway (e.g., accelerated), therapeutic area (e.g., oncology, cardiovascular, endocrine/metabolic, etc.), drug type (e.g., biologic, small molecule), gene or cell therapy, first-in-class mechanism, orphan designation, population size (ultra-rare vs. non-ultra-rare), and first approved in the US.

### 4.1. List Price Analysis

Data on list prices at launch will focus on 2022 – 2025. For drugs approved in 2022 – 2024 and included in ICER’s 2025 Launch Price and Access Report,<sup>14</sup> we will use the list price reported in the original publication. For drugs in scope approved in 2025, we will obtain the list price or Wholesale Acquisition Cost (WAC) from Redbook. We will use the FDA label to determine the appropriate dosage for the approved indication. For drugs with multiple doses, we will use the median dose. We will calculate the annual price of the drug from the WAC based on the recommended dosing. For weight-based dosing, we will use the median body weight for the indicated population or, if reliable data are unavailable, median body weight of the US population.

We will evaluate the median list price for each year (2022, 2023, 2024, 2025) and examine the percentage change in list price in 2023, 2024, and 2025 compared to 2022 (unadjusted analysis). List prices will be inflation-adjusted. In this year’s report, we will focus on additional data from drugs launched in 2025.

Drug prices may vary by certain characteristics listed above, such as the type of drug. To account for differences in drug characteristics (e.g., drug type, orphan designation, etc.), we will conduct trend analyses to examine changes in list prices at launch from 2022 – 2025, controlling for the drug characteristics listed above (adjusted analysis). Specifically, we will use a multiple linear regression model with list price as the dependent variable, and year approved, drug characteristics and their interaction terms as the independent variables. The regression model will allow us to estimate which drug characteristics have the highest correlation with list price, adjust for those drug characteristics, and assess changes in list price over time. We will assess the correlation between the independent variables in the model and consider the removal of highly correlated variables to avoid multicollinearity.

Depending on relevancy, we may conduct a variable selection analysis (e.g., stepwise regression analysis) as a sensitivity analysis. 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. Therefore, we will run an alternative regression model using a variable selection technique to evaluate the robustness of the primary analysis results.

## 4.2. Net Price Analysis

Data on net prices will focus on 2022 – 2025. For drugs approved in 2022 – 2024 and included in ICER’s 2025 Launch Price and Access Report,<sup>14</sup> we will use the net price reported in the original publication. For drugs in scope approved in 2025, we will obtain the net price from multiple data sources (e.g., SSR Health, IPD Analytics, Federal Supply Schedule [FSS]). These sources will be prioritized using a systematic approach. Manufacturers of any drug in scope approved between 2022 – 2025 may submit annual list and net price data at launch through our [manufacturer submission survey](#). Data submitted by manufacturers and deemed reliable may replace previously used estimates of net price.

Similar to the list price analysis, we will evaluate the median net price for each year (2022, 2023, 2024, 2025) and examine percentage change in net price in 2023, 2024, and 2025 compared to 2022 (unadjusted). Net prices will be inflation-adjusted. In this year’s report, we will focus on additional data from 2025. We will conduct trend analyses to examine changes in net price, independent of drug characteristics, using multiple linear regression analyses (adjusted).

## 4.3. Additional Analyses for ICER-Reviewed Drugs

We will conduct a health system impact analysis to identify any drugs that were priced above the ICER Health Benefit Price Benchmark (HBPB) at launch and estimate the excess spending that could have been avoided if they had been priced at the ICER HBPB. Recently approved drugs that were previously reviewed by ICER will be included in this analysis. The analysis will be done at the individual drug level.

ICER HBPBs will be obtained from ICER Final Evidence Reports for the drugs within scope and compared with estimated net price at launch to identify the drugs that were priced above the HBPB. For those exceeding the HBPB, we will estimate the discount needed to reach the HBPB. To estimate the potential savings under HBPB-aligned pricing, we will estimate counterfactual spending under HBPB-aligned pricing by applying the ratio between ICER HBPB and net price to drug spending. Actual US net sales will be used as a proxy for the actual drug spending and will be obtained from sources including SSR Health, Biomedtracker, companies’ financial reports, or IPD

Analytics. Potential savings will be estimated over the first year post-launch, reflecting data availability for recently approved drugs.

To provide further context around the consequences of over-spending on prescription drugs reviewed by ICER, we may estimate health benefits that are forgone among people whose health care expenditures increased to pay for the new drugs (i.e., health opportunity costs). The health opportunity costs could be estimated as follows: (a) the number of individuals losing health insurance coverage using the framework introduced in Vanness et al., which can be translated into the increased mortality attributable to the loss of insurance<sup>15</sup> and (b) the equal value life years (evLYs) lost due to the introduction of new drugs using an approach used in Naci et al.<sup>16</sup> The evLY is a patient-centered measure of health gains commonly used in cost-effectiveness analysis that values the years of life added by a given intervention equally, no matter the person's health status.

Finally, for each drug reviewed by ICER, we will describe information on the justification of pricing provided by the manufacturer. Data on pricing justification will be obtained from manufacturers or publicly available online sources (e.g., press releases).

## 5. Patient Access Evaluation

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We plan to evaluate real-world access to newly launched drugs from multiple perspectives, including: (1) pharmacy and medical claims data to assess how often the drug was able to be obtained by the patient, (2) insurance coverage policies to identify potential coverage barriers to access, and (3) direct patient feedback about their access to newly launched drugs.

### 5.1. Real-World Access

We will obtain point-of-care pharmacy and medical claims data for drugs approved during the second half of 2024 (2H 2024) and the first half of 2025 (1H 2025) to gain insights into access to newly launched drugs. This time period was chosen to ensure that each drug has one full year of claims post-approval. For each drug in scope, we will evaluate the following data points to assess real-world access, including:

- Volume of prescriptions written/dispensed
- Prescription adjudication (e.g., approval/rejection rates, prescription abandonment rates, prior authorization metrics)
- Patient out-of-pocket costs (cost-share, cash pay)

We will not report any identifiable information at the payer or plan level.

### 5.2. Coverage Policy Evaluation

To provide additional context for the real-world access measures described in Section 5.1., we will evaluate coverage policies for a subset of drugs. Specifically, we will review a select set of coverage policies for all ICER-reviewed drugs, as well as for drugs identified in our analysis of real-world access measures in Section 5.1 with significant coverage barriers. We will use ICER's "[Cornerstones of Fair Access](#)" criteria as a benchmark for our evaluation.

For each drug, we will obtain publicly available payer coverage policies from private payers with the most covered lives. We will abstract data from each coverage policy and report, in the aggregate, measures of access such as the proportion of health plans providing coverage and the proportion implementing utilization management strategies (e.g., coverage restrictiveness relative to the FDA label, clinical eligibility, step therapy protocols, and prescriber restrictions). We will then attempt to assess, based on data availability, whether the coverage policies are consistent with ICER's Fair Access criteria.<sup>17</sup>

### 5.3. Patient Experience

For each ICER-reviewed drug in scope and a select subset of drugs of interest, we will directly assess the patient access experience through a drug-specific patient survey. We will partner with the National Health Council in developing and disseminating the survey to patients. Topics covered in the survey will include patient barriers to accessing the drug (e.g., patient awareness of the new treatment, insurance coverage restrictions, out-of-pocket costs, and drug affordability). We will use descriptive statistics and qualitative analysis to summarize our findings from the survey responses. Results will be presented for each drug and, as data permit, by relevant subgroups, for example by demographic characteristics such as age and gender, as well as social determinants of health such as employment status, household income, and urban versus rural area.

## 6. Secondary Research Objective

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For this year's report, as secondary research objectives, we will evaluate the number and types of clinical trial evidence that inform new launches and the timing of their publication, supporting coverage and clinical decision-making.

We will identify characteristics of the pivotal trials that supported FDA approval for drugs approved from July 2024 to June 2025. We will abstract 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, etc.), and publication date of the primary peer-reviewed manuscript(s) reporting trial results. Data will be collected from the FDA Drug Trial Snapshots, FDA labels, clinicaltrials.gov, and published manuscripts.

### 6.1. Analysis

We will provide descriptive statistics (e.g., mean, median) for number of pivotal trials included in FDA approval packages for drugs approved from July 2024 to June 2025. We will assess the time from publication of peer-reviewed manuscript(s) of the pivotal clinical trial(s) to FDA approval of the drug. We will also calculate the proportion of drugs approved in that time frame that received accelerated approval.

# References

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1. Beasley D. Focus: Newly launched U.S. drugs head toward record-high prices in 2022. *Reuters*. Accessed April 3, 2025. <https://www.reuters.com/business/healthcare-pharmaceuticals/newly-launched-us-drugs-head-toward-record-high-prices-2022-2022-08-15/>
2. Beasley D. Prices for new US drugs rose 35% in 2023, more than the previous year. *Reuters*. <https://www.reuters.com/business/healthcare-pharmaceuticals/prices-new-us-drugs-rose-35-2023-more-than-previous-year-2024-02-23/>
3. Miljković MD, Tuia JE, Olivier T, Haslam A, Prasad V. Association Between US Drug Price and Measures of Efficacy for Oncology Drugs Approved by the US Food and Drug Administration From 2015 to 2020. *JAMA Internal Medicine*. 2022;182(12):1319-1320. doi:10.1001/jamainternmed.2022.4924
4. Ross M, Barrueta A. The Real Reasons Drug Prices Are So High. *Health Affairs Forefront*. 2024;
5. Kesselheim AS, Avorn J, Sarpatwari A. The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform. *Jama*. Aug 23-30 2016;316(8):858-71. doi:10.1001/jama.2016.11237
6. Abuloha S, Harvey BP, Niu S, et al. An analysis of US net cancer drug launch prices and clinical efficacy and certainty of evidence from 2008 to 2022. *Health Affairs Scholar*. 2025;3(4):qxaf051. doi:10.1093/haschl/qxaf051
7. Wouters OJ, Berenbrok LA, He M, Li Y, Hernandez I. Association of Research and Development Investments With Treatment Costs for New Drugs Approved From 2009 to 2018. *JAMA Netw Open*. Sep 1 2022;5(9):e2218623. doi:10.1001/jamanetworkopen.2022.18623
8. Angelis A, Polyakov R, Wouters OJ, Torreele E, McKee M. High drug prices are not justified by industry's spending on research and development. *BMJ*. 2023;380:e071710. doi:10.1136/bmj-2022-071710
9. Sullivan SD. Medicare Drug Price Negotiation in the United States: Implications and Unanswered Questions. *Value in Health*. 2023;26(3):394-399. doi:10.1016/j.jval.2022.11.015
10. Cubanski J, Neuman T, Freed M. Explaining the Prescription Drug Provisions in the Inflation Reduction Act. Accessed Jan 24, 2023. <https://www.kff.org/medicare/issue-brief/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act/#>
11. Haque W, Rana I, Zahid S, Hsiehchen D. Lengthy and Variable Delays in Oncology Drug Coverage Determination. *JAMA Oncology*. 2023;9(12):1728-1729. doi:10.1001/jamaoncol.2023.4488
12. Pan Foundation. 2025 Report: State of Patient Access. April 2025. [https://www.panfoundation.org/wp-content/uploads/2025/03/PAN\\_Foundation-State-of-Patient-Access-Report-2025.pdf](https://www.panfoundation.org/wp-content/uploads/2025/03/PAN_Foundation-State-of-Patient-Access-Report-2025.pdf)
13. Blumenthal D, Gumas E, Shah A, Guna M, Williams R. Mirror, Mirror 2024: A Portrait of the Failing U.S. Health System: Comparing Performance in 10 Nations. The Commonwealth Fund. Accessed April 9, 2025. <https://www.commonwealthfund.org/publications/fund-reports/2024/sep/mirror-mirror-2024>
14. Agboola F, Lin G, Lee W, et al. *Launch Price and Access Report*. 2025. [https://icer.org/wp-content/uploads/2025/10/ICER\\_2025\\_Launch-Price-and-Access-Final-Report\\_For-Publication.pdf](https://icer.org/wp-content/uploads/2025/10/ICER_2025_Launch-Price-and-Access-Final-Report_For-Publication.pdf)
15. Vanness DJ, Lomas J, Ahn H. A Health Opportunity Cost Threshold for Cost-Effectiveness Analysis in the United States. *Ann Intern Med*. Jan 2021;174(1):25-32. doi:10.7326/m20-1392

16. Naci H, Murphy P, Woods B, Lomas J, Wei J, Papanicolas I. Population-health impact of new drugs recommended by the National Institute for Health and Care Excellence in England during 2000–20: a retrospective analysis. *The Lancet*. 2025;405(10472):50-60. doi:10.1016/S0140-6736(24)02352-3
17. Pearson SD, Lowe M, Towse A, Segel CS, H. C. *Cornerstones of "Fair" Drug Coverage: Appropriate Cost-Sharing and Utilization Management Policies for Pharmaceuticals*. 2020. <https://icer.org/wp-content/uploads/2020/11/Cornerstones-of-Fair-Drug-Coverage--September-28-2020.pdf>

## Appendix A: List of Drugs in Scope

**Table A1. All Drugs in Scope Approved by CDER or CBER in 2022 to 2025**

2022 Novel FDA Approvals (n=40)		
Adstiladrin® (nadofaragene firadenovec)	Lytgobi® (futibatinib)	Spevigo® (spesolimab-sbzo)
Amvuttra™ (vutrisiran)	Mounjaro™ (tirzepatide)	Sunlenca® (lenacapavir)
Briumvi™ (ublituximab-xiiv)	Nexobrid® (anacaulase-bcdb)	Tecvayli™ (teclistamab-cqyv)
Camzyos™ (mavacamten)	Omlonti® (omidenepeg isopropyl)	Terlivaz® (terlipressin)
Carvykti® (ciltacabtagene autoleucl)	Opdualag™ (nivolumab and relatlimab-rmbw)	Tzield™ (teplizumab-mzww)
Cibinqo™ (abrocitinib)	Pluvicto™ (lutetium Lu 177 vipivotide tetraxetan)	Vabysmo™ (faricimab-svoa)
Daxxify™ (daxibotulinumtoxinA-lanm)	Pyrukynd® (mitapivat)	Vivjoa™ (oteseconazole)
Elahere™ (mirvetuximab soravtansine-gynx)	Quviviq® (daridorexant)	Vonjo™ (pacritinib)
Enjaymo™ (sutimlimab-jome)	Relyvrio® (sodium phenylbutyrate and taurursodiol)	Voquezna Triple Pak™ (vonoprazan, amoxicillin, clarithromycin)
Hemgenix® (etranacogene dezaparvovec-drlb)	Rezlidhia™ (olutasidenib)	Vtama® (tapinarof)
Imjudo® (tremelimumab-actl)	Rolvedon™ (eflapegrastim-xnst)	Xenpozyme™ (olipudase alfa-rpcp)
Kimtrak® (tebentafusp-tebn)	Skysona® (elivaldogene autotemcel)	Ztalmy® (ganaxolone)
Krazati™ (adagrasib)	Sotyktu™ (deucravacitinib)	Zynteglo® (betibeglogene autotemcel)
Lunsumio™ (mosunetuzumab-axgb)		

FDA: Food and Drug Administration, n: number

2023 Novel FDA Approvals (n=62)		
Adzynma® (ADAMTS13, recombinant-krhn)	Izervay™ (avacincaptad pegol)	Rivfloza™ (nedosiran)
Agamree® (vamorolone)	Jaypirca™ (pirtobutinib)	Roctavian® (valoctocogene roxaparvovec-rvox)
Aphexda™ (motixafortide)	Jesduvroq® (daprodustat)	Rystiggo® (rozanolixizumab-noli)
Augtyro™ (repotrectinib)	Joenja® (leniolisib)	Ryzneuta® (efbemalenograstim alfa-vuxw)
Beyfortus™ (nirsevimab-alip)	Lamzede® (velmanase alfa-tycv)	Skyclarys™ (omaveloxolone)
Bimzelx® (bimekizumab-bkzx)	Lantidra™ (donislecel-jujn)	Sohonos™ (palovarotene)
Brenzavvy™ (bexagliflozin)	Leqembi® (lecanemab-irmb)	Talvey™ (talquetamab-tgvs)
Casgevvy® (exagamglogene autotemcel (exa-cel))	Litfulo™ (ritlicitinib)	Truqap™ (capivasertib)
Columvi™ (glofitamab-gxbm)	Loqtorzi® (toripalimab-tpzi)	Vanflyta® (quizartinib)
Daybue™ (trofinetide)	Lyfgenia® (lovotibeglogene autotemcel)	Velsipity™ (etrasimod)
Defencath® (Taurolidine, heparin)	Miebo™ (perfluorhexyloctane)	Veopoz™ (pozelimab-bbfg)
Elevidys® (delandistrogene moxeparvovec-rokl)	Ngenla™ (somatrogon-ghla)	Veozah™ (fezolinetant)
Elfabrio® (pegunigalsidase alfa-iwxj)	Ogsiveo™ (nirogacestat)	Vyjuvek® (beremagene Geperpavec-svdt)
Elrexio™ (elranatamab-bcmm)	Ojjaara® (momelotinib)	Wainua™ (eplontersen)
Epkinly® (epcoritamab-bysp)	Omisirge® (omidubicel-onlv)	Xacduro® (sulbactam, durlobactam)
Exxua® (gepirone)	Omvoh™ (mirkizumab-mrkz)	Xdemvy™ (lotilaner)
Fabhalta® (iptacopan)	Orserdu™ (elacestrant)	Zavzpret™ (zavagepant)
Filspari™ (sparsentan)	Paxlovid® (nirmatrelvir, ritonavir)	Zilbrysq® (zilucoplan)
Filsuvez® (birch triterpenes)	Pombiliti™ (cipaglicosidase alfa-atga)	Zurzuvae™ (zuranolone)
Fruzaqla™ (fruquintinib)	Qalsody™ (tofersen)	Zynyz™ (retifanlimab-dlwr)
Inpefa™ (sotagliflozin)	Rezzayo™ (rezafungin)	

FDA: Food and Drug Administration, n: number

2024 Novel FDA Approvals (n=56)		
Alhemo® (concizumab-mtci)	Kebilidi™ (eladocagene exuparvovec-tneq)	Sofdra™ (sofpironium)
Alyftrek® (vanzacaftor, tezacaftor, and deutivacaftor)	Kisunla™ (donanemab-azbt)	Symvess™ (acellular tissue engineered vessel-tyod)
AMTAGVI® (lifileucel)	Lazcluze™ (lazertinib)	Tecelra® (afamitresgene autoleucel)
Anktiva® (nogapendekin alfa inbakicept-pmIn)	Lenmeldy™ (atidarsagene autotemcel)	Tevimbra® (tislelizumab-jsgr)
Aqneursa™ (levacetylleucine)	Leqselvi™ (deuruxolitinib)	Tryngolza™ (olezarsen)
Attruby® (acoramidis)	Letybo® (letibotulinumtoxinA-wlbg)	Tryvio™ (aprocitentan)
Aucatzyl® (obecabtagene autoleucel)	Livdelzi® (seladelpar)	Unloxcyt® (cosibelimab-ipdl)
Beqvez™ (elaparvovec-dzkt)	Miplyffa™ (arimoclomol)	Vafseo® (vadadustat)
Bizengri® (zenocutuzumab-zbco)	Nemludio® (nemolizumab-ilto)	Voranigo® (vorasidenib)
Cobenfy™ (xanomeline and trospium chloride)	Niktimvo™ (axatilimab-csfr)	Voydeya™ (danicopan)
Crenessity™ (crinecerfont)	Ohtuvayre™ (ensifentrine)	Vyloy® (zolbetuximab-clzb)
Duvyzat® (givinostat)	Ojemda™ (tovorafenib)	Winrevair™ (sotatercept-csrrk)
Ebglyss™ (lebrikizumab-lbkz)	Orlynvah™ (sulopenem etzadroxil, probenecid)	Xolremdi™ (mavorixafor)
Ensacove™ (ensartinib)	Piasky® (crovalimab-akkz)	Yorvipath® (palopegteriparatide)
Exblifep® (cefepime, enmetazobactam)	Rapiblyk™ (landiolol)	Zelsuvmi™ (berdazimer)
Hympavzi™ (marstacimab-hncq)	Revuforj® (revumenib)	Zevtera® (ceftobiprole medocaril sodium)
Imdelltra™ (tarlatamab-dlle)	Rezdiffra™ (resmetirom)	Ziihera® (zanidatamab-hrii)
Iqirvo® (elafibranor)	Ryoncil® (remestemcel-L-rknd)	
Itovebi™ (inavolisib)	Rytelo™ (imetelstat)	

FDA: Food and Drug Administration, n: number

2025 Novel FDA Approvals (n=52)		
Andembry® (garadacimab-gxii)	Hyrnuo® (sevabertinib)	Palsonify™ (paltusotine)
Anzupgo® (delgocitinib)	Ibtrozi™ (taletrectinib)	PAPZIMEOS® (zopapogene imadenovec-drba)
Avance Nerve Graft® (acellular nerve allograft-arwx)	Imaavy™ (nipocalimab-aahu)	penpulimab-kcqx® (penpulimab-kcqx)
Avmapki Fakzynja Co-Pack™ (avutometinib and defactinib)	Inluriyo™ (imlunestrant)	Qfitlia™ (fitusiran)
Blujepa® (gepotidacin)	ITVISMA® (onasemnogene abeparvovec-brve)	Redemplo® (plozasiran)
Brinsupri™ (brensocatic)	Jascayd® (nerandomilast)	Rhapsido® (remibrutinib)
Cardamyst™ (etripamil)	Journavx® (suzetrigine)	Romvimza™ (vimseltinib)
Datroway® (datopotamab deruxtecan-dlnk)	Keytruda Qlex™ (pembrolizumab and berahyaluronidase alfa-pmph )	Sephience® (sepiapterin)
Dawnzera™ (donidalorsen)	Komzifti™ (ziftomenib)	Tryptyr® (acoltremon)
Ekterly® (sebetralstat)	Kygevvi® (doxocitine and doxribtimine)	Vanrafia™ (atrasentan)
Emrelis™ (telisotuzumab vedotin-tllv)	Lerochol® (lerodalcibep-liga)	Vizz™ (aceclidine)
ENCELTO® (revakinagene taroretcel-lwey )	Lynkuet® (elinzanetant)	Voyxact® (sibeprenlimab-szsi)
Enflonsia™ (clesrovimab-cfor)	Lynozyfic™ (linvoseltamab-gcpt)	WASKYRA® (etuvetidigene autotemcel)
Exdensur® (depemokimab-ulaa)	Modeyso™ (dordaviprone)	Wayrilz™ (rilzabrutinib)
Forzinity™ (elamipretide)	Myqorzo™ (aficamten)	Yartemlea® (narsoplimab-wuug)
Gomekli™ (mirdametinib)	Nereus™ (tradipitant)	Zegfrovy™ (sunvozertinib)
Grafapex™ (treosulfan)	Nuzolvence® (zoliflodacin)	ZEVASKYN® (prademagene zamikeracel)
Hernexeos® (zongertinib)		

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