Launch Price and Access Report

Research Protocol

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Table of Contents

1. Background

1.1. Background

The launch prices of drugs in the US have been rising significantly over the past few decades, with many new medications entering the market at prices exceeding $200,000 annually.[1,2] 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.[3-5] 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.[6] 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.[7,8] 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, discount 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.[9,10]

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.[11] 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 has declined over the past year.[12] 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%). 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.[5,13]

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) intends to publish an annual "Launch Price and Access Report." This report will contain hypotheses-generating research to inform current policy conversations and highlight opportunities to enhance affordability and access.

1.2. Objectives

ICER will evaluate the launch prices and patient access to new Food and Drug Administration (FDA) approved drugs. The scope for the 2025 report includes drugs approved in the past three years (2022-2024) (see Section 3 for additional details).

Specifically, we intend to:

- Analyze trends in both list and net prices (where available) of newly approved drugs across the years in scope, as well as the impact of various relevant drug characteristics, such as drug type, therapeutic area, and population size, on list and net prices (see Sections 4.1 and 4.2).

- Conduct an in-depth review of the drugs in scope that have been previously reviewed by ICER – assess the prices of these drugs in relation to ICER's Health Benefit Price Benchmark (HBPB), estimate potential savings in healthcare spending, and identify any opportunity costs associated with overspending on these drugs (see Section 4.3).

    - ICER's Health Benefit Price Benchmark 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.

- Evaluate data on coverage restrictions, patient cost-sharing, and patient experiences on access for a selection of drugs in scope (see Section 5).

2. Role of the Working Group

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
- **Pat Gleason**, PharmD, BCPS, FCCP, FAMCP, Assistant Vice President, Health Outcomes, Prime Therapeutics
- **Clifford Hudis**, MD, FACP, FASCO, CEO, American Society of Clinical Oncology
- **Dan Jones**, MA, Sr. Vice President, Federal Affairs, Alliance of Community Health Plans
- **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.
- **Kim Le**, PharmD, Vice President, National Clinical Pharmacy Services, Kaiser Permanente
- **Julia Logan**, MD, MPH, Chief Medical Officer, Clinical and Programs Division, CalPERS
- **Jennifer Martin**, PharmD, Consultant, Remund Group, LLC
- **Amir Abbas Tahami Monfared**, MD, PhD, Head, Societal Value Platform and Evidence Development, Eisai, Inc.
- **Jimi Olaghere**, Gene Therapy Advocate/Patient
- **Carl Schmid**, MBA, Executive Director, HIV+Hepatitis Policy Institute
- **Heidi Waters**, PhD, MBA, Senior Director, Policy Research, Global Value & Real World Evidence, Otsuka Pharmaceutical

3. List of Included Drugs

The process of developing this report will start by identifying all novel agents approved by The Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) in the US FDA from January 2022 to December 2024. From this list, we will exclude generic products, biosimilars, vaccines, antibiotics, microbiota products, blood or plasma-based products, and imaging or diagnostic agents due to different pricing strategies and market dynamics.

3.1. Drugs in Scope

The drugs approved by CDER and CBER in 2022, 2023, and 2024 are shown below and we have highlighted the drugs in scope for this report in Table 3.1.

Table 3.1. Drugs Approved by CDER and CBER in 2022, 2023, and 2024

FDA Approval Year	Number of Novel Approvals	Number of Exclusions	Number in Scope	Number Reviewed by ICER
2022	51	9	42	10
2023	80	18	62	7
2024	69	13	56	8

FDA: The US Food and Drug Administration, ICER: Institute for Clinical and Economic Review

4. Launch Price Section

We will identify the drug characteristics for each drug included in this report. Drug characteristics of interest include approval pathway (e.g., standard, priority, accelerated, etc.), therapeutic area (e.g., oncology, cardiovascular, endocrine, etc.), drug type (biologic vs. small molecule), gene therapy, first-in-class mechanism, orphan product, population size (rare vs. non-rare), route of administration (e.g., oral, injectable), and first approved in the US.

We will also identify characteristics of the pivotal trials that contributed to the FDA approval for each drug included in this report. We will abstract data on the number and Phase of clinical trials that were part of the FDA submission, type of clinical trial(s) (e.g., randomized trial, single-arm trial, etc.), and type of analysis (e.g., superiority, non-inferiority).

4.1. List Price Analysis

Data on list prices at launch will focus on 2022-2024. For each drug in scope, 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) and examine the percentage change in list price in 2023 and 2024 compared to 2022 (unadjusted analysis). The list price at launch will not be inflation-adjusted.

Drug prices may vary by certain characteristics listed above, such as type of drug. To account for differences in drug characteristics, we will conduct trend analyses to examine changes in list prices at launch from 2022-2024, controlling for the drug characteristics listed above (adjusted analysis). Specifically, we will conduct a regression analysis with list price as the dependent variable, and year approved, drug characteristics and their interaction terms as the independent variables. This model will be also used to identify drug characteristics that are associated with list price as well as those that affect 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 data availability and relevancy, we may conduct a variable selection 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 (e.g., Akaike Information Criterion–based best subsets selection, Least Absolute Shrinkage and Selection Operator [LASSO], stepwise, ridge, or elastic net regression analyses) to evaluate the robustness of the primary analysis results.[14]

4.2. Net Price Analysis

Data on net prices will focus on 2022-2024. For each drug in scope, we will obtain the net price from multiple data sources (e.g., SSR Health, Federal Supply Schedule [FSS]). Similar to list price, we will use the FDA label to determine appropriate dosage; for drugs with multiple doses, we will use median dose, and we will incorporate weight-based dosing. In instances where we are unable to locate the net price, we will use estimates or forecasted net price.

Similar to the list price analysis, we will evaluate the median net price for each year (2022, 2023, 2024) and examine percentage change in net price in 2023 and 2024 compared to 2022 (unadjusted). We will conduct trend analyses to examine changes in net price, independent of drug characteristics, using regression analyses (adjusted). We will also use the model to identify drug characteristics that are associated with net price, and predictors of change in net price across the selected years.

4.3. Additional Analyses for ICER-Reviewed Drugs

We will obtain the ICER Health Benefit Price Benchmark (HBPB) for drugs in scope for the report that were previously reviewed by ICER. We will calculate the percentage of list prices and the percentage of net prices (where available) that fell within the ICER HBPB range. If the net price is not available, we will use estimates or forecasted net price. For drugs with prices that do not fall within the ICER HBPB, we will calculate the discount needed for the list price to reach the ICER HBPB and the additional discount needed for the net price to reach the ICER HBPB (when applicable).

Next, we will conduct an analysis to examine whether specific drug characteristics predicted the level of discount required to meet the ICER HBPB. To do so, we will conduct a regression analysis with the discount needed as the dependent variable and drug characteristics (as listed above) as independent variables.

For the drugs reviewed by ICER with net prices above the ICER HBPB, we will estimate the potential savings in health care spending if drug prices were adjusted to align with the ICER HBPB. Specifically, we will obtain the total spend before applying the ICER HBPB (from total net sales in the US as recorded by the manufacturer from SSR health) and apply a ratio between ICER HBPB and net price. We will examine change in spending before and after applying ICER HBPB using a paired t-Test or Wilcoxon signed-rank tests with a significance level of $P<0.05$.[15]

To provide context around the consequences of over-spending on prescription drugs reviewed by ICER, we will estimate health benefits that are forgone among patients whose health care expenditures are reduced to pay for the new drugs (i.e., health opportunity costs). The health opportunity costs will be estimated as the number of individuals losing health insurance coverage using the framework introduced in Vanness et al. (2021), which can be translated into the increased mortality and morbidity attributable to the loss of insurance.[16] Additionally, we will estimate the equal value life years (evLYs) lost due to the introduction of new drugs using an approach where forgone evLYs are calculated by dividing the incremental costs of the new drugs by the health-opportunity cost of health care expenditure in the US.[17] 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 publicly available online sources (e.g., press releases).

5. Access Section

For this initial year of the Launch Price and Access Report, we will evaluate patient access to drugs approved in 2024. To do this, we will evaluate data on coverage restrictions and patient cost-sharing on these therapies. In addition, we will collaborate with our external partners to collect qualitative feedback from patient groups about patient experience accessing newly launched drugs.

5.1. Coverage Restrictions

To evaluate coverage restrictions, we will utilize the Tufts Medical Center Specialty Drug Evidence and Coverage (SPEC) Database, which includes information on specialty drug coverage decisions issued by up to 18 large US commercial health plans. In this database, coverage decisions are compared against FDA-approved labels with restrictions beyond the FDA approval noted and categorized. From this source, we will abstract data for the proportion of health plans with coverage for each selected drug and proportion of health plans with utilization management strategies imposed for each drug, including but not limited to coverage restrictiveness relative to the FDA label, clinical eligibility, step therapy protocol, and prescriber restrictions.

5.2. Patient Cost-Sharing

To evaluate patient cost-sharing, we will partner with IQVIA, a leading health care data and analytics provider, to gain insights into national-level cost-sharing and patient out-of-pocket costs. For each drug in scope, we will evaluate the following data points from the IQVIA data set:

1. **Prior authorization burden measures, including:**
    - Total written commercial prescriptions
    - Total dispensed commercial prescriptions
    - Total dispensed New to Brand commercial prescriptions
        - % filled
        - % of prescriptions rejected
            - % rejections due to prior authorization or step therapy
            - % rejections due to another reason (e.g., not covered, fill limit, etc.)
            - % reversals
2. **Patient cost-sharing measures by drug, including:**
    - % of claims by out-of-pocket cost, ranges
    - Overall cash pay prescription volume
    - % of claims by cash pay out-of-pocket cost, ranges

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

5.3. Patient Experience

We will conduct facilitated group discussions with patient groups, in partnership with the National Health Council, to discuss access challenges for the drugs approved in 2024 that ICER has previously reviewed. These group discussions will be preceded by surveys to the participants to collect both demographic information as well as key access experiences to better guide the group discussions. We will qualitatively summarize our findings from the initial survey responses and the patient group discussions in the report. Patients will be compensated based on the National Health Council's Fair-Market Value Calculator.[18]

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Appendix A: List of Drugs in Scope

Table A1. All Drugs in Scope Approved by CDER or CBER in 2022 to 2024

2022 Novel FDA Approvals		
Adstiladrin® (Nadofaragene firadenovec)	Lunsumio® (Mosunetuzumab-axgb)	Spevigo® (spesolimab-sbzo)
Amvuttra® (vutrisiran)	Lytgobi® (futibatinib)	Sunlenca® (Lenacapavir)
Briumvi® (ublituximab-xiiy)	Mounjaro® (Tirzepatide)	Tecvayli® (teclistamab-cqyv)
Camzyos® (Mavacamten)	Nexobrid® (Anacaulase-bcdb)	Terlivaz® (Terlipressin)
Carvykti® (ciltacabtagene autoleucel)	Omlonti® (Omidenepag isopropyl)	Tzield® (Teplizumab-mzwv)
Cibinqo® (abrocitinib)	Opdualag® (nivolumab and relatlimab-rmbw)	Vabysmo® (Faricimab-svoa)
Daxxify® (daxibotulinumtoxinA-lanm)	Pluvicto® (Lutetium Lu 177 vipivotide tetraxetan)	Vivjoa® (Osteconazole)
Elahere® (Mirvetuximab soravtansine-gynx)	Pyrukind® (mitapivat)	Vonjo® (pacritinib)
Elucirem® (Gadopiclenol)	Quviviq® (Daridorexant)	Voquenza Triple Pak® (Vonoprazan, amoxicillin, clarithromycin)
Enjaymo® (Sutimlimab-jome)	Relyvrio® (sodium phenylbutyrate and taurursodiol)	Vtama® (tapinarof)
Hemgenix® (Etranacogene dezaparvovec-drlb)	Rezlidhia® (olutasidenib)	Xenoview® (Hyperpolarized Xe-129)
Imjudo® (Tremelimumab-actl)	Rolvedon® (Eflapegrastim-xnst)	Xenpozyme® (Olipudase alfa-rpcp)
Kimmtrak® (Tebentafusp-tebn)	Skysona® (Elivaldogene autotemcel)	Ztalmy® (Ganaxolone)
Krazati® (adagrasib)	Sotyktu® (deucravacitinib)	Zynteglo® (betibeglogene autotemcel)

2023 Novel FDA Approvals		
Agamree® (Vamorolone)	Jaypirca® (pirtobutinib)	Rivfloza® (Nedosiran)
Aphexda® (motixafortide)	Jesduvroq® (daprodustat)	Roctavian® (Valoctocogene Roxaparvovec-rvox)
Augtyro® (Repotrectinib)	Joenja® (Leniolisib)	Rystiggo® (rozanolixizumab-noli)
Beyfortus® (nirsevimab-alip)	Lamzede® (Velmanase alfa-tycv)	Ryzneuta® (Efbemalenograstim alfa-vuxw)
Bimzelx® (Bimekizumab-bkzx)	Lantidra® (Donislecel-jujn)	Skyclarys® (omaveloxolone)
Brenzavvy® (Bexagliflozin)	Leqembi® (Lecanemab-irmb)	Sohonos® (Palovarotene)
Casgevy® (exagamglogene autotemcel (exa-cel))	Litfulo® (Ritlecitinib)	Talvey® (Talquetamab-tgvs)
Columvi® (glofitamab-gxbm)	Loqtorzi® (Toripalimab-tpzi)	Truqap® (Capivasertib)
Daybue® (Trofinetide)	Lyfgenia® (Lovotibeglogene autotemcel)	Vanflyta® (quizartinib)
Defencath® (Taurolidine, heparin)	Miebo® (Perfluorhexyloctane)	Velsipity® (Etrasimod)
Elevidys® (Delandistrogene Moxeparvovec-rokl)	Ngenla® (somatrogon-ghla)	Veopoz® (pozelimab-bbfg)
Elfabrio® (Pegunigalsidase alfa-iwxj)	Ogsiveo® (Nirogacestat)	Veozah® (Fezolinetant)
Elrexfio® (Elrnatamab-bcmm)	Ojjaara® (momelotinib)	Vyjuvek® (Beremagene Geperpavec-svdt)
Epkinly® (Epcoritamab-bysp)	Omisirge® (Omidubicel-onlv)	Wainua® (Eplontersen)
Exxua® (Gepirone)	Omvoh® (Mirkizumab-mrkz)	Xacduro® (sulbactam, durlobactam)
Fabhalta® (iptacopan)	Orserdu® (Elacestrant)	Xdemvy® (lotilaner)
Filspari® (Sparsentan)	Paxlovid® (nirmatrelvir, ritonavir)	Zavzpret® (Zavagepant)
Filsuvez® (birch triterpenes)	Pombiliti® (Cipaglucosidase alfa-atga)	Zilbrysq® (zilucoplan)
Fruzaqla® (Fruquintinib)	Posluma® (Flotufolastat F18)	Zurzuvae® (zuranolone)
Inpefa® (Sotagliflozin)	Qalsody® (Tofersen)	Zynyz® (Retifanlimab-dlwr)
Izervay® (avacincaptad pegol)	Rezzayo® (Rezafungin)	

2024 Novel FDA Approvals		
Alhemo® (concizumab-mtci)	Itovebi® (inavolisib)	Rytelo® (imetelstat)
Alyftrek ® (vanzacaftor, tezacaftor, and deutivacaftor)	Kebilidi® (eladocagene exuparvovec-tneq)	Sofdra® (sofpironium)
Amtagvi® (Lifileucel)	Kisunla® (donanemab-azbt)	Symvess® (acellular tissue engineered vessel-tyod)
Anktiva® (nogapendekin alfa inbakicept-pmln)	Lazcluze® (lazertinib)	Tecelra® (afamitresgene autoleucel)
Aqneursa ® (levacetylleucine)	Lenmeldy® (atidarsagene autotemcel)	Tevimbra® (tislelizumab-jsgr)
Attruby® (acoramidis)	Leqselvi® (deuruxolitinib)	Tryngolza® (olezarsen)
Aucatzyl® (obecabtagene autoleucel)	Letybo® (letibotulinumtoxinA-wlbg)	Tryvio® (aprocitentan)
Beqvez® (elaparvovec-dzkt)	Livdelzi® (seladelpar)	Unloxcyt® (cosibelimab-ipdl)
Bizengri® (zenocutuzumab-zbco)	Miplyffa® (arimoclomol)	Vafseo® (vadadustat)
Casgevy® (Exagamglogene autotemcel)	Nemluvio® (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-csrk)
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)	