



PORTAL

Program On Regulation, Therapeutics, And Law



Division of Pharmacoepidemiology and Pharmacoeconomics
Harvard Medical School | Brigham and Women's Hospital

Determining Upper Payment Limits

Considerations for State Prescription Drug Affordability Boards (PDABs)

February 27, 2024

Matthew J. Martin, MA; Benjamin N. Rome, MD, MPH; Helen Mooney, MPH; Leah Z. Rand, DPhil; Adam J.N. Raymakers, PhD; Liam Bendicksen, BA; Catherine S. Hwang, MD, MSPH; Hussain S. Lalani, MD, MPH, MSc; Ian T.T. Liu, MD, JD, MPH, MS; Jerry Avorn, MD; Aaron S. Kesselheim, MD, JD, MPH

This white paper was developed as part of a collaboration with the National Academy for State Health Policy (NASHP), with support from Arnold Ventures, to assist states implementing Prescription Drug Affordability Boards. The recommendations expressed herein are presented for informational purposes only and do not constitute official legal guidance.

Executive Summary

Several states are aiming to address high prescription drug prices by establishing **prescription drug affordability boards (PDABs)**. These boards are broadly tasked with assessing the affordability of selected drugs sold in the state. For drugs found to be unaffordable to state consumers or the state health care system, some PDABs have the authority to set **upper payment limits (UPLs)**, creating a maximum rate at which the drug can be purchased in the state.

There are several ways states could calculate and select appropriate UPL values. Different methodologies may be more or less useful depending on why a particular drug is deemed unaffordable. This white paper describes three potential strategies PDABs may employ to arrive at a UPL, leveraging the insight and data from the affordability review process. The strategies are presented as follows:

Strategy 1: Reference Pricing. If the price paid for a drug is higher than prices paid for similar drugs or for the same drug in other contexts, PDABs may consider setting a UPL using a reference pricing strategy. This could be done by internally referencing a drug's price to prices of therapeutic alternatives, or by externally referencing to the price of the drug in other countries or prices negotiated by public payers like Medicare or the Department of Veterans Affairs.

Strategy 2: Net Price. For highly-rebated drugs that pose significant out-of-pocket costs to patients, PDABs may consider linking a UPL to the net price of the drug after any rebates or discounts negotiated between the drug manufacturer and PBM. This method may ensure that patient out-of-pocket costs would be based on the net price, although Boards will need to consider the implications of this approach on formulary placement.

Strategy 3: Budgetary Thresholds. For drugs that are clinically effective yet pose affordability challenges due to substantial spending by state and private payers, some PDABs may consider examining a drug's budgetary impact in setting a UPL. This could be done by limiting the drug's contribution to increases in health insurance premiums or by leveraging a modified budget impact analysis to establish cost savings targets.

Background

As of February 2024, seven states have enacted **Prescription Drug Affordability Boards (PDABs)** to address high prescription drug prices and the impact of these prices on patient access to drugs. Several of these boards fulfill this mission by performing affordability reviews of selected drugs to determine if those drugs pose affordability challenges in the state.¹

For drugs deemed unaffordable based on these reviews, four state PDABs have the authority to establish **upper payment limits (UPLs)**, or the maximum rate at which the drug can be purchased in the state. UPLs have the potential to better align drug spending with the benefits that therapies provide to patients, address the budgetary impact of costly drugs to payers, and reduce the financial burden for patients who use some costly medications.

Although the enabling statutes give some guidance on factors PDABs must consider when developing UPLs, boards have the ability to develop specific processes for determining UPLs. This white paper outlines three strategies PDABs could consider in developing such a process. The applicability of each strategy depends on the Board's authorities and priorities. By considering a range of options, state PDABs will be better equipped to implement upper payment limits that improve drug affordability.

From Affordability Review to UPL

If, at the end of the affordability review process, a PDAB finds a drug to be unaffordable, the Board may then determine that a UPL is an appropriate mechanism by which to address that unaffordability. When setting a UPL, Boards are typically statutorily tasked with considering certain criteria, including:

- The cost of administering the selected drug;
- The cost of delivering the selected drug to patients in the state;
- The status of the selected drug on the FDA drug shortage list;² and
- Other administrative costs associated with the manufacturing and delivery of the drug.

Some state PDABs, such as the Colorado board, are additionally tasked with considering the impact of UPLs on older adults and persons with disabilities.³

In considering these criteria, PDABs may leverage the data compiled during the affordability review to inform UPL decision-making as permitted under statute. Doing so would reduce administrative burden and enable a more cohesive analysis. Useful data elements in assessing a drug's affordability and determining UPLs include the drug's price, manufacturer rebates, net sales, average patient out-of-pocket costs, availability of patient financial assistance programs, and other various fees and costs incurred in the pharmaceutical supply chain. Such information could be collected from manufacturers, wholesalers, pharmacies, clinicians, patients, and other stakeholders via voluntary or required submissions as part of the affordability review process.

PDABs are also positioned to use information on a drug's comparative effectiveness and safety in both affordability review and UPL discussions. This information can facilitate a PDAB's understanding of a

¹ For additional information on the affordability review process, please see our companion white paper outlining considerations for affordability reviews.

² Food and Drug Administration (FDA). Drug Shortages Database. <https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>

³ 10-16-1407, 10-16-1412(2), and 10-16-1403(5), C.R.S.

PORTAL | Determining Upper Payment Limits

drug's benefits relative to its therapeutic alternatives and provide a comprehensive picture of the drug's competitive landscape. Comparative effectiveness and safety can be reviewed separately from assessments of a drug's cost-effectiveness, and PDABs must adhere to any statutory limitations on using cost-effectiveness information. For example, some PDABs can use cost-effectiveness analyses incorporating quality-adjusted life-years (QALYs) in their assessment of a drug's affordability, but not when determining the price at which to set an upper payment limit.^{4,5,6}

Many PDABs are also tasked with considering whether a selected drug is currently in shortage. Information on US drug shortages is maintained by both the FDA and the American Society of Health-System Pharmacists (ASHP).^{7,8} When assessing shortage data, it is important to recognize that there are several reasons drugs may be listed as in shortage; shortage data are reported by manufacturers and may be incomplete; and drugs in shortage can vary daily and by both dosage strengths and forms. This means that PDABs should carefully evaluate the source, quality, and completeness of shortage data before using this information to decide whether to set a UPL.

In addition, the emergence of new information relating to a drug's clinical use, regulatory status, or market position may necessitate adjustments to the UPL value over time. As state PDABs consider processes to set UPLs, an important component will be how to incorporate new data and update UPLs over time.

Introduction to Potential UPL Strategies

By combining the information prepared during the affordability review process with additional required statutory elements specific to UPLs, state PDABs can conduct robust analyses and arrive at an appropriate UPL value. However, the process of setting a UPL should be grounded by an understanding the primary drivers of why the PDAB found a drug to be unaffordable. To do so, PDABs may consider the following questions:

- Is the drug overpriced relative to the prices of available therapeutic alternatives or relative to prices paid by other entities?
- Do patients using the drug incur substantial out-of-pocket costs?
- Does spending on the drug place excessive financial burdens on the health care system in the state?

The sections below outline three UPL strategies that may be applicable depending on the answers to these questions. PDABs may consider incorporating one or more of these strategies into their UPL methodology. **The strategies proposed below are not intended to be prescriptive or exhaustive.** Rather, they highlight key considerations for PDABs as they implement an innovative mechanism to improve the affordability of prescription drugs for patients.

Strategy 1: Reference Pricing

Strategy 1A: Referencing to Prices of Therapeutic Alternatives

⁴ 10-16-1407, 10-16-1412(2), and 10-16-1403(5), Colorado Revised Statutes (CRS).

⁵ Revised Code of Washington (RCW) 70.405.050.

⁶ Minnesota Session Laws. Chapter 57 -SF2744, Sec. 35.

⁷ FDA. Drug Shortages Database. <https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>

⁸ American Society of Health-System Pharmacists. Current Drug Shortages. <https://www.ashp.org/drug-shortages/current-shortages>

PORTAL | Determining Upper Payment Limits

For drugs with less costly therapeutic alternatives, PDABs can use the prices of alternatives to determine a UPL, a strategy known as **internal or therapeutic reference pricing**. In cases in which there are no meaningful differences between a drug and its therapeutic alternatives, this approach is straightforward. But even if the safety or effectiveness of a drug differs from therapeutic alternatives, prices can be compared via **efficiency frontiers**, a strategy used in Germany to negotiate prices.⁹ This section discusses the strengths and limitations of this approach.

Therapeutic Reference Pricing

Therapeutic reference pricing refers to the drug pricing approach of establishing maximum spending based on the prices of a drug's comparators. The purpose is to adhere to the principle of paying similar prices for drugs that offer similar benefits to patients. For PDABs, this approach will be most useful for drugs with therapeutic alternatives, at least one of which is priced lower than the drug of interest.

Many payers inside and outside the US use therapeutic reference pricing to lower prescription drug spending. Typically, payers create groups of drugs deemed to be therapeutic alternatives (often, but not always, drugs in the same pharmacologic class) and set an upper reimbursement limit for the group.^{10,11}

For example, Germany uses a reference pricing approach as part of its health technology assessment process. The comparative safety and effectiveness of all new drugs are assessed; those determined to offer no meaningful benefit over therapeutic alternatives are placed in a reference pricing group along with the therapeutic alternatives.^{12,13} To incentivize companies to price their drug at or below the reference price for the group, patients incur higher out-of-pocket costs if a drug is priced higher than the reference price, and no cost-sharing if the drug is 30% lower than the reference price.¹⁴ This approach has contributed to lower average drug prices, health care spending, and patient out-of-pocket costs.¹⁵

US entities have explored implementing reference pricing as well. The RETA Trust, a US-based health care purchaser, began using reference pricing for more than 1,000 prescription drugs in 2013, setting maximum reimbursement rates at the price of the lowest-cost in-class alternative.¹⁶ Scholars have also proposed leveraging therapeutic reference pricing as a means for CMS to maximize drug-level savings from Medicare price negotiations.¹⁷ Overall, the reference pricing approach has been found to result in

⁹ Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG). General Methods. Version 6.1. Published January 24, 2022. https://www.iqwig.de/methoden/general-methods_version-6-1.pdf

¹⁰ Robinson JC, Whaley CM, Brown TT. Association of Reference Pricing with Drug Selection and Spending. *New England Journal of Medicine*. 2017;377(7):658-665. doi:[10.1056/NEJMsa1700087](https://doi.org/10.1056/NEJMsa1700087)

¹¹ Sandmann FG, Mostardt S, Lhachimi SK, Gerber-Grote A. The efficiency-frontier approach for health economic evaluation versus cost-effectiveness thresholds and internal reference pricing: combining the best of both worlds? *Expert Review of Pharmacoeconomics & Outcomes Research*. 2018;18(5):475-486. doi:[10.1080/14737167.2018.1497976](https://doi.org/10.1080/14737167.2018.1497976)

¹² Rand LZ, Kesselheim AS. Getting the Price Right: Lessons for Medicare Price Negotiation from Peer Countries. *Pharmacoeconomics*. 2022;40(12):1131-1142. doi:[10.1007/s40273-022-01195-x](https://doi.org/10.1007/s40273-022-01195-x)

¹³ Robinson JC, Ex P, Panteli D. Drug Price Moderation in Germany: Lessons for U.S. Reform Efforts. *Commonwealth Fund*; 2020. doi:[10.26099/d3g0-mx46](https://doi.org/10.26099/d3g0-mx46)

¹⁴ Wenzel M, Paris V. Pharmaceutical Reimbursement and Pricing in Germany. *OECD*. Published online June 2018. <https://www.oecd.org/health/health-systems/Pharmaceutical-Reimbursement-and-Pricing-in-Germany.pdf>

¹⁵ Herr A, Suppliet M. Tiered co-payments, pricing, and demand in reference price markets for pharmaceuticals. *Journal of Health Economics*. 2017;56:19-29. doi:[10.1016/j.jhealeco.2017.08.008](https://doi.org/10.1016/j.jhealeco.2017.08.008)

¹⁶ Robinson et al. 2017.

¹⁷ DiStefano MJ, Levy JF, Oduard IC, Anderson GF. Estimated Savings From Using Added Therapeutic Benefit and Therapeutic Reference Pricing in United States Medicare Drug Price Negotiations. *Value in Health*. 2023;26(11):1618-1624. doi:[10.1016/j.jval.2023.08.004](https://doi.org/10.1016/j.jval.2023.08.004)

PORTAL | Determining Upper Payment Limits

lower drug prices, increased use of targeted drugs, and lower drug spending by payers and patients while maintaining access.¹⁸

Although state PDABs do not currently have the authority to implement formal reference pricing, similar principles could be used to determine UPLs. For example, states can set UPLs based on the lowest price among a group of therapeutic alternatives. This approach would ensure that the drugs at issue cost no more than similar drugs. However, several key factors are relevant if states choose to pursue this approach:

1. *Defining therapeutic alternatives* – The list of therapeutic alternatives should reflect drugs that can reasonably be used in place of the selected drug. In many cases, such drugs will be in the same pharmacologic class, although there are cases when between-class comparisons are acceptable. For drugs with multiple FDA-approved indications, the list of therapeutic alternatives may differ for each indication. In these cases, states will need to choose an approach, such as (1) only including alternatives that are approved for all the same indications as the selected drug; or (2) setting separate prices based on reference groups for each of the drug’s indications; these per-indication prices could then be combined via an average, weighted by how frequently the drug is used for each indication.¹⁹
2. *Effect on out-of-pocket costs* – Although states have the authority to set UPLs, patient access to and out-of-pocket costs for these drugs are determined by individual health plans, frequently based on tiered formularies set by pharmacy benefit managers (PBMs).²⁰ In cases with multiple therapeutic alternatives, health plans and PBMs often select one or two “preferred” drugs within a class; these preferred drugs often have lower out-of-pocket costs for patients than non-preferred alternatives. Typically, PBMs negotiate rebates in exchange for offering preferred status to one or more drugs in the class. If a PDAB sets a UPL for one drug but not others in the class, PBMs may leverage this UPL to negotiate rebates for other products; the result could be that insurers offer preferred coverage to a therapeutic alternative instead of the drug with the UPL. If allowed under statute, one way to overcome this is to set the same UPL for all the therapeutic alternatives (e.g., all drugs in a class). For example, the PDAB could set the UPL for all therapeutic alternatives based on the lowest-priced drug of the group. This is likely to be most effective if the group of therapeutic alternatives has similar safety and efficacy in treating a specific condition or set of conditions.

Efficiency Frontiers

Even if there are meaningful differences in safety or effectiveness between a drug and its therapeutic alternatives, PDABs could still leverage comparisons between drugs to ensure that prices are aligned with their benefits (i.e., the most effective drugs are allowed the highest prices). One approach to doing

¹⁸ Lee JLY, Fischer MA, Shrank WH, Polinski JM, Choudhry NK. A Systematic Review of Reference Pricing: Implications for US Prescription Drug Spending. *Am J Manag Care*. 2012;18(11): e429-e437. <https://www.ajmc.com/view/a-systematic-review-of-reference-pricing-implications-for-us-prescription-drug-spending>

¹⁹ Preckler V, Espín J. The Role of Indication-Based Pricing in Future Pricing and Reimbursement Policies: A Systematic Review. *Value in Health*. 2022;25(4):666-675. doi:[10.1016/j.jval.2021.11.1376](https://doi.org/10.1016/j.jval.2021.11.1376)

²⁰ This does not apply to uninsured patients, whose access and out-of-pocket costs would be directly impacted by a UPL that reduces the list price of a selected drug.

PORTAL | Determining Upper Payment Limits

so is using **efficiency frontiers**, which compare the costs and benefits of drugs to identify reasonable prices at every level of benefit.^{21,22}

The most prominent example of efficiency frontiers being used is in Germany where the Institute for Quality and Efficiency in Health Care (IQWiG) uses efficiency frontier analyses to inform its drug price negotiation.^{23,24} This process is grounded in a formal assessment of the net benefit of a drug and its therapeutic alternatives. Efficiency frontiers are a **two-dimensional assessment** and thus rely on a **single measure** of a drug's **net benefits** and a **single measure** of its **net costs**.

1. *Net benefits* - The benefits of drugs can be measured using any number of clinical outcomes, such as those measured directly in clinical trials. If a drug and its alternatives vary only across one outcome, the efficiency frontier can be established using that single outcome. If a drug and its therapeutic alternatives vary both in terms of safety and effectiveness or if there are multiple measures of effectiveness, the most prudent approach is to combine these into a single composite measurement, such as quality-adjusted life years (QALYs). However, some PDABs are statutorily prohibited from using QALYs when setting UPLs. These states may be permitted to use other composite measures, such as equal-value life-years gained (evLYG), in their analysis.²⁵
2. *Net costs* - Net costs should include the drug's price minus any offsetting costs from lower health care use (e.g., reduced hospitalizations). It is only necessary to consider offsetting costs that vary between drugs; any cost offsets that are the same across drugs will not affect the results.

To identify the efficiency frontier, a plot is made of each drug's net cost (y-axis) vs. net benefits (x-axis). As shown in **Figure 1**, each number represents a different hypothetical drug in the same class that treats the same disease. Treatments A, C, and E represent the "frontier" (i.e., those offering the greatest benefit for the lowest cost). Treatments B and D are more expensive but offer less benefit; these drugs would need to be priced lower to be cost-effective (shown by the red arrows).

²¹ Nagar S, Rand LZ, Kesselheim AS. What Should US Policymakers Learn from International Drug Pricing Transparency Strategies? *AMA J Ethics*. 2022;24(11):E1083-1090. doi:[10.1001/amajethics.2022.1083](https://doi.org/10.1001/amajethics.2022.1083)

²² Sandmann et al. 2018.

²³ Version 7.0 of the IQWiG General Methods (Allgemeine Methoden) is available online only in German. <https://www.iqwig.de/ueber-uns/methoden/methodenpapier/>

²⁴ Stern AD, Pietrulla F, Herr A, Kesselheim AS, Sarpatwari A. The Impact of Price Regulation on the Availability of New Drugs in Germany. *Health Aff (Millwood)*. 2019;38(7):1182-1187. doi:[10.1377/hlthaff.2018.05142](https://doi.org/10.1377/hlthaff.2018.05142)

²⁵ Institute for Clinical and Economic Review. Cost-Effectiveness, the QALY, and the evLYG. Updated 2023. <https://icer.org/our-approach/methods-process/cost-effectiveness-the-qaly-and-the-evlyg/>

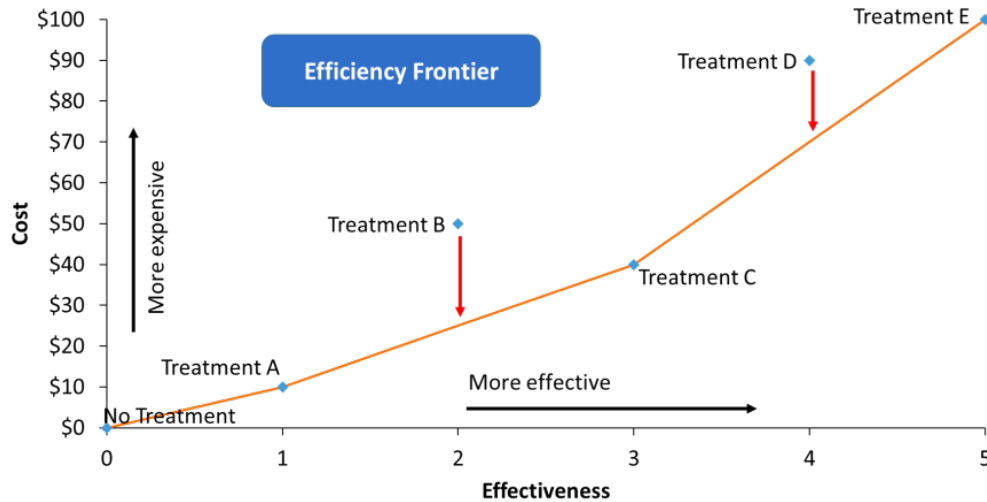


Figure 1. Sample Prescription Drug Efficiency Frontier

Drugs with the best within-group benefits are always on the frontier. Although efficiency frontiers cannot directly determine specific UPL values, states can leverage this tool to set UPLs based on the prices of in-group alternatives.

Limitations of Therapeutic Reference Pricing and Efficiency Frontiers

Reference pricing and efficiency frontiers face limitations when therapeutic alternatives or in-class comparators themselves have high prices. When this is the case, even if the negotiated drug does not have a demonstrated therapeutic advantage over the reference drugs, the resulting price might not yield substantial savings or represent a fair price for the therapeutic value of the drug. It is, therefore, important to consider whether the therapeutic alternatives are similarly unaffordable when deciding to use these approaches. However, this approach leverages existing market competition among therapeutic alternatives, which frequently offer sizeable discounts to obtain preferred formulary position from PBMs and payers. This means that, in some cases, referencing a drug’s price to its therapeutic alternatives could lead to a UPL that is lower than what is deemed cost-effective using traditional approaches. In these circumstances, PDABs may consider leveraging other strategies to identify an appropriate UPL value.

Strategy 1B: Benchmarking to a drug’s price for other entities

Whether or not a drug has therapeutic alternatives, PDABs could use prices negotiated or set by other entities to determine a UPL, a strategy known as **external reference pricing**. This strategy reduces the administrative burden of conducting independent UPL analyses, provided that the external prices used are useful comparators to the PDAB’s state-specific considerations. Some state PDABs are statutorily required to consider certain external pricing sources.²⁶ Other state entities, like Massachusetts’ Health Policy Commission, require manufacturers to submit the prices offered to other US and non-US entities for drugs under price review for the state Medicaid program.²⁷ We highlight the benefits and limitations of this approach using three different external prices: 1) the price of the drug negotiated by other

²⁶ Minnesota Session Laws. Chapter 57 -SF2744, Sec. 35.

²⁷ Massachusetts Health Policy Commission. Drug Pricing Review - Standard Reporting Form. <https://www.mass.gov/info-details/drug-pricing-review>

PORTAL | Determining Upper Payment Limits

countries; 2) the drug's maximum fair price as established by Medicare price negotiation; and 3) the price negotiated by the Department of Veterans Affairs.

International Reference Pricing

On average, drug prices in the US are 2-3 times higher than in other industrialized countries.²⁸ The concept of benchmarking prices in the US to those negotiated by other prices, or **international reference pricing**, has been popular among US policymakers.²⁹ For example, the Elijah E. Cummings Lower Drug Costs Now Act (H.R. 3), which was passed by the US House of Representatives in 2019, proposed that Medicare price negotiation should be based on a price ceiling of 120% of the average cost of medication in six high-income countries.^{30,31} This bill, though never enacted, was projected to save Medicare \$448 billion over a 10 year period.³² Later, a 2020 executive order by the Trump administration proposed that Medicare use the lowest international reference price as a maximum fair price, referred to as the “most favored nation” approach.³³ That order and the associated Most Favored Nation Model were subsequently abandoned.³⁴

The primary reason that other high-income countries pay less for brand-name drugs than the US is that most engage in a health technology assessment (HTA) process for drugs after regulatory approval, through which the benefits of new drugs are evaluated, and national maximum prices are negotiated accordingly. In addition, many countries “cross-reference” prices between countries, meaning that a reduction in price in one country directly and indirectly affects prices in another.³⁵ For example, international reference pricing is an important consideration for Canada's Patented Medicines Prices Review Board (PMPRB) when determining prices for branded prescription drugs, helping the PMPRB negotiate better prices for these drugs.³⁶

Limitations of International Reference Pricing

A key challenge for payers interested in using international reference pricing is that prices negotiated by other countries are often confidential. Although manufacturer list prices in other countries are typically lower than negotiated net prices in the US, many countries negotiate additional confidential discounts that are not reflected in this price. Statutory restrictions on international data sharing may also prohibit PDAB access to other countries' drug pricing information.

Another limitation is that other countries negotiate prices using methods and values that may not match those used by state PDABs. For example, many international HTA bodies perform cost-effectiveness analyses that measure health benefits using quality-adjusted life-years (QALYs), a metric which some

²⁸ Mulcahy AW, Whaley CM, Gizaw M, Schwam D, Edenfield N, Becerra-Ornelas AU. International Prescription Drug Price Comparisons: Current Empirical Estimates and Comparisons with Previous Studies. RAND Corporation; 2021. https://www.rand.org/pubs/research_reports/RR2956.html

²⁹ Rand LZ, Kesselheim AS. International Reference Pricing for Prescription Drugs in the United States: Administrative Limitations and Collateral Effects. *Value Health*. 2021;24(4):473-476. doi:[10.1016/j.jval.2020.11.009](https://doi.org/10.1016/j.jval.2020.11.009)

³⁰ Mulcahy et al. 2021.

³¹ Elijah E. Cummings Lower Drug Costs Now Act, H.R.3. 116th Congress. 2019. <https://www.congress.gov/bill/116th-congress/house-bill/3>

³² Congressional Budget Office (CBO). Budgetary Effects of H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act. Published December 10, 2019. <https://www.cbo.gov/publication/55936>

³³ 85 FR 59649. <https://www.federalregister.gov/d/2020-21129>

³⁴ <https://www.cms.gov/priorities/innovation/innovation-models/most-favored-nation-model>

³⁵ Gowling WLG. Dazed and Confused: A Closer Look at the Amended Patented Medicines Regulations. Lexology; 2019. <https://www.lexology.com/library/detail.aspx?g=9811bef5-ef9f-4cef-969c-b07b8a1aaca7>

³⁶ Rand and Kesselheim. 2022.

PORTAL | Determining Upper Payment Limits

PDABs cannot incorporate in their own analyses. Finally, the FDA is frequently the first regulator to approve new drugs, meaning that external reference prices based on international prices may not be available for newly marketed drugs.³⁷ HTA processes can also take significant time to complete and publicly release.

Medicare Maximum Fair Price

The Inflation Reduction Act (IRA) of 2022 allows the Centers for Medicare and Medicaid Services (CMS) to negotiate **maximum fair prices (MFPs)** for certain eligible drugs in the Medicare program.³⁸ There are important restrictions on which drugs CMS can select for negotiation. Most importantly, drugs must have at least \$200 million in annual Medicare spending and at least 7 years must have elapsed since a drug's first FDA approval (11 years for biologics).³⁹ The initial set of drugs selected for MFP negotiation has somewhat overlapped with the list of drugs eligible for PDAB affordability review, highlighting the value of using a drug's MFP as a reference, if available.

Medicare negotiates MFPs based on several factors, including a drug's benefit as compared to therapeutic alternatives, estimated costs of research and development, public investment in the drug's discovery or development, and the cost of manufacturing and distributing the drug.⁴⁰ CMS will refer to data collected from manufacturers, the FDA, stakeholders, and the literature; of note, CMS is not legally permitted to consider evidence that uses QALYs.⁴¹ CMS plans to use a qualitative approach to combine quantitative information from statutory factors, and ultimately prices are negotiated between CMS and drug manufacturers.

The MFP must be lower than a statutory ceiling price. For drugs reimbursed under Medicare Part D (i.e., retail pharmacy drugs), the ceiling price is the lesser of the average net price including rebates negotiated by Part D plans or a percentage of the non-federal average manufacturer price (non-FAMP), ranging from 75% for drugs FDA-approved between 9 and 12 years earlier, 65% for drugs FDA-approved between 12 and 16 years earlier, and 40% for drugs FDA-approved 16 or more years earlier.⁴² In a simulation of this negotiation using 2018-2020 data, the ceiling price was a median of 66% (IQR 60-77%) lower than Medicare's pre-rebate spending.⁴³ As of January 2024, drugs reimbursed under Medicare Part B (i.e., clinician-administered drugs) are not subject to price negotiation until 2028.

Medicare is required to publish the MFPs for negotiated drugs at the end of the process. The MFPs for the first ten drugs selected by CMS in August 2023 will be published by September 2024.⁴⁴ In addition, CMS will publish a summary of the factors that helped guide negotiation of the MFP, although such

³⁷ Kang SY, DiStefano MJ, Socal MP, Anderson GF. Using External Reference Pricing in Medicare Part D To Reduce Drug Price Differentials with Other Countries. *Health Affairs*. 2019;38(5):804-811. doi:[10.1377/hlthaff.2018.05207](https://doi.org/10.1377/hlthaff.2018.05207)

³⁸ Inflation Reduction Act, H.R.5376. 117th Congress. 2022. <https://www.congress.gov/bill/117th-congress/house-bill/5376/text>

³⁹ Cubanski J, Neuman T, Published MF. Explaining the Prescription Drug Provisions in the Inflation Reduction Act. KFF. Published January 24, 2023. <https://www.kff.org/medicare/issue-brief/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act/>

⁴⁰ Centers for Medicare & Medicaid Services (CMS). Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026. 2023.

<https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf>

⁴¹ Mulcahy A. Medicare Drug Price Negotiation: Key Decisions to Reach A “Fair Price.” *Health Affairs Forefront*. doi:[10.1377/forefront.20221104.450669](https://doi.org/10.1377/forefront.20221104.450669)

⁴² CMS. 2023.

⁴³ Rome BN, Nagar S, Egilman AC, Wang J, Feldman WB, Kesselheim AS. Simulated Medicare Drug Price Negotiation Under the Inflation Reduction Act of 2022. *JAMA Health Forum*. 2023;4(1):e225218. doi:[10.1001/jamahealthforum.2022.5218](https://doi.org/10.1001/jamahealthforum.2022.5218)

⁴⁴ CMS. Medicare Drug Price Negotiation Program: Next Steps in Implementation for Initial Price Applicability Year 2026. Published January 11, 2023. <https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-next-steps-implementation-2026.pdf>

PORTAL | Determining Upper Payment Limits

summaries may not be available immediately; for the first ten drugs, CMS has until March 2025 to publish these summaries.⁴⁵

Limitations of Using the Medicare MFP

Medicare will only negotiate up to twenty drugs each year (fewer in the first three years), and only certain drugs are eligible. As a result, not all drugs eligible for review by state PDABs will have been negotiated by Medicare, including newer drugs and those for which spending is predominantly among Medicaid or commercially insured populations. Additionally, drug manufacturers have initiated numerous legal challenges to Medicare negotiation.⁴⁶ Although the merits of these cases have been questioned, it is unclear if there will be any changes or delays to the process before the first set of MFPs is published in 2024.^{47,48}

Department of Veterans Affairs (VA) Prices

Although Medicare's price negotiation process is novel, other federal health care programs that directly purchase drugs from manufacturers or wholesalers have used negotiation in part to pursue better value for prescription drug prices for years. Perhaps the most prominent is the Department of Veterans Affairs (VA), which receives substantial statutory rebates on drugs and further negotiates prices, reaching a pricing level that is, on average, half of that paid by Medicare for expensive brand-name drugs.⁴⁹

There are several pricing levels at the VA with progressively lower prices as shown in **Figure 2**. At the highest level is the **Federal Supply Schedule (FSS) price** available to all federal purchasers.⁵⁰ FSS prices generally enable federal purchasers to obtain brand-name drugs at prices similar to or below those negotiated between the manufacturer and its "most-favored commercial customer."⁵¹ The four largest federal purchasers (i.e., the VA, Department of Defense, Public Health Service, and the Coast Guard) also have access to the **Big Four price**, which is the lower of the FSS price or the **federal ceiling price (FCP)**. The FCP is equivalent to 76% of the average price at which the drug is purchased by non-federal purchasers. Finally, for some drugs, VA negotiates even steeper discounts using its **National Contract program**. In these cases, the VA typically contracts with the manufacturers of one or a few drugs that are therapeutically similar, leveraging its closed national formulary to require providers to prescribe only those drugs with a national contract price.^{52,53} An exception process is available to provide coverage for drugs that are not on the national formulary but may be necessary under certain circumstances.

⁴⁵ CMS. Fact Sheet: Medicare Drug Price Negotiation Program Revised Guidance. Published June 2023.

<https://www.cms.gov/files/document/fact-sheet-revised-drug-price-negotiation-program-guidance-june-2023.pdf>

⁴⁶ Gostin LO, Hodge JG Jr, Twinamatsiko AJ. Medicare's Historic Prescription Drug Price Negotiations. *JAMA*. 2023;330(17):1621-1622. doi:10.1001/jama.2023.19506

⁴⁷ Tu SS, Tushnet R. Free Speech Challenges to the Inflation Reduction Act. *JAMA*. 2023;330(13):1229-1230. doi:10.1093/jama.2023.19506

⁴⁸ Daval CJR, Kesselheim AS. We can't let drug companies get out of negotiating prices. *Washington Post*. Published October 23, 2023. <https://www.washingtonpost.com/opinions/2023/10/23/medicare-negotiations-drug-prices-lawsuit/>

⁴⁹ Government Accountability Office (GAO). Prescription Drugs: Comparison of DOD, Medicaid, and Medicare Part D Retail Reimbursement Prices. GAO-14-578. Published June 2014. <https://www.gao.gov/assets/gao-14-578.pdf>

⁵⁰ Department of Veterans Affairs (VA). VA Federal Supply Schedule Service. Updated November 2023. <https://www.fss.va.gov/>

⁵¹ CBO. A Comparison of Brand-Name Drug Prices Among Selected Federal Programs. Published February 2021.

<https://www.cbo.gov/system/files/2021-02/56978-Drug-Prices.pdf>

⁵² VA. Pharmacy Benefits Management Services – VA National Formulary. Updated October 2023.

<https://www.pbm.va.gov/PBM/NationalFormulary.asp>

⁵³ VA. VA Formulary Advisor. Updated December 14, 2023. <https://www.va.gov/formularyadvisor/>

PORTAL | Determining Upper Payment Limits

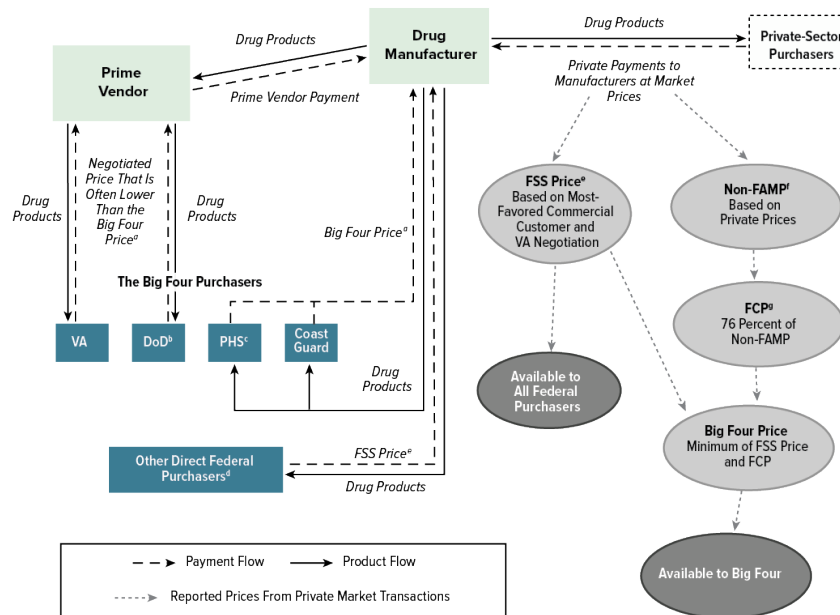


Figure 2. Drug Prices Available to Federal Purchasers.⁵⁴

The VA publicly releases the FSS and Big Four prices for drugs on its formulary; some but not all national contract prices are available.⁵⁵ The robustness of the discounts secured by the VA combined with the transparency of the data makes the VA experience a potentially valuable resource for PDABs seeking UPL price comparators.

Limitations of Using VA Prices

State PDAB should consider the distinct characteristics of VA prices. Although negotiated, federal prices published by the VA are also subject to several statutory discounts that prevent the VA from paying more than non-federal purchasers and limit the impact of price increases over time.⁵⁶ These statutory requirements do not exist for state PDABs, meaning that the circumstances surrounding VA prices may not always match those for PDAB-established UPLs. Rather, VA prices may be best used as one reference among many that PDABs may consider during UPL deliberations. In addition, some of the steepest discounts obtained by the VA through National Contracts are confidential and, thus, may not be accessible to PDABs.

Strategy 2: Net Price

A key purpose of state PDABs is to improve the affordability of prescription drugs for consumers. One important driver of unaffordability is how drug prices affect out-of-pocket costs paid by patients using expensive drugs. States may wish to consider the association between prices and out-of-pocket costs when setting UPLs, including how this relationship is affected by rebates.

⁵⁴ CBO. A Comparison of Brand-Name Drug Prices Among Selected Federal Programs. Published February 2021.

<https://www.cbo.gov/system/files/2021-02/56978-Drug-Prices.pdf>

⁵⁵ VA. Office of Procurement, Acquisition, and Logistics – Pharmaceutical Prices. Updated November 15, 2023.

<https://www.va.gov/opal/nac/fss/pharmPrices.asp>

⁵⁶ McCaughan M. Veterans Health Administration. *Health Affairs*. Published online August 10, 2017. doi:[10.1377/hpb20171008.000174](https://doi.org/10.1377/hpb20171008.000174)

PORTAL | Determining Upper Payment Limits

For drugs dispensed at the pharmacy, the **wholesale acquisition cost (WAC)**, also known as the **list price**, is the price at which the manufacturer offers a drug for sale to a wholesaler or other direct purchaser not including discounts or rebates. The **net price**, by contrast, reflects the price of the drug paid by insurers after **rebates or discounts**, typically negotiated by PBMs in exchange for favorable formulary placement. Unfortunately, financial incentives can lead participants in the supply chain, such as PBMs and some 340B entities, to prefer drugs with high list prices and high rebates. Although both list and net prices for prescription drugs have increased in recent years, the gap between these two values has widened.⁵⁷ The size of rebates varies between drug classes; for example, Medicare Part D rebates average above 50% for diabetes drugs but less than 10% for cancer drugs.⁵⁸

Although health plans use rebates to offset premiums, these rebates do not directly result in lower out-of-pocket costs for patients. Patients with copayments are unaffected by rebates, but coinsurance and deductibles are calculated by health plans based on the retail prices at a pharmacy or health care facility, which are closely tied to list prices.⁵⁹ And, though some patients may use manufacturer coupons or patient assistance programs to reduce out-of-pocket spending, such programs are not available for all drugs and vary in their eligibility criteria and applicability.^{60,61,62} These programs have also been criticized for increasing system-level health care spending by directing patients toward high-cost branded drugs over lower-cost alternatives.^{63,64}

Thus, for highly rebated drugs, PDABs may consider setting UPLs to protect patients from paying high out-of-pocket costs based on list prices, reducing the need for external patient assistance programs. PDABs could set the UPL at or near the drug's existing average net price, making this price the benchmark from which patient out-of-pocket costs are calculated by payers. This approach would benefit patients who use highly-rebated drugs with high list prices. Compared to other approaches, setting a UPL near the drug's net price would be administratively straightforward.

Clinician-administered drugs (e.g., infused and injected medications) have distinct opportunities and challenges. The discounted prices at which hospitals and clinics acquire these drugs (the **average sales price**) are publicly available because they serve as the basis for Medicare reimbursement.⁶⁵ Meanwhile, private-payer reimbursement for these drugs is variable and often exceeds average sales prices. As a result, states could set UPLs based on the publicly available average sales price data to ensure that patients pay out-of-pocket costs based on reimbursement rates that reflect the net price of the drug. This

⁵⁷ Hernandez I, San-Juan-Rodriguez A, Good CB, Gellad WF. Changes in List Prices, Net Prices, and Discounts for Branded Drugs in the US, 2007-2018. *JAMA*. 2020;323(9):854-862. doi:[10.1001/jama.2020.1012](https://doi.org/10.1001/jama.2020.1012)

⁵⁸ Medicare Payment Advisory Commission (MedPAC). July 2023 Data Book, Section 10: Prescription Drugs. Published July 26, 2023. https://www.medpac.gov/wp-content/uploads/2023/07/July2023_MedPAC_DataBook_Sec10_SEC.pdf

⁵⁹ Rome BN, Feldman WB, Desai RJ, Kesselheim AS. Correlation Between Changes in Brand-Name Drug Prices and Patient Out-of-Pocket Costs. *JAMA Network Open*. 2021;4(5):e218816. doi:[10.1001/jamanetworkopen.2021.8816](https://doi.org/10.1001/jamanetworkopen.2021.8816)

⁶⁰ Kang SY, Sen A, Bai G, Anderson GF. Financial Eligibility Criteria and Medication Coverage for Independent Charity Patient Assistance Programs. *JAMA*. 2019;322(5):422-429. doi:[10.1001/jama.2019.9943](https://doi.org/10.1001/jama.2019.9943)

⁶¹ Kang SY, Liu A, Anderson G, Alexander GC. Patterns of Manufacturer Coupon Use for Prescription Drugs in the US, 2017-2019. *JAMA Network Open*. 2023;6(5):e2313578. doi:[10.1001/jamanetworkopen.2023.13578](https://doi.org/10.1001/jamanetworkopen.2023.13578)

⁶² Kirchhoff SM. Prescription Drug Discount Coupons and Patient Assistance Programs (PAPs). *Congressional Research Service*. Updated September 22, 2022. <https://crsreports.congress.gov/product/pdf/R/R44264>

⁶³ Sinha MS, Kesselheim AS, Robertson CT. Patient Assistance Programs and the Anti-Kickback Statute: Charting a Pathway Forward. *JAMA*. 2022;327(13):1231-1232. doi:[10.1001/jama.2022.2043](https://doi.org/10.1001/jama.2022.2043)

⁶⁴ Grande D. The Cost of Drug Coupons. *JAMA*. 2012;307(22):2375-2376. doi:[10.1001/jama.2012.5603](https://doi.org/10.1001/jama.2012.5603)

⁶⁵ CMS. Medicare Part B Drug Average Sales Price. Updated September 6, 2023. <https://www.cms.gov/medicare/payment/fee-for-service-providers/part-b-drugs/average-drug-sales-price>

PORTAL | Determining Upper Payment Limits

would not substantially affect reimbursement by Medicare, but it could lower hospital and physicians' office revenues from private insurers.

Limitations of Using Net Prices

A major challenge to using net prices is that rebates negotiated by PBMs or insurers for specific drugs are confidential. Some national rebate estimates are available from companies including SSR Health, although since these are predicted values, they necessarily have limitations such as the likelihood that they may overestimate the rebates negotiated by private and Medicare Part D plans.^{66,67,68} Some PDABs may be permitted to solicit rebate information from manufacturers or payers, which could overcome this barrier. A second limitation is that rebates vary substantially between payers. Thus, the average rebate amount may reflect an additional discount below net prices for some payers, but may be higher than the current net price for others.

States should also consider how setting a UPL at the net price may have downstream effects on a drug's formulary placement. Typically, PBMs can only negotiate large rebates for drug classes with multiple therapeutic alternatives, with manufacturers being willing to offer rebates to obtain preferred formulary position. If a state sets a UPL for one drug at the net price, that drug's manufacturer would no longer be able to offer large rebates in exchange for PBMs offering preferred formulary position; by contrast, PBMs could continue to negotiate rebates from alternative drugs that do not have UPLs. This could result in payers placing the UPL drug on a less preferred tier than therapeutic alternatives that continue to have high prices and, therefore, higher out-of-pocket costs for some patients.⁶⁹ One way to address this problem is for PDABs to consider setting UPLs for multiple drugs in a therapeutic class, as described in strategy 1A.

For drugs with small rebates (e.g., oncology products and products for rare diseases that often lack competition), this strategy may not offer any substantial benefit because net and list prices will be similar. In these circumstances, PDABs may consider pursuing a different methodology to determine an appropriate UPL value.

Strategy 3: Budgetary Thresholds

Some drugs reviewed by PDAB may be clinically effective but pose affordability challenges to the state health care system either due to high prices, a large treated population, or both. For this subset of drugs, PDABs may consider setting a UPL as a means to lower spending, particularly among state-financed public payers. To do so, PDABs could leverage system-level analyses to optimize a UPL value and model its potential impact.

Premium Growth Thresholds

Though out-of-pocket costs are important drivers of medication adherence and use, drugs with a major budget impact may also result in higher insurance premiums for all insured patients as payers pass drug spending through to consumers. To achieve the goal of improving affordability to patients, state PDABs

⁶⁶ Ippolito B, Levy J. Best Practices Using SSR Health Net Drug Pricing Data. *Health Affairs Forefront*. doi:[10.1377/forefront.20220308.712815](https://doi.org/10.1377/forefront.20220308.712815)

⁶⁷ Feldman WB, Rome BN, Raimond VC, Gagne JJ, Kesselheim AS. Estimating Rebates and Other Discounts Received by Medicare Part D. *JAMA Health Forum*. 2021;2(6):e210626. doi:[10.1001/jamahealthforum.2021.0626](https://doi.org/10.1001/jamahealthforum.2021.0626)

⁶⁸ Rome BN, Feldman WB, Kesselheim AS. Drug Prices, Rebates, and Discounts. *JAMA*. 2020;324(4):399. doi:[10.1001/jama.2020.7983](https://doi.org/10.1001/jama.2020.7983)

⁶⁹ Nagar S, Kesselheim AS, Rome BN. Medicare Drug Price Negotiation: Few Drugs, Big Impact? *Health Affairs Forefront*. Published online June 9, 2023. doi:[10/gs3g3g](https://doi.org/10/gs3g3g)

PORTAL | Determining Upper Payment Limits

may wish to measure and respond to these premium increases using UPLs. This could be particularly impactful for cases for blockbuster drugs that have measurable effects on payers' actuarial decisions.

For example, the approval and expected market entry of the Alzheimer's therapy aducanumab (Aduhelm) in 2021 was directly cited by CMS as a driver of a 15% increase in Medicare Part B premiums in 2022 as the agency confronted the drug's potential budgetary impact.⁷⁰ Similarly, payers and employers have grown increasingly concerned with the budgetary effects of GLP-1 inhibitors for obesity.^{71,72,73}

To evaluate a drug's impact on premiums, PDABs would likely need to engage with payers and directly solicit information on how the selected drug affects plan spending. This may be facilitated through state drug price transparency programs, some of which require payers to report the drugs with the greatest contribution to premium increases.⁷⁴ This payer-reported data on premium increases and plan spending could then be paired with data on the beneficiary population to estimate the average premium or premium increase attributable to a given drug per plan beneficiary per year.

This baseline would then enable PDABs to determine an acceptable premium increase threshold for the selected drug, above which the drug would continue to present affordability challenges to the state. For example, if a drug is found to contribute to an estimated \$100 annual increase in premiums per beneficiary, PDABs could target a UPL that would limit the premium impact to \$50 per beneficiary. Such a framework would enable the Board to model various UPL scenarios to maximize the impact of the mechanism on state health care spending. This option would also provide PDABs an opportunity to demonstrate cost savings that otherwise may not be attainable by focusing solely on patient out-of-pocket spending.

Limitations of Using Premium Thresholds

While evaluating and addressing the system-level impacts of a drug through insurance premium effects may be a feasible option for some PDAB-reviewed drugs, there are limitations to such an approach. Namely, identifying a single drug's impact on premiums may be complex. This may make it more practical for PDABs to assess the premium impacts of a full therapeutic class of drugs during the UPL process if permitted under statute (see Strategy 1).

Additionally, it may be challenging for PDABs to identify an appropriate premium growth threshold, particularly if the premium impact, though sizeable in the aggregate, is small when measured per-beneficiary. For example, targeting a \$15 premium increase instead of a \$20 increase without a UPL could lead to major savings for the health system but the small savings per consumer could pose a messaging challenge for PDABs. Engaging with payers and employers to better understand how such a UPL approach will affect spending may be important to better understand this dynamic.

⁷⁰ CMS. Medicare Program; Medicare Part B Monthly Actuarial Rates, Premium Rates, and Annual Deductible Beginning January 1, 2022. Published November 17, 2023. <https://www.federalregister.gov/d/2021-25050/p-41>

⁷¹ Leo L, Mandowara K. US employers to see biggest healthcare cost jump in a decade in 2024. *Reuters*. Published September 21, 2023. <https://www.reuters.com/world/us/us-employers-see-biggest-healthcare-cost-jump-decade-2024-2023-09-20/>

⁷² Ally A, Bell D, Craff M, et al. *Payer Strategies for GLP-1 Medications for Weight Loss*. Milliman. Published August 2023. https://us.milliman.com/-/media/milliman/pdfs/2023-articles/8-28-23_glp-1s-for-weight-loss_20230824.ashx

⁷³ Robbins R. Buried in Wegovy Costs, North Carolina Will Stop Paying for Obesity Drugs. *New York Times*. January 26, 2024. <https://www.nytimes.com/2024/01/26/business/obesity-drugs-insurance-north-carolina.html>

⁷⁴ NASHP. Prescription Drug Pricing Transparency Law Comparison Chart. Updated December 7, 2023. <https://nashp.org/state-tracker/prescription-drug-pricing-transparency-law-comparison-chart/>

Budget Impact Analysis

One tool PDABs may use to evaluate system-level spending is a **budget impact analysis**, which measures the relative financial impact of a new health technology (e.g., a drug) on a payer's budget. Budget impact analyses can be valuable for informing implementation across a host of health care services, including prescription drugs.⁷⁵

Whereas cost-effectiveness analyses assess the value of a new treatment relative to a standard of care, budget impact analysis helps payers determine the costs and savings associated with covering a new treatment.⁷⁶ Budget impact analysis is an assessment of costs only, rather than costs *and* health outcomes, as is done in cost-effectiveness analyses. Compared to cost-effectiveness models, budget impact is typically examined on a shorter time horizon (e.g., 1 to 5 years). These two analyses are often considered together as components of a health technology assessment to inform coverage and reimbursement decisions.⁷⁷ In the US context, public entities like the VA, which operates with a fixed health care budget, often use budget impact analyses along with other methods to assess new health care interventions.⁷⁸

Although budget impact analyses are typically not the sole factor in decision-making, they can provide important context to determine the feasibility of reimbursing a new drug. For example, many new million-dollar gene therapies may be cost-effective if they substantially improve life expectancy for terminal pediatric diseases, but these treatments' budget impact may cause the technology to be unaffordable to the health care system.

In short, budget impact analysis measures the net financial burden or benefit of implementing a new technology in a health system. Making this assessment requires multiple inputs, many of which may be available to PDABs via data collection during affordability review and UPL processes. These data inputs include the price of the drug, the number of potential patients who could be treated, the price and use of therapeutic alternatives, the downstream health costs offset by the technology, and the expected uptake of the new drug.⁷⁹

Provided that PDABs have access to adequate data and analytic tools to perform a budget impact analysis, this assessment may aid Board understanding of the current state budgetary reality of a selected drug. This baseline could then be used to examine how setting a UPL value may maximize system-level savings. By running scenarios with different UPL values or other assumptions in the analysis (e.g., UPL-related changes in prescriptions, changes in list price), PDABs could generate an estimated range of cost savings from which an ideal UPL value could be identified.

Limitations of Budget Impact Analysis

⁷⁵ Smith NR, Levy DE. Budget impact analysis for implementation decision making, planning, and financing. *Translational Behavioral Medicine*. Published online September 30, 2023. doi:[10.1093/tbm/ibad059](https://doi.org/10.1093/tbm/ibad059)

⁷⁶ For additional information on cost-effectiveness analysis, please see our companion white paper outlining considerations for PDAB affordability reviews.

⁷⁷ Chugh Y, De Francesco M, Prinja S. Systematic Literature Review of Guidelines on Budget Impact Analysis for Health Technology Assessment. *Appl Health Econ Health Policy*. 2021;19(6):825-838. doi:[10.1007/s40258-021-00652-6](https://doi.org/10.1007/s40258-021-00652-6)

⁷⁸ VA. Health Economics Research Center (HERC) – Budget Impact Analysis. Updated May 4, 2023. <https://www.herc.research.va.gov/include/page.asp?id=budget-impact-analysis>

⁷⁹ Sullivan SD, Mauskopf JA, Augustovski F, et al. Budget Impact Analysis—Principles of Good Practice: Report of the ISPOR 2012 Budget Impact Analysis Good Practice II Task Force. *Value in Health*. 2014;17(1):5-14. doi:[10.1016/j.jval.2013.08.2291](https://doi.org/10.1016/j.jval.2013.08.2291)

PORTAL | Determining Upper Payment Limits

Budget impact analysis is not commonly applied to existing, on-market drugs. Rather, this tool is traditionally used to inform payer decision-making on new drugs at the time of market entry. In addition, the analysis is typically done for a single payer, which may present challenges for PDABs with UPL authority extending to multiple private and state-funded health plans, each of which may have different budgetary priorities. Most importantly, budget impact does not capture a drug's benefits to individual patients or society. Nonetheless, PDABs may extract important information from this approach by modelling how different UPL values may impact drug spending by the payer segments under PDAB purview.

Like using a UPL to reach a premium growth threshold, though, PDABs may also find it challenging to identify an appropriate cost savings threshold through budget impact analysis. While a 5% cost savings may have a profound impact on state drug spending and enable funding reallocation to other important services, this savings may seem negligible to patients and other stakeholders. Thus, pairing budget impact analysis with consideration of the objectives of a particular UPL would be a valuable exercise to ensure PDAB goals are effectively articulated and achieved.

Conclusions

As state PDABs begin setting UPLs to address rising prescription drug costs, they are tasked with identifying a reasonable value for the UPL that adequately alleviates the financial burden of the drug while also acknowledging the complexities of the pharmaceutical supply chain. The three broad strategies outlined in this white paper are designed to help states in this process, recognizing that UPL decision-making may be highly dependent on the individual drugs and Board priorities. A summary of these strategies, including their potential strengths and limitations, is provided in **Table 1**.

Each strategy has its strengths and limitations, some of which may be consequential for a given drug under PDAB review. The nuances are important for PDABs to embrace as they consider UPLs, striking the appropriate balance between establishing a consistent deliberation process and allowing enough flexibility to address the underlying drivers of a drug's unaffordability. The strategies detailed in this white paper are not mutually exclusive; states could assess drugs using multiple strategies to determine an appropriate UPL.

Additionally, PDABs may also discover in moving through the UPL process that setting a UPL for a drug may not fully address the drug's affordability challenges. Rather, the UPL may improve one aspect of a drug's affordability, while drawing attention to areas where further policy interventions are needed. PDABs should document these opportunities and request additional authority from state legislators in the future to address them.

Table 1. Summary of Potential Strategies to Reach a UPL Value

Strategy	Description	Strengths	Limitations
Reference Pricing			
Therapeutic Reference Pricing & Efficiency Frontiers	Compare a drug’s price and value to that of its therapeutic alternatives to calculate a UPL.	<ul style="list-style-type: none"> Ensures that a drug’s price is reflective of its value relative to therapeutic alternatives. Uses a straightforward analysis that PDABs could conduct independently with the appropriate data. 	<ul style="list-style-type: none"> May have limited benefits when a drug’s therapeutic alternatives also have high prices. Identifying a drug’s therapeutic alternatives may be challenging. May have implications for a drug’s formulary placement.
International Prices	Calculate a UPL based on the price of a drug in a selection of other industrialized countries.	<ul style="list-style-type: none"> Incorporates other countries’ robust, well-tested health technology assessment processes into UPL deliberations. Leverages lower international prices. Reduces burden of conducting independent UPL analyses. 	<ul style="list-style-type: none"> Prices negotiated by other countries are often confidential. Methodologies and values other countries use to determine price may not match that of PDABs. International prices may not be available for newly marketed drugs.
Medicare Maximum Fair Prices (MFPs)	Set a UPL at a value equivalent to the price of a drug as negotiated by Medicare.	<ul style="list-style-type: none"> Leverages the negotiation power of Medicare. Uses a price already available for some patients in the state. Reduces burden of conducting independent UPL analyses. 	<ul style="list-style-type: none"> Only a small number of drugs will have MFPs each year. Some drugs eligible for PDAB review may not be eligible for Medicare negotiation.
Dept. of Veterans Affairs (VA) Prices	Benchmark the UPL against a drug’s VA-negotiated price(s).	<ul style="list-style-type: none"> Enables the use of publicly reported prices and a long-standing price negotiation regime to derive a UPL value. Reduces burden of conducting independent UPL analyses. 	<ul style="list-style-type: none"> VA prices are subject to statutory discounts that may not directly translate to PDAB processes. Some discounts obtained by the VA through its National Contracts program are confidential.
Net Price			
Net Price	Set a UPL at a drug’s average net price (after rebates and discounts).	<ul style="list-style-type: none"> Leverages existing market negotiations. Ensures that rebates and discounts will be reflected in patient out-of-pocket costs (deductibles and coinsurance). 	<ul style="list-style-type: none"> Rebate information used to determine net price is confidential and varies among payers. May have implications for a drug’s formulary placement. Not useful for drugs with small rebates.
Budgetary Thresholds			
Premium Growth Thresholds	Assess a drug’s insurance premium impacts to identify a UPL value that minimizes attributed premium growth.	<ul style="list-style-type: none"> Addresses the impact of high drug spending across insurance beneficiaries. Leverages existing drug price transparency information to derive premium impacts. PDABs can demonstrate premium savings as improved affordability to consumers. 	<ul style="list-style-type: none"> Identifying the premium impact of one specific drug may be challenging. Drugs may have large aggregate spending but small per-beneficiary premium impact.
Budget Impact Analysis	Conduct a modified budget impact analysis to identify a UPL value that generates system-level cost savings	<ul style="list-style-type: none"> Facilitates PDAB understanding of a drug’s budgetary impact. Can use data already collected by the PDAB or other state entities. Generates multiple UPL scenarios from which to estimate a value that maximizes system-level savings. 	<ul style="list-style-type: none"> Budget impact analysis is typically reserved for new drugs that are not yet on the market. May require multiple analyses by the payer, which could be resource intensive. Reaching a cost savings threshold that achieves the PDAB’s intended goals may be challenging.