Comparison of Prescription Drug Data Collection and Review Processes

October 14, 2025

MN PDAB

Organizations Included in Comparison

- **Colorado PDAB** – Established 2021. Reviews completed for: Enbrel, Cosentyx, Stelara, Genvoya, and Trikafta. Finalized UPL for Enbrel, October3, 2025.
- **Maryland PDAB** – Established 2019. Preliminary reviews completed for use of Farxiga and Jardiance in state sponsored plans. Legislature granted expanded authority to set UPLs in 2025 session.
- **ICER** – Independent, non-profit established in 2005. Began drug reviews in 2014. Performs clinical and cost-effectiveness analyses.
- **CMS** – As part of the Inflation Reduction Act of 2022, CMS was directed to negotiate prices with drug companies for a set list of drugs covered under Medicare Part D (2026) and Part B (2028) and establish a Maximum Fair Price for those drugs.

Review Process Elements for Comparison

- Overview of Process
- Data Collection and Sources
- Drug Selection Criteria for Review
- Primary Factors Considered in Review
- Additional Factors Considered
- Stakeholder and Public Input

Overview of Processes

CO	Process starts with drugs being identified based on statutory criteria or stakeholder input and then the data collection process starts
MD	Process starts with drugs being identified based on statutory criteria or stakeholder input and then the data collection process starts
ICER	This is the only process that is non-binding and ICER picks the drugs to perform reviews on - presumably new ones.
CMS	The drugs identified by a process first and then manufacturers were required to submit the required information.

Data Collection and Sources

CO	Staff compiles information from various sources including Wholesale Acquisition Costs (WAC), National Drug Code (NDC) data, Colorado's All Payer Claims Database (APCD), FDA's Orange and Purple Books, public research, and voluntary submissions from manufacturers, PBMs, and carriers.
MD	Can request non-public information directly from manufacturers, distributors, PBMs, and insurance carriers. This includes internal research on pricing, life cycle management, net price, market competition, revenue, and cost-effectiveness. They may also ask for Manufacturer's R&D costs, Direct-to-consumer marketing costs, and gross and net revenues for the drug. Also uses information that can be identified through public datasets like WAC.

Data Collection and Sources (cont.)

ICER	Manufacturers do not submit data to this process. ICER conducts systematic evidence reviews and synthesizes existing evidence from sources like clinical trial data. They also search databases like clinicaltrials.gov to assess potential publication bias.
CMS	Manufacturers are required to submit information the non-Federal average manufacturer price and other information in "Appendix A". Appendix A appears to be certain R&D costs broken out by specific types (acquisition costs, IND costs, abandoned and failed drug costs etc.), global and US lifetime net revenue for the drug, unit costs, prior federal financial support, patents exclusivities, and approval, market data include sales and revenue data, and evidence about alternative therapies.

Drug Review Selection Criteria

CO	Staff compiles a list of eligible drugs based on statutory criteria. The Board then selects drugs for a full review considering factors like FDA approval date, availability of therapeutic alternatives, pricing and utilization data (from APCD), health equity impact, patient out-of-pocket costs, and orphan drug status.
MD	The Board decides whether to conduct a review after identifying drugs, seeking input from its Stakeholder Council, and considering the drug's average cost-sharing.
ICER	Topics are selected based on criteria such as: projected timing of FDA approval, projected significant budget impact, potential to improve health outcomes, public health significance, and addressing health disparities.
CMS	10 drugs were selected based on criteria in the inflation reduction act.

Selection Criteria to Conduct Review

CO	The Board decides whether to conduct a review after identifying drugs, seeking input from its Stakeholder Council, and considering the drug's average cost-sharing.
MD	Staff compiles a list of eligible drugs based on statutory criteria. The Board then selects drugs for a full review considering factors like FDA approval date, availability of therapeutic alternatives, pricing and utilization data (from APCD), health equity impact, patient out-of-pocket costs, and orphan drug status.
ICER	Topics are selected based on criteria such as: projected timing of FDA approval, projected significant budget impact, potential to improve health outcomes, public health significance, and addressing health disparities.
CMS	10 drugs were selected based on criteria in the inflation reduction act.

Primary Factors Considered in Review

CO	- WAC (initial, current, and changes over time). - Therapeutic alternatives (cost, availability, rebates). - Effect of price on consumer access. - Financial effects on health, medical, or social services costs. - Patient copayment and cost-sharing. - Impact on safety-net providers. - Orphan drug status.
MD	- Wholesale Acquisition Cost (WAC) and other cost indexes. - Price concessions, discounts, and rebates. - Cost of therapeutic alternatives.- Costs to health plans. - Impact on patient access and cost-sharing.- Value of patient access programs. - Financial impacts on health and social services

Primary Factors Considered in Review(cont.)

ICER	The review is guided by ICER's Value Assessment Framework, which is built on two main constructs: "long-term value for money" and "short-term affordability". This includes assessing:- Comparative clinical effectiveness.- Incremental cost-effectiveness.
CMS	CMS analyzes the submitted data determine the maximum fair price

Additional Factors Considered

CO	The Board may also consider: - Manufacturer's rationale for pricing. - Life-cycle management. - Market competition and projected revenue. - Cost-effectiveness. - Off-label usage. - Rebates, discounts, and health equity factors. - Patient assistance program information.
MD	If unable to determine affordability with primary factors, the Board may consider: - Manufacturer's R&D costs. - Direct-to-consumer marketing costs. - Gross and net revenues for the drug.

Additional Factors Considered (cont.)

ICER	- Potential other benefits or disadvantages (e.g., impact on underserved communities, burden on caregivers). - Contextual considerations (e.g., severity of the condition, availability of other treatments). - Potential budget impact analyzed over a five-year timeframe.
CMS	CMS also considers data on therapeutic alternatives, which is not always required but helps inform adjustments. This includes: (a) Comparative effectiveness, (b) Costs of alternatives, (c) Prescribing information, (d) Evidence of unmet medical need and impact on specific patient populations.

Stakeholder & Public Input

CO	A multi-layered input process involving the Prescription Drug Affordability Advisory Council, formal public comment periods, and specific outreach to patients, caregivers, medical professionals, and the Rare Disease Advisory Council.
MD	The Board seeks input from a "Stakeholder Council" when deciding whether to conduct a review.
ICER	ICER's process includes multiple opportunities for stakeholder input, including an Open Input Period, public comment on draft scopes and reports, and participation in public meetings. They conduct explicit outreach to patients, clinicians, insurers, and life science companies.

Stakeholder & Public Input (cont.)

CMS	Public comments can be submitted but there is no official patient or pharma input except through this comment process

MN PDAB - Drug Selection Criteria for Review

- Brand name drugs or biologics for which WAC increases by more than 15 percent or $3,000
- Brand name drugs or biologics with a WAC of $60,000
- Biosimilar drugs that have a WAC that is not at least 20 percent lower than the referenced brand name biologic
- Generic drugs for which WAC is $100 or more for 30-day supply or course treatment less than 30 days
- Increased by 200 percent or more during the preceding 12-months
- Drugs identified in consultation with PDAAC and MDH

MN PDAB - Primary Factors Considered in Review

- Price at which prescription drug product has been and will be sold in the state
- Manufacturer monetary price concessions, discounts, or rebates, and drug-specific patient assistance
- Price of therapeutic alternatives
- Cost to group purchasers
- Measures of patient access, including cost-sharing
- Extent to which it is determined by AG or court a price increase for a generic or off-patent prescription drug product was excessive
- Information a manufacturer chooses to provide
- Other factors determined by the board.