PIPC Partnership to Improve Patient Care

Data Mine Blog
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Medicare Drug Price Negotiation – Is CMS Listening to Patients?

CMS's public explanations leave patients with questions about what evidence shaped negotiated prices and how their input was considered.

The Inflation Reduction Act (IRA) authorizes the Medicare Drug price Negotiation Program under which Maximum Fair Prices are established by the Centers for Medicare & Medicaid Services (CMS) for selected high-expenditure Medicare drugs. In reaching those prices, the law requires CMS to make judgments on factors that go to the heart of what matters to patients in their medical care – about therapeutic alternatives, comparative clinical benefit, therapeutic advances, and unmet medical need.

However, the short deadlines established by the IRA combined with CMS' lack of specificity in implementation have left key questions unanswered about whether, and how, input from patients and people with disabilities and patient-centered outcomes are considered. To try to answer these questions, PIPC worked with leading experts to dig into the public explanations the agency released for its Maximum Fair Price (MFP) decisions. What we found did not inspire confidence. For example, as detailed below, **less than 2% of referenced studies described how patient involvement affected the study design**. Further, referenced studies only rarely considered outcomes that matter to patients, such as caregiver burden or treatment convenience.

Our analysis looked at two key domains: first, how, if at all, was CMS considering patient input and patient-centered outcomes in its process; and second, to what degree was it citing studies that include cost-effectiveness analysis that employs the quality-adjusted life year (QALY). We reviewed the evidence cited for three drugs negotiated for Initial Price Applicability Year 2027.

The findings raise two basic concerns:

- Evidence about patients' priorities made up a small share of the literature, even when relevant patient-focused information was available, and;
- There are still some instances where CMS cites research using QALYs and cost-effectiveness thresholds, without providing sufficient information to demonstrate how the research was considered within the context of legal constraints.

The disability community has long fought for federal policies restricting use of QALYs and similar measures. The Affordable Care Act (ACA) specifically prohibits Medicare from using a QALY, or a similar measure, in a way that discounts the value of a life because of an individual's disability. The Inflation Reduction Act similarly includes additional protections against treating life extension for older adults, people with disabilities, and people with terminal illnesses as having lower value in the process of determining Maximum Fair Prices.

PIPC has a long history advocating for health care policies that are centered on the real-world experiences of patients and people with disabilities. As one Senator said during the IRA debate (p. S3858), Congress expected engagement and consultation of people directly impacted, including

patients and people with disabilities, to inform CMS' decisions. The law requires CMS to publish Maximum Fair Price Explanation documents identifying the evidence considered during negotiations. The documents offer some insight into the evidence used during the agency's deliberations, but do not explain how CMS evaluates different types of evidence or weighs input from patients and people with disabilities.

What the review examined

We selected Ibrance, Otezla, and Vraylar because conditions treated by each drug had been the subject of either an FDA-hosted or externally led Patient-Focused Drug Development meeting, resulting in a Voice of the Patient report. These reports confirmed that patient-experience data were available for the conditions treated by each drug.

Together, the three Maximum Fair Price explanations contained 946 references that were included in our final analysis: 282 for Ibrance, 320 for Otezla, and 344 for Vraylar.

Evidence about patients' priorities was limited

Patient experience appeared in 10% of the Ibrance references (n = 28), 16% of the Otezla references (n=52), and 11% of the Vraylar references (n = 38).

This evidence most often addressed symptoms, functioning, emotional well-being, quality of life, or other day-to-day effects and provided evidence for populations where the condition or treatment had a different impact. References addressing day-to-day experience accounted for 9% of the Ibrance evidence, 10% of the Otezla evidence, and 11% of the Vraylar evidence.

Evidence about other patient priorities is less common. Functioning, treatment burden, side effects, caregiver impact, affordability, and adherence shape whether a treatment works for a patient in daily life. When these issues receive little attention, the evidence provides an incomplete picture of a treatment's benefits and burdens.

Table 1. *Count of references contributing to six domains of patient experience data described as of interest to CMS*

Patient-experience domain	Ibrance (n=282)	Otezla (n=320)	Vraylar (n=344)
Any patient experience[1]	28	52	38
Day-to-day experiences	24	32	33
Populations for whom the condition or treatment has a different impact	25	10	6
Effects on caregivers and families	1	2	2
Patient views of treatment benefits and side effects	1	11	4
Outcomes that matter to patients	3	23	9
Access, adherence, and affordability	5	5	5

[1] Counts of individual domains sum to a total higher than the total *Any patient experience* because a reference could contribute across multiple domains.

We also reviewed how patients influenced the research cited in the explanations. Only 12 evidence sources (1.3% total; Ibrance = 2, Otezla = 8, Vraylar = 2) described how patient involvement affected the study or its findings. Most gave no indication that patients helped select the research questions, outcomes, or approach to interpretation.

Not all cited studies drew on U.S. data or populations, ranging from 63% for Otezla to 69% for Ibrance and 74% for Vraylar. The median publication year ranged from 2019 for Vraylar to 2021 for Ibrance, while the median year of the underlying data ranged from 2013 for Vraylar to 2016 for Otezla. This evidence is particularly relevant because it is not sufficient that patient experience is reflected in the evidence base. Older data may miss changes in treatment options, clinical practice, coverage, and barriers to care. Data used must be current, representative, and reflective of patients' lived experiences, including differences in treatment options, clinical practice, benefit design, affordability, access, adherence, and barriers to care. Reliance on older evidence or evidence from external sources, such as China [Ibrance 232], Japan [Otezla 205], or Latvia [Vraylar 258] may therefore understate or mischaracterize the circumstances patients face in the U.S. today.

CMS inconsistently cited available Voice of the Patient reports and does not cite any PCORI-funded studies.

FDA-led and externally led Patient-Focused Drug Development meetings had produced Voice of the Patient reports for conditions treated by all three drugs. Despite these being high-quality reports published by a sister federal agency, CMS did not cite those resources consistently.

For example, the Otezla explanation referenced FDA's general webpage for the psoriasis meeting but did not cite the specific documents produced through the initiative [Otezla 227]. The Vraylar explanation cited an article on integrating patient-experience data in treatment-resistant depression [Vraylar 145], but it did not cite the Voice of the Patient reports from externally led meetings on major depressive disorder or schizophrenia. The Ibrance explanation did not cite the report from FDA's breast cancer meeting.

FDA developed these reports so that patients' experiences could inform medical product development and regulatory discussions. The reports also offer CMS condition-specific evidence about disease burden, treatment trade-offs, and the outcomes patients value. CMS should review relevant reports as a standard part of each negotiation.

Similarly, none of the 946 documents reviewed during this analysis were directly funded by the Patient-Centered Outcomes Research Institute (PCORI); even though PCORI was created by Congress to answer questions that are relevant to how patients choose and value treatments and communicate findings in a manner that recognizes the differences among subpopulations. Such research may be uniquely valuable in judgments about therapeutic alternatives, comparative clinical benefit, therapeutic advances, and unmet medical need.

Patients and patient organizations also invested significant time in written submissions and CMS listening sessions. Yet, the Maximum Fair Price explanations provided little information about how those submissions influenced the agency's conclusions. Soliciting input without explaining its role leaves patients unable to judge whether their participation affected the process.

Inclusion of cost-effectiveness metrics

The explanations indicate that in some instances, CMS continues to reference studies that involve cost-effectiveness metrics such as the QALY, DALY, and/or EQ-5D.

The EQ-5D is a standardized questionnaire that measures health across broad domains and can be converted into utility values for use in economic analyses such as QALYs. Because it is generic, it may fail to capture disease-specific outcomes and treatment benefits that matter most to patients Relying on EQ-5D-derived utility values can introduce bias against people with disabilities and limit a patient-centered assessment of clinical benefit. [Ibrance 215; Otezla 256; Vraylar 233]

For patient and disability communities, the concern is broader than whether CMS explicitly inserts a QALY calculation into its negotiation formula. PIPC has urged CMS to avoid considering evidence informed by QALYs or similar measures, including the equal value of life year gained (evLYG) and disability-adjusted life years (DALYs). These approaches can embed judgments that systematically undervalue treatments for people with disabilities, serious chronic conditions, and older adults by reducing diverse patient experiences and preferences to standardized assessments of health and value. [Ibrance 189; Otezla 287; Vraylar 12]

Table 2. Count of instances where summary measures appeared in reference documents. Includes measures appearing as part of an analysis and a component of guidance documents

Measure	Ibrance	Otezla	Vraylar
QALY	3	8	6
DALY	1	0	19
EQ-5D	5	10	7

Inclusion of cost-effectiveness organizations and approaches

CMS cited studies and frameworks produced by the Institute for Clinical and Economic Review (ICER), an organization whose value assessments have long incorporated QALY-based cost-effectiveness methodologies. For example, a 2019 reference in the Vraylar explanation included cost-effectiveness threshold ranges [Vraylar 128], and the same MFP explanation cited ICER's 2023 Value Assessment Framework [Vraylar 317]. CMS likewise cited documents from the United Kingdom's National Institute for Health and Care Excellence (NICE) in the Ibrance [Ibrance 189] and Otezla [Otezla 13, 226] explanations. NICE is a health technology assessment agency, which conducts QALY-based cost-effectives assessments to determine whether the National Health Service will cover drugs.

The concern is not simply that CMS cited ICER or NICE. The relevant question is how CMS used the information contained in those sources, especially those cited above where the reports are entirely related to making conclusions based on QALYs and similar measures. CMS should disclose how it screens research for QALYs, cost-per-QALY thresholds, and similar measures; which analyses or conclusions it excludes from consideration; and what safeguards prevent prohibited value judgments from influencing drug price negotiations.

That transparency is particularly important when a cited source was developed primarily for cost-effectiveness analysis or health technology assessment and includes QALY-based modeling or cost-effectiveness thresholds. If CMS relies on such a source for other purposes – for example, to understand patient experience – it should identify precisely what information it used and explain why that information is appropriate for that purpose. Patient experience evidence is better drawn from research designed specifically to capture patients' lived experiences, priorities, preferences, and

unmet needs, rather than from assessments whose primary purpose is determining comparative or cost effectiveness.

CMS should formalize patient engagement and show how evidence was used

CMS has created limited opportunities for patients and people with disabilities to provide information directly. For example, the agency cited to the patient roundtable events and input from speakers, stating for each the input "was important." However, the explanations did not clarify how that information affected the agency's assessment of comparative clinical benefit, unmet medical need, therapeutic alternatives, or the negotiated price. Further insight would be needed to determine whether the roundtables and written input from patients was meaningful in making decisions.

Therefore, PIPC continues to urge the agency to develop a formal, ongoing process for engaging patients and people with disabilities throughout the negotiation process. Engagement should begin early enough for patients to help identify the outcomes, treatment burdens, and differences among patient populations that CMS should examine. It should continue through the agency's review and interpretation of the evidence.

CMS should also establish a consistent process for identifying patient-centered evidence. Relevant sources include Voice of the Patient reports, patient registries, qualitative research, evidence submitted by patient and disability organizations, and research funded by PCORI.

For each selected drug, CMS should:

- identify and review relevant patient-experience data, Voice of the Patient reports, PCORI-funded research, and evidence submitted by patient and disability organizations;
- explain how input from patients and people with disabilities affected its conclusions about clinical benefit, unmet need, and therapeutic alternatives;
- engage patients early and throughout evidence review, including when defining relevant outcomes and interpreting findings;
- disclose how it screens studies for QALYs and similar measures and which information from those studies it excludes; and
- demonstrate how its review complies with federal nondiscrimination protections.

The Medicare Drug Price Negotiation Program will affect access to treatments used by patients with different needs, disabilities, and responses to care. Therefore, CMS should not rely on evidence that treats those patients as averages or leaves their experience at the margins of the analysis.

Patients have done their part by participating in meetings, submitting evidence, and explaining what living with a condition and its treatment entails. Based on our analysis, we are deeply concerned that evidence reflecting the real-world perspectives of patients and people with disabilities did not meaningfully inform CMS' judgments about therapeutic alternatives, comparative clinical benefit, therapeutic advances, and unmet medical need or ultimately its decisions about Maximum Fair Prices.

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