



Medicare Negotiations Strategy: CMS Wants All Relevant Evidence

What does that mean for your Value story?

JAMIE CULP
Lead, Market Access Practice



Medicare negotiations are underway, with CMS sending initial offers of the “maximum fair price” (MFP) Medicare will cover for 10 drugs starting in 2026. More drugs will face Medicare negotiations in the years to follow, and manufacturers are understandably frustrated: selected drugs may see net prices cut in half or more,² reducing funds for future innovation and making planning at every development and marketing stage even more complicated (drugmakers are offered two simpler and worse options: pay excise taxes *starting at* 65% of drug U.S. sales, or withdraw *all* company drugs from Medicare and Medicaid³).

Perhaps this frustration informed language in one lawsuit against HHS and CMS, criticizing not only the negotiations, but also the government’s intent to “conscript citizens (including businesses) to parrot its preferred political messaging.”⁴

But as litigation plays out, we believe companies should prepare for Medicare negotiations to go forward. Manufacturers that participate in current and future cycles will put aside the frustration, each engaging CMS with the same goal: win the best appropriate price for their drug. While aspects of the negotiations process and decision-making remain unstated, now is the time for companies to build a value story drawing on the messages and voices that CMS wants to hear.[†]

“This year Medicare is negotiating lower prices for some of the costliest drugs on the market that treat everything from heart disease to arthritis.

Now it's time to go further and give Medicare the power to negotiate lower prices for 500 drugs over the next decade.”⁵

—President Joe Biden, 2024 State of the Union Address



[†] All opinions and recommendations presented are general in nature, do not consider the specific circumstances of any individual manufacturer, and should not be considered or construed as client advice. For more information, please contact DKI Health.

¹ Centers for Medicare and Medicaid Services (CMS).

<https://www.hhs.gov/about/news/2024/02/01/biden-harris-administration-make-first-offer-drug-price-negotiation-program-launches-new-resource-hub-help-people-access-lower-cost-drugs.html>.

² Congressional Budget Office. *How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act*. February 2023.

³ United States Congress. *Inflation Reduction Act of 2022*. August 16, 2022.

⁴ *Bristol Myers Squibb Co. v. Becerra et al.*, s. Intro., no. 6, pg.3. June 16, 2023.

⁵ The White House. *Remarks of President Joe Biden — State of the Union Address As Prepared for Delivery*.

<https://www.whitehouse.gov/briefing-room/speeches-remarks/2024/03/07/remarks-of-president-joe-biden-state-of-the-union-address-as-prepared-for-delivery-2/>

Tell a Value Story with evidence collected across the ecosystem

CMS is explicit: they “will take a qualitative perspective when reviewing a selected drug and consider the evidence, including real-world evidence, clinical input, and patient and caregiver input, in totality”⁶ (emphasis added). CMS spends more than any payer by far, and has a wealth of data to match: they will compare a selected drug to its “therapeutic alternatives” using multiple price datasets, a universe of clinical evidence, utilization via Medicare claims—and this is just a starting point. Before CMS finalizes a drug’s MFP they will consider “all available, relevant evidence” from stakeholders across the healthcare ecosystem. Fortunately, manufacturers are included, and are asked for evidence showing the selected drug’s value versus therapeutic alternatives: while these value questions may appear short and straightforward, the messages and evidence to drive the best response (and subsequent offer price) certainly are not.

We recommend that companies with drugs facing selection risk develop a value story that addresses each CMS value question. Start by conducting an inventory of the messages and supporting evidence available—a well-built and maintained value dossier should provide at least draft messaging and point to gaps in value story evidence. Then prioritize gaps to address and activate evidence development, understanding that speed is key because the clock is ticking.

Companies should also remember that, while some value questions may sound familiar, approaching Medicare negotiations like those with country payers in Europe, or private payers in the US, will miss the mark, as they all differ in process, evidence review and weighting, and even in foundational thinking and priorities.

Know how Patient Voices impact offer prices

While CMS allows “any interested party” to submit data, they specifically seek patient and caregiver input on the Medicare Negotiation program overall, and the value of selected drugs and their therapeutic alternatives; patient organizations, which have influenced program policy development to this point, “may” also be consulted. While many of these inputs have come quietly through electronic channels, CMS hosted 10 Patient-Focused Listening Sessions—one for each selected drug—in October and November 2023, open to the public and streamed live: “optional discussion topics” included:

- Patient and caregiver experience,
- Drug impacts and the outcomes that matter most,
- Access and affordability of drug versus alternatives.⁷

DKI Health attended these sessions, and while we believe opportunities were missed to engage in a deeper and more meaningful public dialogue with impacted stakeholders across the landscape, a number of compelling arguments were made by patients and advocates; it is possible to likely that these informed CMS’ thinking, and offer prices, for one or more drugs. It is also possible to likely that similar listening sessions will be conducted (or expanded) in future negotiation cycles.

⁶ (and throughout) CMS. *Medicare Drug Price Negotiation Program: Revised Guidance*. June 30, 2023.

⁷ CMS. *Medicare Drug Price Negotiation Program Patient-Focused Listening Sessions*. September 6, 2023.

<https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation-program-patient-focused-listening-sessions>

Advocacy groups represented at 2023 CMS Patient-Focused Listening Sessions



This should be a clarion call to every company facing selection risk to understand their patients, caregivers, and advocates. *Real* understanding, not only of the drug’s clinical benefits, but of patients’ and caregivers’ journeys and holistic unmet needs; and of advocates’ priorities and how they perceive that treatment and company in addressing them.

Understand through their voices, as they will be ringing in CMS’ ears. Find opportunities to bring their voices into value messaging, and show the work done to address their unmet needs.

And if those voices speak of improvements that can be made, listen.

Differentiate on Equity

“Health equity is the first pillar of the CMS Strategic Plan, which builds health equity into the core functions of CMS, including the Negotiation Program.”

--Medicare Drug Price Negotiation Program: Revised Guidance

CMS puts advancing health equity at their strategy’s core, and applies it through Medicare negotiation value questions—and, ultimately, will through prices offered and agreed.

We recommend that any company with products at risk of selection understand health equity as CMS defines it, and their priorities⁸ and goals⁹ for advancing it; those seeking optimal negotiation results should tell a value story including their health equity efforts, successes, and—where appropriate—future opportunities, aligned with CMS priorities and goals.

While a discussion on the strategic value of health equity requires more space than this allows, **we recommend** these messages draw from, and further inform, the company’s broader health equity strategy; and to engage appropriate internal and external stakeholders early in value story development.

"As the nation's largest health insurer, CMS has a critical role to play in driving the next decade of health equity for people who are underserved. Our unwavering commitment to advancing health equity will help foster a health care system that benefits all for generations to come."

--Dr. LaShawn McIver, Director, CMS Office of Minority Health

Walk together through multiple steps and changes

The initial MFP offer opens a six-month negotiations window, during which CMS allows for a series of counteroffers and in-person meetings. Any Medicare value story, especially patient and equity messages, should align with and inform the overall Medicare negotiation strategy.

Medicare negotiations are new: CMS is building the program as they go, and has noted the “ambitious statutory deadlines” imposed on them and “complexity of preparation” required. We expect every stage of this first Medicare negotiations cycle will provide learning experiences for CMS, and will not be surprised if guidance, processes, and rules evolve; as often is the case, companies that are engaged and agile should manage these smoothly, while others may face frustration, delays, and potentially poorer results from negotiations.

⁸CMS. *Framework for Health Equity 2022–2032*. April 2022.

⁹CMS. *CMS Strategic Plan, Health Equity*. May 2023.

Drugs selected for Medicare negotiation

Drug Brand (generic)	US Revenue, \$B 22Q3 - 23Q2 ¹⁰	Part D Spend, \$B Jun 22 - May 23 ¹¹
Eliquis (apixaban)	8.3	16.5
Jardiance (empagliflozin)	*	7.1
Xarelto (rivaroxaban)	2.6	6.0
Januvia (sitagliptin)	1.1	4.1
Farxiga (dapagliflozin)	1.2	3.3
Entresto (sacubitril-valsartan)	2.7	2.9
Enbrel (etanercept)	3.8	2.8
Imbruvica (ibrutinib)	3.0	2.7
Stelara (ustekinumab)	6.5	2.6
Fiasp/NovoLog (insulin aspart)	0.9	2.6

* Jardiance’s US manufacturer, Boehringer Ingelheim, does not report individual product US revenue.

¹⁰ Drug US manufacturer financial reports.

¹¹ CMS. Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026. August 2023.

About the Author



Jamie Culp

Lead and Director, Market Access Practice

As Lead of DKI's Market Access practice, Jamie helps life sciences companies drive optimal access for and with patients. His 15 years of industry experience is deep (in access levers and influences), broad (from early clinical through the product lifecycle), and interconnected (addressing needs across company functions and geographies). He previously held strategy and advisory roles for leading life sciences service providers and product manufacturers. He earned his MBA from the University of North Carolina at Chapel Hill.



DKI
HEALTH

16 E 34th Street,
Suite 19-110 New York,
NY 10016
Phone: +1.855.849.7966
Email: contact@dkihealth.com