EXECUTIVE INSIGHTS

Initial Drugs Selected for Medicare Price Negotiation: Emerging Perspectives

In August 2022, President Joe Biden signed the Inflation Reduction Act (IRA) into law, marking the most significant healthcare reform since the Affordable Care Act. This is a step forward in improving the affordability of and access to innovative treatments. The IRA includes multiple provisions, including a limit on copayments for insulin covered under Part D or furnished through durable medical equipment (DME) under Part B; elimination of out-of-pocket cost sharing for adult vaccines covered under Part D, Medicaid and CHIP (Children's Health Insurance Program); expanded eligibility for low-income subsidies; and, importantly, a $2,000 annual cap on Part D patient out-of-pocket costs.[1] The IRA provision with the potential to most significantly impact future revenues and investment for biopharmaceutical manufacturers is the authorization of the Centers for Medicare and Medicaid Services (CMS) to directly negotiate a maximum fair price for therapies covered under Medicare Parts B and D with substantial punitive measures if manufacturers do not consent to pricing negotiation.

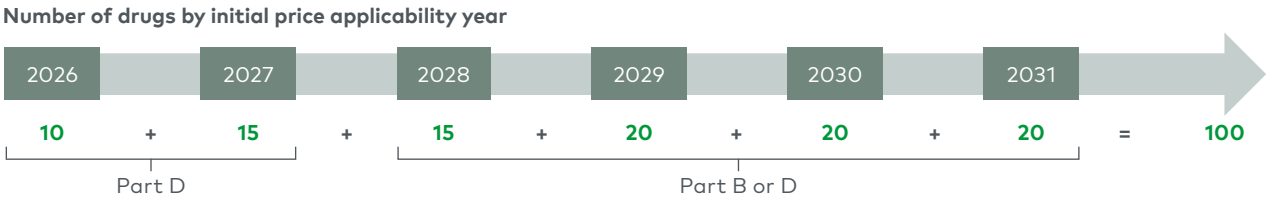
On Aug. 29, 2023, CMS disclosed the first 10 products to be subject to this negotiation beginning in 2026.[2] In this report, L.E.K. Consulting discusses the announcement, the response and the implications for biopharmaceutical companies.

Medicare negotiations will significantly decrease drug prices, cutting revenues for biopharmaceutical manufacturers

Under the IRA, the secretary of the U.S. Department of Health and Human Services is authorized to select products that will be subject to a maximum fair price (MFP) negotiated by CMS. Manufacturers will be required to sell these therapies at no more than the MFP to any Medicare

beneficiaries. Most products covered by Medicare are subject to negotiation on MFP after they have been FDA approved for seven years in the case of small molecule new drug application (NDA) approval or 11 years for biologics approved with biologics license applications and MFP pricing is instituted two years later. CMS is authorized to implement MFP for up to 100 Medicare-covered therapies by 2031. Negotiations will begin with products on Medicare's Part D program (10 subject to MFP by 2026, with 15 more by 2027) before expanding to include both Part D and Part B drugs (see Figure 1).[3] While the MFP only applies to Medicare beneficiaries, commercial payers are likely to follow suit and renegotiate after CMS establishes the MFP.

Figure 1
Timeline and eligibility criteria for Medicare drug price negotiation



Negotiation eligibility criteria

- ✓ **Among the top 50 Part D and top 50 Part B drugs by spend** meeting all the below criteria
- ✓ **Single-source** branded (i.e., no generic or biosimilar)
- ✓ **Nine (small molecules) or 13 years (biologics)** post-approval when prices take effect
- ✓ **>$200 million total expenditures** under Parts B and D*
- × Are NOT **orphan drugs designated** for only one disease or condition and **only approved for that disease or condition**
- × Are NOT derived from **plasma or human whole blood**
- × In initial price applicability years 2026-28, are NOT "small biotech drugs,"** defined as:
  - **<1% of total expenditures** under Part D or Part B AND
  - **≥80% of manufacturer's total Part D or Part B expenditures**
- × Does NOT meet criteria for delayed selection and negotiation of biologics with **upcoming biosimilar entry**

*$200 million in expenditures from 6/1/2022 to 5/31/2023 for 2026 initial price applicability year; threshold adjusted for inflation annually
**Exception does not apply to new formulations of qualifying single-source drugs
Source: Inflation Reduction Act; L.E.K. analysis

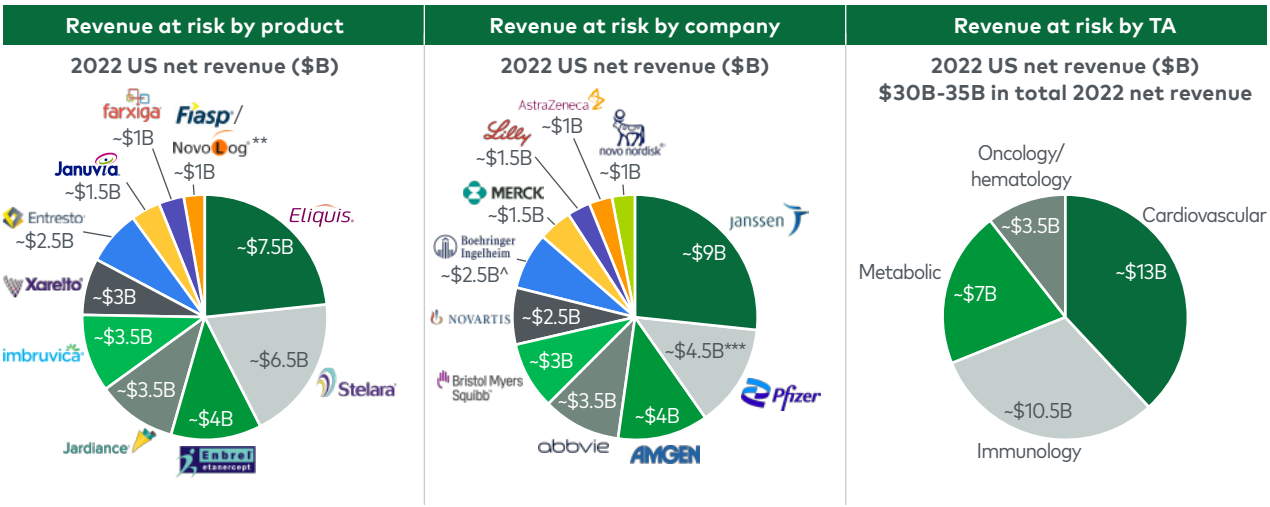
The MFP process has been heavily criticized by biopharmas and other stakeholder groups on the grounds that it is not a true negotiation. Manufacturers are required to participate or are subject to punitive taxes and penalties. The extent of future discounts required by CMS in negotiation is not yet known, and the IRA includes no cap on future discounting. It does, however, include a mandated discounting floor based on the negotiated products' time on the market. MFP is required to be at least 25% below the average manufacturer price for therapies that have been on the market for <12 years and the minimum discount rises to 60% below average manufacturer's price (AMP) for therapies with >16 years on the market.

The first 10 drugs selected for negotiation are among the eligible products by largest Part D spend

On Aug. 29, CMS announced the list of 10 drugs for the first Medicare price negotiation, set for 2026. In total, these selected drugs represent approximately $30 billion in 2022 net revenues (about $50 billion in gross covered Part D prescription drug costs from June 2022 through May 2023) (see Figures 2-3). These products, marketed by established pharmaceutical companies, are concentrated in metabolic (i.e., diabetes), cardiovascular (e.g., stroke, blood clots) and immunological (e.g., psoriasis, rheumatoid arthritis) conditions, with several products spanning multiple indications. The list includes two sets of in-class competitors: Jardiance and Farxiga (SGLT2 inhibitor) and Eliquis and Xarelto (Factor Xa inhibitor).

Figure 2

Negotiated product US Net revenue* at risk by product, company and therapeutic area



*Revenue represents U.S.-only net revenue in 2022
**Includes all Fiasp products (Fiasp, Fiasp FlexTouch, Fiasp PenFill) and NovoLog products (NovoLog, NovoLog FlexPen, NovoLog PenFill)
***BMS and Pfizer split Eliquis revenues 40/60, respectively. Based on Pfizer's press release at the time of the deal (2007), a 60/40 Pfizer/BMS split is directionally displayed. BMS books all Eliquis revenues and shares revenues with Pfizer, so adjustments to total U.S. BMS revenues were made to avoid double counting Eliquis revenues between BMS and Pfizer
^Lilly and BI copromote Jardiance in the U.S. for a total net revenue of $3.6B in 2022, of which Eli Lilly booked ~$1.2B
Note: BI=Boehringer Ingelheim; TA=therapeutic area; BMS=Bristol Myers Squibb
Source: L.E.K. research and analysis; EvaluatePharma

Figure 3 (part 1)
Drugs selected for Medicare negotiations

Eliquis apixaban^ Bristol Myers Squibb Pfizer	**Cardiovascular**	**U.S. net revenues (2022)**	**$7.8B**	**CMS gross spending (June 2022-May 2023)****	**Key branded competitors***
	Deep vein thrombosis, stroke prophylaxis	**Year of U.S. approval** **Estimated LOE**	2012 2028	$16.5B	• **Xarelto (Janssen)**
Jardiance empagliflozin*** Lilly Boehringer Ingelheim	**Metabolic**	**U.S. net revenues (2022)**	**$3.6B**	**CMS gross spending (June 2022-May 2023)****	**Key branded competitors***
	Type 2 diabetes	**Year of U.S. approval** **Estimated LOE**	2014 2028	$7.0B	• Ozempic (NN) • Trulicity (Lilly) • Glyxambi (BI)
Xarelto rivaroxaban janssen	**Cardiovascular**	**U.S. net revenues (2022)**	**$2.5B**	**CMS gross spending (June 2022-May 2023)****	**Key branded competitors***
	Stroke, DVT, PE and CAD	**Year of U.S. approval** **Estimated LOE**	2011 2027	$6.0B	• **Eliquis (BMS/Pfizer)**
Januvia sitagliptin MERCK	**Metabolic**	**U.S. net revenues (2022)**	**$1.3B**	**CMS gross spending (June 2022-May 2023)****	**Key branded competitors***
	Type 2 diabetes	**Year of U.S. approval** **Estimated LOE**	2006 2026	$4.1B	• Ozempic (NN) • Trulicity (Lilly) • **Jardiance (BI)**
farxiga dapagliflzin AstraZeneca	**Metabolic**	**U.S. net revenues (2022)**	**$1.1B**	**CMS gross spending (June 2022-May 2023)****	**Key branded competitors***
	Type 2 diabetes	**Year of U.S. approval** **Estimated LOE**	2014 2026	$3.2B	• Ozempic (NN) • Trulicity (Lilly) • **Jardiance (BI)**
Entresto sacubitril/valsartan NOVARTIS	**Cardiovascular**	**U.S. net revenues (2022)**	**$2.4B**	**CMS gross spending (June 2022-May 2023)****	**Key branded competitors***
	Heart failure	**Year of U.S. approval** **Estimated LOE**	2015 2027	$2.9B	• Jardiance (Lilly) • Farxiga (AZ)
Enbrel etanercept etanercept AMGEN	**Immunology**	**U.S. net revenues (2022)**	**$4.0B**	**CMS gross spending (June 2022-May 2023)****	**Key branded competitors***
	RA, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, plaque psoriasis	**Year of U.S. approval** **Estimated LOE**	1998 2029	$2.8B	• Rinvoq (AbbVie) • Orencia (BMS) • Cimzia (UCB)

*Competitors with >$1B in U.S. sales in 2022 are listed with those that appear in the top 10 drugs in bolded text
**CMS spending on drugs is only reported as gross spend, as net spend may disclose confidential rebating
***Eli Lilly and Boehringer Ingelheim copromote Jardiance
^BMS and Pfizer split Eliquis 40/60, respectively, with BMS recording U.S. sales and paying Pfizer its share
Note: MCL=mantle cell lymphoma; CLL/SLL=chronic/small lymphocytic lymphoma; WM=Waldenstrom macroglobulinemia; MZL=marginal zone lymphoma; GVHD=graft versus host disease; RA=rheumatoid arthritis; LOE=level of effort; CMS=Centers for Medicare and Medicaid Services; NN=Novo Nordisk; BI=Boehringer Ingelheim; UCB=Union Chimique Belge; AZ=AstraZeneca
Source: L.E.K. research and analysis; Evaluate Pharma; CMS database; Endpoints

Figure 3 (part 2)
Drugs selected for Medicare negotiations

imbruvica ibrutinib** abbvie janssen	**Oncology/ hematology**	**U.S. net revenues (2022)**	**$3.4B**	**CMS gross spending (June 2022-May 2023)****	**Key branded competitors***
	MCL, CLL/SLL, WM, MZL, GVHD	**Year of U.S. approval** **Estimated LOE**	2013 2032	$2.6B	• Calquence (AZ) • Venclexta (AbbVie) • Rituxan (Roche)
Stelara ustekinumab janssen	**Immunology**	**U.S. net revenues (2022)**	**$6.4B**	**CMS gross spending (June 2022-May 2023)****	**Key branded competitors***
	Plaque psoriasis Psoriasis arthritis Crohn's disease	**Year of U.S. approval** **Estimated LOE**	2009 2023	$2.6B	• Humira (AbbVie) • Skyrizi (AbbVie) • **Enbrel (Amgen)**
Fiasp / NovoLog insulin aspart^ novo nordisk	**Metabolic**	**U.S. net revenues (2022)**	**$0.9B**	**CMS gross spending (June 2022-May 2023)****	**Key branded competitors***
	Type 2 diabetes	**Year of U.S. approval** **Estimated LOE**	2017/ 2000 2030	$2.5B	• Ozempic (NN) • Trulicity (Lilly) • **Jardiance (BI)**

*Competitors with >$1B in U.S. sales in 2022 are listed with those that appear in the top 10 drugs in bolded text
**CMS spending on drugs is only reported as gross spend, as net spend may disclose confidential rebating
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Source: L.E.K. research and analysis; Evaluate Pharma; CMS database; Endpoints

CMS has chosen to take a largely "mechanical" approach to selection of the products for negotiation. CMS simply selected the eligible products with the greatest Medicare Part D gross spend over the prior year, only excluding those that have an **existing** biosimilar competition (i.e., Humira, Revlimid and Lantus Solostar) or that are ineligible for negotiation due to insufficient time on the market (Ozempic and Trulicity, both of which are expected to become eligible for negotiation in 2025 and 2026, respectively). Notably, CMS has appeared to eschew any other assessment criteria beyond total Medicare spend in the prior year, not considering either history of price increases or total potential lifetime savings.

There were a few modest surprises on the list. Some commentators were surprised CMS selected for 2026 agents including Januvia, Stelara and Novo Nordisk's insulin despite the strong potential that each will face generic/biosimilar competition and pricing decline shortly, even in the absence of negotiation, rather than selecting agents with greater remaining patent protection. If generics/biosimilars for these drugs enter the market ahead of negotiations, these products may be excluded from the process. Additionally, CMS' decision to aggregate multiple Novo Nordisk insulin products (NovoLog and Fiasp) was not widely anticipated.[4,5,6]

One key takeaway from the selected list is that discounts are likely to be substantial, but to what extent remains unknown. Four of the 10 drugs selected (Enbrel, Januvia, NovoLog and Stelara) will have been on the market for more than 16 years at the time of MFP implementation; for those therapies, the minimum discount will be 60% versus the average net price compared to just 25% for therapies launched more recently.

Biopharma manufacturers have continued to respond aggressively to the IRA, with this announcement representing the first major step in the process

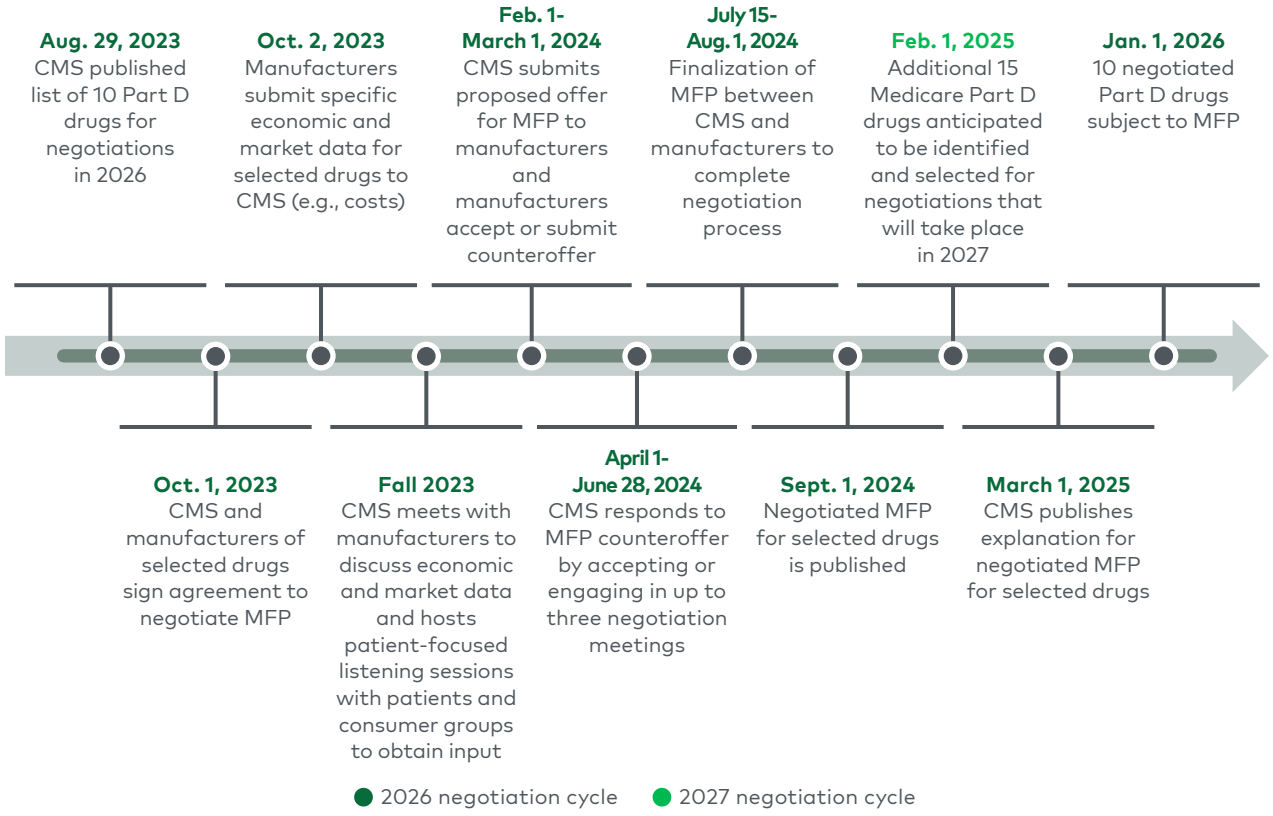
Prior to the announcement, five of the affected biopharmaceutical manufacturers (Astellas,[7] AstraZeneca,[8] Boehringer Ingelheim,[9] Bristol Myers Squibb,[10] Johnson & Johnson[11] and Merck[12]) had filed lawsuits against CMS; Novartis filed suit soon after. Astellas had filed suit in July; however, when its Pfizer-partnered Xtandi was not included for negotiation (as was expected), it withdrew the lawsuit.[13] These lawsuits argue that the legislation infringes on the First Amendment (by compelling speech), Fifth Amendment (by taking property without due process and fair compensation) and, in some cases, the Eighth Amendment (by imposing excessive fines). Separately, AstraZeneca claims the IRA directly counteracts provisions set forth in the Orphan Drug Act, which may disincentivize development of critical medications for patients with rare diseases. Additionally, pharma executives and lobbyists have displayed harsh criticism of the legislation and more lawsuits are likely to ensue.[14, 15]

On Oct. 1, manufacturers must agree to negotiate or they will face substantial penalties. Despite manufacturers' objections, without remediation from the courts, pharmas are expected to agree to negotiation. Any company that does not negotiate has the option to either (1) remove all products, not just the product subject to negotiation, from all federal health programs including Medicare Parts B and D or (2) face an escalating excise tax on the negotiated product that will reach 95% of the product's sale price within nine months. If manufacturers agree to negotiation but do not provide the required information to support CMS assessment or otherwise fail to comply with the negotiation process, they are subject to fines of $1 million per day.

This negotiation will continue throughout the fall and into 2024, with the negotiated price of these 10 drugs published on Sept. 1, 2024 (see Figure 4). The negotiated prices for these drugs will go into effect in 2026.

Figure 4

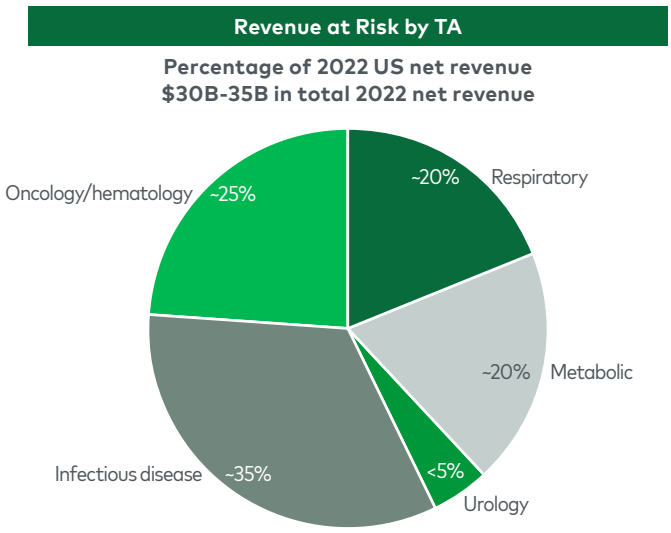
Timeline of key negotiation events leading up to initial price applicability year 2026*



*Adapted from CMS and KFF
Note: CMS=Centers for Medicare and Medicaid Services; MFP=maximum fair price; KFF=Kaiser Family Foundation
Source: L.E.K. research and analysis; CMS; KFF

Attention is also beginning to turn to the next set of therapies eligible for negotiation. An additional 15 Medicare Part D drugs subject to negotiation for an MFP in 2027 are expected to be announced in February 2025. Based on the criteria used to select the first set of therapies, the 15 drugs are anticipated to represent another >$30 billion in 2022 net U.S. sales and impact several therapeutic areas (TAs) not included among this first 10, including infectious disease, respiratory health and urology (see Figure 5).

Figure 5
Potential next 15 drugs up for negotiations in 2027 by TA



Note: TA=therapeutic area
Source: L.E.K. research and analysis; EvaluatePharma

Several key questions remain, which will be answered over the coming months and years

- Questions for 2023:
  - Will any of the manufacturers impacted by this announcement refuse to agree to negotiation at the Oct. 1 deadline? If so, what will be the near-term response from CMS?
  - Will ongoing lawsuits filed by the manufacturers delay the negotiating timeline (either CMS-offered or court-imposed)?
- Questions for 2024:
  - How substantial will the proposed MFP discounts be? Will they significantly exceed the minimum imposed by the IRA legislation?
  - Will they differ significantly by product, class or TA? If so, what factors correlate most substantially with the magnitude of the discounts?
- Questions for 2025 and beyond:
  - How are commercial payers incorporating CMS' MFP in their pricing?
  - Will CMS' rationale for discounting (to be released spring 2025) provide insights into the type of data (e.g., real-world evidence, health economics and outcomes research) that can correlate with lower negotiated discounts?

The implications of this first wave of negotiations are far-reaching, impacting biopharmaceutical manufacturers with therapies set for negotiation today and tomorrow

- Manufacturers with negotiated products will be at the forefront of these new processes, with implications for drug negotiations to come
- Even companies not affected by direct negotiations must plan for the indirect effects, such as the negotiated prices of competitors causing changes to formulary coverage and required rebates, even outside of Medicare patients
- Manufacturers should closely watch upcoming negotiations to understand which of their products may be at risk next, as well as the data generation needed to help maintain strong pricing and access when eligible for negotiation
- These CMS negotiations, along with significant loss of exclusivity cliffs expected later in the decade, are poised to have significant effects on large pharmaceutical manufacturers (e.g., accelerating pipeline development, increasing access to external innovation)
- All manufacturers should include IRA assessments in both R&D planning and business development (BD) asset evaluation

L.E.K.'s Biopharma practice works with clients across a range of strategic issues including preparing for the impact of IRA negotiations on R&D, commercial and BD strategies. If you or your organization is interested in discussing the implications of the IRA on your future opportunities and optimal strategies to prepare, please reach out to us at **healthcare@lekinsights.com**.

Endnotes

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