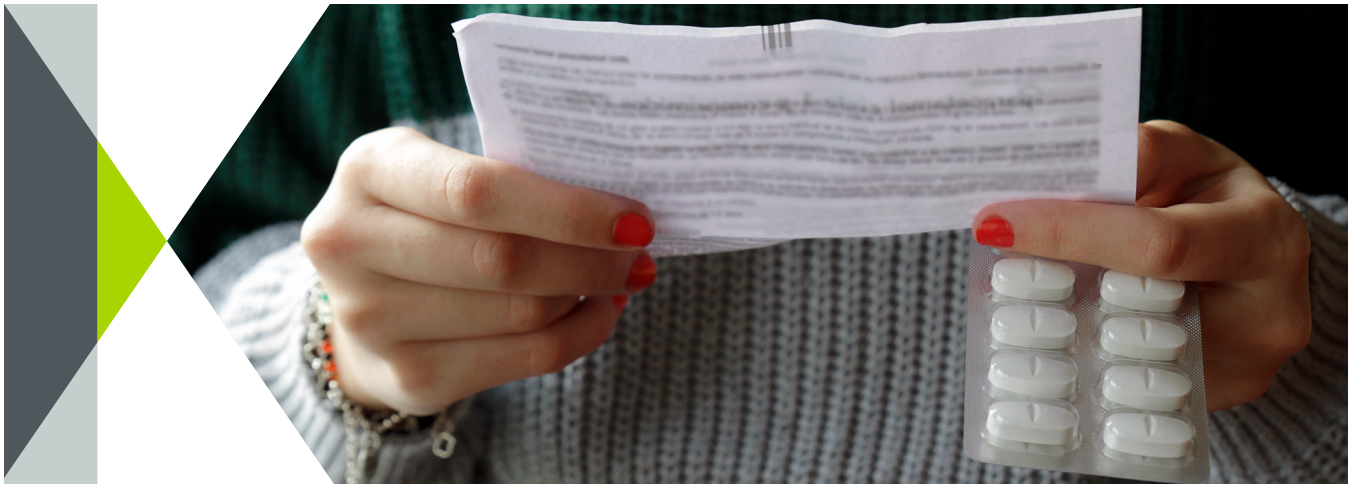


EXECUTIVE INSIGHTS

The Inflation Reduction Act: Implications for Drug Delivery Innovation

The U.S. Inflation Reduction Act (IRA) was signed into law in August 2022.[1] It represents the most significant healthcare reform since the Affordable Care Act, amplifying affordability and access to innovative treatments. While the IRA has many provisions, its authorization of Centers for Medicare & Medicaid Services (CMS) to directly negotiate a maximum fair price for therapies covered under Medicare Parts B and D will have the most significant impact on biopharmaceutical manufacturers' future revenues (see Figure 1). Manufacturers that agree to negotiation will have their drug prices significantly lowered; those that do not will be met with substantial penalties. In August 2023, CMS disclosed the first approximately 10 products to be subject to negotiation in 2026 — the first major step forward.[2]

While the impact of CMS price negotiations under the IRA will directly impact biopharmaceutical manufacturers, the act's repercussions will also flow through to companies providing key inputs into drug product development, such as delivery technology. In this edition of *Executive Insights*, L.E.K. Consulting provides an overview of the IRA and discusses the implications for drug delivery technology providers.

Medicare negotiations will significantly decrease drug prices

Under the IRA, the Health and Human Services Secretary 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 of an MFP after they have been approved by the Food and Drug Administration — for seven years in the case of small molecule

Figure 1
Multiple components of the IRA will impact CMS-covered lives

IRA component	Timing of start	Description	Potential pharma implications
Medicare inflationary rebates	**2023**	• Drugmakers face financial penalties for pricing growth in excess of inflation	• Manufacturers may set higher launch prices to compensate for limits on price increases
Medicare Part D cost-sharing redesign	**2025 (in full)**	• Insurance plans and biopharma manufacturers will have increased responsibility to cover costs of expensive patient-administered therapies	• Lower patient out-of-pocket costs • Potential increase in utilization management as plans aim to avoid catastrophic coverage • Additional costs to pharmas
Medicare drug price negotiations	**2026**	• By 2031, ~100 of the highest-revenue therapies will be subject to pricing discounts (mandated at no less than 25%-75%) when selling to Medicare • Commercial plans expected to pursue similar discounting	• Substantial decreases in prices for negotiated drugs • Biologic development may be prioritized due to longer duration before price negotiation eligibility • Manufacturers may weigh the benefits of generics/biosimilars vs. negotiation • Likely to influence selection of initial indication and whether to pursue additional indication(s)
Other provisions	**Varies**	• Alters cost-sharing for insulin and adult vaccines • Expands low-income subsidy eligibility • Delays implementation of Trump administration's drug rebate rule	• Less substantial pharma implications than the other IRA components

Note: IRA=Inflation Reduction Act; CMS=Centers for Medicare & Medicaid Services
Source: CMS; Inflation Reduction Act; Latham & Watkins; Social Security Act; Kaiser Family Foundation; USC Schaeffer Center; Cornerstone Research; L.E.K. IP; L.E.K. research and analysis

NDA approval, or 11 years for biologics approved with biologics license applications (BLAs) — and MFP pricing is instituted two years later. CMS is authorized to implement an MFP for up to 100 Medicare-covered therapies by 2031.

Negotiations will begin with products on Medicare's Part D program (10 subject to the MFP by 2026, with 15 more by 2027) before expanding to include both Part D and Part B drugs.[3] While the MFP only applies to Medicare beneficiaries, commercial payers are likely to follow suit and renegotiate after CMS establishes the MFP.[4]

The first wave of negotiated drugs is largely orals and injectables; the second wave likely will include inhalables

The first 10 drugs selected for 2026 Medicare negotiations represent around $30 billion in 2022 net revenues (roughly $50 billion in gross covered Part D prescription drug costs from June 2022 to May 2023).[5] These drugs are marketed by established pharmaceutical companies and span therapeutic areas. Some may consider the list to be a first 11, as CMS grouped two of Novo Nordisk's insulin brands as a single product. These insulins, Fiasp and NovoLog, were approved under separate BLAs and differ in the inclusion of vitamin B3.

These initial drugs were selected in a largely "mechanical" fashion, picking eligible products with the greatest Medicare Part D gross spend over the prior year while excluding those with an existing generic/biosimilar. Applying a similar logic, we have predicted drugs that may comprise the next 15 selected.

These products span dose forms and delivery technologies. The first 10 drugs selected include about three injectable therapeutics (grouping the insulins), with autoinjector, pen and prefilled syringe options, representing about $11 billion in net revenues at risk (see Figure 2). Some of these products include multiple forms. For example, the insulins (Fiasp[6] and NovoLog[7]) are offered as prefilled pens, cartridges (compatible with pens or pumps) and vials (see Figure 3A).

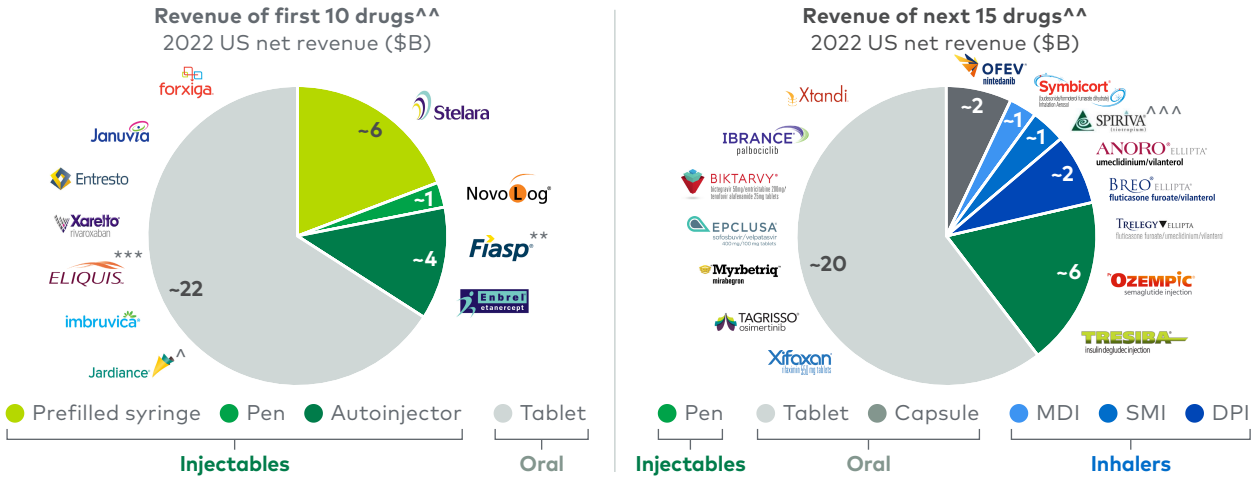
The next 15 drugs selected will likely include more orals and injectables, along with inhalables (see Figure 3B). [Disclaimer: L.E.K.'s "Next 15" represents potential candidates for CMS negotiation selection based on the current IRA framework and guidance. In early 2025, CMS is expected to announce the actual set of drugs for 2027 negotiation]. These inhalable products are tied to different delivery technologies, whether metered dose inhaler (MDI), dry powder inhaler (DPI) or soft mist inhaler (SMI). For example, Spiriva has both DPI and SMI forms, with differently branded technologies (i.e., HandiHaler, a DPI,[8] and Respimat, an SMI[9]).

Unique drug delivery technologies include the following:

- Fiasp and NovoLog's NovoPen Echo® are refillable pens compatible with PenFill® cartridges that have a dose memory display indicating how many units were last injected and the number of hours since that injection; these pens also have more precise dosing that enables insulin delivery in half-unit increments.
- Enbrel's AutoTouch™ is an electromechanical refillable autoinjector compatible with Mini™ cartridges that enables one-handed injection, allows patients to choose from three different injection speeds, has light and sound cues to let patients know when the injection is complete, and is Bluetooth®-enabled to allow patients to automatically track injections in an associated app.
- Spiriva's Respimat® is an SMI that avoids the use of propellants (as is typical with MDIs), improves patient ease of use with a slower and longer spray that does not require coordination of device actuation and inspiration like MDIs, and results in enhanced deposition of the drug in the lungs.
- Anoro, Breo and Trelegy's Ellipta® devices are DPIs that are designed not only to be intuitive for patients but also to have greater versatility for delivering drug combinations due to an

Figure 2

Negotiated products and potential next negotiated products, US net revenue* by product type



Products with multiple injectable dosage forms were categorized according to their most complex/technologically advanced form

*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)
***Pfizer/BMS split Eliquis revenues; 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 copromoted Jardiance in the U.S. for a total net revenue of $3.6 billion in 2022, of which Eli Lilly booked ~$1.2 billion
^^Logo for injectable asset is shown next to format that accounts for majority of asset revenue
^^^Spiriva revenue is almost evenly split between DPI and SMI forms
Note: MDI=metered dose inhaler; SMI=soft mist inhaler; DPI=dry powder inhaler
Source: EvaluatePharma; Symphony Health; press releases; L.E.K. research and analysis

Figure 3A

Drug technology across 10 drugs selected for CMS negotiation

Drug	Manufacturer	Dosage form			
Enbrel etanercept	AMGEN	Vial	Prefilled syringe	SureClick® (single-use autoinjector)	AutoTouch™ and Mini™ (refillable autoinjector and cartridge)
Fiasp	novo nordisk	Vial		FlexTouch® (single-use pen)	PenFill® (cartridge for refillable pen)
NovoLog	novo nordisk	Vial		FlexPen®, FlexTouch® (single-use pen)	PenFill® (cartridge for refillable pen)
Stelara	janssen	Vial			Prefilled syringe
forxiga	AstraZeneca	Tablet			
Januvia	MERCK	Tablet			
Entresto	NOVARTIS	Tablet			
Xarelto rivaroxaban	janssen	Tablet			Oral suspension
ELIQUIS	Bristol Myers Squibb	Tablet			
imbruvica	abbvie janssen	Capsule		Tablet	Oral suspension
Jardiance	Boehringer Ingelheim	Tablet			

Dose form percentage of revenue

≥80% 60%-80% 40%-60% 20%-40% 1%-20% ≤1%

Note: CMS=Centers for Medicare & Medicaid Services
Source: Inflation Reduction Act; Symphony Health; L.E.K. analysis

Figure 3B
Drug technology across 15 potential next drugs selected for CMS negotiation

Drug	Manufacturer	Dosage form	
ANORO ELLIPTA umeclidinium/vilanterol	GSK	Ellipta® (DPI)	
SPIRIVA (tiotropium)	Boehringer Ingelheim	HandiHaler® (DPI)	Respimat® (SMI)
Symbicort	AstraZeneca	MDI	
TRELEGY ELLIPTA fluticasone furoate/umeclidinium/vilanterol	INNOVIVA GSK	Ellipta® (DPI)	
BREO ELLIPTA fluticasone furoate/vilanterol	Theravance Biopharma GSK	Ellipta® (DPI)	
IBRANCE palbociclib	Pfizer	Capsule	Tablet
BIKTARVY	GILEAD	Tablet	
EPCLUSA sofosbuvir/velpatasvir	GILEAD	Tablet	Oral pellet
Myrbetriq mirabegron	astellas	Tablet	Oral suspension
OFEV nintedanib	Boehringer Ingelheim	Capsule	
TAGRISSO osimertinib	AstraZeneca	Tablet	
Xifaxan rifaximin	Salix	Tablet	
Xtandi	astellas Pfizer	Capsule	Tablet
OZEMPIC semaglutide injection	novo nordisk	Pen (single-use)	
TRESIBA insulin degludec injection	novo nordisk	Vial	FlexTouch® (single-use pen)

Dose form percentage of revenue

● ≥80% ● 60%-80% ● 40%-60% ● 20%-40% ● 1%-20% ● ≤1%

Note: CMS=Centers for Medicare & Medicaid Services; DPI=dry powder inhaler; SMI=soft mist inhaler; MDI=metered dose inhaler
Source: Inflation Reduction Act; Symphony Health; L.E.K. analysis

ability to simultaneously aerosolize two sets of blister strips containing different drugs/drug combinations. These are shown to be easier to use than other DPIs (e.g., DISKUS).

Drug delivery technology providers need to incorporate the IRA's implications in their strategic planning

The IRA's effects are not limited to the manufacturer — providers of delivery technology may feel the following effects:

- With lower pricing and increased margin pressure, manufacturers may invest less in product components that lead to higher cost of goods
- With a longer window before negotiations for biologics than for small molecules, drug manufacturers may shift away from small molecules, affecting providers of underlying delivery technology
- Shorter product lifespans may impact drug manufacturers' decisions whether to invest in traditional life cycle management product improvements (e.g., new delivery, new formulation), with unknowns that will be grouped as a single product

- Later-to-market entrants may prioritize drug delivery technology at launch rather than later in the product life cycle in order to maximize differentiation early
- Drug manufacturers may look to develop suites of related products with unique delivery technologies and indications rather than invest in single-product improvements

As delivery technology selection often occurs in the middle of clinical development and as many specifics of the IRA continue to unfold, the impact on drug delivery technology providers may take several years to crystallize.

Here are four key recommendations for drug delivery technology providers

1 Monitor the evolution of the CMS negotiations

- There are significant uncertainties, and technology providers should pay close attention to the insulins and any bundling within the next drugs selected. These actions will likely set the tone for what is considered similar or different across formulations and delivery methods.

2 Start engaging pharmas early

- In the future, the IRA may lead to more multi-indication approaches launching closer together, without additional exclusivity. Pharmas may develop more similar but different molecules. This may lead to different end-user needs across indications, with pharmas considering a variety of devices earlier and in a shorter time span.

3 Focus on cost-effective and/or platform-based innovation

- With a shorter drug product life span, pharmas may be looking to minimize costs through simplifications and/or efficiencies.

4 Drive therapeutic distinction

- When focusing on innovation, look for approaches that improve drug delivery in a manner that is more likely to circumvent drug bundling in eventual CMS negotiations.

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 and commercial and business development 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.

For more information, please contact lifesciences@lek.com.

Endnotes

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