CMS Part D Price Negotiation: Is your drug on their list?

Even if it isn't, learn how this will likely disrupt the entire category. ICON offers an in-advance look at the "probable" list using up-to-date data and implications for both those drugs listed and same-class drugs.

In alignment with the Inflation Reduction Act of 2022, Centers for Medicare & Medicaid Services (CMS) announced its intent to negotiate with drug manufacturers to lower the prices of some top-selling single-source, brand-name Medicare Part D drugs. The new pricing is set to go into effect starting in 2026 for Medicare Part D and 2028 for Medicare Part B.

The implications of the price negotiation go far beyond the 10 drugs that CMS will select during the first round and will likely affect same-class drugs' pricing and profitability as well. An advance look at the possible list can help all manufacturers understand and prepare for the potential impact.

To assist drug companies with preparing for the announced CMS drug price negotiations, ICON has leveraged its healthcare intelligence capabilities and the most current data available to create a list outlining drugs most likely to be selected, along with their same-class competitors.

On 1 September 2023, CMS is scheduled to announce the list of 10 Part D drugs to be negotiated. Drugs eligible for negotiation are those Medicare Part D-covered drugs that are single-source brand-name drugs or biologics with no generic equivalent or biosimilar alternatives. Small-molecule drugs must be at least 7 years past U.S. Food and Drug Administration (FDA) approval or licensure; biologics must be 11 years past FDA approval or licensure, as of the list publishing date. CMS will use earliest approval date in cases where drugs have multiple FDA approvals.

Number of drugs selected to increase over time

The 2026 list selection is just the beginning: 15 additional Medicare Part D drugs will be selected for 2027, 15 more covered by Medicare Part D or Part B in 2028, and 20 more in 2029. This new approach is intended as an ongoing strategy for lowering drug pricing.

Drug selection process

The selected drugs will come from the top 50 negotiation-qualified Part D drugs with the highest total gross prescription drug cost based on spending data from 1 June 2022 to 30 May 2023. CMS will use manufacturer-specific information regarding therapeutic alternatives in negotiating the "maximum fair price." Evaluation factors include:

- Research and development costs and the extent to which they have been recouped
- Unit costs of production and distribution
- Any Federal financial support related to the drug's discovery and development
- Market data, including US revenue and sales volume
- Applications and approvals, including patents and exclusivities

Manufacturers of selected drugs will be required to report back to CMS a variety of information about therapeutic alternatives.

Impact to same-class products can be substantial

Same-class drugs are also likely to be significantly impacted. Lower pricing is a strategy often used to gain market share from higher-priced competitors. Payers also use lowered pricing as a strategy to get other manufacturers to drop their pricing as well, with an implicit threat of lowering purchase volume in the absence of a price reduction. Without a corresponding price change, the lower-priced product could become the highest without a differentiation that warrants the now-highest market price. The result is often a movement to lower pricing for the same-class product.

Without an accompanying lowering of manufacturing costs, the result is lower profit margins for all drugs affected.

Determining the list

ICON is in an advantageous position to identify the potential drug selections by CMS. As a Healthcare Intelligence company, data access and analysis are core strategic capabilities. Our data and analysis are used by Bloomberg and Wall Street.

By leveraging ICON's healthcare intelligence—the very same strategic core capability used in the work for many of our clients—ICON has created a resource to better anticipate the CMS price negotiation impacted drug list prior to release. Our analysis eliminated the single-source drugs that would not be included according to CMS selection guidelines. This approach differentiates ICON's list from others who used a more simplified approach with older data.

The decisions as to which data sets will drive the most accurate picture and match the thinking of CMS are important factors in our analysts' work. The quality of the data, its timeliness, and the thinking behind which data sets are used are the differentiators in constructing our final list.

The list

While producing our list, we included all 50 of the highest expenditure drugs based on the selected criteria. CMS is likely to select the top 10 in expenditure, based on their final calculation. However, the remainder of the list shows other drugs that are within the project scope decisioning now and potentially in the future. We also included the similar class drugs, because of the impact likely to result for them as well.

No one can guarantee an exact match to the CMS list. However, given the publicly announced selection criteria and leveraging our own data access and expertise, we believe this is a good representation of the list that CMS will release.

Medicare Part D Top 50 Drugs

Drug	FDA approval	Status	Category	Some key competitors
Eliquis	2012	Drug	Direct-Acting Oral Anticoagulant	Bevyxxa, Pradaxa, Savaysa, Xarelto
Revlimid	2005	Drug Multisource Ineligible		
Xarelto	2011	Drug	Direct-Acting Oral Anticoagulant	Eliquis, Bevyxxa, Pradaxa, Savaysa
Trulicity	2014	Drug	GLP-1 receptor agonist	Adlyxin, Bydureon, Byetta, Ozempic, Rybelsus, Saxenda
Januvia	2006	Drug	DPP4 inhibitor	Onglyza, Nesina, Tradjenta
Jardiance	2014	Drug	SGLT inhibitor	Brenzavvy, Farxiga, Inpefa, Invokana, Steglatro, Glyxambi, Invokamet, Invokamet XR , Qtern, Segluromet, Steglujan, Synjardy, Trijardy XR, Xigduo XR
Imbruvica	2013	Drug	Bruton's tyrosine kinase (BTK) inhibitor	Brukinsa, Calquence
Humira	20O2	Biologic Multisource Ineligible		
Lantus	2000	Biologic Multisource Ineligible		
Ozempic	2017	Drug	GLP-1 receptor agonist	Adlyxin, Bydureon, Byetta, Rybelsus, Saxenda, Trulicity
Xtandi	2012	Drug	Androgen receptor inhibitor	Asodex, Nilandron, Earleda, Eligard, Lupron, Nubeqa
Trelegy	2017	Drug	LABA/LAMA/ Corticosteroid	Breztri
Enbrel	1998	Biologic	TNF blocker	Humira, Cimzia, Enbrel, Simponi, Remicade, Symponi Aria
Biktarvy	2018	Drug	HIV Fixed-Dose Combination (FDC) Drugs	Atripla, Cabenuva, Cimduo, Combivir, Descovy, Delstrigo, Dovato, Epzicom, Evotaz, Genvoya, Juluca, Kaletra, Odefsky, Prezcobix, Symtuza, Symfi, Symfi Lo, Stribild, Triumeq, Truvada
Myrbetriq	2012	Drug	Beta-3 adrenergic agonist	Gemtesa
Symbicort	2006	Drug	LABA/Corticosteroid	AirDuo, Advair, Breo, Dulera
Ibrance	2015	Drug	Kinase inhibitor	Afinitor, Kisqali, Piqray
Novolog	2000	Biologic Multisource Ineligible		
Entresto	2015	Drug Multisource in 2025 Ineligible		
Restasis	1983	Drug Multisource Ineligible		
Pomalyst	2013	Drug Multisource in 2026 Ineligible		
Stelara	2009	Biologic Multisource in 2024 Ineligible		
Enbrel	1998	Biologic		
Bre Ellipta	2013	Drug	LABA/Corticosteroid	AirDuo, Advair, Dulera, Symbicort

Drug	FDA approval	Status	Category	Some key competitors
Invega	2009	Drug	Long acting atypical antipsychotic injectable	Abilify Maintena, Aristada, Risperdal Consta, Zyprexa Relprevv
Ofev	2014	Drug	Kinase inhibitor	Esbriet
Levemir	2005	Biologic Multisource in 2026 Ineligible		
Jakafi	2011	Drug	JAK inhibitor	Inrebic, Vonjo
Victoza	2011	Drug Multisource in 2023 Ineligible		
Farxiga	2014	Drug	SGLT inhibitor	Brenzavvy, Farxiga, Inpefa, Invokana, Steglatro, Glyxambi, Invokamet, Invokamet XR , Qtern, Segluromet , Steglujan, Synjardy, Trijardy XR, Xigduo XR
Linzess	2012	Drug	Guanylate cyclase-C agonist	Trulance
Latuda	2010	Drug Multisource in 2023 Ineligible		
Tadjenta	2011	Drug	DPP-4 inhibitor	Januvia, Onglyza, Nesina
Creon	2009	Drug	Pancreatic enzymes	
Humalog	1996	Biologic Multisource in 2026 Ineligible		
Spiriva	2004	Drug	Anticholinergic bronchodilators	Incruse, Tudorza, Yupelri, Seebri, Lonhala
Advair	2003	Drug Multisource Ineligible		
Tresiba	2015	Biologic	Long-acting insulin	Humalog, Lantus
Lantus	2000	Biologic Multisource Ineligible		
Epclusa	2016	Drug	Hepatitis C fixed dose combination drug	Harvoni, Sovaldi, Vosevi, Mavyret, Zepatier
Ingrezza	2017	Drug	Vesicular monoamine transporter 2 (VMAT2) inhibitor	Austedo, Austedo XR, Xenazine
Tagrisso	2015	Drug	Kinase inhibitor	Lumakras
Anoro	2013	Drug	LAMA/LABA inhaler	Bevespi, Stilto, Duaklir
Xifaxan	2004	Drug	Rifamycin antibacterial	
Opsumit	2013	Drug	Endothelin receptor antagonist	Tracleer, Letairis, Uptravi, Revatio
Vascepa	2012	Drug Multisource Ineligible		
Janumet	2007	Drug	DPP-4 inhibitor combo	Onglyza, Nesina, Tradjenta combos
Vimpat	2014	Drug Multisource Ineligible		
Calquence	2017	Drug	Bruton's tyrosine kinase (BTK) inhibitor	Brukinsa, Imbruvica
Earleda	2018	Drug	Androgen receptor inhibitor	Asodex, Nilandron, Eligard, Lupron, Nubeqa, Xtandi

You're on the list or in the same class: what can you do about it?

Preparation is the key. Making your best case for value going forward is crucial. Even if your drug isn't selected, the expected drug price negotiations will disrupt the category; same-class products are likely to be significantly impacted as the market adjusts to the competitive changes.

The future

Whether a particular drug is on the list for this round, CMS intends to do the same again over the coming years. If you escaped impact this year, there's no guarantee next year will be the same. Preparing in advance provides you with an advantage over last-minute reactions.

Connect with ICON now.

We want to help build evidence and prove value of your brand for all your audiences, including CMS pricing negotiations and communications with all those target audiences.

For more information on ICON or to schedule a meeting with the ICON team, email us at MarketAccessStrategy@iconplc.com.

Download the list in a single quick-reference PDF document that you can share with others.