CAPITOL STREET

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2027 Projected Drug Negotiation List

Our Initial Take: Xtandi, Trelegy, Ozempic, Others

Relevant Companies

Our Take & Next Up

We provide our projection of likely CMS 2027 selected drugs for negotiation (Part D) in a chart below. The next drug list (15 total) for negotiation is expected to be released by – and could come before – February 1, 2025. In May, CMS released year two negotiation guidance (here) where the agency appears emboldened by stating it will use a larger universe of comparator therapies, and will include "lessons learned" from year one (our take is here). Final guidance is coming this Fall. Ozempic is a potential negotiation target as spend has substantially increased between 2021 and 2022 ($2.6 B to $4.6 B) with GLP-1 spending at the forefront of Medicare policy discussions. Our analysis utilizes the 2022 Medicare Part D spending data (here) and reflects our best estimates based on publicly available (2022) information. However, we note that per statute, CMS will use data from November 1, 2023 to October 31, 2024, to determine total Part D expenditures for each qualifying single source drug.

Key Points

Capitol Street Projected 2027 Drugs for Negotiation***

Drug Name	Manufacturer	Medicare Spending 2022	FDA Approval Date	Disease
Ozempic*	Novo Nordisk	4.6 B	12/5/2017	Type 2 diabetes
Trelegy Ellipta	GSK	3.3 B	9/18/2017	COPD, including chronic bronchitis, emphysema, asthma
Xtandi	Astellas, Pfizer	2.4 B	8/31/2012	Prostate cancer
Ibrance	Pfizer	1.9 B	2/3/2015	Breast cancer
Ofev	Boehringer Ing.	1.8 B	10/15/2014	Lung fibrosis in interstitial lung disease
Pomalyst	BMS	1.7 B	2/8/2013	Multiple myeloma
Linzess	AbbVie, Ironwood	1.6 B	8/30/2012	Irritable bowel syndrome with constipation (IBS-C) and chronic idiopathic constipation (CIC)
Tradjenta	Boehringer Ing.	1.3 B	5/2/2011	Type 2 diabetes

Drug Name	Manufacturer	Medicare Spending 2022	FDA Approval Date	Disease
Janumet	Merck	1.2 B	3/30/2007	Type 2 diabetes
Victoza 3-Pak, 2-Pak	Novo Nordisk	1.2 B	1/25/2010	Type 2 diabetes, reduction of the risk of major cardiovascular events
Calquence	AstraZeneca	1 B	10/31/2017	Mantle cell lymphoma (MCL), chronic lymphocytic leukemia (CLL), small lymphocytic lymphoma (SLL)
Cabometyx**	Exelixis	919 M	4/25/2016	Thyroid, liver, and advanced kidney cancers
Xeljanz	Pfizer	886 M	11/6/2012	Rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, polyarticular course juvenile idiopathic arthritis, and ulcerative colitis
Anoro Ellipta	GSK, Innoviva	867 M	12/18/2013	COPD, including chronic bronchitis, emphysema
Opsumit	JNJ	817 M	10/18/2013	Pulmonary arterial hypertension
Venclexta	AbbVie, Genentech	768 M	4/11/2016	Chronic lymphocytic leukemia (CLL), small lymphocytic lymphoma (SLL)
Otezla	Amgen	710 M	3/21/2014	Plaque psoriasis, psoriatic arthritis, oral ulcers in BD
Vraylar	AbbVie	709 M	9/17/2015	Major depressive disorder (along with an antidepressant), bipolar disorder
Triumeq	GSK	670 M	8/22/2014	HIV/AIDS
Genvoya	Gilead	668 M	11/5/2015	HIV/AIDS
Brilinta	AstraZeneca	638 M	7/20/2011	Decrease risk of acute ischemic stroke, coronary artery disease and acute coronary syndrome
Lenvima	Eisai	626 M	2/13/2015	Differentiated thyroid cancer, advanced renal cell carcinoma, hepatocellular carcinoma, and endometrial carcinoma

Sources: CMS, FDA, Capitol Street, 2024

*It remains unclear if Ozempic will be chosen despite meeting the negotiation criteria due to the benefits of semaglutide on diabetes, cardiovascular disease, and obesity.

** Co. may qualify for the small biotech exemption.

***Having trouble viewing this table? View in browser

Based on Capitol Street projections, the top four drugs (in terms of spending) highlighted are Ozempic (Novo Nordisk), Trelegy Ellipta (GSK), Xtandi (Astellas & Pfizer), and Ibrance (Pfizer). The medications are primarily utilized for treating type 2 diabetes, chronic obstructive pulmonary disease (COPD), prostate cancer, and breast cancer. Notably, among the drugs listed in our analysis, Ozempic utilization is expected to drastically increase for the selected data period. None of the top four drugs have orphan drug indications. A key drug, Invega Sustenna, is not included due to the grouping of all dosage forms and strengths by the agency. It is likely that Invega Sustenna (Paliperidone palmitate) will be excluded from negotiations as it is the depot (injectable) formulation of oral paliperidone which has an available generic. As a reminder, CMS will include all dosage forms and strengths of the drug with the same active moiety and the same holder of a New Drug Application (NDA) when determining qualifying single source drugs. The FDA defines active moiety as “the core molecule or

ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt". Invega Sustenna falls under the same active moiety as oral paliperidone under this definition.

The list was compiled from 2022 CMS Part D drug spending data, which is the most recent data available, and not the dataset CMS will use. As a reminder, the selection period data will be from November 1, 2023 -- October 31, 2024, which has yet to be released. To compile this list, covered Part D drug spending data were analyzed based on the CMS 2027 selection guidance (here).

1. Qualifying single source drugs are identified by excluding orphan drug exclusions, low spend Medicare drugs, plasma-derived products, and initial FDA approval dates.
2. Negotiation eligible drugs are identified through exclusion of 2026 selected drugs and potential small biotech exemption products.
3. Drugs with currently launched biologics and generics are also excluded.
4. Products with expected generic launches in 2026 are included with an expected LOE before the negotiation pricing period. For instance, Stelara (JNJ) is on the 2026 list despite expected biosimilar launches in early 2025.

The top 50 qualifying single source drugs with the highest total Part D spending are eligible for price negotiations. For selected drugs, 7 and 11 years must have elapsed for drug and biological products, respectively. In addition, drugs that only have one orphan designation, drugs with low Medicare expenditures (less than $200 M), plasma-derived products, and small biotechnology drugs (those that make up 80% of a manufacturer's revenue) are exempt from price negotiation. See criteria here, as CMS recently provided guidance for 2027 (here).

Companies are calling out their best guess on what would be included or excluded on the next CMS list. Products can qualify for a small biotech exclusion if the total expenditures under Part D (1) were equal to or less than 1% of the total expenditures under Part D; and (2) were equal to at least 80% of primary manufacturers' total spending in Part D. CMS will also exclude a drug or biological product that is designated as a drug for only one rare disease or condition and for which the only approved indication is for such disease or condition. Company commentary is below.

- **Incyte CEO Hervé Hoppenot noted that Jakafi benefits from the small biotech exclusion** in the early years and benefits from the increased volume from the Part D redesign.

- **Pfizer CEO Albert Bourla indicated that the co. expects to see drugs like Ibrance and Xtandi included** in CMS' 2027 drug negotiations. Notably, these drugs are also approaching their LOE. The comments from Pfizer concur with our projected medicines for the 2027 drug list.

- **Neurocrine states they expect to qualify for the small biotech exemption** in their 10K filing. However, there is a potential for loss of this exemption from future acquisitions or strategic transactions.

- **AstraZeneca noted in 2023 that Tagrisso likely qualifies for the orphan drug exclusion**. On the other hand, they also highlighted the possibility of BTK inhibitors (Calquence) being negotiated as future potential pressure on the class moving forward.

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