# Drugs likely subject to Medicare negotiation, 2026-2028

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### Plain language summary

By 2028, Medicare will negotiate prices for 38 drugs dispensed in pharmacies and 2 drugs provided in physician offices. Medicare drug price negotiation will benefit patients with common diseases such as diabetes, cancer, respiratory conditions, or cardiovascular disease. Our list of drugs expected to be negotiated by Medicare shows patients, clinicians, and insurers which drugs will become more affordable for seniors in the next few years.

### **Implications for** managed care pharmacy

Our list informs health plans of the drugs that will likely see major reductions in price and subsequently cost sharing under Medicare and identifies other top-spend drugs that will be ineligible for negotiation. This information will guide Part D benefit design, formulary placement, and insurer negotiations with manufacturers for discounts.

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### **ABSTRACT**

BACKGROUND: After the passage of the Inflation Reduction Act, Medicare will be able to negotiate drug prices starting in 2026. The Congressional Budget Office has estimated the total savings achieved each year for negotiation but has not publicly identified the drugs anticipated to be negotiated each year.

**OBJECTIVE:** To identify the drugs expected to be negotiated by Medicare in 2026-2028.

METHODS: We identify drugs expected to be negotiated by the Centers for Medicare & Medicaid Services in 2026-2028 based on the statutory criteria, Part B and Part D gross spending in 2020, and estimates of when a drug will be subject to generic or biosimilar competition. We also identify the reasons why other high-spend drugs will be ineligible for negotiation.

RESULTS: In 2026-2028, we estimate that Medicare will negotiate prices for 38 Medicare Part D drugs and 2 Part B drugs. Combined, the 40 products eligible for negotiation in 2026-2028 accounted for \$67.4 billion in gross Medicare spending in 2020. Part D drugs eligible for negotiation in 2026-2028 include 7 inhalers, 8 antidiabetics, 5

kinase inhibitors, and 3 oral anticoagulants. In all but 5 cases, high-spend drugs ineligible for negotiation were disqualified because of generic or biosimilar competition.

CONCLUSIONS: Medicare drug price negotiation has the potential to benefit Medicare beneficiaries across some of the most common disease states. By generating the list of drugs likely subject to Medicare negotiation in the initial years, we hope to provider researchers, policymakers, prescribers, and patient advocates with expectations on which drugs are expected to see reductions in beneficiary cost sharing.

Nearly 20 years after the creation of the Medicare Part D program, the Centers for Medicare & Medicaid Services (CMS) will be able to negotiate drug prices directly with manufacturers following the passage

of the Inflation Reduction Act of 2022.1 Under this new authority, CMS will apply negotiated maximum fair prices for selected small-molecule drugs that have been on the market for at least 9 years and for biologic therapies

marketed for more than 13 years, although the negotiations begin 2 years before they are applied, making the age threshold 7 and 11 years, respectively. Drugs are only eligible if there is no marketed generic or biosimilar

therapy, excluding authorized generics or authorized biosimilars. Drugs approved under an orphan drug application and that only have orphan indications for a single disease or condition will be ineligible for negotiation. Orphan drugs with indications for multiple diseases will, however, remain eligible for negotiation. CMS will negotiate prices on the highest gross spend 10 Part D drugs for implementation in 2026, 15 Part D drugs for 2027, and 15 drugs from across the Medicare Part B and D programs for 2028 (Medicare Part B covers provider-administered drugs, whereas Part D covers retail prescription drugs). From 2029 onward, 20 drugs from across the 2 Parts will be negotiated. In calculating gross spend, CMS includes dispensing fees for Part D drugs and add-on and bundled payments for Part B drugs.

Negotiated prices will remain in effect until the drug becomes ineligible because of generic or biosimilar competition, and the negotiated price will be capped at a certain discount based on the drug's age. Drugs marketed for 9-12 years will be subject to a minimum discount of 25%; drugs marketed 12-16 years face a minimum discount of 35%; and drugs marketed for more than 16 years must discount prices by at least 60%; however, prior to 2030, drugs marketed 12-16 years will only be subject to the 25% minimum discount. Drugs will become ineligible for negotiation when a generic or biosimilar version has been approved and marketed for at least 9 months prior to January 1 of the year in which negotiated prices would apply. The definition of generic or biosimilar marketing status relies on the determination of the US Food and Drug Administration (FDA).<sup>2</sup>

Two years prior to the implementation of negotiated prices, CMS will begin negotiation on the top eligible drugs based on age and generic/biosimilar availability by gross spend, although negotiation for 2026 will begin in 2023 under a timeline provided by CMS.<sup>3</sup> The Congressional Budget Office (CBO) has estimated the total savings achieved each year for negotiation (in 2026, \$3.7 billion; 2027, \$8.3 billion; 2028, \$17.5 billion)<sup>4</sup> but has not publicly identified the drugs anticipated to be negotiated each year. To aid policymakers and practitioners, we leverage public data to project which specific drugs will likely be subject to negotiation from 2026-2028.

# **Methods**

We identify drugs expected to be negotiated by CMS for benefit years 2026-2028 based on drug age, drug or biologic status, orphan drug status, Part B and Part D gross spending in 2020,<sup>5,6</sup> and estimates of when a drug will be subject to generic or biosimilar competition (loss of exclusivity [LOE]). Drug age, drug or biologic status, and orphan drug status were ascertained from the FDA website.<sup>7</sup> Part

B and Part D gross spending in 2020 was obtained from the CMS spending dashboards, which report gross spending per product (inclusive of manufacturer discounts).4,5 For drug products, we estimated LOE based on the latest expiration date of any drug substance or drug product patent listed in the Orange Book;8 this was superseded by any publicly disclosed patent settlement date, for which we performed an online search for each product and generic or biosimilar competitors, as appropriate, and reviewed the most recent annual securities filings from each manufacturer. For biologics, we use estimated LOE from an expert report.9 Notably, for a drug to be ineligible for negotiation because of competition, the generic or biosimilar must have been marketed at least 9 months prior to the year of implementation of negotiated prices. In other words, a reference drug with generic entry in June 2026 would remain eligible for negotiation until 2028.

In addition to our projections of drugs subject to negotiation, we report public information on the minimum discount percentage required by statute based on the drug's years on the market, Medicare gross spending on the drug in 2020 obtained from the dashboards, 5,10 and the CBO's estimated annual savings from negotiation. Finally, we report all high-spend drugs that we excluded from the list of likely negotiated drugs and the reasons for exclusion.

Additional information: The study was not registered.

# **Results**

For 2026, the top drugs projected for negotiation include anticoagulants Eliquis (apixaban) and Xarelto (rivaroxaban), oral antidiabetics Januvia (sitagliptin) and Jardiance (empagliflozin), the tumor necrosis factor inhibitor Enbrel (etanercept), and the inhalers Symbicort (budenoside/formoterol) and Breo Ellipta (fluticasone/vilanterol) (Table 1). Three cancer therapies are projected to be eligible for negotiation in 2026 as well, including the kinase inhibitors Imbruvica (ibrutinib) and Ibrance (palbociclib) and the antiandrogen Xtandi (enzalutamide). In 2020, these 10 products accounted for \$33.7 billion (17%) of Part D gross spending.

Based on their rank by gross spending, drugs likely to be negotiated for 2027 include 4 inhalers, 3 antidiabetics, 2 kinase inhibitors, the antipsychotic Invega Sustenna (paliperidone), the hepatitis C treatment Epclusa (sofosbuvir/velpatasvir), the irritable bowel syndrome therapy Linzess (linaclotide), the pancreatic enzyme mix Creon, the antibiotic Xifaxan (rixafimin), and the tardive dyskinesia therapy Ingrezza (valbenazine). The 15 products projected to be negotiated for 2027 accounted for \$16.4 billion (8.3%) in gross Part D spending in 2020.

Rank	/part	Brand name	Generic name	Manufacturer	Spending in 2020 <sup>a</sup> , \$	Years since approval <sup>b</sup>	loss of exclusivity <sup>c</sup> (by year)	Minimum discount <sup>d</sup> ,	CBO- estimated annual savings <sup>e</sup> , \$	
Subjec	ct to n	egotiation in 20	026				,			
1	D	Eliquis	Apixaban	BMS/Pfizer	9,936,069,814	13.0	2028	25		
2	D	Xarelto	Rivaroxaban	Janssen Pharm.	4,701,314,805	14.5	2027	25	3.7 billion	
3	D	Januvia <sup>f</sup>	Sitagliptin phosphate	Merck Sharp & D	3,865,087,773	19.2	2026	60		
4	D	Imbruvica	Ibrutinib	Pharmacyclics	2,962,909,304	12.1	2033	25		
5	D	Jardiance	Empagliflozin	Boehringer Ing.	2,376,166,292	11.4	2028	25		
6	D	Enbrel	Etanercept	Amgen	2,154,714,778	27.2	2029	60		
7	D	Symbicort	Budesonide/formoterol	Astrazeneca	2,135,408,250	19.5	2028	60		
8	D	Ibrance	Palbociclib	Pfizer US Pharm	2,108,937,188	10.9	2034	25		
9	D	Xtandi	Enzalutamide	Astellas Pharma	1,968,567,948	13.4	2027	25		
10	D	Breo Ellipta	Fluticasone/vilanterol	Glaxosmithkline	1,504,155,910	12.7	2030	25		
Total 2	2026 d	rugs			33,713,332,062					
Subje	ct to n	egotiation in 20	027							
1	D	Trelegy Ellipta	Fluticasone/ umeclidinium/vilanterol	Glaxosmithkline	1,487,802,308	9.3	2027	25		
2	D	Ozempic	Semaglutide	Novo Nordisk	1,455,812,267	9.1	2031	25		
3	D	Invega Sustenna	Paliperidone palmitate	Janssen Pharm.	1,372,610,289	17.4	2031	60		
4	D	Jakafi	Ruxolitinib	Incyte Corporat	1,296,674,522	15.1	2028	25		
5	D	Tradjenta	Linagliptin	Boehringer Ing.	1,288,663,293	15.7	2027	25		
6	D	Ofev	Nintedanib esylate	Boehringer Ing.	1,157,563,828	12.2	2029	25	8.3 billion	
7	D	Spiriva <sup>g</sup>	Tiotropium bromide	Boehringer Ing.	1,153,453,863	22.9	2030	60	(2027	
8	D	Linzess	Linaclotide	Allergan Inc.	1,144,468,128	14.4	2033	25	savings from drugs	
9	D	Anoro Ellipta	Umeclidinium/vilanterol	Glaxosmithkline	1,002,343,776	13.1	2030	25	negotiated i	
10	D	Creon	Lipase/protease/amylase	Abbvie US LLC	960,235,542	17.8	2031	60	2026-2027)	
11	D	Epclusa	Sofosbuvir/velpatasvir	Gilead Sciences	867,053,907	10.5	2034	25		
12	D	Xifaxan	Rifaximin	Salix Pharmaceu	844,562,189	22.6	2027	60		
13	D	Spiriva Respimat <sup>g</sup>	Tiotropium bromide	Boehringer Ing.	804,565,194	12.3	2030	25		
14	D	Ingrezza	Valbenazine tosylate	Neurocrine Bios	792,681,813	9.7	2038	25		
15	D	Janumet	Sitagliptin phos/ metformin hcl	Merck Sharp & D	791,886,114	19.7	2026	60		
Total 2	2027 d	rugs			16,420,377,033		•			

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For 2028, Part B drugs will become eligible for negotiation. However, only 2 Part B products are projected to be subject to negotiation (Keytruda [pembrolizumab] and Opdivo [nivolumab]), as most high-spend Part B drugs will face biosimilar competition by then (Table 2). Given the 2 Part B products, 13 Part D products are projected to be subject to price negotiation for 2028, including 3 antidiabetics and 4 HIV treatments. The 15 products projected to be negotiated for 2028 accounted for \$17.2 billion (8.7%) in gross Medicare spending in 2020. Combined, the 40

T	TABLE 1 Drugs Anticipated to Face Medicare Price Negotiation, 2026-2028 (continued)								
Rank	/part	Brand name	Generic name	Manufacturer	Spending in 2020 <sup>a</sup> , \$	Years since approval <sup>b</sup>	Expected loss of exclusivity <sup>c</sup> (by year)	Minimum discount <sup>d</sup> ,	CBO- estimated annual savings <sup>e</sup> , \$
Subjec	ct to n	egotiation in 2	028						
1	В	Keytruda	Pembrolizumab	Merck Sharp & D	3,500,947,569	13.3	2028	25	
2	D	Trulicity <sup>h</sup>	Dulaglutide	Eli Lilly & Co.	3,284,873,062	13.3	2027	25	
3	В	Opdivo	Nivolumab	BMS	1,586,591,103	13.0	2028	25	
4	D	Biktarvy	Bictegravir/ emtricitabine/tenofovir	Gilead Sciences	1,775,846,507	9.9	2036	25	
5	D	Genvoya	Elvitegravir/cobicistat/ emtricitabine/tenofovir	Gilead Sciences	755,819,244	12.2	2032	25	
6	D	Triumeq	Abacavir/dolutegravir/ lamivudine	Viiv Healthcare	738,986,222	13.4	2029	25	17.5 billion (2028
7	D	Farxiga	Dapagliflozin	Astrazeneca	736,787,564	14.0	2030	25	savings
8	D	Tivicay	Dolutegravir	Viiv Healthcare	656,037,862	14.4	2029	25	from drugs negotiated in
9	D	Lumigan <sup>h</sup>	Bimatoprost	Allergan Inc.	633,540,096	17.4	2027	60	2026-2028)
10	D	Acthar	Corticotropin	Mallinckrodt Ph	621,884,161	77.6	NA	60	
11	D	Incruse Ellipta	Umeclidinium	Glaxosmithkline	605,138,195	13.7	2030	25	
12	D	Pradaxa <sup>h</sup>	Dabigatran	Boehringer Ing.	599,577,175	17.2	2027	60	
13	D	Brilinta	Ticagrelor	Astrazeneca	588,513,924	16.5	2030	60	
14	D	Xeljanz XR	Tofacitinib citrate	Pfizer	575,315,148	11.9	2034	25	
15	D	Invokana	Canagliflozin	Janssen Pharm.	571,448,119	14.8	2031	25	
Total 2	2028 d	rugs			17,231,305,951				
Total 2	2026-2	028 drugs			67,365,015,046				29.5 billion

Estimates represent gross Part D spending in 2020 for Part D drugs and gross Part B spending in 2020 for Part B drugs. Spending estimates were obtained from the Medicare spending dashboards.

products projected to be eligible for negotiation for 2026-2028 accounted for \$67.4 billion in gross Medicare spending in 2020, equivalent to 33.9%) of 2020 Part D spending or 28.4% of combined Part B and D drug spending.

We expect that 2028 will be the first year when a negotiated drug becomes ineligible for negotiated prices for the first time because generic competition, as Januvia and Janumet are expected to have generic competition launch

in mid-2026. This launch timeline would not result in 9 months of a marketed generic prior to the start of 2027; therefore, we anticipate negotiated prices to remain in effect through the end of 2027.

In Table 2, we report high-spend products ineligible for negotiation because of statutory requirements. In all but 7 cases, drugs were disqualified because of generic or biosimilar competition. Products disqualified from negotiation

<sup>&</sup>lt;sup>b</sup>Calculated as the time between drug approval and January 1 of the year that the drug is first expected to be subject to negotiation.

Expected loss of exclusivity was estimated as the latest reported drug substance or drug product patent expiry date, superseded by any publicly announced patent settlement date. 17-19

 $<sup>^{\</sup>rm d}$ Beginning in 2030, drugs from 12 to 15 years of age will be subject to a minimum 35% discount.

<sup>&</sup>lt;sup>e</sup>Annual savings include ongoing savings from negotiated prices achieved in prior years.

<sup>&#</sup>x27;Although the entry of generic sitagliptin is expected in mid-2026, this will not disqualify Januvia from negotiation in 2026, as a generic product must have been marketed for at least 9 months prior to the implementation year for the reference product to be ineligible for negotiation.

<sup>&</sup>lt;sup>9</sup>Spiriva and Spiriva Respimat were considered different products as they have different application numbers.

Patent protection anticipated to expire after the first quarter of 2027, so any approved generics or biosimilars would not meet the 9-month marketing requirement prior to 2028.

BMS=Bristol Myers Squibb; CBO=Congressional Budget Office; NA=not applicable.

TABLE 2	Top-Spending Drugs Ineligible for Medicare Price Negotiation, 2026-2028
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Brand name	Generic name	Manufacturer	Spending in 2020 <sup>a</sup> , \$	Reason ineligible		
art D drugs				-		
Revlimid	Lenalidomide	Celgene/BMS	5,356,050,275	Generic available		
Humira	Adalimumab	Abbvie US LLC	4,166,710,387	Anticipated biosimilar in 2023		
Lantus	Insulin glargine	Sanofi-Aventis	3,719,082,839	Biosimilar available		
Novolog	Insulin aspart	Novo Nordisk	2,972,656,706	Interchangeable biosimilar anticipated by 2026		
Humalog	Insulin lispro	Eli Lilly & Co.	2,064,366,203	Interchangeable biosimilar anticipated by 2026		
Levemir Flextouch	Insulin detemir	Novo Nordisk	1,991,698,847	Interchangeable biosimilar anticipated by 2026		
Victoza	Liraglutide	Novo Nordisk	1,895,291,574	Generic anticipated in 2023		
Pomalyst	Pomalidomide	Celgene/BMS	1,453,860,767	·		
Restasis	Cyclosporine	Allergan Inc.	1,451,534,384	Generic available		
Latuda	Lurasidone	Sunovion Pharma	1,317,919,887	Generic anticipated in 2023		
Entresto	Sacubitril/valsartan	Novartis	1,203,043,540	Generic anticipated by 2025		
Advair Diskus	Fluticasone/salmeterol	Glaxosmithkline	1,160,474,903	Generic available		
Stelara Ustekinumab		Janssen Biotech	1,106,356,248	Biosimilar anticipated in 2024		
Tecfidera	Dimethyl fumarate	Biogen-Idec	1,054,984,601	Generic available		
Shingrix	Varicella-zoster	Glaxosmithkline	875,670,149	Ineligible based on years since approval		
Janumet Sitagliptin/metformin		Merck Sharp & D	791,886,114	Generic anticipated in 2026, and based on spending, it would not qualify until 2027		
Aubagio	Teriflunomide	Sanofi-Aventis	778,201,329	Generic anticipated in 2023		
Vascepa	Icosapent ethyl	Amarin Pharma	754,811,701	Generic available		
Copaxone	Glatiramer acetate	Teva Neuroscien	713,588,637	Generic available		
Vimpat	Lacosamide	UCB Pharma	709,365,915	Generic available		
Basaglar	Insulin glargine	Eli Lilly & Co.	689,339,162	Ineligible based on years since approval		
Dexilant	Dexlansoprazole	Takeda	651,674,922	Generic available		
art B drugs						
Eylea	Aflibercept	Regeneron	3,013,081,886	Biosimilar anticipated in 2024		
Prolia	Denosumab	Amgen	1,626,844,123	Biosimilar anticipated in 2025		
Rituxan	Rituximab	Roche	1,295,821,133	Biosimilar available		
Lucentis	Ranibizumab	Genentech	1,113,026,180	Biosimilar available		
Orencia	Abatacept	BMS	1,023,001,524	Biosimilar anticipated in 2026		
Neulasta	Pegfilgrastim	Amgen	899,790,555	Biosimilar available		
Darzalex	Daratumumab	Johnson & Johnson	837,400,702	Not eligible until 2029 because of years since approve		
Avastin	Bevacizumab	Genentech	680,539,026	Biosimilar available		
Remicade	Infliximab	Janssen	663,412,142	Biosimilar available		
Tecentriq	Atezolizumab	Genentech	624,194,084	Not eligible until 2030 because of years since approve		
Ocrevus	Ocrelizumab	Genentech	618,708,736	Not eligible until 2031 because of years since approv		
Soliris	Eculizumab	Alexion	610,425,468	Biosimilar anticipated in 2025		

<sup>&</sup>lt;sup>a</sup>Estimates represent gross Part D spending in 2020 for Part D drugs and gross Part B spending in 2020 for Part B drugs. Spending estimates were obtained from the Medicare spending dashboards.5,10

BMS = Bristol Myers Squibb.

include insulin products, which are expected to face competition from biosimilars by 2026, and the block-buster Humira (adalimumab), which is expected to face biosimilar competition in 2023.

### **Discussion**

To our knowledge, our article is the first public report of the drugs anticipated to be negotiated by CMS for benefit years 2026-2028. Our estimates differ from an earlier list of negotiation-eligible drugs for 2026 that did not consider LOE after 2022, as acknowledged by the authors.11 With the exception of 2 insulin products, which we believe will face biosimilar competition by 2026, our list is consistent with a previous report of expected drugs to be negotiated in 2026 that did account for LOE.12 We have excluded NovoLog (insulin aspart) from the list of drugs eligible for negotiation as patents have expired and the FDA is currently reviewing a biosimilar application.<sup>13</sup> We have considered Levemir (insulin detemir) ineligible for negotiation because the manufacturer reports that US patents expired in June 2019,14 thus meeting our study exclusion criteria even though no biosimilar is yet available. Additionally, although the generic formulation of Revlimid (lenalidomide) is currently subject to volume limitations until January 2026,15 this generic is considered "marketed" under FDA criteria, thereby excluding Revlimid from negotiation eligibility.

Some Medicare patients will benefit substantially from negotiations on these drugs, as a reduction in the drug's price will result in lower coinsurance and liability during the deductible phase. Overall, negotiations are projected by the CBO to reduce premiums, resulting in lower costs for all Medicare beneficiaries. 4,16 Notably, the minimum price reductions listed

almost certainly underrepresent the price reductions that will be achieved for the Part D drugs, as the negotiated price is required to be below the existing average net price of the drug, which includes confidential rebates. Thus, Medicare patients may see their cost sharing fall by amounts greater than reflected by the minimum price reductions reported, as their cost sharing will reflect, at minimum, existing net prices.

Overall, Medicare negotiation will benefit patients on the specific medications identified across some of the most common disease areas while reducing total Medicare drug spending. The Inflation Reduction Act coupled CMS negotiation with substantial reforms to the Medicare Part D benefit design, most notably a \$2,000 out-of-pocket cap. Absent CMS negotiation, these benefit changes are estimated to increase Medicare spending by \$30 billion, but the savings generated through CMS negotiation offset these increases.<sup>4</sup>

#### **LIMITATIONS**

Our findings are subject to 2 main limitations. First, our selection of top-spending drugs is based on data from 2020, the most recent available at the time of analysis. Changes in drug utilization and pricing over time may affect which drugs are ultimately selected for negotiation based on total spending in the year prior to negotiation. Second, our list of drugs eligible for negotiation is subject to the uncertain outcomes of ongoing patent litigation, which could affect the date of predicted generic or biosimilar entry.

# **Conclusions**

We estimate that Medicare will negotiate 38 Part D and 2 Part B drugs in 2026-2028, including 7 inhalers, 8 antidiabetics, 5 kinase inhibitors, and 3 oral anticoagulants. Combined, the

40 products eligible for negotiation in 2026-2028 accounted for \$67.4 billion in gross Medicare spending in 2020. By identifying a list of drugs likely to be negotiated by CMS, we hope to provide researchers, policymakers, prescribers, and patient advocates with expectations on which drugs will see reductions in beneficiary cost sharing.

#### **DISCLOSURES**

This work was funded by the West Health Policy Center. Dr Hernandez reports consulting fees from Pfizer and Bristol Myers Squibb, outside of the submitted work.

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