Drugs anticipated to be selected for the Medicare Drug Price Negotiation Program in 2025

Emma M. Cousin, PharmD; Sean D. Sullivan, BScPharm, PhD; Ryan N. Hansen, PharmD, PhD; Nico Gabriel, MA; Ayuri S. Kirihennedige, BSc; Inmaculada Hernandez, PharmD, PhD

Plain language summary

Medicare will negotiate the prices of up to 15 Part D products for implementation in 2027. The list of products selected for negotiation will be made publicly available by February 2025. We anticipate the drugs that may be selected for negotiation by Medicare following criteria outlined in the Inflation Reduction Act and Centers for Medicare and Medicaid Services guidance.

Implications for managed care pharmacy

Our analyses are key to informing payers and manufacturers of the drugs and therapeutic classes that will likely see reductions in Medicare prices starting in 2027. The early identification of these products will enable timely payer and manufacturer response and facilitate manufacturer preparation of evidence for submission to Centers for Medicare and Medicaid Services for consideration in negotiations.

Author affiliations

The CHOICE Institute, School of Pharmacy, University of Washington, Seattle (Cousin, Sullivan, Hansen); Department of Health Policy, London School of Economics and Political Science, London, United Kingdom (Sullivan); Skaggs School of Pharmacy, University of California San Diego (Gabriel, Kirihennedige, Hernandez).

AUTHOR CORRESPONDENCE:
Inmaculada Hernandez, 1.858.822.6047;
inhernandez@health.ucsd.edu,
@ihdezdelso

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ABSTRACT

BACKGROUND: The Centers for Medicare and Medicaid Services (CMS) recently announced the Maximum Fair Price for the first 10 Medicare Part D drugs selected for price negotiation. By February 2025, CMS should announce the list of Part D drugs to be negotiated with implementation of the negotiated prices in 2027.

OBJECTIVE: To identify up to 15 Medicare Part D single-source drugs anticipated to be selected by CMS for price negotiation in 2025.

METHODS: We followed selection criteria identified in the Inflation Reduction Act and CMS guidance to identify drugs. We projected 2023 Part D gross spending using 2020-2022 data reported by CMS and linear prediction models. We ranked products according to the projected spending figure and identified those not eligible for selection because of (1) number of years since approval, (2) availability of a biosimilar or generic version, (3) approval for a single orphan indication, (4) whole human blood or plasma-derived, or (5) eligibility for the small biotech exception.

RESULTS: We identified 13 products likely subject to Medicare drug price negotiation, including 4 anticancer therapies, 3 noninsulin antidiabetic products, 2 inhalers, 1 antifibrotic therapy, 1 gastrointestinal agent, 1 enzyme replacement therapy, and 1 product indicated for dyskinesia. These 13 products each had projected annual gross Part D spending more than $1 billion. We identified 7 additional products with uncertainty to complete the list of 15, including an insulin, an antiviral, an antibiotic, an immunologic agent, an antidiabetic, and 2 cancer drugs. These products had projected gross Part D spending between $877 million and $1.399 billion. Twenty-two products with comparable levels of spending were deemed ineligible for selection because of availability of a generic or biosimilar version (10 products), insufficient years since approval (8 products), eligibility for the small biotech exception (3 products), and expected market discontinuation (1 product).

CONCLUSIONS: Our identification of products anticipated to be selected for negotiation in 2025 (with implementation of negotiated prices in 2027) will help inform manufacturers, payers, patients, and policymakers of the products that will likely see a decrease in Medicare drug prices as result of negotiation. We identified 22 products with levels of spending that are comparable with those anticipated to be selected for negotiation but are not eligible, primarily because of generic or biosimilar availability or insufficient time on market.

The Centers for Medicare and Medicaid Services (CMS) recently announced the negotiated prices (Maximum Fair Prices [MFP]) for the first 10 Medicare Part D drugs selected for price negotiation. Following the completion of the first round of negotiations, CMS will identify up to 15 Part D drugs for negotiation in 2025, with implementation of negotiated prices in 2027. Under the Inflation Reduction Act (IRA), single-source drugs are selected for negotiation based on gross Medicare expenditures and time on market (at least 7 years for small molecule drugs and at least 11 years for biologics). Drugs are not eligible if they have a US Food and Drug Administration (FDA)–approved and marketed generic or biosimilar equivalent, are human blood or plasma-derived, and have a single indication for an orphan disease.[1] Additionally, through 2029, products that represent more than 80% of Part D spending for a manufacturer and less than 1% of Part D spending for all Part D products are eligible for the "small biotech exception."

The selection of the first 10 drugs closely followed statute and CMS final draft guidance.[2,3] The list of products selected included a mix of treatments for diabetes, cardiovascular disease, cancer, and immunologic conditions commensurate with diseases of the elderly Medicare population.[4] Novolog and Fiasp—2 branded products—were considered as a qualifying single-source drug because they contain the same active moiety (insulin aspart) and are produced by the same manufacturer.

In early 2023, before publication of the CMS guidance, one of the authors (IH) and her colleague predicted drugs to be selected for the first 3 rounds of negotiation using 2020 gross spending data.[5] A comparison of the 2024 list with the final one published by CMS showed several discrepancies, mostly because of the lag in publicly available CMS spending data. For example, the authors did not anticipate ustekinumab (Stelara) to be selected for negotiation in the first round (price applicability in 2026) based on 2020 spending data. This product, however, rose to the top 10 of eligible drugs by spending after its utilization more than doubled in 2020-2022 and was indeed selected for negotiation in the first round.[6]

Informed by lessons learned from prior work, we now revise our methods to identify drugs anticipated to be negotiated by Medicare for price implementation in 2027.[5] This second cohort will include up to 15 drugs currently reimbursed under Medicare Part D. CMS plans to make the final list available on or before February 1, 2025.

Methods

To predict the drugs selected for negotiation in 2025 for implementation in 2027, we followed the eligibility criteria outlined in the draft CMS guidance in accordance with the IRA.[7] First, we obtained 2020-2022 Medicare Part D gross spending estimates from the CMS Part D dashboard (most recent data available at the time of analysis).[6] After excluding products selected for negotiation in the previous round, we projected 2023 Part D spending using 2020-2022 data and linear regression models for all products with the exception of Humalog (insulin lispro). Although it is expected that CMS will use November 2023 to October 2024 gross spending data (not publicly available), we opted to select drugs using 2023 projections because of the difficulty in projecting trends beyond 1 year, given unpredictable changes in utilization dynamics characteristic of the pharmaceutical market.

For Humalog (insulin lispro), we projected gross spending in November 2023-October 2024 factoring in the list price reduction experienced in January 2024, of approximately 70%.[8] Specifically, we assumed constant utilization as observed in 2022 and applied the list price reduction observed to units representing 10/12 of 2022 utilization (as 10 months of 2024 will be used in the estimation of gross spending figures used to rank drug products). The remaining 2/12 of units were not adjusted by price, as list prices in 2023 were the same as those of 2022. List price adjustments were performed at the formulation level (70% list price reduction for all formulations except for Humalog Kwikpen U-200, which kept constant price, and Humalog vial, which had a list price decrease of 76% in comparison with 2022).

We ranked all Part D products by projected spending in 2023 (with the exception of Humalog), aggregating multiple formulations of the same active moiety produced by the same manufacturer under a single product in accordance with CMS guidance. We then extracted from the FDA website the type of application (new drug application or biologic license application) and the drug approval date. These data were used to estimate whether a drug qualified for negotiation based on years since approval, categorizing as ineligible small molecules marketed for less than 7 years and biologic products for less than 11 years. For the remaining list, we extracted indications from the FDA-approved label to identify whether any drug had a single orphan indication, which would disqualify them from negotiation. We determined whether there were any generic or biosimilar version approved for the active moiety, excluding authorized generics. For approved generic or biosimilar products, we evaluated whether or not they were marketed and regularly and consistently available for purchase by pharmacies using drug wholesaler data. Finally, we used 2022 Part D spending data to evaluate whether any product met the following criteria required to be eligible for the small biotech exception: (1) the drug's Part D expenditure is less than or equal to 1% of total Part D expenditure and

TABLE 1 Drugs Anticipated to be Selected for Medicare Price Negotiation in 2025

Rank	Brand name	Generic name	Manufacturer	Therapeutic area	Gross Part D spending in 2022	Projected gross Part D spending[a]	Time since approval as of 2/2025[b]
1	Ozempic, Rybelsus & Wegovy[c]	Semaglutide	Novo Nordisk	T2DM	$5,603,055,114	$7,476,655,091	7 yrs 1 mo
2	Trelegy Ellipta	Fluticasone/ umeclidinium/ vilanterol	GlaxoSmithKline	COPD	$3,340,110,326	$4,259,329,331	7 yrs 4 mos
3	Xtandi	Enzalutamide	Astellas Pharma Inc.	Prostate cancer	$2,436,795,703	$2,740,436,348	12 yrs 5 mos
4	Ofev	Nintedanib	Boehringer Ingelheim	Lung diseases	$1,762,963,783	$2,077,308,575	10 yrs 3 mos
5	Pomalyst	Pomalidomide	Bristol Myers Squibb	Blood cancers	$1,743,892,720	$1,887,642,864	11 yrs 11 mos
6	Ibrance	Palbociclib	Pfizer Inc.	Breast cancer	$1,948,323,854	$1,822,279,057	9 yrs 11 mos
7	Linzess	Linaclotide	AbbVie Inc.	Gastrointestinal disorders	$1,581,669,987	$1,804,032,885	12 yrs 5 mos
8	Calquence	Acalabrutinb	AstraZeneca	Blood cancers	$1,192,914,435	$1,615,471,380	7 yrs 3 mos
9	Creon	Pancrelipase	AbbVie Inc.	Pancreatic insufficiency	$1,310,801,528	$1,478,112,273	15 yrs 9 mos
10	Breo Ellipta	Fluticasone / vilanterol	GlaxoSmithKline	COPD	$1,427,824,950	$1,408,763,895	11 yrs 8 mos
11	Tradjenta	Linagliptin	Boehringer Ingelheim	T2DM	$1,326,573,079	$1,349,012,342	13 yrs 8 mos
12	Janumet	Metformin/ sitagliptin	Merck and Co., Inc.	T2DM	$1,212,934,060	$1,246,237,036	17 yrs 10 mos
13	Austedo	Deutetrabenazine	Teva Pharmaceuticals	Neurological diseases	$890,369,750	$1,055,519,879	7 yrs 9 mos

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(2) Part D spending was more than or equal to 80% of the manufacturer's total sales.

After excluding ineligible drugs, we identified the top 13 products ranked by projected Part D spending in 2023. We also identified 7 additional drugs that may be eligible for selection to complete the list of 15 products, acknowledging uncertainty surrounding the predictions of gross spending. For these 20 products, we present brand name, generic name, manufacturer, therapeutic area, years since approval, 2022 Part D gross spending, and 2023 projected gross spending. We list noneligible products with comparable or higher levels of Part D gross spending projected in 2023 as well as the reasons why we believe they are ineligible for selection.

Results

We identified 13 Part D products that meet the statutory negotiation eligibility criteria for selection in 2025. Each of the products had projected gross expending in 2023 of more than $1 billion. This list includes the following 4 anticancer therapies: Xtandi (enzalutamide), Pomalyst (pomalidomide), Ibrance (palbociclib), and Calquence (acalabrutinib); 3 noninsulin antidiabetic agents: Ozempic/Rybelsus/Wegovy (semaglutide),Tradjenta(linagliptin),andJanumet(metformin/sitagliptin); 2 inhalers: Trelegy Ellipta (fluticasone/umeclidinium/vilanterol) and Breo Ellipta (fluticasone/vilanterol); 1 tyrosine kinase inhibitor indicated in lung disease: Ofev (nintedanib); 1 gastrointestinal agent: Linzess (linaclotide); 1 enzyme replacement therapy: Creon (pancrelipase); and a product indicated in dyskinesia: Austedo (deutetrabenazine) (Table 1).

We identified an additional 7 drugs that are candidates to complete the list of 15. These included the noninsulin antidiabetic product Victoza (liraglutide), anticancer agent Tagrisso (osimertinib), the insulin product Humalog (insulin lispro), the antibiotic Xifaxan (rifaximin), the antiviral Epclusa (sofosbuvir/velpatasvir), the anti-inflammatory Xeljanz (tofacitinib), and the anticancer drug Venclexta (venetoclax) (Table 1).

TABLE 1 Drugs Anticipated to be Selected for Medicare Price Negotiation in 2025 (*continued*)

Rank	Brand name	Generic name	Manufacturer	Therapeutic area	Gross Part D spending in 2022	Projected gross Part D spending[a]	Time since approval as of 2/2025[b]
Drugs with uncertain negotiation status							
	Victoza[d]	Liraglutide	Novo Nordisk	T2DM	$ 1,557,800,382	$1,399,269,640	15 yrs 0 mos
	Tagrisso[e]	Osimertinib	AstraZeneca	NSCLC	$1,081,280,466	$1,217,143,163	9 yrs 2 mos
	Xifaxan[f,g]	Rifaximin	Salix Pharmaceuticals	Antibacterial	$969,541,694	$1,026,447,056	20 yrs 8 mos
	Humalog[f,h]	Insulin lispro	Eli Lilly and Co	DM	$2,067,729,284	$954,335,188	28 yrs 7 mos
	Epclusa[f]	Sofosbuvir/ velpatasvir	Gilead Sciences	Hepatitis c	$899,944,724	$934,777,002	8 yrs 7 mos
	Xeljanz[f]	Tofacitinib	Pfizer Inc.	Immunological diseases	$886,548,263	$901,642,064	12 yrs 2 mos
	Venclexta[f]	Venetoclax	AbbVie Inc.	Blood cancers	$767,860,286	$876,884,918	8 yrs 9 mos

[a]*We projected 2023 gross spending for all products except for Humalog using a linear regression and 2020 to 2022 Part D gross spending data. Estimates for Humalog represent projected November 2023-October 2024 spending based on the list price reduction effective January 1, 2024.*

[b]*Calculated as the time between drug approval and February 1, 2025.*

[c]*We expect that Ozempic, Rybelsus, and Wegovy will be considered a single product for negotiation, as they contain the same active moiety, semaglutide, and are manufactured by the same firm. Spending estimates listed include the combination of Ozempic and Rybelsus, as Wegovy was not covered by Medicare Part D in 2022 (this is because weight-loss drugs are excluded from Part D coverage by statute). It is likely, however, that some Part D plans will cover Wegovy after its approval for cardiovascular risk reduction.*

[d]*Selection for negotiation will depend on the potential launch of independent generics before February 2025.*

[e]*Tagrisso may be eligible for the orphan drug exclusion, as discussed in the text.*

[f]*The projected gross Part D spending estimates for Xifaxan, Humalog, Epclusa, Xeljanz, and Venclexta are within a close range. The selection of the final product for negotiation will depend on spending trends in 2022-2024 as well as whether Victoza and Tagrisso are eligible for negotiation. As a result, we identify these products as candidates to complete the list of 15 eligible for selection. Final selection will be based on actual spending trends in November 2023-October 2024, which we are not able to observe as recent data are not publicly available.*

[g]*The manufacturer of Xifaxan is Salix Pharmaceuticals, and Xifaxan represents more than 90% of Part D spending for Salix Pharmaceuticals in 2022. For this reason, Xifaxan could qualify for the small biotech exception. However, Salix Pharmaceuticals is a subsidiary of Bausch Health Companies. According to the Inflation Reduction Act, manufacturers with subsidiaries will be treated as a single company as long as they are a single employer under the Internal Revenue Code, which we are not capable of evaluating.*

[h]*Humalog experienced list price decreases on January 1, 2024, of around 70%. We accounted for them in projecting gross spending in November 2023-October 2024, the months of data that will be used by CMS for drug selection. We assumed constant utilization as observed in 2022 and applied the list price reduction effective January 1, 2024, to units representing 10/12s of utilization. The remaining 2/12 of units were not adjusted by price, as list prices in 2023 were the same as those of 2022. List price adjustments were performed at the formulation level (70% list price reduction for all formulations except for Humalog Kwikpen U-200, which kept constant price, and Humalog vial, which had a list price decrease of 76% in comparison with 2022).*

CMS = Centers for Medicare and Medicaid Services; COPD = chronic obstructive pulmonary disease; DM = diabetes mellitus; mos = months; NSCLC = nonsmall cell lung cancer; T2DM = type 2 diabetes mellitus; yrs = years.

Two products (Victoza [liraglutide] and Tagrisso [Osimertinib]) would be selected for negotiation based on projected spending, but their selection remains uncertain given the timing of entry of generic competition and potential eligibility for the orphan drug exclusion, respectively. Victoza (liraglutide) currently has an authorized generic marketed, which does not exclude it from being selected for negotiation, but it is unclear whether the potential launch of independent generics before February 2025 might disqualify this drug from negotiation. Tagrisso (osimertinib) has an orphan drug designation with 4 separate indications, all of which fall within the same solid tumor disease state (specific mutations within nonsmall lung cancer). We believe that CMS will likely consider Tagrisso to meet the orphan drug exclusion and therefore, not be selected. The eligibility of Humalog (insulin lispro) for negotiation depends on the potential approval and commercialization of a biosimilar under review by the FDA.[9] It should be noted that, although there is a competitor insulin lispro available in the market (Admelog), this product does not disqualify Humalog from negotiation as it was approved through the 505(b)(2) pathway.[10] Finally, the remaining 4 drugs in the uncertain category had projected spending between $877 million and $1.026 billion and may be eligible for selection based on updated spending data through October 2024.

TABLE 2 Drugs Not Eligible for 2025 Selection for Medicare Drug Price Negotiation

Rank	Brand name	Generic name	Manufacturer	Gross Part D spending in 2022	Reason for ineligibility
1	Trulicity	Dulaglutide	Eli Lilly and Co.	$6,225,291,668	Not eligible for selection until 2028 because of years since approval
2	Revlimid	Lenalidomide	Bristol Myers Squibb	$5,935,051,092	Generic approved and marketed
3	Humira	Adalimumab	AbbVie Inc.	$5,426,379,715	Biosimilar approved and marketed
4	Lantus/Toujeo	Insulin glargine	Sanofi	$4,568,969,345	Biosimilar approved and marketed
5	Biktarvy	Bictegravir/emtricitabine/ tenofovir	Gilead Sciences	$2,703,581,195	Not eligible for selection until 2028 because of years since approval
6	Myrbetriq	Mirabegron	Astellas Pharma Inc.	$2,252,501,068	Generic approved and marketed
7	Invega	Paliperidone	Janssen Pharmaceuticals	$2,187,077,811	Generic approved and marketed
8	Jakafi	Ruxolitinib	Incyte Corp	$1,756,404,369	Will likely meet small biotech exception
9	Symbicort	Budesonide/formoterol	AstraZeneca	$1,964,824,955	Generic approved and marketed
10	Restasis	Cyclosporine	AbbVie Inc.	$1,722,821,911	Generic approved and marketed
11	Tresiba	Insulin degludec	Novo Nordisk	$1,697,272,112	Not eligible for selection until 2029 because of years since approval
12	Spiriva	Tiotropium	Boehringer Ingelheim	$1,827,052,606	Generic approved and marketed
13	Levemir	Insulin detemir	Novo Nordisk	$1,727,938,074	Expected to be discontinued by the end of 2024
14	Latuda	Lurasidone hydrochloride	Sunovion Pharmaceuticals	$1,448,475,890	Generic approved and marketed
15	Ingrezza	Valbenazine	Neurocrine	$1,272,808,746	Will likely meet small biotech exception
16	Dupixent	Dupilumab	Regeneron Pharmaceutical	$1,078,090,038	Not eligible for selection until 2031 because of years since approval
17	Advair	Fluticasone/salmeterol	GlaxoSmithKline	$1,332,142,779	Generic approved and marketed
18	Cabometyx	Cabozantinib	Exelixis, Inc.	$919,262,057	Will likely meet small biotech exception
19	Cosentyx	Secukinumab	Novartis	$1,029,748,131	Not eligible for selection until 2029 because of years since approval
20	Repatha	Evolocumab	Amgen	$906,530,692	Not eligible for selection until 2029 because of years since approval
21	Vyndamax	Tafamidis	Pfizer Inc.	$845,100,487	Not eligible for selection until 2029 because of years since approval
22	Erleada	Apalutamide	Janssen Pharmaceuticals	$877,671,428	Not eligible for selection until 2028 because of years since approval

The list includes products with projected gross spending in 2023 above $1 billion that do not qualify for selection in 2025. Products selected for negotiation in 2023 are not listed.

We identified 22 drugs with comparable levels of spending (projected 2023 Part D spending of more than $1 billion) that were not eligible for selection (Table 2). Of these, 10 currently have a generic or biosimilar approved and marketed. Eight drugs were considered ineligible as they had not met the minimum number of years since approval. Of these, Trulicity (dulaglutide), Biktarvy (bictegravir/emtricitabine/tenofovir), and Erleada (apalutamide) will be eligible for selection in the following round. Based on 2022 spending data, 3 drugs qualify for the small biotech exception, including Jakafi (ruxolitinib), Ingrezza (valbenazine), and Cabometyx (cabozantinib). Finally, Levemir (insulin detemir) was deemed ineligible as it is expected to be discontinued by the end of 2024.[11]

Discussion

We followed CMS guidance to identify products anticipated to be selected for Medicare price negotiation in 2025, with the MFPs to be implemented in 2027. We identified 13 Part D products likely subject to negotiation, all of which had projected 2023 Part D gross spending greater than $1.0 billion. We further identified 7 additional products with projected gross spending in the $877 million to $1.399 billion range, which are candidates to complete the list of 15 based on recent trends in utilization and pricing. Twenty-two products had comparable levels of spending but were deemed ineligible for selection because of multiple factors, most notably availability of a generic or biosimilar version and insufficient years since approval.

Our analyses represent a refinement of the methodology followed in our prior investigation, which we used 2020 spending data to identify products potentially eligible for selection.[5] In the current analyses, we opted to project 2023 spending databased on the 3 most recent years in order to anticipate potential changes in the rank order of products based on utilization and pricing trends. CMS will use November 2023-October 2024 spending data (unavailable to researchers) to rank gross spending.[7] We followed an approach with available data to conservatively estimate mid-term changes in utilization acknowledging the dynamic nature of the pharmaceutical market. The insulin product Humalog represented an exceptional case because of its marked list price reduction in 2024, which we factored in analyses.

LIMITATIONS

Although we believe that our refined methodology more accurately identifies drugs that will be selected for negotiation in 2025, we acknowledge uncertainty related to trends in 2023-2024 spending, marketing of generic and biosimilar versions, and eligibility for the small biotech exception. In recognition of these sources of uncertainty, we identified 7 candidates to complete the list of 15 products. We hope the identification of these candidate products is helpful to inform patients, payers, manufacturers, and policymakers of the list of products potentially subject to negotiation beginning in 2025.

According to CMS guidance, products containing the same active moiety and manufactured by the same sponsor will be considered a single drug for negotiation. For this reason, we expect that all 3 branded products for semaglutide manufactured by Novo Nordisk (Ozempic, Rybelsus, and Wegovy) will be considered a single drug, as they represent different formulations of the same active moiety. Importantly, spending figures for semaglutide listed in Table 1 represent the summation of projections for Ozempic as Rybelsus. Wegovy spending estimates were not factored, as this product was not eligible for coverage in Medicare Part D until its recent approval for cardiovascular risk reduction.[12] Beyond the lack of inclusion of Wegovy, it is likely that our projected spending figures for semaglutide is underestimated, as our methodology relies on linear trends that may not fully capture the exponential uptake of semaglutide in recent years with its new indications.[13]

We observed a remarkably large number of products with comparable or higher levels of gross Part D spending that did not meet statutory criteria for selection for multiple reasons. Most notably, 10 products were deemed ineligible for selection because of the availability of a generic or biosimilar version. Some of these represent products that have generic versions but only for specific individual formulations, which disqualify all formulations. For instance, Invega (paliperidone) is ineligible because there is a generic version of its tablet formulation, which only accounts for $25.7 million or less than 1.2% of gross sales. Accounting for more than 98% of sales and more than $2 billion in gross spending, the suspension formulations of Invega (Invega Sustenna, Hafyera, and Trinza) do not have generic competition, yet they are ineligible for selection because of the formulation loophole described by Vogel and colleagues.[14] In other cases, products ineligible for selection because of generic/biosimilar competition remained at the top of the spending rank because of entry of generic/biosimilar products or market dynamics in the biosimilar Part D market, in which originator biologics are able to hold to a substantial share of the market after biosimilar entry.[15,16]

In some instances, observations of drugs ineligible for selection with spending considerably above the threshold may be the result of the use of 2022 data. For example, Revlimid (lenalidomide) had gross spending of $5.9 billion in 2022, but this will likely decrease after generic versions entered the market throughout 2022. In others, however, the ineligibility of top-spending products could simply present another IRA formulation problem. It is likely, for example, that Humira (adalimumab) retains a sufficient share of the adalimumab market to continue ranking well above the spending threshold. This is a reflection of the unique dynamics of the self-administered biologic-biosimilar market, whereby originator biologics are able to hold a larger share of the market as compared with branded small molecules.[15,16] One could argue that the lack of recognition of these dynamics by Congress may limit the ability to generate savings, as drugs with gross spending levels above the threshold for negotiation are not

eligible for selection because of this design consideration. Importantly, the ability to generate real savings is related to net and not gross spending—the ultimate miscalculation in IRA criteria for drug selection. Given that competition between originator biologics and biosimilars for formulary placement occurs in the rebate space,[17-19] it is expected that originator biologics with biosimilar versions have a relatively large gross-to-net spread.[20] Therefore, CMS's ability to extract savings for blockbuster biosimilars with biosimilar competition may be more limited than suggested by misleading gross spending figures. The ultimate answer to this question—whether CMS would be able to extract greater savings if biologic products remained eligible for selection beyond biosimilar entry—is contingent on differences in net spending and potential for savings between biologic products with biosimilar competition and products with lower gross spending levels that currently complete the negotiation list instead. A legislative revision to IRA statutory criteria that based drug selection on net spending, independent of biosimilar/generic availability, would be able to overcome these shortcomings.

Conclusions

We followed CMS guidance to identify products anticipated to be selected for Medicare price negotiation in 2025, with the MFPs to be implemented in 2027. We identified 13 Part D products likely subject to negotiation, all of which had projected 2023 Part D gross spending greater than $1.0 billion. We further identified 7 additional products with projected gross spending in the $877 million to $1.399 billion range, which are candidates to complete the list of 15 based on recent trends in utilization and pricing. Twenty-two products had projected Part D gross spending greater than $1.0 billion but were deemed ineligible for selection because of multiple factors. The noneligibility of some of these top-spending products for negotiation may represent new opportunities for IRA redesign.

DISCLOSURES

Dr Sullivan reported receiving consulting fees from Sanofi, Pfizer, Neurocrine, and Novo Nordisk outside the submitted work. Dr Hernandez reported receiving consulting fees from Pfizer and Bristol Myers Squibb outside the submitted work.

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