

### Study Summary

**Study Question:** Which high expenditure, single source drugs will CMS be likely to target as part of the Medicare Drug Price Negotiation Program?

**Study Summary:** Administrative claims data from the Merative™ MarketScan® Medicare Database comprising enrollees in employer-sponsored Medicare Supplemental and Advantage plans was analyzed during the one-year period 10/1/2020-9/31/2021. After applying waiver and exception criteria that CMS has published in conjunction with the program guidance, the drugs deemed most likely to be targeted are:

#### Results:

Rank	Brand Name	Manufacturer
1	Eliquis®	Bristol Myers Squibb
2	Humira®	AbbVie Inc.
3	Xarelto®	Janssen Pharmaceuticals
4	Trulicity®	Eli Lilly & Co.
5	Januvia®	Merck & Co.
6	Imbruvica	Pharmacyclics LLC, an AbbVie Company
7	Xtandi	Astellas Pharma Inc.
8	Jardiance	Boehringer Ingelheim
9	Enbrel Sureclick	Amgen Inc.
10	Spiriva	Boehringer Ingelheim

**Conclusion:** These cost analyses support price negotiation and planning initiatives by drug manufacturers likely to be affected by CMS's initial target list that will be published by September 1, 2023.

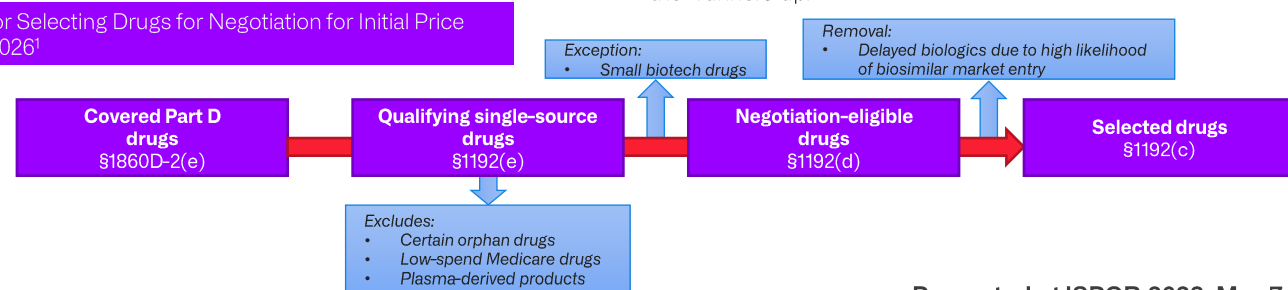
### Background

- The Inflation Reduction Act (IRA) (P.L. 117-169) was signed into law in August 2022 and established the Medicare Drug Price Negotiation Program.
- By September 1, 2023, CMS will announce the first 10 Medicare Part D drugs selected for the Negotiation Program.
- "Maximum fair prices" negotiated for these highest-expenditure drugs will go into effect in 2026.

### Objective

- As a sneak peek at what may happen, this analysis used Medicare claims data to rank and predict the drugs that CMS may target.

Figure 1. Process for Selecting Drugs for Negotiation for Initial Price Applicability Year 2026<sup>1</sup>



### Methods

#### Study Design and Data Source

- Administrative claims data from the Merative™ MarketScan® Medicare Database (comprising enrollees in employer-sponsored Medicare Supplemental and Advantage plans) during the latest one-year period of available data (10/1/2020-9/31/2021) were analyzed using the Treatment Pathways tool.
- This was a retrospective analysis of total Medicare spend on drugs over a one-year period, broken down by drug, to identify the drugs with the highest spend.

#### Outcomes

- Total expenditures on Medicare Part D drugs were calculated by summing the total payments on patient pharmacy claims for each drug. The number of unique users of each drug was also recorded.
- An initial list of high spend drugs was identified by applying the qualifying drug criteria as stated in the initial guidance.<sup>1</sup> These abbreviated criteria include:
  - For drug products, the drug must be considered single source and have been approved for at least 7 years as of September 1, 2023.
  - For biologic products, the biologic must be considered single source and have been approved for at least 11 years as of September 1, 2023.
  - All dosage forms and strengths with the same active ingredient and covered under the same New Drug Application will be considered as one product.
  - Authorized generic drugs will be treated as the same drug.
- The list of high spend drugs was pruned by applying the waiver and exception criteria CMS intends to use in the selection process as stated in the initial guidance.<sup>1</sup> These abbreviated exclusion criteria include:
  - Orphan drugs that are approved for only one rare disease or condition.
  - Low spend drugs with Medicare Part B and D spend less than \$200M annually.
  - Plasma derived biologic products.
  - Drugs from small biotech companies where the drug under consideration accounts for at least 80% of total Medicare spend on products from that biotech company.
  - Biologic products with a high likelihood of biosimilars entering the market in the near term.
  - A final projected list of 20 drugs was formed and ranked in order by highest total expenditure in the recent 1-year time period. The first 10 drugs were deemed the most likely to be targeted by CMS for price negotiation and the remaining 10 drugs were considered the "runners-up."

### Results

Table 1. Medicare Part D Drugs Likely to be Targeted By CMS for Price Negotiation for 2026

Rank <sup>a</sup>	Brand Name	Generic Name	Manufacturer	Mean Payment <sup>b</sup>	Unique Patients <sup>b</sup>	Annual Total Spend <sup>b</sup>
1	Eliquis®	apixaban	Bristol Myers Squibb; Pfizer	\$ 4,088	59,828	\$ 244,555,326
2	Humira®	adalimumab	AbbVie Inc.	\$ 61,700	1,816	\$ 112,047,146
3	Xarelto®	rivaroxaban	Janssen Pharmaceuticals	\$ 4,211	20,849	\$ 87,793,888
4	Trulicity®	dulaglutide	Eli Lilly & Co.	\$ 7,220	11,793	\$ 85,139,681
5	Januvia®	sitagliptin phosphate	Merck & Co.	\$ 4,312	19,277	\$ 83,126,858
6	Imbruvica®	ibrutinib	Pharmacyclics LLC, an AbbVie Company	\$ 129,829	566	\$ 73,482,988
7	Xtandi®	enzalutamide	Astellas Pharma Inc.	\$ 84,200	709	\$ 59,697,793
8	Jardiance®	empagliflozin	Boehringer Ingelheim	\$ 4,067	12,734	\$ 51,790,833
9	Enbrel® Sureclick	etanercept	Amgen Inc.	\$ 56,384	897	\$ 50,576,367
10	Spiriva®	tiotropium bromide	Boehringer Ingelheim	\$ 3,216	13,213	\$ 42,487,591

Table 2. Runners-Up List of Medicare Part D Drugs that CMS May Target for 2026 or Subsequent Year

Rank <sup>a</sup>	Brand Name	Generic Name	Manufacturer	Mean Payment <sup>b</sup>	Unique Patients <sup>b</sup>	Annual Total Spend <sup>b</sup>
11	Ibrance®	palbociclib	Pfizer Inc.	\$ 108,433	361	\$ 39,144,151
12	Myrbetriq®	mirabegron	Astellas Pharma Inc.	\$ 2,731	11,806	\$ 32,247,971
13	Ofev®	nintedanib esylate	Boehringer Ingelheim	\$ 80,447	371	\$ 29,845,707
14	Victoza®	liraglutide	Novo Nordisk Inc.	\$ 7,239	3,830	\$ 27,725,638
15	Pomalyst®	pomalidomide	Bristol Myers Squibb	\$ 124,001	210	\$ 26,040,302
16	Levemir® Flextouch	insulin detemir	Novo Nordisk Inc.	\$ 3,960	6,095	\$ 24,138,394
17	Entresto®	sacubitril/valsartan	Novartis AG	\$ 4,321	5,529	\$ 23,893,518
18	Tradjenta®	linagliptin	Boehringer Ingelheim	\$ 3,767	2,802	\$ 10,554,349
19	Linzess®	linaclotide	Allergan, an AbbVie Company	\$ 2,290	4,504	\$ 10,313,665
20	Invega Sustenna®	paliperidone palmitate	Janssen Pharmaceuticals	\$ 16,095	64	\$ 1,030,108

<sup>a</sup>Rank is in regard to Medicare spend in Treatment Pathways, drugs pulled from CMS to spend list and filtered based on the IRA criteria

<sup>b</sup>Treatment pathways payment, number of unique patients, and spend come from 10/1/2020 to 9/31/2021 to include most recent, non-early view data

### Limitations

- This study is subject to limitations common to all retrospective administrative claims studies.
- MarketScan Medicare Database only contains the claims data from employer-sponsored Medicare Supplemental and Advantage plans which are a subset of all Medicare patients and may not be representative of all Medicare patients.

### Conclusions

- These cost analyses support price negotiation planning initiatives by drug manufacturers likely to be affected by CMS's initial target list for the Medicare Drug Price Negotiation Program.
- Medicare Advantage and Supplemental plan enrollees represent a subset of all Medicare patients and future comparisons of drug spending before and after CMS price controls will benefit from this preliminary evidence.

### References

- Medicare Drug Price Negotiation Program Initial Guidance: <https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-initial-guidance.pdf>

### Disclosure

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