

# -Inflation Reduction Act Research Series-Medicare Enrollees' Use and Out-of-Pocket Expenditures for Drugs Selected for Negotiation under the Medicare Drug Price Negotiation Program

Medicare enrollees taking the 10 drugs covered under Part D selected for negotiation for initial price applicability year 2026 paid a total of \$3.4 billion in out-of-pocket costs in 2022 for these drugs. Average annual out-of-pocket costs per enrollee taking these drugs ranged from a high of \$5,247 per enrollee for Imbruvica to a low of \$121 per enrollee for NovoLog in 2022. Among enrollees who do not receive financial assistance, average annual out-of-pocket costs ranged from a high of \$6,497 per enrollee for Imbruvica to a low of \$261 per enrollee for NovoLog.

# **KEY POINTS**

- The Inflation Reduction Act (IRA) authorizes the Secretary of the Department of Health and Human Services (HHS) to negotiate prices directly with participating manufacturers for selected drugs that have high total spending and are high expenditure, single source drugs without generic or biosimilar competition. Negotiations with participating manufacturers for the first group of selected drugs for initial price applicability year 2026 begin in 2023, with negotiated maximum fair prices going into effect in 2026.
- The 10 drugs covered under Part D selected for negotiation for initial price applicability year 2026 are: Eliquis, Jardiance, Xarelto, Januvia, Farxiga, Entresto, Enbrel, Imbruvica, Stelara, and NovoLog.\* Millions of Medicare enrollees take one or more of these drugs to treat serious conditions such as blood clots, diabetes, cardiovascular disease, heart failure, autoimmune diseases, and chronic kidney disease.
- This Fact Sheet provides descriptive information on the use and out-of-pocket spending in **calendar year 2022**<sup>+</sup> for each of the 10 drugs selected for negotiation for initial price applicability

<sup>&</sup>lt;sup>\*</sup> The complete drug name is NovoLog; NovoLog FlexPen; NovoLog PenFill, Fiasp, Fiasp FlexTouch; Fiasp PenFill.

<sup>&</sup>lt;sup>+</sup> As a general practice, ASPE examines calendar year use and spending for Medicare drug-related analyses. Using calendar year data for this Fact Sheet allows the use and out-of-pocket spending estimates for the 10 drugs to be comparable to other ASPE reports where the data is also reported on a calendar year basis. This is different from the use and spending timeframe that is required to determine qualifying selected drugs under the IRA. Use and spending data reported by CMS for the 10 drugs selected for initial price applicability year 2026 are for June 1, 2022 through May 31, 2023 as required by the IRA.

year 2026 under the Medicare Drug Price Negotiation Program.<sup>‡</sup> We examined the use of these 10 drugs and out-of-pocket spending on them for Medicare Part D enrollees overall, by low-income subsidy (LIS) status, <sup>§</sup> by demographic characteristics, and by state of residence.

- Results indicate that in 2022, about 9 million Part D enrollees used the 10 drugs selected for initial price applicability year 2026, with the highest number of enrollees taking Eliquis (3.5 million), followed by Jardiance (1.3 million), and Xarelto (1.3 million). The estimate for the total number of enrollees taking the 10 selected drugs may include some enrollees *more than once* if they took more than one of the selected drugs in 2022.
- Among enrollees who do not receive LIS, the average annual out-of-pocket spending ranged from a high of \$6,497 per enrollee taking Imbruvica to a low of \$261 per enrollee taking NovoLog in 2022. Out-of-pocket costs were much lower for LIS enrollees, ranging from a high of \$187 per enrollee taking Imbruvica to a low of \$14 per enrollee taking NovoLog.
- Overall, the distribution of Medicare enrollees taking each of the 10 drugs by demographic characteristics follows the general distribution of demographic characteristics among the Medicare Part D population in 2022, with certain exceptions.
- Demographic differences in the share of enrollees taking each drug reflect a variety of factors, including but not limited to differences in risk factors for certain health conditions (e.g., women are at higher risk for rheumatoid arthritis), comorbidities, and access to health care for demographic groups.
  - Jardiance, Farxiga, Entresto, and Imbruvica have a greater proportion of use by men compared to their representation in the Part D population and a much larger share of women take Enbrel than men. Enrollees under the age of 65 make up a much larger share of users for Stelara, Enbrel, and NovoLog compared to this age group's representation in the Medicare Part D population.
  - For Januvia, Farxiga, Entresto, and NovoLog, the share of Black enrollees using each drug is relatively higher compared to Black enrollees' representation in the Part D population.
- Average annual out-of-pocket spending in 2022 was highest for Imbruvica for enrollees (LIS and non-LIS) residing in North Dakota (\$8,237) followed by the same drug for enrollees residing in Utah (\$8,179).

# BACKGROUND

The Inflation Reduction Act (IRA) makes improvements to Medicare to increase accessibility and affordability of prescription drugs for Medicare enrollees, reduce the rate of growth in Medicare drug spending, and improve the financial sustainability of the Medicare program. About 65 million Americans are enrolled in the Medicare program, of whom about 53 million are enrolled in the Part D prescription drug program.<sup>1,2</sup> Under the IRA, the Secretary of the Department of Health and Human Services (HHS) is authorized to directly negotiate the prices of certain high expenditure, qualifying single source drugs without generic or biosimilar competition with participating manufacturers.<sup>3</sup> Drugs selected for negotiation are those that have high total

<sup>&</sup>lt;sup>‡</sup> The estimates presented in this Fact Sheet were not used to identify the 10 drugs selected for negotiation for initial price applicability year 2026.

<sup>&</sup>lt;sup>§</sup> For eligible enrollees whose income and resources are limited, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 established the Low-Income Subsidy, also known as Extra Help. Subsidies are paid by the Federal government to drug plans and provide assistance with premiums, deductibles, and co-payments. Under the IRA, beginning in 2024, the LIS program is expanded to individuals with limited financial resources and incomes up to 150 percent of the Federal Poverty Limit (FPL), which is about \$21,870 per individual in 2023. For more information, please see <u>here</u>.

Medicare gross expenditures and meet other criteria defined in the legislation and in program guidance issued by the Centers for Medicare & Medicaid Services (CMS), in accordance with the law. \*\*

In 2023, CMS will begin negotiations with participating manufacturers for the first group of drugs selected for negotiation that are covered under Medicare Part D. The law specifies that these negotiations will occur in 2023 and 2024, with the negotiated prices effective beginning in 2026. By September 1, 2024, CMS will publish the maximum fair prices that have been negotiated for these initial selected drugs. In future years, CMS will select for negotiation up to 15 additional drugs covered under Part D for 2027, up to 15 additional drugs for 2028 including drugs covered under Part B and Part D, and up to 20 additional drugs for each year after that, as outlined in the IRA. <sup>4</sup>

Affordability of prescription drugs is a challenge for many Medicare enrollees, with nearly half of all Medicare enrollees estimated to have annual incomes below \$30,000 in 2019.<sup>5,6</sup> About 1.5 million enrollees who do not receive the low-income subsidy (LIS)<sup>++</sup> reached the catastrophic coverage phase of the Part D benefit, paying an average of \$3,100 out-of-pocket for their Part D drugs in 2022.<sup>7</sup> Some enrollees who have specific types of health conditions pay even more out-of-pocket. For example, non-LIS enrollees with cystic fibrosis who reached the catastrophic coverage phase paid an average of nearly \$9,500 for their Part D covered drugs in 2021.<sup>8</sup>

Prices set by drug manufacturers affect how much Medicare spends on prescription drugs as well as out-ofpocket costs paid by enrollees who use the drug. Authorizing the Secretary to negotiate for selected high-cost drugs is one change, among other changes required by the IRA. Examples of other provisions include: limiting cost-sharing for a month's supply of covered insulin products to \$35 a month, removing cost-sharing for recommended adult vaccines covered under Medicare Part D, placing an annual cap on out-of-pocket costs under the Part D program starting at \$2,000 in 2025, and other key provisions collectively designed to make prescription drugs more affordable, improve health outcomes, and reduce costs for enrollees and taxpayers.<sup>‡‡</sup>

Previous ASPE analyses estimated that about 1 in 3 (or 18.7 million) Part D enrollees are projected to save under the IRA's drug related provisions that are in effect in 2025, with average savings of about \$400 per enrollee among this population.<sup>9</sup> This estimate includes the impact of the \$2,000 out-of-pocket cap that begins in 2025 and is indexed to inflation annually thereafter. However, this estimate is for the period before the maximum fair prices negotiated with participating manufacturers take effect in 2026.

The purpose of this Fact Sheet is to examine Medicare Part D enrollees' use and total out-of-pocket spending in calendar year 2022 for each of the 10 drugs selected for negotiation for initial price applicability year 2026 under the IRA.

# **METHODS**

We used Prescription Drug Event (PDE) data and Part D enrollment data to examine prescription drug use and out-of-pocket spending in Medicare Part D in calendar year 2022 for each of the 10 drugs covered under Part D

<sup>\*\*</sup> For complete details on the process of selecting drugs for negotiation for initial price applicability year 2026, please see CMS revised guidance that was released on June 30, 2023, which is available here: <u>Medicare Drug Price Negotiation Program: Revised Guidance</u>, <u>Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026 (cms.gov)</u>.

<sup>&</sup>lt;sup>++</sup> For eligible enrollees whose income and resources are limited, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 established the Low-Income Subsidy, also known as Extra Help. Subsidies are paid by the Federal government to drug plans and provide assistance with premiums, deductibles, and co-payments. Under the IRA, beginning in 2024, the LIS program is expanded to individuals with limited financial resources and incomes up to 150 percent of the Federal Poverty Limit (FPL), which is about \$21,870 per individual in 2023. For more information, please see here.

<sup>&</sup>lt;sup>‡‡</sup> For a full list of IRA drug related provisions, please see: Inflation Reduction Act Timeline (cms.gov).

selected for negotiation for initial price applicability year 2026. For the purposes of this Fact Sheet, out-ofpocket spending is based on the actual enrollee payment and does not include any third-party payments or rebates. We examined prescription drug use and out-of-pocket spending for each of the 10 drugs for all Part D enrollees and separately by whether an enrollee receives the LIS. We present estimates separately for LIS and non-LIS enrollees because non-LIS enrollees, who make up about 72 percent of the program's enrollment, have higher out-of-pocket costs than enrollees who receive LIS.<sup>10</sup> We also examined the demographic characteristics of enrollees who used each of the selected drugs in calendar year 2022.

We constructed use and out-of-pocket spending estimates for each of the selected drugs by following CMS' approach for identifying each drug. That is, we identified each drug based on the active moiety/active ingredient and the holder of the marketing application and used National Drug Codes (NDCs) to identify these drugs in the PDE data. <sup>§§</sup> Consistent with CMS guidance, the NDCs for drugs with the same active moiety/active ingredient and the same primary manufacturer are considered a single drug, so Part D use and spending estimates for these NDCs are summed. The NDCs for drugs that have the same active moiety/active ingredient but different marketing application holders are considered distinct drugs so Part D use and spending estimates for these drugs are reported separately.

Our approach to analyzing use and spending for the 10 selected drugs for initial price applicability year 2026 is different from CMS: we examine use and out-of-pocket spending for the full 2022 calendar year whereas CMS, as required by the IRA, examines use and total gross drug spending from June 1, 2022 through May 31, 2023. Thus, differences between the estimates presented in this Fact Sheet and the figures reported by CMS reflect differences in the time periods examined for the analyses.

### **FINDINGS**

### Use and Spending of Drugs Selected for Negotiations

Table 1 presents the 10 drugs covered under Part D selected for negotiation for 2026 and the commonly treated conditions for these drugs along with the number of enrollees taking each drug in 2022, overall and separately by LIS and non-LIS status.

These drugs are indicated for treatment of various acute and chronic health conditions. As shown in Table 1, these conditions include blood clots (treated by Eliquis and Xarelto), diabetes (treated by Jardiance, Farxiga, Januvia, and NovoLog), heart failure (treated by Entresto, Jardiance and Farxiga), coronary or peripheral artery disease (treated by Farxiga), chronic kidney disease (treated by Farxiga), rheumatoid arthritis (treated by Enbrel), psoriasis (treated by Enbrel and Stelara), blood cancers (treated by Imbruvica), and Crohn's disease and ulcerative colitis (treated by Stelara). These conditions do not represent the complete list of health conditions that are treated by each of these drugs.

The drugs selected for negotiation are approved by the FDA to treat serious health conditions that are prevalent among the Medicare population. For example, Medicare enrollees are at higher risk of blood clots due to age and other comorbidities present among this population.<sup>11</sup> Existing data shows that among the traditional Medicare population, about 1 in 10 Medicare enrollees have heart conditions that put them at risk for blood clots.<sup>12</sup> Moreover, about 28 percent of Medicare enrollees have diabetes, which also increases individuals' risk for heart disease and stroke.<sup>13,14</sup> About 27 percent of enrollees have coronary heart disease and 15 percent have been diagnosed with heart failure.<sup>15,16</sup> Additionally, about 1 in 4 enrollees have chronic

<sup>§§</sup> For a complete description of how CMS defines a drug and the drug aggregation policy, please see Section 30 of the CMS revised guidance, which is available here: <u>Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 –</u> <u>1198 of the Social Security Act for Initial Price Applicability Year 2026 (cms.gov)</u>.

kidney disease, which has been increasing over time among Medicare enrollees, with an increase of about 10 percentage points between 2012 and 2020.<sup>17</sup>

Overall, Eliquis (3.5 million), Jardiance (1.3 million), and Xarelto (1.3 million) have the highest number of Medicare Part D enrollees who used each drug in 2022. Altogether, about 9 million enrollees in 2022 used the 10 drugs selected for negotiation for initial price applicability year 2026. However, this estimate does not represent unduplicated counts of enrollees because there may be some enrollees who used more than one of the 10 selected drugs.<sup>\*\*\*</sup> Additionally, the drug use estimates include all Part D enrollees who used each drug in 2022; they are not limited to enrollees taking each drug for only the conditions shown in Table 1, as some enrollees may have used a drug for conditions not listed below.

Drug Name	Commonly Treated Conditions	Total Number of Medicare Part D Enrollees Taking the Drug in CY2022ª					
		LIS	Non-LIS	Total			
Eliquis	Prevention and treatment of	1,013,000	2,492,000	3,505,000			
	blood clots						
Jardiance	Diabetes; Heart failure	562,000	759,000	1,321,000			
Xarelto	Prevention and treatment of	370,000	941,000	1,311,000			
	blood clots; Reduction of risk for						
	patients with coronary or						
	peripheral artery disease						
Januvia	Diabetes	426,000	459,000	885,000			
Farxiga	Diabetes; Heart failure; Chronic	280,000	359,000	639,000			
	kidney disease						
Entresto	Heart failure	203,000	318,000	521,000			
Enbrel	Rheumatoid arthritis; Psoriasis;	26,000	21,000	47,000			
	Psoriatic arthritis						
Imbruvica	Blood cancers	4,000	18,000	22,000			
Stelara	Psoriasis; Psoriatic arthritis;	10,000	10,000	20,000			
	Crohn's disease; Ulcerative colitis						
NovoLog; NovoLog	Diabetes	431,000	332,000	763,000			
FlexPen; NovoLog							
PenFill; Fiasp; Fiasp							
FlexTouch; Fiasp PenFill							

# Table 1. Medicare Part D Enrollees' Calendar Year 2022 Use of Drugs Selected for Negotiation for Initial Price Applicability Year 2026

Source: ASPE analysis of 2022 Medicare Prescription Drug Event data and Part D Enrollment Data.

Notes: Drugs are identified using NDCs, with aggregation of NDCs for each drug consistent with CMS approach for identifying each drug. ASPE estimates may differ from drug use figures reported by CMS due to differences in the time period that is examined.

<sup>a</sup>The drug use estimates are for all Part D enrollees using the drug and not limited to those using the drug for the conditions shown in this Table.

<sup>\*\*\*</sup> CMS examined use and total gross spending for the drugs selected for negotiation for price applicability year 2026 for the time period required by the IRA. CMS reports that there are 8.2 million unique enrollees taking these drugs from June 1, 2022 through May 31, 2023.

# \$3.4 billion

Spent in 2022 in out-ofpocket costs across 9 million Part D enrollees taking drugs selected for negotiation Table 2 presents out-of-pocket spending in 2022 for each Part D drug selected for negotiation for 2026, for LIS and non-LIS enrollees. As expected, enrollees receiving LIS had lower out-of-pocket payments for each drug compared to enrollees not receiving LIS. Average out-of-pocket spending for each drug among LIS enrollees ranged from a high of \$187 for Imbruvica to a low of \$14 for NovoLog<sup>+++</sup> among enrollees taking the drug.

Among non-LIS enrollees, out-of-pocket costs were considerably higher, ranging from a high of \$6,497 for Imbruvica to a low of \$261 for NovoLog among enrollees taking the drug.

	LIS		Non-Ll	S	Total	
Drug Name	Total Out- Of-Pocket Spending in CY 2022 (\$)	Average Out-Of- Pocket Spending Per Enrollee (\$)	Total Out-Of- Pocket Spending in CY 2022 (\$)	Average Out-Of- Pocket Spending Per Enrollee (\$)	Total Out-Of- Pocket Spending in CY 2022 (\$)	Average Out-Of- Pocket Spending Per Enrollee (\$)
Eliquis	\$31,396,000	\$31	\$1,514,962,000	\$608	\$1,546,358,000	\$441
Jardiance	\$11,029,000	\$20	\$372,318,000	\$490	\$383,346,000	\$290
Xarelto	\$11,011,000	\$30	\$580,598,000	\$617	\$591,609,000	\$451
Januvia	\$8,488,000	\$20	\$230,403,000	\$502	\$238,891,000	\$270
Farxiga	\$5,156,000	\$18	\$160,870,000	\$448	\$166,026,000	\$260
Entresto	\$5,176,000	\$25	\$180,625,000	\$569	\$185,802,000	\$357
Enbrel	\$529,000	\$21	\$42,658,000	\$2,005	\$43,187,000	\$921
Imbruvica	\$823,000	\$187	\$115,666,000	\$6,497	\$116,489,000	\$5,247
Stelara	\$299,000	\$29	\$40,800,000	\$4,207	\$41,099,000	\$2 <i>,</i> 058
NovoLog; NovoLog FlexPen; NovoLog PenFill; Fiasp; Fiasp FlexTouch; Fiasp PenFill	\$6,140,000	\$14	\$86,532,000	\$261	\$92,672,000	\$121

# Table 2. Annual Total and Average Per Enrollee Out-Of-Pocket Part D Drug Spending in CalendarYear 2022 for Each Drug Selected for Negotiation for Initial Price Applicability Year 2026

Source: ASPE analysis of 2022 Medicare Prescription Drug Event data and Part D Enrollment Data. Notes: Drugs are identified using NDCs, with aggregation of NDCs for each drug consistent with CMS' approach to identifying each drug. ASPE estimates may differ from figures reported by CMS due to differences in the time period that is examined. Out-Of-Pocket spending is based on the actual enrollee payment, not including third party payments, as it represents the amount paid by enrollees and may play an important role in drug affordability and an enrollee's decision to purchase the medication or forgo it.

<sup>&</sup>lt;sup>+++</sup> The complete drug name is NovoLog; NovoLog Flexpen; NovoLog Penfill, Fiasp, Fiasp Flextouch; Fiasp Penfill.

### **Demographic Characteristics of Enrollees Using the Selected Drugs**

Tables 3A and 3B present the demographic characteristics of all (LIS and non-LIS) individuals enrolled in the Part D program in 2022 as well as the Part D enrollees taking each of the 10 drugs selected for negotiation for 2026. With certain exceptions discussed below, the distribution of Medicare enrollees taking each of the selected drugs follows the general distribution of demographic characteristics among the Medicare Part D population in 2022. Differences in the share of enrollees taking each drug by demographic characteristics reflect a variety of factors, including but not limited to specific health conditions that are more prevalent in certain populations (e.g., women are more likely to develop rheumatoid arthritis than men) and differences in risk factors, comorbidities, and access to health care.<sup>18</sup>

The gender distribution of enrollees using these drugs in 2022 was similar to that of the general Medicare Part D population for about half of the drugs. For the remaining drugs, there was a 10 percentage point or greater difference between men and women's representation in the Medicare Part D population compared to the share of men represented in the Part D population and the share of men and women using each drug. Jardiance, Farxiga, Entresto, and Imbruvica have a greater proportion of use by men compared to the share of men represented in the Part D population. For users of Enbrel, there was a much larger share of women (72 percent) taking the drug than men (28 percent).

There are some differences in the share of enrollees who take each drug by age group compared to the age distribution of the overall Part D population. For example, enrollees under the age of 65, who may be eligible for Medicare based on disability or End-Stage Renal Disease (ESRD), make up a much larger share of users for Stelara (43 percent), Enbrel (33 percent), and NovoLog (30 percent) compared to this age group's representation in the Medicare Part D population (19 percent). Enrollees under the age of 65 make up a smaller share of users for Eliquis (9 percent) and Imbruvica (7 percent) compared to their representation in the Part D population.

In general, the share of users for each drug among ages 65 – 79 is similar to the proportion of enrollees represented in the Part D population. Enrollees in the 80 – 84 age group represent about 11 percent of the Part D population and generally, the share of users for this age group is also similar for most of the drugs. Eliquis and Imbruvica have the highest share of enrollees using each of these drugs in the 80 – 84 age group (17 percent for each drug). The lowest shares of enrollees in this age group are for Stelara (4 percent) and Enbrel (6 percent).

Enrollees in the 85 and older age group represent about 10 percent of the Part D population and generally, differences between the share of the Part D population in this age group and the share of users for each drug are less than 10 percentage points. The greatest difference is for Eliquis (about 9 percentage point difference compared to the share in the Part D population); about 19 percent of Eliquis users are 85 or older. The share of enrollees ages 85 and older are less than 5 percent for Jardiance, Enbrel, and Stelara.

Consistent with trends in enrollment among the entire Medicare Part D population, the majority of enrollees taking each of the 10 drugs selected for negotiation for initial price applicability year 2026 are White. For Januvia and Farxiga, the difference between the share of White enrollees taking each of these drugs and this group's representation in the Part D population is greater than 10 percentage points, with a smaller share of White enrollees taking these drugs compared to this group's representation in the Part D population.

For other racial/ethnic groups, the share of users is generally similar to the group's representation in the Part D population, with some exceptions. Black enrollees represent about 16 percent of the total users for Januvia, 16 percent for Farxiga, 18 percent for Entresto, and 17 percent for NovoLog. For these drugs, the share of

Black enrollees using each drug is relatively high compared to Black enrollees' representation in the Part D population (11 percent).

For other racial and ethnic groups, there were small differences (less than 5 percentage points) between the group's representation in the general Part D population and their use for each drug. For example, the highest share of Latino enrollees was observed for Januvia and Enbrel (about 7 percent for each drug), which is about 3 percentage points greater than their representation in the Part D population (3.6 percent).

The majority of both Part D enrollees and enrollees taking each drug reside in urban areas. Differences in the share of enrollees in urban and rural areas taking each drug compared to the overall Part D population residing in urban and rural areas are minimal.

	Medicare Part D					
<b>Enrollee Characteristics</b>	Population	Eliquis	Jardiance	Xarelto	Januvia	Farxiga
Total (N in Millions)	53.1	3.5	1.3	1.3	0.9	0.6
Gender						
Women	56.4%	52%	45%	49%	55%	46%
Men	43.5%	48%	55%	51%	45%	54%
Age						
<65	18.8%	9%	21%	11%	16%	20%
65-69	22.1%	15%	28%	19%	22%	26%
70-74	21.7%	19%	24%	21%	22%	23%
75-79	16.5%	20%	16%	20%	18%	16%
80-84	10.7%	17%	8%	15%	12%	9%
85+	10.1%	19%	4%	14%	10%	5%
Race & Ethnicity						
White non-Latino	77.5%	83%	69%	83%	65%	67%
Black non-Latino	11.0%	10%	14%	9%	16%	16%
Latino	3.6%	2%	6%	2%	7%	6%
Asian American	2.9%	2%	5%	2%	6%	5%
American Indian	0.3%					
/ Alaska Native		0%	1%	0%	0%	0%
Other or Unknown	4.6%	3%	6%	4%	6%	5%
Geographic Area						
Urban	89.7%	90%	91%	90%	91%	90%
Rural <sup>a</sup>	6.8%	7%	6%	7%	7%	7%

# Table 3A. Demographic Characteristics of Medicare Part D Enrollees in Calendar Year 2022 Taking Drugs Selected for Negotiation for Initial Price Applicability Year 2026

Source: ASPE analysis of 2022 Medicare Prescription Drug Event data and Part D Enrollment Data. Notes: Percentages are calculated for each demographic category using the total number of enrollees as the denominator. Percentages may not add up to 100 due to missing data.

ASPE estimates may differ from drug use figures reported by CMS due to differences in the time period that is examined. <sup>a</sup>Rural estimates are based on mapping of beneficiary county and zip code information in the Medicare Enrollment Database to Census Core-Based Statistical Areas (CBSAs). Enrollees living within a CBSA are classified as urban, whether their CBSA is further classified as metropolitan or micropolitan. Enrollees are classified as rural if they can be mapped to a county and a zip code and those locations are not part of a CBSA. Table 3B. Demographic Characteristics of Medicare Part D Enrollees in Calendar Year 2022 TakingDrugs Selected for Negotiation for Initial Price Applicability Year 2026

Enrollee Characteristics	Medicare Part D Population	Entresto	Enbrel	Imbruvica	Stelara	NovoLog; NovoLog FlexPen; NovoLog PenFill; Fiasp; Fiasp FlexTouch; Fiasp PenFill
Total (N in Millions)	53.1	0.5	0.05	0.02	0.02	0.8
Gender						
Women	56.4%	38%	72%	42%	59%	54%
Men	43.5%	62%	28%	58%	41%	46%
Age						
<65	18.8%	18%	33%	7%	43%	30%
65-69	22.1%	20%	25%	18%	23%	22%
70-74	21.7%	20%	20%	24%	18%	20%
75-79	16.5%	18%	13%	22%	11%	14%
80-84	10.7%	13%	6%	17%	4%	8%
85+	10.1%	10%	3%	12%	2%	6%
Race & Ethnicity						
White non-Latino	77.5%	73%	74%	84%	80%	70%
Black non-Latino	11.0%	18%	11%	10%	10%	17%
Latino	3.6%	3%	7%	2%	3%	5%
Asian American	2.9%	2%	2%	1%	1%	3%
American Indian / Alaska Native	0.3%	0%	1%	0%	0%	1%
Other or Unknown	4.6%	4%	4%	4%	5%	4%
Geographic Area	1					
Urban	89.7%	91%	91%	91%	91%	89%
Rural <sup>a</sup>	6.8%	7%	7%	7%	6%	8%

Source: ASPE analysis of 2022 Medicare Prescription Drug Event data and Part D Enrollment Data. Notes: Percentages are calculated for each demographic category using the total number of enrollees as the denominator. Percentages may not add up to 100 due to missing data.

ASPE estimates may differ from drug use figures reported by CMS due to differences in the time period that is examined. <sup>a</sup>Rural estimates are based on mapping of beneficiary county and zip code information in the Medicare Enrollment Database to Census Core-Based Statistical Areas (CBSAs). Enrollees living within a CBSA are classified as urban, whether their CBSA is further classified as metropolitan or micropolitan. Enrollees are classified as rural if they can be mapped to a county and a zip code and those locations are not part of a CBSA.

### State Estimates of Use and Out-Of-Pocket Spending for Selected Drugs

Table A-1 in the Appendix presents state estimates of use and average (mean) out-of-pocket spending among all (LIS and non-LIS) Medicare Part D enrollees for the drugs selected for negotiation for initial price applicability year 2026. The combinations of state and drug with the largest number of enrollees were both for Eliquis, with about 282,000 users in Florida and about 277,000 users in California. Average annual out-of-pocket costs were highest for Imbruvica, for enrollees (LIS and non-LIS) residing in North Dakota (\$8,237) and Utah (\$8,179). Fewer than 500 enrollees used Imbruvica in each of these two states.

### CONCLUSION

In 2022, average annual out-of-pocket spending of Medicare Part D enrollees who used one of the 10 drugs selected for negotiation for initial price applicability year 2026 ranged from a high of \$5,247 per enrollee for Imbruvica to a low of \$121 per enrollee for NovoLog. Enrollees who do not receive the LIS have higher out-of-pocket spending: in 2022, their average annual spending on out-of-pocket costs for these drugs ranged from a high of \$6,497 per enrollee for Imbruvica to a low of \$261 per enrollee for NovoLog per enrollee taking the drug.<sup>###</sup>

The distribution of Medicare enrollees taking each of the selected drugs by demographic characteristics follows the general distribution of demographic characteristics among the Medicare Part D population in 2022, however, there are key exceptions. For example, for Enbrel, there was a much larger share of women taking the drug than men, and enrollees under the age of 65, who may be eligible for Medicare based on disability or ESRD, make up a much larger share of users for Stelara, Enbrel, and NovoLog compared to this age group's representation in the Medicare Part D population. These and other differences in the share of enrollees taking each drug may reflect a variety of factors, including but not limited to specific health conditions that may arise in certain demographic populations and differences in risk factors, comorbidities, and access to health care.

The IRA includes provisions to increase accessibility and affordability of prescription drugs for Medicare enrollees, reduce the rate of growth in Medicare drug spending, and improve the financial sustainability of the Medicare program. These IRA provisions include authorizing the HHS Secretary to directly negotiate with participating manufacturers the prices of certain high expenditure, single source drugs without generic or biosimilar competition that meet the eligibility criteria set forth in the law.

<sup>&</sup>lt;sup>+++</sup> The estimate for the total number of enrollees using the 10 selected drug for initial price applicability year 2026 does not represent unduplicated counts of enrollees because there may be some enrollees who used more than one of the 10 selected drugs in 2022.

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# APPENDIX

# Table A-1. State Estimates of Medicare Part D Enrollees Use and Out-of-Pocket Spending in Calendar Year 2022 for Drugs Selected for Negotiation for Initial Price Applicability Year 2026

State	Eliquis Number of Enrollees, in thousands (Mean OOP)	Jardiance Number of Enrollees, in thousands (Mean OOP)	<u>Xarelto</u> Number of Enrollees, in thousands (Mean OOP)	Januvia Number of Enrollees, in thousands (Mean OOP)	<u>Farxiga</u> Number of Enrollees, in thousands (Mean OOP)	Entresto Number of Enrollees, in thousands (Mean OOP)	Enbrel Number of Enrollees, in thousands (Mean OOP)	Imbruvica Number of Enrollees, in thousands (Mean OOP)	<u>Stelara</u> Number of Enrollees, in thousands (Mean OOP)	NovoLog; NovoLog FlexPen; NovoLog PenFill; Fiasp; Fiasp FlexTouch; <u>Fiasp PenFill</u> Number of Enrollees, in thousands (Mean OOP)
Alabama	65 (\$375)	24 (\$268)	21 (\$384)	17 (\$257)	14 (\$207)	12 (\$306)	1 (\$742)	* (\$4,794)	* (\$1,969)	12 (\$116)
Alaska	6 (\$282)	2 (\$202)	2 (\$285)	1 (\$148)	1 (\$209)	1 (\$240)	(\$778)	(\$1,450)	(\$739)	1 (\$80)
Arizona	71 (\$481)	21 (\$310)	25 (\$508)	14 (\$287)	12 (\$299)	9 (\$441)	1 (\$1,107)	* (\$6,319)	* (\$2,744)	12 (\$126)
Arkansas	36 (\$460)	11 (\$308)	12 (\$493)	7 (\$318)	6 (\$282)	8 (\$381)	* (\$746)	* (\$5,461)	* (\$1,699)	8 (\$117)
California	277 (\$378)	164 (\$197)	113 (\$373)	103 (\$182)	64 (\$198)	46 (\$287)	5 (\$775)	2 (\$4,297)	2 (\$1,727)	54 (\$64)
Colorado	43 (\$514)	15 (\$322)	21 (\$447)	6 (\$361)	5 (\$308)	4 (\$440)	1 (\$1,221)	(\$5,307)	(\$2,620)	6 (\$124)
Connecticut	49 (\$433)	19 (\$263)	19 (\$409)	13 (\$261)	8 (\$249)	7 (\$349)	1 (\$1,081)	* (\$4,659)	* (\$1,447)	7 (\$117)
Delaware	13 (\$456)	5 (\$333)	6 (\$488)	3 (\$319)	3 (\$307)	2 (\$384)	(\$725)	(\$4,337)	(\$1,854)	3 (\$145)
District of Columbia	4 (\$258)	2 (\$106)	1 (\$277)	1 (\$90)	(\$133)	1 (\$113)	(\$451)	(\$4,826)	(\$1,877)	1 (\$41)
Florida	282 (\$424)	83 (\$309)	105 (\$434)	62 (\$252)	47 (\$252)	49 (\$356)	3 (\$1,042)	(\$5,588)	(\$2,454)	58 (\$86)
Georgia	107 (\$419)	36 (\$289)	35 (\$446)	29 (\$282)	26 (\$249)	17 (\$324)	(\$738)	(\$4,998)	(\$2,363)	27 (\$119)
Hawaii	10 (\$302)	(\$218)	(\$320)	4 (\$191)	(\$179)	2 (\$249)	(\$1,004)	(\$3,455)	(\$3,024)	(\$135)
Idaho	(\$570)	5 (\$442)	6 (\$607)	(\$ 10 2) (\$ 397)	(\$376)	(\$588)	(\$1,324)	(\$6,536)	(\$3,043)	4 (\$167)

State	Eliquis Number of Enrollees, in thousands (Mean OOP)	Jardiance Number of Enrollees, in thousands (Mean OOP)	Xarelto Number of Enrollees, in thousands (Mean OOP)	<u>Januvia</u> Number of Enrollees, in thousands (Mean OOP)	<u>Farxiga</u> Number of Enrollees, in thousands (Mean OOP)	Entresto Number of Enrollees, in thousands (Mean OOP)	Enbrel Number of Enrollees, in thousands (Mean OOP)	Imbruvica Number of Enrollees, in thousands (Mean OOP)	Stelara Number of Enrollees, in thousands (Mean OOP)	NovoLog; NovoLog FlexPen; NovoLog PenFill; Fiasp; Fiasp FlexTouch; <u>Fiasp PenFill</u> Number of Enrollees, in thousands (Mean OOP)
Illinois	132	53	53	31	18	21	1	1	1	31
	(\$481)	(\$333)	(\$506)	(\$339)	(\$324)	(\$403)	(\$935)	(\$5,474)	(\$2,584)	(\$127)
Indiana	81 (\$470)	30 (\$358)	30 (\$480)	18 (\$367)	14 (\$321)	14 (\$396)	1 (\$1,007)	(\$6,228)	(\$1,506)	19 (\$133)
lowa	36	12	15	7	4	3	*	*	*	11
	(\$652)	(\$469)	(\$641)	(\$488)	(\$437)	(\$568)	(\$1,308)	(\$6,868)	(\$2,808)	(\$246)
Kansas	29	10	12	6	5	3	*	*	*	10
	(\$585)	(\$466)	(\$597)	(\$460)	(\$419)	(\$544)	(\$1,115)	(\$6,305)	(\$3,513)	(\$180)
Kentucky	60	23	23	20	15	11	1	*	*	16
	(\$373)	(\$260)	(\$382)	(\$249)	(\$238)	(\$304)	(\$615)	(\$5,568)	(\$1,862)	(\$114)
Louisiana	55	23	19	16	11	13	1	*	*	13
	(\$372)	(\$237)	(\$391)	(\$236)	(\$232)	(\$289)	(\$514)	(\$4,500)	(\$1,015)	(\$93)
Maine	21	7	6	4	2	1	*	*	*	4
	(\$413)	(\$262)	(\$432)	(\$228)	(\$223)	(\$338)	(\$940)	(\$4,994)	(\$1,783)	(\$89)
Maryland	49	19	19	11	8	8	1	*	*	12
	(\$422)	(\$268)	(\$444)	(\$280)	(\$285)	(\$319)	(\$749)	(\$3,747)	(\$1,571)	(\$122)
Massachusetts	89	30	26	16	8	8	1	1	1	16
	(\$429)	(\$261)	(\$457)	(\$237)	(\$217)	(\$341)	(\$913)	(\$3,927)	(\$1,977)	(\$103)
Michigan	140	43	50	35	23	19	2	1	1	34
	(\$381)	(\$262)	(\$397)	(\$271)	(\$272)	(\$344)	(\$958)	(\$4,793)	(\$1,708)	(\$132)
Minnesota	48	15	25	7	3	4	1	*	*	16
	(\$620)	(\$415)	(\$609)	(\$431)	(\$417)	(\$563)	(\$1,795)	(\$6,349)	(\$2,791)	(\$187)
Mississippi	33	14	13	9	10	8	*	*	*	12
	(\$416)	(\$284)	(\$442)	(\$262)	(\$221)	(\$326)	(\$616)	(\$6,040)	(\$3,875)	(\$103)
Missouri	75	26	27	15	14	11	1	*	*	18
	(\$482)	(\$353)	(\$497)	(\$339)	(\$323)	(\$412)	(\$921)	(\$6,462)	(\$2,342)	(\$127)
Montana	10	3	4	2	1	1	*	*	*	3
	(\$590)	(\$418)	(\$624)	(\$445)	(\$433)	(\$559)	(\$1,195)	(\$6,617)	(\$2,698)	(\$163)
Nebraska	20	7	10	3	3	3	*	*	*	5
	(\$657)	(\$503)	(\$666)	(\$502)	(\$443)	(\$555)	(\$1,508)	(\$7,527)	(\$4,466)	(\$202)
Nevada	26	10	11	5	5	4	*	*	*	5
	(\$438)	(\$325)	(\$468)	(\$298)	(\$291)	(\$385)	(\$1,182)	(\$6,307)	(\$3,007)	(\$122)

State	Eliquis Number of Enrollees, in thousands (Mean OOP)	Jardiance Number of Enrollees, in thousands (Mean OOP)	Xarelto Number of Enrollees, in thousands (Mean OOP)	<u>Januvia</u> Number of Enrollees, in thousands (Mean OOP)	<u>Farxiga</u> Number of Enrollees, in thousands (Mean OOP)	Entresto Number of Enrollees, in thousands (Mean OOP)	Enbrel Number of Enrollees, in thousands (Mean OOP)	Imbruvica Number of Enrollees, in thousands (Mean OOP)	Stelara Number of Enrollees, in thousands (Mean OOP)	NovoLog; NovoLog FlexPen; NovoLog PenFill; Fiasp; Fiasp FlexTouch; <u>Fiasp PenFill</u> Number of Enrollees, in thousands (Mean OOP)
New Hampshire	16 (\$548)	4 (\$429)	5 (\$598)	2 (\$421)	1 (\$349)	1 (\$486)	* (\$1,385)	* (\$6,391)	* (\$1,679)	2 (\$147)
New Jersey	99 (\$409)	34 (\$312)	39 (\$442)	33 (\$265)	22 (\$258)	16 (\$365)	1 (\$882)	(\$4,711)	(\$2,091)	15 (\$142)
New Mexico	15 (\$396)	6 (\$234)	10 (\$386)	5 (\$236)	3 (\$225)	2 (\$350)	(\$986)	* (\$5,371)	* (\$945)	5 (\$100)
New York	232	96	86	85	53	43	4	2	2	50
	(\$342)	(\$205)	(\$347)	(\$174)	(\$195)	(\$265)	(\$754)	(\$3,479)	(\$1,459)	(\$89)
North Carolina	128	48	44	26	21	17	2	1	1	27
	(\$462)	(\$309)	(\$468)	(\$292)	(\$265)	(\$362)	(\$912)	(\$5,273)	(\$1,817)	(\$122)
North Dakota	7	2	2	1	1	*	*	*	*	3
	(\$740)	(\$607)	(\$816)	(\$653)	(\$606)	(\$656)	(\$2,299)	(\$8,237)	(\$1,099)	(\$251)
Ohio	155	47	57	39	27	21	1	1	1	33
	(\$480)	(\$335)	(\$499)	(\$354)	(\$330)	(\$411)	(\$1,270)	(\$5,940)	(\$1,851)	(\$126)
Oklahoma	45	15	13	9	8	7	1	*	*	12
	(\$459)	(\$349)	(\$494)	(\$325)	(\$307)	(\$408)	(\$711)	(\$5,732)	(\$1,496)	(\$129)
Oregon	46	14	15	4	3	5	1	*	*	7
	(\$597)	(\$383)	(\$576)	(\$375)	(\$380)	(\$509)	(\$1,025)	(\$5,723)	(\$1,357)	(\$123)
Pennsylvania	187	71	67	37	21	23	2	1	1	45
	(\$431)	(\$312)	(\$437)	(\$330)	(\$277)	(\$375)	(\$997)	(\$5,687)	(\$2,662)	(\$140)
Rhode Island	14	5	5	2	1	1	*	*	*	2
	(\$464)	(\$299)	(\$521)	(\$276)	(\$297)	(\$433)	(\$871)	(\$6,022)	(\$2,116)	(\$111)
South Carolina	67	23	21	17	16	12	1	*	*	14
	(\$461)	(\$312)	(\$477)	(\$312)	(\$293)	(\$347)	(\$909)	(\$4,969)	(\$2,759)	(\$128)
South Dakota	9	3	4	1	1	1	*	*	*	3
	(\$729)	(\$544)	(\$748)	(\$576)	(\$537)	(\$601)	(\$1,154)	(\$6,312)	(\$387)	(\$195)
Tennessee	85	28	30	18	16	13	1	*	*	19
	(\$446)	(\$300)	(\$448)	(\$295)	(\$267)	(\$380)	(\$1,142)	(\$6,346)	(\$2,608)	(\$138)
Texas	221	99	86	70	58	35	4	1	1	48
	(\$430)	(\$289)	(\$444)	(\$264)	(\$250)	(\$365)	(\$743)	(\$5,267)	(\$1,810)	(\$131)
Utah	22	7	8	3	3	1	*	*	*	5
	(\$567)	(\$475)	(\$610)	(\$440)	(\$418)	(\$521)	(\$1,724)	(\$8,179)	(\$3,349)	(\$152)

State	Eliquis Number of Enrollees, in thousands (Mean OOP)	Jardiance Number of Enrollees, in thousands (Mean OOP)	<u>Xarelto</u> Number of Enrollees, in thousands (Mean OOP)	Januvia Number of Enrollees, in thousands (Mean OOP)	<u>Farxiga</u> Number of Enrollees, in thousands (Mean OOP)	Entresto Number of Enrollees, in thousands (Mean OOP)	Enbrel Number of Enrollees, in thousands (Mean OOP)	Imbruvica Number of Enrollees, in thousands (Mean OOP)	<u>Stelara</u> Number of Enrollees, in thousands (Mean OOP)	NovoLog; NovoLog FlexPen; NovoLog PenFill; Fiasp; Fiasp FlexTouch; <u>Fiasp PenFill</u> Number of Enrollees, in thousands (Mean OOP)
Vermont	9 (\$492)	3 (\$332)	3 (\$587)	1 (\$339)	1 (\$317)	1 (\$441)	* (\$1,385)	* (\$4,686)	* (\$1,673)	2 (\$128)
Virginia	81 (\$507)	26 (\$336)	26 (\$520)	20 (\$329)	13 (\$301)	11 (\$406)	(; 1,137)	(\$6,262)	(\$2,740)	15 (\$126)
Washington	58 (\$568)	26 (\$348)	27 (\$555)	9 (\$321)	6 (\$346)	6 (\$449)	1 (\$1,341)	(\$6,113)	(\$1,956)	11 (\$149)
West Virginia	27 (\$325)	10 (\$227)	10 (\$347)	9 (\$227)	5 (\$214)	5 (\$288)	(\$635)	(\$3,967)	(\$1,330)	10 (\$92)
Wisconsin	68 (\$534)	22 (\$390)	23 (\$563)	11 (\$390)	6 (\$363)	6 (\$443)	1 (\$1,250)	(\$6,113)	(\$1,959)	15 (\$152)
Wyoming	6 (\$653)	1 (\$503)	2 (\$659)	1 (\$473)	1 (\$453)	(\$589)	(\$1,274)	(\$7,118)	(\$2,945)	1 (\$186)
Total for the United States <sup>a</sup>	3,505 (\$441)	1,321 (\$290)	1,311 (\$451)	885 (\$270)	639 (\$260)	521 (\$357)	47 (\$921)	22 (\$5,247)	20 (\$2,058)	763 (\$121)

Source: ASPE analysis using the Medicare Prescription Drug Event data and Part D Enrollment Data. Notes: ASPE estimates may differ from drug use figures reported by CMS due to differences in the time period that is examined.

\* Fewer than 500 enrollees

<sup>a</sup> Total includes enrollees residing in U.S. territories or outside the United States.

OOP = Out-Of-Pocket

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