

—Inflation Reduction Act Research Series— Medicare Drug Price Negotiation Program: Understanding Development and Trends in Utilization and Spending for the Selected Drugs

Medicare enrollees paid a total of \$3.4 billion in out-of-pocket costs in 2022 for the 10 drugs selected for the first cycle of Medicare drug price negotiations. Seven of the 10 drugs selected for negotiation received at least one form of federal support towards their drug development or utilized a federally funded invention.

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 certain high expenditure, qualifying single source Medicare drugs without generic or biosimilar competition. Negotiations with participating manufacturers for the first group of 10 drugs selected for the first cycle of Medicare drug price negotiations began in 2023, with any negotiated maximum fair prices going into effect in 2026.
- The 10 drugs covered under Part D selected for the first cycle of Medicare drug price negotiations are: Eliquis, Jardiance, Xarelto, Januvia, Farxiga, Entresto, Enbrel, Imbruvica, Stelara, and NovoLog/Fiasp.* 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 conditions, and chronic kidney disease.†
- As required by the IRA, selected drugs need to have been approved or licensed by the Food and Drug Administration (FDA) for a considerable amount of time to be eligible for negotiation:‡ Enbrel has been licensed longest (nearly 25 years as of September 1, 2023 when the list of 10 drugs selected for the first cycle of drug price negotiations was required to be published), while Entresto has been approved the shortest (about 8 years as of September 1, 2023).
- The federal government supports biomedical research relevant to the discovery and development of new drugs. Seven of the 10 drugs selected for negotiation received at least one form of federal support towards their drug development or utilized a federally funded invention.

* The drug is also identified with the proprietary names: NovoLog; NovoLog FlexPen; NovoLog PenFill; Fiasp; Fiasp FlexTouch; Fiasp PenFill.

† Previous ASPE analyses find that about 9 million Medicare enrollees used one or more of the selected drugs, however, as noted in the [ASPE Fact Sheet](#), this estimate does not represent unduplicated counts of enrollees because some enrollees used more than one of the 10 selected drugs. Analysis presented in this report finds that about 1.1 million enrollees used more than one of the selected drugs. Overall, about 7.7 million unique Medicare enrollees used one or more of the selected drugs in 2022.

‡ Per the IRA, small molecule drugs must be approved by the FDA for seven years and biologics must be licensed by the FDA for 11 years before they are eligible to be selected for the negotiation program.

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- Total Medicare spending for the selected drugs was \$46.4 billion in 2022, which represents about 19 percent of total Part D gross spending in 2022. Annual total gross spending per enrollee was highest for Imbruvica (\$129,000) and lowest for NovoLog/Fiasp (\$3,300) in 2022. *
 - Overall, total Part D gross spending for the 10 selected drugs more than doubled from 2018 to 2022, going from about \$20 billion to about \$46 billion, an increase of 134 percent. The rate of growth in spending for these 10 drugs is more than 3 times as fast as all Part D drugs over the same time period.
 - Over 5 million Medicare enrollees report affordability challenges in obtaining their prescription medications, with the share of Black and Latino enrollees reporting affordability challenges about 1.5 to 2 times higher than their White counterparts. ¹
 - Overall, for enrollees who take at least one of the selected drugs, spending on the selected drugs represents about 52 percent of average annual spending per enrollee on all of their Part D covered drugs.
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* As a general practice, ASPE examines calendar year use and spending for Medicare drug-related analyses. Using calendar year data for this Report allows the use and 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 the first cycle of Medicare drug price negotiations are for June 1, 2022 through May 31, 2023 as required by the IRA.

A. INTRODUCTION, BACKGROUND, AND PURPOSE

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. Over 65 million Americans are enrolled in the Medicare program, of whom about 53 million are enrolled in the Part D prescription drug program.^{2,3} 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.⁴ Drugs selected for negotiation are those that have high total Medicare gross expenditures and meet other criteria defined in the law, including criteria outlined in program guidance issued by the Centers for Medicare & Medicaid Services (CMS), in accordance with the law.*

The purpose of this Report is to provide an in-depth review of certain characteristics associated with the 10 drugs selected for the first cycle of Medicare drug price negotiations. Specifically, we examine whether the selected drugs received federal contributions and support during development. We also examine existing information on the common conditions treated by the selected drugs and identify key health disparities among populations with these conditions. Finally, we present Medicare prescription drug utilization and spending trends for each of the 10 drugs over a 5-year period of time, from 2018 through 2022.

This report was prepared by the Office of the Assistant Secretary for Planning and Evaluation (ASPE), but CMS is the component of HHS that has primary responsibility for implementing the Negotiation Program. As explained in several places in this document, at times, ASPE and CMS may have made different methodological choices, or may have considered data from different sources, in considering the same (or related) questions about the drugs selected for the negotiation program. CMS has described the data that it will consider and its approach to the evaluation of statutory factors under the IRA in guidance documents, but those documents do not constrain ASPE from considering other factors or data for the purpose of preparing an informative research report like this one. Accordingly, to the extent that any of the methodological choices or data underlying this report may be inconsistent with the requirements of the IRA, CMS guidance, or other applicable law, CMS (and all components of HHS) will disregard them for purposes of implementing the Negotiation Program.

The Inflation Reduction Act

The IRA was signed into law on August 16, 2022. This historic law includes several provisions that are lowering prescription drug costs and improving affordability of and access to prescription drugs for the more than 65 million Americans enrolled in the Medicare program.⁵

The cost of prescription drugs under the Medicare Part D program has been rising over time, presenting financial challenges for the Medicare program and affordability challenges for enrollees. In 2021, spending under Medicare Part D totaled about \$215.7 billion, which represents an average increase of about 8.6 percent annually in nominal dollars from 2014 – 2021.⁶ Although many factors contribute to the growth in total spending under Part D, the price of prescription drugs has been identified as a key driver of increasing costs. This has downstream effects on out-of-pocket costs for Medicare enrollees, making it difficult for many to afford their medications, and taxpayers, who pay more for the Medicare program as costs rise.

Nearly half of all Medicare enrollees were estimated to have annual incomes below \$30,000 in 2019 and about nine percent reported affordability concerns related to their prescription drugs.^{7,8} In 2022, about 1.5 million

* For complete details on the process of selecting drugs for negotiation for the first cycle of Medicare drug price negotiations, please see CMS revised guidance that was released on June 30, 2023, which is available here: [Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026 \(cms.gov\)](https://www.cms.gov/medicare/coverage/policies/2023/spl/medicare-drug-price-negotiation-program-revised-guidance-implementation-of-sections-1191-1198-of-the-social-security-act-for-initial-price-applicability-year-2026).

enrollees who do not receive the low-income subsidy (LIS)* reached the catastrophic coverage phase of the Part D benefit where enrollees have five percent cost-sharing; these enrollees paid an average of \$3,100 out-of-pocket annually for their Part D drugs.^{†,9}

Drug prices affect how much Medicare spends on prescription drugs as well as out-of-pocket costs paid by enrollees who use the drugs. Authorizing the Secretary to negotiate for certain selected high expenditure, single source drugs is just one change required by the IRA that aims to make prescription drugs more affordable for Medicare enrollees. The IRA also includes provisions to institute a \$35 out-of-pocket cap for a month's supply of each covered insulin product (effective January 2023 for insulin covered under Part D and July 2023 for insulin covered under Part B), eliminate cost-sharing for recommended adult vaccines covered by Part D (effective January 2023), and institute a \$2,000 cap on out-of-pocket costs for all prescription drugs covered under Part D (effective 2025), among other provisions. These provisions, along with drug price negotiation, will help to make prescription drugs more affordable for Medicare enrollees and taxpayers. For a full set of IRA drug-related Medicare provisions and an overview of the estimated impacts of the IRA, please see [here](#) and [here](#).

Early studies estimating the impacts of the Medicare drug-related IRA provisions are promising, suggesting that one in three enrollees will save about \$400 in out-of-pocket costs under the IRA's drug related provisions that are in effect in calendar year 2025.[‡] However, these studies examine impacts for the period before the maximum fair prices negotiated with participating manufacturers take effect in 2026. Therefore, they do not include impacts that may accrue after the maximum fair prices for the initial set of 10 drugs are in effect.

Key dates for the first cycle of Medicare drug price negotiations are listed below.^{§,10}

- In 2023, CMS began 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 must occur in 2023 and 2024.
- By September 1, 2024, CMS will publish any maximum fair prices that have been negotiated for this first group of selected drugs.
- Any negotiated prices will be effective beginning on January 1, 2026.
- 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.¹¹

On August 29, 2023, CMS published the full list of 10 drugs covered under Medicare Part D whose manufacturers were invited to participate in the negotiation process for initial price applicability year 2026 and ASPE released a Fact Sheet outlining Medicare enrollees' use and out-of-pocket costs for the 10 selected drugs in calendar year 2022.¹² Among negotiation eligible drugs, these 10 drugs had some of the highest total gross

* 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](#).

† Those with certain health conditions paid even more – 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 2022. This estimate is for average annual out-of-pocket spending for all phases of the Part D benefit for enrollees who reached the catastrophic coverage phase in 2022.

‡ For more details, please see Appendix Section A.

§ Under the IRA negotiation process, as required by the law, CMS will consider manufacturer-submitted data and available evidence about the selected drug and therapeutic alternatives in developing an initial offer and in responding to a manufacturer's counteroffer, if any.

Part D spending between June 1, 2022 through May 31, 2023, which is the time period required by the IRA to identify total expenditures for purposes of selecting drugs for the Negotiation Program. In this Report, we present an in-depth analysis of the selected drugs.

The estimates presented in this Report were not used to identify the 10 drugs selected for the first cycle of Medicare drug price negotiations. In addition, this Report does not necessarily align fully with the scope of the statutorily specified factors that CMS must consider and the information that is to be collected by CMS per the law for purposes of negotiating the maximum fair price of a selected drug. For more details on the scope of information collected by CMS and how CMS will use this information to develop the initial offer, please see [here](#).

B. OVERVIEW OF SELECTED DRUGS

SUMMARY: Of the 10 selected drugs, seven are small molecule drugs and three are biological products. The selected drugs will have been approved or licensed for a range of more than 10 years to more than 27 years by the time the first negotiated prices take effect in 2026. The federal government supported the development of seven of the 10 selected drugs by providing tax credits for research and development (R&D) costs and through the use of inventions made with government support.

Background on Drug Prices

Drug prices are high in the United States for many reasons.¹³ High prescription drug prices are, in part, the result of the complex U.S. drug supply chain and payment system. In general, the pharmaceutical supply chain for drugs covered under Medicare Part D is comprised of five basic entities before a drug reaches a patient:

1. Drug manufacturers bring drugs to market and set a list price.
2. Drugs are sold by manufacturers to wholesalers and distributors at the wholesale acquisition cost (WAC) price.
3. Wholesalers and distributors sell drugs to pharmacies (average wholesale price, AWP, is an estimate of this cost).
4. Health plans contract with pharmacy benefit managers (PBMs) to manage formularies, negotiate prices and rebates with drug manufacturers, and reimburse pharmacies at negotiated rates for drugs obtained by their enrollees.
5. In Medicare, drugs are paid for by a Medicare enrollee's health plan and the enrollee's out-of-pocket payment.

At each stage of the supply chain, entities mark up the cost of a drug, including for their profit.^{14,15} Each entity also competes for market share. For example, drug manufacturers compete against each other for formulary coverage by negotiating confidential rebates with PBMs, which result in a "net" price.¹⁶ Medicare enrollees who pay a percentage of the list price, either in the deductible phase (where they pay 100 percent of gross drug cost) or as coinsurance, do not directly benefit from negotiated rates or rebates that typically occur at the point-of-sale.^{*,17} They may still be impacted indirectly through lower coinsurance rates resulting from changes in formulary placement or potentially from downstream impacts on premiums (to the extent that savings are passed through to patients from insurance plan competition).

A lack of robust competition is another one of the primary causes of high drug prices for many drugs. Competition has been stymied for many reasons. Medicare is required to cover some or all drugs, depending on the class, which in turn reduces plans' bargaining power. In addition, brand drug manufacturers sometimes exploit the patents and exclusivities that are intended to promote innovation with "patent thickets,"[†] "product hopping,"[‡] "pay-for-delay,"[§] and other anti-competitive practices to keep cheaper generics and biosimilars off the market. They also pay PBMs rebates to cover their drugs, with no guarantee that the savings will be passed on to patients. PBMs use their market power to collect fees from independent pharmacies. The three PBMs that manage 77 percent of prescription claims have consolidated with major health insurance companies

* Beginning in 2024, pharmacy DIR will be applied at the point-of-sale.

† "Patent thickets" are dense webs of overlapping intellectual property rights that generic or biosimilar manufacturers must navigate in order to commercialize generic drugs and biosimilar products.

‡ "Product hopping" occurs when a brand manufacturer makes a minor change to its product before a generic competitor enters and may even withdraw the original product from the market.

§ Under "pay-for-delay" agreements, brand manufacturers pay potential generic and biosimilar competitors to keep their products off the market.

and one of them is also the largest pharmacy/mail-order chain.¹⁸ Firms in the pharmaceutical supply chain currently have limited or no incentives to reduce drug costs for patients and the government and challenge anti-competitive actions.

The Medicare Drug Price Negotiation Program specifically identifies single source drugs that have high total Medicare Part D spending and have been approved or licensed for an extended period of time but do not have generic or biosimilar competition.* In markets without competitive pressures to lower their prices, and because Medicare enrollees are not fully able to take advantage of net prices,[†] drug price negotiation is a mechanism for reducing drug prices, enhancing competition, and, in turn, increasing access and affordability of drug products.

Background on 10 Selected Drugs

Table 1 lists the 10 selected drugs for the first cycle of Medicare drug price negotiations and select drug characteristics. Of the 10 drugs, seven are small molecule drugs and three are biological products. There is significant variation with regard to their time on the market. The earliest approved product is Enbrel, which was first approved by the FDA in 1998, meaning it will have been on the market for more than 27 years by the time any negotiated prices take effect in 2026—or alternatively, nearly 25 years as of September 1, 2023, when the list of 10 drugs selected for the first cycle of Medicare drug price negotiations was required to be published. The most recent drug approved is Entresto, which was approved in 2015.

Table 1. Characteristics of the 10 Selected Drugs for the First Cycle of Medicare Drug Price Negotiations

Drug Name	Active Ingredient Or Active Moiety	Small Molecule Drug or Biological Product	Year of First FDA Approval [‡]
Eliquis	Apixaban	Small Molecule Drug	2012
Jardiance	Empagliflozin	Small Molecule Drug	2014
Xarelto	Rivaroxaban	Small Molecule Drug	2011
Januvia	Sitagliptin	Small Molecule Drug	2006
Farxiga	Dapagliflozin	Small Molecule Drug	2014
Entresto	Sacubitrilat/Valsartan	Small Molecule Drug	2015
Enbrel	Etanercept	Biological Product	1998
Imbruvica	Ibrutinib	Small Molecule Drug	2013
Stelara	Ustekinumab	Biological Product	2009
NovoLog/Fiasp	Insulin Aspart, Human	Biological Product	2000

Source: ASPE analysis of Drugs@FDA¹⁹

* Under the IRA, there are other factors that are considered to determine eligibility for negotiation. For complete details on the process of selecting drugs for the first cycle of Medicare drug price negotiations, please see CMS revised guidance that was released on June 30, 2023, which is available here: [Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026 \(cms.gov\)](https://www.cms.gov/medicare/medicare-eligibility/medicare-drug-price-negotiation/medicare-drug-price-negotiation-revised-guidance-implementation-of-sections-1191-1198-of-the-social-security-act-for-initial-price-applicability-year-2026).

[†] For example, Part D plan sponsors often use direct and indirect remuneration to reduce premiums rather than reduce drug prices at the point of sale.

[‡] This is the year of the first FDA drug approval or biologics licensure. However, drugs and biological products could have additional approvals for new indications in later years.

Federal Contributions or Support Relevant to Development of Selected Drugs*

The IRA directs CMS to consider certain factors for the purposes of negotiating a maximum fair price for each of the selected drugs. These factors[†] include:

1. Research and development (R&D) costs of the Primary Manufacturer for the selected drug and the extent to which the Primary Manufacturer has recouped those costs;
2. Current unit costs of production and distribution of the selected drug;
3. Prior federal financial support for novel therapeutic discovery and development with respect to the selected drug;
4. Data on pending and approved patent applications, exclusivities recognized by the FDA, and applications and approvals under section 505(c) of the Federal Food Drug & Cosmetic Act or section 351(a) of the Public Health Service Act for the selected drug; and
5. Market data and revenue and sales volume data for the selected drug in the United States.

The methodology and findings presented in this section regarding an assessment of factor 3 do not necessarily fully capture the data that CMS will consider in evaluating factor 3 as part of the negotiation process. For this Report, ASPE has conducted its own analysis from publicly available data sources, including from Securities and Exchange Commission (SEC) filings and the FDA Orange Book. More specifically, ASPE's data sources are proxy measures, while CMS will be obtaining information on the negotiation data elements directly from the manufacturers for purposes of the negotiation process. The information presented in this section will not necessarily be used by CMS in the negotiation process for initial price applicability year 2026, rather it is meant to be illustrative of federal contributions or support relevant to drug development.[‡]

There are a variety of ways to evaluate the impact of federally supported biomedical R&D, and likewise a variety of methods to assess government contributions relevant to new drug development. For the purposes of this report, we examine two types of federal contributions or support relevant to the 10 selected drugs for the first cycle of Medicare drug price negotiations:

- 1) tax credits provided to pharmaceutical companies for their R&D costs, and
- 2) patents acknowledging a “government interest.”

The federal R&D tax credit, typically reserved for American pharmaceutical companies, subsidizes qualified research costs, including those associated with drug discovery, preclinical research, and clinical research.²⁰ A “government interest” patent is one in which the invention was made with government support, meaning the government has certain rights to the invention as required by the Bayh-Dole Act of 1980.²¹

Seven of the 10 drugs were developed with at least one form of federal support. We identified that seven of the 10 drugs have publicly declared claiming tax credits for R&D costs, and one of those drugs also has a “government interest” patent.

* Please see Appendix, Section C for more details on the datasets and methodology used for this analysis.

[†] For more details, please see CMS revised guidance that was released on June 30, 2023, which is available here: [Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026 \(cms.gov\)](#).

[‡] As stated earlier, this Report does not necessarily align fully with the scope of statutorily specified factors that CMS must consider and the information that is to be collected by CMS per the law for purposes of negotiating the maximum fair price of a selected drug. For more details on the scope of information collected by CMS and how CMS will use this information to develop the initial offer, please see [here](#).

To contextualize these high-level results, we present two case studies that detail how publicly declared federal support and contributions can factor into a drug's development. Our two drugs of interest are:

- 1) Januvia, which received both forms of federal support
- 2) Entresto, which received no forms of federal support

Januvia: Januvia treats diabetes and was developed with both forms of federal support. To identify use of U.S. tax credits for R&D costs, we examined Merck & Co., Inc's* 2005 annual report to the SEC (the year in which the pivotal clinical trial is reported in FDA's medical review of the new drug application). The annual report to the SEC explicitly disclosed the performance of U.S. based clinical trials and disclosure of the R&D tax credit.^{22, 23, 24} Next, we identified a total of 7 patents associated with Januvia, of which 3 patents acknowledge a government interest. The patents with a government interest tend to focus on the treatment of diabetes (i.e., use of the class of DPP-4 inhibitors to treat diabetes). In contrast, the non-government interest patents tend to focus on the specific mechanism of action that differentiates Januvia from other drugs in its class, including its chemical composition, manufacturing process, and method of administration. This means that the government interest patents are broader scope patents, while the non-government interest patents tended to cover drug specific information required to commercialize a product.

Entresto: In contrast to Januvia, Entresto does not satisfy our two metrics for federal support. We examined Novartis Pharmaceutical Corporation's 2013 annual report which confirms that clinical trials were being conducted in the United States, but there was no corresponding mention of the R&D tax credit.²⁵ However, it is important to note that although Novartis does not explicitly mention the R&D tax credit, it does calculate the "effect of tax credits and allowances" on its effective tax rate and also indicates that 36 percent of its "noncurrent assets" (assets not convertible to cash within a year such as plants, property, equipment) were located in the United States, which suggests that Novartis had substantial operations within the United States at the time. The combination of an ongoing clinical trial with U.S. sites, substantial assets located in the United States, and the use of tax credits more broadly suggests, but does not confirm, that Novartis may have received the R&D tax credit for research expenses associated with Entresto. We then examined the six patents that Entresto has associated with it, but none of them declared a government interest.

While it was outside of the scope of this report, the government often supports broader scope, disease specific or basic research, which can be used to support private-sector development of drugs. Federal investments provide critical foundation and support for drug development across the continuum, from knowledge generated through basic science to clinical trials investigating the safety and efficacy of a product in patients. While it has been well-established that nearly every medical product can be linked to basic research funded by the federal government, it can be challenging to connect federal support for R&D to specific drug products. Merely by way of example, published findings from basic biomedical research can also be used to support a variety of subsequent studies, including multiple drug development efforts, and both successes and failures. For example, one recent study found NIH funding contributed to publications associated with 99.4 percent (354 out of 356) of new drugs approved by the FDA from 2010-2019.²⁶ In this report we focused on two proximal federal supports relevant to the IRA: use of the federal R&D tax credit and government interest patents.

* Merck & Co., Inc filed this annual report on behalf of itself as well as its subsidiaries, including Merck Sharp & Dohme, which has signed an agreement with CMS under the Negotiation Program.

C. HEALTH CONDITIONS TREATED BY SELECTED DRUGS

SUMMARY: The 10 drugs selected for the first cycle of Medicare drug price negotiations are approved for the treatment of both acute and chronic conditions, including blood clots, diabetes, cardiovascular conditions, chronic kidney disease, and autoimmune conditions. There are significant racial and ethnic health disparities associated with some of these conditions (e.g., diabetes). Gender related disparities exist for heart disease, certain types of cancers, and autoimmune disease. Due to the high cost of medication and treatment for many of these conditions, enrollees with these conditions may experience affordability challenges. Research shows that over 5 million Medicare enrollees report affordability challenges in obtaining their prescription medications.

As shown in Table 2, the conditions treated by the 10 drugs include blood clots (treated by Eliquis and Xarelto), diabetes (treated by Jardiance, Januvia, Farxiga, and NovoLog/Fiasp), heart failure (treated by Jardiance, Farxiga, and Entresto), coronary or peripheral artery disease (treated by Xarelto), 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, nor do they represent the indications for the drug. A complete list of FDA approved indications for each drug is available in Appendix, Section B.

Table 2. Most Commonly Treated Conditions for Each of the 10 Drugs Selected for the First Cycle of Medicare Drug Price Negotiations

Drug Name	Most Commonly Treated Condition
Eliquis	Prevention and treatment of blood clots
Jardiance	Diabetes; Heart failure
Xarelto	Prevention and treatment of blood clots; Reduction of risk for patients with coronary or peripheral artery disease
Januvia	Diabetes
Farxiga	Diabetes; Heart failure; Chronic kidney disease
Entresto	Heart failure
Enbrel	Rheumatoid arthritis; Psoriasis; Psoriatic arthritis
Imbruvica	Blood cancers
Stelara	Psoriasis; Psoriatic arthritis; Crohn’s disease; Ulcerative colitis
NovoLog/Fiasp	Diabetes

Source: Most commonly treated conditions were identified by CMS using the FDA indications for each drug.²⁷

Notes: Drugs are identified using NDCs, with aggregation of NDCs for each drug consistent with CMS approach for identifying each drug. The 10 drugs selected for the first cycle of Medicare drug price negotiations are not the sole drugs used to treat these conditions and treatment may include other medications and non-drug related health care services in addition to or in lieu of the 10 selected drugs.

Overview of Common Conditions that are Treated by the Selected Drugs

With the exception of some types of blood clots, the conditions treated by the selected drugs typically require long-term treatments consisting of both medications and lifestyle changes. If adequate treatment is not available or is unsuccessful in managing these conditions, the downstream consequences can be severe and include complications that lead to greater health care use, reduced quality of life, and increased morbidity and mortality for patients. For example, blood clots can result in heart attacks, strokes, and even death if they are not treated immediately.²⁸ Diabetes, cardiovascular conditions, and chronic kidney disease can all cause permanent damage to vital organs; if these conditions are left untreated, they may result in acute emergencies

that require immediate care to preserve life.^{29,30,31} Among the Medicare population, in 2020, about 283,000 enrollees had hospitalizations for complications, specifically amputations and ketoacidosis, that arise when diabetes is not appropriately controlled; health care costs were nearly \$40,000 per enrollee for these hospitalizations.³²

Moreover, people with one of the commonly treated conditions usually have comorbidities and increased risk for some of the other common conditions listed as well. For example, uncontrolled diabetes can result in heart and kidney damage, contributing to the development of chronic kidney disease and heart problems. People with rheumatoid arthritis are more likely to develop kidney disease due to the inflammation and medications. They also have increased risk of lymphoma, a type of blood cancer.³³ Psoriasis and psoriatic arthritis patients are also more likely to develop diabetes and high blood pressure, which can lead to cardiovascular disease.³⁴

For a description of each condition and examples of serious health consequences if these conditions are not adequately managed and/or if disease progresses, please see Appendix Section B. Note that the 10 drugs selected for the first cycle of Medicare drug price negotiations may not be the sole drugs used to treat these conditions and treatment may include other medications and non-drug health care services in addition to or in lieu of the 10 selected drugs.

Prevalence of Common Conditions Treated by the Selected Drugs and Clinical Consequences

The drugs selected for the first cycle of Medicare drug price negotiations are approved by the FDA to treat serious health conditions that are prevalent in the United States and among the Medicare population. For example:

- The Centers for Disease Control and Prevention (CDC) reports that one person dies of a blood clot every six minutes in the United States.³⁵ Medicare enrollees are at higher risk of blood clots due to age and other comorbidities present among this population.³⁶ Existing data shows that among the traditional Medicare population, about one in 10 Medicare enrollees have heart conditions that put them at risk for blood clots.³⁷
- Diabetes is one of the top 10 leading causes of death in the United States. About 28 percent of Medicare enrollees have diabetes, which also increases individuals' risk for heart disease and stroke.^{38,39}
- Heart disease is the leading cause of death in the United States. About 42 percent of Medicare enrollees ages 65 and older have at least one heart related condition and these enrollees have more inpatient admissions than those who do not have a heart condition.⁴⁰ About 27 percent of enrollees have coronary heart disease and 15 percent have been diagnosed with heart failure.^{41,42}

Additional prevalence estimates for Medicare enrollees for these commonly treated conditions are available in Appendix, Section B.

Health Disparities

Many of the health conditions treated by the selected drugs for the first cycle of Medicare drug price negotiations are associated with disparities in prevalence, health care access (including access to some types of medications), and outcomes based on race and ethnicity. Table 3 presents examples of key racial and ethnic disparities related to these conditions.

Table 3. Key Health Disparities Among Racial and Ethnic Groups for Conditions Commonly Treated by the Drugs Selected for the First Cycle of Medicare Drug Price Negotiations

Commonly Treated Conditions	Key Health Disparities Among Racial and Ethnic Groups
Pulmonary Embolism	Black individuals are more likely to develop and die from pulmonary embolisms compared to other racial and ethnic groups. ⁴³ One study finds that Black patients are less likely to receive anticoagulants, which are used to prevent or treat embolisms, than patients of other racial and ethnic groups. Access to specialists, out-of-pocket costs, health literacy, and other socio-demographic factors may contribute to this disparity. ⁴⁴
Cardiovascular Disease	Black individuals are more likely to die from cardiovascular disease than their White counterparts. ^{45,46} Among Medicare enrollees, the prevalence of heart failure was highest among Black enrollees (17 percent) relative to other race and ethnicity groups, including American Indian/Alaska Native enrollees (15 percent), White enrollees (14 percent), Hispanic (13 percent), and Asian enrollees (11 percent). ⁴⁷ For coronary artery disease, American Indians/Alaska Native Medicare enrollees had the highest prevalence (28 percent) compared to enrollees of other races, whose prevalence estimates range from 27 percent for White Medicare enrollees to 22 percent for Asian American enrollees. ⁴⁸
Diabetes	Among Medicare enrollees, recent research finds higher rates of diabetes among American Indian/Alaska Native enrollees (41 percent), Black/African American enrollees (37 percent), and Asian/Pacific Islander enrollees (35 percent) compared to White (24 percent) enrollees. ⁴⁹
Chronic Kidney Disease	Chronic kidney disease is more common among Black individuals and Latinos compared to their White counterparts. ^{50,51}
Rheumatoid Arthritis	There are limited studies of the prevalence of rheumatoid arthritis for specific racial and ethnic populations. One study using a national survey found that African Americans have higher rates of rheumatoid arthritis than non-Hispanic Whites. ⁵² There is also concern that the prevalence of this disease is as high as 5 percent among certain American Indian populations. ⁵³ There may be other racial and ethnic populations with high rates as well. It is unclear whether and to what extent there are disparities due to small sample sizes of individuals from racial and ethnic groups and overrepresentation of non-Hispanic Whites in studies examining rheumatoid arthritis prevalence and outcomes. ⁵⁴
Ulcerative Colitis (UC)	White individuals have a higher risk of UC relative to other racial and ethnic populations. ⁵⁵ However, studies have also found that disease severity, hospitalization, and mortality rates are higher among non-Hispanic Black patients than their White counterparts for inflammatory bowel disease related conditions and there is increasing concern that Black patients are less likely to receive certain types of treatment, including biological products, than their White counterparts. ^{56,57}
Blood Cancers	Research suggests that there is a greater incidence of some types of blood cancer among Black and Hispanic groups, and treatment outcomes are poorer for these populations than their White counterparts. For example, the incidence of multiple myeloma among Black individuals is about double what it is for their White counterparts and existing research suggests that Black individuals have reduced access to novel therapies for treatment. ⁵⁸

Source: ASPE analysis of peer reviewed and grey literature.

Notes: The 10 drugs selected for the first cycle of Medicare drug price negotiations may not be the sole drugs used to treat these conditions and treatment may include other medications and non-drug related health care services in addition to or in lieu of the 10 selected drugs.

There are also disparities in the prevalence and outcomes of these health conditions by gender. For example, among Medicare enrollees, men have a higher prevalence (32 percent) of ischemic heart disease relative to women (22 percent).⁵⁹ Autoimmune conditions, such as rheumatoid arthritis, are more prevalent among women, with research finding that up to 80 percent of autoimmune conditions occur among women.⁶⁰ Studies have also found higher rates of inflammatory bowel diseases (e.g., Crohn's disease and ulcerative colitis) among women relative to men.⁶¹ Among blood cancers, existing data finds that men are at higher risk of developing leukemia, myeloma, and lymphoma as well as elevated risk of dying from leukemia than women.^{62,63,64,65}

Disparities in the prevalence and outcomes of these condition are driven by a variety of factors, including health-related risk factors; genetic factors; socio-economic factors; and structural inequities, such as food and nutrition insecurity, language and cultural differences, historical mistrust of the health care system, implicit bias and provider discrimination, lack of adequate access to health care services, and affordability challenges.^{66,67} These and other drivers of disparities may impact whether individuals are diagnosed with these conditions, the treatment and medications they receive, and their health and wellness outcomes.

Affordability Challenges for Medicare Enrollees

Existing research shows that prior to the COVID-19 pandemic, the median income of Medicare enrollees was estimated to be about \$30,000 per person and about one in four Medicare enrollees were estimated to have incomes below \$17,000.⁶⁸ Due to the high cost of medication and treatment for many of these conditions, enrollees with these conditions, particularly those with limited incomes and assets, may experience affordability challenges, which can impact their ability to take medications as prescribed. For example, among patients with cancers, including blood cancers, financial toxicity, which refers to the adverse financial effects that cancer treatment can have due to high out-of-pocket costs and lost productivity, has been identified as a key concern.⁶⁹ Among older individuals (ages 50 and older) newly diagnosed with cancer, a substantial proportion (about 42 percent) spend their life savings within a two-year timeframe. People with more severe disease, certain comorbid conditions, such as diabetes, and lower income have higher odds of draining their assets.⁷⁰

Although studies on affordability for specific drugs are limited, the available research shows there are reasons to be concerned about high-priced drugs. One study finds that among people taking the oral anticoagulant Eliquis, up to 21 percent report not taking the medication as directed for many reasons, with about 12 percent citing the cost of medication as a barrier.⁷¹ In qualitative interviews with patients taking the drug, cost is cited as a major barrier to accessing this medication.⁷² In another study using data from the National Health Interview Survey, researchers used a weighted sample, representing about 6 million patients with diabetes who use insulin, to examine rationing behavior. Results show that an estimated 1.3 million (of 6 million) or 17 percent of American insulin users report rationing their insulin in 2021 for cost-related reasons.⁷³

In 2020, on average, Medicare beneficiaries paid \$2,218 in out-of-pocket costs for their health care services, which represents about 7 percent of income for a typical Medicare beneficiary.^{74*} Some enrollees have a much higher cost burden. Specifically, 1.5 million non-LIS Part D enrollees who reached the catastrophic coverage phase of the Part D benefit paid an average of \$3,100 annually in out-of-pocket costs for *only* their Part D prescription drugs.⁷⁵ In one study, researchers linked Medicare claims data with electronic health record data from 2012 to 2018 to examine the proportion of Part D enrollees who do not fill new prescription drugs for

* This is based on existing research that shows the median income among Medicare enrollees is about \$30,000 per year. Please see [here](#) for more details.

four conditions within a 90-day period of the drug being prescribed. Results show that Medicare enrollees who do not receive financial assistance are less likely to fill their prescriptions to initiate treatment than those who do receive financial assistance. Researchers note that the higher out-of-pocket spending among those who do not receive the low-income subsidy (LIS) is likely a major driver of this finding.⁷⁶

Research using the 2017 Medicare Current Beneficiary Survey (MCBS) finds that 11 percent of Medicare beneficiaries, which translates to about 7.2 million individuals, report having trouble paying for their health care and among these beneficiaries, nearly 75 percent report being in medical debt and/or being contacted by debt collectors.⁷⁷ Other analysis finds that over 5 million Medicare enrollees report affordability challenges in obtaining their prescription medications, with the share of Black and Latino enrollees reporting affordability challenges about 1.5 to 2 times higher than their White counterparts.⁷⁸ Moreover, enrollees with certain chronic conditions, such as diabetes, report higher rates of affordability challenges than other enrollees.⁷⁹

Although there are a variety of factors that shape individuals' use of medications, out-of-pocket spending plays a role in affordability and access. In the next section, we focus specifically on the 10 drugs selected for the first cycle of Medicare drug price negotiation to determine the total cost to Medicare and the out-of-pocket cost to Medicare enrollees for these drugs.

D. MEDICARE UTILIZATION AND SPENDING FOR SELECTED DRUGS

SUMMARY: Altogether, about 7.7 million unique Medicare enrollees in 2022 used *one or more* of the 10 drugs selected for the first cycle of Medicare drug price negotiations, which represents about 15 percent of all Medicare Part D enrollees in 2022. Overall, total spending for the 10 selected drugs more than doubled, going from about \$20 billion in 2018 to about \$46 billion in 2022, an increase of 134 percent. This increase is more than three times as fast as the rate of growth in total spending on all Part D drugs over the same time period. Overall, enrollee out-of-pocket spending totaled \$3.4 billion in 2022, a 116 percent increase since 2018. Among enrollees who do not receive the low-income subsidy (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/Fiasp in 2022.

We used Prescription Drug Event (PDE) data and Part D enrollment data to examine prescription drug use and spending in Medicare Part D in calendar year 2022 for each of the 10 drugs covered under Part D selected for the first cycle of Medicare drug price negotiations. We followed CMS's approach for identifying each drug. For the purposes of this report, total drug spending is based on gross drug costs, which represent total spending for the prescription claim, including Medicare, plan, and beneficiary out-of-pocket spending. Out-of-pocket spending is based on the actual enrollee payment and does not include any third-party payments or rebates. We examined use, total spending, and out-of-pocket spending for each of the 10 drugs among all Part D enrollees and separately by whether an enrollee receives 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.⁸⁰ We also examined the demographic characteristics of enrollees who used each of the selected drugs in calendar year 2022.

Our approach to analyzing use and spending for the 10 selected drugs is different from CMS: *we examined use, total gross drug spending, and out-of-pocket spending for the full 2022 calendar year whereas CMS examined use and total gross drug spending from June 1, 2022 through May 31, 2023.* Thus, differences between the estimates presented in this report and the figures reported by CMS reflect differences in the time periods examined for the analyses. Additional details on the methodology are presented in the Appendix, Section B.

Use of the Selected 10 Drugs

Table 4 presents utilization of the 10 drugs covered under Part D selected for the first cycle of Medicare drug price negotiations, separately for LIS and non-LIS enrollees and for both sets of enrollees combined.

Altogether, about 7.7 million unique enrollees in 2022 used one or more of the 10 drugs selected, which represents about 15 percent of all Medicare Part D enrollees (about 53 million) in 2022. About 1.1 million enrollees took more than one of the selected drugs; most enrollees took only one of the selected drugs. These drug use estimates include all Part D enrollees who used each drug in 2022; they are not limited to enrollees who used these drugs for the conditions shown in Table 2.

Among the 53 million Medicare Part D enrollees in 2022, 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.* The 3.5 million Part D enrollees who used Eliquis in 2022 represent about 6.6 percent of all Part D enrollees. Imbruvica and Stelara had the lowest share of Part D enrollees who took the drug in 2022 (less than 0.1 percent).

* 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.

Overall, a greater share of LIS enrollees used the selected drugs compared to the share of non-LIS enrollees (18 percent of all LIS enrollees compared to 13 percent of all non-LIS enrollees). The largest difference is seen for NovoLog/Fiasp (2 percentage point difference between the proportion of LIS enrollees taking the drug and non-LIS enrollees taking the drug). Differences are consistent with existing research that shows people with lower income have greater prevalence of chronic conditions such as diabetes.^{81*}

Table 4. Medicare Part D Enrollees’ Calendar Year 2022 Use of Drugs Selected for the First Cycle of Medicare Drug Price Negotiations

Drug Name	LIS		Non-LIS		All	
	Total Number of LIS Enrollees Taking the Drug in CY 2022 ^a	Share of LIS Enrollees Taking Each Drug Among the Entire LIS Part D Population ^b	Total Number of Medicare Part D Non-LIS Enrollees Taking the Drug in CY2022	Share of LIS Enrollees Taking Each Drug Among the Entire Non-LIS Part D Population ^b	Total Number of Medicare Part D Enrollees Taking the Drug in CY2022	Share of Medicare Enrollees Taking Each Drug Among the Entire Part D Population ^b
Eliquis	1,013,000	6.8%	2,492,000	6.5%	3,505,000	6.6%
Jardiance	562,000	3.8%	759,000	2.0%	1,321,000	2.5%
Xarelto	370,000	2.5%	941,000	2.5%	1,311,000	2.5%
Januvia	426,000	2.8%	459,000	1.2%	885,000	1.7%
Farxiga	280,000	1.9%	359,000	0.9%	639,000	1.2%
Entresto	203,000	1.4%	318,000	0.8%	521,000	1.0%
Enbrel	26,000	0.2%	21,000	0.1%	47,000	0.1%
Imbruvica	4,000	< 0.1%	18,000	< 0.1%	22,000	< 0.1%
Stelara	10,000	< 0.1%	10,000	< 0.1%	20,000	< 0.1%
NovoLog/Fiasp	431,000	2.9%	332,000	0.9%	763,000	1.4%
Total Unduplicated Number of Enrollees Taking these Drugs^c	2,724,000	18%	5,019,000	13%	7,743,000	15%

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.

^aThe 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 Table 2.

^bThe denominators are about 15 million LIS enrollees, about 38 million non-LIS enrollees, and about 53 million total Part D enrollees.

^cAbout 1.1 million enrollees took more than one of these drugs in 2022.

For most of the selected drugs, the number of Medicare enrollees taking each drug increased between 2018 and 2022 (see Appendix Section D for detailed estimates), however there were some notable exceptions. Among drugs with increased use over time, the greatest increases in utilization were for Jardiance (505

* Disparities in health by socioeconomic status, including income, are well documented in existing research and driven by a number of factors, such as access to care and reduced access to social resources such as stable housing. For more information, please see [here](#).

percent), Farxiga (454 percent), Entresto (246 percent), and Eliquis (113 percent). These increases in use may reflect many factors, including, for example, the addition of new labeled indications, increased incidence of the conditions treated by these drugs, and greater enrollment in Medicare Part D.

There were two drugs where use declined over time. The use of Januvia declined about 4 percent and the use of NovoLog/Fiasp declined about 5 percent from 2018 to 2022. There was one drug, Imbruvica, where utilization estimates fluctuated over time, increasing from 2018 to 2021 and then declining in 2022.

Total Gross Drug Spending for Each of the Selected Drugs

Table 5 presents total gross drug spending by LIS status in 2022 for each of the 10 drugs selected for the first cycle of Medicare drug price negotiations. Total gross drug spending for all selected drugs across all enrollees (LIS and non-LIS) was \$46.4 billion in 2022, which represents about 19 percent of total Part D spending in 2022. * Total gross drug spending was higher for non-LIS enrollees than LIS enrollees because there are more non-LIS enrollees than LIS enrollees taking the selected drugs.

Average annual total spending per enrollee for each selected drug was generally similar for LIS and non-LIS enrollees. For all enrollees, annual total gross drug spending per enrollee was highest for Imbruvica (\$129,000), followed by Stelara (\$117,000) and Enbrel (\$57,000), and lowest for NovoLog/Fiasp[†] (\$3,300), followed by Farxiga (\$4,000) and Eliquis (\$4,300) in 2022.

* Part D total gross drug spending in 2022 was about \$240 billion.

† The drug is also identified with the proprietary names: NovoLog; NovoLog FlexPen; NovoLog PenFill; Fiasp; Fiasp FlexTouch; Fiasp PenFill.

Table 5. Medicare Enrollees’ Average Annual Total and Average Annual Per Enrollee Total Drug Spending in Calendar Year 2022 for Each Part D Drug Selected for the First Cycle of Medicare Drug Price Negotiations

Drug Name	LIS		Non-LIS		All	
	Total Gross Drug Spending in CY 2022	Average Annual Total Drug Spending Per Enrollee Taking the Drug	Total Gross Drug Spending in CY 2022	Average Annual Total Drug Spending Per Enrollee Taking the Drug	Total Gross Drug Spending in CY 2022	Average Annual Total Drug Spending Per Enrollee Taking the Drug
Eliquis	\$4,327,661,000	\$4,272	\$10,893,089,000	\$4,371	\$15,220,750,000	\$4,342
Jardiance	\$2,696,085,000	\$4,800	\$3,156,148,000	\$4,156	\$5,852,233,000	\$4,430
Xarelto	\$1,664,938,000	\$4,496	\$4,108,174,000	\$4,365	\$5,773,111,000	\$4,402
Januvia	\$2,072,517,000	\$4,864	\$2,025,788,000	\$4,416	\$4,098,305,000	\$4,631
Farxiga	\$1,213,446,000	\$4,340	\$1,371,404,000	\$3,817	\$2,584,850,000	\$4,046
Entresto	\$1,023,359,000	\$5,035	\$1,466,361,000	\$4,616	\$2,489,720,000	\$4,780
Enbrel	\$1,440,679,000	\$56,270	\$1,214,619,000	\$57,083	\$2,655,298,000	\$56,639
Imbruvica	\$574,326,000	\$130,529	\$2,279,703,000	\$128,059	\$2,854,029,000	\$128,548
Stelara	\$1,277,103,000	\$124,292	\$1,062,480,000	\$109,545	\$2,339,583,000	\$117,131
NovoLog / Fiasp	\$1,400,059,000	\$3,248	\$1,135,711,000	\$3,421	\$2,535,770,000	\$3,323
Total*	\$17,690,173,000	-	\$28,713,477,000	-	\$46,403,649,000	-

Source: ASPE analysis using the 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 drug definition. ASPE estimates differ from drug use and spending estimates produced by CMS primarily due to differences in the time period examined. Enrollees are included in the analysis if they have taken a selected drug during the time period examined. Total drug spending is based on gross drug costs, which represent total spending for the prescription claim, including Medicare, plan, and beneficiary payments.

Table 6 presents average annual total gross spending per enrollee over time. Results show that from 2018 to 2022, there was an increase in total drug costs per enrollee over time for each of the 10 selected drugs. Average total gross spending per enrollee changed the most for Stelara, with a 97 percent increase (\$59,000 per enrollee in 2018 to \$117,000 per enrollee in 2022), Entresto, with a 51 percent increase (\$3,200 per enrollee in 2018 to \$4,800 per enrollee in 2022), and Imbruvica, with a 51 percent increase (\$85,000 per enrollee in 2018 to \$129,000 per enrollee in 2022). For comparison, the average Social Security benefit increased 24.9 percent over the same period. * For all of the selected drugs, with the exception of NovoLog/Fiasp, average gross drug spending per enrollee exceeded the increase in average total Part D drug spending per enrollee during the same time period.

Overall, total gross spending for the 10 selected drugs more than doubled, going from about \$20 billion in 2018 to about \$46 billion in 2022, an increase of 134 percent. At the same time, Part D total gross drug spending grew by about 43 percent, going from about \$168 billion in 2018 to \$240 billion in 2022. The rate of

* ASPE analysis of Social Security Administration data (<https://www.ssa.gov/policy/docs/statcomps/supplement/2023/5c.html#table5.c2>, accessed October 4, 2023).

growth in spending for these 10 drugs is more than three times as fast as spending for all Part D drugs over this period.

The increase in gross drug cost per enrollee taking each of the selected drugs is consistent with existing research on the increases in the list price of each drug over time. For example, since Eliquis first came on the market in 2012, its list price has increased by 124 percent while the corresponding increase in the Consumer Price Index for All Urban Consumers (CPI-U), measuring price changes for all goods and services, was 31 percent.⁸² Similarly, Stelara has had multiple price increases, with the most recent price increase of about 4 percent occurring in January 2023.⁸³ Since its approval in 2009, Stelara’s price has increased by about 184 percent.⁸⁴ A third example is Imbruvica, which has had a lifetime price change of about 108 percent since it came on the market in 2013.⁸⁵

Table 6. Average Annual Total Gross Spending per Enrollee Taking Each Drug Selected for the First Cycle of Medicare Drug Price Negotiations Over Time (2018 – 2022)

Drug Name	2018	2019	2020	2021	2022	Annual Average Percent Change Per Year (2018 – 2022)	Percent Change from 2018 – 2022
Eliquis	\$3,031	\$3,369	\$3,761	\$4,024	\$4,342	9%	43%
Jardiance	\$3,063	\$3,433	\$3,995	\$4,224	\$4,430	10%	45%
Xarelto	\$3,197	\$3,595	\$3,968	\$4,154	\$4,402	8%	38%
Januvia	\$3,511	\$3,769	\$4,135	\$4,344	\$4,631	7%	32%
Farxiga	\$3,093	\$3,622	\$3,799	\$3,686	\$4,046	7%	31%
Entresto	\$3,162	\$3,649	\$4,250	\$4,363	\$4,780	11%	51%
Enbrel	\$41,500	\$44,470	\$48,890	\$51,475	\$56,639	8%	36%
Imbruvica	\$85,128	\$95,787	\$110,363	\$120,964	\$128,548	11%	51%
Stelara	\$59,355	\$72,934	\$85,671	\$97,027	\$117,131	19%	97%
NovoLog/Fiasp	\$3,002	\$3,158	\$3,221	\$3,248	\$3,323	3%	11%

Source: ASPE analysis using the 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 drug definition. ASPE estimates differ from drug use and spending estimates produced by CMS primarily due to differences in the time period examined. Enrollees are included in the analysis if they have taken a selected drug during the time period examined. Spending estimates are not adjusted for inflation. Total spending is based on gross drug costs, which represent total spending for the prescription claim, including Medicare, plan, and beneficiary payments.

Total Annual Out-Of-Pocket Spending for Selected Drugs

In 2022, out-of-pocket costs for the drugs selected for the first cycle of Medicare drug price negotiations totaled \$3.4 billion. Out-of-pocket spending in calendar year 2022 for each of the 10 drugs is presented in Table 7. 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 was less than \$35 per enrollee, with the exception of Imbruvica, which had the highest average out-of-pocket costs at about \$187 per enrollee in 2022.

Among non-LIS enrollees, average out-of-pocket costs were considerably higher, ranging from a high of about \$6,500 for each enrollee taking Imbruvica to a low of about \$261 for each enrollee taking NovoLog/Fiasp in 2022.

For all enrollees, average annual out-of-pocket spending per enrollee was highest for Imbruvica (\$5,247), followed by Stelara (\$2,048), and Enbrel (\$921). These out-of-pocket spending estimates are driven largely by

non-LIS enrollees, who represented about 72 percent of the program’s enrollment in 2022. The average out-of-pocket spending as a share of total spending was highest for Eliquis and Xarelto; for each of these drugs, out-of-pocket spending per enrollee represented about 10 percent of total gross drug costs per enrollee. Across all 10 drugs, total out-of-pocket spending for the selected drugs for price applicability year 2026 represented about 7 percent of total gross drug spending for these drugs in 2022.

Table 7. Average Annual Part D Out-Of-Pocket Spending in Calendar Year 2022 for Each Drug Selected for the First Cycle of Medicare Drug Price Negotiations

Drug Name	LIS		Non-LIS		Total		
	Total Out-Of-Pocket Spending in CY 2022	Average Annual Out-Of-Pocket Spending Per Enrollee	Total Out-Of-Pocket Spending in CY 2022	Average Annual Out-Of-Pocket Spending Per Enrollee	Total Out-Of-Pocket Spending in CY 2022	Average Annual Out-Of-Pocket Spending Per Enrollee	Out-Of-Pocket Spending as a Percent of Gross Drug Spending ^a
Eliquis	\$31,396,000	\$31	\$1,514,962,000	\$608	\$1,546,358,000	\$441	10%
Jardiance	\$11,029,000	\$20	\$372,318,000	\$490	\$383,346,000	\$290	7%
Xarelto	\$11,011,000	\$30	\$580,598,000	\$617	\$591,609,000	\$451	10%
Januvia	\$8,488,000	\$20	\$230,403,000	\$502	\$238,891,000	\$270	6%
Farxiga	\$5,156,000	\$18	\$160,870,000	\$448	\$166,026,000	\$260	6%
Entresto	\$5,176,000	\$25	\$180,625,000	\$569	\$185,802,000	\$357	7%
Enbrel	\$529,000	\$21	\$42,658,000	\$2,005	\$43,187,000	\$921	2%
Imbruvica	\$823,000	\$187	\$115,666,000	\$6,497	\$116,489,000	\$5,247	4%
Stelara	\$299,000	\$29	\$40,800,000	\$4,207	\$41,099,000	\$2,058	2%
NovoLog/Fiasp	\$6,140,000	\$14	\$86,532,000	\$261	\$92,672,000	\$121	4%
Total	\$80,048,000	-	\$3,325,431,000	-	\$3,405,479,000	-	7%

Source: ASPE analysis using the 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 drug definition. ASPE estimates differ from drug use and spending estimates produced by CMS primarily due to differences in the time period examined. Enrollees are included in the analysis if they have taken a selected drug during the time period 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. Total spending is based on gross drug costs, which represent total spending for the prescription claim, including Medicare, plan, and beneficiary payments.

^aPercent is calculated by dividing average annual out-of-pocket spending per enrollee by average annual total gross drug spending per enrollee for each selected drug and multiplying by 100, with the exception of the total row. For this row, percent is calculated by dividing total annual out of pocket spending across all selected drugs by total annual gross drug spending across all selected drugs and multiplying by 100.

From 2018 to 2022, total out-of-pocket spending on the selected drugs grew 116 percent, going from \$1.6 billion in 2018 to \$3.4 billion in 2022; this is substantially greater than total out-of-pocket spending for all Part D drugs, which increased by about 10 percent in the same time period.*

Table 8 shows how enrollee average annual out-of-pocket spending for each drug changed over time, from 2018 to 2022. During this time period, average out-of-pocket spending per enrollee increased at least 10 percent for all drugs, with the exception of NovoLog/Fiasp, which showed a reduction of about 28 percent for all enrollees, from \$168 per enrollee in 2018 to \$121 in 2022. However, the average annual out-of-pocket

* ASPE analysis of PDE data finds that out-of-pocket spending for all Part D drugs totaled \$16.7 billion in 2018 and \$18.5 billion in 2022.

spending estimates for NovoLog/Fiasp fluctuated from year to year between 2018 to 2022, with declines in more recent years. *

For the remaining drugs, average annual out-of-pocket spending per enrollee increased more than 10 percent from 2018 to 2022. Stelara had the largest increase (190 percent) in annual out-of-pocket spending from 2018 to 2022, going from \$709 per enrollee in 2018 to \$2,058 in 2022. This is followed by Imbruvica where out-of-pocket spending grew by about 36 percent from \$3,854 per enrollee in 2018 to \$5,247 per enrollee in 2022. These increases may be driven by the nearly 25 percent statutory increase in the catastrophic threshold in 2020, going from \$5,100 in 2019 to \$6,350 in 2020, which resulted in greater cost-sharing for enrollees, particularly those who take higher cost drugs.

For eight of the drugs, average annual out-of-pocket spending declined from 2018 to 2019 before increasing again in subsequent years. This decline may reflect multiple factors, including the closing of the Part D coverage gap which began with the Affordable Care Act in 2010 and accelerated with the Bipartisan Budget Act of 2018.

Table 8. Average Annual Part D Out-Of-Pocket Spending per Enrollee Taking the Selected Drugs from 2018 to 2022 for Each Drug Selected for the First Cycle of Medicare Drug Price Negotiations

Drug Name	2018	2019	2020	2021	2022	Annual Average Percent Change in Out-of-Pocket Spending (2018–2022)	Percent Change in Out-of-Pocket Spending from 2018 – 2022
Eliquis	\$358	\$348	\$405	\$422	\$441	6%	23%
Jardiance	\$256	\$226	\$277	\$285	\$290	4%	13%
Xarelto	\$357	\$356	\$419	\$435	\$451	6%	26%
Januvia	\$240	\$224	\$258	\$264	\$270	3%	12%
Farxiga	\$206	\$214	\$255	\$242	\$260	6%	26%
Entresto	\$315	\$300	\$362	\$351	\$357	4%	13%
Enbrel	\$803	\$758	\$839	\$870	\$921	4%	15%
Imbruvica	\$3,854	\$3,885	\$4,591	\$5,043	\$5,247	8%	36%
Stelara	\$709	\$662	\$863	\$1,272	\$2,058	33%	190%
NovoLog/Fiasp	\$168	\$151	\$173	\$134	\$121	-7%	-28%

Source: ASPE analysis using the 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 drug definition. ASPE estimates differ from drug use and spending estimates produced by CMS primarily due to differences in the time period examined. Enrollees are included in the analysis if they have taken a selected drug during the time period 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.

Out-of-Pocket Spending for Specific Populations

We carried out additional analyses to understand out-of-pocket spending on the selected drugs for specific populations. First, separately for enrollees taking at least one of the selected drugs and those taking more

* The reason for this decline is not known and may be due to a variety of factors, including the implementation of the Part D Senior Savings Model (PDSS) with certain Part D sponsors, which went into effect January 1, 2021. The Model tests changes to the Part D benefit design and includes requirements that enrollees of participating plans would generally not need to pay more than \$35 for a monthly supply of certain insulin products. Details about the PDSS Model are available here: <https://innovation.cms.gov/innovation-models/part-d-savings-model>.

than one of the selected drugs, we examined the total Part D out-of-pocket spending to better understand how spending on selected drugs contributes to their total Part D drug spending. We also examined the number of enrollees who spent more than \$1,000 in out-of-pocket costs for each of the selected drugs.

Total Part D Out-Of-Pocket Spending Among Enrollees Taking the Selected Drugs

Among enrollees who take at least one of the selected drugs, those taking Imbruvica had the highest average annual out-of-pocket spending per enrollee on all Part D drugs (\$5,700) and those taking Januvia had the lowest average annual out-of-pocket spending per enrollee on all Part D drugs (\$690). For enrollees who take Imbruvica, about 93 percent of their total average Part D out-of-pocket costs are for the selected drugs. (Table 9). Overall, for the entire population of enrollees who take at least one of the selected drugs, out-of-pocket spending on the selected drugs represents about 52 percent of the average annual spending per enrollee on all of their Part D drugs.

Table 9. Total Part D Out-Of-Pocket Spending and Out-Of-Pocket Spending on Selected Drugs

Drug Name	All			
	Number of Enrollees	Average Out-of-Pocket Spending Per Enrollee for <i>all</i> Part D Drugs	Average Out-of-Pocket Spending Per Enrollee for <i>Selected Drugs</i> ^a	Share of Out-of-Pocket Spending on Selected Drugs as a Percentage of Total Part D Out-of-Pocket Spending
Eliquis	3,505,000	\$917	\$496	54%
Jardiance	1,321,000	\$830	\$402	48%
Xarelto	1,311,000	\$923	\$514	56%
Januvia	885,000	\$686	\$369	54%
Farxiga	639,000	\$827	\$393	48%
Entresto	521,000	\$954	\$588	62%
Enbrel	47,000	\$1,137	\$943	83%
Imbruvica	22,000	\$5,677	\$5,290	93%
Stelara	20,000	\$2,347	\$2,086	89%
NovoLog/Fiasp	763,000	\$692	\$208	30%
Total	7.7 million	\$852	\$440	52%

Source: ASPE analysis using the 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 drug definition. ASPE estimates differ from drug use and spending estimates produced by CMS primarily due to differences in the time period examined. Enrollees are included in the analysis if they have taken selected drugs during the time period examined.

^aAverage out-of-pocket spending captures out-of-pocket costs for all selected drugs. If an enrollee takes more than one of the selected drugs, then the average out-of-pocket cost shown for each drug includes their spending on all of the selected drugs they use.

About 1.1 million enrollees used more than one of the selected drugs in 2022. For these enrollees, average out-of-pocket spending for all Part D drugs and average out-of-pocket spending on the selected drugs are presented in the Appendix, Section D. Among this population, average annual out-of-pocket spending per enrollee for all Part D drugs is highest for enrollees who take Imbruvica (\$5,400) and lowest for NovoLog/Fiasp (\$800). Similarly, the share of average out-of-pocket spending for selected drugs as a percentage of average Part D out-of-pocket spending for all drugs per enrollee is highest for enrollees who take Imbruvica (91 percent) and lowest for enrollees who take NovoLog/Fiasp (43 percent). Overall, average out-of-pocket spending per enrollee on the selected drugs accounts for about 59 percent of average out-of-pocket spending per enrollee for all Part D drugs among this group of enrollees.

Enrollees with Out-of-Pocket Spending of more than \$1,000 on the Selected Drugs

We also examined enrollees with out-of-pocket spending of more than \$1,000 for each drug in 2022. Imbruvica had the highest percentage of enrollees (64%) with out-of-pocket payments of more than \$1,000, with average out-of-pocket spending of \$8,162 per enrollee among this population. This is followed by Stelara where about 27 percent of enrollees taking the drug paid more than \$1,000 in out-of-pocket costs in 2022; average out-of-pocket spending was \$7,280 per enrollee for this drug. The largest number of enrollees spending more than \$1,000 in annual out-of-pocket costs was for Eliquis, with about 591,000 such enrollees spending an average of \$1,326. Please see Appendix Section D for the full set of estimates for each drug.

Demographic Characteristics of Enrollees Taking the 10 Selected Drugs

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 the first cycle of Medicare drug price negotiations are available in Appendix Section D. 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.⁸⁶

Gender: 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 and women using each drug. Jardiance, Farxiga, Entresto, and Imbruvica have a greater proportion of use by men compared to their share of the Part D population. Enbrel had a much larger share of women (72 percent) taking the drug than men (28 percent).

Age Group: 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, make up a much larger share of users for Stelara (43 percent), Enbrel (33 percent), and NovoLog/Fiasp (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 is less than 5 percent for Jardiance, Enbrel, and Stelara.

Racial and Ethnic Groups: Consistent with the composition of the entire Medicare Part D population, the majority of enrollees taking each of the 10 drugs selected for the first cycle of Medicare drug price negotiations 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/Fiasp. 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, differences were 5 percentage points or less between the group's representation in the Part D population and their share of users for each drug, with one exception. We observed the highest share of Latino enrollees using Januvia (about 16 percent), a proportion that is 6 percentage points greater than Latino representation in the Part D population (10 percent).

Geographic Area: In general, the majority of both Part D enrollees and enrollees taking each drug reside in urban areas.

We also examined average out-of-pocket spending for all enrollees by demographic characteristics for all enrollees (Appendix Section D). There are differences in average out-of-pocket payments by demographic characteristics, notably for gender, where men have higher payments than women across all drugs. In general, enrollees under the age of 65 pay less than those in other age groups for each of the selected drugs. Across all drugs, White enrollees pay more out-of-pocket than enrollees from other racial and ethnic groups. For the majority of selected drugs, enrollees residing in rural areas pay more in average out-of-pocket costs than enrollees in urban areas, with the exception of Enbrel and Stelara. These differences in average out-of-pocket spending for the selected drugs are likely driven by a variety of factors, including differences in LIS status and eligibility for patient assistance programs.

State and Territory Estimates

Table E1 in the Appendix presents state and territory 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 the first cycle of Medicare drug price negotiations. 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. Many of the estimates for American Samoa, Guam, the Northern Mariana Islands, and the U.S. Virgin Islands are suppressed due to the small Medicare population in these territories and CMS disclosure rules.⁸⁷

Collectively, these results show that the gross drug costs for the 10 drugs selected for price applicability year 2026 represent a substantial portion of total Medicare gross drug spending and enrollees taking these drugs spend about \$3.4 billion in out-of-pocket costs. For enrollees taking the selected drugs, average out-of-pocket costs for the selected drugs represent about 52 percent of their average total out-of-pocket drug spending in 2022. For the majority of these drugs, gross drug spending and out-of-pocket spending has increased over time.

E. CONCLUSION

Seven of the 10 selected drugs relied on at least one form of federal contribution or support relevant to their drug development, although the nature of federal support was unique to each drug. The most common type of federal support was use of the R&D tax credit, which applies to seven drugs. Government interest patents are a less common type of support, which only one drug received.

Our findings show that the total drug costs for the 10 drugs selected for the first cycle of Medicare drug price negotiations are substantial. In 2022, the total Medicare gross drug costs for the selected drugs were \$46.4 billion, which represents about 19 percent of total Medicare Part D drug spending.* About 15 percent of all Part D enrollees used one of the selected drugs in 2022. Moreover, Medicare gross drug spending has been increasing for these drugs from 2018 to 2022 at more than three times the rate of spending for all Part D drugs.

For enrollees who take these drugs, the out-of-pocket costs can be significant. In 2022, average annual out-of-pocket spending of Medicare Part D enrollees who used one of the 10 drugs selected for the first cycle of Medicare drug price negotiations ranged from a high of \$5,247 per enrollee for Imbruvica to a low of \$121 per enrollee for NovoLog/Fiasp. 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/Fiasp. Additionally, from 2018 to 2022, out-of-pocket spending per enrollee increased for all drugs, with the exception of NovoLog/Fiasp. Stelara had the largest increase (190 percent) in annual average out-of-pocket spending from 2018 to 2022, going from \$709 per enrollee in 2018 to \$2,058 in 2022.

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 end stage renal disease, made up a much larger share of users for Stelara, Enbrel, and NovoLog/Fiasp 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.

Prior to the COVID-19 pandemic, the median income of Medicare enrollees was estimated to be about \$30,000 per person and about 1 in 4 Medicare enrollees were estimated to have incomes of below \$17,000.⁸⁸ If a typical Medicare enrollee with a median income of about \$30,000 annually was taking Imbruvica, their out-of-pocket cost for that drug alone would be about 22 percent of their income, which could pose significant financial hardship.

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. In addition, the \$2,000 cap on out-of-pocket spending under Part D that goes into effect in 2025 is also expected to help enrollees who take high-priced prescription drugs, such as some of the selected drugs presented in this report.[†] Collectively, the IRA

* ASPE analysis indicates that total gross drug spending in 2022 was about \$240 billion.

† As required by the IRA, the amount of the cap will be adjusted annually to reflect the rate of growth in per capita Part D costs.

Medicare drug-related provisions will strengthen the program's ability to serve people with Medicare now and for generations to come.

APPENDIX

Section A: Inflation Reduction Act Projected Impacts

Existing research finds that the IRA's Medicare drug-related provisions are expected to save Medicare enrollees and taxpayers billions of dollars. For example:

- Had the insulin cap for Medicare Part B and Part D been in effect in 2020, 1.5 million Medicare enrollees would have paid \$761 million less in out-of-pocket costs, which translates to about \$500 a year in average annual savings per person among those benefiting from the provision.⁸⁹
- The elimination of cost-sharing for Advisory Committee on Immunization Practices (ACIP) recommended adult vaccines covered under Part D would have saved 3.4 million enrollees who received a vaccine under Part D in 2021 about \$234 million in out-of-pocket costs, which translates to about \$70 per enrollee receiving a vaccine.⁹⁰
- When the vaccine, insulin, and Part D redesign provisions, which include a \$2,000 annual cap that begins in 2025 and is adjusted for inflation annually thereafter, are all in effect in 2025, researchers project about a \$7.4 billion reduction in annual out-of-pocket spending. This would affect nearly 1 in 3 Part D enrollees (18.7 million enrollees in 2025) and these enrollees are expected to save about \$400 per year.⁹¹ About 1.9 million of these enrollees are projected to save even more -- at least \$1,000 in 2025 -- under the IRA.⁹²

Section B: Clinical Context for Selected Drugs for the First Cycle of Medicare Drug Price Negotiations

Table B1. FDA Indications of the Ten Selected Drugs*

Drug Name	FDA Indications
Eliquis (apixaban)	Factor Xa inhibitor indicated: <ol style="list-style-type: none"> 1. To reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation 2. For prophylaxis of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE), in patients who have undergone hip or knee replacement surgery 3. For the treatment of DVT and PE, and for the reduction in the risk of recurrent DVT and PE following initial therapy
Jardiance (empagliflozin)	Sodium-glucose co-transporter 2 (SGLT2) inhibitor indicated: <ol style="list-style-type: none"> 1. To reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure 2. To reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease 3. As an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients aged 10 years and older with type 2 diabetes mellitus
Xarelto (rivaroxaban)	Factor Xa inhibitor indicated: <ol style="list-style-type: none"> 1. To reduce risk of stroke and systemic embolism in nonvalvular atrial fibrillation 2. For treatment of DVT 3. For treatment of pulmonary embolism PE 4. For reduction in the risk of recurrence of DVT or PE 5. For the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery 6. For prophylaxis of venous thromboembolism (VTE) in acutely ill medical patients 7. Reduce the risk of major cardiovascular events in patients with coronary artery disease 8. Reduce the risk of major thrombotic vascular events in patients with peripheral artery disease (PAD), including patients after recent lower extremity revascularization due to symptomatic PAD 9. Treatment of VTE and reduction in the risk of recurrent VTE in pediatric patients from birth to less than 18 years 10. For thromboprophylaxis in pediatric patients 2 years and older with congenital heart disease after the Fontan procedure
Januvia (sitagliptin phosphate)	Dipeptidyl peptidase-4 (DPP-4) inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus
Farxiga (dapagliflozin)	SGLT2 inhibitor indicated: <ol style="list-style-type: none"> 1. Reduce the risk of sustained eGFR decline, end stage kidney disease, cardiovascular death, and hospitalization for heart failure in adults with chronic kidney disease at risk of progression 2. To reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in adults with heart failure 3. Reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and either established cardiovascular disease or multiple cardiovascular risk factors 4. As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus

* FDA Indications are based on the most recent label for the product as of September 2023.

Drug Name	FDA Indications
Entresto (sacubitril*; valsartan)	<ol style="list-style-type: none"> 1. To reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart failure. Benefits are most clearly evident in patients with left ventricular ejection fraction below normal 2. For the treatment of symptomatic heart failure with systemic left ventricular systolic dysfunction in pediatric patients aged one year and older. Entresto reduces NT-proBNP and is expected to improve cardiovascular outcomes
Enbrel (etanercept)	<p>A tumor necrosis factor (TNF) blocker indicated for the treatment of:</p> <ol style="list-style-type: none"> 1. Rheumatoid Arthritis 2. Polyarticular Juvenile Idiopathic Arthritis in patients aged 2 years or older 3. Psoriatic Arthritis (PsA) 4. Ankylosing Spondylitis 5. Plaque Psoriasis in patients 4 years or older
Imbruvica (ibrutinib)	<p>Kinase inhibitor indicated for the treatment of:</p> <ol style="list-style-type: none"> 1. Adult patients with chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL) 2. Adult patients with CLL/SLL with 17p deletion 3. Adult patients with Waldenström’s macroglobulinemia 4. Adult and pediatric patients age 1 year and older with chronic graft versus host disease after failure of one or more lines of systemic therapy
Stelara (ustekinumab)	<p>Human interleukin-12 and -23 antagonist indicated for the treatment of:</p> <p>Adult patients with:</p> <ol style="list-style-type: none"> 1. Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy 2. Active PsA 3. Moderately to severely active Crohn’s disease 4. Moderately to severely active ulcerative colitis <p>Pediatric patients 6 years and older with:</p> <ol style="list-style-type: none"> 1. Moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy 2. PsA
NovoLog/Fiasp (insulin aspart recombinant)	<p>Rapid-acting human insulin analog indicated to improve glycemic control in adults and pediatric patients with diabetes mellitus</p>

Source: ASPE analysis of Drugs@FDA

* The active moiety as defined by CMS is sacubitrilat.

Table B2. Common Health Conditions Treated by the Selected Drugs and Clinical Health Consequences

Condition	Description	Health Consequences of Disease Progression
Blood clots	An acute condition where a mass of blood cells and other substances form in blood vessels to reduce or obstruct blood flow. ⁹³ Depending on the location of the blood clot, immediate treatment may be required.	Without immediate treatment, certain types of blood clots can cause life threatening complications, such as pulmonary embolisms, which can lead to heart attack, stroke, and death if not treated immediately. ⁹⁴
Diabetes	<p>A chronic condition caused by insulin dysfunction. There are two types⁹⁵:</p> <p>Type 1: An autoimmune disease where the body does not make insulin (or only makes a small amount).</p> <p>Type 2: The body does not produce sufficient insulin (insulin deficiency) or becomes resistant to insulin's function leading to limited efficiency of the insulin that is produced. (This is the most common type of diabetes among the Medicare population.)</p>	Over time, uncontrolled diabetes damages organs. Serious complications include diabetic ketoacidosis, chronic hyperglycemia, heart disease, stroke, kidney problems, end-stage renal disease, nerve damage, amputations, and others. ⁹⁶
Cardiovascular Disease, including coronary or peripheral artery disease and heart failure	<p>Coronary artery disease occurs when there is a build-up of plaque in the artery walls that lead to the heart causing them to narrow over time, resulting in reduced blood flow to the heart.⁹⁷</p> <p>Peripheral artery disease occurs when there is a build-up of plaque in the artery walls that are in the legs or lower extremities.⁹⁸</p> <p>Heart failure occurs when the heart muscles have weakened and cannot pump sufficient amounts of blood throughout the body.⁹⁹</p>	<p>Coronary artery disease can cause permanent damage to the heart and other organs (e.g., liver and kidneys) and increased risk of sudden heart attack and stroke.</p> <p>Peripheral artery disease can lead to limb amputation and increased risk of heart attack and stroke.</p> <p>Heart failure can lead to other problems including changes in the size and functioning of the heart, damage to liver and kidneys, fluid retention in organs and limbs, and sudden cardiac arrest, stroke, and death.¹⁰⁰</p>
Chronic Kidney Disease	Chronic kidney disease is a progressive disease that results in a gradual decline of kidney function. Loss of kidney function causes buildup of waste and excess fluids in the body. ¹⁰¹	Chronic kidney disease can lead to end stage kidney failure, which can be fatal without dialysis or a kidney transplant.
Autoimmune conditions: Psoriasis, psoriatic arthritis,	<p>Psoriasis is a chronic skin condition that causes build-up of skin cells and inflammation of the skin due to immune system overreaction. It causes red and scaly rashes and inflammation.</p> <p>Psoriatic arthritis is a form of arthritis with a skin rash (psoriasis). It causes pain in the joints and chronic inflammation of the joints. Patients experience pain and fatigue.</p>	Although there is no cure for psoriasis, if it goes untreated, it can result in inflammation of joints and increased risk for other conditions such as joint damage, heart disease, inflammatory bowel disease, and (type 2) diabetes. ¹⁰² It can also lead to psoriatic arthritis, which may cause damage to other organs and result in limited mobility and pain.

Condition	Description	Health Consequences of Disease Progression
Rheumatoid arthritis	An autoimmune condition that causes chronic inflammation of the joints. Patients with this condition have flare ups of pain, swelling, and fatigue.	Severe damage to joints and major organs from inflammation, leading to serious complications, such as loss of mobility, blockages and clots in arteries and blood vessels, and damage to organs (e.g., lungs and kidneys).
Autoimmune conditions: Crohn's disease and ulcerative colitis	Crohn's disease is a chronic, inflammatory, autoimmune disease of the digestive tract that causes inflammation of the small and large intestines. Ulcerative colitis is a chronic inflammatory autoimmune disease that causes inflammation of and ulcers on the large intestine.	Untreated Crohn's disease and ulcerative colitis can result in serious conditions, such as bowel obstruction, colorectal cancer, life-threatening abscesses, sepsis, and death. ¹⁰³ They can lead to life-threatening complications, such as toxic megacolon, in which inflammation spreads into the deepest layers of the colon causing the colon to stop working. This condition requires immediate treatment that may include surgery. ¹⁰⁴
Blood Cancers	Blood cancers affect development or function of blood cells, often occurring when there is unrestrained blood cell growth, which affects the functioning of normal blood cells. Leukemia, lymphoma, and myeloma are the three major types of blood cancers.	Without adequate treatment, patients with blood cancers have reduced lifespan. With treatment, 5-year survival rates are 67 percent for leukemia, 74 percent for non-Hodgkin's lymphoma, 89 percent for Hodgkin's lymphoma, and 60 percent for myeloma. ^{105, 106, 107}

Source: ASPE analysis of peer reviewed and grey literature.

Notes: ^aEven with appropriate treatment and management of these conditions, patients can experience progressive worsening of health due to the nature of the condition.

Prevalence of Clinical Conditions Among Medicare Enrollees

Our review of existing data finds that the conditions treated by the selected drugs are prevalent among the Medicare population. For example:

- About 1 in 4 enrollees have chronic kidney disease, which has been increasing over time among Medicare enrollees, with an increase of about 10 percentage points between 2012 and 2020.¹⁰⁸
- Although estimates for the number of Medicare enrollees with rheumatoid arthritis are not available, the data that is available indicates that about 35 percent of traditional Medicare enrollees have arthritis (osteoarthritis or rheumatoid arthritis).¹⁰⁹
- Among Medicare fee-for-service enrollees, in 2018, about 0.40 percent of 25.1 million Medicare enrollees (about 100,000 enrollees) ages 67 or older had a diagnosis of Crohn's disease and 0.64 percent (about 161,000) had a diagnosis of ulcerative colitis.¹¹⁰
- Although prevalence estimates for blood cancers is not available for recent years among the Medicare population, existing research shows that about 15 percent of Medicare enrollees have a cancer diagnosis.¹¹¹

Section C: Data and Methods

Examining Federal Contributions and Support Relevant to Drug Development for the Selected Drugs

The Bayh-Dole Act of 1980 requires that patents developed from federally funded research must acknowledge the federal support in a government interest statement within the patent. Therefore, government interest statements are a strong indicator of federal investment in the development of the intellectual property that underpins a drug. To identify patents associated with each small molecule drug, we used a compilation of FDA's Orange Book data from 2005 through 2018. We used data from a range of dates because patents expire and are removed from the Orange Book in subsequent publications so relying on a single extract may result in missing some patents associated with a drug. We then matched the patent numbers to the U.S. Patent and Trademark Office's PatentsView database¹¹² as well as NIH patent and licensing data^{113, 114} to identify government interest statements (we use both the government interest statement and assignee data files).

The federal R&D tax credit subsidizes qualified research expenses, including drug discovery, preclinical research, and clinical research.¹¹⁵ The most expensive part of drug development are clinical trials,¹¹⁶ so we first identified which clinical trials a manufacturer used for FDA approval and whether the trials were conducted in the United States. Then, we searched the Security and Exchange Commission's data from the corporate filing the year of the clinical trials. We searched for mentions of the 10 selected drugs and the R&D tax credit.¹¹⁷ We do not count drugs where the R&D credit was not explicitly mentioned, even though it is possible that a company claimed it without reporting it in the filings.

Across both of these measures, we use a conservative approach. There are also other ways one could evaluate federal contributions to a drug's development.

Medicare Enrollees' Use and Expenditures for the Selected Drugs

We used Prescription Drug Event (PDE) data and Part D enrollment data to examine prescription drug use and spending in Medicare Part D over time (2018 – 2022) for each of the 10 drugs selected for the first cycle of Medicare drug price negotiations. We examined prescription drug use and spending for each of the 10 drugs for all Part D enrollees and separately by whether an enrollee receives LIS. We present estimates separately because enrollees who do not receive LIS, who make up about 72 percent of the program's enrollment, have higher out-of-pocket costs than enrollees who receive LIS.¹¹⁸ We also examined demographic characteristics of enrollees who used each of the 10 selected drugs in calendar year 2022 and their average out-of-pocket spending. Estimates are also presented by state of residence.

We constructed use and 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.* 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.

Our approach to analyzing use and spending for the 10 drugs differs from CMS in the time period examined. Although we present trends over time, we focus specifically on calendar year 2022. We examine use and spending for calendar year whereas CMS, as required by the IRA, examines total gross drug spending from

* 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: [Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026 \(cms.gov\)](https://www.cms.gov/medicare/medicare-drug-price-negotiation/medicare-drug-price-negotiation-revised-guidance-implementation-of-sections-1191-1198-of-the-social-security-act-for-initial-price-applicability-year-2026).

June 1, 2022 to May 31, 2023. Thus, differences in use and spending estimates between this Report and CMS estimates primarily reflect differences in the time period examined for analyses. *

* Other sources of differences between the CMS and ASPE drug use and spending estimates arise from differences in claims runout.

Section D: Medicare Utilization and Spending Estimates for Selected Drugs

Table D1. Number of Medicare Enrollees Using the 10 Selected Drugs over the 2018-2022 Period

Drug Name	2018	2019	2020	2021	2022	Percent Change (2018 – 2022)
Eliquis	1,647,000	2,169,000	2,642,000	3,125,000	3,505,000	113%
Jardiance	218,000	422,000	595,000	885,000	1,321,000	505%
Xarelto	1,051,000	1,134,000	1,185,000	1,258,000	1,311,000	25%
Januvia	920,000	938,000	935,000	935,000	885,000	-4%
Farxiga	115,000	140,000	194,000	386,000	639,000	454%
Entresto	151,000	222,000	283,000	395,000	521,000	246%
Enbrel	46,000	46,000	44,000	46,000	47,000	2%
Imbruvica	22,000	25,000	27,000	26,000	22,000	1%
Stelara	10,000	11,000	13,000	16,000	20,000	103%
NovoLog / Fiasp	805,000	802,000	783,000	774,000	763,000	-5%

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. Enrollees are included in the analysis if they have taken a selected drug during the time period examined.

Table D2. Total Part D Out-Of-Pocket Spending for Enrollees Taking More than One of the Selected Drugs for Price Applicability Year 2026

Drug Name	Number of Enrollees	Average Out-of-Pocket Spending Per Enrollee for all Part D Drugs	Average Out-of-Pocket Spending Per Enrollee for All Selected Drugs ^a	Share of Average Out-of-Pocket Spending for Selected Drugs as a Percentage of Average Part D Out-of-Pocket Spending Per Enrollee for all Drugs
Eliquis	543,745	\$1,117	\$674	60%
Jardiance	459,589	\$988	\$576	58%
Xarelto	235,949	\$1,085	\$649	60%
Januvia	312,148	\$844	\$522	62%
Farxiga	263,454	\$967	\$556	58%
Entresto	310,270	\$1,090	\$723	66%
Enbrel	8,184	\$1,122	\$885	79%
Imbruvica	4,629	\$5,383	\$4,899	91%
Stelara	3,478	\$2,372	\$2,041	86%
NovoLog/Fiasp	268,505	\$802	\$346	43%
Total	1.1 million	\$1,000	\$593	59%

Source: ASPE analysis using the 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 drug definition. ASPE estimates differ from drug use and spending estimates produced by CMS primarily due to differences in the time period examined. Spending estimates are not adjusted for inflation. Total spending is based on gross drug costs, which represent total spending for the prescription claim, including Medicare, plan, and beneficiary payments.

^aAverage out-of-pocket spending captures out-of-pocket costs for all selected drugs. If an enrollee takes more than one of the selected drugs (as is true for all the population shown in this table), then the average out-of-pocket cost shown for each drug includes their spending on all of the selected drugs they use.

Table D3. Number of Enrollees Spending More than \$1,000 in Out-of-Pocket Costs in 2022 on Selected Drugs for Price Applicability Year 2026

Drug Name	Share of Enrollees Taking Each Drug who Spent More than \$1,000 in Out-of-Pocket Costs	Number of Enrollees Who Spent More than \$1,000 in Out-of-Pocket Costs for Each Drug	Average Out-of-Pocket Spending Per Enrollee for Each Drug Among Those who Spent More than \$1,000
Eliquis	17%	591,351	\$1,326
Jardiance	10%	125,910	\$1,312
Xarelto	17%	227,383	\$1,324
Januvia	9%	79,590	\$1,287
Farxiga	8%	48,641	\$1,319
Entresto	14%	71,130	\$1,362
Enbrel	19%	8,915	\$4,433
Imbruvica	64%	14,127	\$8,162
Stelara	27%	5,480	\$7,280
NovoLog/Fiasp	1%	9,822	\$1,347

Source: ASPE analysis using the 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 drug definition. ASPE estimates differ from drug use and spending estimates produced by CMS primarily due to differences in the time period 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.

Table D4. Demographic Characteristics of Medicare Part D Enrollees in Calendar Year 2022 Taking Drugs Selected for the First Cycle of Medicare Drug Price Negotiations

Enrollee Characteristics	Medicare Part D 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	72.3%	80%	63%	79%	57%	61%
Black non-Latino	10.7%	9%	14%	9%	16%	16%
Latino	10.1%	6%	13%	7%	16%	14%
Asian American	3.7%	2%	6%	2%	7%	6%
American Indian / Alaska Native	0.3%	0%	1%	0%	0%	0%
Other or Unknown	2.8%	2%	4%	3%	3%	3%
Geographic Area^a						
Urban - Metropolitan	80.9%	80%	82%	80%	82%	80%
Rural - Micropolitan	8.9%	10%	9%	10%	9%	10%
Rural - All Other	6.3%	7%	6%	7%	7%	7%
Unclassified	3.9%	3%	2%	3%	3%	2%

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.

^aGeographic area 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 residing within a CBSA that is metropolitan are classified as urban. Enrollees are classified as rural if they reside in areas that can be mapped to a county and a zip code that is either a micropolitan area (rural - micropolitan) or an area that is not a metropolitan or a micropolitan area (rural – all other).

Table D5. Demographic Characteristics of Medicare Part D Enrollees in Calendar Year 2022 Taking Drugs Selected for the First Cycle of Medicare Drug Price Negotiations

Enrollee Characteristics	Medicare Part D Population	Entresto	Enbrel	Imbruvica	Stelara	NovoLog/Fiasp
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	72.3%	68%	68%	81%	77%	65%
Black non-Latino	10.7%	18%	11%	10%	9%	17%
Latino	10.1%	9%	14%	5%	7%	11%
Asian American	3.7%	3%	3%	2%	2%	3%
American Indian / Alaska Native	0.3%	0%	1%	0%	0%	1%
Other or Unknown	2.8%	3%	3%	3%	4%	3%
Geographic Area ^a						
Urban - Metropolitan	80.9%	81%	80%	81%	82%	77%
Rural - Micropolitan	8.9%	10%	10%	10%	9%	11%
Rural - All Other	6.3%	7%	7%	7%	6%	8%
Unclassified	3.9%	2%	2%	3%	3%	3%

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.

^aGeographic area 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 residing within a CBSA that is metropolitan are classified as urban. Enrollees are classified as rural if they reside in areas that can be mapped to a county and a zip code that is either a micropolitan area (rural - micropolitan) or an area that is not a metropolitan or a micropolitan area (rural – all other).

Table D6. Average Out-of-Pocket Spending per Enrollee in 2022 by Demographic Characteristics for Enrollees Taking Drugs Selected for the First Cycle of Medicare Drug Price Negotiations

Enrollee Characteristics	Eliquis	Jardiance	Xarelto	Januvia	Farxiga
Total (Avg OOP Cost)	\$441	\$290	\$451	\$270	\$260
Gender					
Women	\$418	\$232	\$420	\$235	\$209
Men	\$466	\$338	\$481	\$312	\$303
Age					
<65	\$124	\$95	\$135	\$76	\$91
65-69	\$416	\$333	\$439	\$277	\$305
70-74	\$480	\$361	\$505	\$318	\$318
75-79	\$493	\$349	\$510	\$325	\$304
80-84	\$488	\$322	\$509	\$315	\$279
85+	\$470	\$284	\$487	\$299	\$252
Race & Ethnicity					
White non-Latino	\$499	\$373	\$512	\$367	\$339
Black non-Latino	\$170	\$134	\$179	\$144	\$132
Latino	\$171	\$114	\$160	\$101	\$104
Asian American	\$241	\$172	\$220	\$148	\$149
American Indian / Alaska Native	\$268	\$194	\$264	\$162	\$144
Other or Unknown	\$466	\$328	\$488	\$270	\$292
Geographic Area ^a					
Urban - Metropolitan	\$439	\$286	\$447	\$264	\$258
Rural - Micropolitan	\$452	\$304	\$468	\$302	\$269
Rural - All Other	\$457	\$318	\$481	\$302	\$272
Unclassified	\$435	\$295	\$447	\$269	\$260

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.

^aGeographic area 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 residing within a CBSA that is metropolitan are classified as urban. Enrollees are classified as rural if they reside in areas that can be mapped to a county and a zip code that is either a micropolitan area (rural - micropolitan) or an area that is not a metropolitan or a micropolitan area (rural - all other).

Table D7. Average Out-of-Pocket Spending Per Enrollee in 2022 by Demographic Characteristics for Enrollees Taking Drugs Selected for the First Cycle of Medicare Drug Price Negotiations

Enrollee Characteristics	Entresto	Enbrel	Imbruvica	Stelara	NovoLog/Fiasp
Total (N in Millions)	\$357	\$921	\$5,247	\$2,058	\$121
Gender					
Women	\$311	\$813	\$5,016	\$1,900	\$106
Men	\$385	\$1,195	\$5,411	\$2,285	\$140
Age					
<65	\$120	\$284	\$2,531	\$693	\$52
65-69	\$360	\$1,157	\$5,383	\$2,982	\$148
70-74	\$421	\$1,286	\$5,750	\$3,152	\$164
75-79	\$434	\$1,350	\$5,665	\$3,294	\$157
80-84	\$431	\$1,267	\$5,387	\$2,955	\$142
85+	\$407	\$1,099	\$4,732	\$2,575	\$114
Race & Ethnicity ^b					
White non-Latino	\$441	\$1,169	\$5,601	\$2,360	\$152
Black non-Latino	\$153	\$243	\$3,649	\$777	\$59
Latino	\$148	\$198	\$3,092	\$665	\$49
Asian American	\$196	\$750	\$3,060	\$1,000	\$82
American Indian / Alaska Native	\$221	\$861	\$4,939	\$573	\$96
Other or Unknown	\$381	\$1,310	\$5,555	\$2,303	\$137
Geographic Area ^a					
Urban - Metropolitan	\$353	\$941	\$5,227	\$2,130	\$119
Rural - Micropolitan	\$368	\$856	\$5,433	\$1,763	\$130
Rural - All Other	\$371	\$777	\$5,286	\$1,590	\$136
Unclassified	\$391	\$958	\$5,041	\$1,915	\$102

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.

^aGeographic area 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 residing within a CBSA that is metropolitan are classified as urban. Enrollees are classified as rural if they reside in areas that can be mapped to a county and a zip code that is either a micropolitan area (rural - micropolitan) or an area that is not a metropolitan or a micropolitan area (rural - all other).

Section E: State and Territory Estimates

Table E1. State and Territory Estimates of Medicare Part D Enrollees Use and Out-of-Pocket Spending in Calendar Year 2022 for Drugs Selected for the First Cycle of Medicare Drug Price Negotiations

State/Territory	<u>Eliguis</u> Number of Enrollees (Mean OOP)	<u>Jardiance</u> Number of Enrollees (Mean OOP)	<u>Xarelto</u> Number of Enrollees (Mean OOP)	<u>Januvia</u> Number of Enrollees (Mean OOP)	<u>Farxiga</u> Number of Enrollees (Mean OOP)	<u>Entresto</u> Number of Enrollees (Mean OOP)	<u>Enbrel</u> Number of Enrollees (Mean OOP)	<u>Imbruvica</u> Number of Enrollees (Mean OOP)	<u>Stelara</u> Number of Enrollees (Mean OOP)	<u>NovoLog/ Fiasp</u> Number of Enrollees (Mean OOP)
Alabama	65,335 (\$375)	23,631 (\$268)	20,718 (\$384)	16,934 (\$257)	13,779 (\$207)	12,165 (\$306)	736 (\$742)	356 (\$4,794)	403 (\$1,969)	11,923 (\$116)
Alaska	5,674 (\$282)	2,072 (\$202)	1,902 (\$285)	1,016 (\$148)	751 (\$209)	804 (\$240)	91 (\$778)	33 (\$1,450)	39 (\$739)	897 (\$80)
Arizona	70,671 (\$481)	20,731 (\$310)	25,329 (\$508)	13,697 (\$287)	11,821 (\$299)	8,739 (\$441)	963 (\$1,107)	397 (\$6,319)	264 (\$2,744)	11,918 (\$126)
Arkansas	36,101 (\$460)	11,071 (\$308)	11,662 (\$493)	6,653 (\$318)	6,001 (\$282)	7,745 (\$381)	367 (\$746)	172 (\$5,461)	160 (\$1,699)	8,372 (\$117)
California	276,925 (\$378)	163,642 (\$197)	112,892 (\$373)	102,974 (\$182)	63,762 (\$198)	46,328 (\$287)	5,360 (\$775)	2,140 (\$4,297)	1,616 (\$1,727)	54,355 (\$64)
Colorado	42,767 (\$514)	14,724 (\$322)	20,995 (\$447)	5,757 (\$361)	5,374 (\$308)	3,561 (\$440)	667 (\$1,221)	302 (\$5,307)	262 (\$2,620)	5,780 (\$124)
Connecticut	49,040 (\$433)	18,638 (\$263)	18,638 (\$409)	13,037 (\$261)	7,965 (\$249)	6,970 (\$349)	585 (\$1,081)	341 (\$4,659)	321 (\$1,447)	6,961 (\$117)
Delaware	12,619 (\$456)	5,192 (\$333)	6,213 (\$488)	3,173 (\$319)	2,620 (\$307)	1,779 (\$384)	153 (\$725)	72 (\$4,337)	76 (\$1,854)	2,885 (\$145)
District of Columbia	4,021 (\$258)	2,111 (\$106)	1,449 (\$277)	1,391 (\$90)	495 (\$133)	954 (\$113)	42 (\$451)	24 (\$4,826)	17 (\$1,877)	982 (\$41)
Florida	281,663 (\$424)	82,611 (\$309)	105,434 (\$434)	62,352 (\$252)	47,164 (\$252)	49,033 (\$356)	3,122 (\$1,042)	1,709 (\$5,588)	1,287 (\$2,454)	57,830 (\$86)
Georgia	106,973 (\$419)	36,439 (\$289)	35,030 (\$446)	28,811 (\$282)	26,436 (\$249)	17,090 (\$324)	1,485 (\$738)	689 (\$4,998)	613 (\$2,363)	26,579 (\$119)
Hawaii	9,667 (\$302)	7,905 (\$218)	4,462 (\$320)	4,044 (\$191)	2,965 (\$179)	2,206 (\$249)	129 (\$1,004)	85 (\$3,455)	31 (\$3,024)	1,718 (\$135)
Idaho	19,243 (\$570)	5,043 (\$442)	5,603 (\$607)	1,939 (\$397)	3,029 (\$376)	1,300 (\$588)	262 (\$1,324)	116 (\$6,536)	114 (\$3,043)	3,638 (\$167)
Illinois	131,629 (\$481)	52,659 (\$333)	53,451 (\$506)	31,294 (\$339)	18,199 (\$324)	20,577 (\$403)	1,432 (\$935)	894 (\$5,474)	674 (\$2,584)	30,527 (\$127)
Indiana	80,679 (\$470)	29,884 (\$358)	29,714 (\$480)	18,414 (\$367)	13,920 (\$321)	13,785 (\$396)	919 (\$1,007)	472 (\$6,228)	419 (\$1,506)	18,711 (\$133)
Iowa	36,099 (\$652)	11,639 (\$469)	14,759 (\$641)	6,822 (\$488)	4,115 (\$437)	3,170 (\$568)	289 (\$1,308)	262 (\$6,868)	164 (\$2,808)	11,236 (\$246)

State/Territory	<u>Eliquis</u> Number of Enrollees (Mean OOP)	<u>Jardiance</u> Number of Enrollees (Mean OOP)	<u>Xarelto</u> Number of Enrollees (Mean OOP)	<u>Januvia</u> Number of Enrollees (Mean OOP)	<u>Farxiga</u> Number of Enrollees (Mean OOP)	<u>Entresto</u> Number of Enrollees (Mean OOP)	<u>Enbrel</u> Number of Enrollees (Mean OOP)	<u>Imbruvica</u> Number of Enrollees (Mean OOP)	<u>Stelara</u> Number of Enrollees (Mean OOP)	<u>NovoLog/ Fiasp</u> Number of Enrollees (Mean OOP)
Kansas	28,706 (\$585)	9,856 (\$466)	11,761 (\$597)	5,838 (\$460)	4,763 (\$419)	3,290 (\$544)	226 (\$1,115)	194 (\$6,305)	161 (\$3,513)	9,847 (\$180)
Kentucky	60,145 (\$373)	23,016 (\$260)	22,756 (\$382)	20,109 (\$249)	15,035 (\$238)	11,013 (\$304)	867 (\$615)	360 (\$5,568)	467 (\$1,862)	16,191 (\$114)
Louisiana	55,173 (\$372)	23,375 (\$237)	19,267 (\$391)	15,999 (\$236)	10,933 (\$232)	13,396 (\$289)	638 (\$514)	312 (\$4,500)	331 (\$1,015)	13,175 (\$93)
Maine	21,411 (\$413)	7,087 (\$262)	6,123 (\$432)	4,003 (\$228)	2,030 (\$223)	1,382 (\$338)	305 (\$940)	114 (\$4,994)	212 (\$1,783)	3,904 (\$89)
Maryland	49,133 (\$422)	18,635 (\$268)	19,246 (\$444)	11,489 (\$280)	8,310 (\$285)	7,991 (\$319)	574 (\$749)	283 (\$3,747)	328 (\$1,571)	12,342 (\$122)
Massachusetts	89,220 (\$429)	29,592 (\$261)	26,488 (\$457)	15,912 (\$237)	7,623 (\$217)	8,474 (\$341)	1,480 (\$913)	506 (\$3,927)	780 (\$1,977)	16,175 (\$103)
Michigan	140,497 (\$381)	43,186 (\$262)	49,997 (\$397)	34,939 (\$271)	23,433 (\$272)	18,828 (\$344)	2,157 (\$958)	908 (\$4,793)	758 (\$1,708)	34,262 (\$132)
Minnesota	47,666 (\$620)	15,339 (\$415)	24,882 (\$609)	6,579 (\$431)	3,343 (\$417)	3,643 (\$563)	595 (\$1,795)	468 (\$6,349)	315 (\$2,791)	15,608 (\$187)
Mississippi	32,758 (\$416)	14,424 (\$284)	12,700 (\$442)	9,070 (\$262)	9,836 (\$221)	8,263 (\$326)	460 (\$616)	237 (\$6,040)	277 (\$3,875)	11,751 (\$103)
Missouri	75,267 (\$482)	25,761 (\$353)	26,606 (\$497)	15,360 (\$339)	13,602 (\$323)	10,755 (\$412)	724 (\$921)	444 (\$6,462)	402 (\$2,342)	17,935 (\$127)
Montana	10,246 (\$590)	3,175 (\$418)	4,486 (\$624)	1,928 (\$445)	991 (\$433)	858 (\$559)	197 (\$1,195)	83 (\$6,617)	62 (\$2,698)	2,759 (\$163)
Nebraska	20,217 (\$657)	6,539 (\$503)	9,688 (\$666)	3,015 (\$502)	3,446 (\$443)	2,701 (\$555)	136 (\$1,508)	145 (\$7,527)	91 (\$4,466)	5,120 (\$202)
Nevada	26,095 (\$438)	10,084 (\$325)	11,072 (\$468)	4,567 (\$298)	5,122 (\$291)	3,531 (\$385)	246 (\$1,182)	187 (\$6,307)	77 (\$3,007)	4,605 (\$122)
New Hampshire	15,661 (\$548)	4,225 (\$429)	5,303 (\$598)	2,330 (\$421)	1,247 (\$349)	1,084 (\$486)	199 (\$1,385)	105 (\$6,391)	145 (\$1,679)	2,254 (\$147)
New Jersey	98,962 (\$409)	34,158 (\$312)	38,816 (\$442)	33,088 (\$265)	21,978 (\$258)	15,827 (\$365)	1,397 (\$882)	576 (\$4,711)	625 (\$2,091)	15,427 (\$142)
New Mexico	15,148 (\$396)	5,927 (\$234)	9,830 (\$386)	5,122 (\$236)	3,128 (\$225)	1,802 (\$350)	415 (\$986)	126 (\$5,371)	93 (\$945)	4,686 (\$100)
New York	232,211 (\$342)	96,359 (\$205)	85,662 (\$347)	84,846 (\$174)	52,838 (\$195)	42,893 (\$265)	3,549 (\$754)	1,619 (\$3,479)	1,687 (\$1,459)	50,246 (\$89)
North Carolina	128,168 (\$462)	48,497 (\$309)	43,875 (\$468)	25,622 (\$292)	20,963 (\$265)	17,228 (\$362)	1,512 (\$912)	734 (\$5,273)	657 (\$1,817)	27,304 (\$122)
North Dakota	6,950 (\$740)	2,156 (\$607)	2,049 (\$816)	1,113 (\$653)	782 (\$606)	442 (\$656)	39 (\$2,299)	52 (\$8,237)	30 (\$1,099)	3,127 (\$251)

State/Territory	<u>Eliquis</u> Number of Enrollees (Mean OOP)	<u>Jardiance</u> Number of Enrollees (Mean OOP)	<u>Xarelto</u> Number of Enrollees (Mean OOP)	<u>Januvia</u> Number of Enrollees (Mean OOP)	<u>Farxiga</u> Number of Enrollees (Mean OOP)	<u>Entresto</u> Number of Enrollees (Mean OOP)	<u>Enbrel</u> Number of Enrollees (Mean OOP)	<u>Imbruvica</u> Number of Enrollees (Mean OOP)	<u>Stelara</u> Number of Enrollees (Mean OOP)	<u>NovoLog/ Fiasp</u> Number of Enrollees (Mean OOP)
Ohio	154,951 (\$480)	47,381 (\$335)	56,550 (\$499)	38,828 (\$354)	27,466 (\$330)	20,776 (\$411)	1,449 (\$1,270)	1,037 (\$5,940)	785 (\$1,851)	32,535 (\$126)
Oklahoma	45,287 (\$459)	15,093 (\$349)	13,333 (\$494)	8,885 (\$325)	7,602 (\$307)	6,783 (\$408)	674 (\$711)	232 (\$5,732)	130 (\$1,496)	11,924 (\$129)
Oregon	46,189 (\$597)	14,035 (\$383)	14,539 (\$576)	4,416 (\$375)	3,156 (\$380)	4,591 (\$509)	505 (\$1,025)	269 (\$5,723)	327 (\$1,357)	7,187 (\$123)
Pennsylvania	186,859 (\$431)	70,774 (\$312)	67,493 (\$437)	37,064 (\$330)	20,515 (\$277)	23,179 (\$375)	1,770 (\$997)	1,138 (\$5,687)	1,135 (\$2,662)	44,881 (\$140)
Rhode Island	13,648 (\$464)	4,708 (\$299)	4,694 (\$521)	2,335 (\$276)	909 (\$297)	1,162 (\$433)	153 (\$871)	57 (\$6,022)	95 (\$2,116)	1,539 (\$111)
South Carolina	67,064 (\$461)	22,809 (\$312)	20,889 (\$477)	16,588 (\$312)	15,667 (\$293)	12,138 (\$347)	747 (\$909)	403 (\$4,969)	398 (\$2,759)	13,936 (\$128)
South Dakota	8,519 (\$729)	2,775 (\$544)	3,691 (\$748)	1,463 (\$576)	1,131 (\$537)	660 (\$601)	65 (\$1,154)	62 (\$6,312)	29 (\$387)	2,984 (\$195)
Tennessee	84,509 (\$446)	27,776 (\$300)	29,840 (\$448)	18,364 (\$295)	16,434 (\$267)	12,537 (\$380)	1,162 (\$1,142)	467 (\$6,346)	406 (\$2,608)	19,085 (\$138)
Texas	221,456 (\$430)	98,642 (\$289)	86,347 (\$444)	69,546 (\$264)	58,231 (\$250)	35,489 (\$365)	3,772 (\$743)	1,239 (\$5,267)	940 (\$1,810)	47,933 (\$131)
Utah	22,004 (\$567)	6,746 (\$475)	8,482 (\$610)	3,021 (\$440)	3,359 (\$418)	1,184 (\$521)	234 (\$1,724)	103 (\$8,179)	115 (\$3,349)	4,527 (\$152)
Vermont	9,439 (\$492)	2,722 (\$332)	2,531 (\$587)	1,369 (\$339)	673 (\$317)	707 (\$441)	152 (\$1,385)	66 (\$4,686)	83 (\$1,673)	1,627 (\$128)
Virginia	80,720 (\$507)	25,676 (\$336)	25,864 (\$520)	19,855 (\$329)	12,823 (\$301)	11,410 (\$406)	832 (\$1,137)	478 (\$6,262)	405 (\$2,740)	15,480 (\$126)
Washington	57,670 (\$568)	25,794 (\$348)	26,808 (\$555)	9,017 (\$321)	6,186 (\$346)	5,922 (\$449)	1,023 (\$1,341)	374 (\$6,113)	427 (\$1,956)	10,926 (\$149)
West Virginia	27,045 (\$325)	10,492 (\$227)	9,994 (\$347)	9,104 (\$227)	4,879 (\$214)	5,211 (\$288)	363 (\$635)	141 (\$3,967)	165 (\$1,330)	9,942 (\$92)
Wisconsin	67,515 (\$534)	22,370 (\$390)	23,365 (\$563)	10,727 (\$390)	6,224 (\$363)	6,439 (\$443)	768 (\$1,250)	441 (\$6,113)	402 (\$1,959)	15,070 (\$152)
Wyoming	5,775 (\$653)	1,384 (\$503)	1,939 (\$659)	858 (\$473)	720 (\$453)	302 (\$589)	68 (\$1,274)	35 (\$7,118)	22 (\$2,945)	1,262 (\$186)
American Samoa	15 (\$750)	*	*	*	*	*	**	**	**	**
Guam	137 (\$736)	87 (\$596)	76 (\$1,006)	115 (\$830)	17 (\$725)	31 (\$564)	**	**	*	*
Northern Mariana Islands	28 (\$733)	*	13 (\$657)	15 (\$533)	*	*	**	**	**	*

State/Territory	<u>Eliquis</u> Number of Enrollees (Mean OOP)	<u>Jardiance</u> Number of Enrollees (Mean OOP)	<u>Xarelto</u> Number of Enrollees (Mean OOP)	<u>Januvia</u> Number of Enrollees (Mean OOP)	<u>Farxiga</u> Number of Enrollees (Mean OOP)	<u>Entresto</u> Number of Enrollees (Mean OOP)	<u>Enbrel</u> Number of Enrollees (Mean OOP)	<u>Imbruvica</u> Number of Enrollees (Mean OOP)	<u>Stelara</u> Number of Enrollees (Mean OOP)	<u>NovoLog/ Fiasp</u> Number of Enrollees (Mean OOP)
Puerto Rico	22,623 (\$100)	12,070 (\$55)	15,745 (\$90)	13,620 (\$58)	14,898 (\$61)	2,553 (\$154)	813 (\$167)	140 (\$3,165)	148 (\$63)	1,005 (\$38)
U.S. Virgin Islands	724 (\$479)	222 (\$392)	199 (\$480)	319 (\$421)	64 (\$329)	126 (\$399)	* (*)	* (*)	* (*)	24 (\$211)
Total for the United States ^a	3,505,000 (\$441)	1,321,000 (\$290)	1,311,000 (\$451)	885,000 (\$270)	639,000 (\$260)	521,000 (\$357)	47,000 (\$921)	22,000 (\$5,247)	20,000 (\$2,058)	763,000 (\$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.

* Data suppressed as per CMS disclosure rules (<https://resdac.org/articles/cms-cell-size-suppression-policy>).

** No utilization reported.

^a Total includes enrollees residing outside the United States.

OOP = Out-Of-Pocket

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