

Inflation Reduction Act (IRA)

Overview of the Provisions of the New Prescription Drug Law

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Presentation Goals

- Understand the key provisions of the new drug law, the Inflation Reduction Act (IRA):
 1. Vaccine Cost-sharing
 2. Insulin Caps (Part-D and -B)
 3. Inflation Rebate Program
 4. Medicare Drug Price Negotiation Program
 5. Expansion of Extra Help
 6. Part D Improvements
- Understand how the IRA affects Medicare beneficiaries
- Know where to locate and how to utilize CMS IRA resources

Overview of the Inflation Reduction Act

- The Inflation Reduction Act (IRA) was signed into law in August 2022.
- The new law makes improvements to Medicare that will expand benefits, lower drug costs, and improve the sustainability of the Medicare program for generations to come.
- The law provides meaningful financial relief for millions of people with Medicare by improving access to affordable treatments and strengthening Medicare, both now and in the long run.

IRA Provision Timeline

**August 16,
2022**

Signing of the Inflation
Reduction Act

July 1, 2023

Insulin Cap for Part B

2024

Elimination of
Catastrophic Phase,
Expansion of Extra Help

2026

Medicare Drug Price
Negotiation Program
continues to select new
drugs and make Part B and
D drugs available at MFP

**January 1,
2023**

No Cost-Sharing Vaccines,
Insulin Cap for Part D

**September 1,
2023**

First 10 Medicare Part D drugs
selected for the Drug Price
Negotiation Program

2025

\$2000 Part D out-of-pocket cap
15 more Medicare Part D drugs
will be selected for negotiation
15 Medicare Part B drugs will be
selected for negotiation

Inflation Reduction Act (IRA) CMS Provisions

- Places a \$35 monthly out-of-pocket cap on Medicare-covered insulins under Part-D (Jan 1, 2023) and Part B (July 1, 2023)
- Makes ACIP-recommended vaccines free under Medicare Part D prescription drug coverage. (2023)
- Requires State Medicaid and CHIP programs to provide coverage for approved adult vaccines recommended by the ACIP (and their administration) without cost sharing (effective Oct 2023)
- Temporarily increases Medicare payment for qualifying biosimilars to encourage use **(2023)**
- Requires manufacturers to pay rebates to Medicare if their price increases for certain drugs exceed inflation (2022 and 2023).
- Makes Medicare Part D prescription drug coverage more affordable

Inflation Reduction Act CMS Provisions (continued)

- This Year: People with very high prescription drug costs will no longer pay once they reach the “catastrophic phase”
- This Year: Full low-income subsidy expanded for people with low incomes, lowering premiums and out-of-pocket costs for their prescription drug coverage
- 2025: All people with Medicare Part D will have a \$2,000 annual out-of-pocket cap on their drug costs
- Allows Medicare to negotiate the price of certain high-cost, brand name prescription drugs

Drug Inflation Rebates in Medicare

Requires drug companies that raise prices for certain products faster than the rate of inflation to pay Medicare Part B or Part D a rebate

- Rebates calculated quarterly (Part B) or annually (Part D)
- Liability for rebates began as of October 1, 2022 for Part D and as of January 1, 2023 for Part B
- Lower out-of-pocket costs under Part B: this quarter (January 1st, 2024 – March 31st, 2024) beneficiaries may pay reduced inflation-adjusted coinsurance rates for 48 Part B rebatable drugs

Drug Price Inflation Rebates in Medicare (continued)

- Requires CMS to monitor drug prices during the applicable period, compare them to the benchmark price (adjusted for inflation), make adjustments in certain cases (e.g. drugs shortages), and invoice manufacturers for the remaining difference
- In each case, we are to identify and exclude 340B units from rebate billings (began January 1, 2023 for Part B and starting January 1, 2026 for Part D). This is to avoid manufacturers paying a Medicare inflation rebate and a 340B discount on the same drug.
- Under the Medicare Part B Drug Inflation Rebates, which began in April 1, 2023, if the Medicare payment amount for a calendar quarter exceeds the inflation-adjusted payment amount, beneficiary coinsurance is equal to 20% of the inflation-adjusted payment amount

The Medicare Drug Price Negotiation Program (1 of 3)

- Medicare will be able to negotiate (and re-negotiate) drug prices of certain high expenditure Medicare drugs with drug manufacturers
- For the drug companies of selected drugs that elect to participate in the Negotiation Program, the maximum fair prices that are negotiated will apply beginning in 2026.
- CMS will select up to an additional 15 drugs for negotiation for 2027, up to an additional 15 drugs (including drugs covered under Part B) for 2028, and up to an additional 20 drugs for 2029 and subsequent years

The Medicare Drug Price Negotiation Program (2 of 3)

The negotiated maximum fair prices for the first 10 drugs will apply beginning in 2026



October 1, 2023

Deadline for companies of drugs selected for the Negotiation Program to sign agreements to participate in the negotiation process for 2026.



October 2, 2023

Deadline for companies of drugs selected for the Negotiation Program to submit manufacturer-specific data to CMS to consider in the negotiation of maximum fair price.



February 1, 2024

CMS sends initial offers of a maximum fair price with a justification for a selected drug to each company participating in the Negotiation Program. The negotiation period begins.



March 2, 2024

Companies have 30 days from receiving offers of a maximum fair price for a drug to accept the offer or propose a counteroffer, if desired.



August 1, 2024

The negotiation period ends.



September 1, 2024

CMS will publish maximum fair prices for drugs selected for negotiation for 2026.

The Medicare Drug Price Negotiation Program (3 of 3)

Patient-focused Listening Sessions:

- 10 Listening Sessions this fall, one for each selected drug.
- October 30 – November 15, 2023.

Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026



In August 2022, President Biden signed the Inflation Reduction Act of 2022 (P.L. 117-169) into law. The new law makes improvements to Medicare by expanding benefits, lowering drug costs, and improving the sustainability of the Medicare program for generations to come. The law provides meaningful financial relief for millions of people with Medicare by improving access to affordable treatments and strengthening Medicare, both now and in the long run.

For the first time, the law provides Medicare the ability to directly negotiate the prices of certain high expenditure, single source drugs without generic or biosimilar competition. Below is the list of 10 drugs covered under Medicare Part D selected for negotiation for initial price applicability year 2026, based on total gross covered prescription drug costs under Medicare Part D and other criteria as required by the law.

Drug Name	Commonly Treated Conditions	Total Part D Gross Covered Prescription Drug Costs from June 2022-May 2023	Number of Medicare Part D Enrollees Who Used the Drug from June 2022-May 2023
Eliquis	Prevention and treatment of blood clots	\$16,482,621,000	3,706,000
Jardiance	Diabetes; Heart failure	\$7,057,707,000	1,573,000
Xarelto	Prevention and treatment of blood clots; Reduction of risk for patients with coronary or peripheral artery disease	\$6,031,393,000	1,337,000
Januvia	Diabetes	\$4,087,081,000	869,000
Farxiga	Diabetes; Heart failure; Chronic kidney disease	\$3,268,329,000	799,000
Entresto	Heart failure	\$2,884,877,000	587,000
Enbrel	Rheumatoid arthritis; Psoriasis; Psoriatic arthritis	\$2,791,105,000	48,000
Imbruvica	Blood cancers	\$2,663,560,000	20,000
Stelara	Psoriasis; Psoriatic arthritis; Crohn's disease; Ulcerative colitis	\$2,638,929,000	22,000
Flasp; Flasp FlexTouch; Flasp PenFill; NovoLog; NovoLog FlexPen; NovoLog PenFill	Diabetes	\$2,576,586,000	777,000

Note: Numbers are rounded to the nearest thousands.

Expansion of Extra Help

- Since January 1, 2024, nearly 300,000 low-income people with Medicare currently enrolled in the Extra Help program are newly eligible for expanded benefits including no deductible, no premiums and fixed, lowered copayments for certain medications. An additional 3 million people could benefit from the Extra Help program now but aren't currently enrolled
- Expands eligibility for the full low-income subsidy (LIS) benefit (also known as “Extra Help”) to individuals with limited resources and incomes up to 150% of the federal poverty level
- People with Medicare who are currently enrolled in partial Extra Help have been automatically converted to full Extra Help; they don't need to take any action

Part D Improvements

Redesigns the Part D benefit and revises its parameters as follows:

- People with very high prescription drug costs will no longer pay once they reach the “catastrophic phase”
- Provides for Part D premium stabilization beginning this year, by capping base beneficiary premium increases per year to no more than 6% through 2029
- Beginning in 2025:
 - People with Medicare prescription drug coverage will benefit from a yearly cap (\$2,000 in 2025) on what they pay out-of-pocket for covered prescription drugs, starting in 2025. They’ll also have the option to pay their prescription costs in monthly amounts spread over the year rather than all at once, beginning in 2025.
 - The new discount program will require drug manufacturers to pay discounts on certain brand-name drugs and other types of drugs called biologics and biosimilars, both in the initial coverage phase and in the catastrophic phase of the Medicare prescription drug benefit. In general, manufacturers must provide a 10% discount in the initial phase and a 20% discount in the catastrophic phase.

The Inflation Reduction Act: Resources

Partner Resources

- <https://www.cms.gov/inflation-reduction-act-and-medicare>
- <https://www.cms.gov/inflation-reduction-act-and-medicare/resources-0>
- CMS Newsroom (www.cms.gov/newsroom)

Beneficiary Resources

- [Medicare.gov](https://www.Medicare.gov)
- 1-800-MEDICARE
- SHIPs - <https://www.shiphelp.org/about-medicare/regional-ship-location>

The Inflation Reduction Act: Final Takeaways

Key Things to Remember

- Medicare-covered insulin available at \$35 for each month supply for covered insulin and no deductible is effective now
- Access to ACIP-recommended adult vaccines without cost-sharing and no deductible is effective now.
- People with Original Medicare and Medicare Advantage may, depending on their coverage, pay a lower coinsurance amount for certain Part B drugs with price increases higher than inflation since April 1, 2023.
- The new drug law expands eligibility for the full low-income subsidy benefit—known as the Extra Help program—to individuals with limited resources and incomes up to 150% of the federal poverty level beginning January 1st, 2024.

Questions

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