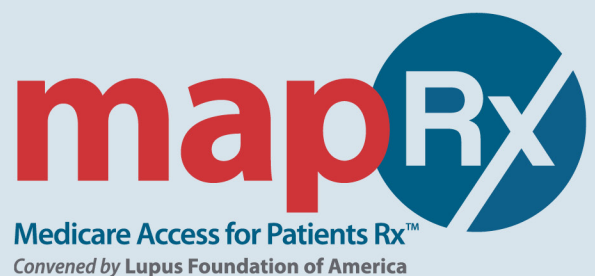


Protecting the Promise of Part D:

Coverage, Choice, and Affordability at 20 Years



SUMMARY

The Medicare outpatient prescription drug benefit (Part D) was created through the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 and implemented in 2006 to address a major Medicare gap: the lack of broad outpatient prescription drug coverage. Today, more than 56 million Americans rely on Part D to help pay for their medications.¹ Designed as a voluntary, privately administered benefit subsidized by the federal government, Part D allows beneficiaries to obtain coverage through standalone prescription drug plans (PDPs) or Medicare Advantage plans with drug benefits. Over time, the program evolved through major reforms, including the Affordable Care Act (ACA) provisions that closed the “donut hole” coverage gap and the Inflation Reduction Act (IRA) changes that redesigned the benefit, strengthening protections against high out-of-pocket (OOP) costs by setting an annual cap on beneficiary drug spending of \$2,000 in 2025^a and creating the Medicare Prescription Payment Plan (MPPP), which allows beneficiaries to spread out drug costs across the plan year.

Over its 20-year history, Part D has provided important benefits beyond expanded access to prescription medications, including incentives for research, improved health outcomes, greater financial protection for many older adults and people with chronic conditions and disabilities, and additional support for low-income beneficiaries.

Part D is best understood as both a landmark Medicare expansion that has positively affected millions of beneficiaries and an evolving policy compromise that requires ongoing review and improvement. In Part D, private health plans compete for enrollment based on formularies, premiums, pharmacy networks, and cost-sharing. The Centers for Medicare & Medicaid Services (CMS) oversees the Part D program by establishing and monitoring beneficiary protections, conducting formulary reviews, and ensuring plan compliance.

Part D transformed Medicare by making prescription drug coverage a core component of care for older adults and people with disabilities. Its value rests on 3 essential commitments: coverage of needed medicines, meaningful choice among plans, and affordable access to treatment. A strong range of plan options helps beneficiaries find coverage that fits their medications, pharmacy preferences, and budgets, while financial protections help reduce the burden of prescription costs. Preserving these commitments requires pairing lower costs with robust formularies and timely access to the treatments patients need.

The pharmaceutical innovation landscape has flourished since 2006, and Part D and its evolution have been vital in ensuring patients have affordable access to innovative medicines. While the Part D program has been largely successful, with high enrollment and beneficiary satisfaction, new challenges have emerged, including concerns about future premium growth and the increasing use of utilization management (UM) tools to delay or deny access to medication. Congress and future administrations must take action to ensure the Part D program remains strong and continues to provide affordable access to prescription drugs for future generations of Medicare beneficiaries.

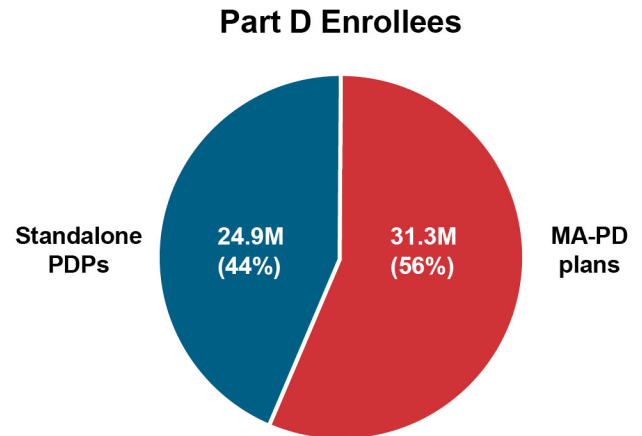
Founded in 2005 after Part D was created, Medicare Access for Patients Rx (MAPRx) is a coalition of more than 75 national patient, family caregiver, and health professional organizations committed to safeguarding the well-being of people with chronic diseases and disabilities who rely on Medicare’s prescription drug coverage.

Representing every segment of Medicare beneficiaries, MAPRx has brought the patient advocacy community together to ensure all beneficiaries have access to the medications they need in Part D. For 20 years, the coalition has worked with Congress, CMS, the Medicare Payment Advisory Commission (MedPAC), and every other relevant stakeholder to strengthen Part D as it has evolved over these two decades. Today, the coalition continues to advocate on behalf of beneficiaries to protect and improve Part D and ensure it delivers on the promise of prescription drug coverage, choice, and affordability for all beneficiaries.

^aThe IRA alleviated the catastrophic segment of the Part D benefit in 2024, effectively creating a beneficiary OOP cap of between \$3,300 and \$3,800 for 2024 (see <https://www.cms.gov/files/document/lower-out-pocket-drug-costs-2024-and-2025-article.pdf>). Beginning in 2025, the OOP cap was set at \$2,000 and increases annually based on the annual percentage increase in average expenditures for Part D drugs per eligible beneficiary.

PART I: THE FOUNDATION—PART D, INNOVATION, AND VALUE

Medicare Part D is a voluntary program established by the MMA that provides a long-missing outpatient prescription drug benefit to Medicare beneficiaries. Beneficiaries can opt into Part D by enrolling in either a standalone Part D PDP that functions alongside Original Medicare (Parts A and B) or a Medicare Advantage plan, a managed care plan that includes medical benefits along with a prescription drug benefit (MA-PD plan). Before Part D, Medicare beneficiaries (including people over age 65 and those with disabilities and certain chronic conditions) lacked consistent outpatient prescription coverage, relying on Medicaid, scant employer coverage, or paying cash out of pocket. When it took effect on January 1, 2006, Part D became the biggest change to Medicare since its inception in 1965.²



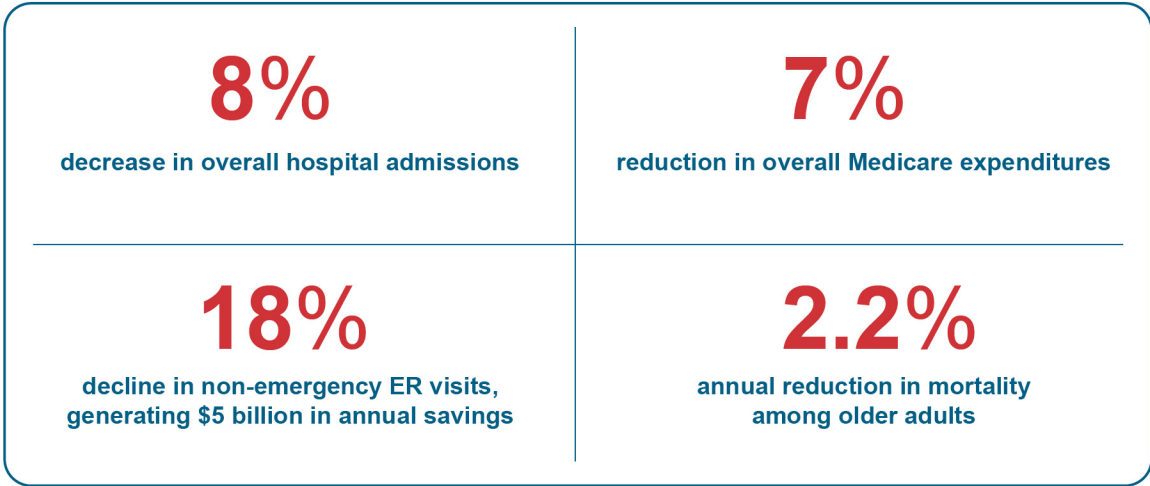
Beneficiaries can choose between PDPs and MA-PD plans available in their geographic area each year during the open enrollment period. People under age 65 may qualify for Medicare due to disability, end-stage renal disease, or amyotrophic lateral sclerosis (ALS). Part D has given people with disabilities or chronic conditions access to prescription drugs, evolving treatment options, and technological advances. Enrollment in Medicare Part D has grown steadily since the program's creation, rising from 21.8 million in 2006¹ to 56.3 million in 2026,³ with over 80% of beneficiaries enrolled in a Part D plan.⁴

Since the program's inception, the United States has witnessed extraordinary progress in the availability of outpatient drug therapy options.⁵ Diagnostic and treatment advances, combined with beneficiary access through Part D, have influenced life expectancy for millions of Americans by incentivizing research that has led to scientific breakthroughs, including new therapies that have fundamentally changed how many diseases are treated. Over the last two decades, drug therapy has become more advanced and personalized, marked by the widespread adoption of complex biologics, specialty medications, and targeted therapies for chronic diseases.⁶

Glucagon-like peptide-1 agonists, or GLP-1s, illustrate how innovation and drug coverage work together to improve the health of the Medicare population. The Food and Drug Administration approved the first GLP-1 agonist in 2005 to treat type 2 diabetes, a chronic condition affecting millions of Medicare recipients. As GLP-1s entered the market and were recognized as among the most powerful glucose-lowering therapy agents, further research revealed their impact on cardiometabolic health, including weight loss.⁷ Obesity is highly prevalent in the Medicare population, with more than two-thirds of beneficiaries considered obese or overweight.⁸ Despite this, the MMA specifically prohibited coverage of anti-obesity agents under Part D, carrying over the Medicaid statute's list of drugs that states may exclude; agents used for weight loss are on this list.⁹

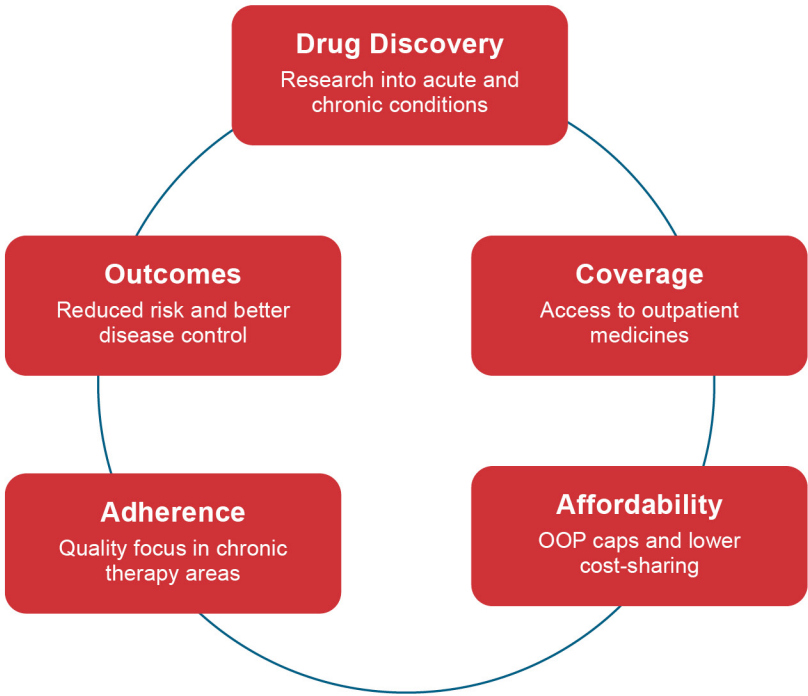
The advent of GLP-1s as safe and effective obesity treatments approved for use in the Medicare population created an opportunity to expand access to GLP-1s for beneficiaries with obesity or who are overweight with concurrent chronic conditions. Coverage of GLP-1s by Medicare could reduce the estimated \$524 billion in lifetime Medicare expenses attributable to current Medicare beneficiaries with obesity and related conditions.¹⁰ CMS created the Medicare GLP-1 Bridge pilot and made it available on July 1, 2026. The temporary program allows eligible beneficiaries to access GLP-1s for weight loss outside of the Part D program for \$50 a month.¹¹ Data from the pilot could lead to statutory changes that result in full coverage of the drugs after the pilot expires in December 2027.

Figure 1. Part D is Associated with Lower Non-Drug Costs and Improved Outcomes¹²



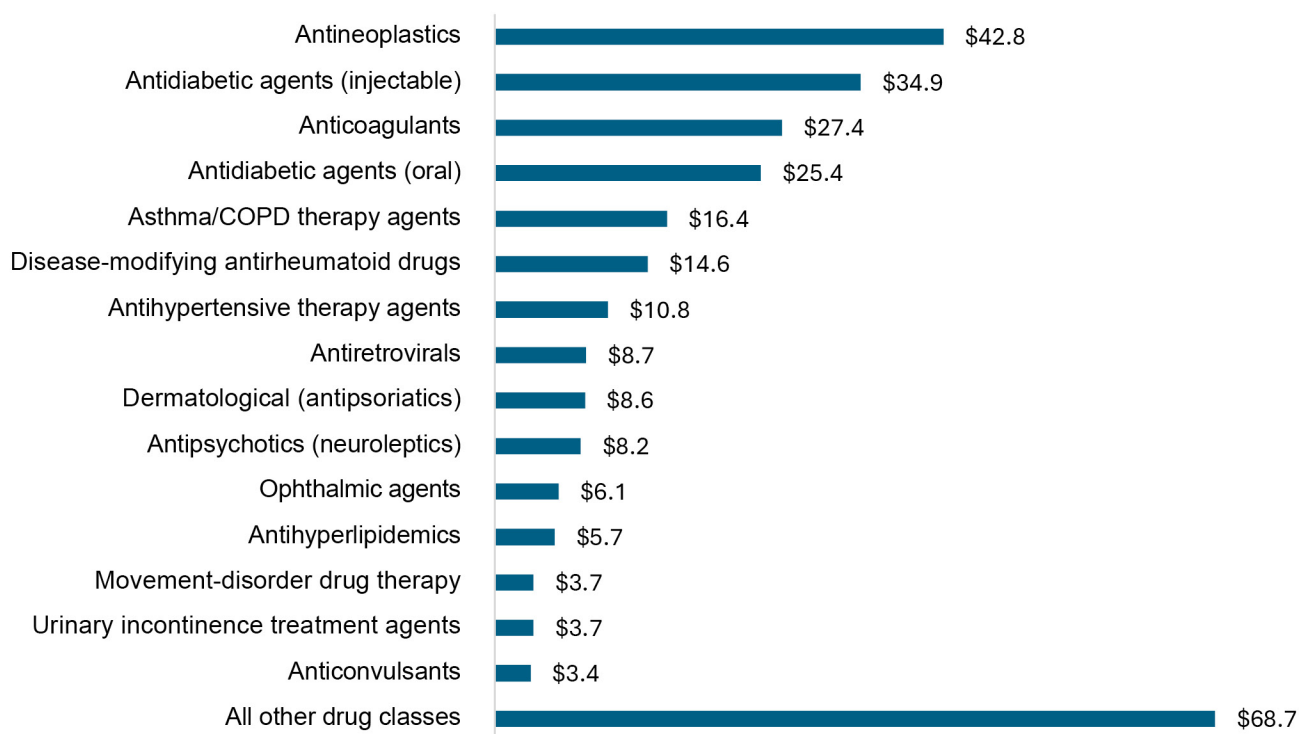
Part D has fostered a virtuous cycle between coverage and discovery (**Figure 2**), and the massive expansion of access to treatment is one reason the program has overwhelming support.

Figure 2. The Part D Value Pathway



Medicare Part D ensures access to therapies across a range of conditions (**Figure 3**). Coverage for the most commonly treated conditions includes treatments for cancer, diabetes, heart and lung disease, autoimmune conditions, and other illnesses, giving beneficiaries access to medicines across many stages of life. As new therapies are developed, Part D remains an important pathway for bringing pharmaceutical innovation to older adults and people with disabilities. This range of common conditions underscores why beneficiaries need plan choices with comprehensive formularies and affordable access to treatments suited to their individual needs. Survey data from eHealth in 2024 reported that at least 92% of Medicare Part D beneficiaries were satisfied with their current plans, indicating that most beneficiaries continue to receive meaningful value.¹³

Figure 3. Spending on Commonly Used Therapeutic Classes in Medicare Part D (in Billions), 2024¹⁴



Key: COPD – chronic obstructive pulmonary disease.

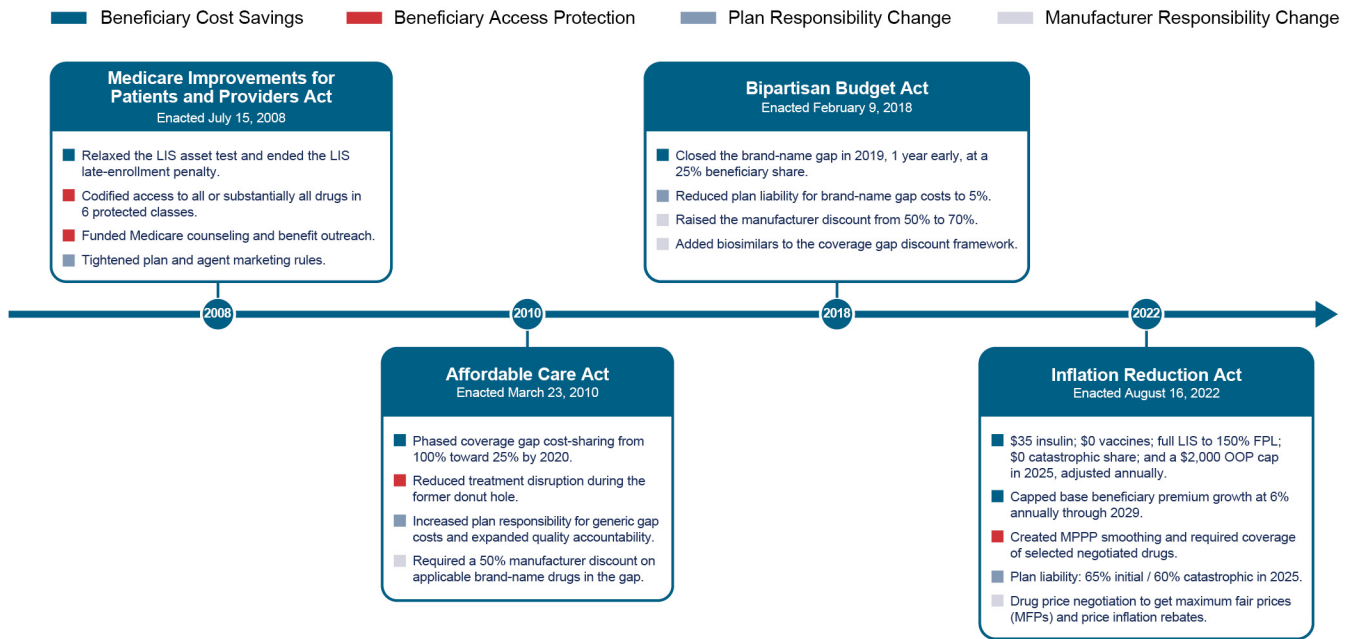
PART II: HOW PART D HAS EVOLVED—INCREASED BENEFICIARY AFFORDABILITY AND IMPROVED ACCESS THROUGH POLICY CHANGES

Policy Changes Result in Lower Beneficiary Costs

As Part D enters its third decade, it is important to recognize how the program's benefit design has evolved. Policymakers initially recognized the importance of modeling Part D after the commercial insurance market structure, while also designing a clear government role in providing funding and establishing benefit safeguards. Within the guardrails created by law and CMS regulations and guidance, regional and national plans developed a variety of offerings to meet beneficiaries' healthcare needs. From the start, federal subsidies helped cover program costs, lowering premiums for beneficiaries and absorbing a large share of the expenses plans incurred for high-cost patients.

Despite the program's success over time, beneficiaries and policymakers recognized shortcomings in its design. Since 2006, 4 major pieces of enacted legislation have altered the Part D program to make it more affordable for beneficiaries: the Medicare Improvements for Patients and Providers Act (MIPPA), the ACA, the Bipartisan Budget Act (BBA), and the IRA (**Figure 4**).

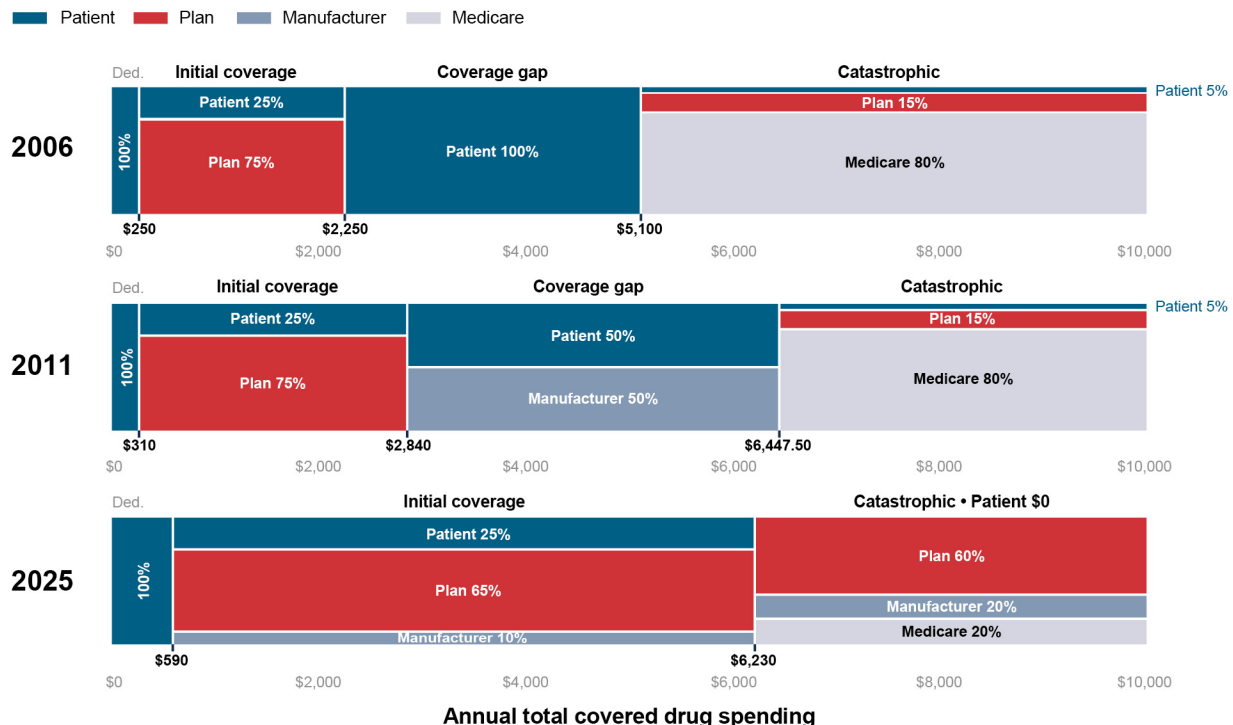
Figure 4. The Evolution of the Part D Benefit, Legislative Changes, 2008–2022



Key: FPL – federal poverty level; LIS – Low-Income Subsidy.

In 2006, the Part D benefit design included 4 phases that required significant OOP spending for non–low-income subsidy (LIS) beneficiaries: 1) a \$250 deductible; 2) an initial coverage phase with up to 25% cost-sharing (up to \$2,250 in covered expenses); 3) a coverage gap, or “donut hole,” where beneficiaries paid 100% of prescription costs after the initial phase coverage limit was met; and 4) a catastrophic phase requiring the beneficiary to pay a 5% coinsurance after \$3,600 in OOP spend (\$5,100 in total drug costs) in covered Part D expenses was reached (**Figure 5**).

Figure 5. Evolution of the Part D Standard Benefit Design: 2006, 2011, 2025



Initially, the LIS or “Extra Help” program was created to assist Part D beneficiaries who met the defined income and resource limits by providing premium assistance and lower prescription cost-sharing. Changes to LIS resource limits under MIPPA excluded the value of life insurance and in-kind payments and eliminated the LIS late enrollment penalty. MIPPA also wrote the protected classes policy into statute, directing CMS to identify classes of clinical concern. Under that authority, plan formularies must cover all or substantially all drugs in 6 protected classes (6PC): anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants.¹⁵

Two years after MIPPA, the ACA provided relief for high-needs beneficiaries by closing the coverage gap. The ACA aimed to gradually shift responsibility to other stakeholders, reducing beneficiaries’ share of gap costs to 25% of spending during that phase of the benefit between 2011 and 2020, rather than 100%.¹⁶ Responsibility for spending during the coverage gap shifted in part to manufacturers, who were required to provide 50% discounts on brand drugs dispensed; additional costs also shifted to plans (**Figure 5**). As beneficiaries’ cost-sharing decreased during the coverage gap phase, plans paid the residual costs.

The BBA accelerated the closure of the coverage gap by a year.¹⁷ Other significant BBA changes included increasing brand manufacturers’ discount responsibility to 70% in the coverage gap and adding biosimilar manufacturers to that mandate. By 2019, beneficiaries paid 25% during the coverage gap, plans paid 5%, and manufacturers paid the remaining balance of 70%.

The Ups and Downs of the IRA: Beneficiary Protections Aimed at Decreasing Costs and Improving Access

Despite these periodic attempts to improve affordability in Part D, some beneficiaries still faced access concerns. Critically, the IRA established an annual OOP cap in Part D for the first time, shifting patient spending and plan responsibility significantly. The cap (\$2,000 in 2025 and \$2,100 in 2026) is adjusted annually based on growth in Part D spending. This change is already having tangible impacts on beneficiary affordability and access. Between 2023 and 2025, OOP spending fell by 50% for the highest-spending 10% of enrollees, and average per-enrollee OOP spending fell by \$200 (25%), including a 30% decline in cost-sharing and a 16% decline in premium spending.¹⁸

Other significant beneficiary affordability provisions included expanding full LIS benefits to beneficiaries up to 150% of the federal poverty level (FPL) starting in 2024 from the previous limit of 135%, which significantly increased the number of Medicare beneficiaries eligible for LIS.¹⁹ Today, nearly 14 million LIS beneficiaries qualify for \$0 premiums when enrolled in a benchmark plan, \$0 deductibles, and low drug cost-sharing. The average program benefit for LIS beneficiaries is \$5,700 per year, or \$475 a month.²⁰ However, education and outreach need improvement, as about 4 million additional Medicare beneficiaries are eligible for LIS but not enrolled.²¹

With these changes, the IRA fundamentally redesigned the Part D benefit, limiting beneficiary costs and shifting more financial responsibility to manufacturers and plans (**Figure 5**). Additional IRA affordability changes included \$0 beneficiary cost for recommended vaccines, \$35 monthly cost-sharing for insulin, and the creation of the MPPP, which allows beneficiaries to spread their prescription drug OOP costs into monthly payments during the plan year instead of paying the full amount at the pharmacy. Nearly 9 million non-LIS, non-employer group Part D beneficiaries had high OOP drug costs in 2025, yet fewer than 3% of them enrolled in the MPPP, which could have spread their payments over the coverage year.²²

PART III: WHERE PART D FALLS SHORT

The Hidden Beneficiary Costs of Drug Price Negotiation Under the IRA

Against this backdrop of beneficiary protections and improved affordability, the IRA also established the Medicare Drug Price Negotiation Program, which requires CMS to negotiate prices for selected high-spend brand-name drugs without generic or biosimilar competition. The program applies to 10 drugs covered under Part D in 2026, 15 drugs covered under Part D in 2027, 15 drugs covered under Part B and Part D in 2028, and up to 20 drugs covered under Part B and Part D annually beginning in 2029.²³ The set prices, known as maximum fair prices (MFPs), for the first 10 selected drugs took effect in January 2026.²⁴ Plans must cover these drugs, and CMS relies on its current regulatory and subregulatory processes to review formularies during the bid cycle and evaluate any limitations that plans place on selected drugs. However, CMS has not adopted any new rules to protect access to selected drugs.²⁵

Lower prices for selected drugs haven't always meant lower costs for beneficiaries. A recent study found that two-thirds of Part D beneficiaries are enrolled in a standalone PDP or MA-PD plan that shifted drugs with negotiated prices from a fixed copay to coinsurance between 2023 and 2026. These beneficiaries are expected to pay more, on average, for 5 of the 10 drugs with negotiated prices in 2026. For example, enrollees in these plans are expected to pay 24.5% more, on average, for one selected blood thinner, and up to 55.8% more for other selected drugs.²⁶

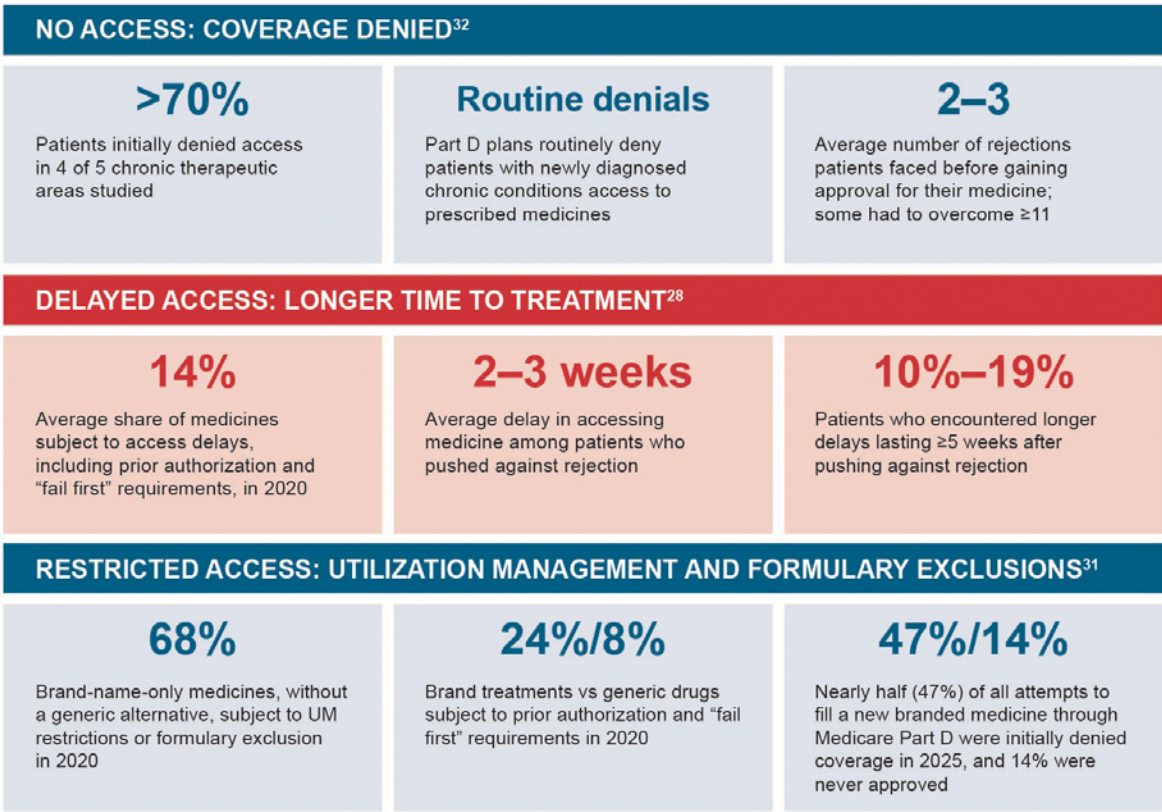
Patient groups are also watching whether the program affects development of new indications and treatments for rare and chronic conditions, on which Part D beneficiaries disproportionately rely.

Beneficiaries Face More Access Challenges and Less Plan Choice

The IRA reshaped the distribution of costs among beneficiaries, plans, manufacturers, and the federal government, particularly in the catastrophic phase of the Part D benefit, where beneficiaries' costs were eliminated and the federal government, plans, and manufacturers were given new liabilities. Because Part D plans now cover a larger share of prescription costs and the government covers less, plans have stronger incentives to limit covered drug spending. In response, plans have created more roadblocks for beneficiaries, including narrowing formularies, requiring more prior authorization or step therapy, and replacing fixed copays with percentage-based coinsurance.²⁷ A recent [MAPRx report](#), "Inflation Reduction Act: Access Barriers Undermine Affordability," explains these effects in more detail.

Increases in formulary restrictions and UM lead to fewer treatment options for beneficiaries and providers²⁸ and delays in accessing therapies (**Figure 6**). In the short time since the IRA, UM, cost-shifting to beneficiaries, and formulary limitations have continued to increase.²⁹ Initial Part D rejection rates for new branded prescriptions increased from 37% in 2021 to 47% in 2025.³⁰ Most rejected prescriptions are eventually approved, but 14% of all new branded prescription attempts are never approved,³¹ leaving beneficiaries without the prescribed drug.

Figure 6. Part D Access Restrictions and Delays

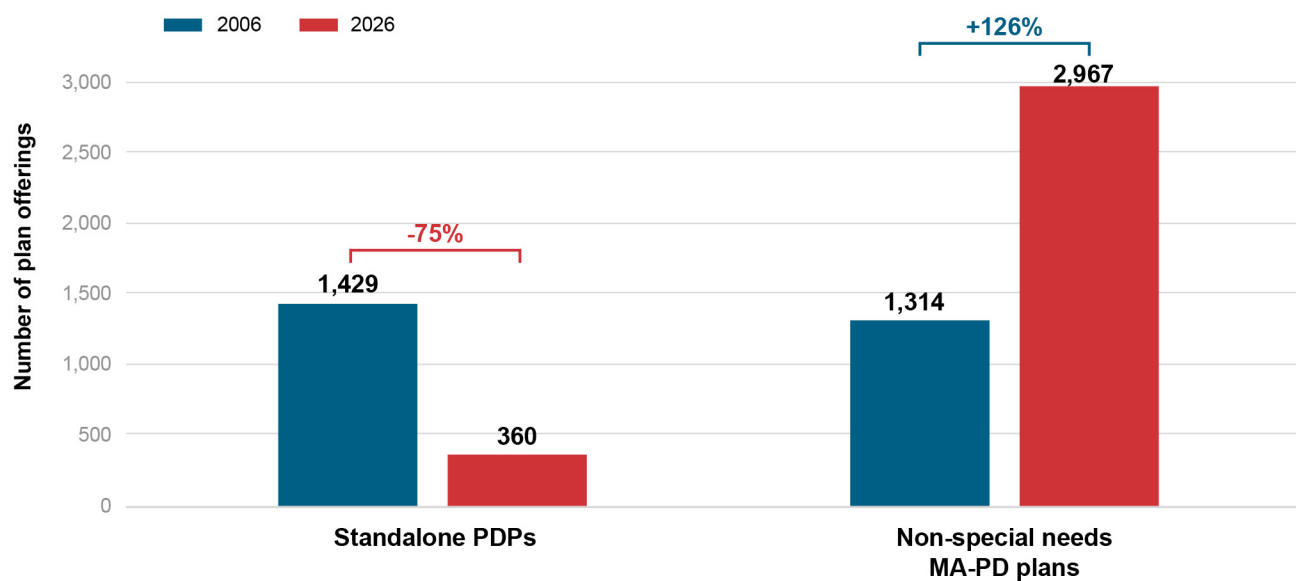


Beneficiary Impact of Challenges Faced by the PDP Market

The redesigned Part D benefit creates unique challenges for the standalone PDP market, which serves more than 40% of Part D enrollees. The profits MA-PD plans can earn from other parts of their business, along with differences in federal payment policies between MA-PD plans and PDPs, create an uneven playing field. As the portion of plan payments financed through risk-adjusted payments increases, PDP formularies could be further restricted.¹⁸ In addition, because all Part D plans now cover a larger share of prescription costs, they have stronger incentives to limit covered drug spending and have responded by creating more barriers for beneficiaries, likely accompanied by higher PDP premiums.³³

Further evidence of negative beneficiary impacts appears in the drop in the number of available PDPs (**Figure 7**). The range of plan offerings and competition in Part D in 2006 was an incredible success; but since then, the number of PDP offerings has dropped significantly, while the number of MA-PD plan offerings has increased. Participating insurers have also consolidated.³⁴

Figure 7. Change in Available PDPs and MA-PD Plans, 2006 vs 2026³⁵⁻³⁷



Beneficiaries who rely on standalone PDPs now have nearly half as many plan options as they did in 2024, and far fewer than at Part D's launch. In 2006, beneficiaries had an average of 43 standalone PDP choices per PDP region³⁸; in 2026, they had only 8 to 12 per state.³⁶ Between 2025 and 2026, the number of available PDPs decreased by 22%, and the number of companies sponsoring plans decreased from 19 to 17.³⁶ Fewer choices mean more one-size-fits-all formularies, which can result in plan choices that do not provide sufficient coverage to meet individual beneficiaries' needs.³⁹

The discontinuation of the CMS Premium Stabilization Demonstration for 2027 will increase premiums and change the PDP market,⁴⁰ though not all beneficiaries will experience this in the same way. In 2027, 21% of non-LIS beneficiaries are expected to be enrolled in plans with a monthly premium increase of \$30 or more, while 27% are in plans with a monthly premium change of less than \$5. Additionally, almost 2 million LIS beneficiaries are enrolled in a plan that will no longer qualify as a benchmark plan (so it will not be available at the \$0 premium), and in 14 states, LIS beneficiaries will have only 1 benchmark plan option.⁴¹

PART IV: BUILDING ON THE PROMISE OF PART D—COVERAGE, CHOICE, AFFORDABILITY

In many ways, it is hard to believe that Part D is only 20 years old. It has become a foundational part of Medicare, relied on by more than 56 million people, most of whom are satisfied with their coverage.¹³ It has also changed substantially since 2006. The coverage gap is gone, beneficiaries' OOP costs are capped each year, insulin costs no more than \$35 a month, and recommended vaccines cost nothing. OOP spending for beneficiaries with the highest drug costs fell by half between 2023 and 2025.¹⁸ Expanded Extra Help eligibility means more low-income beneficiaries pay little or nothing for their coverage.¹⁹ These are real gains, and they are worth protecting.

However, threats to the program's stability and beneficiary access require stakeholder attention. Lower negotiated prices haven't consistently reached beneficiaries at the pharmacy counter, as plans have shifted selected drugs to coinsurance and added UM. At the same time, increased access barriers imposed by plans prevent beneficiaries from getting the medicines their providers prescribe, even in the protected classes.⁴² And without access to a robust set of plan choices with an affordable premium, Part D cannot continue to succeed.

Coverage: Transparency, Protections, and Exceptions in Formularies

Continued evolution of the Part D benefit requires changes that help ensure beneficiaries are offered and can select the most appropriate coverage for their needs. Changes that would strengthen access to the best coverage include:

- **Improve beneficiary-facing transparency:** CMS should show UM requirements for formulary and non-formulary drugs in the Medicare Plan Finder so beneficiaries can compare plans accurately.
- **Permit exception requests for specialty tier medicines:** CMS should allow tiering exceptions for specialty tier drugs, with clear criteria and efficient review.
- **Strengthen oversight of formulary design:** CMS should monitor formularies, cost-sharing, and UM, including for negotiated drugs, and ensure the 6 protected classes are maintained.
- **Require standardized public reporting:** CMS should publish plan-level UM data, including prior authorization approval and denial rates.
- **Modernize the exceptions and appeals process:** CMS should simplify notices, reduce administrative barriers, and publicly report denials, overturn rates, and timelines.
- **Incorporate beneficiary input:** CMS should create a formal process for beneficiary and caregiver input into Part D oversight.

Choice: Ensuring Beneficiary Plan Options

Beneficiaries have increasingly limited options as plans scramble to recoup dollars they are losing due to changes in benefit design. To preserve patient choices of viable plans, it will be necessary to:

- **Ensure plan availability for LIS beneficiaries:** Benchmark plan options are declining.⁴³ CMS should set minimum standards for LIS benchmark availability and trigger corrective actions when available plans fall below them.
- **Strengthen the PDP marketplace:** CMS and Congress should provide time-limited, targeted premium support for standalone PDPs, conditioned on access protections such as stable formularies and cost-sharing and reasonable UM.
- **Maintain competition in the Part D landscape:** Shifting more financial risk onto plans has hit standalone PDPs hardest, and enhanced PDP offerings fell 35% between 2025 and 2026.⁴⁴ CMS should consider transitional risk protection, with guardrails that keep plans from shifting costs to beneficiaries.

Affordability: Expand Assistance and Beneficiary Outreach

Affordability protections only work if beneficiaries can use them, and many who need help still lack it.

- **Increase outreach and education for the LIS program:** About 4 million eligible beneficiaries are not enrolled in LIS.²¹ CMS should expand outreach and auto-enrollment.
- **Expand LIS eligibility:** Congress should raise the LIS income limit to 200% of FPL and eliminate the asset test.
- **Base cost-sharing on net prices:** Congress should base Part D coinsurance on net prices, building on the Senate Finance Committee's bipartisan 2023 proposal.
- **Improve uptake in the MPPP:** Fewer than 3% of eligible high-cost beneficiaries enrolled in the MPPP.⁴⁵ CMS should enable opt-in at the pharmacy counter by 2027 and expand education and "likely to benefit" outreach.

CONCLUSION

Part D's next chapter should continue building on the transformative promise established in 2006. Policymakers now have an opportunity to strengthen the program by improving formulary transparency and oversight, preserving plan choice and PDP competition, and expanding affordability help for the beneficiaries who need it most. Future reforms should place beneficiaries at the center, ensuring the Part D benefit continues to provide affordable access, meaningful choice, and timely treatment. Part D has earned its place as one of Medicare's success stories. Keeping it that way means fixing what isn't working while protecting what is.

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