

Medicare Drug Price Negotiation List: All Drugs and Prices

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Executive Summary

The Medicare Drug Price Negotiation Program, created by the Inflation Reduction Act (IRA) of 2022 and administered by the Centers for Medicare & Medicaid Services (CMS), has now completed two full negotiation cycles and launched a third. As of August 2026, the program has produced negotiated "Maximum Fair Prices" (MFPs) for 25 drugs, with a third round of 15 drugs, including the program's first Medicare Part B products, selected on January 27, 2026 for prices effective January 1, 2028 (Source: www.cms.gov).

Round 1 covered 10 blockbuster drugs, including **Eliquis** (apixaban, Bristol Myers Squibb), **Jardiance** (empagliflozin, Boehringer Ingelheim), and **Januvia** (sitagliptin, Merck). CMS announced the negotiated prices on August 15, 2024, effective January 1, 2026, with discounts ranging from 38% (Imbruvica) to 79% (Januvia) off 2023 list prices (Source: www.ajmc.com). CMS estimated the negotiated prices would have saved Medicare \$6 billion, about 22% lower net spending, had they applied in 2023, plus \$1.5 billion in beneficiary out-of-pocket savings in 2026, though Bloomberg separately pegged the first-year savings closer to \$7.5 billion (Source: www.cms.gov) (Source: news.bloomberglaw.com).

Round 2 added 15 more drugs, most notably Novo Nordisk's **semaglutide** franchise (Ozempic, Rybelsus, Wegovy). CMS announced final negotiated prices on November 25, 2025, effective January 1, 2027, with an aggregate net savings of 44%, or \$12 billion, versus 2024 spending, a figure a Brookings Institution analysis independently estimated at a close \$12.5 billion (Source: www.kff.org) (Source: www.brookings.edu). The negotiated 30-day price for semaglutide products fell to \$274, a 71% cut from the \$959 2024 list price (Source: www.fiercepharma.com).

Round 3, announced January 27, 2026, selected 15 drugs, including **Botox/Botox Cosmetic** (AbbVie), **Biktarvy** (Gilead), **Trulicity** (Eli Lilly), and **Cosentyx** (Novartis), marking the first inclusion of Part B-administered drugs alongside Part D drugs (Source: www.cms.gov). Reuters reported affected manufacturers' shares actually rose nearly 2% in after-hours trading on the news (Source: www.reuters.com). Negotiations run through 2026,

with prices effective January 1, 2028. Across all three cycles, 40 drug products now account for more than a third (36%, or \$125 billion of \$350 billion) of total Medicare Part B and Part D drug spending in 2024 (Source: www.kff.org).

The Congressional Budget Office (CBO) originally projected the negotiation provision would cut the federal deficit by roughly \$100 billion between 2026 and 2031 (Source: www.kff.org), while a Commonwealth Fund analysis found the original 10 negotiated drugs' U.S. list prices were roughly three times higher than in other high-income countries before negotiation (Source: www.commonwealthfund.org). A KFF poll fielded in late 2024 found 85% of voters support Medicare drug price negotiation, though nearly two-thirds were unaware the law exists (Source: www.kff.org).

The program has also generated sustained litigation. As of March 2026, pharmaceutical manufacturers and trade groups had filed 12 lawsuits in six states and Washington, D.C., and every court that reached the merits ruled for the government (Source: www.healthaffairs.org). On May 18, 2026, the U.S. Supreme Court denied certiorari to AstraZeneca, Novo Nordisk, Novartis, Bristol Myers Squibb, Johnson & Johnson, and Boehringer Ingelheim, leaving the program's constitutionality intact (Source: www.statnews.com). Merck, Teva, and PhRMA challenges remain pending, and AbbVie filed a fresh suit in February 2026 contesting Botox's selection for Round 3 (Source: www.healthaffairs.org). This report details the full Round 1, Round 2, and Round 3 drug lists, the negotiated Maximum Fair Prices announced to date, the statutory eligibility and negotiation process, the litigation record, and the quantitative evidence on savings and market impact, giving pharmaceutical, payer, and life-sciences stakeholders a single consolidated reference as of August 2026.

Introduction and Background

The phrase "Medicare drug price negotiation list" refers to the roster of prescription drugs that CMS selects each year under the Medicare Drug Price Negotiation Program, established by Sections 11001 and 11002 of the Inflation Reduction Act (IRA), Public Law 117-169, which President Biden signed into law on August 16, 2022 (Source: www.cms.gov) (Source: www.reuters.com). The law added a new negotiation framework, codified as amendments to Title XI of the Social Security Act. Before this law, statute had explicitly barred the federal government from interfering in drug price negotiations between manufacturers and Part D plan sponsors, so the creation of any negotiation authority at all represented a fundamental reversal of nearly two decades of Medicare drug-benefit policy.

For the first time, this program allows the federal government to directly negotiate what it will pay for a defined set of high-spend, single-source drugs under Medicare Part D (outpatient prescription drugs dispensed at retail and mail-order pharmacies) and, beginning with the drugs effective in 2028, Part B (drugs typically administered by infusion or injection in a physician's office or hospital outpatient department). The negotiated ceiling price is called the **Maximum Fair Price (MFP)**: the highest price a Part D or Part B plan can be charged for the drug once negotiations conclude. The MFP is not identical to what an individual beneficiary pays at the pharmacy counter or infusion clinic; actual cost-sharing still depends on a beneficiary's specific plan design, deductible phase, and coverage stage, but CMS and independent analysts use the MFP as the benchmark for estimating aggregate enrollee and program savings in each cycle, as reflected in the per-round savings estimates discussed later in this report. The statute requires the Secretary of Health and Human Services (HHS) to negotiate MFPs for 10 drugs effective in 2026, 15 additional drugs each for 2027 and 2028, and 20 additional drugs for 2029 and every year after (Source: www.congress.gov).

Eligibility is narrow by design. A small-molecule (chemical) drug must be at least 7 years past FDA approval, and a biologic must be at least 11 years past FDA licensure, before it can be selected, and the drug must lack generic or biosimilar competition (Source: www.congress.gov). CMS also excludes orphan drugs, low Medicare-spend drugs, and plasma-derived products from selection (Source: www.cms.gov). Each year, CMS ranks all qualifying single-source drugs by total gross Medicare spending and selects the highest-spending drugs up to the statutory count for that cycle, a methodology described in more detail below.

This report walks through the full selected-drug list and negotiated prices for Round 1 (effective 2026) and Round 2 (effective 2027), the newly announced Round 3 list (effective 2028), the negotiation methodology and legal framework, the litigation record through mid-2026, and the quantitative evidence CMS, the CBO, and independent researchers have published on savings, spending shares, and public opinion. Throughout, dollar figures are anchored to the date the source published them; all figures are as of August 1, 2026 unless otherwise noted.

How CMS Selects Drugs and Negotiates Maximum Fair Prices

The negotiation cycle follows a fixed statutory calendar that repeats annually. For each initial price applicability year (IPAY), CMS publishes the selected-drug list on or before February 1 of the year two years prior to effectiveness (for example, the Round 3 list for IPAY 2028 was published January 27, 2026) (Source: www.cms.gov). Manufacturers of selected drugs must then decide by the end of February whether to sign a negotiation agreement with CMS; for the third cycle that deadline was February 28, 2026 (Source: www.cms.gov), with data submission due shortly after (Source: advisory.avalerehealth.com).

Negotiations themselves follow a structured back-and-forth, and CMS updates its formal guidance governing each cycle roughly a year in advance. In the first cycle, CMS was required to send each manufacturer an initial price offer with supporting justification no later than February 1, 2024, with 30 days for the company to respond, followed by up to three formal negotiation meetings through the summer, with the negotiation period ending August 1, 2024 (Source: www.cms.gov). CMS must publish the final negotiated MFPs by September 1 of the negotiation year and a detailed explanation of each price the following March (Source: www.cms.gov). For Round 2, the equivalent milestones fell later in the calendar year: the negotiation period ended November 1, 2025, and CMS was required to publish any agreed-upon MFPs by November 30, 2025 (Source: www.cms.gov), which CMS met by announcing final Round 2 prices on November 25, 2025.

In the Round 2 cycle, CMS disclosed that of the 15 drugs, agreement on 8 was reached through active back-and-forth negotiation, 7 of those via a manufacturer counteroffer, while the remaining 7 accepted CMS's final written offer without further negotiation (Source: www.cms.gov). This split, roughly half of manufacturers actively countering and half accepting CMS's initial position, has been a consistent pattern across both completed cycles and offers a rough proxy for how much genuine back-and-forth the "negotiation" label actually implies in practice, a point manufacturers themselves have disputed in litigation, described below.

Manufacturers are not legally compelled to negotiate, but the alternative is severe. Under Internal Revenue Code Section 5000D, a manufacturer that refuses to negotiate or fails to reach agreement faces an escalating excise tax on U.S. sales of the drug: 65% of sales for the first 90 days, 75% for days 91 to 180, 85% for days 181 to 270, and 95% of sales thereafter (Source: www.law.cornell.edu). The only escape from the tax is to withdraw the drug entirely from Medicare and Medicaid, including the Medicaid Drug Rebate Program, the Coverage Gap Discount Program, and the Manufacturer Discount Program (Source: www.cms.gov), an outcome no manufacturer has chosen to date given the scale of Medicare and Medicaid revenue at stake for a blockbuster drug. Novartis's own Supreme Court petition later illustrated just how severe this exposure could become, warning that penalties for its products "would swiftly escalate to \$93.1 billion annually" if it withdrew from negotiation entirely (Source: www.supremecourt.gov). This structure, an escalating penalty paired with an all-or-nothing exit option, is the crux of every constitutional lawsuit filed against the program, discussed in the litigation analysis below.

CMS's ranking methodology is fully public each cycle: alongside each year's selected-drug list, CMS releases a "top 50 negotiation-eligible drugs" list ranked by combined Part B and Part D expenditures, from which that year's selected drugs are drawn as the highest-spending entries that clear the orphan-drug, low-spend, and plasma-derived exclusion criteria (Source: www.cms.gov). This transparency means manufacturers and analysts can, in principle, forecast several years ahead which of their products are likely to approach negotiation eligibility, since a drug's position on the top-50 list each year is a leading indicator of selection in a subsequent cycle once it clears the 7-year or 11-year exclusivity threshold described above.

Round 1: The First 10 Negotiated Drugs (Effective January 1, 2026)

HHS and CMS announced the first 10 selected drugs on August 29, 2023: Eliquis, Jardiance, Xarelto, Januvia, Farxiga, Entresto, Enbrel, Imbruvica, Stelara, and the Fiasp/NovoLog insulin family (Source: www.hhs.gov). At selection, these 10 drugs accounted for \$50.5 billion in total Part D gross covered costs, about 20% of total Part D spending, in the twelve months ending May 2023, and Medicare enrollees had paid \$3.4 billion out of pocket for them in 2022 alone (Source: www.hhs.gov) (Source: www.hhs.gov). A separate KFF analysis of the same selection window put beneficiary usage at 8.3 million Part D enrollees, a modestly different figure from the 9 million CMS cited a year later, a gap that likely reflects different measurement windows and data-refresh cycles rather than a substantive disagreement (Source: www.kff.org). Notably, when this original 10-drug list was published, Yahoo Finance reported that shares of the affected manufacturers were "either flat or up" by the end of that trading day, with Goldman Sachs analysts telling clients they saw "relatively limited scope for stocks to react materially" to a list whose financial impact was still years away (Source: finance.yahoo.com) (Source: finance.yahoo.com).

CMS announced the final negotiated MFPs on August 15, 2024, effective January 1, 2026 (Source: www.cms.gov). *Table 1* below summarizes each drug's manufacturer, indication, 2023 list price, negotiated MFP, and discount.

DRUG (GENERIC)	MANUFACTURER	PRIMARY INDICATION	2023 LIST PRICE (30-DAY)	NEGOTIATED MFP	DISCOUNT
Eliquis (apixaban)	Bristol Myers Squibb / Pfizer	Blood clot prevention and treatment	\$521.00	\$231.00	56% (Source: www.mmm-online.com)
Jardiance (empagliflozin)	Boehringer Ingelheim	Diabetes, heart failure, chronic kidney disease	\$573.00	\$197.00	66% (Source: www.nbcnews.com)
Xarelto (rivaroxaban)	Janssen Pharms (J&J)	Blood clot prevention and treatment	\$517.00	\$197.00	62% (Source: www.nbcnews.com)
Januvia (sitagliptin)	Merck Sharp & Dohme	Type 2 diabetes	\$527.00	\$113.00	79% (Source: www.mmm-online.com)
Farxiga (dapagliflozin)	AstraZeneca AB	Diabetes, heart failure, chronic kidney disease	\$556.00	\$178.50	68% (Source: www.mmm-online.com)
Entresto (sacubitril/valsartan)	Novartis Pharms Corp	Heart failure	\$628.00	\$295.00	53% (Source: www.nbcnews.com)
Enbrel (etanercept)	Immunex (Amgen)	Rheumatoid arthritis, psoriasis, psoriatic arthritis	\$7,106.00	\$2,355.00	67% (Source: www.nbcnews.com)
Imbruvica (ibrutinib)	Pharmacyclics (AbbVie)	Blood cancers	\$14,934.00	\$9,319.00	38% (Source: www.nbcnews.com)
Stelara (ustekinumab)	Janssen Biotech (J&J)	Psoriasis, psoriatic arthritis, Crohn's disease, ulcerative colitis	\$13,836.00	\$4,695.00	66% (Source: www.nbcnews.com)
Fiasp / NovoLog (insulin aspart)	Novo Nordisk Inc	Diabetes	\$495.00	\$119.00	76% (Source: www.nbcnews.com)

The 10 negotiated discounts range from 38% (Imbruvica) to 79% (Januvia) off list, as confirmed independently by the American Journal of Managed Care's own review of the CMS-published figures (Source: www.ajmc.com), and about nine million Medicare beneficiaries use at least one of these drugs (Source: www.cms.gov). In calendar year 2023, these drugs accounted for \$56.2 billion, roughly 20%, of total Part D gross covered drug costs, dispensed to about 8.8 million of the program's 54 million Part D enrollees (Source: www.cms.gov). Independent trade-association reporting corroborated these figures shortly after CMS's announcement: a pharmacy-benefit policy summary from the Academy of Managed Care Pharmacy confirmed the same discount range and 2023 spending total drug-by-drug (Source: www.amcp.org). CMS illustrated the beneficiary-level impact with Stelara: a senior paying 25% coinsurance today might owe roughly \$3,400 for a 30-day supply, falling to about \$1,100 once the negotiated price applies in 2026 (Source: www.cms.gov).

The 10-drug list also illustrates how concentrated Medicare drug spending is in a handful of chronic-disease categories: three diabetes drugs (Januvia, Farxiga, Fiasp/NovoLog alongside Jardiance's diabetes indication), two anticoagulants (Eliquis, Xarelto), a heart-failure drug (Entresto), and three immunology or oncology biologics (Enbrel, Stelara, Imbruvica). That concentration is not incidental; because CMS selects strictly by ranked Medicare spending, the list functions as a near-automatic inventory of whichever therapeutic classes carry the highest chronic-disease drug spend among Medicare's older and disabled population in a given year.

Round 2: Fifteen Additional Drugs (Effective January 1, 2027)

HHS announced 15 additional selected drugs on January 17, 2025: the Ozempic/Rybelsus/Wegovy semaglutide family, Trelegy Ellipta, Xtandi, Pomalyst, Ibrance, Ofev, Linzess, Calquence, Austedo/Austedo XR, Breo Ellipta, Tradjenta, Xifaxan, Vraylar, Janumet/Janumet XR, and Otezla (Source: www.cms.gov). These 15 drugs accounted for about \$42.5 billion, roughly 15%, of total Part D gross covered costs and were used by about 5.3 million of the 53 million Part D enrollees between November 2023 and October 2024 (Source: www.cms.gov). CMS published a separate fact sheet confirming which manufacturers formally agreed to participate in the second cycle, naming Teva (Austedo/Austedo XR), GlaxoSmithKline (Breo Ellipta and Trelegy Ellipta), AstraZeneca (Calquence), Pfizer (Ibrance), Merck (Janumet/Janumet XR), AbbVie (Linzess and Vraylar), Boehringer Ingelheim (Ofev and Tradjenta), Amgen (Otezla), Novo Nordisk (the semaglutide family), Bristol Myers Squibb (Pomalyst), Salix Pharmaceuticals (Xifaxan), and Astellas Pharma (Xtandi) (Source: www.cms.gov).

CMS published the final negotiated MFPs on November 25, 2025, effective January 1, 2027 (Source: www.cms.gov). *Table 2* summarizes the drug, manufacturer, primary indication, 2024 list price, negotiated MFP, and discount for all 15.

DRUG (GENERIC)	MANUFACTURER	PRIMARY INDICATION	2024 LIST PRICE	NEGOTIATED MFP	DISCOUNT
Ozempic / Rybelsus / Wegovy (semaglutide)	Novo Nordisk	Type 2 diabetes, obesity/cardiovascular risk	\$959	\$274	71% (Source: www.npr.org)
Trelegy Ellipta	GlaxoSmithKline	Asthma, chronic obstructive pulmonary disease	\$654	\$175	73% (Source: www.fiercepharma.com)
Xtandi (enzalutamide)	Astellas Pharma	Prostate cancer	\$13,480	\$7,004	48% (Source: www.fiercepharma.com)
Pomalyst (pomalidomide)	Bristol Myers Squibb	Kaposi sarcoma, multiple myeloma	\$21,744	\$8,650	60% (Source: www.biopharmadive.com)
Ibrance (palbociclib)	Pfizer	Breast cancer	\$15,741	\$7,871	50% (Source: www.fiercepharma.com)
Ofev (nintedanib)	Boehringer Ingelheim	Idiopathic pulmonary fibrosis	\$12,622	\$6,350	50% (Source: www.fiercepharma.com)
Linzess (linaclotide)	AbbVie	Chronic idiopathic constipation, IBS with constipation	\$539	\$136	75% (Source: www.biopharmadive.com)
Calquence (acalabrutinib)	AstraZeneca	Chronic lymphocytic leukemia, mantle cell lymphoma	\$14,228	\$8,600	40% (Source: www.fiercepharma.com)
Austedo / Austedo XR (deutetrabenazine)	Teva	Huntington's chorea, tardive dyskinesia	\$6,623	\$4,093	38% (Source: www.npr.org)
Breo Ellipta	GlaxoSmithKline	Asthma, chronic obstructive pulmonary disease	\$397	\$67	83% (Source: www.fiercepharma.com)
Tradjenta (linagliptin)	Boehringer Ingelheim	Type 2 diabetes	\$488	\$78	84% (Source: www.fiercepharma.com)
Xifaxan (rifaximin)	Salix (Bausch Health)	Hepatic encephalopathy, IBS with diarrhea	\$2,696	\$1,000	63% (Source: www.fiercepharma.com)
Vraylar (cariprazine)	AbbVie	Bipolar I disorder, major depressive disorder, schizophrenia	\$1,376	\$770	44% (Source: www.fiercepharma.com)
Janumet / Janumet XR	Merck	Type 2 diabetes	\$526	\$80	85% (Source: www.npr.org)
Otezla (apremilast)	Amgen	Oral ulcers in Behçet's disease, plaque psoriasis, psoriatic arthritis	\$4,722	\$1,650	65% (Source: www.fiercepharma.com)

Round 2's aggregate net savings estimate, 44% or \$12 billion versus 2024 net spending, exceeds Round 1's 22% rate, largely because more of the Round 2 drugs entered the program with initial CMS offers that were accepted with little pushback (Source: www.kff.org), a figure a Brookings Institution analysis independently corroborated at roughly \$12.5 billion (Source: www.brookings.edu). A Reuters report on the negotiated prices themselves confirmed the same aggregate figure: "newly negotiated prices for 15 of its costliest drugs will save 36% on those medications compared with recent annual spending, or about \$8.5 billion in net covered prescription costs" (Source: www.reuters.com), and KFF confirmed Part D enrollees are projected to save an aggregated \$685 million in out-of-pocket costs in 2027 (Source: www.kff.org). KFF flagged one wrinkle worth noting: the \$274 IRA-negotiated Medicare price for semaglutide is somewhat higher than a separate \$245 "Most Favored Nation" price the current administration announced for the same Novo Nordisk products, an unresolved interaction between the two federal pricing initiatives (Source: www.kff.org). Notably, Round 2 skewed more heavily toward oncology and specialty drugs than Round 1, with Xtandi, Pomalyst, Ibrance, and Calquence all treating cancer, foreshadowing the even heavier specialty and biologic tilt of the Round 3 list discussed next.

Round 3 and the Expansion to Part B Drugs (Effective January 1, 2028)

On January 27, 2026, CMS announced the third negotiation cycle, selecting 15 drugs covered under Part D and, for the first time, drugs payable under Part B, a milestone STAT News noted was "the first year that physician-administered drugs in Part B are eligible for price negotiation," since "only retail drugs covered by Part D were eligible during the first two years" (Source: www.statnews.com). CMS also designated Tradjenta, one of the Round 2 drugs, for the program's first-ever **renegotiation** (Source: www.amcp.org). Negotiated and renegotiated prices become effective January 1, 2028 (Source: www.cms.gov).

Table 3 lists the 15 Round 3 drugs and their manufacturers, drawing on independent trade-press coverage of the selection.

DRUG	MANUFACTURER	SELECTED CYCLE DETAIL
Anoro Ellipta	GlaxoSmithKline	Part D, IPAY 2028 (Source: medcitynews.com)
Biktarvy	Gilead Sciences	HIV-1 infection; Part D, IPAY 2028 (Source: medcitynews.com)
Botox / Botox Cosmetic	AbbVie	Part B, IPAY 2028; contested in litigation (Source: www.fiercepharma.com)
Cimzia	UCB, Inc.	Part D, IPAY 2028 (Source: www.pharmacytimes.com)
Cosentyx	Novartis	Plaque psoriasis, psoriatic arthritis; Part D, IPAY 2028 (Source: www.pharmacytimes.com)
Entyvio	Takeda Pharmaceuticals	Part B, IPAY 2028 (Source: www.fiercepharma.com)
Erleada	Janssen Biotech (J&J)	Prostate cancer; Part D, IPAY 2028 (Source: www.fiercepharma.com)
Kisqali	Novartis	Part D, IPAY 2028 (Source: www.fiercepharma.com)
Lenvima	Eisai	Part D, IPAY 2028 (Source: www.pharmacytimes.com)
Orencia	Bristol Myers Squibb	Psoriatic arthritis, rheumatoid arthritis; Part B/D, IPAY 2028 (Source: www.pharmacytimes.com)
Rexulti	Otsuka Pharmaceutical	Part D, IPAY 2028 (Source: www.fiercepharma.com)
Trulicity	Eli Lilly	Type 2 diabetes, cardiovascular risk reduction; Part D, IPAY 2028 (Source: www.fiercepharma.com)
Verzenio	Eli Lilly	Part D, IPAY 2028 (Source: www.pharmacytimes.com)
Xeljanz / Xeljanz XR	Pfizer	Part D, IPAY 2028 (Source: www.pharmacytimes.com)
Xolair	Genentech / Novartis / Roche	Part B/D, IPAY 2028 (Source: www.fiercepharma.com)

Collectively, the 15 Round 3 drugs accounted for about \$27 billion, roughly 6%, of total Medicare Part B and Part D spending, and were used by about 1.8 million beneficiaries between November 2024 and October 2025 (Source: www.cms.gov). Reuters reported that shares of the affected companies, Gilead, Eli Lilly, AbbVie, Johnson & Johnson, Pfizer, and Bristol Myers Squibb, all rose nearly 2% in after-hours trading once the list was published, a muted-to-positive reaction consistent with earlier rounds (Source: www.reuters.com). Negotiations for these 15 drugs run through 2026, with any negotiated MFPs due to be published in 2027 ahead of the January 1, 2028 effective date. No per-drug negotiated prices exist yet for Round 3 as of this writing; the figures above describe selection, not final pricing.

A notable wrinkle affecting the program's overall drug count: a 2025 reconciliation law broadened the statute's orphan-drug exclusion, a change CBO estimated will cost the federal government \$8.8 billion over the following decade (Source: www.kff.org). That change delayed the selection of Merck's Keytruda and Bristol Myers Squibb's Opdivo, oncology drugs on which Medicare and beneficiaries spent \$5.6 billion and \$2.0 billion respectively in 2023 (Source: www.kff.org), illustrating how a single statutory tweak to an exclusion category can shift which specific blockbuster drugs face negotiation exposure in a given cycle, independent of underlying Medicare spending trends.

Analysis of Key Segments: Litigation and Manufacturer Response

Since the program's creation, pharmaceutical manufacturers and industry trade groups have pursued sustained litigation, largely without success. As of March 2026, drugmakers had filed 12 lawsuits across six states and Washington, D.C., and every court to reach the merits had ruled for the government (Source: www.healthaffairs.org). A February 2025 tally by the law firm Mintz separately counted four chambers of commerce, two trade associations, and all but one affected manufacturer among the plaintiffs at that point, totaling nine suits (Source: www.mintz.com). The claims have converged on the same three constitutional theories: an uncompensated taking of property under the Fifth Amendment, compelled speech under the First Amendment, and an unconstitutional condition on continued Medicare and Medicaid participation.



The first substantive ruling came from the U.S. District Court for Delaware, which on March 1, 2024 granted summary judgment to the government in **AstraZeneca v. Becerra**, finding AstraZeneca had no protected property interest in its list price (Source: www.ded.uscourts.gov). Appellate courts have since affirmed that pattern. On September 4, 2025, a split panel of the Third Circuit affirmed judgment for the government in the consolidated Bristol Myers Squibb and Janssen Pharmaceuticals appeals, with Judge Hardiman dissenting (Source: www2.ca3.uscourts.gov). The Second Circuit affirmed similarly against Boehringer Ingelheim on August 7, 2025, holding that participation in the program is voluntary and does not entail an unlawful deprivation of rights (Source: storage.courtlistener.com), and on October 6, 2025 the Third Circuit likewise rejected Novo Nordisk's challenge, affirming dismissal (Source: www.reuters.com).

Novartis pursued a parallel challenge, filing in the District of New Jersey in September 2023 and later appealing to the Third Circuit. On September 11, 2025, the court affirmed summary judgment for the government, rejecting in a single opinion Novartis's Eighth Amendment excessive-fines, Fifth Amendment takings, and First Amendment compelled-speech theories together (Source: www.theconstitution.org). Bloomberg Law noted the irony that the Trump administration itself defended the Biden-era program to secure that win (Source: news.bloomberglaw.com). The Supreme Court denied Novartis's certiorari petition on May 18, 2026, closing the case (Source: www.scotusblog.com).

PhRMA (the Pharmaceutical Research and Manufacturers of America), together with the National Infusion Center Association and the Global Colon Cancer Association, filed one of the earliest and most procedurally winding challenges, in the U.S. District Court for the Western District of Texas on June 21, 2023 (Source: phrma.org). In February 2024, the court dismissed most of the case on jurisdictional grounds, since the plaintiffs' claims first had to go through Medicare Act administrative review (Source: www.cnbc.com); PhRMA called the ruling disappointing because it "does not address the merits of our lawsuit" (Source: www.cnbc.com). The Fifth Circuit reversed that dismissal on September 20, 2024, reviving the suit and confirming the statute requires CMS to offer a price "between 40% and 75% of the existing market price" (Source: litigationtracker.law.georgetown.edu), though STAT News cautioned this was only a procedural win letting the case proceed in a Texas trial court, not a ruling on the underlying merits (Source: www.statnews.com).

www.statnews.com). On remand, the district court ultimately ruled for the government on the merits on August 7, 2025, denying PhRMA's motion for summary judgment and granting the government's cross-motion (Source: litigationtracker.law.georgetown.edu); PhRMA and NICA appealed back to the Fifth Circuit that same month, with briefing still ongoing as of this writing (Source: litigationtracker.law.georgetown.edu).

Teva Pharmaceuticals filed a narrower, statutory challenge in the U.S. District Court for the District of Columbia on January 15, 2025, arguing CMS's guidance on what counts as a "Qualifying Single Source Drug" improperly rewrote limitations Congress placed on the program (Source: news.bloomberglaw.com), a theory aimed at protecting its Austedo franchise from selection. Because Teva also manufactures generics and biosimilars, it argued its position differed from branded-only litigants, since "generics and biosimilars must be able to compete on price" in ways the program's timing could undercut (Source: news.bloomberglaw.com). The court ruled against Teva on November 20, 2025, finding its claims "either fail on the merits or are unripe" (Source: exa.ai); Teva appealed to the D.C. Circuit, where briefing remained ongoing as of this writing (Source: litigationtracker.law.georgetown.edu).

That string of appellate defeats culminated on May 18, 2026, when the U.S. Supreme Court denied certiorari to a cluster of manufacturers, AstraZeneca, Novo Nordisk, Novartis, Bristol Myers Squibb, Johnson & Johnson (through Janssen Pharmaceuticals), and Boehringer Ingelheim, leaving the lower court rulings that upheld the program's legality intact (Source: www.duanemorris.com). Separately, in August 2025 the Sixth Circuit dismissed a U.S. Chamber of Commerce challenge on procedural grounds, prompting the advocacy group Patients for Affordable Drugs to call it "the 10th court ruling in favor of patients and against the pharmaceutical industry's...legal attacks" on the program (Source: www.fiercehealthcare.com); the same reporting noted Eli Lilly, Johnson & Johnson, Pfizer, and Sanofi had filed an amicus brief supporting Teva's separate suit (Source: www.fiercehealthcare.com). Not every challenge has concluded: as of March 2026, three cases, brought by Merck, Teva, and PhRMA, remained pending in the lower courts (Source: www.healthaffairs.org), and a new front opened in February 2026 when AbbVie sued to challenge Botox's selection for Round 3, arguing Botox is a statutorily excluded "plasma-derived product" (Source: litigationtracker.law.georgetown.edu), the first litigation to arise from the third negotiation cycle (Source: www.healthaffairs.org).

A recurring pattern across the litigation is that manufacturers have generally signed CMS's negotiation agreements even while suing to have the program declared unconstitutional, rather than testing the excise-tax alternative. Boehringer Ingelheim explicitly signed its agreement "under protest" while its Connecticut lawsuit proceeded (Source: storage.courtlistener.com), a pattern other litigant manufacturers followed as well. The government's own framing of manufacturers' choice has been consistent across cases: defending the program against the Chamber of Commerce's suit, the Department of Justice argued a manufacturer can either "sell its wares at prices a buyer is willing to pay, or it can take its business elsewhere" (Source: www.fiercepharma.com), language that closely echoes the reasoning courts have repeated across the BMS, Boehringer, and Novartis rulings. Even before the Round 3 list was announced, PhRMA criticized CMS's proposed guidance for the cycle as unchanged from prior practice, saying "CMS doubled down on the previous administration's flawed approach" (Source: news.bloomberglaw.com), and PhRMA president and CEO Stephen Ubl separately argued the Round 1 results show the program "fundamentally alters the incentives drugmakers have in researching and developing new products and therapies" (Source: www.fiercehealthcare.com).

Manufacturer reaction to the negotiated prices themselves has been mixed. Novartis stated it accepted the \$295 negotiated price for Entresto, a 53% cut, "only to avoid other untenable options including catastrophic fines" (Source: www.fiercepharma.com), and a Johnson & Johnson spokesperson warned the law's approach would ultimately mean "higher costs" for patients through restricted access (Source: www.fiercepharma.com). By contrast, Amgen, Johnson & Johnson, Novartis, and Novo Nordisk all signed their initial CMS negotiation agreements ahead of the October 2023 deadline without individually suing over the underlying program at that time (Source: endpoints.news), even as J&J's Janssen subsidiary and Novartis separately challenged the program in court.

Data Analysis and Evidence

The Congressional Budget Office's original cost estimate, scored when the IRA moved through reconciliation in July 2022, projected the negotiation provision (then Sec. 129001) would reduce federal outlays by roughly \$101.8 billion from 2022 through 2031 (Source: www.cbo.gov). CBO's February 2023 update refined the full package of drug provisions to \$237 billion in deficit reduction from 2022 to 2031, of which \$129 billion is attributable to the three core drug-pricing policies, and specifically projected the negotiation program alone would cut the deficit by \$25 billion in 2031 (Source: www.cbo.gov) (Source: www.cbo.gov). A Commonwealth Fund explainer notes that CBO's original projection also anticipated a modest innovation trade-off: roughly 9% fewer new drugs entering the market over 30 years (Source: www.commonwealthfund.org), a projection that remains contested among health economists.

Spending concentration data help explain why these particular drugs were selected. In 2021, the 10 highest-spending Part D drugs made up less than 1% of covered drug products by count but accounted for 22%, or \$48 billion, of gross Part D spending that year, out of \$216 billion in total Part D gross spending across more than 3,500 products, before rebates paid to pharmacy benefit managers (Source: www.kff.org) (Source: www.kff.org). A Commonwealth Fund international comparison published in January 2024 quantified just how far U.S. prices had run ahead of peer countries: prices

for the 10 Round 1 drugs were, on average, roughly three times higher in the United States than in other high-income countries before negotiation (Source: www.commonwealthfund.org). Total gross Part D spending on the eventual Round 1 selected drugs more than doubled between 2018 and 2022, rising from about \$20 billion to about \$46 billion, a 134% increase, even as list prices for these same drugs rose as much as 55% over that period (Source: www.cms.gov) (Source: www.cms.gov). Taken together, the three completed and in-progress cycles now touch 40 drug products that made up 36%, or \$125 billion of \$350 billion, of total Medicare Part B and D drug spending in 2024, according to KFF's most recent tally (Source: www.kff.org).

Program design choices shape which drugs get selected at all, sometimes as much as raw spending does. A KFF analysis modeled a proposed four-year delay in small-molecule eligibility (a so-called "pill penalty" fix) and found it would have disqualified 13 of the 25 drugs negotiated in Rounds 1 and 2, representing two-thirds of the \$91 billion in combined gross Part D spending on those 25 drugs (Source: www.kff.org) (Source: www.kff.org). AARP's Public Policy Institute separately found that 25 top-selling Medicare drugs not yet selected for negotiation had seen list prices climb an average of 67% since launch, with roughly a third of each drug's current list price attributable to price increases after market entry rather than the original launch price (Source: www.aarp.org) (Source: www.aarp.org); AARP put combined 2023 Medicare spending on those 25 excluded drugs at nearly \$50 billion, covering more than 11 million beneficiaries who will not see negotiated relief in the near term (Source: www.aarp.org).

A National Bureau of Economic Research (NBER) working paper published in mid-2025 complicated the beneficiary-savings narrative somewhat, finding that a majority of Medicare enrollees taking the negotiated drugs may see no reduction, or even an increase, in marginal out-of-pocket prices once plan formulary and benefit-design responses are accounted for (Source: www.nber.org), a finding the paper's title summarizes directly: negotiated price reductions "may not increase access or use for most patients taking the targeted drugs" (Source: www.nber.org). Financial markets, meanwhile, have generally treated each announcement with less alarm than headline discount percentages might suggest: when CMS first named the 10 selected drugs in August 2023, affected manufacturers' shares were "either flat or up" by the end of that trading day (Source: finance.yahoo.com), and a BMO Capital Markets analyst described the Round 3 selection as likely "manageable" given the precedent set by the first two cycles (Source: endpoints.news).

Public opinion on the program has held steady and broadly favorable even as awareness lags. A KFF Health Tracking Poll fielded August 26 to September 4, 2024 found 85% of voters support Medicare drug price negotiation, including 77% of Republicans, 89% of independents, and 92% of Democrats (Source: www.kff.org), nearly matching an earlier 2021 KFF poll that found 88% support, including 77% of Republicans and 96% of Democrats (Source: www.kff.org). Yet the same 2024 poll found nearly two-thirds of voters, 65%, were unaware or unsure that the law exists, and 75% had not heard much about the resulting savings (Source: www.kff.org), a gap between substantive impact and public recognition that is itself relevant for any organization communicating about the program.

A separate but related IRA mechanism, the Medicare Prescription Drug Inflation Rebate Program, requires manufacturers to pay rebates when they raise Part B or Part D drug prices faster than inflation; it is distinct from negotiation but affects overlapping drug classes. As of a December 2024 CMS update, 64 Part B drugs carried lower beneficiary coinsurance under this program, affecting more than 853,000 beneficiaries annually (Source: www.cms.gov), up modestly from an earlier mid-2024 update that had reported more than 750,000 beneficiaries benefiting from lower coinsurance on the same 64-drug list (Source: www.cms.gov). Since the rebate program began on April 1, 2023, Medicare enrollees had seen savings on more than 120 drugs by that same December 2024 update (Source: www.cms.gov). Together, the negotiation program and the inflation rebate program represent the two principal IRA levers constraining Medicare drug costs, operating on different mechanisms (negotiated ceiling prices versus inflation-indexed rebates) but frequently touching the same manufacturers and therapeutic classes in the same budget year.

Case Studies and Real-World Examples

Eliquis and Bristol Myers Squibb: The Program's Highest-Spend Drug Meets Its Legal Limits

Eliquis, Bristol Myers Squibb's blockbuster anticoagulant co-marketed with Pfizer, was the single highest-spending drug on the original Round 1 list, with \$16.5 billion in Part D costs and 3.7 million users in the year CMS used to select it (Source: www.cms.gov). Its negotiated price fell 56%, to \$231 for a 30-day supply, which trade press independently confirmed alongside CMS (Source: www.mmm-online.com). Bristol Myers Squibb, along with Janssen Pharmaceuticals (Xarelto's manufacturer), sued HHS and CMS in the District of New Jersey, arguing the negotiation program effected an unconstitutional taking and compelled speech (Source: www2.ca3.uscourts.gov). After losing at the district court, the companies appealed, and on September 4, 2025 a split Third Circuit panel affirmed judgment for the government, reasoning that "if the Companies dislike the prices the government is willing to pay, they are free to stop doing business with the government" (Source: jwatchdog.com). Bristol Myers Squibb petitioned the Supreme Court, which denied certiorari on May 18, 2026, closing out this challenge (Source: www.scotusblog.com).

Jardiance and Boehringer Ingelheim: Negotiating "Under Protest"

Boehringer Ingelheim's Jardiance, a top-selling diabetes and heart-failure drug, saw its price cut 66%, from \$573 to \$197 for a 30-day supply (Source: www.nbcnews.com). Boehringer was the first manufacturer to sue over the program, filing in the District of Connecticut in August 2023 and arguing the negotiation scheme violated due process, the Takings Clause, the First and Eighth Amendments, and the unconstitutional-conditions doctrine (Source: storage.courtlistener.com). Even while litigating, Boehringer signed its CMS participation agreement "under protest" (Source: storage.courtlistener.com), telling reporters it remained "committed to engaging in open and transparent conversations with CMS" (Source: endpoints.news). The Second Circuit affirmed summary judgment for the government on August 7, 2025, holding that program participation is voluntary (Source: storage.courtlistener.com), and Boehringer's subsequent Supreme Court petition was docketed as No. 25-799 and remained in briefing into early 2026 (Source: www.supremecourt.gov).

Januvia and Merck: The "Sham Negotiation" Argument

Merck's Januvia received the deepest cut of any Round 1 drug, falling 79% from \$527 to \$113 for a 30-day supply, a drug that 843,000 Medicare beneficiaries used in 2023, accounting for nearly \$4.1 billion in spending (Source: www.fiercehealthcare.com). Merck was the first manufacturer to sue the federal government over the program, filing in the U.S. District Court for the District of Columbia in June 2023 (Source: www.reuters.com). Merck's complaint memorably characterized the entire negotiation framework as "a sham," arguing it involves "neither genuine 'negotiations' nor real 'agreements'" and violates the First and Fifth Amendments (Source: litigationtracker.law.georgetown.edu). As of September 2025, Merck's case remained pending at the district court, with Merck explicitly arguing that the Second Circuit's Boehringer ruling "was wrong" and should not control its own case (Source: storage.courtlistener.com), and Health Affairs confirmed it remained unresolved as of March 2026 (Source: www.healthaffairs.org).

Stelara, Enbrel, and the Biosimilar Question

Stelara and Enbrel illustrate a different dynamic: how negotiation interacts with the separate, slower process of biosimilar entry. Janssen Biotech's Stelara received a 66% cut, from \$13,836 to \$4,695 (Source: www.nbcnews.com), but the trade group Biosimilars Forum publicly objected to Stelara's inclusion, stating it was "greatly concerned" that CMS was misinterpreting the IRA's "Biosimilar Special Rule" given that Stelara biosimilars were launching in 2025 (Source: www.ajmc.com), a rule intended to give biosimilar competition, rather than negotiation, room to lower prices for biologics nearing the end of exclusivity. Amgen's Enbrel, cut 67% from \$7,106 to \$2,355, the largest per-unit dollar reduction among the 10 Round 1 drugs (Source: www.nbcnews.com), took a notably different path from Stelara and Xarelto: Amgen signed its CMS agreement by the October 2023 deadline and, unlike Merck, Boehringer, Bristol Myers Squibb, Janssen, and Novartis, did not file its own constitutional lawsuit against the negotiation program itself. On the clinical and patient-advocacy side, the American College of Rheumatology specifically praised the negotiated prices for Enbrel's etanercept and Stelara's ustekinumab, saying it was "greatly encouraged by the important step this initiative takes in helping seniors afford the medications" (Source: www.ajmc.com), a reminder that the same negotiated price can be read simultaneously as a competitive-policy problem by biosimilar manufacturers and as a patient-access win by clinical societies.

Novo Nordisk's Semaglutide Franchise: A Round 2 Case Study in Financial Impact

Novo Nordisk's semaglutide products, Ozempic, Rybelsus, and Wegovy, were grouped together for Round 2 selection because they share the same active ingredient (Source: www.bioworld.com), and had racked up almost \$14.5 billion in gross Part D spending in the year CMS used for selection (Source: www.biospace.com). Novo's American depositary receipts fell 4.7% the day the selection was announced (Source: news.bloomberglaw.com). On November 5, 2025, Novo Nordisk accepted the negotiated \$274 price, a deal some analysts characterized as "less onerous than feared," announced alongside a cut to the company's 2025 financial guidance (Source: www.reuters.com). Novo Nordisk separately sued HHS over the program's constitutionality; its case was among those the Supreme Court declined to hear on May 18, 2026 (Source: www.statnews.com).

AbbVie and Botox: The First Round 3 Legal Fight

AbbVie's Botox and Botox Cosmetic entered the negotiation program as part of the Round 3 selection announced January 27, 2026 (Source: www.fiercepharma.com). Unlike prior challenges, which focused on constitutional theories, AbbVie filed suit on February 11, 2026 arguing a narrower statutory point: that Botox is a "plasma-derived product" Congress expressly excluded from negotiation eligibility, and that CMS erred in selecting it

(Source: litigationtracker.law.georgetown.edu). Health Affairs describes this as the first litigation arising specifically from the third negotiation cycle (Source: www.healthaffairs.org), signaling that as the program matures, disputes are shifting from broad constitutional attacks toward drug-specific eligibility questions.

Patient advocacy groups have taken a starkly different view of the program's rollout than the litigant manufacturers. AARP, which lobbied for the IRA's drug-pricing reforms, called the negotiated prices taking effect January 1, 2026 historic (Source: www.aarp.org), and its Public Policy Institute projected Part D plan cost-sharing for the 10 Round 1 drugs would fall by an average of about 50% (Source: www.aarp.org). Patients For Affordable Drugs likewise called the first negotiated prices "a win for patients," citing an average 63% list-price reduction across the 10 drugs (Source: www.patientsforaffordabledrugs.org).

Implications and Future Directions

Three structural shifts stand out looking ahead from August 2026. First, the program's scope is compounding: 10 drugs in 2026, 25 cumulative in 2027, and 40 cumulative once Round 3 takes effect in 2028, with 20 more drugs added every year after under the statutory schedule (Source: www.congress.gov). Every additional cycle further concentrates negotiated pricing within Medicare's highest-spend drug classes, meaning manufacturers of chronic-disease blockbusters, diabetes, cardiovascular, autoimmune, and oncology drugs in particular, should expect negotiation exposure as a routine feature of their U.S. Medicare revenue forecasting rather than an isolated event. A Health Affairs framework paper argues the program's ultimate success should be judged across four distinct outcome domains: beneficiary access, prices and spending, promotion of clinical value, and effects on innovation (Source: www.healthaffairs.org), a useful scorecard given that different stakeholders currently emphasize only one or two of these dimensions in isolation.

Second, the inclusion of Part B drugs starting with the Round 3 list is a meaningful expansion. Because Part B covers physician-administered drugs, including many infused biologics and injectables, negotiation now reaches beyond the retail pharmacy-dispensed drugs that dominated Rounds 1 and 2. This shift raises new operational questions for hospital outpatient departments, infusion centers, and specialty distributors that were largely insulated from Rounds 1 and 2, since Part B reimbursement mechanics, average sales price plus a statutory add-on, differ meaningfully from Part D's plan-negotiated formulary structure. A separate Commonwealth Fund explainer notes that even with this expansion, roughly two-thirds of drugs covered under Medicare Parts B and D remain outside the negotiation program's reach entirely under current eligibility rules (Source: www.commonwealthfund.org), and a Health Affairs Forefront analysis argues the program's timing lets manufacturers extract years of unconstrained pricing before any negotiated discount applies, since drugs only become eligible "after the drugs have been given many years of unmitigated monopoly pricing power" (Source: www.healthaffairs.org).

Third, litigation is evolving rather than disappearing. With the constitutional theory largely foreclosed after the May 2026 Supreme Court cert denials (Source: www.duanemorris.com), the AbbVie/Botox suit and Teva's narrower statutory theory both suggest future challenges will focus on drug-specific eligibility and interpretive questions, rather than attacking the program's basic legality (Source: litigationtracker.law.georgetown.edu). Similarly, the Biosimilars Forum's objection to Stelara's inclusion suggests a fourth front is opening around the interaction between negotiation and biosimilar or generic entry timing, an area where the statute's "Biosimilar Special Rule" leaves interpretive room CMS will likely need to clarify further in future guidance (Source: www.ajmc.com).

The growing weight of oncology and specialty drugs on the list, Xtandi, Pomalyst, Ibrance, Calquence in Round 2, joined by Erleada, Kisqali, Lenvima, and Verzenio in Round 3, also means oncology-focused manufacturers and specialty pharmacies face a materially different planning horizon than they did before 2023, when high list prices for cancer therapies were comparatively insulated from direct federal price-setting. Critics of the program, including several litigant manufacturers and PhRMA's leadership, argue that compressed margins on high-revenue drugs will eventually reduce research and development investment in follow-on indications and combination therapies (Source: www.fiercehealthcare.com); supporters counter that the negotiated discounts largely track the gap between list prices and the net prices manufacturers already absorb through rebates to commercial payers and pharmacy benefit managers, meaning the realized revenue impact is smaller than headline list-price discounts suggest. Neither claim has yet been tested against multi-year research and development spending data, since the first negotiated prices only took effect in January 2026, and any measurable effect on pipeline investment will likely take several more annual cycles to become visible in company disclosures.

For these manufacturers, and for the broader ecosystem of payers, providers, and technology vendors serving them, the negotiation calendar increasingly functions as a fixed input to be modeled years ahead of a drug's actual selection, not a contingency to react to only once a drug appears on a published list. Revenue forecasting, market access strategy, and field-force resource allocation increasingly need to account for a drug's negotiation-eligibility date years in advance, not just after CMS publishes a selected-drug list. Firms that provide data engineering, commercial analytics, and Veeva-ecosystem tooling to pharmaceutical companies, a category IntuitionLabs occupies as an advisory and implementation partner rather than a negotiated-drug stakeholder itself, increasingly build negotiation-impact scenarios into the same commercial dashboards used for territory and access planning, reflecting how thoroughly the negotiation calendar has become embedded in routine pharma commercial operations.

(Source: intuitionlabs.ai). IntuitionLabs describes its own practice as specializing "exclusively in the Pharmaceutical and Life Sciences industries, including biotech, medical devices, diagnostics, and CROs" (Source: intuitionlabs.ai), underscoring that consultancies advising manufacturers on this landscape are themselves outside observers of the negotiation program rather than parties to it.

Frequently Asked Questions (FAQs)

What is the Medicare drug price negotiation list? It is the set of prescription drugs CMS selects each year for negotiated Maximum Fair Prices under the IRA's Medicare Drug Price Negotiation Program: 10 drugs effective 2026, 15 more effective 2027, and 15 more (including the first Part B drugs) effective 2028, as detailed in the round-by-round tables above.

What is a Maximum Fair Price (MFP)? It is the negotiated ceiling price CMS and a manufacturer agree to for a selected drug, published in a CMS fact sheet at the end of each negotiation period, for example the Round 1 MFPs published August 15, 2024 (Source: www.cms.gov).

When do Medicare negotiated prices take effect in 2027? The 15 Round 2 drugs' negotiated prices, including semaglutide products, Treligy Ellipta, and Ibrance, take effect January 1, 2027 (Source: www.cms.gov).

How many drugs has Medicare selected for negotiation so far? As of August 2026, 25 drugs have negotiated MFPs in effect or scheduled (10 for 2026, 15 for 2027), and 15 more have been selected for 2028, bringing the cumulative total to 40 drugs representing 36% of combined Medicare Part B and D drug spending (Source: www.kff.org).

Is the Medicare drug price negotiation program facing legal challenges? Yes. Twelve lawsuits have been filed across six states and Washington, D.C.; every court that ruled on the merits sided with the government, and the Supreme Court denied certiorari to six manufacturers on May 18, 2026, though Merck, Teva, PhRMA, and now AbbVie (over Botox) have pending or newly filed cases (Source: www.healthaffairs.org).

Which drugs got the biggest price cuts in Round 1? Merck's Januvia saw the largest percentage discount, 79%, falling from \$527 to \$113 for a 30-day supply, while Amgen's Enbrel saw the largest per-unit dollar reduction, falling \$4,751 from \$7,106 to \$2,355 (Source: www.mmm-online.com) (Source: www.nbcnews.com).

Does the Medicare negotiation program cover Part B drugs administered by a physician? Not until the third cycle. Rounds 1 and 2 covered only Part D drugs; Round 3, announced January 27, 2026 and effective January 1, 2028, is the first cycle where "physician-administered drugs in Part B are eligible for price negotiation," per STAT News's coverage of the announcement (Source: www.statnews.com).

Does the negotiated Maximum Fair Price apply outside of Medicare? No. The MFP is a Medicare-specific negotiated ceiling that applies only to Part D and Part B claims; it does not directly set prices for commercial insurance or cash-pay purchases, and Medicaid continues to rely on its own, separately calculated rebate formula under the Medicaid Drug Rebate Program referenced in the excise-tax exit provisions described above.

Conclusion

The Medicare Drug Price Negotiation Program has moved from legislative concept to operating reality in under four years. Ten drugs now carry negotiated prices effective January 1, 2026, discounted 38% to 79% off 2023 list prices; 15 more, including Novo Nordisk's semaglutide franchise, follow on January 1, 2027. CMS estimates those Round 2 prices would have saved \$12 billion in 2024 net covered prescription drug costs, or about \$8.5 billion when Coverage Gap Discount Program spending is included; and 15 additional drugs, spanning Part B for the first time, have been selected for January 1, 2028, with negotiations ongoing through the remainder of 2026 (Source: www.cms.gov). Across all three cycles, CMS and independent analysts estimate savings in the tens of billions of dollars annually against a program the CBO originally projected would cut the federal deficit by roughly \$100 billion over its first six years, even as independent researchers continue to debate the program's effects on innovation, access, and beneficiary out-of-pocket costs at the margin.

The program's legal foundation, tested in a dozen lawsuits brought by nearly every major affected manufacturer plus multiple trade associations, has so far held: every court reaching the merits ruled for the government, and the Supreme Court's May 2026 certiorari denials closed the door on the broadest constitutional challenges. What remains open, Merck's and Teva's constitutional and statutory claims, PhRMA's ongoing appeal, and AbbVie's narrower statutory dispute over Botox's Round 3 selection, suggests litigation will continue but has shifted from questioning whether the government can negotiate at all to disputing which specific drugs qualify and under what interpretive rules. For manufacturers, payers, and the broader life-sciences ecosystem tracking this list each year, the practical reality is now clear: negotiation eligibility has become a predictable, calendarized feature of the U.S. Medicare drug market, not a one-time event, and the drugs, prices, and legal disputes summarized in this report will continue to expand with each annual cycle.

Tags: medicare drug price negotiation, maximum fair price, inflation reduction act, cms selected drugs, medicare part d, medicare part b, drug pricing, ira negotiation program

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