

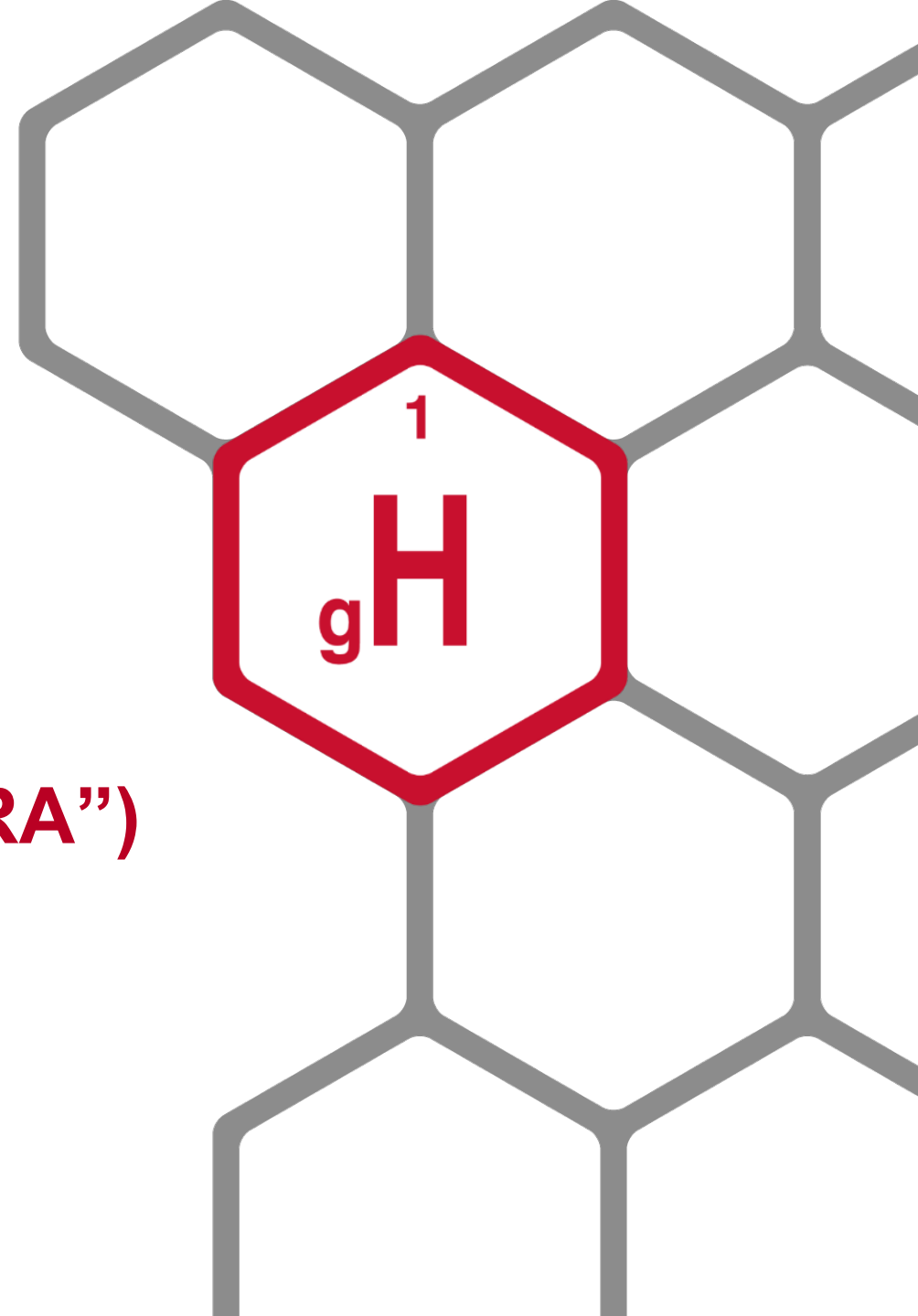


[Download Link](#)

Inflation Reduction Act of 2022 (“IRA”) – Impact on Drug Pricing

Prepared by Emily Donnell

October 2023





Executive Summary





Key Topics

1. 3 Key Mechanisms in the IRA
2. Medicare Drug Price Negotiation
 - Criteria for Inclusion in IRA Negotiations
 - Criteria for Exclusion from IRA Negotiations
 - Prioritization Criteria for Inclusion in IRA Negotiations
 - Timelines and Key Deadlines for Price Negotiation
 - List of 10 Drugs Selected for 2026 Price Negotiation
3. Inflation Rebates in Medicare
 - Inflation Rebate Calculation and Potential Impact on Drug Price
 - Part B & D Drug Price Increase Compared to Inflation Rate Between 2017 and 2021
4. Part D Manufacturer Discount Requirement
 - 4 Part D Coverage Phases Before IRA Implementation
 - Expansion of Discount Requirement
5. Decision Trees





There are three key mechanisms in the IRA that will enable Medicare to exert pricing pressure on drug manufacturers

Mechanism	Descriptions
<p>Medicare drug price negotiation</p>	<p>IRA authorizes Medicare to directly negotiate drug prices for certain high expenditure, single source Medicare drugs covered under Part B (physician-administered products) and Part D (retail products), (i.e. drugs with no generic or biosimilar competition).</p>
<p>Inflation rebates in Medicare</p>	<p>IRA requires drug manufacturers to pay a rebate to the federal government if prices for single-source drugs and biologicals covered under Medicare Part B and nearly all covered drugs under Part D increase faster than the rate of inflation (CPI-U).</p>
<p>Part D manufacturer discount requirement</p>	<p><i>Before the IRA implementation</i>, there were 4 Medicare Part D phases: deductible, initial coverage, coverage gap and catastrophic coverage, each with its own cost-sharing structure and responsibilities for beneficiaries, plan sponsors, drug manufacturers and Medicare, manufacturers are required to provide 70% price discount for Part D branded drugs during the coverage gap phase.</p> <p><i>With the IRA implementation</i>, the coverage gap phase will be eliminated, drug manufacturers are required to pay 10% price discount during the initial coverage phase and 20% in the catastrophic coverage phase for Part D branded drugs, replacing the 70% price discount in the coverage gap phase.</p>





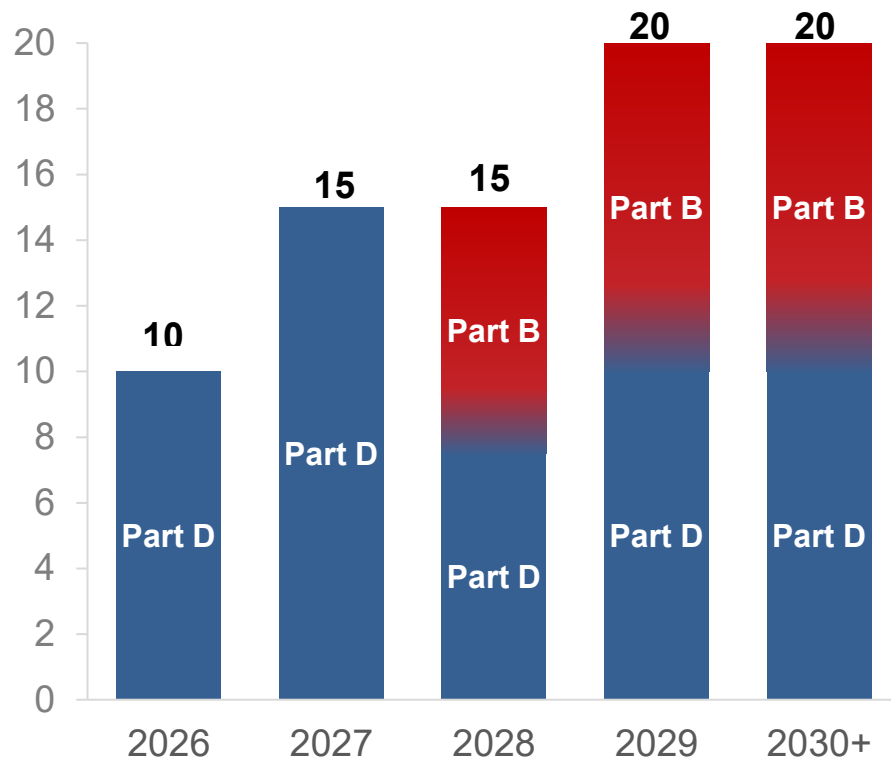
Medicare Drug Price Negotiation



Single-source branded drugs with high budget impact will be required to participate in the price negotiation, with those having highest budget impact being prioritized for initial negotiations

Total Drugs Undergoing IRA Negotiation

Medicare Parts D and B



Small molecules

- **Single-source brand-name** drugs will be prioritized for negotiation
- Must be at least **7 years** since FDA approval date*, as of the date that the list of drugs selected for negotiation is published:
 - For 2026 negotiation: list to be published on September 1, 2023, so the small-molecule drugs selected must have been approved on or before September 1, 2016

Biologics

- Biological products without **therapeutically-equivalent generic or biosimilar alternatives**
- Must be at least **11 years** since licensure date*, as of the date that the list of drugs selected for negotiation is published:
 - For 2026 negotiation: list to be published on September 1, 2023, so the biological products selected must have been licensed on or before September 1, 2012

* The IRA's reference to FDA approval is the section of the Federal Food, Drug, and Cosmetic Act that establishes the traditional approval pathway or licensure of biological products under the Public Health Service Act, not FDA's accelerated approval program



Orphan drugs, small biotech drugs, plasma-derived products, low-budget impact drugs are excluded from IRA price negotiations; biologics with high likelihood of near-term biosimilar launches within two years are indirectly excluded

Direct Exclusions

Orphan Drugs

- Drugs that have “Orphan Drug Designation(s)” from the FDA **for only one rare disease** or condition are excluded from IRA price negotiations
 - If a drug has designations for more than one rare disease or condition, it will not qualify for the Orphan Drug Exclusion even if the drug has not been approved for any indications for the additional rare disease(s) or condition(s)
 - CMS will only consider active designations and active approvals (as opposed to “withdrawn” designations/approvals) when evaluating a drug for exclusion

Low Budget Impact Drug

- Drugs with annual Medicare spending of **less than \$200M** are excluded
 - E.g., the 2026 determination is based on data from June 1 ‘22 to May 31 ‘23

Small Biotech Drug

- The IRA excludes so-called “small biotech” drugs from price negotiations, but only from **2026 to 2028**
- To qualify under this “Small Biotech Exception”, manufacturers must prove that this drug represents:
 - Less than 1%** of total expenditures for drugs under Medicare Part D, and
 - More than 80%** of the company’s Medicare Part D revenues (i.e. ≥80% of the company’s Medicare revenue must from a single Part D drug)

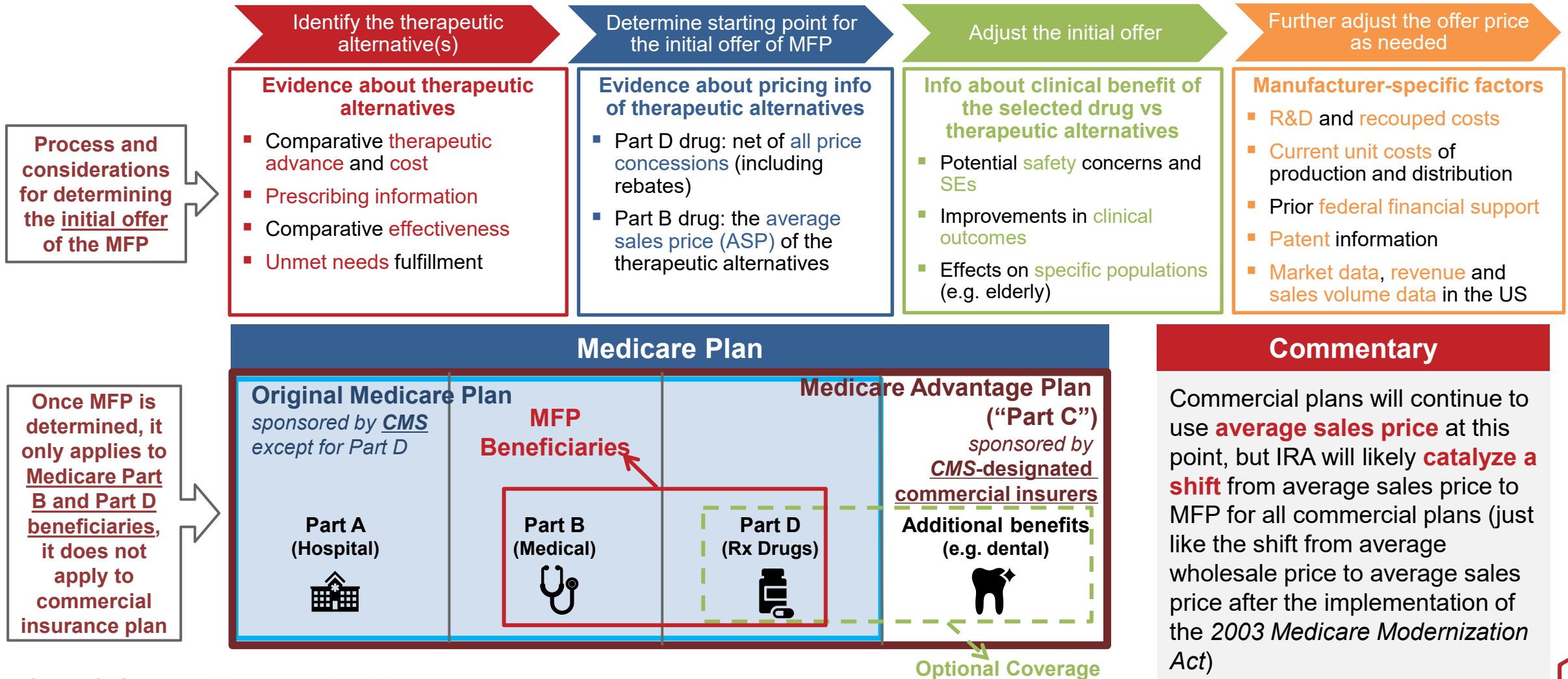
Plasma-derived Product

- All plasma-derived products are excluded from IRA price negotiations

Indirect Exclusions: Biosimilar Delay

- Biologics with **high likelihood** of imminent launches of biosimilar competitors **within the next two years** are excluded because they are likely to undergo steep price declines irrespective of IRA negotiation
 - For **2026**, the licensure and marketing of a biosimilar must be highly likely to occur before **September 1, 2025**
- CMS will decide whether there is a high likelihood of biosimilar market entry based on two factors:
 - Whether an **application for licensure** of the biosimilar product has been **accepted for review** or **already approved by the FDA**, and
 - “Clear and convincing” evidence that the biosimilar product will be marketed within two years of the selected drug publication date, including demonstrating that there are **no patent barriers** to entry and **operational readiness** to bring the biosimilar product to market
- CMS will **NOT** grant a request to delay selection of a reference product for negotiation if **more than one year** has passed between licensure of the biosimilar and its marketing

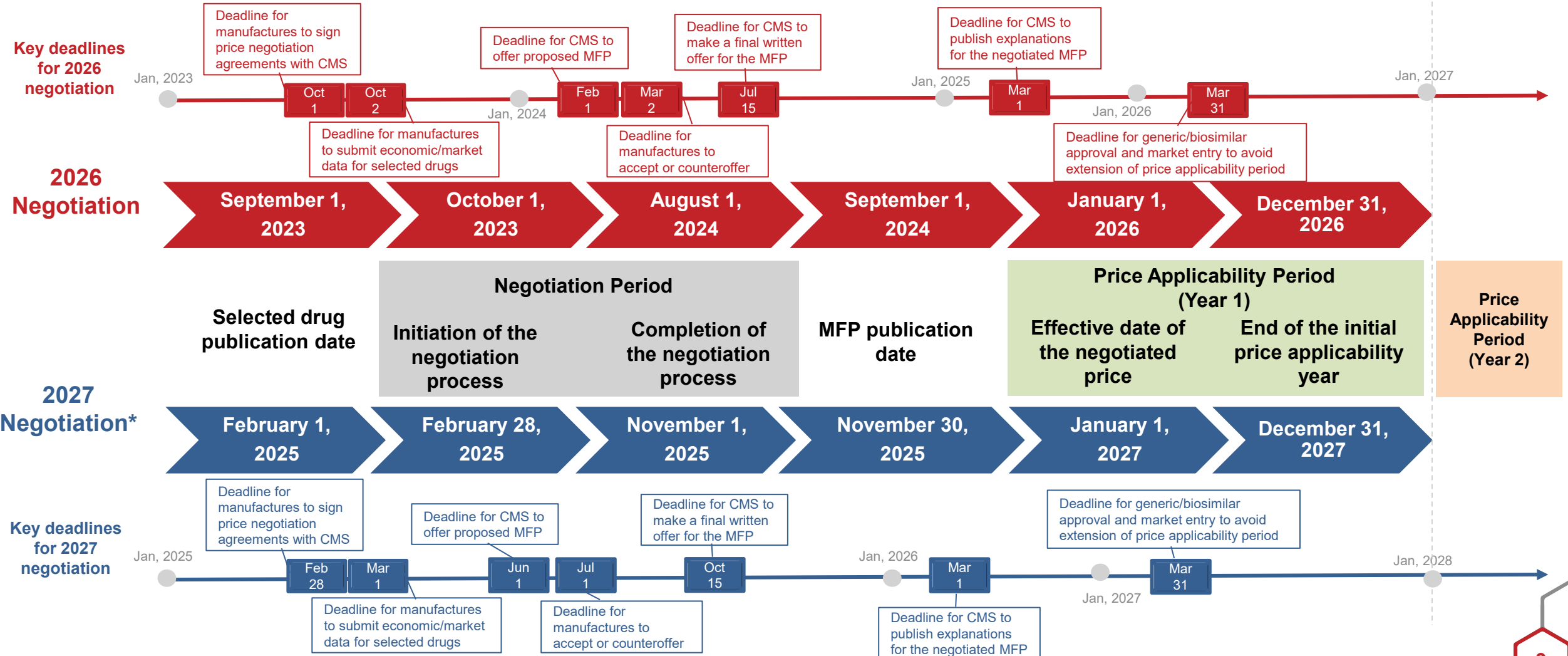
The IRA requires CMS to consider certain manufacturer-specific factors and information about therapeutic alternatives in negotiating the “maximum fair price (MFP)” for selected drugs within the statutory price ceiling



Source: CMS.gov, groupH research and analysis

* IRA implementation refers to MFP implementation for Part B drugs in 2028 and for Part D drugs in 2026

While the first negotiation cycle takes place between October 2023 and August 2024, the timelines for a regular negotiation cycle of subsequent years are different from years but they are consistently the same



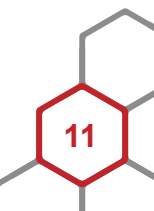
Source: groupH research and analysis of Medicare Drug Price Negotiation Initial Memorandum
 * 2027 negotiation timeline represents a regular negotiation timeline for the subsequent years' negotiations

More than half of the first 10 drugs selected for 2026 price negotiation are high-selling blood thinners or antidiabetics, 7 out of 9 manufacturers on the list have filed lawsuit against IRA drug negotiation program

Drug Name	Manufacturer	Indication	Class / MOA	Manufacturer's Comment
Eliquis (apixaban) tablets 5mg, 2.5mg	Bristol Myers Squibb	Cardiovascular diseases	Anticoagulant (Factor Xa inhibitor)	"Unlike a true 'negotiation,' this program guarantees that the government will secure the products it wants at the prices it dictates."
Jardiance (empagliflozin) tablets 10mg	Boehringer Ingelheim	Type 2 diabetes	Antidiabetic (SGLT2 inhibitor)	"Those draconian provisions impose fines two-and-a-half to 25 times greater than the statutory penalty for criminal tax fraud, making clear that they are unconstitutionally excessive as a matter of law."
Xarelto rivaroxaban tablets & oral suspension	Janssen PHARMACEUTICAL COMPANIES OF Johnson & Johnson	Cardiovascular diseases	Anticoagulant (Factor Xa inhibitor)	"That provision is the legal equivalent of a gun to the head because it would require the manufacturer to give up access to nearly 40% of the U.S. health care market. It is akin to the government taking your car on terms that you would never voluntarily accept and threatening to also take your house if you do not 'agree' that the taking was 'fair.'"
Stelara (ustekinumab)		Autoimmune diseases	IL-12 / IL-23 monoclonal antibody	
Januvia (sitagliptin) 25 mg, 50mg, 100mg tablets	MERCK	Type 2 diabetes	Antidiabetic (DPP-4 inhibitor)	"This is not 'negotiation.' It is tantamount to extortion."
farxiga (dapagliflozin) 5mg & 10mg tablets	AstraZeneca	Type 2 diabetes	Antidiabetic (SGLT2 inhibitor)	"IRA's Medicare price negotiation measures 'run headlong into the goals' of the 1983 Orphan Drug Act."
Entresto (sacubitril/valsartan) tablets 24/26mg, 48/51mg, 97/103mg	NOVARTIS	Heart failure	Angiotensin receptor neprilysin inhibitor	"The result would fundamentally jeopardize the development and supply of essential, life-saving drugs for the people who depend on them."
Enbrel etanercept	AMGEN	Autoimmune diseases	Anti-TNF	"The enactment of the Inflation Reduction Act is a loss for patients and the future of innovation. This law misses the mark on both fronts."
imbruvica (ibrutinib) 420, 280, 140 mg tablets 140, 70 mg capsules 70 mg/mL oral suspension	pharmacyClics An AbbVie Company	B-cell cancers	BTK inhibitor	"The Senate reconciliation package proposes price controls rather than government negotiations."
Novo Log Fiasp	NOVO NORDISK	Diabetes	Antidiabetics (insulin analog)	"Unfortunately, we have seen CMS take aggressive steps to carry out unilateral price setting without consideration for the impact on patients living with chronic disease or the overall healthcare system."



Inflation Rebates in Medicare



Most Medicare-covered drugs will be subject to the inflation rebate requirement under the IRA, which may potentially impact on future drugs launch prices

IRA requires drug manufacturers to pay a rebate to the federal government if **prices for single-source drugs and biologics covered under Medicare Parts B and D** increase faster than the rate of inflation (CPI-U)

Inflation Rebate Calculation

- The IRA will require drug manufacturers to pay back the **difference between their drug price increases and the rate of inflation**
 - For example, if a drug price increases 5.4% YoY and matches 5.4% inflation, then no rebate is owed
 - If drug price increases 10% YoY, but inflation is 5.4%, then a 4.6% rebate is owed for each unit sold

Differences Between Parts D & B

- **Nearly all Part D drugs** are subject to the inflation rebate requirement, while **only single-source agents and biologics in Part B** are subject to the rebate requirement
- Price changes for Medicare Part B will be measured based on the **average sale price (ASP)**
- Price changes for Medicare Part D will be measured based on the **average manufacturer price (AMP)***

Potential Impact on Drug Price

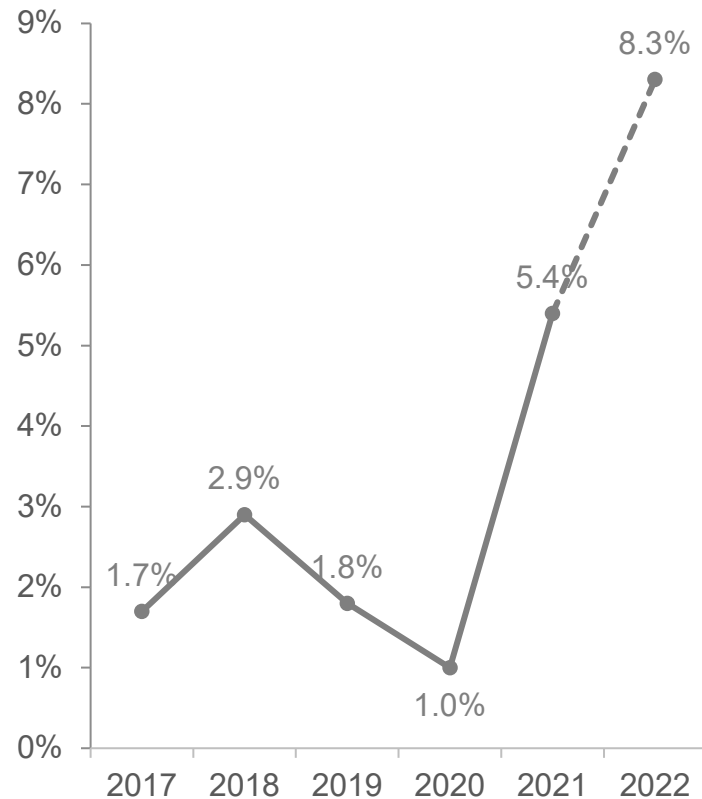
- Manufacturers are incentivized to launch at a **higher price**, “baking in” price increases into the **initial launch price** and foregoing real price increases year-to-year
 - However, Medicare Part D plan sponsors and commercial insurers are still be able to negotiate rebates and refuse coverage for drugs with very high launch prices
- For drugs that have **no therapeutic alternatives** available or if they are covered under a **Part D “protected class”** (drugs that are mandatorily covered by Part D plans), they may have more leverage on drug launch price increase and are less impacted by the inflation rebate penalties
- Manufacturers’ willingness to take a higher price increase and pay the rebate may also depend on the **proportion of sales to commercial plans as the rebate only applies to the sales to Medicare**



The percent of Part B and D drugs that have annual price increases greater than inflation fell sharply in 2021, but this is likely due to an abnormally higher inflation rate that exceeded most price increases

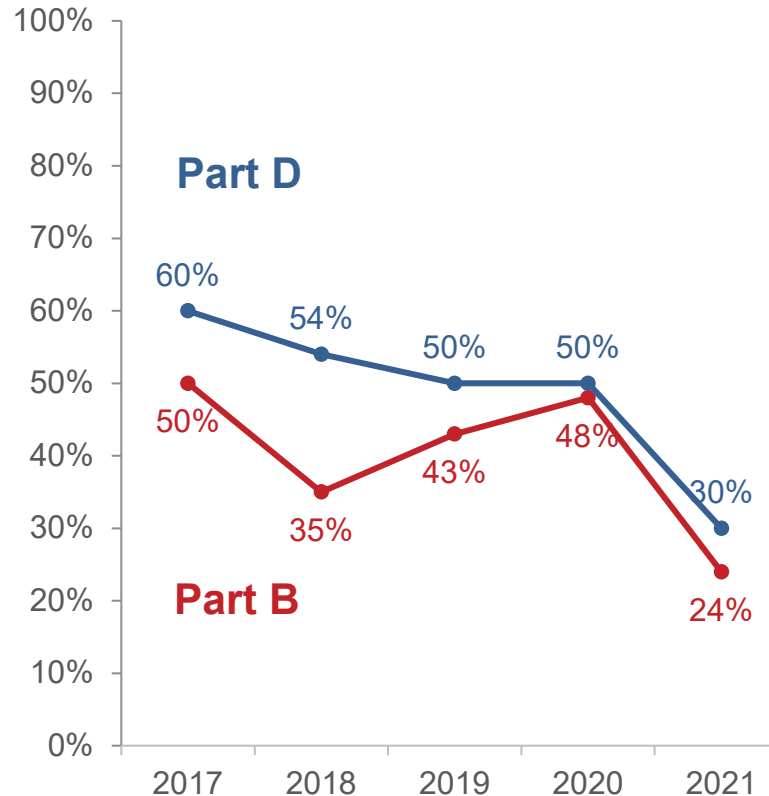
US Inflation Rate

2017-2021



Percent of Drugs with Price Increases Exceeding Inflation

Medicare Part B & Part D Drugs; 2017-2021



Insights

- Inflation rate has a significant impact on the numbers of drugs with price increases exceeding the inflation rate – a higher inflation rate generally translates to fewer drugs exceeding that rate
- A greater proportion of Part D drugs have price increases that exceed inflation than Part B
- Drug developers have more latitude to raise prices in years where inflation is higher and not incur inflation rebate penalties

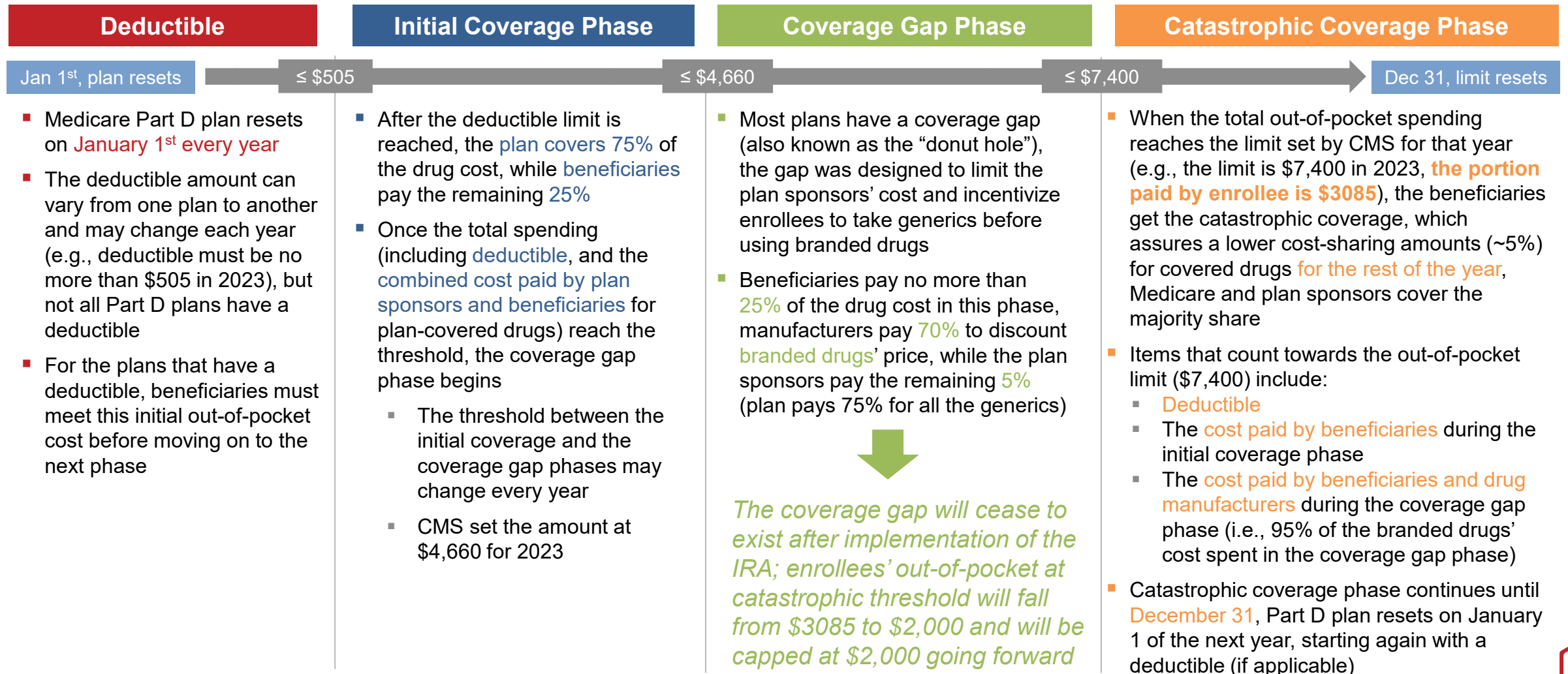


Part D Manufacturer Discount Requirement



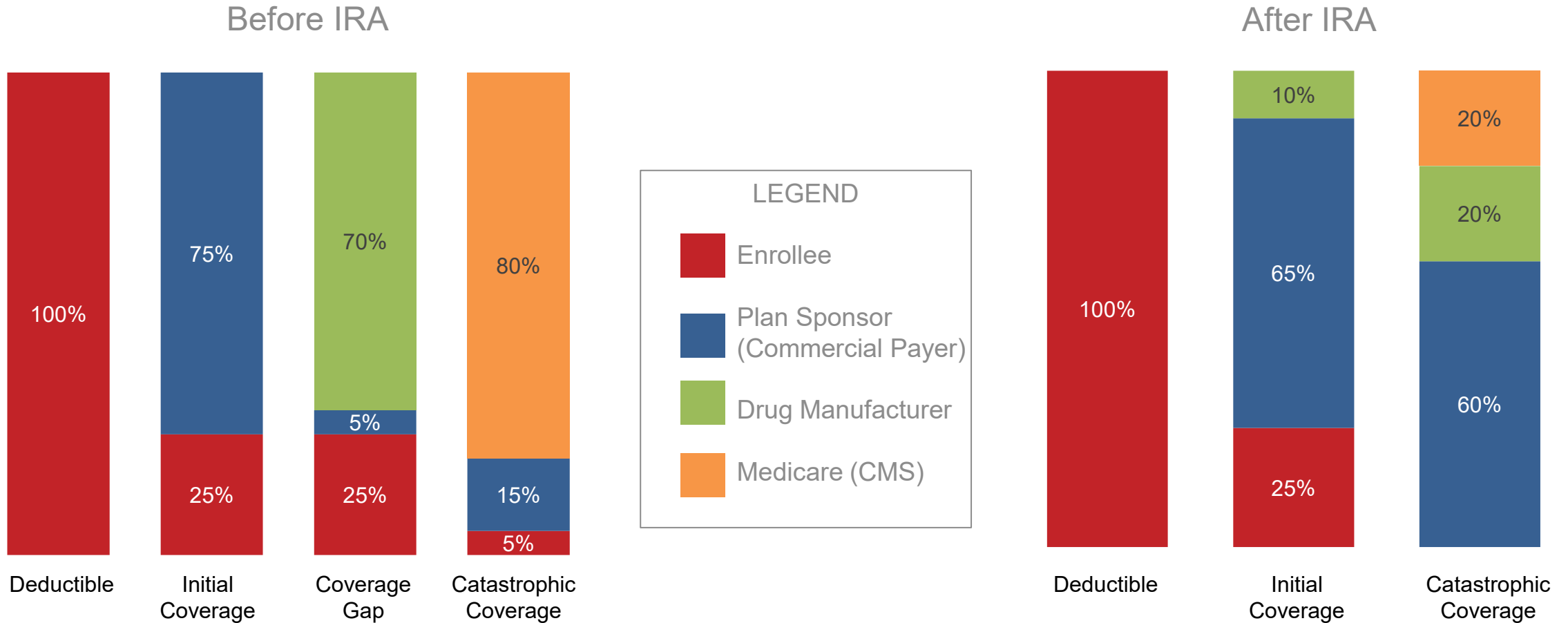


There are 4 Medicare Part D coverage phases before the IRA implementation; enrollees, plan sponsors, drug manufacturers and Medicare are responsible for a certain percentage of the drug cost depending on which phase they are in





IRA expanded manufacturers' discount requirements through replacing a limited cost-sharing in coverage gap phase with a no-limit share in catastrophic coverage phase, in addition to expanding discounts to LIS* beneficiaries



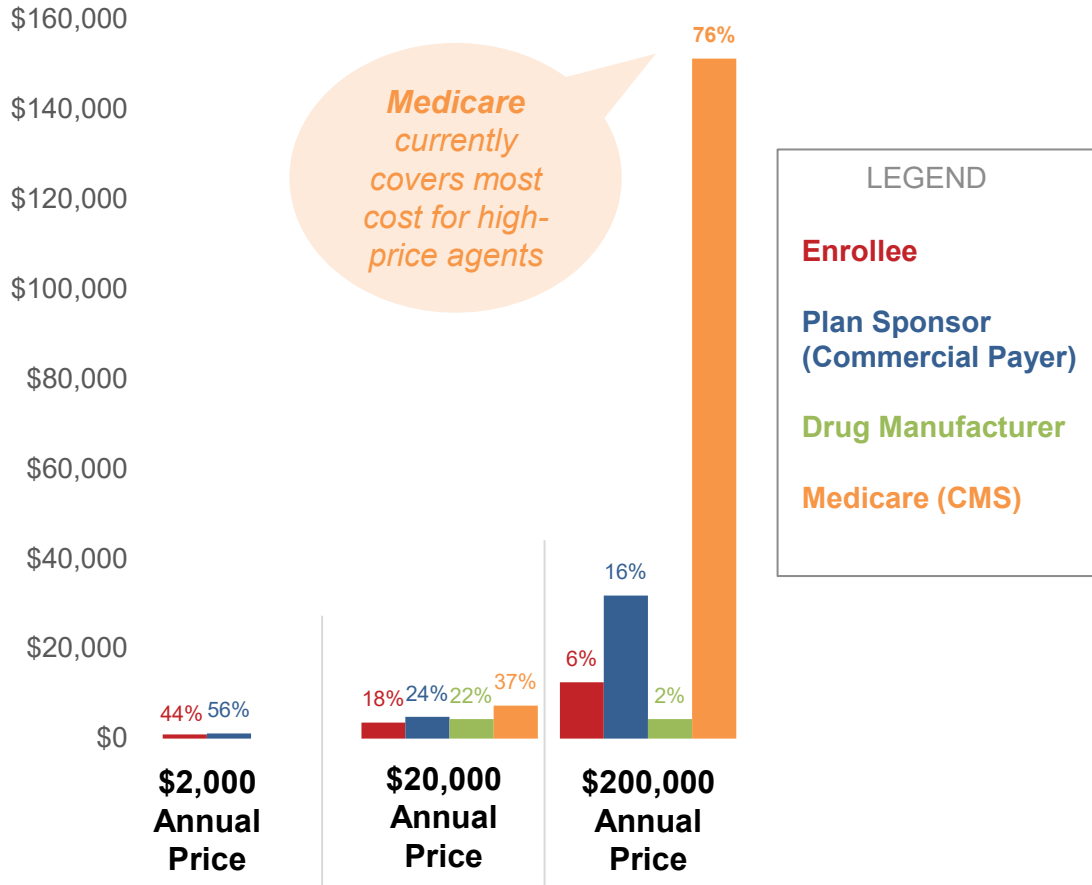
Source: CMS.gov, groupH research and analysis
 * LIS: Low-income subsidies beneficiaries



IRA implementation will dramatically incentivize enrollees to use expansive drugs with minimal costs and negligible burden to CMS, despite at the tremendous expense of manufacturers and plan sponsors

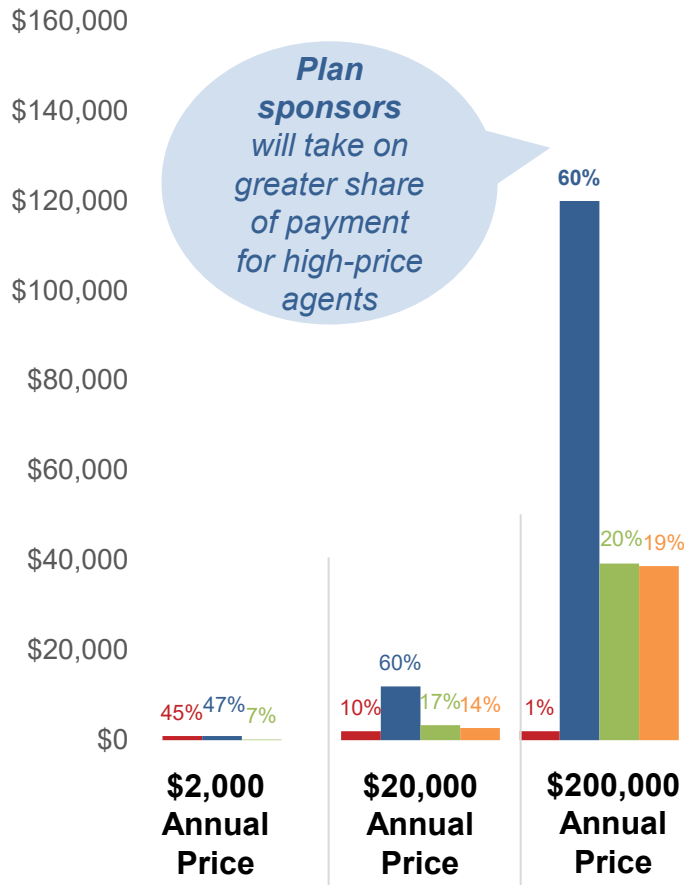
Pre-IRA* Drug Coverage Duties

US; By Payer Type



Post-IRA** Drug Coverage Duties

US; By Payer Type



Commentary

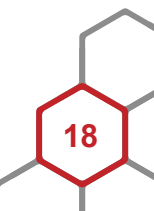
- The increase of plan sponsor's share will likely push it to take appropriate measures to reduce utilization of expensive drugs:
 - Remove certain expensive drugs (drugs with therapeutic alternatives and are not within the 6 Part D protected classes) from formulary
 - Create more restrictive prescription prioritization criteria and step-through requirements to limit use of brand-name drugs
- All Part D plans are required to add drugs that have Medicare negotiated prices to the formulary, this will likely create pricing pressure on other drugs with similar indication or push them off the formulary

Source: CMS.gov, groupH research and analysis

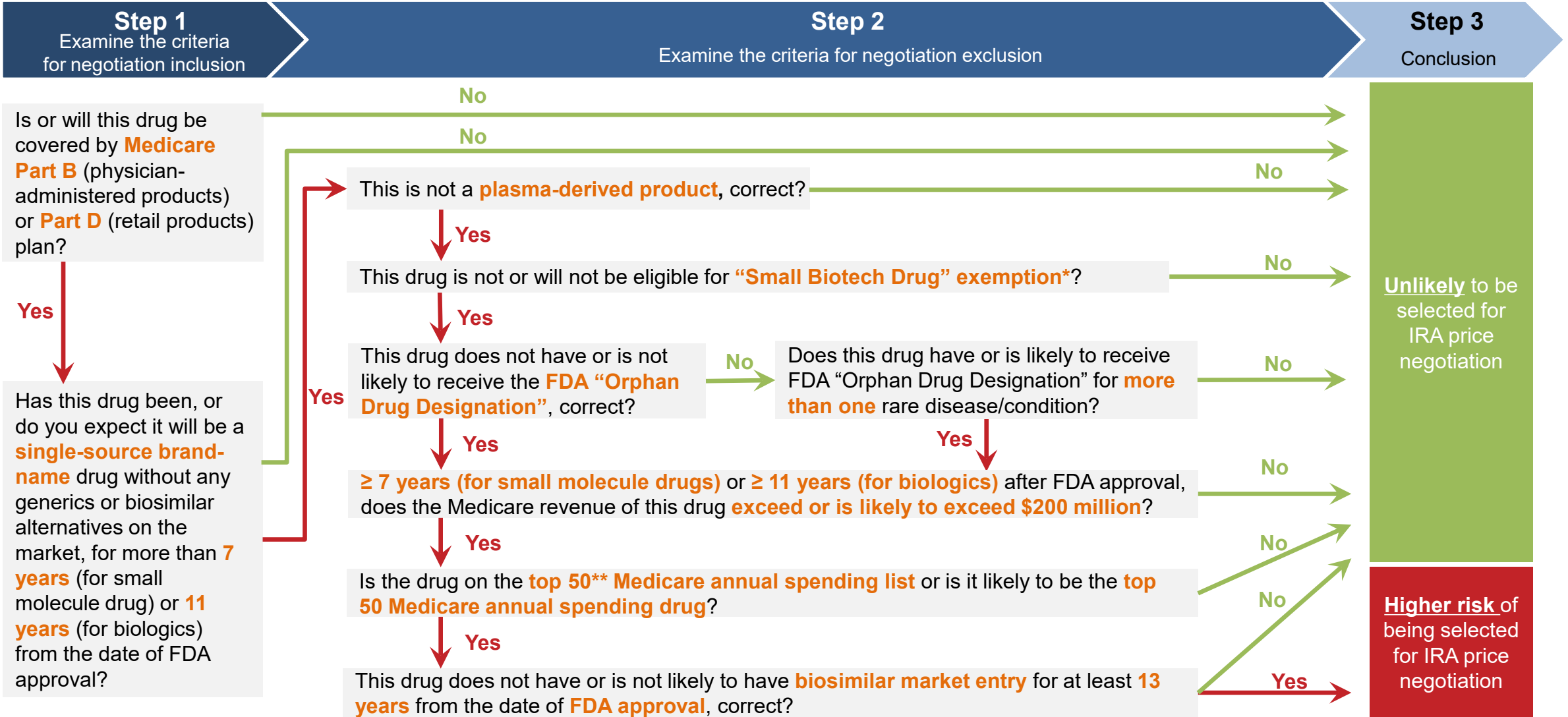
* Calculations based on 2023 thresholds ** In 2025 (the first year after IRA implementation), the thresholds toward "Initial Coverage" and "Catastrophic Coverage" are \$540 and \$6,380 respectively



Decision Tree



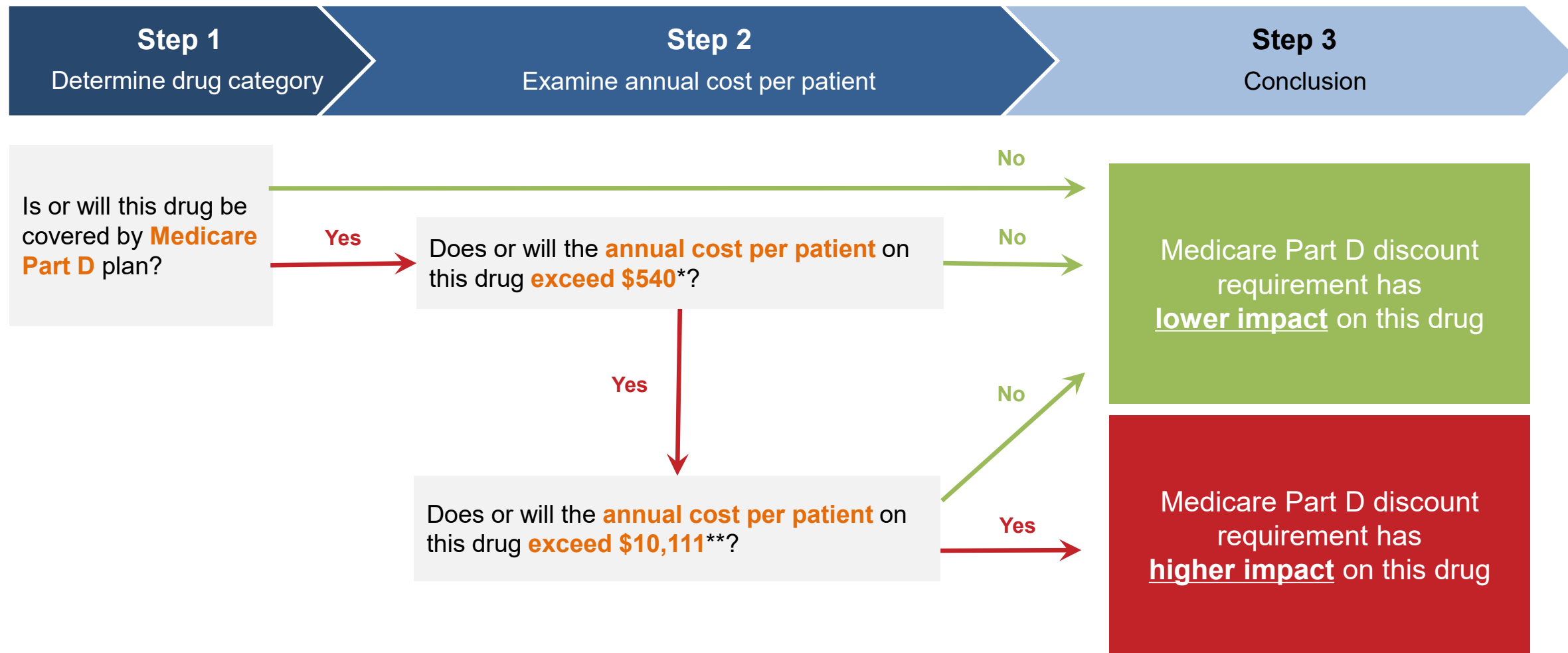
Whether a drug is likely to be selected for IRA price negotiation?



Source: CMS.gov, groupH research and analysis

* Only for the first 3 years’ negotiation (2026-2028) ** latest data: 2021 top 50 Medicare spending is ≥ 788.5 million for Part D and ≥ 197.5 million for Part B

Risk assessment for Medicare Part D discount requirement

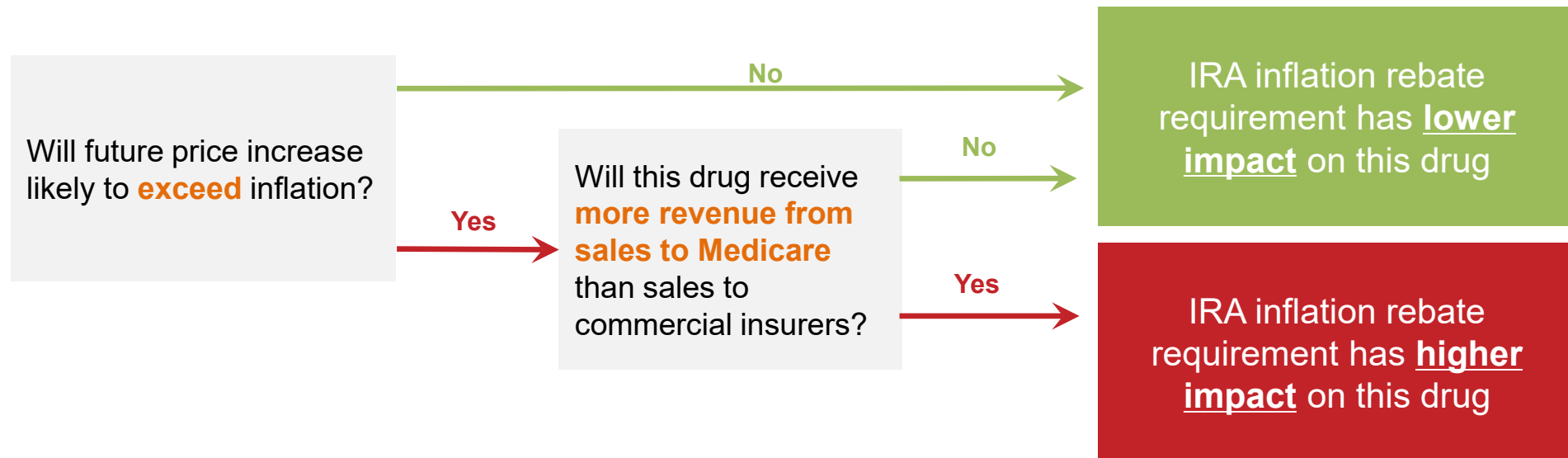
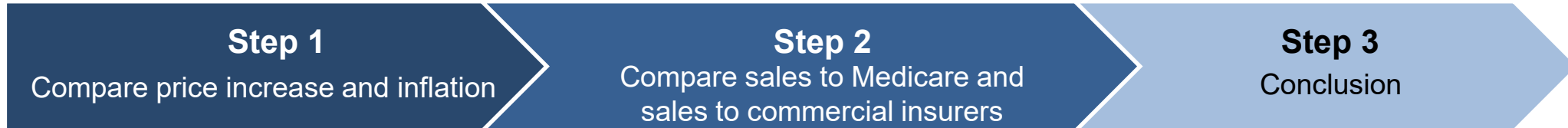


Source: CMS.gov, groupH research and analysis

** \$540 is the threshold where a Part D drug is required to provide discount

** \$10,111 is the cutting point where manufacturers are required to provide more discount than the maximum discount prior to IRA implementation

Risk assessment for inflation rebate requirement



Emily Donnell

emily.donnell@groupH.com

Zach Donnell, PhD

zach.donnell@groupH.com

m +1 415-619-4750



LONDON

SAN FRANCISCO