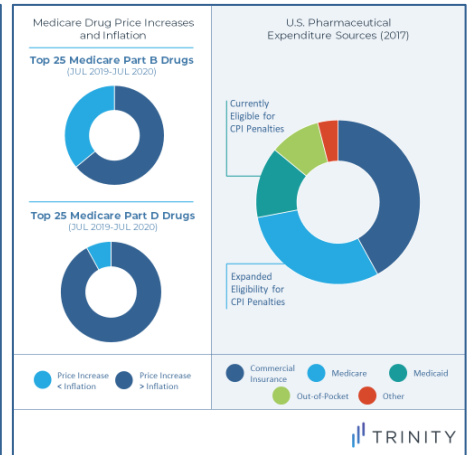
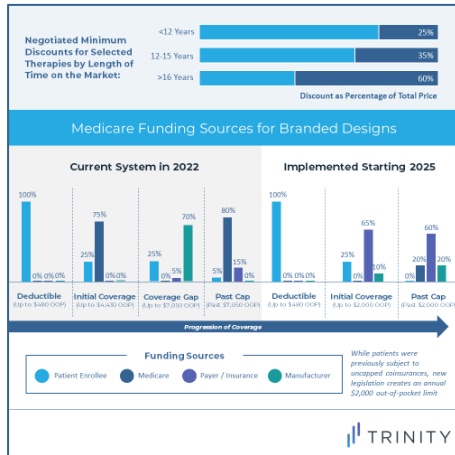
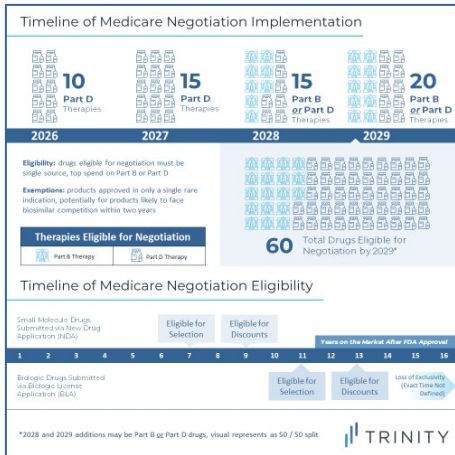




Inflation Reduction Act of 2022: No Room for Negotiation

INFOGRAPHIC



Timeline of Medicare Negotiation Implementation



10
Part D
Therapies



15
Part D
Therapies



15
Part B
or Part D
Therapies



20
Part B
or Part D
Therapies

2026

2027

2028

2029

Eligibility: drugs eligible for negotiation must be single source, top spend on Part B or Part D

Exemptions: products approved in only a single rare indication, potentially for products likely to face biosimilar competition within two years



60 Total Drugs Eligible for Negotiation by 2029*

Therapies Eligible for Negotiation



Part B Therapy



Part D Therapy

Timeline of Medicare Negotiation Eligibility

Small Molecule Drugs Submitted via New Drug Application (NDA)

Eligible for Selection

Eligible for Discounts

Years on the Market After FDA Approval

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16

Biologic Drugs Submitted via Biologic License Application (BLA)

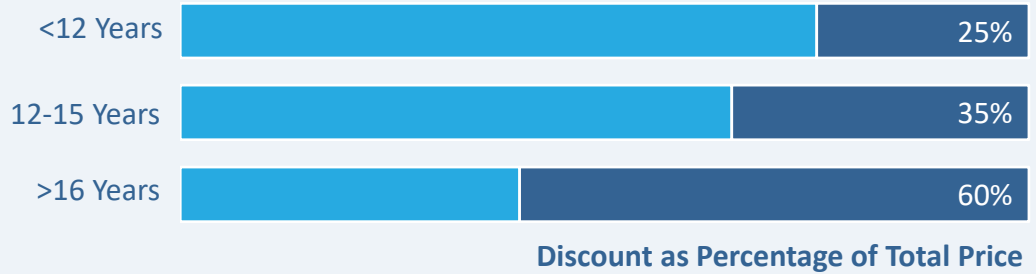
Eligible for Selection

Eligible for Discounts

Loss of Exclusivity (Exact Time Not Defined)

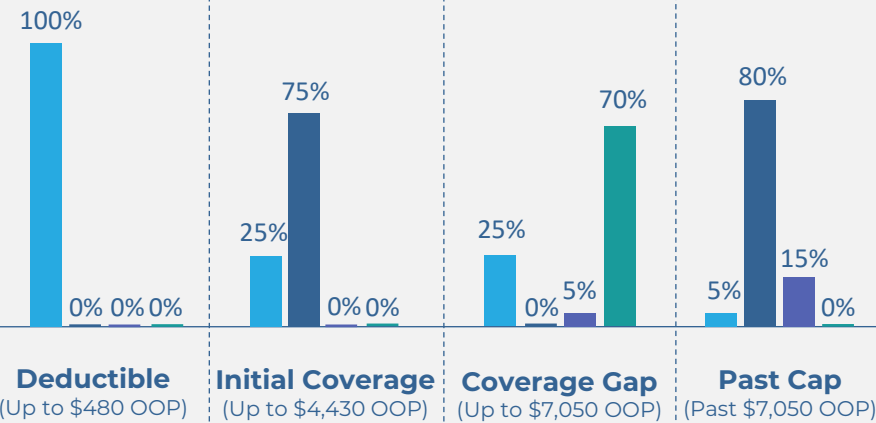
*2028 and 2029 additions may be Part B or Part D drugs, visual represents as 50 / 50 split

Negotiated Minimum Discounts for Selected Therapies by Length of Time on the Market:

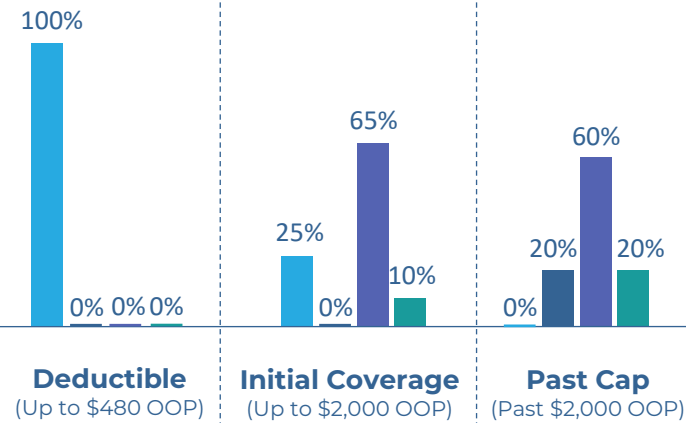


Medicare Funding Sources for Branded Designs

Current System in 2022



Implemented Starting 2025



Progression of Coverage

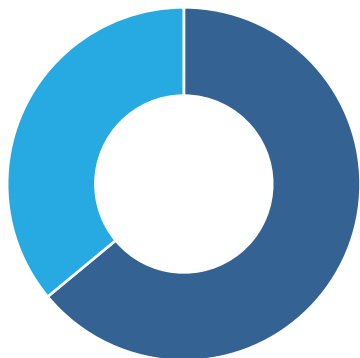
Funding Sources



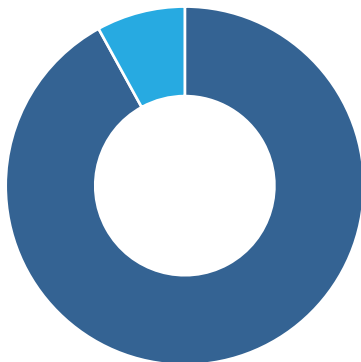
While patients were previously subject to uncapped coinsurances, new legislation creates an annual \$2,000 out-of-pocket limit

Medicare Drug Price Increases and Inflation

Top 25 Medicare Part B Drugs (JUL 2019-JUL 2020)

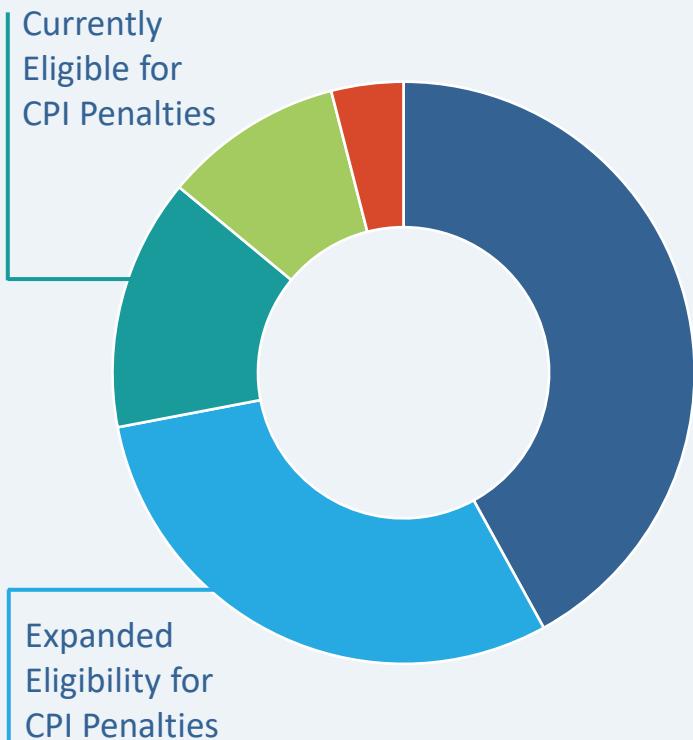


Top 25 Medicare Part D Drugs (JUL 2019-JUL 2020)



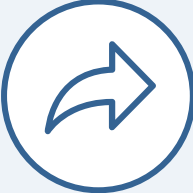


● Price Increase < Inflation ● Price Increase > Inflation

U.S. Pharmaceutical Expenditure Sources (2017)



● Commercial Insurance ● Medicare ● Medicaid
● Out-of-Pocket ● Other

Medicaid CPI Penalties vs. New Medicare Rebates

	Medicaid CPI (est. 1990)	New Medicare Rebate (est. 2022)
 Rebate Recipient	State and federal government share	Federal government only (Medicare Insurance Trust Fund)
 Participation Incentives	Medicaid covers almost all FDA approved drugs from manufacturer; drugs eligible for federal matching funds	Penalty of 125% of amount owed
 Rebate Conditions*	Greater of: [23.1% of <i>Average Manufacturer Price</i> <u>or</u> (<i>AMP – Best Price</i>)] + Inflationary Component	Units of therapy sold to Medicare for previous year X rate by which therapy's price increase exceeded inflation**

*Rebate conditions of brand drugs that are not exclusively approved for pediatric conditions or certain clotting factors; **Simplified – full equations available in subsequent graphics

Medicare Part B Rebate Calculations Implemented Q3 2023*

Part B Rebate

of Medicare Part B units during rebate quarter**



Amount rebate quarter exceeds inflation-adjusted benchmark rate

Inflation-Adjusted Benchmark Rate

Part B payment rate Q3 2021



% by which CPI-U JAN 2021 is exceeded by CPI-U for first month of quarter that is two months before the rebate quarter

Medicare Part D Rebate Calculations Implemented OCT 01, 2023***

Part D Rebate

of Medicare Part D units during rebate year****



Amount by which volume-weighted average annualized average manufacturers price (AMP) for rebate year exceeds inflation-adjusted volume-weighted average annualized AMP for the benchmark year

Volume-Weighted Average Annualized AMP

Quarterly AMP for Unit of Drug*****



Ratio of number of AMP-reported units for the year

Inflation-Adjusted Volume-Weighted Average Annualized AMP for the Benchmark Year

Volume-Weighted Annualized AMP



100% + % by which the benchmark period CPI-U^ is exceeded by the CPI-U for the first month of the rebate year

*Drugs approved after DEC 01, 2020 will first owe rebate after Q1 2023 or the sixth calendar after the drug was first marketed; **Excludes 340B units; ***Benchmark changes for drugs approved after OCT 1, 2021; ****Excludes 340B units beginning in 2026; *****Add with rate from three other quarters to find annualized Benchmark; ^Benchmark as JAN 2021

About the Authors



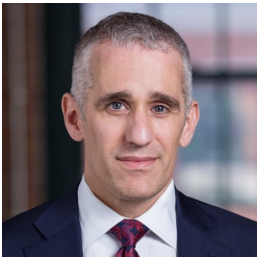
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