



Inflation Reduction Act

Looking Ahead to 2024

NOVEMBER 2023



EXECUTIVE SUMMARY

Signed into law in 2022, the Inflation Reduction Act is starting to impact pharmaceutical manufacturers now that HHS selected the first 10 drugs for price negotiation. Meanwhile, other key measures of the IRA will begin in 2024, including the AMP cap expiration. The purpose of this POV is to help market access teams prepare as the IRA more directly impacts the industry.

2024: 10 Drugs Up for Price Negotiation

The Bottom Line for Pharma: Expect the Unexpected

1

A few surprise products on the list: They address many common ailments among seniors, but there are a few surprise inclusions and exclusions, namely the inclusion of Stelara and Farxiga and the exclusion of Trulicity.

2

Hematology/Oncology emerged relatively unscathed, with only Imbruvica making the cut. This may be more reflective of Imbruvica's past than its future, as second-generation BTKi's have started to make inroads into Imbruvica's market share. Pricing changes driven by CMS' negotiations may not have class effects across BTKi's given meaningful clinical differentiation among the class.

3

Pending biosimilar entrance does not prevent selection: Stelara was a surprise inclusion on the list. Stelara was selected despite pending biosimilar entrance in 2024 and not being in Medicare Part D's top 20 high-spend drugs.

4

Many of the drugs are at the end of their lifecycle. The list accelerates the decrease in late-life contribution of agents that get on these lists.

5

Major savings are likely but are not certain, given the assumed significant rebates on some of these drugs.

2024: Inflation Reduction Act Timeline

JANUARY 1, 2024

Medicare Part D beneficiaries included in the catastrophic phase will not have to pay any coinsurance or co-payments.

Average premium increases across most Part D plans will be limited to 6% year over year through 2029.

Part D beneficiaries who earn less than 150% of the federal poverty level will be eligible for the low-income subsidy program.

FEBRUARY 1, 2024

CMS sends initial maximum fair price offers to each participating company. The negotiation period begins.

MARCH 2, 2024

Companies have 30 days to respond to the maximum fair price offer.

JULY 1, 2024

Part B payments will be capped for new biosimilars when the average sales price data is unavailable.

AUGUST 1, 2024

The negotiation period ends.

SEPTEMBER 1, 2024

CMS will publish maximum fair prices negotiated for the first 10 Medicare Part D drugs, and the prices will take effect in 2026.

IMPACT #1:

Price Negotiation Will Affect Drug Formularies and Decrease Net Cost to Plans

WHAT:

The IRA establishes an upper limit for the negotiated price, which CMS calls the “maximum fair price.”

- The new fair market value rates will take effect as follows: 10 drugs in 2026, 15 additional drugs in 2027, and 20 additional drugs in 2029.
- Drugs subject to negotiation include qualifying single-source drugs among the 50 highest in Part B or D total expenditures.
- Licensure timing requirements are applied; at least seven years must have elapsed for small molecule drugs or 11 years for biologics.

“I think it will lead to a unified formulary among sponsors for those 10 drugs and decrease rebate revenue for a sponsor, but potentially lower costs overall. CMS is likely going to get huge concessions from these 10 drugs.”



*Senior Pharmacy Director,
National Health Insurer*

VALUATE INSIGHT:



There is still a great deal of uncertainty over the IRA’s formula for determining which drugs will qualify for price negotiation. As subsequent deadlines draws closer, manufacturers need to align closely with their legal departments to better understand the qualifying requirements.

IMPACT #2:

The \$35 Insulin Cap Will Likely Increase Patient Adherence and Affect Patient Advocacy

WHAT:

Insulin cost sharing is coming for Part B and Part D recipients.

- For Part D, the user cost share for select insulin products will be no more than \$35 for a 30-day supply.
- For Part B, starting in July 2023, insulin furnished through Durable Medical Equipment is exempt from beneficiary deductibles and coinsurance will not exceed \$35.
- High Deductible Health Plans will no longer require a deductible for select insulin products.

“That’s the big one. We have a biosimilar now but even as a practicing physician, it was never clear to me how come nobody was able to regulate insulin payment.”



*Chief Medical Officer,
Regional Health Insurer*



VALUATE INSIGHT:

The \$35 cap on insulin aligns with the Biden administration’s goal to increase patient adherence.

IMPACT #3:

The \$2,000 Out-of-Pocket Cap Should Increase Patient Adherence but Not Significantly

WHAT:

Part D recipients will benefit from a \$2,000 annual cap on prescription drugs beginning in 2025.

- Prescription drug plan premium increases will be capped at 6% per year between 2024 and 2029.
- Part D beneficiaries will receive adult vaccines without a cost share beginning January 2023. Previously, only Part B vaccines were covered without a cost share to beneficiaries.

"I don't think the people who have a \$2,000 out-of-pocket expense are taking diabetes medicine reliably and would benefit. I was in rural practice, and I can tell you that there's a lot of people that don't have two nickels to put between their hands."



*Medical Director,
Regional Health Insurer*



VALUATE INSIGHT:

Capping Medicare patients' out-of-pocket expenses at \$2,000 could enhance patient adherence. However, some experts believe the cap is still too high and patients will likely still need the support of advocacy foundations.

IMPACT #4: Low Income Subsidies Will Expand

WHAT:

Low Income Subsidies (LIS) and Affordable Care Act federal health insurance subsidies will expand.

- Under Part D, the LIS qualifying income amount will increase from the current Federal Poverty Level of 135% to 150% in 2024 – an approximate monthly increase of \$229.
- Affordable Care Act federal health insurance subsidies are extended through 2025.
- Individuals at 150% of FPL will receive full subsidies with \$0 premium contribution. Premium tax credits are also expanded to individuals with incomes above 400% FPL.

“It may help members but I’m always skeptical [because they are] health exchange programs and I don’t think these programs necessarily are as comprehensive as patients think.”



*Chief Medical Officer,
Regional Health Insurer*



VALUATE INSIGHT:

Previously uninsured Americans may now qualify for LIS which will have an impact on many manufacturers’ support programs.

IMPACT #5:

Fiduciary Responsibility Will Shift to Manufacturers and Plans

WHAT:

The combination of patients shifting between segments, inflation rebates, and Medicare Part D redesign will shift costs from the federal government to payers and manufacturers.

- Part B and D rebates are established for drugs with price increases higher than the Consumer Price Index.
- For biosimilars, Medicare's ASP payment methodology is amended in cases where the ASP during the first quarter of sales is unavailable. After July 1, 2024, during the "initial period," the payment would be the lesser of the biosimilars WAC plus 3% or ASP plus 6% of the reference product.
- The ASP add-on Part B payment for certain biological products increased from 6% to 8% for five years, beginning October 1, 2022.

"It's going to put some financial burden on plans, particularly in the catastrophic [coverage] phase, which is going to cause us to rethink our benefit design and the rigor of our PA criteria for some specialty drugs and ... potentially delete some drugs from formulary. We'd respond with tighter management for drugs. That could typically push someone to catastrophic."



*Senior Pharmacy Director,
Regional Health Insurer*



VALUATE INSIGHT:

Manufacturers can expect shifts in patient segments and increased gross to net responsibility in 2024 and beyond driven by an increase in Medicaid as a percentage of patients, inflation penalties and Part D benefit re-designs.

IMPACT #6:

Anticipate Additional Benefits to Price Negotiation

WHAT:

Part D plans will need to adjust for drugs selected for future negotiation – but patients and manufacturers may benefit.

- The first round of 10 drugs selected for price negotiation yielded a few surprise selections.
- Pharmaceutical manufacturers now have some historical context from the first 10 selections on which to forecast future drugs up for price negotiation.
- As with any major federal legislation, the Inflation Reduction Act could have unintended consequences – both positive and negative – for patients and businesses.

“Part D plans will have to justify to CMS any placement of top 10 drugs on a non-preferred benefit level. This would encourage Part D plans to lower out-of-pocket costs for their members and reduce financial toxicity for those with prescriptions. Part D plans will also have to justify prior authorization and other utilization management processes for these top 10 drugs. One unintended positive consequence is that if you do participate in negotiations, you will likely face lower barriers to access for your drug.”

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*John Hennessy,
Senior Principal, Valuate*



VALUATE INSIGHT:

The IRA could have unintended positive consequences on affordability and access.

MANUFACTURERS' NEXT STEP

Estimate the Potential Impact of IRA

The IRA is complex and has a myriad of implications for GTN.

To help you estimate the impact of the IRA on your therapeutic area, consider working with Valuate Health.

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¹Patient Protection and Affordable Care Act § 2501(e), Pub. L. No. 111-148, 124 Stat. 119, 309 (2010).

³S. Amend. 891, 117th Cong. § 9816 (2021) (amending American Rescue Plan Act of 2021, HR 1319, 117th Cong. § 3106 (2021)). The Senate version of the bill — which later passed in the House and was signed by the President — amended the effective date of the rebate cap elimination in the original House passed bill from 2023 to 2024.

⁴83 Fed. Reg. 22,692, 22,698 (May 16, 2018).



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How can we help you optimize access?