A Tale of Two Drugs: How the Inflation Reduction Act of 2022 Impacts Drug Classes Differently

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Background and objective

The Inflation Reduction Act (**IRA**)[1] introduces several key healthcare reforms that will have several downstream impacts on the cost of healthcare for the U.S. population.
The overview of the reforms is described below.

Category	Inflation Reduction Act Reforms
Drug Price Negotiation	▸ Allows for Medicare to negotiate Part B / D drug prices for top Medicare expenditure drugs
Inflation Reduction	▸ Requires manufacturers to pay a rebate if Part B / D drug prices increase faster than the rate of inflation (CPI-U)* ▸ Limit on Medicare Part D premiums to no more than 6% growth per year
Limits on Patient OOP Spending	▸ Elimination of the 5% coinsurance for Part D catastrophic coverage ▸ Part D OOP spending capped at $2,000 ▸ Option for Part D enrollees to opt in for a 'maximum monthly cap' on OOP spend (equal to annual OOP minus costs already incurred divided across the remaining months of the year)
Rx Drug Discounting	▸ Elimination of the "Coverage Gap Discount Program" (e.g., 'donut hole') ▸ New "Part D Discount Program" allows for a 10% discount in the 'initial coverage' phase and 20% discount in the 'catastrophic coverage' phase (operationalized via manufacturer rebates)
Increased Access to Care	▸ Coinsurance for insulin capped at $35 for a one month's supply ▸ Extension of coverage requirement of all ACIP-recommended vaccines to Medicaid and CHIP, and removal of cost-sharing for ACIP-recommended vaccines under Medicare Part D / Medicaid / CHIP ▸ Eligibility for Part D low-income subsidies expands to 150% FPL up from 135% FPL
Other	▸ Temporary increase in Part B payment for biosimilars (ASP + 8% up from ASP + 6%) through 2027 ▸ Delay of the Drug Rebate Rule to 2032, which will restrict manufacturer rebates to PBMs/plans

Note: OOP = Out of Pocket; CPI-U = Consumer Price Index for all Urban Consumers; ACIP = Advisory Committee on Immunization Practices; FPL = Federal Poverty Line; Vx = Vaccine; *Excludes vaccines, drugs experiencing a shortage or supply chain issue, or a drug with average annual cost <$100; Source: 1. "How Will the Prescription Drug Provisions in the Inflation Reduction Act Affect Medicare Beneficiaries" (Aug 2022); Inflation Reduction Act of 2022 (H.R.5376 – 117th Congress); Putnam Analysis 2022

Because of its different provisions that will not apply uniformly to all classes of drugs, the **IRA** will impact drug classes differently in the coming years.

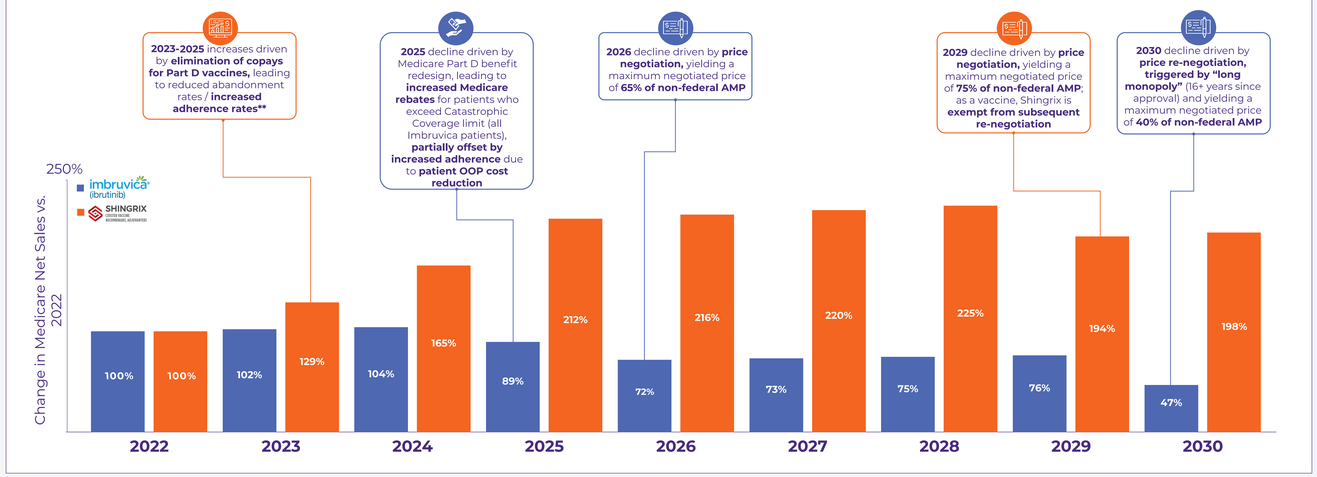
Methods

- To illustrate how the **IRA** may impact drug classes differently in the coming years, we selected:
- **Shingrix (Zoster Vaccine Recombinant, Adjuvanted)** for the prevention of shingles (herpes zoster)
- **Imbruvica (Ibrutinib),** a kinase inhibitor indicated for several blood cancers.
  We evaluated the impact of Medicare Part D benefit redesign, selection by HHS for Medicare price negotiation, increased Medicare rebates, and eligibility for or exemption from subsequent price re-negotiation triggered by "long monopoly" status (16+ years since approval) to estimate the impact on annualized **Medicare Net Sales** for each product through 2030 vs. a 2022 baseline.
- Leveraging **Putnam's proprietary Medicare Price Negotiation Database**, we expect:
- **Imbruvica** to be subject to price negotiation in the first Applicability Year (**2026**).
- **Shingrix** will be subject to price negotiation in its first year of eligibility based on approval data (**2029**).
  This database is supported by a comprehensive review of the most recent Medicare Part B and Part D Spending by Drug[2] that is available from CMS (2021), drug-specific sales projections from external analysts, product approval and expected loss of exclusivity (LOE) dates, and an analysis of eligibility for exclusion from Medicare price negotiation based on other conditions as outlined in the Inflation Reduction Act of 2022 (e.g., small biotech drugs, drugs approved for a single orphan disease, etc.).
  The analysis provides directional estimates only based on publicly available data.
- In estimating the **net sales impact caused by Medicare price negotiation**, our analysis assumes that:
- The **negotiated Maximum Fair Price** for **Shingrix** and **Imbruvica** yield a **price equal to the statutory maximum** based on the drug's time since approval.
- Non-Federal Average Manufacturer Price (**Non-FAMP**) is equal to **97%** of the drug's Wholesale Acquisition Cost (**WAC**).
- As such, our estimates may ultimately reflect **higher net prices** than are ultimately observed following negotiation.
- In estimating the **net sales impact caused by the redesign of the Part D benefit** and resulting manufacturer rebates for enrollees who reach the Catastrophic Coverage limit, our analysis assumes that:
- All patients who are prescribed **Imbruvica** reach the **Catastrophic Coverage limit** based on a current annualized **WAC** of **$207,051.**[3]
- With a much lower **WAC** of **$183 per dose** for **Shingrix** , the proportion of Medicare enrollees who have reached the **Catastrophic Coverage limit** when they receive **Shingrix** is **16%,** consistent with the most recent estimates for Part D enrollees generally.[4]
- **Imbruvica** and **Shingrix** both take **2% annual price increases** , which do not trigger inflation penalty rebates. We use the ceteris paribus assumption and exclude the impact of any market changes not driven by the **IRA** (e.g., disease epidemiology, product preference share, indication expansion, etc.).
- In response to the elimination of patient co-pays for Medicare Part D vaccines, we assumed that **Shingrix adherence rates rise** from their historical baseline of **34.5%** to **69.0%,** using the 65+ pneumococcal vaccination rates as an analog since these Part B vaccines have historically observed higher adherence rates in the absence of any patient co-pay responsibility.[1,5]
- In response to the reduction in patient out-of-pocket costs associated with the Part D benefit redesign, was assume that **adherence rates for Imbruvica improve** by a more modest **5%** in 2025, which is sustained through the end of the analysis period in 2030.

Results

The figure below illustrates how the Inflation Reduction Act of 2022 impacts drug classes differently.

Medicare Net Sales Impact Driven by Inflation Reduction Act Provisions:
Imbruvica vs. Shingrix (2022-2030)*



*Directional estimate only based on publicly available data; Excludes impact of any market changes not driven by the IRA (e.g., disease epidemiology, product preference share, indication expansion, etc.); Assumes 2% price increases that do not trigger inflation penalties; **Assumes Shingrix adherence rates rise from 34.5% to 69.0% based on 65+ pneumococcal vaccination rates as an analog; Source: Inflation Reduction Act of 2022 (H.R.5376 – 117th Congress); Lu et al, Surveillance of Vaccination Coverage Among Adult Populations (2018); Putnam Medicare Price Negotiation Database 2022; Putnam Analysis 2022

1. First, starting from **2023** the **elimination of co-pays for Part D vaccines** is likely to lead to reduced abandonment rates and **increased adherence rates**[6] for **Shingrix**, resulting in a **consistent increase in net sales** over the 2022 baseline.
2. Starting in **2025**, the Medicare Part D benefit resign will affect **Imbruvica** net sales in 2 ways: (1) a decline in the effective net price per Medicare patient driven by increased rebate obligations for patients who exceed the Catastrophic Coverage limit (assumed to be all Imbruvica patients), which is partially offset by (2) **increased adherence (+5%)** due to patient **out-of-pocket cost reductions**.
3. In **2026**, the erosion of net sales will continue for **Imbruvica**, driven by **price negotiation**, yielding a maximum negotiated price of **65% of Non-FAMP**. This is partially offset by the **elimination of Catastrophic Coverage rebates**, which are not paid on drugs and biologics subject to a Maximum Fair Price.
4. For **Shingrix**, in **2029** net sales will erod as a result of **price negotiation**, yielding a maximum negotiated price of **75% of Non-FAMP**, which is also partially offset by the **elimination of Catastrophic Coverage rebates**; As a vaccine, **Shingrix** is **exempt from subsequent re-negotiation**.
5. Finally in **2030**, a further decline in net sales is expected for **Imbruvica**, driven by **price re-negotiation triggered by "long monopoly"** status (16+ years since approval) and yielding a maximum negotiated price of **40% of Non-FAMP.**

Our projection estimate that the **IRA** will lead to a **decline in Imbruvica net sales in 2030 to 47%** of the 2022 baseline and an **increase in Shingrix net sales in 2030 to 198%** of the 2022 baseline.

Conclusion

The analysis illustrates how the **IRA** will have disparate impact on drugs depending on various factors including drug class, current adherence rates, and net price per patient, leading to either increased or decreased Medicare net sales. This impact is not limited to currently marketed drugs but will extend to new molecular entities, which is likely to impact novel drug development with investment possibly shifting away from development of the most at-risk drug classes (e.g., multi-indication small molecule oncology drugs) in favour of classes with additional protections (e.g., vaccines, biologics, and drugs pursuing indications in only 1 orphan disease).

References:
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