Brand-name Drug Pricing in the US: The Medicare Negotiation Era

March 5, 2024

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Financial Disclosures

- Scientific advisory board / consulting for Pfizer/BMS on apixaban (not current)
- Funding from West Health Policy Center & The Commonwealth Fund
• How does Medicare pay for drugs dispensed by pharmacies?

• The Inflation Reduction Act of 2022
  – Medicare price negotiation
  – Inflation rebates
  – Out-of-pocket limit
How does Medicare pay for brand-named drugs dispensed by pharmacies?

Medicare Part D is a public program, but it is administered by private plans.

Reimbursement of provider-administered products follows a different model.

Flow of product: Manufacturer → Wholesaler → Pharmacy → Patient

Flow of funds: Private Insurer → Pharmacy Benefits Manager → Federal Government
Rising disconnect between list prices and net prices due to increasing rebates

Dickson S, (...) Hernandez I et al. JAMA Health Forum 2023
Rising disconnect between list prices and net prices due to increasing rebates

**Original Humira**

<table>
<thead>
<tr>
<th>Year</th>
<th>List Price</th>
<th>PBM Rebate</th>
<th>Net Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>$22,400</td>
<td>$97.6%</td>
<td>$3000</td>
</tr>
<tr>
<td>2014</td>
<td>$24,800</td>
<td>$95.4%</td>
<td>$2800</td>
</tr>
<tr>
<td>2015</td>
<td>$26,900</td>
<td>$91.2%</td>
<td>$2630</td>
</tr>
<tr>
<td>2016</td>
<td>$29,100</td>
<td>$83.0%</td>
<td>$2470</td>
</tr>
<tr>
<td>2017</td>
<td>$31,200</td>
<td>$79.4%</td>
<td>$2330</td>
</tr>
<tr>
<td>2018</td>
<td>$33,300</td>
<td>$77.6%</td>
<td>$2200</td>
</tr>
<tr>
<td>2019</td>
<td>$35,400</td>
<td>$69.6%</td>
<td>$2050</td>
</tr>
<tr>
<td>2020</td>
<td>$37,500</td>
<td>$65.1%</td>
<td>$1925</td>
</tr>
</tbody>
</table>
Drug pricing approach in Medicare before IRA

• Manufacturers freely set up list prices

• Part D plans negotiate discounts in exchange for formulary space

• Large variability in discounts across therapeutic classes based on:
  – Competition
  – Whether a drug belongs to a protected drug class
Inflation Reduction Act

- Drug negotiation
- Out-of-pocket cap
- Inflation discounts
• Medicare will negotiate prices of highest gross-spending drugs
  – 10 pharmacy-dispensed drugs in 2026 (selected in 2023)
  – 15 pharmacy-dispensed drugs in 2027
  – 15 pharmacy-dispensed or provider-administered drugs in 2028
  – 20 pharmacy-dispensed or provider-administered drugs per year after 2029

• **Medicare** (and not the plans) will negotiate
  – Negotiated price “maximum fair price” will apply to all Medicare plans
Drug negotiation under the Inflation Reduction Act

• Selection based on
  – Gross Medicare spending
  – Time on the market
    • Small Molecule Drugs - 9 years from FDA approval
    • Biologics - 13 years from FDA approval

• Drugs are ineligible for negotiation if
  – They have a generic / biosimilar marketed
  – They only have orphan indications
  – They account for 80% of company’s revenue
  – They are plasma-derived
Drug negotiation under the Inflation Reduction Act

- **February 1**: CMS sends initial offer of a maximum fair price
- **March 2**: Manufacturer has 30 days from when it receives offer to propose a counteroffer, if desired
- **March 1**: Publish maximum fair price public explanation
- **November**: Publish List of 10 Part D selected drugs for 2026
- **October**: Deadline for companies of drugs selected to sign agreements
- **Deadline for companies of drugs selected to submit data to CMS**
- **February 1**: CMS sends initial offer of a maximum fair price
- **March 1**: Publish maximum fair price public explanation
- **2023**
- **2024**
- **2025**
- **2026**
- **January 1, 2026**: Price applicability begins for selected drugs
## First 10 drugs selected for 2026

<table>
<thead>
<tr>
<th>Rank</th>
<th>Brand</th>
<th>Company</th>
<th>Therapeutic Area</th>
<th>Gross Spending</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Eliquis</td>
<td>BMS</td>
<td>Cardiovascular</td>
<td>$16.5B</td>
</tr>
<tr>
<td>2</td>
<td>Jardiance</td>
<td>BI</td>
<td>Cardiovascular, Diabetes</td>
<td>$7B</td>
</tr>
<tr>
<td>3</td>
<td>Xarelto¹</td>
<td>J&amp;J</td>
<td>Cardiovascular</td>
<td>$6B</td>
</tr>
<tr>
<td>4</td>
<td>Januvia</td>
<td>Merck &amp; Co.</td>
<td>Diabetes</td>
<td>$4.1B</td>
</tr>
<tr>
<td>5</td>
<td>Farxiga</td>
<td>AstraZeneca</td>
<td>Diabetes, Cardiovascular</td>
<td>$3.3B</td>
</tr>
<tr>
<td>6</td>
<td>Entresto</td>
<td>Novartis</td>
<td>Cardiovascular</td>
<td>$2.8B</td>
</tr>
<tr>
<td>7</td>
<td>Enbrel</td>
<td>Amgen</td>
<td>Immunomodulators</td>
<td>$2.8B</td>
</tr>
<tr>
<td>8</td>
<td>Imbruvica</td>
<td>Abbvie</td>
<td>Oncology</td>
<td>$2.6B</td>
</tr>
<tr>
<td>9</td>
<td>Stelara¹</td>
<td>J&amp;J</td>
<td>Immunomodulators</td>
<td>$2.6B</td>
</tr>
<tr>
<td>10</td>
<td>Novolog, Fiasp</td>
<td>Novo Nordisk</td>
<td>Diabetes</td>
<td>$2.6B</td>
</tr>
</tbody>
</table>
Drug negotiation under the Inflation Reduction Act

• The statute sets a cap for the negotiated price, which is the lower of:
  – Average net price paid by Part D plans in 2022 (after discounts)
  – Minimum discount based on time since approval, until 2030:
    » 25% for 9-16 years
    » 60% for 16+ years
The statute sets a cap for the negotiated price, which is the lower of:

- Average net price paid by Part D plans in 2022 (after discounts)
- Minimum discount based on time since approval, until 2030:
  - 25% for 9-16 years
  - 60% for 16+ years
- Current market-based approach to price negotiation:
  - Will continue to apply on the earlier years after market entry
  - Will set the reference for price negotiation once a drug is eligible for negotiation
Drug negotiation under the Inflation Reduction Act

- Simplified overview of process to determine initial price offer

- Qualitative integration of clinical benefit and pricing data
  - No implicit threshold of willingness to pay
  - No QALY-based data

- Other factors will be used to adjust price offer: unmet need, population-specific data, R&D costs, production and distribution costs, % of R&D subsidized by federal funds
Sources of uncertainty

- What is considered a therapeutic alternative?
- How is the price – clinical benefit trade-off quantified?
Inflation Reduction Act

- Drug negotiation
- Out-of-pocket cap
- Inflation discounts
Out-of-pocket expenses towards pharmacy-dispensed drugs capped at $2,000 / year

- Will benefit 15% of beneficiaries (3.1-3.5 million)
- Average savings of $1,529/beneficiary

No limit for provider administered drugs
Inflation Reduction Act

Drug negotiation

Out-of-pocket cap

Inflation discounts
Inflation discounts

- Drugs with prices that increase faster than inflation will be subject to rebates for the amount that exceeds inflation
- Price protection against post-launch increases
- Concerns regarding incentives for higher launch prices

Illustration of Price Increase Penalty

Drug Price with 5% Annual Increase
CPI-U with 3% Annual Inflation*

<table>
<thead>
<tr>
<th>Year</th>
<th>Drug Price</th>
<th>CPI-U</th>
</tr>
</thead>
<tbody>
<tr>
<td>2021</td>
<td>$100</td>
<td>$100</td>
</tr>
<tr>
<td>2022</td>
<td>$105</td>
<td>$113</td>
</tr>
<tr>
<td>2023</td>
<td>$110</td>
<td>$122</td>
</tr>
<tr>
<td>2024</td>
<td>$115</td>
<td></td>
</tr>
<tr>
<td>2025</td>
<td>$120</td>
<td></td>
</tr>
</tbody>
</table>

%△ CPI-U = 13% (1.00 to 1.13)
%△ P = 22% ($100 to $122)
rebate = $122 - $113 = $9

Inflation index is consumer price index January 2021

ASP = average sales price; AMP = average manufacturer’s price; CPI-U = consumer price index for all urban consumers; FFS = fee for service; MA = Medicare Advantage

*Note: Inflation-adjusted payment is never allowed to drop below original nominal benchmark payment amount
• The Inflation Reduction Act of 2022 is the most significant pharmaceutical policy reform in the US since Medicare Part D was enacted

• Medicare price negotiation may be the most known provision, but not the only one
  – Inflation discounts provide protection from post-launch increases and apply to all drugs
  – Out-of-pocket maximum will limit patient liability for pharmacy-dispensed drugs

• Private insurer negotiation for rebates will remain the main approach
  – Before drugs become eligible for negotiation
  – For drugs ineligible for negotiation
Thank you!

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