Options to increase the affordability of specialty drugs and biologics in Medicare Part D

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Outline of this presentation

- Specialty-tier drug spending in Part D
- Cost sharing for specialty-tier drugs
- Two potential policy directions
  - A limit on cost sharing for each specialty-tier prescription
  - Replace the coverage-gap discount with a cap discount and restructure the catastrophic benefit
- Next steps
Specialty-tier drugs made up about one quarter of gross Part D spending in 2017

Part D gross spending before rebates

<table>
<thead>
<tr>
<th>Year</th>
<th>Specialty-tier spending, in billions</th>
<th>Specialty-tier spending as a % of total Part D spending</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>$0.0</td>
<td></td>
</tr>
<tr>
<td>2008</td>
<td>$0.0</td>
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<td>2009</td>
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<td>2010</td>
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<td>2011</td>
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<td>2012</td>
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<td>2014</td>
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<td>2015</td>
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<tr>
<td>2016</td>
<td>$0.0</td>
<td></td>
</tr>
<tr>
<td>2017</td>
<td>$0.0</td>
<td></td>
</tr>
</tbody>
</table>

Top 10 specialty-tier drugs ranked by spending

<table>
<thead>
<tr>
<th>Drug</th>
<th>Total gross spending in billions</th>
<th>Average spending per claim</th>
<th>Part D enrollees with claims</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revlimid</td>
<td>$3.3</td>
<td>$12,756</td>
<td>37,459</td>
</tr>
<tr>
<td>Harvoni</td>
<td>2.6</td>
<td>31,208</td>
<td>32,397</td>
</tr>
<tr>
<td>Humira pen</td>
<td>2.0</td>
<td>5,436</td>
<td>51,835</td>
</tr>
<tr>
<td>Copaxone</td>
<td>1.5</td>
<td>6,464</td>
<td>26,171</td>
</tr>
<tr>
<td>Sensipar</td>
<td>1.4</td>
<td>1,458</td>
<td>154,448</td>
</tr>
<tr>
<td>Ibrance</td>
<td>1.4</td>
<td>11,141</td>
<td>20,441</td>
</tr>
<tr>
<td>Imbruvica</td>
<td>1.4</td>
<td>10,432</td>
<td>18,744</td>
</tr>
<tr>
<td>Enbrel Sureclick</td>
<td>1.2</td>
<td>5,153</td>
<td>32,005</td>
</tr>
<tr>
<td>Tecfidera</td>
<td>1.0</td>
<td>7,990</td>
<td>17,055</td>
</tr>
<tr>
<td>Epclusa</td>
<td>0.9</td>
<td>25,011</td>
<td>14,073</td>
</tr>
</tbody>
</table>

Note: Data are preliminary and subject to change. Gross spending does not reflect postsale rebates and discounts. Source: MedPAC based on data from Acumen LLC and CMS’s 2017 Part D drug data dashboard.
Part D cost sharing for specialty-tier drugs

- Front loaded in the year (25% to 33% coinsurance)
- Open-ended 5% coinsurance in catastrophic phase
- Beneficiary pays coinsurance on undiscounted price
- Some evidence of association between higher cost sharing and abandoning prescriptions

Note: Non-LIS (enrollee who does not receive Part D’s low-income subsidy). TNF (tumor necrosis factor).
Data are preliminary and subject to change.
Source: MedPAC based on Medicare Plan Finder.
Goals for addressing specialty-tier drug benefits

- Coverage that reduces barriers to appropriate use
- Incentive for plans to manage benefit spending
- Tension on manufacturer pricing decisions
- Downward pressure on premiums and Medicare program spending
Option 1: Apply an out-of-pocket (OOP) limit to each specialty-tier prescription

- Policymakers would set a maximum amount, e.g., the lesser of 33% coinsurance or $200 per 30-day supply.
- In 2017, a $200/prescription cap only for non-LIS enrollees:
  - Would have lowered specialty-tier cost sharing by about two-thirds for over 400,000 non-LIS enrollees.
  - Could be financed through higher premiums or actuarially equivalent higher cost sharing for all Part D enrollees.
  - Full estimate of effects on premiums and program spending would take into account behavioral effects, growth in spending for specialty drugs, possible application of the policy to LIS enrollees.

Note: Non-LIS (enrollee who does not receive Part D’s low-income subsidy).
Tradeoffs in using a per-prescription OOP cap

- More generous benefit to users of specialty-tier drugs
  - Better insurance protection when lower-cost alternatives are not as effective
  - Would even out cost sharing during benefit year
  - May lead to fewer abandoned prescriptions

- Disadvantages
  - May increase use of both appropriate and inappropriate drugs
  - May make it more difficult for plan sponsors to manage spending
  - All enrollees would pay higher premiums or cost sharing
  - Higher Part D program spending
  - Manufacturers may increase prices further or launch even higher...
Part D’s current design may contribute to growth in drug prices

- High rebates in some drug classes generally used by plan sponsors to keep premiums competitive
- LIS and non-LIS enrollees have different benefit structures
  - LIS coverage gap paid primarily by Medicare subsidies
  - Brand manufacturer discount in non-LIS coverage gap
- Plans have low liability for enrollees’ spending in large portions of the benefit (e.g., Medicare reinsurance in catastrophic phase)
- Misaligned incentives may affect
  - Plan formulary decisions
  - Manufacturer pricing decisions
Most coverage-gap discounts apply to non-specialty tier drugs, 2017

- In 2017, coverage-gap discounts totaled about $5.8 billion
- Concentrated among three “non-specialty tier” classes
  - Diabetes drugs
  - Asthma/COPD
  - Anticoagulants
- Average price per claim ranged from about $480 to $580
- Drug classes typically placed on specialty tiers (e.g., antivirals, cancer drugs, therapies for inflammatory conditions) each accounted for 3% or less

Notes: COPD (chronic obstructive pulmonary disease). Therapeutic classification is based on the First DataBank Enhanced Therapeutic Classification System 1.0. Results are preliminary and subject to change. Source: CMS dashboard data and MedPAC analysis of Medicare Part D prescription drug event data from CMS.
Option 2: Restructure Part D’s benefit to provide better formulary and pricing incentives

- Replace the coverage-gap discount with a manufacturer “cap discount” and restructure the catastrophic benefit*
  - Provide stronger incentives to use generics
  - Increase affordability for enrollees and Medicare (taxpayers)
  - Provide stronger incentives for plans to manage spending
  - May provide disincentive for manufacturers to set high launch prices and/or increase prices rapidly
- Standard (non-LIS) benefit applies to LIS enrollees for simplicity and better plan formulary incentives
- Risk corridors would remain (protect plans from large losses)

Notes: LIS (low-income subsidy). *Many of the changes to the catastrophic benefit, including the new “cap discount,” are similar to the proposal by the American Action Forum to redesign Medicare Part D (https://www.americanactionforum.org/research/redesigning-medicare-part-d-realign-incentives-1/).
Benefit parameters for the new catastrophic benefit should aim to balance access and affordability vs. program costs:

- Enrollee cost sharing
- Reinsurance
- Plan liability
- Manufacturer “cap discount” rate
Need balance of plan and manufacturer liability to keep pressure on drug prices

% of catastrophic benefit paid by plans and manufacturer, after any reinsurance and enrollee cost sharing

- Higher benefit costs/premiums (−)
- Stronger plan incentives to manage spending (+)
- Potential for higher rebates in competitive therapeutic classes (+)
- Limited ability to negotiate price concessions for some therapies (−)

- Lower benefit costs/premiums (+)
- Weaker plan incentives to manage spending (−)
- Guaranteed discounts on therapies with few/no competitors (+)
- May slow price growth, but effects likely vary by manufacturer/product (+) or (−)

Notes: The sum of the plan share and reinsurance, if any, would be the total catastrophic benefit costs that would be paid for by Medicare’s subsidies and enrollee premiums.
A “cap discount” would increase the discounts on specialty-tier drugs

- Discounts would apply to high-priced drugs typically placed on specialty tiers, less on diabetic therapy
- Prices range from thousands to >$30,000
- Four classes would account for over 50% vs. 12% under gap discount policy
  - Antineoplastics
  - Antivirals
  - Anti-inflammatory
  - Multiple sclerosis
- Not including LIS prescriptions would change the incidence of discounts across drug classes

Notes: CNS (central nervous system), LIS (low-income subsidy). Therapeutic classification is based on the First DataBank Enhanced Therapeutic Classification System 1.0. Results are preliminary and subject to change.
Source: CMS dashboard data and MedPAC analysis of Medicare Part D prescription drug event data from CMS.
Implications of the restructured Part D benefit for the OOP threshold

- Without manufacturer discounts counting towards the OOP threshold, some enrollees would have to pay more to reach the OOP threshold ($6,350 vs. about $2,750 in 2020)*
- Policymakers could lower the OOP threshold, but there are tradeoffs
  - **Advantages**: May lower costs for some/all enrollees and taxpayers
    - Reduce OOP costs for enrollees who reach the OOP threshold
    - Lower benefit and premium costs if benefit (reinsurance + plan liability) covers less than 75% above the OOP threshold
  - **Disadvantages**: Certain behavior could push up benefit and premium costs
    - Increased use of both appropriate and inappropriate therapies
    - May weaken plan incentives to manage high spending if plan liability above the OOP threshold is too low

Notes: *The expected OOP costs under current law depends on the mix of brand-name and generic drugs. Because manufacturer discounts do not apply to generic drugs, enrollees using only generic drugs would pay the same amount to reach the OOP threshold under the policy as under current law ($6,350 in 2020).
Goals for addressing specialty-tier drug benefits

- Coverage that reduces barriers to appropriate use
- Incentive for plans to manage benefit spending
- Tension on manufacturer pricing decisions
- Downward pressure on premiums and Medicare program spending

<table>
<thead>
<tr>
<th>Redesigned benefit with cap discount</th>
<th>Per-prescription OOP limit</th>
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Next steps

- Questions or comments?
- Material presented to be included in the June 2019 report
- Guidance about how to proceed in the next cycle?