Biosimilars in Medicare Part D

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Overview of this presentation

- Background on biologics and biosimilars
- Spending and use in Part D
- How Part D’s coverage-gap discount may slow takeup of biosimilars
- Chairman’s draft recommendation
- Next steps
What are biologics and biosimilars?

- **Biologics**: therapies derived from living cells or organisms and manufactured through biological processes
  - Treatments for diabetes, cancer, rheumatoid arthritis, multiple sclerosis
  - Injected or infused
  - Prices typically high

- **Biosimilars**: follow-on products that are highly similar to originator biologics
  - Like generic drugs, may introduce price competition
  - Unlike generic drugs
    - Not exact replicas of the originator products
    - But molecular structure of originators can also vary
How Medicare pays for biologics and biosimilars in Part D

- Costs of biologics are included in plans’ bids
  - Medicare pays plans
    - Capitated amount (direct subsidy)
    - 80% reinsurance above out-of-pocket (OOP) threshold
  - Plan sponsors negotiate
    - Pharmacy payment rates, discounts, and fees
    - Rebates from manufacturers
- Enrollees who use high-priced biologics tend to reach the OOP threshold
  - Beneficiary pays 5% cost sharing
  - Medicare bearing most of catastrophic costs
Spending for and use of biologics under Part D, 2011-2015

<table>
<thead>
<tr>
<th></th>
<th>2011</th>
<th>2015</th>
<th>Cumulative growth</th>
<th>Average annual rate</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gross spending (billions)</strong></td>
<td>$6.8</td>
<td>$18.7</td>
<td>$11.9</td>
<td>29%</td>
</tr>
<tr>
<td><strong>As % of all Part D</strong></td>
<td>8.0%</td>
<td>13.6%</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Number of prescriptions (millions)</strong></td>
<td>25.3</td>
<td>37.0</td>
<td>$11.7</td>
<td>10%</td>
</tr>
<tr>
<td><strong>As % of all Part D</strong></td>
<td>1.7%</td>
<td>1.7%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Over 80% of Part D biologics spending and nearly 90% of spending growth attributable to three treatment categories:
  - Insulin
  - inflammatory diseases (e.g., rheumatoid arthritis)
  - Multiple sclerosis
- Double-digit percentage increases in prices per prescription

Note: Data are preliminary and subject to change. Gross spending means claims amounts prior to post-sale rebates and discounts.
Source: MedPAC based on CMS prescription drug event data.
Will biosimilars be used by Part D enrollees?

- How Part D plans treat biosimilars on their formularies will affect takeup
- Plans generally encourage use of lower-priced products to keep premiums low
- **BUT** coverage-gap discount provides financial advantage to originator biologics over biosimilars
- Plans may want to include originators on their formularies
- Beneficiaries may have higher cost sharing with biosimilars
Coverage-gap discount currently favors originator biologics

**Originator biologic, 2020**

- Enrollee: 25%
- Manufacturer: 50%
- Plan: 25%
- Medicare: 80%
- Deductible

**Biosimilar, 2020**

- Enrollee: 25%
- Plan: 75%
- Medicare: 80%
- Catastrophic phase / out-of-pocket threshold

Counts as “true OOP”
Example of how current law coverage-gap discount distorts price signals

- **Originator biologic, gap discount** ($30,000 w/ 20% rebate)
- **Biosimilar, no gap discount** ($25,500, w/ 20% rebate)

**50% discount**

Plan liability lower with originator biologic

Lower price
Policy option improves price signals

- **Originator biologic, gap discount, excluded from OOP ($30,000 w/ 20% rebate)**
  - Beneficiary
  - Manufacturer discount
  - Plan liability
  - Medicare reinsurance
  - Lower price

- **Biosimilar, gap discount, excluded from OOP ($25,500 w/ 20% rebate)**
  - 50% discount
  - Plan liability lower with lower-priced biosimilar

Lower price
Applying coverage-gap discount to biosimilars would align incentives

<table>
<thead>
<tr>
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<th>Current law</th>
<th>Under policy option</th>
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<tbody>
<tr>
<td></td>
<td>Coverage-gap discount applies</td>
<td>Discount treated as enrollees’ OOP</td>
</tr>
<tr>
<td>Brand-name drugs</td>
<td>✓</td>
<td>yes</td>
</tr>
<tr>
<td>Originator biologics</td>
<td>✓</td>
<td>yes</td>
</tr>
<tr>
<td>Biosimilars</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Note: OOP (out of pocket), N/A (not applicable). The estimated share of gross spending is based on 2015 Part D prescription drug event data. Data are preliminary and subject to change.
The Commission’s June 2016 Part D recommendations

- Change Part D to:
  - Transition Medicare’s reinsurance from 80% to 20% of catastrophic spending and keep Medicare’s overall subsidy at 74.5% through higher capitated payments
  - Exclude manufacturers’ discounts in the coverage gap from enrollees’ “true OOP” spending
  - Eliminate cost sharing above the OOP threshold
- Make moderate changes to LIS cost sharing to encourage use of generics and biosimilars
- Greater flexibility to use formulary tools
Next steps

- Revisions based on commissioner comments
- Vote in January 2018
- Include in March 2018 Report to the Congress