Addressing high prices of drugs covered under Medicare Part B

Nancy Ray and Kim Neuman
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Today’s session

- Background on coverage and payment of Part B drugs
- Concerns about trends in drug pricing and spending
- Policy options to address:
  - High launch prices of new Part B drugs with uncertain clinical benefit
  - Lack of price competition among Part B drugs with therapeutic alternatives
  - Financial incentives associated with the percentage add-on to Medicare Part B’s drug payment rates
Part B covers a range of products

- Drugs infused or injected in physician offices or hospital outpatient departments
- From expensive biologics (e.g., eye injections) to inexpensive products (e.g., corticosteroid injections)
- Some other types of drugs:
  - inhalation drugs administered via nebulizer
  - certain oral-anticancer, antiemetic, and immunosuppressive drugs
  - small number of home infusion drugs
  - four preventive vaccines
Price has been the largest driver of Part B drug spending growth

<table>
<thead>
<tr>
<th><strong>Part B</strong></th>
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<tr>
<td><strong>Spending in 2020:</strong></td>
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<td><strong>Spending growth from 2009-2020:</strong></td>
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<tr>
<td><strong>Largest driver of the spending growth from 2009-2020:</strong></td>
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| **Spending is highly concentrated:** | • 20 products account for 52% of spending  
• Examples of indications of top products: cancer, macular degeneration, inflammatory conditions |

Notes: *Program spending and cost sharing. Data are preliminary and subject to change. MedPAC publications are the definitive reference source for all analyses and results.*
Most Part B drugs are paid at a rate of 106% of average sales price (ASP)

- ASP reflects the average price realized by the drug manufacturer for sales to most purchasers, net of most rebates, discounts, and price concessions
  - Manufacturers report ASP data to CMS quarterly
  - ASP+6% payment rate is based on ASP data from 2 quarters prior
- Biosimilars are paid at rate of 100% of own ASP plus 6% or 8% of originator product’s ASP
- Exceptions: new drugs before ASP data are available, preventive vaccines
- Medicare pays separately for drug administration services

Note: ASP (average sales price)
Medicare Part B has limited tools to influence drug prices

- FFS Medicare covers drug indications that the FDA approves*
- How products are assigned to billing codes affects price competition
  - Assigning drugs to the same billing code—brand and generic drugs—spurs price competition
  - Assigning drugs to their own billing code—single-source drugs, originator biologics, and biosimilars—does not spur competition
- Medicare cannot consider a drug’s clinical benefit compared to the standard of care

Note: ASP (average sales price). FDA (Food and Drug Administration).

* For a service to be covered, it must be in a Medicare benefit category, not excluded by the statute, and reasonable and necessary for the treatment of an illness or injury. Medicare is also required to cover off-label use of anti-cancer drugs if supported in the cancer compendia or peer-reviewed literature.
Concerns about high and growing drug prices

- Estimates suggest that U.S. drug prices are roughly double the prices in other countries*
- Higher prices in the U.S. reflect higher launch prices and more post-launch price growth
- Some products approved under the FDA’s accelerated approval pathway are launching at high prices with uncertain clinical benefit

* Comparator countries are members of the Organization for Economic Co-operation and Development (ASPE 2020).
Addressing high drug prices and price growth: Policy objectives for Medicare

- Improve payment for drugs with uncertain clinical benefit
- Spur price competition among drugs
- Improve financial incentives under the Part B drug payment system
- Maintain incentives for innovation
Options to improve Medicare’s payment for Part B drugs

- Part B drugs with uncertain clinical benefit: Set a cap on payment until post-marketing trial confirms drug’s clinical benefit
- Part B drugs with similar health effects that treat a given condition: Apply reference pricing
- Modify ASP add-on payment
Paying for Part B drugs with uncertain clinical benefit

- At time of approval, there is uncertainty about whether accelerated approval (AA) drugs impact clinical outcome
- Until confirmatory trial shows clinical benefit:
  - Set a cap based on:
    - AA drug’s estimated net clinical benefit and cost relative to standard of care
    - Some increment of the payment rate for the standard of care
    - 106 percent of the AA drug’s ASP for 3 years and thereafter, based on payment rate for standard of care
  - Establish rebates based on percentage of AA drug’s ASP
Paying for Part B drugs with limited clinical evidence (cont.)

- Transparent and predictable process with opportunities for public comment
- Process for identifying the standard of care
- Process for identifying sources of clinical evidence
Paying for Part B drugs with therapeutic alternatives: Reference pricing

- Insufficient price competition for single-source products with therapeutic alternatives, each paid according to their own ASP
- In 2017, the Commission recommended a type of reference pricing (consolidated billing code) for biosimilars and originator biologics
- Reference pricing could be considered for Part B products with similar health effects
  - Would result in savings for beneficiaries and taxpayers
Paying for Part B drugs with therapeutic alternatives: Reference pricing (cont.)

- Each product remains in its own billing code
- Set a payment rate for a group of drugs with similar health effects based on:
  - Lowest ASP of product in reference group (i.e., least costly alternative),
  - Volume-weighted ASPs of all products in reference group, or
  - Lower of the volume-weighted ASPs of all products in reference group or the ASP of the specific product furnished
Paying for Part B drugs with therapeutic alternatives: Reference pricing (cont.)

- Develop a transparent and predictable process with opportunities for public comment to:
  - Establish reference groups of therapeutically similar drugs
  - Consider medical exceptions process for higher-cost products
- Provide pricing information to beneficiaries and clinicians
- Address whether Medigap policies could cover beneficiary cost sharing that is greater than the reference price
Addressing financial incentives: ASP add-on

- Part B generally pays providers ASP + 6 percent for drugs
- While clinical factors play a central role in prescribing, concern exists that the 6 percent add-on may create financial incentives for use of higher-priced drugs when lower-priced products are available
- Several studies found growth in utilization of higher-priced products that may reflect the effect of the 6 percent add-on
- In the June report, we explored several approaches to modify the 6 percent add-on (e.g., a dollar cap, converting a portion of percent add-on to fixed fee, or a combination approach)
Policy option to restructure ASP add-on

- Policy option:
  Add-on = Lesser of 6%, 3%+ $21, $175 per drug per day

- This approach:
  - Converts a portion of percent add-on to fixed fee (3% + $21), and
  - Caps add-on for lower-priced drugs (6%) and high-priced drugs ($175)
  - Numbers are illustrative; others could be considered
Add-on amounts for differently priced drugs under current policy and policy option

<table>
<thead>
<tr>
<th>ASP per drug admin.</th>
<th>Current policy</th>
<th>Option</th>
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<tbody>
<tr>
<td></td>
<td>6%</td>
<td>Lesser of: (6%, 3% + $21, $175)</td>
</tr>
<tr>
<td>$5</td>
<td>$0.30</td>
<td>$0.30</td>
</tr>
<tr>
<td>100</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>700</td>
<td>42</td>
<td>42</td>
</tr>
<tr>
<td>1,000</td>
<td>60</td>
<td>51</td>
</tr>
<tr>
<td>3,000</td>
<td>180</td>
<td>111</td>
</tr>
<tr>
<td>5,000</td>
<td>300</td>
<td>171</td>
</tr>
<tr>
<td>15,000</td>
<td>900</td>
<td>175</td>
</tr>
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- Add-on reduced for drugs with ASP per administration > $700
- Reduces differences in add-on payments
  - For $1,000 vs $3,000 drug, add-on difference is $120 (current policy) and $60 (policy option)
  - Largest reduction for highest priced products (e.g., $5,000 vs. $15,000 drug)

Note: “ASP per drug admin.” refers to ASP per drug administered and is defined as a drug’s ASP unit price times the number of units of the drug administered to the patient on a particular day. For drugs furnished by suppliers (e.g., nebulizer drugs and certain oral drugs), it refers to ASP per prescription. ASP and add-on payments reflect payment amounts before the sequester. Data are preliminary and subject to change.
Simulation of policy options to modify ASP add-on

- Simulated first year effect on total Part B drug payments using 2019 data assuming no utilization changes
- If policy option shifted use toward lower-priced drugs, savings could be higher
- Simulation findings:
  - Estimated 2.6 percent reduction in Part B drug payments
  - Size of effect would vary across specialty / provider type depending on prices of drugs furnished

Note: Simulation includes all Part B–covered drugs paid under the ASP+6 percent system, excluding drugs billed through not otherwise-classified billing codes. Excluded from the analysis are beneficiaries with Medicare secondary payer and Part B drugs furnished by 340B hospitals that were paid ASP-22.5 percent in 2019, critical access hospitals, and Maryland hospitals. Data are preliminary and subject to change.
Implications for providers' ability to acquire drugs at Medicare rate

- Manufacturers set their own prices and have an incentive to price products at a level that providers can acquire for Medicare rates.
- Although data on providers’ drug acquisition costs are limited, there is evidence of manufacturers changing pricing patterns in response to past policy changes.
Feedback and next steps

Questions?

We would like your feedback on policy options:

- For Part B drugs with limited clinical evidence, set a cap on payment until post-marketing trial confirms drug’s clinical benefit
- For Part B drugs with therapeutic alternatives, apply reference pricing
- For Part B drugs, modify the ASP add-on payment