Addressing high prices of drugs covered under Medicare Part B

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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

	Part B
Spending in 2020:	• $40.7 billion*
Spending growth from 2009-2020:	• Over 9 percent per year on average
Largest driver of the spending growth from 2009-2020:	• Growth in average price per Part B drug, which reflects post-launch price growth; launch of new, higher-priced products; and shifts in mix of drugs
Spending is highly concentrated:	• 20 products account for 52% of spending • Examples of indications of top products: cancer, macular degeneration, inflammatory conditions

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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

FDA (Food and Drug Administration).
*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

ASP per drug admin.	Current policy 6%	Option Lesser of: (6%, 3% + $21, $175)
$5	$0.30	$0.30
100	6	6
700	42	42
1,000	60	51
3,000	180	111
5,000	300	171
15,000	900	175

- 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