Addressing high prices of drugs covered under Medicare Part B

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Commission's work on improving payment for Part B drugs

- June 2017 recommendation to improve price competition by applying a type of reference pricing to pay for biosimilars and originator biologic
- June 2019 report discussed improving price competition among drugs with therapeutic alternatives
- June 2022 report and September 2022 public meeting discussed policy levers to:
  - Improve payment for drugs with uncertain clinical benefit
  - Spur price competition among drugs with therapeutic alternatives
  - Improve financial incentives under the Part B drug payment system

Today's session

- Concerns about trends in drug pricing and spending
- Package of potential policies:
  - Policy 1: Setting a cap on the payment of accelerated approval drugs
  - Policy 2: Establishing a single ASP-based payment rate for groups of drugs and biologics with similar health effects
  - Policy 3: Reducing the add-on payment for drugs and biologics paid ASP and eliminating the add-on payment for drugs and biologics paid WAC
- Based on your feedback, the Chair's goal is to develop draft recommendations that we would present in the Spring

Notes: ASP (average sales price). WAC (wholesale acquisition cost)

Price has been the largest driver of Part B drug spending growth

Part B drug spending	
Spending in 2021:	• $42 billion*
Total FFS spending growth from 2009-2021:	• About 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 more than 50% of spending • Examples of indications of top products: cancer, macular degeneration, inflammatory conditions

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Notes: FFS (fee-for-service). *Program spending and cost sharing. Data are preliminary and subject to change.

Most Part B drugs are paid at a rate of 106% of average sales price (ASP)

- ASP reflects the manufacturer's average price based on sales to most purchasers net of price concessions (with some exceptions)
  - 106% ASP payment rate is based on ASP data from 2 quarters prior
- Biosimilars: 100% of own ASP plus 6% or 8% of originator's ASP
- Drugs lacking ASP data are paid based on wholesale acquisition cost (WAC), an undiscounted list price
  - WAC+3% for new drugs; WAC+6% for other drugs lacking ASP data

- Medicare pays separately for drug administration services

Note: Preventive vaccines are paid differently (95 percent of average wholesale 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: 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.

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

Policy 1: Addressing the high prices of accelerated approval drugs with limited clinical evidence

- At time of approval, there is uncertainty about whether accelerated approval drugs impact clinical outcome
- Some manufacturers do not always complete their post-confirmatory trials promptly
- This policy would:
  - Give the Secretary the authority to cap the Medicare payment rate of drugs and biologics that are approved under the accelerated approval program until the product has converted to full approval.

Policy 1: Addressing the high prices of accelerated approval drugs with limited clinical evidence (cont.)

- *Which drugs to apply the cap?* Give Secretary discretion to target drugs with little evidence on the clinical benefit, high pricing relative to expected clinical benefit, and relatively large spending impact on beneficiaries and taxpayers
- *How to apply the cap?* Could be set based on the clinical benefit and cost of the accelerated approval drug relative to the standard of care
- *When to set the cap?* Give Secretary the flexibility to apply cap either at launch or over time to incentivize the completion of confirmatory trials

Policy 2: Improving price competition among drugs with similar health effects

- 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 for biosimilars and originator biologics
- Building on that recommendation, this policy would extend reference pricing beyond biosimilars:
  - Give the Secretary the authority to establish a single ASP-based payment to drugs and biologics with similar health effects

Note: ASP (average sales price).

Policy 2: Improving price competition among drugs with similar health effects (cont.)

- Each product remains in its own billing code
- Could base payment on the volume-weighted ASPs of all products in reference group
- To define reference groups, Medicare could consider various factors, including organizing reference groups by clinical indications and drug classification and ease of implementation
- Provide pricing information to beneficiaries and clinicians

Note: ASP (average sales price).

Policy 3: Improving financial incentives associated with Part B drug add-on payment

- Concern that the percentage add-on payment for Part B drugs creates incentives for use of higher-priced drugs
- The policy would:
  - Give the Secretary the authority to reduce add-on payments for Part B drugs paid based on average sales price (ASP) to improve financial incentives, and
  - Eliminate the add-on payments for Part B drugs paid based on wholesale acquisition cost (WAC).

Policy 3: Improving financial incentives associated with Part B drug add-on payment (cont.)

- Policy approach:

  ASP Add-on = Lesser of 6%, 3%+ $24, $220 per drug per day

- Maintains current add-on for lower-priced drugs, converts part of percent add-on to flat fee for higher-priced drugs, and caps add-on for most expensive drugs
- Effects
  - Add-on reduced for drugs with ASP per administration > $800
  - Improves financial incentives by reducing differential in add-on payments across products, particularly among most expensive drugs
  - Savings for taxpayers and beneficiaries from reduced add-on

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Note: ASP (average sales price).

Feedback and next steps

- Questions and clarifications
- Feedback on material presented and package of policies to improve payment for Part B drugs:
  - Policy 1: Setting a cap on the payment of accelerated approval drugs
  - Policy 2: Establishing a single ASP-based payment rate for groups of drugs and biologics with similar health effects
  - Policy 3: Reducing the add-on payment for drugs and biologics paid ASP and eliminating the add-on payment for drugs and biologics paid WAC

Notes: ASP (average sales price). WAC (wholesale acquisition cost).