Addressing the 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 use reference pricing to pay for biosimilars and originator biologics to improve price competition
- June 2019 report discussed improving price competition among drugs with therapeutic alternatives
- June 2022 discussed policy levers to:
  - Address 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
- Current cycle: Identify approaches best suited to balancing incentives for innovation with affordability for beneficiaries and taxpayers

Today's session

- Concerns about trends in drug pricing and spending
- Package of policies under consideration today:
  - Policy 1: Applying 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 add-on payment for drugs and biologics paid ASP and eliminating add-on payment for drugs and biologics paid WAC

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

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

- In 2021, Medicare spending for Part B drugs was $42 billion*
- Between 2009 and 2021, spending grew 9 percent per year on average
- Largest driver of spending growth is the rise in the average price per Part B drug, which reflects post-launch price growth, launch of new higher-priced products, and shifts in mix of drugs
- Estimates suggest that U.S. drug prices are roughly double the prices in other countries**
- Part B drug spending is highly concentrated

*Program spending and cost sharing.
**Comparator countries are members of the Organization for Economic Co-operation and Development (ASPE 2020).
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 under the physician fee schedule and outpatient prospective payment system

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Note: *For drugs paid 106 percent of ASP, after application of the 2 percent sequester, Medicare's net payment is 104.3 percent of ASP. Preventive vaccines are paid differently (95 percent of average wholesale price).

Historically, Medicare Part B has had few 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). FFS (fee-for-service).
* 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

- Address 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 payment for accelerated approval drugs

- At time of approval, there is uncertainty about whether accelerated approval drugs improve clinical outcomes
  - The FDA approves drugs more quickly under the accelerated approval pathway than under traditional approval
  - Accelerated approval is based on a surrogate or intermediate clinical endpoint that is *reasonably likely* to predict a clinical benefit
  - Some drugs are approved with little evidence about their effect on the Medicare population

Policy 1: Addressing payment for accelerated approval drugs (cont.)

- Some manufacturers do not always complete their post-confirmatory trials promptly
  - More than one-third of accelerated approval drug applications have incomplete confirmatory trials*
- Some manufacturers establish high pricing relative to their drug's expected clinical benefit resulting in relatively large spending impacts on beneficiaries and taxpayers

*Source: Office of Inspector General 2022.

Implementation considerations: Addressing payment for accelerated approval drugs

- Once a manufacturer verifies a drug's clinical benefit, the cap on the payment rate could cease and revert to current law
- The Secretary could set the payment cap based on the clinical benefit and cost of the accelerated approval drug relative to the standard of care (in most instances)
- The Secretary could operationalize the cap using a rebate under which manufacturers pay Medicare the difference between the otherwise applicable ASP-based payment amount and the cap based on use of the drug for the accelerated approval diagnosis

Note: ASP (average sales price).

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

- Insufficient price competition for single-source drugs, biologics, and biosimilars 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, a policy to extend reference pricing to products with similar health effects would spur price competition and reduce Medicare and beneficiaries' spending

Note: ASP (average sales price).

Implementation considerations: Improving price competition among drugs with similar health effects

- Each product could remain in its own billing code
- Could base payment on the volume-weighted ASPs of all products in reference group
- To define reference groups, the Secretary could consider various factors, including organizing reference groups by clinical indications and drug classification and ease of implementation, beginning with:
  - Biosimilars and originator biologics
  - 505(b)(2) drugs and related brand and generics
  - Drugs for which reference pricing has been implemented or considered previously

Note: ASP (average sales price).

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

- While clinical factors play a central role in prescribing, financial considerations can also play a role
- 6% add-on to ASP may create incentives for use of higher-priced drugs when lower-priced alternatives are available
- Commission has developed a three-part approach to restructure the ASP add-on that could improve financial incentives
  - Example ASP add-on = lesser of 6%, 3%+ $24, $220 per drug per day
- For drugs paid based on WAC (a generally higher price than ASP because it does not incorporate discounts), eliminating the add-on could improve incentives and reduce excess payments

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

Implementation considerations: Improving financial incentives associated with Part B drug add-on payment

- When implementing the reduced add-on, CMS should assess the separate drug administration payment rates to ensure they are adequate
- CMS should monitor utilization patterns among providers (e.g., drug administration frequency)

Feedback and next steps

- Questions and clarifications
- Feedback on policies:
  - Policy 1: Applying a cap on the payment of accelerated approval drugs
  - Policy 2: Reference pricing for products with similar health effects
  - Policy 3: Reducing the ASP add-on and eliminating the WAC add-on

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