Advising the Congress on Medicare issues

Addressing the high prices of drugs covered under Medicare Part B

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MEDPAC

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 to balance incentives for innovation with affordability for beneficiaries and taxpayers

Today's session

- Concerns about trends in drug pricing and Medicare spending
- Package of Part B policies under consideration today:
  - Policy 1: Applying a cap on the payment of accelerated approval drugs and biologics
  - 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
- Draft recommendations

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

Background

- In 2021, Medicare spending for Part B drugs was $43 billion*
- Part B drug spending has grown 9 percent per year on average since 2009
- Largest driver of spending growth is the rise in the average price per Part B drug, which reflects:
  - Launch of new higher-priced products,
  - Post-launch price growth, and
  - Shifts in mix of drugs.
- Under the ASP-based payment method, Medicare has few tools to influence Part B drug prices

Note: ASP (average sales price). Results are preliminary and subject to change.
*Program spending and cost sharing.

Policy 1: Addressing payment for accelerated approval drugs

- At time of approval, there is uncertainty about whether accelerated approval drugs improve clinical outcomes
- Medicare lacks tools to differentiate payment for accelerated approval drugs whose clinical benefit is not verified, confirmatory trial is late, or which are covered under a CED policy
- Current Part B drug payment does not spur manufacturers to complete their confirmatory trials promptly

Note: CED (coverage with evidence development).

Policy 1: Addressing payment for accelerated approval drugs

- Capping payment for select accelerated approval drugs would spur manufacturers to complete their confirmatory trials promptly and help ensure Medicare is not overpaying when a product's clinical benefit is not confirmed
- The payment cap could be set based on the clinical benefit and cost of the drug relative to the standard of care
- The cap could be operationalized using a rebate approach
- Once clinical benefit is verified, the payment rate would revert to current law

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

- Insufficient price competition for drugs and biologics with similar health effects
  - Part B pays for single source drugs, 505(b)(2) drugs, biologics, and biosimilars based on each product's 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: 505(b)(2) drugs are drugs approved under FDA's 505(b)(2) pathway, which is a hybrid between the generic approval process (under 505(j)) and a full new drug application (under 505 (b)(1)). ASP (average sales price).

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

- A policy to establish a single ASP-based payment rate for drugs with similar health effects would improve price competition
  - 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, factors that could be considered include a drug's clinical indications and classification and ease of implementation, beginning with:
    - Biosimilars and originator biologics,
    - 505(b)(2) drugs and related brand and generic products, and
    - 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

- Part B pays providers ASP + 6 percent for drugs (and makes a separate payment for drug administration under the PFS or OPPS)*
- While clinical factors play a central role in prescribing, financial considerations can also play a role
  - Percentage add-on to ASP may create incentives for use of higher-priced drugs when lower-priced alternatives are available
  - For drugs lacking ASP data, Medicare pays a percentage add-on to WAC, a generally higher price than ASP because it does not incorporate discounts

*Like all Medicare services, Part B drug payments are subject to the 2 percent sequester through March 2032.
Note: ASP (average sales price). PFS (physician fee schedule). OPPS (outpatient prospective payment system). WAC (wholesale acquisition cost).

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

- A policy that reduces add-on payments for costly Part B drugs paid based on ASP would improve financial incentives
- General approach would:
  - Maintain the 6% ASP add-on for lower-priced drugs
  - Reduce add-on payments for mid- and high-priced drugs by reducing the percent add-on and adding a fixed fee
  - Place a fixed dollar cap on the add-on for the costliest drugs
- Illustrative ASP add-on: Lesser of 6%, 3%+$24, or $220
  - Policymakers could consider other percentages or dollar amounts
- A policy that eliminates add-on payments for drugs paid based on WAC would improve financial incentives and reduce excess payments

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

Conclusion

- Questions
- Discussion
  - Policy 1: Applying a cap on Medicare's payment of Part B 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

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