Two Medicare payment strategies to improve price competition and value for Part B drugs: reference pricing and binding arbitration

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Medicare Part B drug spending is growing rapidly

- Part B covers drugs administered by physicians and HOPDs
- Medicare Part B drug spending: $32 billion in 2017
- Spending has grown 9.6% per year since 2009, with more than half of this growth due to price growth
- Most drugs are paid 106% of average sales price (ASP)
  - ASP reflects the manufacturers' average sales price to most purchasers net of rebates and discounts with some exceptions
  - ASP is an average; each provider's acquisition price can vary

Note: HOPD (Hospital outpatient department)

The Commission's 2017 Part B drug recommendation: Package of reforms

- Improving the current ASP system
  - Consolidated billing codes for biosimilars and reference product
  - ASP inflation rebate
- Drug value program (DVP): alternative to ASP system
  - Physicians and HOPDs could choose to enroll in DVP
  - Vendors would negotiate prices for Part B drugs using tools including binding arbitration in certain circumstances
- Reduce ASP add-on to encourage DVP enrollment

Potential approaches to improve price competition and value for Part B drugs

- Reference pricing
  - Approach to improve price competition and value among single-source products with similar health effects
- Binding arbitration
  - Approach to address high launch prices for products with limited competition

Reference pricing to improve payment for Part B drugs

- Insufficient price competition between therapeutically similar drugs
- ASP payment policy does not consider whether a drug results in better outcomes than alternatives
- Instances in which a drug's ASP is higher than alternatives even when there is not evidence on whether the product results in better outcomes
- The Commission has held that Medicare should pay similar rates for similar care
- Opportunity to increase price competition and value with reference pricing

What is reference pricing?

- Payers set a maximum payment rate for a group of drugs with similar health effects based on the minimum, median, or other point along the range of prices within the drug group
- Provides an incentive for use of lower-cost alternatives while maintaining access to care
- If beneficiary and provider select higher-priced treatment, beneficiary pays difference in higher cost sharing
- Findings from literature review suggest that reference pricing reduced drug prices and lowered payers' spending

Approaches to and use of reference pricing

- Two approaches to reference pricing:
  - Internal: reference price is established for a group of drugs with similar health effects based on a payer's own pricing data
  - International: reference price is established by considering the prices other countries pay for a drug
- Reference pricing is an emerging benefit design for commercial payers and employers
- Reference pricing is used in nearly all European countries, Australia, Canada, and Japan

Between 1995 and 2000, Medicare applied reference pricing policies to Part B drugs

- Least costly alternative (LCA) and functional equivalence policies set payment based on the least costly agent
- Both policies used existing Medicare payment data (e.g., ASP data); no new data collection was necessary
- In 2010, CMS withdrew LCA policies following a successful challenge in Federal court
- Evidence that LCA policies resulted in savings for beneficiaries and taxpayers
- Medicare would need explicit legislative authority to apply reference pricing policies to Part B drugs

Policy option: Establish reference pricing for Part B drugs

- Development of a transparent process for:
  - Considering evidence on drugs' comparative clinical effectiveness and defining groups of products with similar health effects
  - Setting and updating the payment rate
  - Public input and comment
  - Exceptions if it is medically necessary
  - Revisiting policy as evidence changes
- Address whether Medigap policies could cover beneficiary cost sharing that is greater than the reference price

Advantages and disadvantages of reference pricing

- Advantages
  - Increased priced competition would reduce drug prices, which could yield substantial savings for beneficiaries and taxpayers
  - Increased economic engagement of beneficiaries and providers
- Disadvantages
  - Some beneficiaries could face higher cost sharing
  - Design and implementation complexities

Binding arbitration to address high launch prices

- Commission included binding arbitration as a tool within the DVP for high-cost Part B drugs with limited competition
- Launch prices have been increasing
- Medicare lacks tools to balance an appropriate reward for innovation with value and affordability
- Examples of binding arbitration's use to establish prices for health care (e.g., states' out-of-network billing, Germany)
- Opportunity to use binding arbitration to impact launch prices

Expanding binding arbitration beyond the DVP

- Expanding binding arbitration beyond DVP could spread its benefits more broadly to:
  - High-cost Part B drugs with limited competition paid under the ASP payment system
  - Possibly Part A providers paid under larger payment bundles

Illustrative model of binding arbitration

- Type: Final offer (baseball arbitration)
- Arbitrator: Neutral arbitrator or arbitration panel selected by nonpartisan government agency
- Eligibility criteria:
  - For a product with limited competition and cost exceeding a specified threshold, the Secretary would have authority to request arbitration
  - Manufacturer would be required to enter arbitration and abide by the arbitrator's decision as a condition of Medicare payment

Illustrative model of binding arbitration (cont'd)

Example of steps in process:

- Trigger: Secretary requests arbitration for a new costly drug that meets criteria
- Offer prices: Secretary and manufacturer submit offer prices and supporting information to arbitrator
- Arbitrator criteria: Criteria would be specified for arbitrator to consider in making a decision
  - For example: comparative clinical effectiveness, prices of existing treatments, rare condition/special need, product costs, affordability
- Arbitrator decision: Arbitrator selects one of the parties' offers

Illustrative model of binding arbitration (cont'd)

- Operationalizing arbitration price:
  - Option 1: Adjust Part B rate with manufacturer requirement
    - Set Part B payment rate based on arbitration price
    - Require manufacturer to sell product to providers for Medicare patients at a price no higher than the arbitration price. Could include Part A providers.
  - Option 2: Manufacturer rebate for Part B drugs
    - Providers continue to be paid ASP+6 for Part B drugs
    - Manufacturer pays Medicare a rebate on its Part B drug utilization
    - Providers' drug acquisition prices are unaffected
- Revisiting arbitration price: Process to reconsider arbitration price after certain time period or in certain circumstances

Advantages and disadvantages of binding arbitration

- Advantages
  - Practical approach to address launch prices for Part B drugs
  - Could yield substantial savings for beneficiaries and taxpayers
  - Potential to lower prices for Part A providers
- Disadvantages
  - Design and implementation complexities
  - Some stakeholders may point to access concerns; however, Medicare's market size and arbitration design elements would provide strong incentives for a manufacturer to choose to participate

Conclusion and next steps

- Each strategy would apply an element of the 2017 recommendation more broadly
  - *Reference pricing:* improve price competition and value among drugs with similar health effects
  - *Binding arbitration:* address high launch prices for drugs with limited competition
- Seeking Commissioner feedback on further developing these strategies for next cycle