



Advising the Congress on Medicare issues

Addressing high prices of drugs covered under Medicare Part B

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Today's session

- Concerns about trends in drug pricing and spending
- Potential policy options to address:
 - High launch prices of new first-in-class Part B drugs with limited clinical evidence
 - High and growing prices for Part B drugs with therapeutic alternatives
 - Financial incentives associated with the percentage add-on to Medicare Part B's drug payment rates

Price increases have been the largest driver of Part B drug spending growth

Part B	
Spending in 2020:	<ul style="list-style-type: none">• \$40.7 billion*
Spending growth:	<ul style="list-style-type: none">• Nearly 10% annually from 2009-2019• About 4% in 2020
Largest driver of the spending growth from 2009-2019:	<ul style="list-style-type: none">• Higher prices, which reflects increased prices for existing products and introduction of new, higher priced products
Spending is highly concentrated:	<ul style="list-style-type: none">• 20 products account for 52% of spending• Examples of indications of top products: cancer, macular degeneration, rheumatoid arthritis

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 limited evidence of their clinical benefit

Addressing high drug prices and price growth: Policy objectives for Medicare

- Spur price competition among drugs
- Ensure the program's payment does not exceed a product's comparative clinical benefit
- Maintain incentives for innovation
- Improve financial incentives under the Part B drug payment system

Medicare has few tools to cover and pay for Part B drugs

- FFS Medicare is required to cover drug indications approved by the FDA*
- Most Part B drugs paid based on average sales price (ASP)
- Billing codes affect payment
 - Own code
 - Sole-source drug and originator biologic: 106% of own ASP
 - Biosimilar: 100% of own ASP + 6% originator ASP
 - Consolidated billing code: Brand and generic versions of drug paid based on 106% of volume-weighted average ASP

*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.

Potential policy options

- First-in-class Part B drugs with limited clinical evidence
 - Set a cap on payment using evidence on comparative clinical effectiveness and cost effectiveness and apply coverage with evidence development
- Part B drugs with therapeutic alternatives
 - Apply reference pricing
- Modify ASP add-on payment

Addressing high launch prices of first-in-class drugs with limited clinical evidence

- A combined approach:
 - apply coverage with evidence development, and
 - set a cap on payment based on cost-effectiveness analysis
- Focus on products that the FDA approves based on surrogate or intermediate clinical endpoints, e.g., via its accelerated approval pathway
- Has the potential to improve post-market evidence development and the Part B drug payment

Addressing high launch prices of first-in-class drugs with limited clinical evidence (cont.)

- Under this approach:
 - Apply coverage with evidence development (CED) to generate evidence on a new drug's risks, benefits, and impact on quality of life and functional status
 - Use cost-effectiveness analysis (CEA) – a comparison of the incremental clinical effectiveness (outcomes) and costs of two or more products, to set a cap on the payment rate

Addressing high launch prices of first-in-class drugs with limited clinical evidence (cont.)

- Need a transparent and predictable process with opportunities for public comment
- Process for identifying drugs for this approach
- Designing coverage with evidence development policies
 - Developing study design, methods, and outcomes
 - Defining timeframe
- Designing cost-effectiveness analyses
 - Measuring costs and outcomes
 - Defining alternative treatments, perspective, and horizon

Addressing 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

Addressing 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
 - Minimum of the volume-weighted ASPs of all products in reference group or the ASP of the specific product furnished

Addressing 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
 - Medical exception process for higher-cost products
 - A process for instances when clinician and beneficiary opt for more costly product not supported by medical necessity
- Provide pricing information to beneficiaries and clinicians
- Address whether Medigap policies could cover beneficiary cost sharing that is greater than the reference price

Issues to consider

- CMS statutory authority and resources
- Acceptance by beneficiaries and stakeholders
- Implications for investments in research and development

Addressing financial incentives: ASP add-on

- While clinical factors play a central role in prescribing, financial considerations may also play a role in some circumstances
- Part B pays providers ASP + 6% for drugs; ASP is the manufacturer's average price net of price concessions with certain exceptions
- Concern exists that the 6 percent add-on creates incentives for providers to choose higher-priced drugs
- Several studies found growth in utilization of higher-priced products that may reflect the effect of the 6 percent add-on
- In October, Commissioners expressed interest in exploring alternatives to 6 percent add-on

Illustrative policy options to modify the ASP add-on

Option 1	Option 2	Option 3
<p>Lesser of: (6% or \$175)</p> <ul style="list-style-type: none"> • Caps 6% add-on for very expensive drugs at \$175 • Affects drugs with ASP per administration > \$2,917 • Other drugs unaffected 	<p>3% + \$21</p> <ul style="list-style-type: none"> • Lowers add-on from 6% to 3% and adds \$21 fee per drug administered • Reduces differences in add-on payment across products • Increases add-on for drugs with ASP <\$700, particularly for very low-cost drugs 	<p>Lesser of: (6%, 3%+\$21, or \$175)</p> <ul style="list-style-type: none"> • Maintains 6% for drugs with ASP < \$700 • Reduces add-on to 3% + \$21 for drugs with ASP >\$700 • Caps add-on at \$175 for very expensive drugs (ASP >\$5,133)

Note: In each option, the ASP add-on is calculated based on the total ASP per drug administered, which is defined as the 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), the add-on is calculated based on the total ASP per prescription.

Add-on amounts for differently priced drugs under current policy and policy options

ASP per drug admin.	Current policy	Option 1	Option 2	Option 3
	6%	Lesser of: (6%, \$175)	3% + \$21	Lesser of: (6%, 3% + \$21, \$175)
\$5	\$0.30	\$0.30	\$21.15	\$0.30
100	6	6	24	6
1,000	60	60	51	51
3,000	180	175	111	111
5,000	300	175	171	171
15,000	900	175	471	175

Comparison of options:

- Option 1 has most effect across high-priced products
- Option 2 has most effect across low- and mid-priced products
- Option 3 has most effect across mid- and high-priced products

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 options shift use toward lower-priced drugs, savings could be higher

Option 1 Lesser of: (6% or \$175)	Option 2 3% + \$21	Option 3 Lesser of: (6%, 3% + \$21, or \$175)
<ul style="list-style-type: none"> • Aggregate savings of 1.9% • Decrease in payments across specialties/provider types by varied amounts 	<ul style="list-style-type: none"> • No aggregate savings • Increase in payments for some specialties/provider types and decrease for others 	<ul style="list-style-type: none"> • Aggregate savings of 2.6% • Decrease in payments across specialties/provider types by varied amounts

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 paid ASP-22.5 percent, critical access hospitals, and Maryland hospitals. Data are preliminary and subject to change.

Issues to consider

- Providers' ability to acquire drugs at Medicare rate
 - Data on providers' drug acquisition costs are limited, but manufacturers have an incentive to price products at a level that providers could acquire for Medicare rates
 - There is evidence of manufacturers changing pricing patterns in response to past policy changes
- Effects on providers' incentives
 - Each option addresses incentives to choose higher-priced drugs but would focus on products in different price ranges
 - Would policy options create any countervailing incentives (e.g., in terms of dosing frequency or volume)?

Feedback and next steps

- Questions?
- We would like your feedback on potential policy options:
 - For first-in-class Part B drugs with limited clinical evidence, set a cap on payment rate using evidence on comparative clinical effectiveness and cost effectiveness and apply coverage with evidence development
 - For Part B drugs with therapeutic alternatives, apply reference pricing
 - For Part B drugs, modify the ASP add-on payment