

Addressing high prices of pharmaceutical products (and other technologies) covered under Medicare

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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 spending growth

| | Part B | Part D |
|--|--|---|
| Spending in 2019* | \$39 billion | \$105 billion |
| Growth since 2009 | Nearly 10% annually | Nearly 6% annually |
| Largest driver of the cost growth | <ul style="list-style-type: none"> Higher prices | <ul style="list-style-type: none"> Reinsurance for catastrophic costs incurred by <10% of enrollees (~16% per year growth) Almost entirely due to higher prices |
| Spending is highly concentrated | <ul style="list-style-type: none"> 10 products account for 41% of spending Indications of top products: macular degeneration, cancer, rheumatoid arthritis | <ul style="list-style-type: none"> Brand spending accounts for nearly 80% of total (gross) spending Just 2 classes accounted for 35% of brand spending: cancer and diabetes |

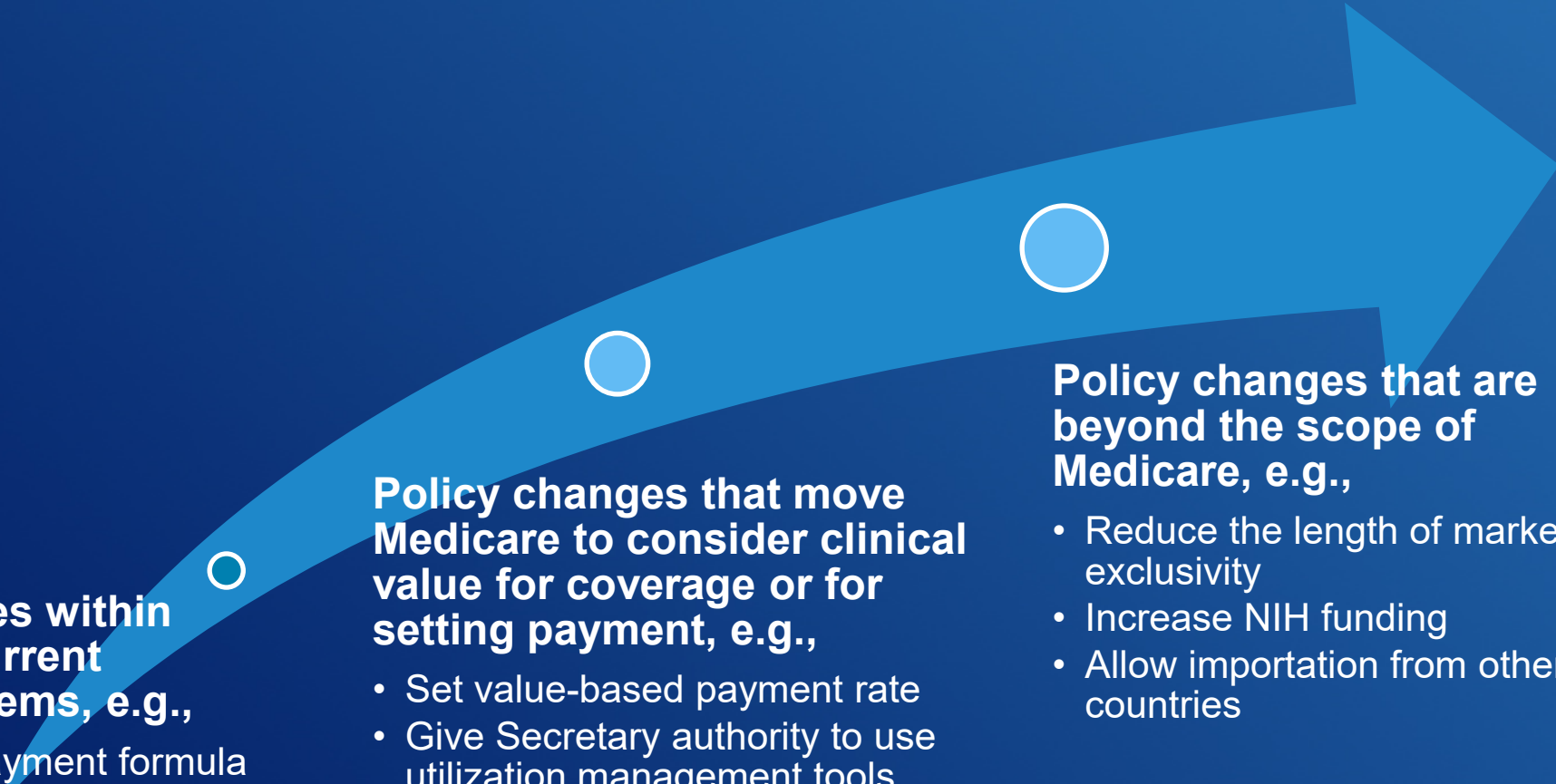
Concerns about high and growing drug prices

- 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
 - According to researchers, launch prices for cancer drugs have been increasing, unrelated to the value of products
 - Prices have grown rapidly for certain existing drugs without evidence of a change in the products' effectiveness
- Products approved under the Food and Drug Administration's accelerated approval pathway are launching at high prices with limited evidence of their effectiveness

Aduhelm highlights Medicare's challenges with coverage and payment of drugs with limited clinical evidence

- Aduhelm approved for Alzheimer's disease with unclear evidence on clinical benefit and side effects
 - Accelerated approval drugs are approved by the FDA based on surrogate or intermediate clinical endpoints
- Potential for very large effect on Part B drug spending
 - Manufacturer price of \$56,000 per year has potential for large effect on Part B spending
 - About 6 million with Alzheimer's dementia; if 500,000 received product in a year, Medicare spending would increase by ~\$29B (i.e., nearly 75% of \$39 billion total spent in 2019)

Addressing high drug prices and price growth



Policy changes within Medicare's current payment systems, e.g.,

- Modify ASP payment formula
- Lower Medicare's Part D reinsurance

Policy changes that move Medicare to consider clinical value for coverage or for setting payment, e.g.,

- Set value-based payment rate
- Give Secretary authority to use utilization management tools

Policy changes that are beyond the scope of Medicare, e.g.,

- Reduce the length of market exclusivity
- Increase NIH funding
- Allow importation from other countries

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

- Better align what the program and beneficiaries pay for drugs with the value of those products
- Spur price competition among drugs
- Limit beneficiaries' and taxpayers' financial risk for products with limited evidence on clinical effectiveness

Potential policy options

- First-in-class Part B drugs with limited clinical evidence
 - Set a value-based 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 average sales price add-on payment

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

- FFS Medicare is required to:
 - Pay average sales price (ASP) + 6% for sole-source Part B drugs
 - Cover drug indications approved by the Food and Drug Administration*
- A combined approach of setting payment based on cost-effectiveness analysis and applying coverage with evidence development has the potential to increase the value of Medicare spending and improve post-market evidence development

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

- Focus on products that the FDA approves based on surrogate or intermediate clinical endpoints, e.g., via its accelerated approval pathway
- Value-based approach would:
 - Use cost-effectiveness analysis – a comparison of the incremental costs and clinical effectiveness (outcomes) of two or more technologies, to set a value-based payment rate, and
 - Apply coverage with evidence development (CED) to generate evidence on, for example, a new drug's risks, benefits, and impact on quality of life and functional status

Addressing Part B drugs with therapeutic alternatives: Reference pricing

- Insufficient price competition among products with therapeutic alternatives
- Part B's payment for each single-source product based on its own ASP does not promote price competition
- In 2017, the Commission recommended combined billing code policy for biosimilars and originator biologics
- Reference pricing could be considered for Part B products with similar health effects to increase price competition and value

Addressing Part B drugs with therapeutic alternatives: Reference pricing (cont.)

- Internal reference pricing option for Part B drugs
 - Set a maximum payment rate for a group of drugs with similar health effects (e.g., based on minimum, median, or average price)
 - If beneficiary and provider select higher-priced treatment, beneficiary pays difference in higher cost sharing (with exceptions process for medical need)
 - Would require development of transparent process for establishing and updating drug payment groups and rates
- Could explore additional approach of one-time rebasing (e.g., informed by international pricing data)

Addressing financial incentives: ASP add-on

- Medicare generally pays providers ASP+6% for Part B drugs; a provider's margin can be greater or less than 6%
- Concern exists that the 6% add-on may create incentives for providers to choose higher-priced drugs in situations where differently priced therapeutic alternatives are available
- Literature is limited on the potential effect of the 6% add-on on prescribing behavior
- Options to modify the ASP add-on could be considered:
 - Reduce percentage add-on (Commission recommended in 2017)
 - Convert all or part of the percentage add-on to a fixed fee
 - Place dollar cap on percentage add-on payment

Challenges to consider

- Implementation issues associated with value-based pricing, CED, and reference pricing
 - Technical complexities specific to each option
 - A well-defined, transparent, and consistent approach is key
- Stakeholder acceptance
- Implications for manufacturers' investments in research and development

Feedback and next steps

- Questions?
- We would like your input on potential policy options to address:
 - High launch prices of new first-in-class Part B drugs with limited clinical evidence using a value-based approach of cost-effectiveness analysis and CED
 - High and growing prices for Part B drugs with therapeutic alternatives using reference pricing
 - Financial incentives by modifying the 6% add-on to the ASP payment rates