

Cost Review: Process for Selecting Drugs to Undergo Cost Review

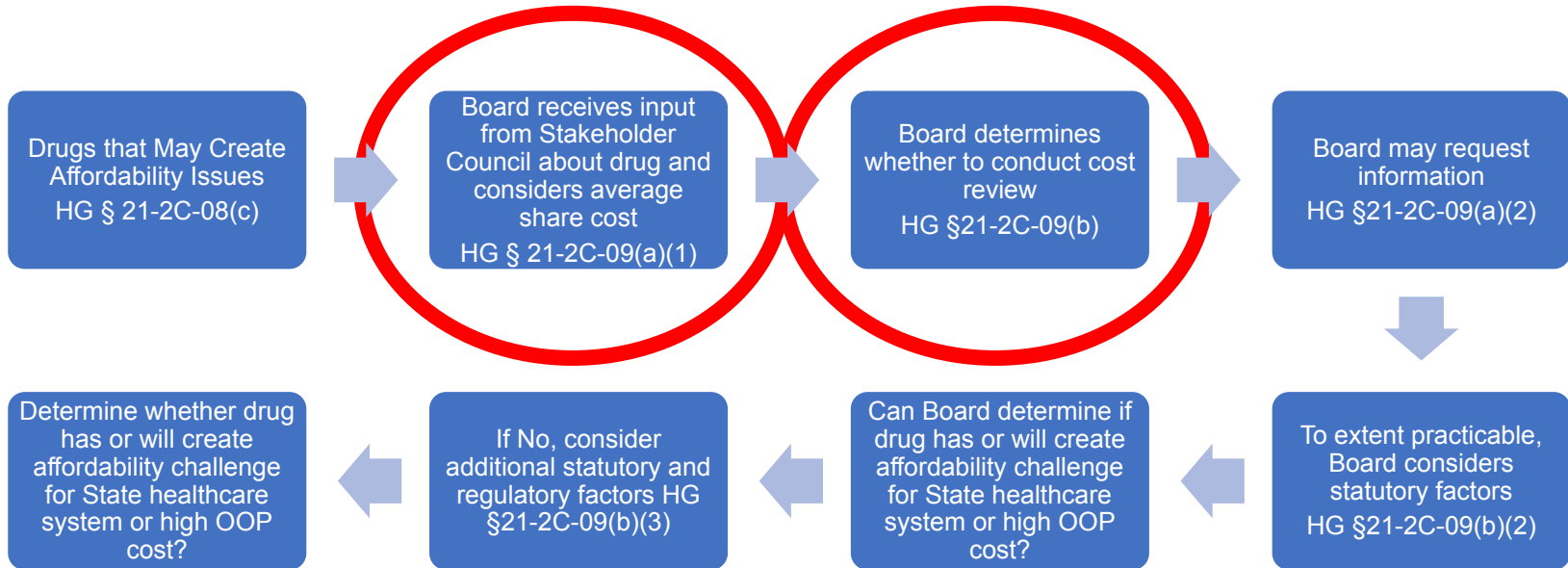
October 24, 2022

PDAB Staff

Agenda

- Introduce Possible Ways to Select Drugs to Undergo Cost Review
- Next Steps

Overview of Statutory Cost Review Process Under HG § 21-2C-09



Identifying Drugs Eligible for Cost Review

- Identify the universe of drugs eligible for selection for cost review
- 2 Sources:
 - Legislative metrics defined in HG § 21-2C-08
 - Additional metrics selected by the Board HG § 21-2C-08(c)(4)
 - “Other prescription drug products that may create affordability challenges for the State health care system and patients, in consultation with the Stakeholder Council”



Eligible Drugs Identified by Metrics

- Applying each metric to the data set generates a list of drugs meeting that metric
- Each metric/metric-generated list identifies potentially hundreds of drugs eligible for cost review
- Next issue: How to select drugs for cost review from the hundreds or thousands identified?

Framework for Selecting Drugs to Undergo Cost Review

- Working from the universe of drugs identified by the metrics, the Board, with input from the Stakeholder Council and considering the average share cost, selects drugs for Cost Review process



Possible Options for Selecting Drugs for Cost Review

- Develop a screen that identifies drugs meeting multiple metrics and consider enhancing factors/metrics
- Develop a screen that identifies drugs based on factors/metrics and consider enhancing factors/metrics
- Board considers specific factors set forth in regulation and selects drugs for review
- Combination



Screen Identifying Drugs Satisfying Multiple Metrics

- Cross-reference metrics-generated lists to identify drugs appearing on multiple lists
 - Some metrics can be used to make drugs eligible for Cost Review, while others can be used to provide additional information for the selection of drugs (enhancement)
 - Able to prioritize certain metrics



Screen Identifying Drugs Based on Weighted Metrics

- Cross-reference metrics-generated lists
 - Able to prioritize and/or weight certain metrics
 - Other metrics can be used to provide additional information for the selection of drugs (enhancement)

Board Considers Enumerated Regulatory Factors

For example,

- Class of Prescription Drug and Therapeutic Equivalents
- Aggregated Data
- Health Equity Impact

And Board Considers Statutory Factor and Obtains Stakeholder Council Input (for all options)

- Average Cost Share of the prescription drug (statutory)
- Input from Stakeholder Council

Types of Metrics

- “Eligibility” Metrics
 - High Volume
 - High Cost
- “Enhancement” Metrics



List of Metrics

- Brand name drugs with launch Wholesale Acquisition Cost (WAC) of \$30,000 or more per year OR increase of \$3,000 or more in 12 month period (Brand Name Launch WAC Metrics and Brand Name WAC Increase Metric)
- Biosimilar drugs with WAC that is not at least 15% lower than reference biologic (Biologics WAC Metric)
- Generic drugs with WAC of \$100 for 30 days AND increase by 200% or more during immediately preceding 12-month period (Generics Metric)



List of Metrics (con't)

- Drugs with the highest overall spend
- Drugs with the highest per-patient spend
- Drugs with the highest patient out-of-pocket cost
- Drugs with the highest price increases (% and gross)
- Drugs that are reported to cause affordability issues for Marylanders

List of Measures (con't)

- Drugs that are Approved through an FDA Accelerated Approval Pathway
- Drugs that are the Only Drug in Class
- Drugs with the Highest Advertising Spend
- Drugs with the Longest Patent Extensions
- Insulins

Eligibility Metrics- High Volume

- Drugs with the highest overall spend



Eligibility Metrics- High Costs

- Brand name drugs with launch Wholesale Acquisition Cost (WAC) of \$30,000 or more per year OR increase of \$3,000 or more in 12 month period (Brand Name Launch WAC Metrics and Brand Name WAC Increase Metric)
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Eligibility Metrics- High Costs

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Eligibility Metrics- High Costs (con't)

- Drugs with the highest per-patient spend
- Drugs with the highest patient out-of-pocket cost
- Drugs with the highest price increases (% and gross)
- Drugs that are reported to cause affordability issues for Marylanders
- Insulins



Enhancement Metrics

- Drugs that are Approved through an FDA Accelerated Approval Pathway
- Drugs that are the Only Drug in Class
- Drugs with the Highest Advertising Spend
- Drugs with the Longest Patent Extensions



Discussion

- Feedback from the Stakeholder Council

Next Steps

- Present to PDAB on November 28, 2022



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