

Cost Review: Additional Metrics for Identifying Potential Drugs

August 22, 2022

PDAB Staff



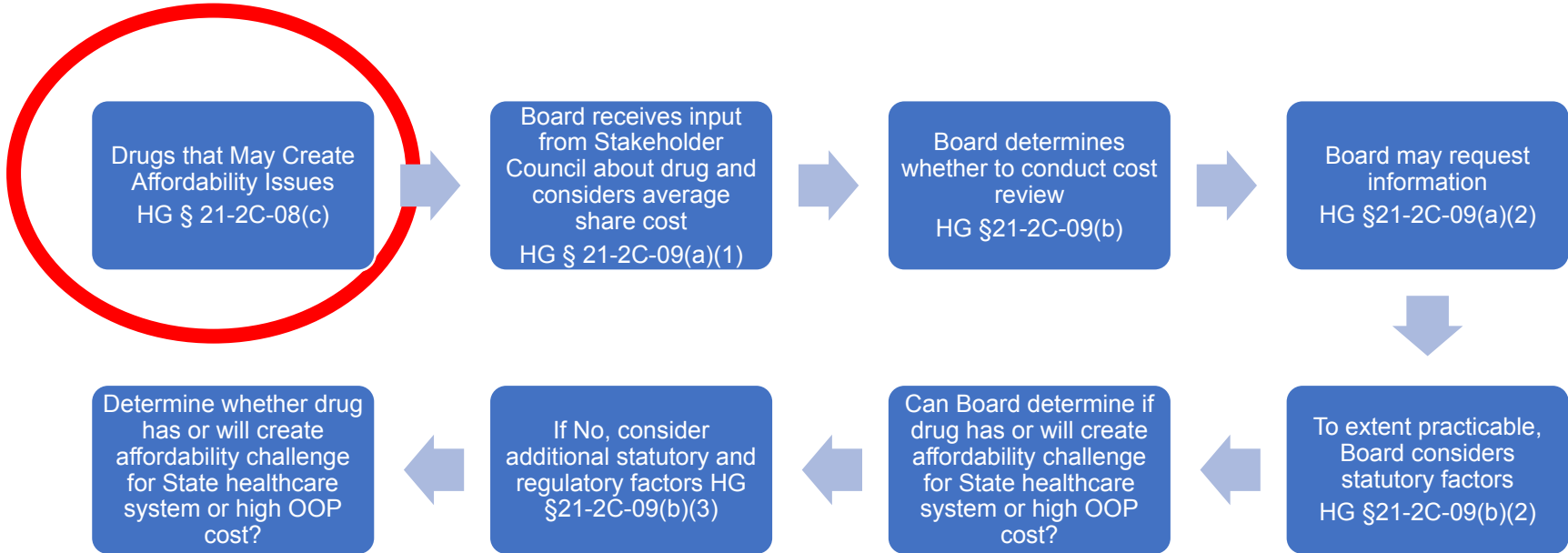
MARYLAND
Prescription Drug Affordability Board

Agenda

- Overview of Identifying Drugs that are Eligible for the Cost Review
- Potential Metrics



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



Identifying Drugs Eligible for Cost Review

- The first step of our process is to identify the universe of drugs that are eligible to be selected for the 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”



Identifying Drugs Eligible for Cost Review: Legislative Metrics

- Brand name drugs with launch WAC of \$30,000 or more per year OR increase of \$3,000 or more in 12 month period
- Biosimilar drugs with WAC that is not at least 15% lower than reference biologic
- Generic drugs with WAC of \$100 for 30 days AND increase by 200% or more during immediately preceding 12-month period



Identifying Drugs Eligible for Cost Review: Additional Metrics

- The Board can select additional metrics to identify drugs that may be eligible for cost reviews
- These metrics can supplement the legislative metrics to ensure that all drugs that may be causing affordability issues are eligible for cost reviews



Suggested Options for Additional Metrics

- 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 prices increases (% and gross)
- Drugs that are reported to cause affordability issues for Marylanders



Additional Metrics from Public Comment

- 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



Highest Overall Spend

- We can use the MCDB to identify the drugs with the highest overall spend in the state
 - Likely identifies high-volume and high-cost drugs
- Example metric:
 - Top 100 NDCs by Gross Spend for Total APCD, Medicare, Medicaid, and Commercial



Highest Per-Patient Spend

- We can use the MCDB to identify the drugs with the highest per-patient spend in the state
 - Likely identifies high-cost drugs
- Example metric:
 - Top 100 NDCs for per-patient spend for the APCD, Medicaid, Medicare, and Commercial



Highest Out-Of-Pocket Cost

- We can use the MCDB to identify the drugs with the highest patient OOP spend in the state
 - Likely identifies drugs with the highest patient burden
- Example metric:
 - Top 100 NDCs by total OOP costs
 - Top 100 NDCs by 90th percentile patient-level OOP spending per year



Highest Price Increases

- We can use the WAC to identify the drugs with the price increases over time
 - Likely drugs with the highest patient burden
- Example metric:
 - Top 100 NDCs by highest annual % increase; 5 year % increase
 - Top 100 NDCs by highest annual price increase; 5 year price increase



Patient Reporting

- We can develop a process for Marylanders to report drugs that are causing affordability challenges
- Example metric:
 - NDCs of drugs that are reported by Marylanders to cause affordability issues ranked by the number of complaints



Accelerated Approval

- We can use the list of drugs approved under FDA accelerated approval pathways
- Example metric:
 - NDCs of drugs approved under FDA accelerated approval pathways based on surrogate endpoints



Drugs that are the Only Drug in Class

- We can identify drugs that are the only drug in their class
- Example Metric:
 - NDCs of drugs approved under FDA accelerated approval pathways based on surrogate endpoints



Drugs with the Highest Advertising Spend

- We can use publicly advertising data to identify drugs that have the highest spending on advertising
- Example metric:
 - Top 25 drugs by publicly available advertising spend



Drugs with the Most Patent Extensions

- We can review patents listed in the Orange Book and the Purple Book to identify drugs with the most patent extensions
- Example metric:
 - Top 25 with the most patent extensions



Next Steps

- Feedback from Board, Stakeholder Council, and public
- August 22, 2022- Topic Presented to PDASC for consultation
- September 26, 2022- Board decide on additional metrics





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Insulins

- We can include all insulin drugs
- Example metric:
 - All insulin drugs

