



Themes from Expert Roundtable on Medicaid Policy on High-Cost Drugs

—
Medicaid and CHIP Payment and Access Commission

Amy Zettle and Chris Park

Overview

- Background
 - Medicaid Drug Rebate Program
 - High-cost specialty drugs
- Roundtable themes
 - Key challenges
 - Potential policy options
- Next steps

Background

- Medicaid Drug Rebate Program (MDRP)
- Supplemental rebates
- Commission's past work on prescription drugs
 - 2018 and 2019 recommendations would improve operations of the MDRP, increase rebates, and provide states some additional flexibility in coverage

Specialty Drugs

- There is no consistent definition of specialty products
- Unique attributes can include:
 - complex manufacturing and handling requirements,
 - lack of clinical alternatives,
 - high up-front costs,
 - distribution in a medical setting, and
 - less clinical evidence.

Spending on Specialty Drugs

- 12 of the top 20 Medicaid drugs by spending are specialty drugs
- Specialty drug spending is growing at a faster rate than traditional drugs
 - Cost of traditional drugs fell by 2.6 percent but increased for specialty drugs by 6.1 percent between 2017 and 2018
- This trend is expected to continue
 - Specialty drugs are expected to represent 50 percent of Medicaid drug spending by 2020
- Pipeline includes cell and gene therapies
 - 40 to 50 cell and gene therapies are expected by 2030

Expert Roundtable

- The roundtable included federal and state officials, legal experts, drug payment experts, Medicaid managed care organizations (MCOs), drug manufacturers, patient advocates, and providers.
- The roundtable sought input from participants on the following topics:
 - defining the challenges of specialty drugs;
 - reviewing current state models; and
 - exploring the range of policy solutions that could manage Medicaid specialty drug spending.

Roundtable Themes

Key Challenges

- High list price
 - Mandatory rebates may not be sufficient to manage state spending for certain high-cost drugs
 - Agreement that list price should reflect a drug's value and incentivize innovation
 - Monopoly pricing allows manufacturers to account for discounts or rebates offered
- Lack of clinical evidence
 - Focus on accelerated approval drugs and broader indications than what was studied in the clinical trial
 - Concerns related to safety, efficacy, cost and value

Key Challenges (cont.)

- Lack of competition
 - Products with no clinical alternatives are the hardest to manage for all payers
 - Concern that states have less negotiating power because of their inability to exclude coverage
- Predictability and budgetary constraints
 - Predicting Medicaid drug spending based on the pipeline can be challenging for states and MCOs
 - Most states are required to balance their budgets; increased spending could result in significant trade-offs for states

Limitations of Current Models

- Requires significant staffing and resources to develop and implement alternative payment models
- Largely limited to drugs with multiple drugs in a class
- Outcomes-based models are limited by the available data
- Concern that rebates associated with any model would already be accounted for in the list price

Roundtable Themes – Potential Policy Options

Potential Policy Options

- More information about drugs in pipeline
 - CMS could disseminate information to states before a drug's launch
- Differential mandatory rebates
 - Change rebate amounts to create incentives for manufacturers to provide evidence or to lower launch prices
- Increased federal match
 - Increase match for certain high-cost specialty drugs to help reduce the budgetary burden on states

Potential Policy Options (cont.)

- Closed formulary
 - Exclude coverage for a targeted set of drugs (e.g., combination therapies)
 - Change medical necessity to allow more flexibility in coverage (e.g., drugs with less clinical evidence)
- Pay over time
 - Paying over several years could help make spending more manageable and predictable
- Value-based pricing
 - Entity to establish value-based price that could be used to negotiate rebates or establish market price

Potential Policy Options (cont.)

- Risk pools
 - National level risk pool for certain drugs to spread risk across states
 - Multi-payer risk pool to spread costs across all payers
- MDRP carve-out
 - Carve out subset of drugs (e.g., gene therapy) from MDRP to apply targeted set of policy options

Next Steps

- Is Commission interested in any of the potential policy options?
- What types of additional information would be needed to move forward?



Themes from Expert Roundtable on Medicaid Policy on High-Cost Drugs

—
Medicaid and CHIP Payment and Access Commission

Amy Zettle and Chris Park