MACPAC

Medicaid Coverage of New and High-Cost Drugs

Medicaid and CHIP Payment and Access Commission

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Overview

- Issues and policy options related to coverage of complex and high-cost drugs
  - Coverage requirements for new drugs
  - Accelerated approval drugs
  - High-cost drugs
  - Rebate cap
- Next steps

Coverage of New Drugs

Coverage Requirements for New Drugs

- State Medicaid programs generally must cover all covered outpatient drugs upon approval by the Food and Drug Administration (FDA)
- State Pharmacy & Therapeutics (P&T) committees determine coverage guidelines and formulary placement for new drugs
  - Coverage guidelines may be based on drug's label, studies conducted for FDA
  - Generally look at safety, relative effectiveness, and cost
- P&T committee review can be time and resource intensive

Coverage Requirements for Other Federal Payers

- Medicaid coverage requirements is unique among federal payers
- Medicare Part D Plans – Decision must be made within 180 days, 90 days for protected classes
  - New drugs in protected classes are placed on formulary if no decision after 90 days
- Qualified Health Plans – Decision within 180 days

Allow Medicaid Programs a Grace Period

- Medicaid could adopt a grace period for coverage similar to other federal payers
  - Could align with Medicare Part D (180 days) or protected classes (90 days)
- Would give state Medicaid programs time to make informed clinical decisions
- May pair with a policy to require formulary placement after a certain number of days

Considerations

- Could affect access for beneficiaries
- Manufacturers would likely oppose as Medicaid's grand bargain is unique among federal payers
- Once a drug is on the formulary, it can still be subject to restrictions

Accelerated Approval Drugs

Accelerated Approval Drugs

- FDA has several ways to speed up certain drug approvals
- Accelerated approval pathway allows drug to be approved based on a surrogate endpoint
  - Surrogate endpoint is a proxy for a clinical benefit
  - Manufacturer is required to conduct studies after approval to confirm a clinical benefit

Cost and Effectiveness

- Accelerated approval drugs are generally expensive
  - 27 drugs granted accelerated approval since 2014
  - Total Medicaid gross spending (before rebates) was $686 million in fiscal year (FY) 2017
  - In FY 2017, Medicaid spent over $6,600 per claim on these drugs
- Questions about validity of surrogate endpoints
- Safety concerns for accelerated approval drugs

Policy Options

- Value-based arrangements
  - Could be mandatory or merely encouraged
- Higher statutory rebate
  - Additional rebate could be linked to completion of postapproval study or other real-world evidence
  - Could mitigate the cost to Medicaid of covering these drugs
- Flexibility to exclude coverage or further restrict use

Considerations

- Higher rebate could provide an incentive to complete postapproval studies
- Value-based arrangements may not be feasible for all drugs
- A higher statutory rebate would be opposed by manufacturers
- Could lead to high launch prices or potential cost shift to other payers
- Coverage flexibility may affect access
  - Many accelerated approval drugs are not controversial and offer benefits to patients
  - Could undermine the structure of the rebate program

High-Cost Drugs

Medicaid Drug Spending Trends

- Since FY 2014, the proportion of claims attributable to brand drugs has decreased but proportion of spending has increased
  - Share of total claims went from 18.9 percent in FY 2014 to 16.5 percent in FY 2017
  - Share of total gross spending (before rebates) went from 76.6 percent in FY 2014 to 80.8 percent in FY 2017
- Since FY 2014, the average spending on a brand drug increased 40 percent
  - $294 per claim in FY 2014 to $411 per claim in FY 2017
- This increase is due in part to an increase in the use and price of high-cost drugs

Medicaid Claims and Gross Spending on Drugs over $1,000 per Claim

Fiscal year	Drug claims (millions)	Gross spending ($ billions)	Spending per claim	Percent of total claims	Percent of total spending
2014	5.2	$13.4	$2,597	0.9%	31.1%
2015	6.5	$18.4	$2,822	1.0%	34.4%
2016	7.3	$23.9	$3,252	1.0%	39.2%
2017	8.8	$27.8	$3,174	1.2%	43.7%

Notes: Includes federal and state funds. Gross expenditures are before the application of rebates. To assign brand and generic status, we linked the state drug utilization data to the Medicaid drug product data from CMS using the National Drug Code, the universal product identifier for drugs. Excludes drugs that could not be matched to the drug product data. Virginia data were corrected for an apparent error in fee-for-service spending in the second quarter of 2014 and $294 million in anomalous spending was excluded in 2017. Does not include Medicare Part D clawback payments.
Source: MACPAC analysis of Medicaid state drug rebate utilization and product data as reported by states of July 2018.

High-Cost Drugs

- Wide variety of high-cost drugs includes both widely used medications and orphan drugs
- Spending for high-cost drugs projected to increase in future
  - Specialty drug trends are expected to exceed that for traditional drugs
  - Specialty and orphan drugs are large proportion of new drug pipeline

Policy Options

- Value-based arrangements
  - Could be mandatory or merely encouraged
  - Subscription model
- Higher statutory rebate
  - Could be tied to independent assessment of economic value
- Flexibility to exclude coverage or further restrict use

Considerations

- Value-based arrangements may not be feasible for all drugs
- A higher statutory rebate would be opposed by manufacturers
- Could lead to high launch prices or potential cost shift to other payers
- Coverage flexibility may affect access
  - High-cost drugs may be the standard of care

Cap on Medicaid Rebates

Rebate Cap

- Total rebates are capped at 100 percent of a drug's average manufacturer price
- Generally applies to drugs that have a substantial inflationary rebates due to large price increases
- Can limit a manufacturer's incentive to moderate price increases once the cap is reached

Remove the Rebate Cap

- Policymakers have recently proposed removing the cap
- Will result in higher Medicaid rebates
- More downward pressure on price increases
- Would allow any other rebate increase to achieve full effect

Considerations

- Removing cap would essentially require some manufacturers to pay Medicaid for using their drug
- Larger rebates would be opposed by manufacturers
- Could lead to higher launch prices or cost shift to other payers
- Does not address all high-cost drugs, only those with large price increases over time

Next Steps

- Commissioner feedback on options that merit further research and analysis
  - What data or analysis would be helpful in making decisions on potential recommendations
- Commissioner feedback on goals in this subject area
- Future MACPAC work
  - Comparison of Medicaid coverage and utilization management tools to other payers

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