

## Policy in Brief: A Quick Guide

**Purpose:** The purpose of a MACPAC Policy in Brief is to summarize an area of policy interest to states and Congress where MACPAC has made recommendations or has collected a body of evidence. A good Policy in Brief reflects an issue that is of timely interest to Congress or the states. In addition, the Policy in Brief format can be a good option to quickly summarize state policy compendium in an easily digestible format.

**Audience:** The primary audience for these briefs are congressional or state staff who need a quick read on an issue.

**Format:** These briefs are intended to act as one-pagers (front and back). Depending on the design and graphic elements, they may run between 650 to 850 words. They typically contain a quick summary, background, and a recommendations section if applicable.

February 2024 | Drugs

# Policy in Brief



## High-Cost Drugs and the Medicaid Program: MACPAC Evidence and Recommendations

### Summary

*While Medicaid drug spending is growing, it is increasingly driven by high-cost specialty drugs.*

In fiscal year (FY) 2021, Medicaid spent approximately \$80.6 billion on outpatient prescription drugs and collected \$42.5 billion in rebates, bringing net drug spending to \$38.1 billion. In FY 2021, drugs over \$1,000 per claim accounted for less than 2 percent of utilization but more than half of Medicaid spending. From 2018 to 2021, the average cost of a brand drug has increased almost 50 percent from \$430.51 to \$651.16, reflecting the introduction of new, high-cost specialty drugs (Table 1). In December 2023, the U.S. Food and Drug Administration (FDA) approved two cell-based gene therapies, Casgevy and Lyfgenia, for the treatment of sickle cell disease. These two therapies have prices of \$2.2 and \$3.1 million respectively for the course of treatment (Kolata 2023).

MACPAC's work has been focused on how to address states' concerns about the growing costs associated with specialty drugs, as well as how to ensure that beneficiaries who could benefit from these new therapies would still have access to them.

**TABLE 1. Medicaid Gross Drug Spending, by Brand versus Generic Status, FYs 2018–2021**

Fiscal year	Gross brand drug spending per claim	Gross generic drug spending per claim	Gross total drug spending per claim
2018	\$430.51	\$17.77	\$83.76
2019	486.71	18.68	92.88
2020	553.38	19.91	100.75
2021	631.16	20.82	111.10

Notes: Includes federal and state funds. Gross expenditures are before the application of rebates. Does not include Medicare Part D clawback payments. To assign brand and generic status, we linked the state drug utilization data to the Medicaid drug product data from the Centers for Medicare & Medicaid Services using the National Drug Code, the universal product identifier for drugs.

Source: MACPAC, 2022, analysis of Medicaid state drug rebate utilization and product data as reported by states as of September 2022.

### Background

Under the Medicaid Drug Rebate Program (MDRP), drug manufacturers must provide Medicaid rebates, but in exchange, states must generally cover all FDA-approved drugs. This coverage requirement can limit states' ability to manage utilization and spending for high-cost drugs.

Additionally, an increasing number of high-cost drugs are being approved through the accelerated approval pathway on the basis of a surrogate endpoint that has not yet demonstrated a clinical benefit. States have concerns about having to cover and pay high prices for drugs that do not have a verified clinical benefit.

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**By the numbers...**

In FY 2021

- \$80.6 billion** was spent on outpatient prescription drugs
- \$42.5 billion** was collected in rebates, equaling a total of
- \$38.1 billion** in net spending

Drugs are likely to have lower rebates than other brand drugs launch at a high price but do not increase prices they are likely to have lower inflationary rebates.

subset of specialty drugs that are receiving significant rebates and potential as durable (i.e., having long-term benefit) or gene therapies have list prices over \$1 million for the

2020 identified 45 cell or gene therapies indicated for therapies indicated for adults in Phase III or later (e.g., a new

very five children in the U.S. are Medicaid beneficiaries, of particular importance for Medicaid. While Medicaid is strain Medicaid budgets.

gene therapies can create significant budget volatility if uncertainties about whether these therapies will national drug benefits for cell and gene therapies that iv for new coverage, payment, or rebate requirements e MDRP for all other outpatient drugs.

id innovation is exploring a new Medicaid cell is negotiate outcomes-based contracts with tes greater rebates should a therapy not achieve the odel is expected to begin in 2025.

balance states' concerns about the high cost of drugs without a verified clinical ing the Medicaid rebates on accelerated approval drugs until the clinical benefit daily, allowing states to implement a Medicare coverage with evidence requirement clinical benefits of a drug for populations prevalent in Medicaid. MACPAC's litigation to cover these drugs.

ations related to high-cost drugs:

ts that Congress amend sections of the Social Security Act to allow states to drugs based on coverage with evidence development requirements implemented tion. In addition, the Commission recommends that Congress amend to stent care contracts conform to the state's policy with respect to any exclusion ifferent drug based on coverage with evidence development requirements

that Congress increase the minimum rebate percentage on drugs approved that manufacturer has verified the clinical benefit. The Commission also nition. In addition, the Commission recommends that Congress amend to stent care contracts conform to the state's policy with respect to any exclusion ifferent drug based on coverage with evidence development requirements

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### Reference

Kolata, G. 2023. F.D.A. approves sickle cell treatments, including one that uses CRISPR. *New York Times*, December 8. <https://www.nytimes.com/2023/12/08/health/sickle-cell-crispr.html>

### Further reading

[Addressing High-Cost Specialty Drugs](#)

[Strengthening Evidence under Medicaid Drug Coverage](#)

[Trends in Medicaid Drug Spending and Rebates](#)

[Priority Pipeline Specialty Drugs for Medicaid](#)

### About MACPAC

The Medicaid and CHIP Payment and Access Commission (MACPAC) is a non-partisan legislative branch agency that provides policy and data analysis and makes recommendations to Congress, the Secretary of the U.S. Department of Health and Human Services, and the states on a wide array of issues affecting Medicaid and the State Children's Health Insurance Program (CHIP).

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