mhpa Medicaid Health Plans of America

Access & Sustainability:

Public Policy Considerations for Addressing High-Cost Drugs in Medicaid

The Food and Drug Administration (FDA) approved 55 novel drugs in 2023 across a range of diseases and conditions.[i] While innovative, some of these new medicines are expensive. In addition to traditional medicines for chronic or acute conditions, more curative single dose treatments are now reaching the market as game-changers for the treatment of diseases with significantly high price tags. In December 2023, for example, the FDA approved Casgevy and Lyfgenia, two potentially curative treatments for sickle cell disease with list prices of $2.2 million and $3.1 million respectively. These are important breakthroughs. However, pharmaceutical manufacturer pricing strategies have created significant access challenges, particularly for programs such as Medicaid that serve vulnerable populations and have limitations based on state budgets.

Medicaid & Prescription Drugs

Prescription drug costs have become a major source of spending for state Medicaid programs. In fiscal year (FY) 2021 Medicaid spent $38.1 billion (net) on prescription drugs. The Centers for Medicare & Medicaid Services (CMS) Office of the Actuary predicts the introduction of new drugs will push spending growth upward across payers from 2027-2032.[ii] **Notably, drug spending trends in Medicaid will likely increase being driven by high-cost specialty drugs, including cell and gene therapies.** Under the Medicaid Drug Rebate Program (MDRP), participating drug manufacturers provide the Medicaid program with rebates in exchange for state coverage of almost all FDA-approved drugs, with some statutory exceptions, referred to as covered outpatient drugs. These rebates are shared between the states and the federal government. Some states also require supplemental rebates for preferential placement on state preferred drug lists (PDLs).

Federal law sets overarching requirements for state Medicaid coverage of certain benefits but provides states some flexibility related to operational aspects of coverage and reimbursement, such as whether a therapy is covered under the medical or pharmacy benefit. Generally, a drug delivered through the pharmacy would be subject to outpatient pharmacy coverage policies. However, while a physician-administered drug is most likely covered under the medical benefit, state policy could instead require coverage for certain physician-administered drugs under the pharmacy benefit.

The Role for Medicaid Managed Care Organizations

As of 2021, more than 70% of nationwide Medicaid prescriptions have been paid by Medicaid managed care organizations (MCOs).[iii] In states with managed care, states can either include the pharmacy benefit within Medicaid MCO contracts (known as a carved-

in benefit) or they can manage the pharmacy benefit separately through a fee-for-service (FFS) model that is administered by the state or another entity known as a pharmacy carve-out.

States that include the pharmacy benefit in Medicaid MCO contracts may also require MCOs to adhere to a unified formulary and/ or PDL to create uniformity in the pharmacy benefit across MCOs. In some states, Medicaid MCOs may also negotiate supplemental rebates for some or all drugs.

Most states that contract with MCOs include Medicaid pharmacy benefits in the state-MCO contract. As of July 2022, of the 41 states that contracted with MCOs, only six states used a pharmacy carve-out approach, and one used a hybrid model. One survey of state Medicaid programs found that nine states had implemented a uniform PDL for all drug classes and an additional seven had a uniform PDL in place for at least some drug classes.[iv] Some of the specific drug classes carved out from MCO capitation payments included hemophilia products, spinal muscular atrophy agents, hepatitis C drugs, and certain behavioral health drugs.

Given the uncertainties regarding when a new drug enters the U.S. market, Medicaid MCO contracts that are negotiated months prior to the contract year may not necessarily account for new and expensive products in their negotiated capitation rate. With risk unable to be adequately captured in rate setting, even a single claim for a single member for one high-cost novel drug can have a significant financial impact for Medicaid MCOs.

Medicaid Drug Spending - Drivers & Trends

Since FY 2019, prescription drug spending has increased every year with substantial drug price increases beyond the rate of inflation due to increasingly higher pharmaceutical manufacturer launch prices for new drugs. “Specialty drugs” (the term generally used for medicines that are complex to manufacture, distribute, and/or administer) are often very expensive and are a rapidly growing segment of Medicaid drug spending. Specialty drugs can include oral and self-injectable drugs and physician-administered infusions and may be covered under the medical or pharmacy benefit.

Given its role in financing coverage for high-need populations, Medicaid pays for a disproportionate share of some high-cost specialty drugs. Notably,

from 2010 to 2015, net spending on specialty drugs in Medicaid almost doubled, growing from $4.8 billion (25% of total net drug spending) to $9.9 billion (35% of total net drug spending).[v]

Novel cell and gene therapies are a subset of specialty drugs that involve the transfer of cellular and genetic material and target populations with rare diseases that have limited or no treatment options. Cell and gene therapies are extremely costly and are often only available through a limited number of qualified treatment centers.

Because more than two out of every five children are Medicaid beneficiaries, high-cost pediatric products are of particular importance for Medicaid with even a small number of patients potentially generating high drug spending. Cell and gene treatments for rare diseases that disproportionately affect children, such as hemophilia A and B and Duchenne muscular dystrophy, are in various stages of the drug pipeline. By 2025, the FDA anticipates approving 10 to 20 cell and gene therapies a year with spending expected to reach $25 billion annually over the next ten years.[vi] The Accelerated Approval (AA) pathway can help facilitate early access to these gene therapies, but this approach can also present unanticipated financial challenges for state Medicaid budgets and AA-approved therapies require continued monitoring for clinical effectiveness by pharmaceutical manufacturers.

Recent drug approvals for some non-specialty drugs are also impacting state coverage decisions and drug spending. With the launch of new medications for weight loss, several states require coverage of these medications for obesity treatment – traditionally a drug class that states have excluded from Medicaid coverage. **Medicaid utilization and gross spending on new drugs used for weight loss (GLP-1 agonists) have both increased rapidly in recent years, nearly doubling each year since 2019.[vii] This has resulted in GLP-1 agonists becoming the highest cost drug spend category in some states.**

State Medicaid Programs - Addressing Drug Costs

Prescription drug spending continues to be a priority focus of state Medicaid programs. The increasing number of high-cost specialty drugs reaching the market and their required coverage under the MDRP presents a significant challenge for state Medicaid programs that are unlikely to have factored these costs into their Medicaid budgets or in the capitation rates for Medicaid MCOs.

The December 2023 KFF Annual Survey of State Medicaid Programs found that over two-thirds of states reported new or expanded initiatives to contain prescription drug costs. Notably, over one-third of responding states reported working toward, implementing, or expanding value-based agreement efforts in FY 2023 or FY 2024. Other cost containment initiatives reported by states included policy changes related to approprate use of treatments and therapies, maximization of Medicaid rebates, carve-outs/carve-ins, and efforts specifically focused on specialty drugs.

MHPA Policy Position

MHPA is encouraged by the promising pipeline of novel and innovative medicines that bring hope to patients with current unmet needs; however, we remain concerned that high drug prices will persist as a significant barrier for patient access. **To facilitate patient access to appropriate treatment and to support the financial sustainability of the Medicaid program, MHPA recommends consideration of the following approaches to address rising prescription drugs costs in the Medicaid program with a focus on the increasing number of high-cost specialty drugs.**

PRINCIPLES

- **Appropriate access.** Beneficiaries should have timely access to treatments and therapies that are clinically appropriate, improve quality of life, and best meet their needs.
- **Financial sustainability.** Policies should consider and support the continued viability of state-Medicaid managed care partnerships and the long-term sustainability of the Medicaid program.
- **Beneficiary/Patient/Enrollee engagement**. Policies should support engagement of beneficiaries, their families, and caregivers to take into account their perspectives on care delivery, including issues of access and quality.
- **Transparency.** Transparency of drug costs are insightful for stakeholders and can help inform policy solutions to address high prices and to support patient access.

Approach	Description	MHPA Position (Proposed)
Ensure Safe and Appropriate Use of Therapies and Treatments	Processes that support safe and appropriate use can help ensure that medicines are providing maximum health benefit while minimizing health risk. Examples include prior authorization, quantity limits, and step therapy.	Support for processes that ensure safe and appropriate use to ensure therapies and treatments are used with the right population, at the right amount, and for the right duration.
Encourage Generic Drug & Biosimilar Utilization	A generic drug is identical (bioequivalent) to a branded drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use. A biosimilar has no clinically relevant differences to the biologic reference product in terms of safety, purity, and potency. Increased appropriate utilization of generic drugs and biosimilars supports a competitive marketplace, helping to lower drug prices and spending.	Support for efforts by Congress to ensure that patients have access to affordable generic drugs and biosimilars.
New to Market/ High-Cost Drugs - Mechanisms for utilization/drug cost data collection	Uncertainties about timing for when a new, high-cost drug enters the market (e.g., after the beginning of the contract period) and the lack of historical claims can present challenges for Medicaid MCO rate-setting. Mechanisms accounting for this uncertainty can facilitate access to these treatments while supporting Medicaid program stability.	Support for certain high-cost drugs to be non-risk to MCOs temporarily while utilization patterns and cost data is gathered for rate setting purposes.
High-Cost Drug Risk Corridor for High-Cost Drugs in Managed Care Contracts	Risk corridors allow for sharing profits or losses between states and health plans if aggregate spending falls above or below predetermined thresholds.	Support for risk corridors that should be viewed in the context of other mechanisms and the full scope of rate setting arrangements unique to each state.
Federal Financial Support	Federal Medical Assistance Percentages (FMAPs) determine the amount of Federal matching funds for State Medicaid expenditures. Increased FMAP for certain high-cost drugs can help address the budgetary challenge for state Medicaid programs that are unlikely to have factored these costs into their Medicaid budgets or in the capitation rates for Medicaid MCOs.	Support for policies that would enhance the federal government's role in covering Medicaid costs for high-cost specialty drugs (e.g., enhanced FMAP).

[i]KFF, State Fact Sheets. Available at: https://www.kff.org/other/state-indicator/total-medicaid-mco-enrollment/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D

[ii]CMS website, available at: https://www.medicaid.gov/medicaid/program-information/medicaid-and-chip-enrollment-data/report-highlights/index.html

[i]https://www.fda.gov/media/175253/download?attachment

[ii]Jacqueline Fiore, Andrew Madison & John Poisal, Office of the Actuary, Centers for Medicare & Medicaid Services, National Health Expenditure Projections 2023–32 (June 12, 2024); available at: https://www.cms.gov/files/document/national-health-expenditure-projections-results-presentation.pdf.

[iii]Medicaid Managed Care Enrollment and Program Characteristics, 2021; available at: https://www.medicaid.gov/sites/default/files/2023-07/2021-medicaid-managed-care-enrollment-report.pdf.

[iv]Gifford K, Winter A, Wiant L, Dolan R, Tian M, Garfield R. How state Medicaid programs are managing prescription drug costs results from a state Medicaid pharmacy survey for state fiscal years 2019 and 2020. Kaiser Family Foundation. April 2020. Accessed August 3, 2021; available at: https://files.kff.org/attachment/How-State-Medicaid-Programs-are-Managing-Prescription-Drug-Costs.pdf.

[v]Congressional Budget Office, Prices for and Spending on Specialty Drugs in Medicare Part D and Medicaid, March 2019; available at: https://www.cbo.gov/system/files/2019-03/54964-Specialty_Drugs.pdf

[vi]Food and Drug Administration, Statement from FDA Commissioner Scott Gottlieb, M.D. and Peter Marks, M.D., Ph.D., Director of the Center for Biologics Evaluation and Research on new policies to advance development of safe and effective cell and gene therapies, (January 15, 2019); available at: https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-and-peter-marks-md-phd-director-center-biologics.

[vii]Kristin Niakan, MPH Brittany Schock, PharmD , Milliman white paper, GLP-1 agonists in Medicaid: Utilization, growth, and management; available at: https://www.milliman.com/-/media/milliman/pdfs/2024-articles/1-18-24_glp1-agonists-in-medicaid-utilization-growth-and-management.ashx.

[viii]Elizabeth Hinton et al., KFF, Amid Unwinding of Pandemic-Era Policies, Medicaid Programs Continue to Focus on Delivery Systems, Benefits, and Reimbursement Rates: Results from an Annual Medicaid Budget Survey for State Fiscal Years 2023 and 2024 (November 2023); available at: https://www.kff.org/report-section/50-state-medicaid-budget-survey-fy-2023-2024-pharmacy/.