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Medicaid Coverage of Physician-administered Drugs

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Overview

- Medicaid Drug Rebate Program (MDRP)
  - Coverage
  - Rebates
  - Payment
- Physician-administered drugs (PAD)
  - Coverage and rebates
  - Payment
  - Challenges
- PAD utilization and spending
- Next steps

Medicaid Drug Rebate Program (MDRP)

- Drug manufacturers must provide rebate in order for their products to be recognized for federal Medicaid match
- States must generally cover a participating manufacturer's products but may limit use (e.g., prior authorization, preferred drug list (PDL))
- Covered outpatient drugs are a subset of drugs
  - Generally a drug that can only be dispensed with a prescription, has been approved by the Food and Drug Administration (FDA), and manufacturer has a Medicaid rebate agreement

Statutory Rebates

- Based on average manufacturer's price (AMP)
- Single source and innovator, multiple source (e.g., brand drugs)
  - Basic rebate calculated as the greater of (a) 23.1 percent of AMP[1] or (b) AMP minus best price
  - Additional inflationary rebate
  - Line extension alternative rebate
- Non-innovator, multiple source (e.g., generic drugs)
  - Basic rebate is 13 percent of AMP
  - Additional inflationary rebate
- Prior to January 1, 2024, total rebate amount could not exceed 100 percent of AMP

[1] 17.1 percent of AMP for certain blood clotting factor drugs or drugs that are exclusively pediatric indications

Supplemental Rebates

- States can negotiate supplemental rebates with drug manufacturers in addition to the federal rebates
- Manufacturers pay these rebates to ensure that their products get placed on a state's PDL or have fewer restrictions on use
- Managed care organizations (MCOs) can negotiate their own rebates with manufacturers similar to state supplemental rebates

Payment to Pharmacies

- Fee-for-service (FFS) payment to pharmacies includes two components:
  - **Ingredient cost** covers the pharmacy's cost of acquiring a drug. States must pay on a basis actual acquisition cost (AAC)
  - **Dispensing fee** covers cost associated with the professional services to dispense the drug
- MCOs typically use a similar payment structure of ingredient cost and dispensing fee
  - Can use a pharmacy benefit manager (PBM) to negotiate payment terms with individual pharmacies
  - Do not have to pay on the basis of AAC
- Beneficiary may pay cost sharing

340B Program

- 340B program provides substantial discounts to specified facilities (e.g., federally qualified health centers)
- Creates a ceiling on the maximum price manufacturers can charge these covered entities
  - Ceiling price calculated by subtracting Medicaid federal rebate amount from AMP
- Drugs for Medicaid enrollees purchased under the 340B program are not eligible for federal rebates
  - Units of drugs purchased through 340B should be excluded from the state's rebate invoice to prevent duplicate discount
- Under FFS, 340B pharmacies are paid at acquisition cost (i.e., ceiling price)

Physician-administered Drugs

Physician-administered Drugs (PAD)

- A drug typically administered by a health care provider in a physician's office or other clinical setting
- PADs (other than vaccines) may also be eligible for the Medicaid statutory rebate, depending on payment method
  - If a state bills and pays for the drug as a part of a bundled service within certain settings (e.g., a clinic visit or hospital stay), then it cannot claim the statutory rebate
  - If a state makes a direct payment for the drug separately from the other services, it can claim the statutory rebate
  - May 2023 proposed rule would change the definition so that a drug included in a bundled payment for a service could be considered a covered outpatient drug if the drug and its itemized cost are identified separately on the claim

Payment for PADs

- Two components: (1) cost of drug and (2) cost of administration and professional services
- Payment for drug cost not required to be on the basis of AAC
  - Payment for drug cost often includes a mark-up
  - Payment to 340B providers not required to be at the 340B ceiling price

Methodology for drug cost	Number of states
ASP + 6 percent	23
Between ASP and ASP + 6 percent	11
ASP – other percent	2
Other benchmark (e.g., WAC, AAC, AWP)	14

Notes: ASP is average sales price. WAC is wholesale acquisition cost. AAC is average acquisition cost. AWP is average wholesale price. Many states utilize a lesser of methodology, which means that the state pays the lower of different formulas based on different benchmarks, for example, the state pays either ASP + 6 percent or usual and customary charges, depending on whichever is lower for that treatment. This table only counts a state once for its primary payment benchmark. Includes 49 states and the District of Columbia.
Source: MACPAC 2022, analysis of Medicaid state plans.

Coverage for Dually Eligible Beneficiaries

- PADs under Medicaid would generally be covered under Medicare Parts A (e.g., inpatient) and B (e.g., outpatient)
  - Medicare pays ASP plus 6 percent for most Part B drugs
- Medicaid pays the beneficiary's cost for Part A or Part B drugs (e.g., coinsurance)
  - For Part B drugs, beneficiaries generally face 20 percent cost sharing
- States can receive the full amount of the statutory MDRP rebate if they pay some or all of the cost sharing for a Part A or B drug
- Medicaid does not pay for Part D drugs or any associated cost sharing

Challenges in Managing PAD Use and Spending

- Payment amount generally higher under the medical benefit
  - Mark-up above acquisition cost
  - Waste may occur if entire amount of vial is not administered
- Claims processing limitations for medical claims can lead to less use of utilization management tools
- Cost and payment may vary by site of care
- Rebate collection can be more challenging
  - Lack of proper NDC field on medical claim form
  - Differences in billing units
  - PADs under bundled payment are not eligible for rebates
- Overlap between medical and pharmacy benefit

PAD Utilization and Spending

PAD Utilization and Spending Analysis

- Little information publicly available specific to Medicaid utilization of and spending for PADs
- Analyzed Transformed Medicaid Statistical Information System (T-MSIS) data for fiscal year 2021
  - Identified PADs and administration using list of procedure codes from Medicare Part B and publicly available PAD lists from five states
  - Included full-benefit, non-dually eligible beneficiaries and dually eligible beneficiaries
- Only captured drugs that were separately identified on outpatient claim (i.e., drug-specific procedure code)
  - Did not include drugs that may have been included in a bundled payment (e.g., inpatient hospital Diagnosis-related Group payment)
  - As such, this analysis is likely an undercount of PAD utilization and spending
- Spending is gross spending before rebates

PAD Drug Utilization and Spending, FY 2021

Population group	FYE (millions)	Drug			Administration		
		Percent PAD users	Claims (millions)	Spending ($ millions)	Percent PAD users	Claims (millions)	Spending ($ millions)
Full-benefit, non-dually eligible	**65.1**	**17.6%**	**70.2**	**$8,412.6**	**11.1%**	**26.8**	**$1,635.3**
Child	29.8	8.2%	8.0	$871.2	4.0%	2.8	$175.9
New adult[1]	19.3	22.1%	27.6	$2,998.6	14.1%	10.2	$617.0
Other adult[2]	10.6	29.9%	18.1	$1,638.2	21.3%	7.9	$440.6
Disabled	5.0	30.1%	15.4	$2,747.5	20.5%	5.7	$382.3
Aged	0.5	20.8%	1.2	$157.1	10.9%	0.3	$19.5
Dually eligible	**12.3**	**24.5%**	**36.3**	**$1,938.1**	**14.7%**	**9.9**	**$208.6**
Total	**77.4**	**18.7%**	**106.5**	**$10,350.7**	**11.7%**	**36.8**	**$1,843.9**

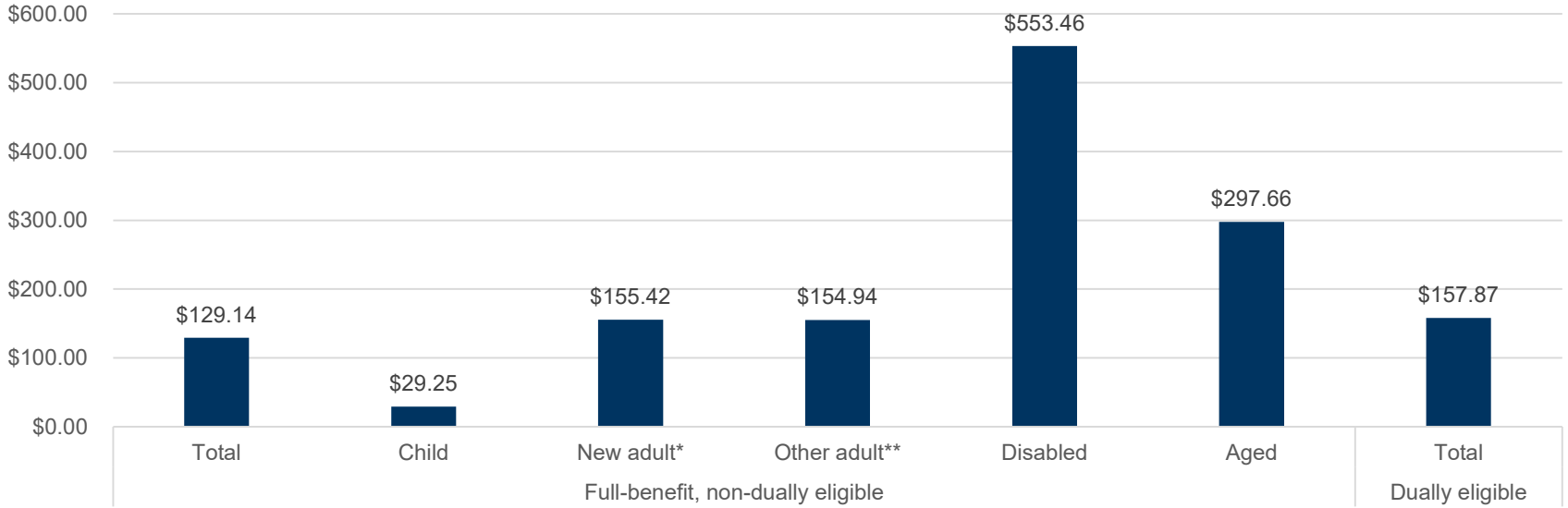
Notes: FYE is full-year equivalent. PAD is physician-administered drug. PADs were selected using HCPCS drug and administration codes used in Medicare Part B and publicly available lists of PADs from five states. Users were identified as those beneficiaries with at least one claim during the year. Spending is gross spending before rebates. Children and adults under age 65 who qualify for Medicaid on the basis of disability are included in the disabled category. Individuals age 65 and older eligible through an aged, blind, or disabled pathway are included in the aged category. Full-benefit enrollees excludes those reported by states in T-MSIS as receiving coverage of only family planning services, assistance with Medicare premiums and cost sharing, emergency services, or COVID-19 diagnostic products or testing-related services.

[1] Includes both newly eligible and not newly eligible adults who are eligible under Section 1902(a)(10)(A)(i)(VIII) of the Act.

[2] Includes adults under age 65 who qualify through a pathway other than disability or Section 1902(a)(10)(A)(i)(VIII) of the Act (e.g., parents and caretakers, pregnancy).

Source: MACPAC, 2023, analysis of T-MSIS data.

PAD Spending per FYE, FY 2021



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Source: MACPAC, 2023, analysis of T-MSIS data.

Next Steps

- Present roundtable findings at March meeting
- Commissioners should ask clarifying questions regarding the background information provided today
- Other feedback on particular topics or challenges related to PAD may be able to be addressed in the March session

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