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Themes from Expert Roundtable on Physician-administered Drugs

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Overview

- Background
  - Medicaid Drug Rebate Program (MDRP)
  - Policy differences between pharmacy and physician-administered drugs
- Roundtable themes
- Potential strategies
- Next steps

Background

Medicaid Drug Rebate Program (MDRP)

- Drug manufacturers must provide rebates 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))
- Drugs included in MDRP are known as covered outpatient 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

[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

340B Program

- 340B program provides substantial discounts to specified safety-net providers (e.g., federally qualified health centers (FQHCs))
- Creates a ceiling on the maximum price manufacturers can charge these covered entities
  - Ceiling price calculated by subtracting Medicaid federal rebate amount from AMP
- Although the 340B program sits outside of Medicaid, it interacts with Medicaid rebate and payment policy
  - Drugs for Medicaid enrollees purchased under the 340B program are not eligible for federal rebates
  - Medicaid pays providers for drugs purchased through the 340B program and dispensed to Medicaid beneficiaries

Physician-administered Drugs (PAD)

- A drug typically administered by a health care provider in a physician's office or other clinical setting and generally covered through the medical benefit
- PADs (other than vaccines) may be included in the MDRP, 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

Medicaid Drug Payment

Pharmacy

- Claim based on NDC code
- Ingredient cost and dispensing fee
- Fee for service (FFS) payment regulation requires ingredient cost payment at actual acquisition cost (AAC)
  - 340B providers at 340B ceiling price

PAD (medical benefit)

- Claim based on billing code (e.g., HCPCS or DRG)
- Cost of drug and administration fee
- No specific FFS payment regulations; states often pay a mark-up over acquisition cost
  - States can pay 340B providers similar to non-340B providers, including mark-up

Notes: NDC is National Drug Code. HCPCS is Healthcare Common Procedure Coding System. DRG is diagnosis related group.

Coverage for Dually Eligible Beneficiaries

Pharmacy

- Medicare Part D
- Medicaid does not pay for Part D drugs or any associated cost sharing

PAD (medical benefit)

- Medicare Part A or B
- Medicaid may pay premiums and cost sharing (20 percent in Part B)
- Medicaid can claim MDRP statutory rebate when paying cost sharing

Roundtable Themes

Expert Roundtable

- Milliman convened roundtable to discuss challenges associated with PADs and strategies to address them
  - Panel included federal and state officials, drug payment experts, Medicaid MCOs, drug manufacturers, beneficiary advocates, and providers
- Key themes
  - Tension between paying the mark-up on drug cost and overall payment adequacy
  - Challenges in utilization management under medical benefit
  - Provider role in managing spending
  - Administrative burden of value-based arrangements (VBA)
  - High-cost and limited access to cell and gene therapies

Drug Mark-up and Payment Adequacy

- Appropriate mark-up
  - Not all states pay a mark-up. There were a couple of state examples where they paid for PADs through pharmacy benefit at acquisition cost
  - Mark-up should reflect upfront risk posed for purchasing high-cost drugs, but the typical mark-up (e.g., 6 percent) could be excessive for very high-cost drugs
  - Providers rely on drug mark-up to subsidize costs not covered by the administration fee
- Drug payment could be tiered to limit mark-up on higher cost drugs
  - Administration fees need to be adjusted to account for difference in service intensity and costs across different treatments
- Manufacturer could consider a higher rebate so long as the additional amount was passed along to provider in form of higher payment

Drug Mark-up and Payment Adequacy, cont.

- Payment to 340B providers at 340B ceiling price could lower spending
  - Concern that 340B providers need the spread (difference between payment and 340B price) to provide charity care and community benefits
  - State example of paying a mark-up over the 340B ceiling price but limiting it to $600
  - Different payment tiers based on amount of charity care and community benefit provided
- Bundled payments often do not adequately cover drug costs, particularly for cell and gene therapies
  - Delay in updating DRGs to account for cost of new therapies
  - Payment outside of bundle is more likely to be at acquisition cost
- State not eligible for MDRP rebate if paid in a bundle

Challenges in PAD Utilization Management

- Greater challenges managing PADs under the medical benefit
  - Prior authorization processes are not as robust under the medical benefit and may be managed separately from pharmacy benefit
  - States do not always have staff and capacity to develop robust clinical guidelines for complex therapies
- Better integration between clinical teams under medical and pharmacy benefits would be beneficial
  - Some states are working towards integration, but it takes time and resources
- Split between medical and pharmacy benefit is confusing under a drug carve-out of managed care
- Concern over prior authorization turnaround time for PADs
  - PADs are more complex and require more information to get approval
  - Need for more standardization across FFS and managed care

Provider Role in Managing Spending

- Providers should have an active role in managing spending
  - Challenging because provider does not know the net cost after rebates
  - State could assign a cost ranking (e.g., 1 to 4 dollar signs) to indicate relative net cost
- Payment structures based on net cost tiers
  - Lower net cost drug would have a higher mark-up
- Shared savings with providers in which provider gets a bonus for using the most cost-effective drugs
- Concern about making cost a primary factor in provider prescribing decisions
  - Need a standardized and robust medical exceptions process, particularly for conditions that require more personalized treatment

Administrative Burden with VBAs

- VBAs and outcomes-based contracts (OBCs) are challenging to develop and administer
- Generally easier to enter into these arrangements with state Medicaid programs rather than MCOs
  - One agreement covers entire population and doesn't trigger best price concerns
- Administrative barriers include:
  - Burden and lack of resources to support outcomes tracking and reporting
  - Uncertainty on who bears responsibility for monitoring and tracking outcomes between state, MCOs, manufacturers, and providers
  - Lack of negotiating power under the MDRP

Cost of and Access to Cell and Gene Therapies

- Cell and gene therapies have extremely high-cost and access only at a small number of qualified treatment centers (QTC)
- Additional operational challenges because a QTC may not be in the state
  - Need for out-of-state provider agreements
  - Additional services such as transportation
- Provider administering cell or gene therapy may be different than the provider performing follow-up care
- Therapy cost and payment structures limit ability to use different providers
  - Current outpatient administration fees are not sufficient to cover risk of such specialized treatment
  - Smaller providers don't have upfront capital to purchase cell and gene therapies
  - Bundled payment may not sufficiently cover cost of therapy and discourage some providers from seeking QTC status

Potential Strategies

- Reduce mark-up on drug and increase payment on administration fee and other services
  - Could tier payment to providers based on drug characteristics (e.g., higher relative mark-up on drugs with lower net cost)
  - Could tie payment to 340B providers to amount of charity care and community benefit provided
  - Could implement payment incentives (e.g., shared savings) to encourage use of lower net cost products
- Remove high-cost drugs (e.g., cell and gene therapies) from bundled payment arrangements
- Unify prior authorization across pharmacy and medical benefits

Next Steps

- Staff can draft an issue brief highlighting the variety of challenges of PADs and potential payment and utilization management strategies
  - Strategies identified by the participants are all activities states could pursue under current authority
- Commissioner feedback on the findings of the roundtable and if there is additional work you would like to pursue in this area

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