January 26, 2023

Medicaid Coverage based on Medicare National Coverage Determination: Review of Draft Chapter and Recommendations for March Report

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Overview

- Chapter review
  - Medicaid Drug Rebate Program
  - Medicare Part B coverage
- Outstanding issues
  - Just allow CED requirements
  - State versus plan authority
- Draft recommendations
  - Options for recommendations
  - Rationale
  - Implications

Medicaid Drug Rebate Program (MDRP)

- Drug manufacturers must provide rebate for their products to be recognized for federal Medicaid match
- Generally required to cover all of a participating manufacturer's products for a medically accepted indication as soon as they have been approved by the FDA, but may limit use (e.g., prior authorization, preferred drug list (PDL))
- Different than federal requirements for plans sold on health insurance exchanges and Medicare Part D plans

Medicare Part B Drug Coverage

- Medicare Part B covers physician-administered drugs
- Medicare Part B must cover services, including drugs, that are reasonable and necessary
- CMS can develop coverage requirements that apply nationwide through the national coverage determination (NCD) process
- Coverage with evidence development (CED) is an option under an NCD
  - Under CED, CMS can link coverage of an item or service to participation in an approved clinical study or the collection of additional clinical data
  - Most recently applied to antiamyloid monoclonal antibodies for the treatment of Alzheimer's disease (e.g., Aduhelm)

Outstanding Issues

Just Allow CED Requirements

- Medicare NCDs have been issued fewer than 20 times on prescription drugs
  - Largely confirmed that coverage is allowed for the FDA-approved label indications or clarified off-label use
  - Coverage criteria not specific to a 65 and older population
- NCD without CED requirements are generally similar to states' medical necessity criteria
- CED requirements have only been applied to drugs three times, including the recent application to Alzheimer's disease drugs
- CED requirements are the key feature of a Medicare NCD that states do not explicitly have the authority to implement under current law

State versus Plan Authority

- Covered outpatient drugs are subject to MDRP rebate requirements when dispensed under managed care or fee for service (FFS)
- MDRP does not require that Medicaid plans modify their formularies to mirror a state's FFS drug coverage policies
  - Plans have the flexibility to establish their own prior authorization or PDL requirements (in accordance with statutory MDRP provisions)
- States have authority under managed care rules to require plans to follow specific coverage provisions, including drug coverage policies
  - Can specify in contract that plans must follow the state's drug coverage criteria
  - Can carve-out specific drugs from contract and cover under FFS

Draft Recommendations

Draft Recommendation 3.1 Options

1. Congress should amend § 1927(d)(1)(B) of the Social Security Act to allow states to exclude or otherwise restrict coverage of a covered outpatient drug based on a Medicare national coverage determination, including any coverage with evidence development requirements.
2. Congress should amend § 1927(d)(1)(B) of the Social Security Act to allow states to exclude or otherwise restrict coverage of a covered outpatient drug based on coverage with evidence development requirements implemented under a Medicare national coverage determination.

Draft Recommendation 3.2 Options

1. Congress should amend Section 1903(m)(2)(A)(xiii) to require the managed care contract conform to the state's policy with respect to any exclusion or restriction of coverage of a covered outpatient drug based on a Medicare national coverage determination, including any coverage with evidence development requirements.
2. Congress should amend Section 1903(m)(2)(A)(xiii) to require the managed care contract conform to the state's policy with respect to any exclusion or restriction of coverage of a covered outpatient drug based on coverage with evidence development requirements implemented under a Medicare national coverage determination.

Rationale

- Establish Medicare as a marker for acceptable coverage
- CED requirement can help develop evidence in a timely manner for the Medicaid population
  - Encourage recruitment of a more diverse Medicaid population in clinical trials and studies
  - Spur negotiation of outcomes-based contracts
- State decision – nothing prohibits a state from providing broader coverage than allowed under Medicare
- State should require MCOs to follow the state's decision on implementing a Medicare NCD or CED requirement
- NCD process includes formal periods for public comment

Implications – Federal and State

- Unlikely to affect many drugs but could still alleviate some budget pressure for states
- Decrease in federal and state spending to the extent utilization is reduced
- Provides another tool for states to use to obtain evidence of the clinical benefit
- CED requirements could provide additional leverage for states to negotiate outcomes-based contracts

Implications – Drug Manufacturers

- Drug manufacturers have opposed CED requirements under Medicare and commented that Medicaid coverage should not be restricted further than currently allowed under the MDRP
  - Randomized, controlled trials can significantly reduce access
  - Prospective studies provide broader availability than a clinical trial but could still result in reduced access
- CED requirements could provide an incentive for manufacturer to demonstrate the clinical benefit and get traditional approval from FDA

Implications – Beneficiaries and Providers

- Beneficiaries are generally opposed to CED requirements because such policies can reduce access to particular drugs
- CED requirement can restrict the number of people able to access the drug and could result in some beneficiaries not receiving a potentially beneficial treatment
  - Participation in a clinical trial can introduce additional burdens (e.g., travel) that disproportionately affect low-income populations
- CED requirements provide some benefit by providing additional information on the efficacy of the drug and occurrences of adverse events in the Medicaid population
- Providers could face some administrative burden in the collection and reporting of data

Next Steps

- Decide on recommendation options to bring back for vote on Friday
- Finalize recommendation language
- Feedback on draft chapter

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Vote on Recommendations for March Report

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Recommendation 3.1

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Recommendation 3.2

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