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Medicaid Coverage based on Medicare National Coverage Determination: Moving Towards Recommendations

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Overview

- Background
  - Medicaid Drug Rebate Program
  - Medicare Part B coverage
- Authority for states to follow Medicare national coverage determination
  - Draft recommendation
  - Rationale
  - Implications
- Next steps

Medicaid Drug Rebate Program (MDRP)

- Outpatient prescription drugs are an optional benefit that all states provide
- 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))
- May include physician-administered drugs
  - If a state makes a direct payment for the drug separately from the service, it can claim the statutory rebate

Medicaid Coverage Requirements

- Generally required to cover all of a participating manufacturer's products as soon as they have been approved by the FDA and enter the market
- Different than federal requirements for plans sold on health insurance exchanges and Medicare Part D plans, which can:
  - Exclude coverage of some drugs
  - Take 90 to 180 days to make coverage decisions

Medicare Part B Drug Coverage

- Part B covers drugs that are not usually self-administered by the patient and are furnished as part of a physician's services in an outpatient setting (e.g., physician-administered drugs)
- Medicare Part B must cover services, including drugs, that are reasonable and necessary
  - Generally covers drugs approved by the FDA for on-label indications or uses supported in CMS-approved compendia
- CMS can develop coverage requirements for drugs that apply nationwide through the national coverage determination (NCD) process

Medicare Coverage with Evidence Development

- Coverage with evidence development (CED) is an option under a 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
- CED has rarely been used for prescription drugs
- Most recent example of a CED for prescription drugs was for antiamyloid monoclonal antibodies for the treatment of Alzheimer's disease (e.g., Aduhelm)
  - Coverage is limited to participation in a clinical trial or other approved comparative study, depending on the FDA approval pathway

Authority for States to Follow Medicare NCD

- States may implement prior authorization or use a PDL to limit use of prescription drugs; however, it is not clear to what extent states can restrict coverage
- Medicaid directors have asked CMS for the flexibility to apply the same coverage requirements as Medicare
  - CMS does not explicitly have the authority to allow that request
- Any Medicaid coverage restrictions could be subject to legal challenge under MDRP coverage requirements
- A statutory change is needed to ensure states can implement coverage criteria based on a Medicare NCD, including CED requirements

Draft Recommendation

- 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.

Rationale

- Give states flexibility to align their coverage criteria with a federal determination of reasonable and necessary coverage
  - Commission has previously made recommendation to align Medicaid's time frame for coverage decisions with Medicare Part D and exchange plans
- This would not be a national coverage decision for Medicaid. Nothing prohibits a state from providing broader coverage than the Medicare NCD
- Allows for the collection of data on the clinical benefits of a drug in the Medicaid population
  - States could link CED requirement to an outcomes-based contract to obtain larger rebates if the drug does not provide the expected clinical benefit
- Medicare NCD process includes periods for public comment that allow the agency to solicit and address stakeholder concerns

Implications

- Unlikely to affect many drugs but could still alleviate some budget pressure for states
- Decrease in federal and state spending for drugs subject to CED requirements
- Beneficiaries and drug manufacturers have opposed CED requirements under Medicare and are concerned such policies reduce access to particular drugs
  - Collection of data under CEDs could provide important information on adverse events and the potential benefits and risks of treatment in specific subpopulations
  - CED requirements could provide an incentive for manufacturer to demonstrate the clinical benefit and get traditional approval from FDA
- Providers could face some administrative burden in the collection and reporting of data

Next Steps

- Feedback on draft recommendation language and rationale
- Decide whether to move forward with the recommendation
- Chapter and final recommendation for vote at January 2023 meeting

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