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Medicaid Coverage of Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease

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Overview

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  - Medicare Part B coverage
  - Accelerated approval drugs
- Aduhelm and antiamyloid monoclonal antibodies
  - Medicare coverage decision
- Implications for Medicaid
- Policy option
- 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))
- 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

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
  - Can exclude coverage of some drugs
  - 90 to 180 days to make coverage decisions

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
- Until January 1, 2024, total rebate amount cannot 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

Physician-administered Drugs

- A drug typically administered by a health care provider in a physician's office or other clinical setting
- Physician-administered drugs (other than vaccines) may also be eligible for the Medicaid statutory rebate
  - If a state bills the drug as a part of a bundled service within certain settings (e.g., a clinic visit or hospital stay) and pays for it as part of those services, then it cannot claim the statutory rebate
  - If a state makes a direct payment for the drug separately from the service, it can claim the statutory rebate

Medicare Part B

- 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)
- Part B drugs are paid at 106 percent of average sales price
  - Beneficiaries generally contribute 20 percent cost sharing
- 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 or Medicare administrative contractors (MACs) can make explicit coverage determinations
  - MACs are responsible for making local coverage determinations
  - CMS can develop coverage determination that applies nationwide

Coverage with Evidence Development

- Coverage with evidence development (CED) is an option under a national coverage decision (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
  - Used when there are outstanding questions about the service's health benefit in the Medicare population
- CED has rarely been used for prescription drugs

Accelerated Approval Drugs

- FDA can approve a drug based on a surrogate endpoint that is reasonably likely to predict a clinical benefit, but a clinical benefit has not been verified
- Manufacturer must conduct post-market clinical trial to confirm clinical benefit
  - Confirmatory trials often delayed; many take over five years to complete
- MDRP requires states to cover all FDA approved drugs, including accelerated approval drugs
  - States are concerned about being required to cover accelerated approval drugs when clinical benefit has not been verified

Aduhelm and antiamyloid monoclonal antibodies for the treatment of Alzheimer’s disease

Aduhelm

- In June 2021, FDA granted accelerated approval to Aduhelm for the treatment of Alzheimer's disease
  - Granted against the recommendation of the FDA's advisory committee
- Concerns over approval
  - Lack of clinical evidence
  - Safety concerns
  - Overly broad indication (subsequently narrowed to mild cognitive impairment or mild dementia due to Alzheimer's disease)
  - Lengthy timeline for confirmatory trials
- High cost – initial price was $56,000 per year for average patient
  - Subsequently reduced to $28,200 per year in December 2021

Aduhelm and Medicare

- Estimated that over 6 million people in the U.S. have Alzheimer's disease
- Vast majority are over 65 years old and likely to be covered by Medicare
- Aduhelm is an intravenous medication administered by physicians, so it would be covered under Medicare Part B
- At the current price, Medicare Part B spending and beneficiary cost sharing could total $1.5 billion per 50,000 beneficiaries who receive the product

Medicare CED for Aduhelm

- CMS initiated an NCD in July 2021
- Final decision in April 2022 was to cover Aduhelm under a CED policy
- CED applies to entire class of antiamyloid monoclonal antibodies for the treatment of Alzheimer's disease
  - Currently, Aduhelm is the only FDA-approved drug in the class but at least three other drugs are currently undergoing phase 3 clinical trials
- Coverage is limited to participation in a clinical trial or other approved comparative study, depending on the FDA approval pathway
  - Accelerated approval - randomized controlled trial conducted under an investigational new drug application
  - Traditional approval - CMS-approved prospective comparative studies
  - National Institutes of Health (NIH)-supported trials

Implications for Medicaid

Medicaid Coverage of Aduhelm

- States are required to cover Aduhelm and other antiamyloid monoclonal antibodies once approved
  - Non-dually eligible Medicaid beneficiaries: all medically accepted indications
  - Dually eligible beneficiaries: coverage is limited to the terms of the Medicare NCD (i.e., participation in a clinical trial or other approved comparative study)
    - Medicaid does not cover dually eligible beneficiaries when drug is not covered under the terms of the Medicare NCD
- Medicaid costs related to antiamyloid monoclonal antibodies:
  - Drug cost for non-dually eligible Medicaid beneficiaries
  - Medicare Part B premiums for dually eligible beneficiaries
  - Medicare Part B cost sharing (20 percent coinsurance) for full-benefit dually eligible beneficiaries and partial-benefit dually eligible beneficiaries under the Qualified Medicare beneficiary (QMB) program

Number of Medicaid Enrollees with Diagnosis of Alzheimer's Disease or Mild Cognitive Impairment, CY 2019

Group	Low population estimate (both Alzheimer's disease and mild cognitive impairment)	High population estimate (either Alzheimer's disease or mild cognitive impairment)
Non-dually eligible	**1,027**	**59,564**
Dually eligible	**23,530**	**649,753**
Full dual	21,764	599,875
Partial – QMB	891	26,090
Partial – Other	875	23,788
Total	**24,557**	**709,317**

Notes: QMB is Qualified Medicare beneficiary. Dually eligible status was assigned using dual-eligible indicators from Medicare eligibility records. Low population estimate includes individuals who had at least one claim with a diagnosis of Alzheimer's disease and one claim with a diagnosis of mild cognitive impairment during the year. High population estimate includes individuals who had at least one claim with a diagnosis of Alzheimer's disease or one claim with a diagnosis of mild cognitive impairment during the year. Because we used only diagnoses from Medicare fee-for-service claims to identify the relevant conditions, the count of dually eligible beneficiaries is understated.
Sources: MACPAC, 2022, analysis of T-MSIS data as of December 2020 and Medicare data from the Medicare Enrollment Database, Common Medicare Environment, and Medicare Common Working File.

Potential Medicaid Spending for Antiamyloid Monoclonal Antibodies for Non-dually Eligible Beneficiaries

Drug cost	Gross Medicaid Spending ($ Millions)[1]	
	Low population estimate (both Alzheimer's disease and mild cognitive impairment)	High population estimate (either Alzheimer's disease or mild cognitive impairment)
Low price ($28,200 per year)	$29.0	$1,679.7
High price ($56,000 per year)	$57.5	$3,335.6

Notes: Low population estimate includes individuals who had at least one claim with a diagnosis of Alzheimer's disease and one claim with a diagnosis of mild cognitive impairment during the year. High population estimate includes individuals who had at least one claim with a diagnosis of Alzheimer's disease or one claim with a diagnosis of mild cognitive impairment during the year.
[1] Gross Medicaid spending represents payment for the drug before the application of rebates.
Sources: MACPAC, 2022, analysis of T-MSIS data as of December 2020 and Medicare data from the Medicare Enrollment Database, Common Medicare Environment, and Medicare Common Working File.

Potential Medicaid Spending on Antiamyolid Monoclonal Antibodies for Dually Eligible Beneficiaries

- Part B cost sharing (gross spending before rebates)
  - Low-price scenario ($28,200 per year): $127.8 million (low population estimate) to $3.5 billion (high population estimate)
  - High-price scenario ($56,000 per year): $253.7 million (low population estimate) to $7.0 billion (high population estimate)
- States get full Medicaid rebate, thus net spending after the application of rebates on Part B cost sharing may not be significant; could create a cashflow issue
- Increase in Part B premiums attributable to these drugs
  - CMS Office of the Actuary reexamination of 2022 Part B premium estimated monthly premium increases between $0.10 and $9.80 depending on price and utilization assumptions
  - States could spend between $13 million and $1.3 billion for the premium increase

Potential Policy Option

- Medicaid directors have asked for CMS to allow states the flexibility to apply the same coverage requirements as Medicare
- CMS does not explicitly have the authority to allow that request
- Any coverage restrictions could be subject to legal challenge under MDRP coverage requirements
- Commission could recommend a statutory change to allow states to implement coverage criteria based on a Medicare NCD

Next Steps

- Feedback on potential policy option
- Interest in potential recommendation
- Any additional information needed

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