NC Medicaid
Outpatient Pharmacy
Prior Approval Criteria
Aduhelm Injection

Medicaid and Health Choice
Effective Date: April 1, 2022

Therapeutic Class Code: H1H

Therapeutic Class Description: Amyloid Directed Monoclonal Antibody

Medication
Aduhelm Injection™

Eligible Beneficiaries
NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

NC Health Choice (NCHC) beneficiaries, ages 6 through 18 years of age, shall be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified. **EPSDT does not apply to NCHC beneficiaries**.

EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of Age

42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product, or procedure
a. that is unsafe, ineffective, or experimental/investigational.
b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

a. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
b. IMPORTANT ADDITIONAL INFORMATION about EPSDT and prior approval is found in the NCTracks Provider Claims and Billing Assistance Guide, and on the EPSDT provider page. The Web addresses are specified below.

NCTracks Provider Claims and Billing Assistance Guide:
https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html

EPSDT provider page:
https://medicaid.ncdhhs.gov/medicaid/get-started/find-programs-and-services-right-you/medicaid-benefit-children-and-adolescents

Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Beneficiaries ages 6 through 18 years of age

EPSDT does not apply to NCHC beneficiaries. If a NCHC beneficiary does not meet the clinical coverage criteria within **the Outpatient Pharmacy prior approval** clinical coverage criteria, the NCHC beneficiary shall be denied services. Only services included under the Health Choice State Plan and the DMA clinical coverage policies, service definitions, or billing codes shall be covered for NCHC beneficiaries.

Criteria for Coverage:

1. Beneficiary has mild cognitive impairment (MCI) due to Alzheimer's disease or has mild Alzheimer's dementia as evidenced by all of the following:
    a. Clinical Dementia Rating (CDR)-Global Score of 0.5; **AND**
    b. Objective evidence of cognitive impairment at screening; **AND**
    c. Mini-Mental Status Exam (MMSE) score between 24 and 30 (inclusive) OR equivalent tool indicating MCI or mild dementia (NOTE: range of scores may be adjusted based on educational status of patient); **AND**
    d. Positron Emission Tomography (PET) scan is positive for amyloid beta plaque OR Cerebrospinal Fluid Test (collected via lumbar puncture) is positive for amyloid ;

    AND
2. Beneficiary is age 50 or older

    AND
3. Beneficiary has undergone testing to rule out reversible causes of dementia (ex. CBC, CMP, TSH, B12, urine drug screen, RPR/VDRL, (folate (if alcohol abuse is present), HIV (if risk present) and has had an assessment including a review of current medications as a cause of intellectual decline

    AND
4. Beneficiary has had a recent (within one year) brain magnetic resonance imaging (MRI) prior to initiating treatment

    AND
5. Prescriber has assessed and documented baseline disease severity utilizing an objective measure/tool (e.g., MMSE, Alzheimer's Disease Assessment Scale-Cognitive Subscale [ADAS-Cog-13],

Alzheimer's Disease Cooperative Study-Activities of Daily Living Inventory-Mild Cognitive Impairment version [ADCS-ADL-MCI], Clinical Dementia Rating-Sum of Boxes [CDR-SB]).

6. Beneficiary does NOT have history or increased risk of amyloid related imaging abnormalities-edema (ARIA-E), which includes brain edema or sulcal effusions and amyloid related imaging abnormalities hemosiderin deposition (ARIA-H), which includes microhemorrhage and superficial siderosis

   AND
7. Beneficiary has had a failure of or inability to tolerate at least one other preferred cholinesterase inhibitor Alzheimer therapy for at least four months

   AND
8. The provider attests to obtain MRIs prior to the 7th infusion (first dose of 10 mg/kg) and 12th infusion (sixth dose of 10 mg/kg)

   AND
9. Beneficiary does NOT have hypersensitivity to any components of Aduhelm™

   AND
10. Aduhelm™ is being prescribed by or in consultation with a neurologist or geriatrician or geriatric psychiatrist.

Procedures:

Initial approval for up to 6 months to ensure that the MRI is done prior to approving the 7th dose and every 6 months after that.

If the follow-up MRI demonstrates 10 or more new incident microhemorrhages or 3 or more focal areas of superficial siderosis (radiographic severe ARIA-H) is observed, treatment may be continued with caution only after a clinical evaluation and a follow-up MRI demonstrates radiographic stabilization (i.e., no increase in size or number of ARIA-H).

References

1. Prescribing Information-Aduhelm ™ (aducanumab-avwa) injection, for intravenous use. Biogen, Inc., Cambridge, Massachusetts 02142. July 2021.

Criteria Change Log

04/01/2022	Criteria effective date