TX CLINICAL CRITERIA & PROCEDURE

CRITERIA NAME: Aducanumab-avwa (Aduhelm®)	**CRITERIA ID:** TX.CC.PHAR.18
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy
EFFECTIVE DATE: 1/1/2022	**PRODUCT(S):** STAR, STAR Health, STAR Kids, STAR Plus, CHIP, CHIP Perinate
REVIEWED/REVISED DATE: 7/1/2022, 7/14/2022, 7/12/2023, 11/3/2023, 03/15/2024	
REGULATOR MOST RECENT APPROVAL DATE(S):	

CRITERIA STATEMENT:
The purpose of this clinical criteria is to provide a guide to medical necessity reviews for aducanumab-avwa (Aduhelm®).

PURPOSE:
Consistent with the regulation at 42 CFR Section 438.210 and 42 CFR Section 457.1230(d), services covered under managed care contracts, including clinician-administered drugs, must be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services specified in the state plan. While MCOs may place appropriate limits on drugs, MCOs may not use a standard for determining medical necessity that is more restrictive than what is used in the state plan, i.e., developed by the Vendor Drug Program. For example, if a member is denied a clinician administered drug in managed care because of the MCO's prior authorization criteria but would have received the drug under the criteria specified in the state plan, then the MCO's prior authorization criteria would violate the amount, duration, and scope requirements cited above. HHSC intends to amend the Managed Care Contracts at the next opportunity to include this requirement. This same standard applies to CHIP formulary and CAD coverage.

Refer to the Outpatient Drug Services Handbook of the Texas Medicaid Provider Procedure Manual for more details on the clinical criteria and prior authorization requirements.

This medication is a non-risk based (NRB) payment drug and should follow state guidance for medical necessity review for Medicaid/CHIP due to the manner in which it is reimbursed. All determinations will be performed by a Medical Director. A pharmacy clinician will review the prior authorization request and make a recommendation to the Medical Director but will not make the ultimate determination on any case.

SCOPE:
This criteria applies to all directors, officers, and employees of Centene Corporation, its affiliates, health plans, and subsidiary companies (collectively, the "Company").

DEFINITIONS:
Magnetic Resonance Imaging (MRI)
Amyloid Related Imaging Abnormalities (ARIA)
Amyloid Related Imaging Abnormalities – hemosiderin deposition (ARIAH)

POLICY:
It is the policy of Superior HealthPlan and Centene Pharmacy Services to follow state guidance for medical necessity review of aducanumab-avwa (Aduhelm®); procedure code: J0172.

Exclusion: The clinical prior authorization applies to Medicaid clients only. Dual eligible clients must follow the Medicare National Coverage Determination policy guidelines for monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease.

Description:
Aducanumab-avwa (Aduhelm®) is an amyloid-beta directed antibody indicated to treat Alzheimer's disease by reducing amyloid-beta plaques.

FDA Approved Indication(s):
Aduhelm is indicated for the treatment of Alzheimer's disease (AD). Treatment with Aduhelm should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials.

PROCEDURE:

Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Alzheimer's disease (must meet all):

1. A Medical Director is required to review and approve or deny all requests. A pharmacy clinician will make a recommendation on the prior authorization, but ultimate determination will be made by the Medical Director only.
2. The client has a confirmed diagnosis of Alzheimer's disease (diagnosis codes G30.0, G30.1, G30.8, G30.9).
3. Prescriber attestation that other forms of dementia except Alzheimer's disease have been ruled out by appropriate lab and/or other diagnostic testing.
4. Prescriber's confirmation of amyloid beta-plaques presence.
5. Documentation of clinical testing that confirms the client has mild cognitive impairment caused by Alzheimer's disease or mild stage of Alzheimer's disease.
6. Documentation that client has received a baseline brain-magnetic resonance imaging (MRI) before initiating treatment (within the past year) to evaluate for pre-existing Amyloid Related Imaging Abnormalities (ARIA).
7. Prescriber attestation to the following monitoring requirements during the Aduhelm treatment period:
    - Prescriber must ensure client is currently not taking any anti-coagulant (except for aspirin at a prophylactic dose or less) or have history of a clotting disorder.
    - Prescriber must monitor for amyloid related imaging abnormalities (ARIA) during the first eight doses of treatment, particularly during titration.
    - Prescriber's attestation to obtain a brain magnetic resonance imaging (MRI) prior to the 5th, 7th, 9th, and 12th infusion to check for asymptomatic (ARIA)
    - Clients with severe amyloid related imaging abnormalities hemosiderin deposition (ARIA-H) may continue therapy only if radiographic stabilization has been confirmed by a follow-up brain MRI and supported by clinical evaluation.

Approval duration: 6 months

II. Continued Therapy

A. Alzheimer's disease (must meet all):

1. A Medical Director is required to review and approve or deny all requests. A pharmacy clinician will make a recommendation on the prior authorization, but ultimate determination will be made by the Medical Director only.
2. The client continues to meet all of the initial authorization approval criteria.
3. The client has not progressed to moderate or severe dementia caused by Alzheimer's disease.
4. The client has experienced positive clinical response to therapy as demonstrated by no increase in amyloid plaque or radiographic stabilization as compared to baseline.
5. Documentation of a brain MRI prior to the 5th, 7th, 9th and 12th infusion to check for ARIA with Aduhelm treatment.
6. The client has not experienced any complications or unacceptable toxicities during Aduhelm treatment.

Approval duration: 6 months

REFERENCES:
Texas Medicaid Provider Procedure Manual: Outpatient Drug Services Handbook

ATTACHMENTS: N/A

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
Ad Hoc Review	Formatted to new template Added initial criteria for attestation to obtain MRI prior to 5th, 7th, 9th, and 12th infusion to check for asymptomatic amyloid-related imaging abnormalities (ARIA) and enhanced clinical vigilance for ARIA is recommended during the first eight doses of Aduhelm and for patients with radiographic findings of ARIA. Additional monitoring and MRIs may be considered if clinically indicated.	07/01/2022

	Added continuation criteria of documentation of a brain MRI prior to the 5th, 7th, 9th and 12th infusion to check for ARIA. Updated references Added exclusions	
Ad Hoc Review	Added additional monitoring parameters per July 2022 TMPPM Updated functional area to state Pharmacy only	7/14/2022
Annual Review	Clarified step 5 to better align with TMHP. Removed bullet 2 under step 8 as its redundant with step 7.	7/12/2023
Ad Hoc Review	Added reference to Centene Pharmacy Services Adjusted Intro Section: Policy Statement, Purpose etc to algin with other TX.PHAR policies. Minor formatting changes Added ending verbiage to I.A.6, removed I.A.8, adjusted I.A.7. and removed II.A.4. to align with updated verbiage in TMHP CAD Manual Removed III.A. Exclusion and added to POLICY section	11/03/2023
Ad Hoc Review	Updated to TX.CC.PHAR format template Added Centene copyright statement	03/15/2024