POLICY AND PROCEDURE

POLICY NAME: Aducanumab-avwa (Aduhelm)	**POLICY ID:** TX.PHAR.101
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	
REGULATOR MOST RECENT APPROVAL DATE(S):	

POLICY STATEMENT:
It is the policy of Superior HealthPlan (SHP) to follow state guidance for medical necessity review of aducanumab-avwa (Aduhelm).

PURPOSE:
This medication is a pass through 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 Superior 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.

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 policy and prior authorization requirements.

All determinations will be performed by a Superior HealthPlan 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.

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

SCOPE:
This policy applies to Superior HealthPlan Pharmacy Department, Medical Directors, Claims.

DEFINITIONS:
N/A

POLICY:
It is the policy of Superior HealthPlan to follow state guidance for medical necessity review aducanumab-avwa (Aduhelm). This medication is a pass through 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 Superior 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.

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. Diagnosis of Alzheimer's disease (diagnosis codes G30.0, G30.1, G30.8, G30.9)

2. Prescriber attestation of other forms of dementia except Alzheimer's disease were ruled out by appropriate lab or another diagnostic testing
3. Prescriber's confirmation of amyloid beta-plaques presence
4. Clinical testing confirming client has mild cognitive impairment caused by Alzheimer's disease or mild stage of Alzheimer's disease
5. Client is not currently taking any anti-coagulant (except for aspirin at a prophylactic dose or less) or have a history of a clotting disorder
6. Documentation that client has received a baseline brain-magnetic resonance imaging (MRI) before initiating treatment (within the past year)
7. Prescriber's attestation to obtain a brain magnetic resonance imaging (MRI) prior to the 5th, 7th, 9th, and 12th infusion to check for asymptomatic amyloid-related imaging abnormalities (ARIA).
8. The following are the monitoring requirements during the treatment period:
   - Prescriber must monitor for amyloid related imaging abnormalities (ARIA) during the first eight doses of treatment, particularly during titration.
   - Prescriber attestation to obtain a brain MRI prior to the 5th, 7th, 9th and 12th infusion to check for asymptomatic ARIA.
   - Enhanced clinical vigilance for ARIA is recommended during the first 8 doses of Aduhelm and for clients with radiographic findings of ARIA. Additional monitoring and MRIs may be considered if clinically indicated.

   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. Client continues to meet the initial authorization approval criteria.
2. Client has not progressed to moderate or severe dementia caused by Alzheimer's disease.
3. Client experienced positive clinical response to therapy as demonstrated by no increase in amyloid plaque or radiographic stabilization as compared to baseline.
4. 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 MRI and supported by clinical evaluation
5. Documentation of a brain MRI prior to the 5th, 7th, 9th and 12th infusion to check for ARIA.
6. Client has not experienced any complications or unacceptable toxicities during Aduhelm treatment.

Approval duration: 6 months

III. Exclusions

A. 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.

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

ATTACHMENTS:

ROLES & RESPONSIBILITIES: N/A

REGULATORY REPORTING REQUIREMENTS: N/A

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
Ad Hoc Review	Formatted to new template	07/01/2022

	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. 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

POLICY AND PROCEDURE APPROVAL

The electronic approval retained in RSA Archer, the Company's P&P management software, is considered equivalent to a signature.