Policy and Procedure

DEPARTMENT: Pharmacy, Medical Directors	**DOCUMENT NAME:** Aducanumab-avwa (Aduhelm)
PAGE: 1 of 4	**REPLACES DOCUMENT:**
APPROVED DATE:	**RETIRED:**
EFFECTIVE DATE: 1/1/2022	**REVIEWED/REVISED:**
PRODUCT TYPE: Star, Star Health, Star Kids, Star Plus, Chip, Chip Perinate	**REFERENCE NUMBER:** TX.PHAR.101

SCOPE:
Superior HealthPlan Pharmacy Department, Medical Directors

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 policy and prior authorization requirements.

BACKGROUND:
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:
• treatment of Alzheimer's disease (AD) with mild cognitive impairment or mild dementia stage of disease

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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)

   Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid

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 AD.
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 MRI before the 7th and 12th infusion to check for ARIA.
6. Client has not experienced any complications or unacceptable toxicities during Aduhelm treatment.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid

REFERENCES:

1. Outpatient Drug Services Handbook of the Texas Medicaid Provider Procedure Manual, Accessed December 2021

ATTACHMENTS:

REVISION LOG

REVISION	DATE

POLICY AND PROCEDURE APPROVAL

Karen Tadlock, V.P., Pharmacy Operations — Approval on file

Dr. David Harmon, Sr. V.P., Chief Medical Officer — Approval on file

Pharmacy & Therapeutics Committee: — Approval on file

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