09/14/2023

Prior Authorization Criteria for Leqembi Begins Nov. 1, 2023

Background:

HHSC added Leqembi (procedure code J0174) as a benefit of Medicaid and CHIP with an effective date of July 6, 2023, and will implement prior authorization criteria for fee-for-service Medicaid on Nov. 1, 2023.

Key Details:

Leqembi (Lecanemab-irmb) is an amyloid-beta directed antibody indicated to treat Alzheimer's disease (AD) by reducing amyloid-beta plaques. Treatment with Leqembi should be initiated in patients with mild cognitive impairment or mild dementia stage of disease.

Action:

Prior Authorization Requirements

Initial prior authorization approval of Leqembi (Lecanemab-irmb) infusion therapy will be considered when the client meets the following criteria :

- The client has a confirmed diagnosis of Alzheimer's disease (diagnosis codes G30.0, G30.1, G30.8, or G30.9).
- Prescriber attestation that other forms of dementia, except Alzheimer's disease has been ruled out by appropriate lab and/or other diagnostic testing.
- Prescriber's confirmation of amyloid beta-plaques presence.
- Clinical testing must confirm that the client has mild cognitive impairment caused by Alzheimer's disease or mild dementia stage of disease.
- Client must currently not be taking any anti-coagulant (except for aspirin at a prophylactic dose or less) or have a history of a clotting disorder.
- Documentation that the 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).

Monitoring Requirements

Monitoring requirements during Leqembi treatment period include:

- Prescriber must monitor for Amyloid Related Imaging Abnormalities (ARIA) during the first 14 weeks of treatment.
- Prescriber attestation to obtain an MRI prior to the 5^{th}, 7^{th}, and 14^{th} infusion to check for 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 MRI and supported by clinical evaluation.

Renewal or Continuation Therapy

For renewal or continuation therapy, the client must meet the following requirements:

- The client has met all the initial prior authorization approval criteria at the time of initial approval.
- The client has not progressed to moderate or severe dementia caused by AD.
- The client experienced a positive clinical response to therapy as demonstrated by no increase in amyloid plaque or radiographic stabilization as compared to baseline.
- Documentation of MRI to check for ARIA with Leqembi treatment.
- The client has not experienced any complications or unacceptable toxicities during treatment with Leqembi.

HHSC will implement the FFS criteria on Nov. 1, 2023. However, MCOs do not need to wait for publication in the TMPPM before implementation. MCOs may choose to implement the updated requirements but cannot make them more restrictive. Please refer to the TMPPM for more details on the clinical policy and prior authorization requirements.

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Type: Informational

To: CHIP; STAR; STAR+PLUS; STAR_KIDS

From: VDP