Lecanemab (Leqembi)– PA Criteria

HCPC: J0174

Leqembi is an amyloid beta-directed antibody indicated for the treatment of Alzheimer's disease. Treatment with Leqembi should be initiated in patients with mild cognitive impairment or mild dementia stage of disease. It is covered by South Dakota Medicaid following prior authorization when the patient meets the following criteria:

- **Initial Therapy (must meet all):**
  - Therapy is prescribed by a neurology provider
  - Individual is ≥ 50 years of age
  - Presence of amyloid beta disease pathology is confirmed with the use of either a PET scan or lumbar puncture prior to initiating treatment
  - Individual has mild cognitive impairment (MCI) or mild dementia as evidenced by **both** of the following:
    - Mini-mental State Examination (MMSE) score of ≥22 OR Montreal Cognitive Assessment (MOCA) of ≥16
    - Clinical Dementia Rating global score (CDR-GS) of 0.5 or 1
  - Documentation is provided that all other medical and neurological conditions that might contribute to the cognitive impairment have been ruled out
  - A recent (within one year) brain MRI has been performed prior to initiating treatment
  - Physician has a documented plan to obtain repeat brain MRIs prior to the 5th, 7th, and 14th infusion for monitoring of the development of amyloid related imaging abnormalities (ARIA)
  - None of the following are present:
    - Stroke, TIA, or unexplained loss of consciousness in the last year
    - Clinically significant unstable psychiatric illness in the past 6 months
    - History of unstable angina, myocardial infarction, advanced chronic heart failure, or clinically significant conduction abnormalities within the past year
    - Impaired renal or liver function
    - Significant systemic illness or infection in the past 30 days
    - Bleeding disorder, cerebrovascular abnormalities, or relevant brain hemorrhage
    - Contraindication to MRI or PET scans
    - Documentation of alcohol or substance abuse in the past year
    - Use of antiplatelet or anticoagulant (with the exception of aspirin at a dose ≤81mg)
  - Approval duration: 1 year
- **Continuation of Therapy (must meet all):**
  - Individual continues to meet initial criteria
  - Documentation is submitted indicating MRIs obtained from the last year of therapy shows no increase in size or number of ARIA
  - Repeat cognitive testing does not show presence of significant cognitive decline as demonstrated by **any** of the following:
    - MMSE ≤18
    - MOCA <16
    - CDR GS of ≥2
  - Approval duration: 1 year