Penn Medicine

LEQEMBI® SCREENING PROCESS

for Primary Care and Geriatrics Providers

The Federal Drug Administration recently approved Alzheimer's drug Leqembi (lecanemab), an infusion therapy given every two weeks. Leqembi has been found to slow cognitive decline in people with early-stage Alzheimer's disease.

INITIAL INCLUSION/EXCLUSION CRITERIA

Is your patient eligible?:

- ☑ Ages 50 to 90 years of age, inclusive (with additional consideration for physician judgement in patients under 50 or over 90 years of age).
- ☑ Has a clinical syndrome believed to be consistent with underlying symptomatic Alzheimer's disease clinical phenotypes, including the following:
  - Mild cognitive impairment
  - Probable Alzheimer's disease dementia
- ☑ Eligible and willing to receive requisite safety MRIs in screening during at least the first year of treatment (and beyond one year of follow up if clinician judgement deems it necessary for patient safety).
- ☑ Women of childbearing potential and all men must agree to adequate, highly effective, methods of contraception during drug treatment period.
- ☑ Able to understand the risks of Lecanemab (including increased risk associated with *APOE* e4 allele(s)) and provide ongoing informed consent for treatment.
- ☑ A care partner (that interacts with the patient regularly enough to follow for adverse events and clinical progression) is strongly recommended.
- ☑ Is independent in all activities of daily living (e.g. personal hygiene, bathing, toileting, dressing, eating).

IF YOUR PATIENT HAS ANY OF THESE, THEY ARE NOT ELIGIBLE:

1. Treatment with anticoagulants (DOACs, warfarin, lovenox, heparin, fondaparinux, etc.).
2. Dual antiplatelet therapy within 4 weeks is a relative contraindication for Lecanemab. Non-aspirin antiplatelets (clopidogrel, ticagrelor, etc.) and aspirin (up to 325 mg PO daily) are permitted.
3. Individuals' clinical features suggesting an alternative neurodegenerative disorder that is likely to be significantly contributing to primary neurological symptoms despite positive AD biomarkers.
4. Any co-morbid medical condition that might pose a safety risk to treatment initiation including but not excluded to:
   - Known history of a stroke clinical syndrome in the preceding 12 months
   - Uncontrolled hypertension (e.g. blood pressure confirmed to be >165/100 on repeated measures at screening and potentially rescreening to rule out white coat's syndrome)
   - Uncontrolled endocrine disorders (such as diabetes or thyroid disease)
   - History of uncontrolled seizure disorder during adulthood (even if well controlled)
   - Significant active autoimmune or inflammatory disease
   - Recent (within 24 months) cancer diagnosis not in remission (excluding skin cancers, localized prostate cancer)
   - Uncontrolled HIV or Viral hepatitis
   - Bleeding disorders or laboratory evidence thereof
   - Uncontrolled major depression or other psychiatric illness that will interfere with comprehension of the requirements, potential benefit, and potential harms of treatment or participation in treatment
5. Breastfeeding/Lactation during treatment period.
6. Current use of immunomodulatory drugs, including systemic corticosteroids, parenteral immunoglobulin, blood products, plasma derivatives, plasma exchange, and plasmapheresis. Systemic immunosuppressive drugs are not permitted for 3 months before starting anti-amyloid therapy, but may be considered on a case-by-case basis after starting therapy.

PATIENT SCREENING PROCESS

This pathway provides primary care and geriatrics physicians step-by-step instructions for determining initial eligibility of Leqembi (lecanemab).

1

Patient Meets Inclusion/Exclusion Criteria
See front page.

Discuss FAQ Sheet with Patient/Caregiver
Is the patient interested in proceeding?

Administer a MoCA or MMSE
Does patient fall within target range score?
MoCA: 17 to 26
MMSE: 23 to 28

NO/END

YES/PROCEED

2

Order Baseline MRI and Labs

MRI:
- MR Head Anti-Amyloid Therapy Initial Work-up without IV Contrast [**IMGMR0375**]

Labs:
- Vitamin B12 Level [**C3501790**]
- Thyroid Stimulating Hormone [**C3501740**]

3

Evaluate MRI and Labs
Is there anything that would disqualify patient?

YES/END

NO/PROCEED

4

Refer patient for anti-amyloid therapy through the "Consult to Neurology" order in Epic. Select Cognitive/Memory Center Division.

Patient will receive a call from an Administrative Coordinator to schedule appointment and review next steps, including confirmation of amyloid, genetic testing, and surveillance MRIs.

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