Norton Neuroscience Institute
Memory Center

Anti-Amyloid Therapy Patient and Care Partner Education

What are anti-amyloid therapies?

Anti-amyloid therapies are medications designed to remove a protein called beta amyloid from the brain. This protein is thought to be involved in the development and progression of Alzheimer's Disease. These medications are currently administered via IV (intravenously) or subcutaneous (SQ) routes. Lecanemab (Leqembi) is now available for SQ injections at home.

These two medications are currently FDA approved and available for use: lecanemab (Leqembi) and donanemab (Kisunla). Both are monoclonal antibody therapies targeting beta-amyloid and slow progression of Alzheimer's Disease by about 30%. These medications do not cure or reverse symptoms, but rather slow the rate of cognitive decline when used in the mild stages of disease.

The primary side effects that have been noted with these therapies are infusion/injection site reactions and amyloid related imaging abnormalities (ARIA).

What are infusion reactions?

About a quarter of patients receiving lecanemab and about 9% of patients receiving donanemab will experience a mild infusion reaction. Symptoms might include fever, chills, headache, rash, nausea or other flu-like symptoms. These symptoms can usually be controlled with medications such as Tylenol or Benadryl if necessary.

What are injection site reactions?

Injection site reactions (ISRs) are localized changes in the skin and underlying tissues that occur after receiving an injection, such as a vaccine, biologic, or chemotherapy drug. Common symptoms include: redness, swelling, pain or tenderness, warmth or itching at the injections site. Most reactions resolve within 1-2 days on their own.

Amyloid related imaging abnormalities (ARIA):

ARIA is a condition that indicates swelling or bleeding in the brain. This occurs in about 1 in 5 people receiving lecanemab and 1 in 3 people receiving donanemab, though most often causes no symptoms and resolve without any treatment. However, more severe cases can occur, leading to symptoms such as headache, confusion, visual changes, dizziness, nausea and seizures. In rare cases, this can even lead to death. Overall about 3% of patients receiving lecanemab and 6% of patients receiving donanemab have symptoms related to ARIA.

Additionally, because of the risk of bleeding it is recommended that patients receiving these anti-amyloid therapies not be treated with very strong blood thinners or receive clot-busting medications.

Am I eligible for anti-amyloid therapy

Those with a diagnosis of mild cognitive impairment or mild Alzheimer's disease might be eligible. First, we need to confirm this diagnosis by an assessment of medical history, an MRI, and blood work, as well as additional testing to confirm the presence of amyloid. An additional genetic test (ApoE genotyping) through a blood draw can determine the risk of ARIA (see above).

****Some medications can exclude you from receiving lecanemab or donanemab. Please share all medications with your Healthcare provider.**

****Please make sure our office has an updated medication list.****

Currently available anti-amyloid medications are classified as monoclonal antibodies. Patients taking other monoclonal antibody therapies may be excluded from consideration of lecanemab and donanemab. Some examples of medical conditions that often prescribe these medications include but are not limited to: osteoporosis, asthma, inflammatory and autoimmune disorders, cancer, and migraines.

Navigation Services and Anti-Amyloid Therapy Program

We are committed to supporting you throughout your care journey. As part of your treatment, you will receive services through our Nurse Navigation Program. A dementia diagnosis and treatments can be complex, therefore our experts with our Navigation Program will help guide people through the Anti Amyloid Therapy eligibility process as well as post-diagnostic care and support. Services may include care coordination with multiple providers, personalize guidance, education and accessing resources to help you and your loved one manage your diagnosis.

Beginning January 2024, Centers for Medicare and Medicaid Services (CMS) and some private insurers recognize and reimburse these services. If applicable, these services will appear on your bill and may be covered in part or in full by your insurance plan.

If you would like an estimate of your out-of-pocket cost for Nurse Navigator services, please contact Norton Healthcare's Price Estimate Line at **(502) 272-5330**. To receive an estimate, you will need to provide your insurance information and the service codes **99426** and **99427**. Coverage and patient responsibility may vary based on your insurance plan.

Anti-Amyloid Therapy Patient Journey and Next Steps:

Patients can expect first infusion to be scheduled approximately 3 months from start of eligibility process.

1. **Provider determines eligibility for treatment**
   Timeline: 3-4 Weeks*

   What is involved for determining eligibility?

   - Confirmation of Alzheimer's disease and additional testing (CSF, MRI, ApoE genotyping)
   - Provider review of medical history and medications

**Timeline based on scheduling and receiving the above diagnostics, therefore timeline may be extended.*

2. **Patient schedules Pre-Therapy Initiation Consultation with NNI Memory Center Navigator:**
   Timeline: 1-2 weeks

   This consultation may be in-person or via telephone.

   During this consultation, the navigator will review that the eligibility criteria is complete before starting infusions. They will guide you through next steps to therapy and answer any questions you may have. We want to make sure you have a full understanding before starting this medication.

   Required paperwork will be reviewed and completed at this time.

3. **Financial counselor investigates benefits**
   Timeline: 2-3 weeks

   The Financial Support Services documents and your insurance information will be sent for authorization of drug coverage. The timeline to hear from financial counselors depends on the approval or any denials.

   The financial department will communicate with you about your benefits investigation after receiving the drug authorization.

4. **Infusions scheduled/SQ start date scheduled**

   Timeline (IV): Varies based on location
   Timeline (SQ): 1-2 weeks after finances have been discussed. The first two injections must be done under supervision by a healthcare professional. Injections will be performed under the guidance of the specialty pharmacy staff.

NORTON NEUROSCIENCE INSTITUTE

**Expected timeframes for determining eligibility and scheduling infusions vary from patient to patient. See *Patient Journey and Next Steps* in this document for more details.

What do I need to know while I take this drug?

- Tell all your health care providers that you are on an Anti-Amyloid therapy. This includes your doctors, nurses, pharmacists, and dentists.

- Tell your NNI Provider if you have <u>any</u> changes in health conditions or medications while receiving Anti-Amyloid Therapy.

- Monitor for infusion reactions. About 9% of people receiving Donanemab and 26% of people receiving Lecanemab note symptoms of an infusion reaction. This is most common with the first 2-4 of infusions. In some cases reactions can be delayed for several hours after the infusion. Fortunately, these symptoms are typically mild, though some can be moderate to severe.
    - Mild infusion reactions include flu-like symptoms such as: fever, chills, aches, shaking, or joint pain; upset stomach or vomiting.
    - Moderate to severe reactions may present as: signs of high or low blood pressure like dizziness or passing out, headache, or change in eyesight; abnormal or pounding heartbeat; or trouble breathing.
    - *Tell you're the healthcare team right away if you have any of these signs or other effects during <u>OR</u> after the infusion.*

- Most symptoms are self-limiting, resolve within 24 hours, and can be managed easily with over the counter medications such as acetaminophen (Tylenol) 650mg – 1000mg every 6 hours, or diphenhydramine (Benadryl) 25mg- 50mg every 6 hours.
    - Please use caution with Benadryl as it can cause confusion, impaired coordination, dizziness and drowsiness.

Call 911 or go to your nearest emergency room for any urgent medical needs

What if I miss a dose?

- **<u>IV</u>**: You will skip the missed infusion and proceed with the next scheduled infusion.
- **<u>SQ</u>**: If a scheduled dose of the subcutaneous LEQEMBI IQLIK is missed, administer LEQEMBI IQLIK as soon as possible up to 6 days after the missed dose and administer the next dose on the regularly scheduled day. Thereafter, resume the original dosing schedule.

When to call your provider:

- **If you are experiencing infusion or drug related reactions:**
  flu-like symptoms such as fever, chills, aches, shaking, or joint pain; upset stomach or vomiting; signs of high or low blood pressure like dizziness or passing out, headache, or change in eyesight; abnormal or pounding heartbeat; or trouble breathing.

- **Inform your healthcare provider:**
  - **If there are any changes to your health conditions or medication,**
  - **If you need to miss an infusion of the drug, or**
  - **If you have a change in care partner.**

NNI Memory Center:

Hannah Hust, BSN, RN
Anti-Amyloid Nurse Navigator

Deborah Lockridge, BSN, RN
Brain Health Navigator

Main number: (502) 394-6460
8:00am – 4:00pm

Specialty Pharmacy number:
(502) 559-1310

After hours on-call physician:
(502) 394-6460 (main number)

Patient Information Website:

NORTON NEUROSCIENCE INSTITUTE