

October 3, 2024

At Northwestern Medicine, our patients are our top concern. Know that we closely study each medication before we recommend it for you. We look at its benefits and risks. With this in mind, we want to provide some information and context regarding two new medicines called **lecanemab (Leqembi)** and **donanemab (Kisunla)**, which are both in a class of medications called anti-amyloid monoclonal antibody therapies.

As of July 6, 2023 lecanemab has been fully approved by the FDA. Please visit this website regarding the news release from the FDA for more information: <https://www.fda.gov/news-events/press-announcements/fda-converts-novel-alzheimers-disease-treatment-traditional-approval>. To learn more about patient assistance programs, please visit: <https://www.eisareimbursement.com/patient/leqembi/?leq=4>

As of July 2, 2024 donanemab has also been fully approved by the FDA. For more information regarding FDA approval: <https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-treatment-adults-alzheimers-disease>. To learn more about patient assistance programs, please visit <https://kisunla.lilly.com/support-resources>.

CMS has determined that the cost of lecanemab and donanemab will be covered by Medicare as long as the patient is enrolled in a National Patient Registry. The out-of-pocket cost of lecanemab is set at \$26,500 per year and the out-of-pocket cost of donanemab is set at \$32,000 per year, not including costs of required MRIs and visits to infusion center. Some private insurance companies have also started covering this class of medications, but patients should speak directly with their insurances companies to ensure coverage.

Anti-amyloid monoclonal antibody therapies are designed to remove the amyloid protein that builds up in the brain in Alzheimer disease. The results of two a large, phase III clinical trials suggest that this treatment can slow the rate of cognitive decline by about 25-30% over 18 months, though it does not offer any improvement of symptoms that can be noticed by family or physician. These medications do not reverse existing disease symptoms or halt the progression.

Lecanemab is given every two weeks by vein in an infusion center. Donanemab is given every 4 weeks by the vein in an infusion center. Side effects can include swelling and/or bleeding in the brain which is usually minor and asymptomatic, but rarely can cause symptoms and be life threatening. This swelling and bleeding usually do not cause symptoms, but some people can experience headaches, falls, dizziness, vision changes, nausea, diarrhea, seizures, and confusion. Carriers of the ApoE4 gene are at a higher risk of experiencing these side effects. The risk of a symptomatic brain bleed also seems to be higher in those on certain blood thinners, and we will not be recommending this medication for any patient who is on such medications.

Speak with your neurologist to discuss if it is the right choice, this decision is made on a case-by-case basis. We have teamed with our infusion centers at Northwestern Memorial Hospital to develop and optimize a plan for safely administering these medications and monitoring for side effects. Due to the frequency of infusions and requirement of frequent MRI scans to monitor for side effects, we currently are only prescribing these medications to patients who can get the infusions at one of our locations.

To be potentially eligible to receive these medications, a patient must have an amyloid PET scan or spinal tap evidence of amyloid in the brain and must be at the stage of mild symptoms, determined by a specialist in dementia care. Patients must also be able to have frequent brain MRIs to monitor for bleeding and swelling.

Though we are certainly glad to see the science of Alzheimer disease treatment advance, we also recognize that not all treatments will be right for everyone.

Sincerely,



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