

July 7, 2023

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 a new medicine called lecanemab (Leqembi), which as of July 6, 2023 has been fully approved by the FDA. Please visit the website below 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.eisaireimbursement.com/patient/leqembi/?leq=4>

CMS has determined that the cost of Lecanemab will be covered by Medicare as long as the patient is enrolled in a National Patient Registry. We are still obtaining information about what type of information needs to be submitted to this registry. The out of pocket cost of this medication is set at \$26,500, not including costs of required MRIs and visits to infusion center.

Lecanemab is a medication given every two weeks by vein in an infusion center and is designed to remove the amyloid protein that builds up in the brain in Alzheimer disease. The results of a large, phase III clinical trial suggest that this treatment can slow the rate of cognitive decline by about 27% over 18 months, though it does not offer any improvement of symptoms that can be noticed by family or physician. Lecanemab does not reverse existing disease symptoms or stop the progression.

Side effects can include swelling and/or bleeding in the brain which is usually minor but can occur in approximately 1 in 6 people receiving the drug. 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.

We are optimizing a process for consultation with one of our neurologists to determine if a person is eligible to receive this medication, and to discuss if it is the right choice on a case-by-case basis. We are working with Northwestern Memorial Hospital to develop and optimize a plan for safely administering this medication 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 this medication to patients who can get the infusions at one of our Northwestern locations.

To be potentially eligible to receive this medication, 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. Patients must also be able to have frequent brain MRIs to monitor for bleeding and swelling.

Recently, another medication in the same class as lecanemab has been reported to have positive results in a phase III clinical trial; this is called donanemab. This medication has not received approval from the FDA at this point, and we await full data from a clinical trial to be made public for peer review later in July 2023.

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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