CMS Proposes Limited Coverage of Aducanumab – Patients Must Participate in Trials to Receive Treatment

On January 11, the Centers for Medicare & Medicaid Services (CMS) released its proposed National Coverage Determination (NCD) relating to monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease (AD). This NCD is the culmination of a National Coverage Analysis that was triggered by the FDA's approval of aducanumab (brand name Aduhelm) in June of 2021. The approval of aducanumab sparked significant controversy due to the accelerated approval pathway through which it was approved and questions over its clinical effectiveness and potential side effects.

CMS proposes to:

- Use a Coverage with Evidence Development to further study the drug. Amyloid therapies will only be covered by Medicare in the context of CMS-approved randomized controlled trials or trials supported by the NIH
- Restrict trials to hospital-based outpatient facilities
- Require trials to meet diversity and inclusion standards to ensure traditionally underrepresented populations are not excluded
- Allow for one PET scan for amyloid in the patient's lifetime to be performed on participating patients to confirm amyloid positivity
- Apply the coverage determination to all amyloid monoclonal antibody therapies for the treatment of AD, not just aducanumab. Multiple therapies within the same class are working through the approval process right now

The AAN has been engaging with the FDA, CMS, and other key stakeholders on issues relating to aducanumab. This NCD realizes many of the AAN's advocacy efforts such as coverage of PET to confirm amyloid positivity for prospective patients, limitation of coverage to patients with mild cognitive impairment or mild AD, further clinical trials to confirm clinical benefit, and more inclusive trial data to reflect the diverse patient population affected by AD. The AAN will submit official comments, and members may also comment within the 30-day comment period. CMS will announce a final decision by April 11.

Find more information and resources on our Aducanumab Resources page.