CMS Proposes Medicare Coverage Policy for Monoclonal Antibody–Based Alzheimer Treatment

On January 11 the U.S. Centers for Medicare & Medicaid Services (CMS) released a proposed National Coverage Determination (NCD) decision memorandum that would cover U.S. Food and Drug Administration (FDA)–approved monoclonal antibodies that target β-amyloid for the treatment of Alzheimer disease (AD) through coverage with evidence development (CED). This means that FDA-approved drugs in this class would be covered for people with Medicare only if they are enrolled in qualifying clinical trials.

Aducanumab (Aduhelm; Biogen, Inc. [Cambridge, MA] and Eisai, Co., Ltd. [Tokyo, Japan]) is currently the only monoclonal antibody directed against β-amyloid approved by the FDA for treatment of AD. The FDA issued conditional approval of the drug on June 7, 2021. At that time, Biogen announced that the cost of the drug would be $56,000 per year ($4,300/monthly infusion). Widespread public and scientific media coverage focused on the high cost, as well as on efficacy data and potential side effects. In November 2021, CMS announced that Medicare Part B premiums would be increased by almost 15% in 2022, citing the potential impact of coverage for aducanumab as 1 of 5 factors in projected costs. On December 20, Biogen announced a 50% reduction in the price for aducanumab, to $28,000/year.

The January 11 announcement of the proposed NCD and limited coverage of the drug included a 30-day period for public comment. After reviewing all comments received on the proposed determination, CMS will announce its final decision by April 11, 2022. If the proposed NCD is finalized, CMS will review each submitted clinical trial to determine whether specific criteria are met. All CMS-approved clinical trials would be posted on the CMS Coverage website. In addition to CMS-approved trials, National Institutes of Health (NIH)–sponsored clinical trials would be covered. Medicare patients participating in these trials would be eligible to receive coverage of the drug, related services, and other routine costs, which may include 1 β-amyloid PET scan if required by a clinical trial protocol.

"We believe that any appropriate assessment of patient health outcomes must weigh both harm and benefit before arriving at a final decision," said Lee Fleisher, MD, CMS Chief Medical Officer and Director of the Center for Clinical Standards and Quality. "Therefore, based on the public comments submitted previously and evidence CMS reviewed, the potential for harm, and important questions that remain, we have determined that coverage with evidence development through clinical trials is the right decision for Medicare patients, clinicians, and caregivers, and we look forward to receiving feedback on the proposal."

SNMMI Reacts to CMS Coverage Decision

On January 12 SNMMI released the following statement on the CMS proposed NCD, including the decision to cover only 1 β-amyloid PET scan per patient in the approved trials:

In our first round of comments to CMS, we stressed the greater benefits of β-amyloid PET scans for early and accurate diagnosis of AD (compared to cerebrospinal fluid and blood biomarkers). Currently, PET is the only FDA-approved biomarker for identifying β-amyloid plaque.

Beta-amyloid PET is critical in the process of selecting patients who can benefit from therapy with aducanumab. Patients who are clinically thought to have AD but who show no evidence of brain amyloid in a PET scan do not have AD; they very likely would not be helped by the drug, and they could be negatively affected by drug-related toxicities. Although amyloid PET was not required by recent FDA prescribing information, the trials that led to approval of aducanumab required PET biomarker confirmation of positive amyloid status before therapy.

National coverage of β-amyloid PET will increase patient access to this therapy and will also more clearly identify patients who are amyloid negative and would not be eligible for most trials. Currently, 3 FDA-approved radiopharmaceuticals are approved for use with PET to identify β-amyloid plaque: ^{18}F-florbetapir, ^{18}F-flutemetamol, and ^{18}F-florbetaben. Their very limited use currently is covered under CED through the New IDEAS Study, a successor to the IDEAS Study that is focused on minority populations. Outside of this trial, however, these tracers are not covered by CMS.

We are concerned that CMS did not significantly change their CED requirement for β-amyloid PET scans. This may continue to limit access of patients to clinical trials of the drug. Removing the CED requirement would have been timely—given the approval of aducanumab and the coverage of tau PET diagnostics as of January 1—and would also have helped ensure equitable access to the new therapy. In addition, the current limited CMS coverage pays the provider far less than the cost of the imaging agent, a situation that limits access to the scans for our most vulnerable populations.

SNMMI is continuing to review the proposed NCD and will be submitting comments to CMS. Our preliminary thoughts are that CMS's decision to cover AD therapy under CED is an incomplete solution rather than a productive resolution that would allow widespread and equitable patient access to monoclonal antibody therapy or clinical trials of that treatment. We hope CMS will change its position in its final decision, due in April 2022. The Society seeks broad national coverage of the scans either by a positive NCD or at Medicare Administrative Contractor (MAC) discretion.