

CAPITOL STREET

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CMS Finalizes Expanded Alzheimer's PET Coverage

Per Our Preview; Good News for Alzheimer's mABs

Relevant Companies



Today, CMS finalized the decision to remove the current CED (coverage with evidence determination) restricting PET scans for use in neurodegenerative diseases (1 per lifetime). The decision is consistent with CMS's proposed decision released earlier this summer. Link to decision [here](#).

»» Our Take & Next Up

As a reminder, the removal of the once-per-lifetime limit provides access to likely multiple PET scans as coverage lies with Medicare Administrative Contractors (MACs) now. We expect each MAC to start the local coverage determination process. MACs are incentivized to coordinate coverage to ensure national uniformity (which is what patients and providers want), but regional variability is also possible based on how the administrators weigh the benefits of imaging and anti-amyloid therapies with costs of treatment. CMS is assuring stakeholders that there will be consistent coverage based on the MAC's evidence-based process for coverage determination. By the time LCD decisions are finalized (within a year of a local coverage determination request), we will likely have two anti-amyloid therapies (BIIB & Eisai, LLY) available in the US.

»» Key Points

CMS noted that some stakeholders requested a new National Coverage Determination (NCD) without a CED restriction. Stakeholders have asked the agency to provide an NCD due to concerns of regional inconsistency. But the agency appears to believe that is unnecessary due to the level of evidence supporting the use of PET scans which is expected to meet the MACs bar for coverage. Other commenters requested a separate payment for radiotracers used in PET imaging as the service is provided at a loss. CMS noted that payment for diagnostic radiopharmaceuticals used in the physician office setting are determined by the MACs with diagnostic radiopharmaceuticals typically receiving packaged payment in the Outpatient Prospective Payment system.

PET imaging results are expected to be collected by CMS as a part of their coverage with registry for Leqembi (Eisai & BIIB). As a reminder, Medicare will cover Leqembi when physicians and clinical teams actively participate in collecting real-world evidence through a registry. PET scans are one of the methods that is used to determine a patient's eligibility for the therapy and also measure if the therapy is working. There are three radiopharmaceuticals approved for PET A β imaging, Amyvid (LLY), Neuraceq (Life Molecular Imaging) and Vizamyl (GEHC), to estimate A β plaque density in patients with cognitive impairment who are being evaluated for Alzheimer's disease (AD).

BACKGROUND

On July 17, CMS [proposed](#) to lift the national coverage determination (NCD) that restricted Medicare coverage to one amyloid-detecting positron emission tomography (PET) exam in a lifetime. The agency referenced the need to improve access and the management of anti-amyloid treatments in the wake of new data and the recent full FDA approval of Leqembi.

Since 2013, Medicare’s CED coverage of PET scans limited coverage to 1 scan per lifetime and only for use within a CMS-approved study. At the time, CMS refused widespread coverage for PET diagnostics due to insufficient evidence that imaging is “reasonable and necessary for the diagnosis or treatment” of neurodegenerative diseases. Research has advanced since the original CED. Now scientists use PET scans to assess amyloid buildup and tau, a brain protein that is believed to impact the disease state, with higher tau levels indicating a more advanced stage of Alzheimer’s. As a reminder, the current anti-amyloid treatments are most effective for those who are in the earlier stages of the disease.

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