CAPITOL STREET

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CMS Likely to Finalize PET Scan Coverage

Due Oct 15; Good News for Alzheimer's Monoclonal Antibody Therapies

Relevant Companies

Our Take & Next Up

We expect CMS to finalize the removal of the once-per-lifetime PET scan coverage limitations, so that PET scan access will not be a problem. Local coverage will likely be determined by the Medicare Administrative Contractors (MACs), who will review new local coverage determination process (LCDs) requests within 60 days. LCDs generally take 9 -12 months to develop with finalization within a year. We believe MACs will allow for a limited number of scans for patients on Leqembi (definitely more than one) with possible restrictions such as one scan every 6 months or one scan per year as seen in clinical trials. MACs are incentivized to coordinate coverage to ensure national uniformity (which is what patients and providers want), but regional variability is possible based on how the administrators weigh the benefits of imaging and anti-amyloid therapy with costs of treatment.

Key Points

By October 15, we expect CMS to finalize 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 expected to be consistent with CMS's proposed decision. 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. PET scans help confirm whether brain amyloid exists and can guide future treatment. A removal of the NCD would allow Medicare Administrative Contractors (MACs) to make the coverage determinations. We expect each MAC to start the local coverage determination process shortly after.

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.

The decision to expand PET scan coverage comes with the commercial launch of 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. Registries typically require providers to collect patient imaging info, including PET scans. Leqembi rollout is ongoing with health systems and neurology clinics slowly beginning to prescribe the drug.

Leqembi scripts were strong in August, and we predict prescriptions will continue to accelerate as PET policy is solidified. Part of the uptake issue that BIIB is facing is that hospitals and clinics need time to work out the administrative and coverage policies, including imaging to screen eligibility for the drug. More consistent PET scan coverage policy by Medicare is expected to improve uptake in 2024. Several health systems and academic medical centers have publicly announced they will be offering Leqembi. These include BJC HealthCare in St. Louis, Mayo Clinic, Northwestern Memorial, Hospital of University of Pennsylvania, and Cedars-Sinai. More medical centers and neurology clinics are expected to start providing treatment by Q1 2024.

In other news, Donanemab (LLY) full FDA approval is expected before the end of 2023 and PET scans may be necessary to determine if patients can discontinue treatment. In Phase 3 trials, Donanemab was shown to slow the progression of Alzheimer's by 22% or 29% for all patients, depending on the cognitive test, and slowed progress for those in the early stages by 35%. LLY also highlighted that half of participants were able to stop taking Donanemab once they achieved amyloid plaque clearance (unlike Leqembi). We expect LLY to receive full FDA approval as their efficacy results are comparable to Leqembi. PET scans may be a necessity for those who take Donanemab as they will have the option to discontinue the drug with enough plaque clearance. The number of patients that would meet the criteria for starting either therapy make up just a portion of individuals diagnosed with Alzheimer’s disease. With the introduction of a competitor, we may see pricing changes or rebating impact as BIIB and LLY compete for space and patient uptake.

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