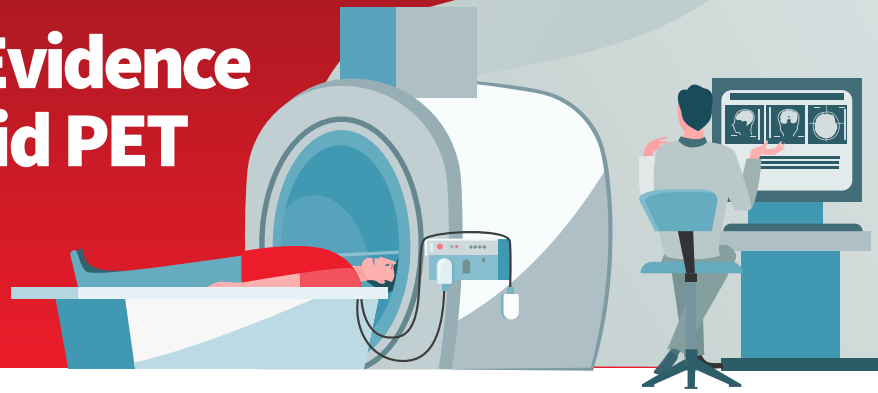




The Overwhelming Evidence in Support of Amyloid PET

Medicare Coverage Must Keep Pace with the Science

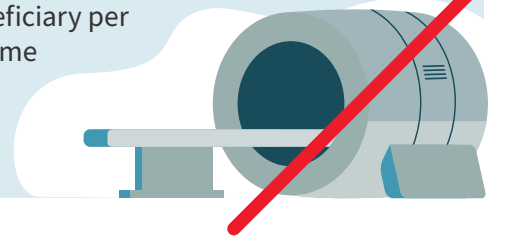


The Centers for Medicare and Medicaid Services (CMS) recently began the process of reconsidering its 2013 decision to significantly limit Medicare coverage of amyloid beta (A β) proton emission tomography (PET) scans. This is an important opportunity to greatly expand access to this critical diagnostic tool for millions of patients at risk of developing Alzheimer's disease.

2013

CMS issues National Coverage Determination (NCD) for A β PET which significantly constrained access to this procedure. To receive coverage for a PET scan, Medicare beneficiaries:

- Must be enrolled in a clinical trial to obtain access
- Are limited to only 1 scan per beneficiary per lifetime



Between 2012 and 2020, more than 30 academic manuscripts have been published showing how A β PET scans have empirically and repeatedly – even in the absence of disease-modifying therapeutics – demonstrated significant clinical utility by causing changed clinical management, changed patient diagnoses, and improved provider confidence.

- The clinical evidence for A β PET scans is now clear and well-developed.



2022

JUNE – JULY: Following CMS' decision to limit coverage of anti-amyloid therapies to treat Alzheimer's, the agency began the reconsideration process for the PET scan NCD.

During the public comment period, 30+ patient advocacy organizations weighed in:

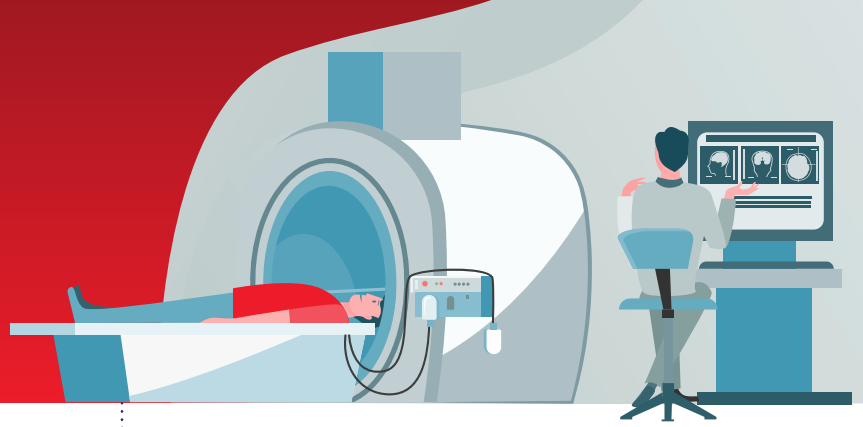
- 100% expressed support for reconsideration
- 100% support more than 1 scan in a patient's lifetime
- 70% cited health equity concerns that reconsideration could help address



**A draft decision is due
December 16, 2022**



The Overwhelming Evidence in Support of Amyloid PET



A Brighter Future for Millions of Patients

Should CMS keep pace with the science of today and allow broader patient access to A β PET scans, these diagnostic tools have the potential to help identify many more patients who could most benefit from new therapies, improving outcomes for millions. For example:

2023

PATIENT 1: John, a 70-year old retired engineer, was experiencing memory loss, forgetting doctors appointments frequently, and telling the same stories to his family in a short span of time. His complete medical history, routine lab tests, and physicals are normal, however, his neurological exam showed some mild memory loss. Due to a PET scan, however, his doctor identified moderate amyloid plaque presence in his brain – an early indication of Alzheimer’s disease. Now, John and his family can pursue treatment options that he otherwise would not have known he needed, or may not have been eligible for.



PATIENT 2: Ellen, a 65-year old accountant, had become increasingly withdrawn from her usual social activities. Her husband noticed a few memory lapses, her friends were worried as she was much quieter during book club, and her coworkers noticed a few accounting errors that were unlike her. Ellen had some irregular medical history and thanks to a negative PET scan - inconsistent with a neuropathological diagnosis of Alzheimer’s making it unlikely that her cognitive impairment is due to the fatal disease - Ellen and her husband can rule out Alzheimer’s and work with her doctors to identify the causes of her symptoms.



PATIENT 3: Vincent, 72-year old retired teacher, was diagnosed with early Alzheimer’s after a PET scan identified moderate amyloid plaque in his brain. He was fortunate to participate in clinical trials with the hopes that an innovative amyloid targeting therapy would remove the plaque before the disease could progress significantly. After several months of treatment, a PET scan assessed a high clearance of the plaque and Vincent now knows that the new drug candidate is removing the plaques from his brain. He will continue to monitor his cognitive abilities, but is hopeful the new drug will slow the course of the disease and give him more years with his family and friends.

