



From: New IDEAS Study Team

Approved: February 9, 2021

Subject: New IDEAS: Imaging Dementia—Evidence for Amyloid Scanning Study - **Clinical Trial Coverage Clarification**

Dear

The Centers for Medicare and Medicaid Services (CMS) issued a National Coverage Determination (NCD) on September 13, 2013 that provides Medicare coverage for the use of positron emission tomography (PET) amyloid-Beta (A β) imaging for Dementia and Neurodegenerative Disease for approved CMS studies under coverage with evidence development (Decision Memo for Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease [CAG-0043N]).

The clinical study “New IDEAS: A Study to Improve Precision in Amyloid PET Coverage and Patient Care” ([NCT#04426539](#)) was approved by CMS on April 21, 2020 under coverage with evidence development (CED), and is covered by Medicare. Medicare Advantage Organizations (MAO) such as _____ are required to provide similar coverage to Medicare Part A and B and therefore should provide coverage for the New IDEAS study. Please refer to section 10.7.3 of Chapter 4 of the [Medicare Managed Care Manual](#) relevant text extracted below:

10.7.3 – Payment for Clinical Studies Approved Under Coverage with Evidence Development (CED) (Rev. 120, Issued: 01-16-15, Effective: 01-01-15, Implementation: 01-01-15) In National Coverage Determinations (NCDs) requiring CED, Medicare covers items and services in CMS-approved CED studies. MAOs are responsible for payment of items and services in CMS-approved CED studies unless CMS determines that the significant cost threshold is exceeded for that item or service (see 42 CFR 422.109). Approved CED studies are posted on the [CMS Coverage with Evidence Development webpage](#).

New IDEAS is an approved NCD with CED study that aims to determine the clinical usefulness on patient outcomes of a brain positron emission tomography (PET) scan that detects amyloid plaques, a core feature of Alzheimer's disease.

Amyloid PET scans and related services performed in New IDEAS should be covered by MAOs if a patient is enrolled in a Medicare-approved clinical study and the criteria of the NCD with CED are met. As with coverage of any Medicare benefit, coverage of amyloid PET scans and related services in New IDEAS should be medically reasonable and necessary and MAOs may require preauthorization. Enrollee cost-sharing for New IDEAS should be at the in-network rate for similar services.

Attached to this letter you will find correspondence from the Health Plan Management System regarding coverage clarification specific to the original IDEAS study. The coverage information within that letter aligns with the information stated above and remains applicable to the New IDEAS study.

Sincerely,

The New IDEAS Study Team

Directed by The Alzheimer's Association
Sponsored and Managed by The American College of Radiology
newideas@acr.org

From: HPMS

Sent: Monday, October 03, 2016 4:50:07 PM (UTC-05:00) Eastern Time (US & Canada)

To:

Subject: Imaging Dementia—Evidence for Amyloid Scanning Clinical Trial Coverage Clarification

This email provides information about the clinical trial, Imaging Dementia-Evidence for Amyloid Scanning (IDEAS), and reminds Medicare Advantage Organizations (MAOs) of their responsibility to cover national coverage determinations approved under coverage of evidence (NCDs with CED) as specified in section 10.7.3 of Chapter 4 of the Medicare Managed Care Manual.

The IDEAS clinical trial is an NCD with CED that will determine the clinical usefulness on patient outcomes of a brain positron emission tomography (PET) scan that detects amyloid plaques, a core feature of Alzheimer's disease. CMS has learned that some MAOs are denying claims for IDEAS as they do not believe they are responsible for covering this trial. As with all NCDs with CED, IDEAS must be covered by MAOs if a patient is enrolled in a Medicare-approved clinical study and the criteria of the NCD with CED are met.

As with coverage of any Medicare benefit, coverage of IDEAS must be medically reasonable and necessary and MAOs may require preauthorization. Enrollee cost-sharing for IDEAS must be at the in-network rate for similar services.

We are including information on this clinical trial as a link at the end of this email.

If you have any questions about this email please contact your Regional Office Account Manager.

<https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Amyloid-PET.html>