

Memorandum

To: The New IDEAS Study Network
From: New IDEAS Study Leadership
Date: February 15, 2024
Subject: New IDEAS Study Accrual Closure

Announcement

New IDEAS Study leadership commends the participating dementia practices and PET imaging facilities for their continued enthusiasm and commitment to the New IDEAS Study since the first participant was registered in December 2020. After careful consideration of numerous factors and evaluation of the risk-benefit tradeoff for patients, **Study leadership has decided to end Study accrual on Friday, March 1, 2024 at 11:59pm EST**. At that time, patient registration into the Study Portal will be closed. This deadline is applicable to all race/ethnicity cohorts of the Study.

This decision was difficult; however, Study leadership is confident that this is the best course of action based on the following factors:

- **CMS retiring of National Coverage Determination (NCD) on amyloid PET**, ending Coverage with Evidence Development (CED) as a criterion for coverage of these scans.
- **Recent increases in prior authorization denials** of Study participants' amyloid PET scans, namely for patients with Medicare Advantage (MA) plans.
- **Disconnect between the protocol and the real-world** may jeopardize the relationship between the patient, practice, and imaging facilities, and poses billing risks outside of the control of Study Team oversight.

Background for the Decision

The New IDEAS Study protocol was developed and approved as a Coverage with Evidence Development (CED) Study under the supervision of the Centers for Medicare & Medicaid Services (CMS). On October 13, 2023, CMS issued a [public announcement](#) that retired the National Coverage Determination (NCD) on amyloid PET and ended CED as a criterion for coverage of amyloid PET scans. As a result of the retirement of the NCD, CED is no longer applicable to the Study, and Medicare contractors reserve the right to determine their own coverage policies. Recently, practices and facilities have brought to light several real-world complexities that impact Study patients and the ability to access a covered amyloid PET scan.

Despite the leadership team’s strong desire to achieve the study’s pre-determined accrual goals, the new landscape for billing procedures and coverage of amyloid PET scans has proven to be inconsistent across insurance plans, namely Medicare Advantage (MA) plans. Among patients with traditional Medicare plans and select MA plans, the Study Team has seen successful reimbursement of scans post-NCD retirement. However, for some MA plans, we are unable to advise practices and facilities on a pathway to successful prior authorization in cases where plan-managed criteria for coverage have changed. In summary, we can no longer rely on the now retired NCD for justification of coverage. The Study Team is concerned that the disconnect between the protocol and the real-world may jeopardize the relationship between the patient, practice, and imaging facilities, and poses billing risks outside of the control of Study Team oversight.

Additionally, inclusivity of patients with Medicare Advantage plans is important to the New IDEAS Study, and due to nature of the Study’s protocol inclusion criterion, “Medicare beneficiary with Medicare as primary insurance,” the Study must consider the feasibility of our protocol against new structural barriers. Additionally, the retirement of the NCD on amyloid PET, which means that patients can now obtain amyloid PET scans without needing to participate in New IDEAS, may negatively impacts recruitment efforts at participating practices and create confusion for patients during the informed consent process.

Considering all variables, and after careful evaluation of the risk-benefit tradeoff for patients, Study leadership determined that the best course of action is to close accrual study-wide.

Patients registered prior to this announcement and those registered through the registration deadline (March 1, 2024) should continue completing Study-related procedures, as outlined in the protocol. Beyond the scope of the Study protocol, practices should continue to provide culturally sensitive memory care, serve as advocates for their patients and allocate appropriate resources to stay engaged in their communities to increase access to memory care.

What We Have Accomplished

The New IDEAS accrual total to date is a testament to the collaborative efforts of participating dementia practices, community partners and volunteers who made the Study possible. Study leadership acknowledges that despite not meeting pre-specified cohort accrual goals, **New IDEAS represents one of the largest datasets of its kind and is an important milestone in Alzheimer's research prioritizing inclusion of patients who self-identify as Black/African American and Hispanic/Latinx, populations that share the greatest burden of dementia. The Study Team is committed to seeing through the planned analyses and objectives of the Study, despite early closure to accrual.** Updated Study accrual numbers can be found on the [New IDEAS Recent Study Updates](#) webpage.

Next Steps

Please review the [frequently asked questions on study closure](#). Dementia practices and imaging facility staff should contact the study's operational team at newideas@acr.org with any questions or concerns. We remain committed to maintaining open communication and providing guidance to ensure your site or facility is comfortable navigating the new amyloid PET scan landscape beyond New IDEAS. In the coming weeks and months, sites and facilities can expect to receive a personalized email from the operations team to touch base about outstanding data, individual timelines and additional closure procedures.

Thank You

Your commitment to patient care and research has been instrumental in the Study's accrual success. Study leadership is looking forward to sharing the Study results with the greater scientific community, research participants who complete the Study as well as offering opportunities for investigators to access Study data in the future to explore their own research questions, advance the science and celebrate inclusive research. We want to express our gratitude for your partnership and support of the New IDEAS mission to address important gaps in knowledge that will help advance the study and care for diverse groups of people with dementia. Your expertise and dedication have been invaluable throughout this process. While your involvement in this Study may be ending, we look forward to future opportunities for collaboration.

Sincerely,

New IDEAS Study Leadership