

IDEAS Study Opens Registration

In a press release issued on October 28, the American College of Radiology (ACR), the American College of Radiology Imaging Network (ACRIN), and the Alzheimer's Association announced the opening of online registration for participation by dementia specialists and PET imaging centers in the Imaging Dementia—Evidence for Amyloid Scanning (IDEAS) Study. The IDEAS Study protocol was developed in response to the 2013 Centers for Medicare & Medicaid Services (CMS) National Coverage Decision (NCD) on amyloid PET imaging in dementia and neurodegenerative disease (CAG 00431N). In that decision CMS denied coverage of amyloid PET imaging because it had “determined that the evidence is insufficient to conclude that the use of PET amyloid- β imaging is reasonable and necessary for the diagnosis or treatment of illness or injury” or to improve function in Medicare beneficiaries with dementia or neurodegenerative disease. As part of this NCD, however, CMS allowed coverage of a single amyloid- β PET scan per patient through the coverage with evidence development (CED) process.

The IDEAS Study will use the CED mechanism to follow almost 19,000 Medicare beneficiaries for up to 4 years, with a goal of providing sufficient evidence to demonstrate that awareness of the results of amyloid PET imaging can assist physicians in making more informed decisions about clinical management. CMS will provide reimbursement to participating PET facilities for costs associated with PET imaging, and additional funding to support research infrastructure and analysis of results is being provided by the Alzheimer's Association and a consortium of radiopharmaceutical manufacturers. The study will be led by the Alzheimer's Association and managed by ACR and ACRIN and is expected to begin enrolling patients in the first quarter of this year.

Research from the IDEAS Study will determine the clinical utility and value of a brain PET scan in detecting amyloid- β associated with Alzheimer disease and in diagnosing and managing treatment for individuals with mild cognitive impairment (MCI) or dementia where the cause is uncertain. The study has 2 specific aims:

- To assess the impact of PET on the management of patients meeting appropriate use criteria (as developed by a working group from the Alzheimer's Association and SNMMI) for brain amyloid PET imaging; and
- To assess the impact of amyloid PET imaging over a period of 12 months on major medical outcomes, such as hospital admissions and emergency room visits, in patients enrolled in the study and in a group of matched patients not in the study.

Board-certified neurologists, psychiatrists, and geriatric medicine physicians interested in becoming referring

physicians for the IDEAS study and PET facilities that would like to join the study as imaging sites may apply for participation at Ideas-Study.org using the Login/Register portal. Background on the study, requirements for participation, and a set of frequently asked questions are available on the website. SNMMI has posted a free informational webinar on the IDEAS Study at <https://www.snmmilearningcenter.org/Activity/3690043/Detail.aspx>.

As participating providers in the IDEAS Study, dementia specialists will team with radiologists and nuclear medicine physicians at qualified PET facilities. All participating physicians will consent to fulfill study training as well as data and timeline requirements. The IDEAS Study will not directly recruit patients; instead, patients will be referred into the study by dementia specialists. Dementia specialists will enroll patients whose cases meet the study enrollment criteria and refer them for an amyloid PET scan. PET scans will be performed and interpreted by a nuclear medicine physician or radiologist with results provided to the ordering physician for disclosure to the patient and to support further diagnostic decisions. Scan results and diagnoses will be captured for the study. Participating PET imaging providers will be reimbursed for the scans under the CMS CED mechanism. The total budget for the study is estimated at \$100 million over 4 years.

The IDEAS Study is modeled after the National Oncologic PET Registry (NOPR). NOPR assessed whether PET used for diagnosing and evaluating treatment of individuals with cancer would have an impact on patient management. The study generated evidence that guided CMS decisions regarding expansion of coverage of PET for multiple cancers.

“Through NOPR, we learned a great deal about how to conduct this type of study and determine the value of PET in situations where understanding the presence of hallmarks of a disease is important to making care decisions,” said Barry Siegel, MD, professor of radiology at Washington University (St. Louis, MO), IDEAS Study investigator, and cochair of NOPR. “We expect that by following the model and involving NOPR personnel in the creation and launch of IDEAS, we can efficiently determine the value of amyloid PET in managing care for individuals with Alzheimer's.”

“Dementia specialists who participate in the study will be able to offer easier access to appropriate patients, and use amyloid status to refine their diagnosis and optimize the management of these individuals,” said Gil D. Rabinovici, MD, IDEAS study chair and associate professor of neurology at the University of California, San Francisco. “Participating providers also will help to amass sufficient data to assess whether amyloid imaging has a positive impact on patient outcomes that could lead to expansion of Medicare coverage for this important diagnostic tool.”