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REGISTRATION NOW OPEN FOR DEMENTIA SPECIALISTS AND PET IMAGING CENTERS TO PARTICIPATE IN RESEARCH STUDY OF BRAIN AMYLOID SCANNING

Study Offers Reimbursement for PET Imaging for Diagnosis of Alzheimer’s and Dementia

RESTON, VA. and CHICAGO, October 28, 2015 – Dementia specialists and PET imaging providers can now register to participate in the Imaging Dementia – Evidence for Amyloid Scanning (IDEAS) Study at Ideas-Study.org.

Research from the IDEAS Study will determine the clinical usefulness and value of a brain PET scan that detects the hallmark brain amyloid accumulation of Alzheimer’s disease in diagnosing and managing treatment for people with mild cognitive impairment (MCI) or dementia where the cause is uncertain. Individuals who meet these requirements are eligible for enrollment in the study, which is expected to begin in early 2016.

The IDEAS Study is led by the Alzheimer’s Association and managed by the American College of Radiology (ACR) and American College of Radiology Imaging Network (ACRIN). The Centers for Medicare & Medicaid Services (CMS) will provide reimbursement to participating PET facilities for the costs associated with the PET scans. Additional funding to support the research infrastructure and analysis is being provided by the Alzheimer’s Association and a consortium of PET tracer manufacturers.

“There is tremendous interest in this groundbreaking trial. Amyloid PET can be incredibly useful in assessing diagnostically challenging patients with MCI or dementia. However, patient access has been severely restricted by lack of reimbursement. 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, M.D., 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.”

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.

Diagnosing Alzheimer’s is complex and there is no single test available for detecting the disease. Diagnosis is currently based on a person’s history, physical examination, and cognitive testing. When a comprehensive exam does not lead to a clear diagnosis of the cause of cognitive impairment, it can be frustrating for patients, families and physicians, and may have a negative impact on patient care. For
example, some people improperly diagnosed may be prescribed the wrong medications for their situation or no medications at all when they may be beneficial.

Amyloid PET imaging represents a potential major advance in the clinical assessment of people with cognitive impairment. Amyloid plaques and tau tangles are prime suspects in damaging and killing nerve cells in Alzheimer’s. Amyloid plaques are deposits of the protein fragment amyloid-beta that build up in the spaces between nerve cells. On an amyloid PET scan, the plaques in the brain are visualized, enabling for the first time accurate detection of the plaques in living people. Before amyloid PET imaging was available, the only way to confirm the presence of plaques was examining the brain upon autopsy.

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) to not provide Medicare coverage of the scans because “the evidence is insufficient to conclude that the use of positron emission tomography (PET) amyloid-beta (Aβ) imaging is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of... Medicare beneficiaries with dementia or neurodegenerative disease.”

The study will follow almost 19,000 Medicare beneficiaries for up to four years to provide a sufficient amount of evidence to demonstrate that knowing the results of an amyloid PET scan may help physicians make more informed treatment decisions.

“The Alzheimer’s Association is leading the IDEAS Study because we understand the importance of early and accurate diagnosis and management of dementia for individuals with the disease and their families,” said Maria Carrillo, Ph.D., Alzheimer’s Association chief science officer and IDEAS Study co-chair. “There has never been a study of this scale to evaluate the clinical value of brain amyloid imaging in diagnosing and caring for those affected by Alzheimer’s. The dementia specialists and facilities that register for the IDEAS Study will play an essential role in engaging the almost 19,000 individuals needed in the study and carrying out the amyloid PET scans.”

As participating providers in the IDEAS Study, dementia specialists will team with trained radiologists and nuclear medicine physicians at qualified PET facilities, all of whom will consent to fulfilling study training, data, and timeline requirements. The IDEAS Study will not directly recruit patients, who must instead 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. Amyloid 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 diagnosis will be captured for the study.

Participating PET scan providers will be reimbursed for the scans under the CMS Coverage with Evidence Development (CED) policy that requires research study participation as a condition of Medicare payment. The total budget for the study is estimated at $100 million over four years.

The IDEAS Study is modelled 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, M.D., professor of radiology at Washington University in St. Louis, IDEAS Study investigator, co-chair of NOPR, and member of the American College of Radiology Commission on Clinical Research & Information Technology. “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.”
The IDEAS Study in More Detail

Amyloid PET imaging alone does not establish a diagnosis of Alzheimer’s disease but must be considered in the context of the person’s medical history, physical examination, and cognitive testing. To guide clinicians on how best to apply amyloid PET in the clinical evaluation of people with cognitive decline, a working group convened by the Alzheimer’s Association and the Society of Nuclear Medicine and Molecular Imaging (SNM-II) developed appropriate use criteria (AUC) for brain amyloid PET scans.

The AUC indicate that amyloid PET should only be considered in patients with clear, measurable cognitive deficits when there is substantial diagnostic uncertainty after a comprehensive evaluation by a dementia specialist. According to AUC, amyloid PET may have greatest value in patients with either: (1) progressive, unexplained mild cognitive impairment; or (2) dementia of uncertain cause due to atypical or mixed symptoms, or unusually early age-of-onset. A total of 18,488 Medicare beneficiaries age 65 and older meeting AUC will be enrolled over 24 months at approximately, but not limited to, 200 sites throughout the United States. Study participants will be recruited into one of two subgroups: (1) progressive, unexplained MCI, and (2) dementia of uncertain cause.

The IDEAS Study will address two specific aims:

- Assess the impact of amyloid PET on the management of patients meeting AUC.
- Assess the impact of amyloid PET over 12 months on major medical outcomes, such as hospital admissions and emergency room visits, in patients enrolled in the study compared to matched patients not in the study.

The IDEAS Study Leadership

The IDEAS Study Chair is Gil D. Rabinovici, M.D., associate professor of neurology at the University of California, San Francisco, a behavioral neurologist with research expertise in amyloid PET. The leadership team includes Bruce E. Hillner, M.D., from Virginia Commonwealth University and Barry A. Siegel, M.D., from Washington University, the chair and co-chair, respectively, of the National Oncologic PET Registry (NOPR), one of the most influential registries developed in response to the CMS CED requirements. Data management and statistical analyses will be managed by the American College of Radiology/American College of Radiology Imaging Network and Brown University School of Public Health, which were the data hosts for statistical evaluations in NOPR under the leadership of Constantine Gatsonis, Ph.D. The study leadership team further includes Rachel Whitmer, Ph.D., a senior scientist and epidemiologist at Kaiser Permanente Division of Research and an expert on population-based studies of dementia risk factors and outcomes. The IDEAS Study protocol development has been coordinated by the Alzheimer’s Association, under the leadership of Maria Carrillo, Ph.D., chief science officer, and the ACR.

The American College of Radiology, founded in 1924, is a professional medical society dedicated to serving patients and society by empowering radiology professionals to advance the practice, science, and professions of radiological care.

The Alzheimer’s Association is the leading voluntary health organization in Alzheimer’s care, support and research. It is the largest nonprofit funder of Alzheimer’s research. The Association’s mission is to eliminate Alzheimer’s disease through the advancement of research; to provide and enhance care and support for all affected; and to reduce the risk of dementia through the promotion of brain health. Its vision is a world without Alzheimer’s. Visit alz.org or call 800.272.3900.

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