Draft Decision Memo Public Comments for PET and Other Neuroimaging Devices for Suspected Dementia CAG-00088R June 15-July 15, 2004

Comment #1:
Submitter: Donald Margouleff, M.D
Organization: North Shore University Hospital
Date: Wed, Jun 16, 2004 12:11 PM
Comment:
I am Medical Director of the PET Facility at the North Shore University Hospital. We have been performing PET since 1987. The use of PET in evaluating Alzheimer's should be approved. With the development of treatments to slow or halt the progression of disease, it is vital to make the diagnosis early in the course of the disease and to have an objective means to monitor the effect of the medications. PET has the potential to be useful in both diagnosis and treatment monitoring

Comment #4:
Submitter: LouAnn Reid
Organization:
Date: Wed, Jun 16, 2004 3:47 PM
Comment:
I feel it is imperative to approve PET for the dectection of Alzheimer's disease. So many of our elderly patients are being misdiagnosed or not even tested at all. This leads to an exorbitant number of patients that are missing the opportunity for treatment. PET offers physicians a noninvasive modality to detect abnormalities within the brain, therefore allowing AlzheimerÆs patients the benefit of therapy and prolong their quality of life. Like other PET applications, approval for AlzheimerÆs will benefit the patient in a positive manner and allow for proper treatment.

Comment #5:
Submitter: Howard fillit
Organization:
Date:
Comment:
coverage of PET imaging for the diagnosis of dementia will have an important impact on the quality of care for patients with dementia, promoting early diagnosis by physicians. however, to confirm the diagnosis, better methods for neuropsychological examination is needed. Advancements in the field of computerized cognitive testing, such as Mindstreams (at www.neurotrax.com), make objective cognitive testing in primary care possible and would complete the attempt to bring diagnosis of dementia into the mainstream of modern medicine by enabling doctors to use technology in a practical manner, with a reasonable business model. i highly recommend the panel incorporate some method for practical computerized, internet based, quality and standardized cognitive assessment into the overall guideline for diagnosis and assessment.

Comment #6:
Submitter: Jeff Ervin, CNMT, ARRT (R,N)
Organization: MD Nuclear Imaging
Date:

Comment:

Proposed reimbursement criteria seem quite reasonable and well researched. Please finalize this important decision soon, as there are many untreated individuals that need to be assessed. We recently did a PET scan on a man in his late fifties who payed out of pocket, which demonstrated a clear cut parietotemporal defect, explaining his symptoms of early alzheimer's disease. He is soon to undergo treatment for AD, which will undeniably save him, his family, and the medical community a lot of money and grief.

Comment #7:
Submitter: Walter Gaman, MD
Organization: Healthcare Associates
Date:
Comment:
To Whom It May Concern,

My name is Dr. Walter Gaman and I am a Family Practitioner. I believe this proposal would benefit our patientÆs greatly. I do however have a few concerns on some of the conditions that must be met before it would be covered.

First of all, in your condition numbered one bullet point two, it states in the paragraph ôPhysical and mental status examination aided by cognitive scales OR neuropsychological testingö but in your bullet point seven it states a list of information that must be collected and both the MMSE and neuropsychological testing are asked for. This clearly needs to be clarified. In my opinion, neuropsychological testing is a test that might not be necessary with all the other testing that would be performed on each patient. It is also a very tedious test that not many professionals are qualified to perform, so finding a professional who does perform the test could be that much harder and delay necessary testing with the PET scan.

Second, the Alzheimer Association recommends that doctors that would be allowed to order the scans would have to be spend at least 25% of their practice focusing on dementia. This is not realistic. We generally see newborns to elderly patients. Personally my elderly patients would make up the 25% of my practice, but not all elderly patients have Dementia or AlzheimerÆs disease. A percentage should not be placed on a doctor.

I know the CMS office will carefully consider all the comments that are presented in the next thirty days. Thank you for your time and consideration.

Comment #8:

Submitter: Neil Corpus

Organization: Pioneer PET

Date:

Comment:

I am a registered Nuclear Medicine Technologist specializing in PET Imaging in the Phoenix area. Based on the guidelines and clinical testings UCLA have done in this field, I believe that the use of FDG-PET imaging can significantly help the clinician as well as the patient and his loveones manage

his care properly. Accurate early diagnoses of AD can change the whole management care of the patient. Thank you for your time.

Comment #9:

Submitter: Albert L. Berarducci, Jr. MD

Organization: The Neurological Associates, Inc.

Date:

Comment:

I question the need for PET scan in the diagnosis of Alzheimer disease as it relates to the general practice of neurology, internal medicine, and gerontology. Since we have no effective treatment for the disease, what use would there be to know about its presence sooner rather than later? I can envision a groundswell of demand for the test since there is such paranoia in the patients I see about "memory loss". You can bet that there will be more tests ordered than are necessary, especially in those on the younger end of the age spectrum worried about AD. Most have "benign forgetfulness" and not AD. Do we really need a test to make people feel more secure about this one issue?...and for and estimated $1800 per test?!? What will become of the test's false positives and false negatives... How will both of these classes of people impact the economic system as decisions about estate planning begin taking the PET scan results into account?

While the PET scan for diagnosis of Alzheimer disease is theoretically a good idea, I would only feel comfortable with medicare reimbursement if the test is ordered only after a patient qualifies for it by passing the most stringent of clinical filters and criteria. It should not be "out there" for the general consumption of the medical system as it is currently organized. Be smart! Make it VERY DIFFICULT to have this test reimbursed. It should be insulated from for-profit imaging centers at very least! We do not need slap-dash PET studies done and interpreted in the current entrepreuerial environment of modern medicine USA! Thanks for listening...

Comment # 10:

Submitter: Ely Simon

Organization: Neuro Trax Corp.

Date: Fri, July 9, 2004 4:18 AM

Comment:

PET scanning for dementia. It is a step forward in the care of the elderly. My comment pertains to a problematic point in application of the decision (CAG-00088R) to community-based medical practice, where the vast majority of elderly are treated. According to the decision, patients are eligible for PET only if they have undergone comprehensive clinical evaluation including ômental status examination aided by cognitive scales or neuropsychological testingö. This requirement poses a considerable challenge, as comprehensive neuropsychological evaluations as performed by neuropsychologists are expensive and time consuming. As a board-certified neurologist, I know that our bedside examination for mental status is neither standardized nor quantitative. Also, brief screens like the MMSE are not

sensitive for early signs and have poor specificity for more advanced cases of cognitive impairment. Further, the need for demonstration of decline over 6 months is not addressed by office-based tools. As such, there is inadequate availability of tools and resources for proper comprehensive cognitive assessment, except in the few specialized dementia care centers. I would like to direct your attention to the recent development of validated tools for computerized cognitive assessment. Such tools are standardized, low-cost, and may be deployed in the office environment. Computerized tools from NeuroTrax are available for comprehensive assessment to detect and track mild impairment (approx. 35 minutes), to track longitudinal changes through the stages fo dementia severity (approx. 12 minutes), and for screening (under 10 minutes, to determine which patients need comprehensive assessment). These tools are used in clinical research, in addition to patient care applications.

Comment #11

Submitter: Michael Phelps

Organization: UCLA

Date: Tue, Jul 13, 2004 5:19 PM

Comment:

The following refinements to the language in the CMS Decision Memorandum (CAG #00088R), part I, subpart 1, are recommended.

> replace the phrase ôwho meet diagnostic criteria for both AlzheimerÆs disease (AD) and fronto-temporal dementia (FTD),ö along with the first additional condition, ôThe onset, clinical presentation, or course of cognitive impairment is aberrant for AD, and FTD is suspected as an alternative neurodegenerative cause of the cognitive declineö with the following (more explicit/less ambiguous) language, which will be listed as the first additional condition: Eligible patients will meet diagnostic criteria for AlzheimerÆs disease (AD), or would meet criteria for AD

except for the presence of certain atypical signs or symptoms. Such signs or symptoms would include one or more of the following: 1) personality or behavioral changes occurring early with respect to the onset of clinical symptoms, or occurring out of proportion to the degree of cognitive impairment observed; 2) changes in language abilities or executive function occurring out of proportion to impairment of memory and other cognitive domains; 3) onset of new somatic complaints coincident with the onset of cognitive symptoms which cannot be accounted for by physical findings; 4) one (but not more than one) of the following û auditory and/ or visual hallucinations, motor symptoms of parkinsonism not explained by extrapyradimal effects of medications, or spontaneous fluctuations in cognition, alertness and attention; 5) frontal atrophy or enlargement of Sylvian fissures greater that would be expected for patientÆs age.

> add to the sixth additional condition (ôA brain SPECT or PET scan has not been obtained for the same indication,ö) the following phrase: unless there has been a significant change in the signs or symptoms upon which the patientÆs dementia diagnosis is based following the time the prior scan was obtained, and the patient continues to meet all other qualifying criteria listed above and below.

> add to the condition ôneuropsychological testing,ö the phrase: when needed to establish the involvement of multiple cognitive domains.

> add to the condition ôstructural imaging,ö the phrase: when indicated.

Sincerely,

Ahmed, Iqbal, M.D., M.R.C. Psych. (UK), Professor of Psychiatry, Vice-Chair for Education, Program Director General and Geriatric Psychiatry Residency Programs, John A. Burns School of Medicine, University of Hawaii

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Simon, Jennifer Jones, President Jennifer Jones Simon Foundation for Mental Health

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Wong, Dean, M.D., Ph.D., Professor of Radiology, Johns Hopkins School of Medicine

Yesavage, Jerome, M.D., Professor, Director, AlzheimerÆs Disease Center, Stanford University School of Medicine, Stanford, California

Comment #12

Submitter: Gary Dillehay, M.D.

Organization: The Society of Nuclear Medicine

Date: July 14, 2004

Comment:

The Society of Nuclear Medicine (SNM) representing more than 14,000 physicians, physicists, scientists, pharmacists and nuclear medicine technologists, appreciates the opportunity to comment on the June 15, 2004 draft decision memorandum for Positron Emission Tomography (FDG) and other Neuroimaging Devices for Suspected Dementia (CAG-00088R)

As stated in previous written comments, the SNM continues to support expanded coverage of FDG PET and is generally pleased with CMS's June 15th 2004 proposed decision memorandum. The SNM encourages CMS and the community to collect the relevant data to continue to expand and provide these valuable medical services to the Medicare population. We commend CMS for this initial action and believe that the proposed decision memorandum is a positive step forward for Medicare beneficiaries.

The SNM would like to address one issue which is not mentioned in this decision memorandum; CMS instructions and choice of coding by providers. For many years CMS has chosen to implement complex G series HCPCS codes for billing PET procedures, in spite of the presence of CPT codes for the same procedures. We understand that G codes for PET (cardiac procedures) were originally created to track and monitor the clinical use of PET. We are not aware of CMS's use of those G codes, nor are we convinced that further tracking and data collection of this type is meaningful or useful.

There currently exist CPT codes for PET procedures, CPT *78459 Myocardial imaging, positron emission tomography (PET) metabolic evaluation*, CPT 789491 *Myocardial imaging, positron emission tomography (PET) perfusion; single study at rest or stress*, CPT 78492 *Myocardial imaging, positron emission tomography (PET) perfusion; multiple studies at rest and /or stress*, CPT 78608 *Brain imaging, positron emission tomography (PET); metabolic evaluation* , CPT 78609 *Brain imaging, positron emission tomography (PET); perfusion evaluation* and CPT 78810 *Tumor imaging, positron emission tomography (PET), metabolic evaluation.* Effective January 1, 2005 CPT will publish new and refined PET codes specifically for tumor imaging, which we believe better meet the provider and global payer needs. Additionally, with the implementation of category III CPT codes, the need for G series HCPCS procedure codes should become unnecessary except in absence of any appropriate CPT I or CPT III category code.

Therefore, the SNM urges CMS **not to create** separate G series HCPCS codes for this expanded coverage. This is administratively burdensome for providers, creating cumbersome charge description masters based on a variety of payers. **The SNM recommends that CMS use the current existing PET Brain imaging CPT code 78608**
Brain imaging, positron emission tomography (PET); metabolic evaluation . Additionally, we recommend that CMS adopt the RUC approved values and update Medicare values for each professional, technical and global payment rates for this code. We do not recommend that CMS leave payment setting for well established procedures such as PET to carrier discretion, which do create inconsistent payment across the country.

We believe that simplifying the coding process will facilitate implementation for both the CMS as well as for the providers. CMS has developed NCDs for other procedures. CMS can oversee the coverage determination without the use of G codes. As stated in the proposed requirements, "The referring and billing providers(s) have documented the appropriate evaluation of the Medicare Beneficiary…" is sufficient to validate compliance as necessary. Use of G codes does not ensure compliance.

Again, the SNM appreciates the opportunity to comment on this proposed expanded coverage for Alzheimer's disease and other suspected dementia.

Comment #13:

Submitter: Eric J. Hall

Organization: Alzheimer’s Foundation of America

Date: July 15, 2004

Comment:

On behalf of the Alzheimer's Foundation of America, attached for your information is a copy of comments submitted on-line in support of the CMS Draft Decision Memorandum for Positron Emission Tomography and other neuroimaging devices for suspected dementia (CAG-00088R).

Thank you for your consideration.

July 15, 2004

Centers for Medicare and
of Clinical Standards and
Analysis Group Attn: Public
7500 Security Boulevard
21244-1850

Alzheimer's Foundation of America

Medicaid Services Office
Quality Coverage and
Comments, S3-02-01
Baltimore, MD

Re: Draft Decision Memorandum for Positron Emission Tomography and Other Neuroimaging Devices for Suspected Dementia (CAG-00088R)

Dear Sir or Madam:

The Alzheimer's Foundation of America (AFA) supports the proposal by the Centers for Medicare and Medicaid Services (CMS) to provide Medicare reimbursement of Positron Emission Tomography (PET) for detection of Alzheimer's disease.

Our support is based on the belief that this will drive early intervention for the increasing— and alarming—number of Americans with Alzheimer's disease. Utilization of this technology will become even more critical in the future, as the number of Americans with dementia is projected to triple by mid-century.

The proposed expansion of Medicare coverage is consistent with AFA's call for a national public-private memory screening initiative that would expand access to free screenings and education regarding prevention wellness to those concerned about memory problems. Our nation needs a complete strategy that involves both research for a cure, as well as a national system of care that involves cognitive wellness, early intervention and disability compression.

With no "silver bullet" for dementia in the immediate future, we need to fully use all preventive measures and early interventions. Early recognition is essential to maximize the therapeutic effects of available and evolving treatments. Screening is the only way to systematically find treatable cases. PET studies will provide a valuable tool in predicting disease, and steering those with a diagnosis of Alzheimer's or related illnesses to the appropriate clinical and social service resources.
Diagnosis in the early stages of the disease is vital, providing multiple benefits to individuals with the disease, families and society. For the affected individual, identification of early stage dementia allows early aggressive use of available treatments. When dementia is identified and diagnosed, individuals can receive available therapy. Early identification allows optimal therapy with available and emerging medications. Most FDA-approved medications slow the onset of disability when presented in early stages of dementia.

Once dementia is identified, health care management can be adjusted to incorporate treatment strategies that accommodate a person with cognitive impairment. Issues such as patient education, self-medication, compliance, and hospital care can be adjusted to meet the needs of a mildly demented person who is at risk for common complications such as delirium and depression. Home-based support systems can be adjusted to maximize home placement for these individuals. Safeguards can be taken to prevent avoidable complications such as delirium during hospitalization.

Further, the early identification of dementia supports individual patient rights and self-determination.

Mildly impaired patients are capable of charting the future course of their care and making substantial decisions on issues like end-of-life care, resuscitation, disposition of wealth, etc. Advanced directives can be initiated that incorporate the wishes of individuals with dementia, thereby reducing the burden on the family of surrogate decision-making.

Lastly, individuals with the disease can take advantage of social services and other support that can improve quality of life. These include counseling, verbal support groups and cognitive stimulation therapies. These strategies may prolong activities of daily living, and promote a sense of dignity.

Family caregivers benefit from early identification at several levels. About one-third of elders live by themselves, and these individuals are at greater risks for accidents, injuries, exploitation, and other adverse outcomes. Early identification allows safeguards and home assistance to assure continued maximization of home placement. As noted above, early identification reduces the family burden with regard to decision-making, because families can follow the instructions of the patient.

In addition, this process allows family caregivers to benefit early on from support groups, education and other interventions that address their unique and pressing needs. Such knowledge and support can empower them to be better caregivers and can reduce their incidence of depression and other mental and physical health problems.

Screening and early identification may also benefit society by protecting individuals and reducing the costs of health care. Unrecognized dementia can increase the likelihood of avoidable complications such as delirium, adverse drug reactions, noncompliance, etc. These complications reduce the autonomy of the patient.
By contrast, enhancing compliance and protecting patients produces tangible financial benefits to the health care system. Intervention can enable individuals to remain independent longer and can reduce the costs of insurance, absenteeism and lost productivity at work for primary caregivers—currently estimated at $60 billion annually.

PET scans also can be beneficial for those individuals who do not present a diagnosis of Alzheimer's disease. These negative results can allay fears and provide reassurance. Just as importantly, physicians can take this opportunity to present individuals with prevention and wellness education—a strategy that promotes successful aging.

In conclusion, AFA believes this proposal represents an important step forward in our collective efforts to improve care for individuals with Alzheimer's disease. We welcome the opportunity to work collaboratively with CMS in advancing this initiative.

Comment #14:

Submitter: Sheldon Goldberg

Organization: Alzheimer's Association

Date: July 15, 2004

Comment:

The Alzheimer's Association appreciates the opportunity to comment on the Decision memorandum for FDG-PET for diagnosis of early dementia in elderly patients. The Alzheimer's

Association is the premier source of information and support for the 4.5 million Americans with Alzheimer's disease. Through its national network of chapters, it offers a broad range of programs and services for people with the disease, their families, and caregivers and represents their interests on Alzheimer-related issues before federal, state, and local government and with health and long term care providers. The largest private funder of Alzheimer research, the Association has committed nearly $150 million toward research into the causes, treatment, prevention, and cure of Alzheimer's disease.

The Alzheimer's Association applauds the process utilized by CMS to engage the scientific, clinical and patient advocacy community in its discussion regarding this coverage matter. CMS staff sought out the opinions of this broad and varied group and held a constructive, open dialogue with individuals that have knowledge and opinions on the value of PET. This process resulted in the best possible synthesis of opinion.

The Alzheimer's Association commends the CMS decision for Medicare coverage of PET for the differential diagnosis of Alzheimer's disease versus other dementing conditions (such as FTD) only after a complete diagnostic workup is completed and is found to be inconclusive. We are pleased that CMS was able to develop appropriately narrow coverage parameters for PET in the diagnosis of Alzheimer's disease and related dementias. These parameters are particularly important to prevent unnecessary use of PET.

It is important to reiterate that unnecessary PET scanning has a number of potentially serious consequences, including unnecessary exposure of patients to radiation, misdiagnosis and unnecessary use of medical resources. Even though the CMS coverage decision is not final, in some regions of the country PET is already being heavily marketed for use in diagnosing Alzheimer's disease. The Association is especially concerned about consumers being misled, given the increasing use of media advertisements directly to patients for various diagnostic services and treatments.

As Dr. Thies discussed during his presentation at the CMS/NIA Expert Panel on neuroimaging, it is imperative that CMS inform all the stakeholders regarding the limited parameters of this coverage decision. In particular, primary care physicians, patients and their family members should be properly educated to avoid confusion about the appropriate diagnostic process. To this end, the Alzheimer's Association will continue to dedicate resources to provide educational materials regarding the diagnosis of Alzheimer's disease. In addition, we strongly urge CMS to use all available tools to provide oversight and enforcement of the coverage parameters.

Upon implementation of the coverage decision, we urge CMS to continue to study the use of PET for diagnosis of Alzheimer's disease with regard to the contribution to diagnosis, appropriate patient selection, effect on treatment selection, and patient satisfaction. Our knowledge of the use of PET scans in AD continues to evolve. The willingness of CMS to cooperate in collecting data that will assure the best possible patient outcomes when this technique is used shows a true appreciation of the fluid nature of the practice of medicine and a firm commitment to supporting that practice in the best manner possible.

Finally, we strongly support CMS' reimbursement for PET scans for the diagnosis of patients with MCI or early dementia who are participating in clinical trials. As indicated in the decision memorandum, there is currently inadequate scientific evidence to support the use of PET for this population. However, CMS should use its resources to encourage research in this area as permitted under the law. The Alzheimer's Association is available to provide guidance and support as needed to develop parameters, criteria or guidelines to implement this clinical trial.

We appreciate the opportunities the Alzheimer's Association has had to participate in this decision-making process. The decision memorandum, and the process leading up to it, should be applauded by anyone who cares about people with Alzheimer's disease.

Comment #15:
Submitter: Harvey L. Neiman, M.D., FACR
Organization: American College of Radiology
Date: July 15, 2004
Comment:
The American College of Radiology (ACR) has reviewed the June 15, 2004 CMS draft decision memorandum for Positron Emission Tomography (FDG) and other neuroimaging devices for suspected dementia (CAG-00088R) including Alzheimers and appreciates this opportunity to provide comments. The ACR represents over 32,000 radiologists including nuclear medicine physicians and medical physicists. We commend CMS for encouraging further studies of PET in a broader patient population who develop symptoms of dementia and agree that further research is needed to help determine if PET contributes to the effective diagnosis and management of patients with early dementia or adds to the information in managing the disease.

As described in the draft coverage decision, CMS is planning to work with the National Institute on Aging (NIA), Agency for Healthcare Research and Quality (AHRQ), Alzheimer's Association (AA) and experts in Alzheimers Disease and imaging to develop a large practical clinical trial. The ACR recommends that the NIA sponsor those trials through a request for application (RFA) and supports the general clinical trial concepts set forth in the draft coverage decision language. The ACR agrees that PET can be a valuable tool and encourages facilities to maintain appropriate training and accreditation to ensure the quality of patient care and the quality of images. The ACR is committed to ensuring that proper use of PET is maintained and to providing education regarding the appropriate process of care of this medical service. The ACR seal of accreditation has become the distinctive symbol of quality for more than 300 nuclear medicine practices with over 100 sites accredited in PET. The ACR provides a PET course for physician continuing medical education (CME) regarding clinical and practice issues for the radiologist and nuclear medicine physicians and also has developed practice guidelines for the performance of FDG PET scintigraphy and a technical standard for the use of radiopharmaceuticals that includes a section on qualifications of personnel. All of these programs are available to the entire physician community regardless of specialty.

The ACR recommends that the CMS consider the utility of the aforementioned ACR resources with respect to the following CMS conditions for PET coverage:

+The FDG-PET scan is performed in facilities that have all the accreditation necessary to operate such equipment. +The reading of the scan should be done by an expert in nuclear medicine, radiology, neurology, or psychiatry with experience interpreting such scans in the presence of dementia.

In reference to the specific CMS guidelines whereby the ordering and billing physicians must document medical necessity, the ACR recommends that CMS collect information by site of service, specialty ordering, and ownership in the facility in an effort to help identify and reduce potential problems associated with medical necessity and utilization. Although unintentional, this CMS condition for coverage may increase administrative burdens. Therefore, we ask that clarification and guidelines be provided to help reduce confusion. For example, all the required elements of documentation for the medical necessity checklist should be provided by the referring physician at the time of the request for examination and retained for documentation by the billing provider. Additionally, guidelines as to what the appropriate clinical parameters are would be helpful. For example, if B12 is minimally low, does that preclude the use of PET? The ACR also recommends follow up communication to the medical community on the results of the medical necessity checklists/reports. Thank you for this opportunity to provide comment and for your consideration.

Comment #16:
Submitter: Robert G. Britain
Organization: National Electrical Manufacturers Association
Date: July 15, 2004
Comment:

This letter is in response to the "Draft Decision Memorandum for Positron Emission Tomography (FDG) and Other Neuroimaging Devices for Suspected Dementia (CAG-00088R)", which was issued on June 15, 2004. The National Electrical Manufacturers Association (NEMA) appreciates the opportunity to share our views with you.

In the Draft Decision Memorandum (DM), CMS has made the determination that an FDG PET scan is reasonable and necessary in patients with a recent diagnosis of dementia and documented cognitive decline of at least six months, who meet specific diagnostic criteria for both Alzheimer's disease (AD) and fronto-temporal dementia (FTD), and who have satisfied certain enumerated conditions. NEMA believes that this determination is a positive step in the right direction, and wishes to commend CMS for its recognition of the diagnostic value of PET for patients who exhibit symptoms indicating that either AD and FTD may be present.

It is important to recognize that the ability of the clinician to obtain an early diagnosis and promptly begin treatment of an Alzheimer's patient can slow the progression of the disease and greatly enhance the quality of life for patients and their caregivers. Moreover, an early, differential diagnosis can prevent the administration of cholinesterase drugs indiscriminately to patients who do not have AD. Given the prevalence of co-morbidities in patients with dementia, prevention of the administration of drugs to those who do not have AD can eliminate the incidence of potential side effects, complications or adverse drug interactions in these patients.

Second, an early diagnosis will reduce the unnecessary expenditure of funds which would have been spent on administration of these drugs. With the emergence of dementia as a critical problem in the Medicare population, the number of affected individuals will grow sharply as the baby boom generation ages. Obtaining an early diagnosis of AD will thus prevent administration of drugs to the expected substantial quantity of patients who have dementia of a type other than Alzheimer's disease.

We appreciate the opportunity to share our views with you and look forward to working with you on these issues of vital importance to patient care.

Comment #17:
Submitter: Sue Halliday
Organization:
Date: July 15, 2004
Comment:
I am submitting two (2) comments for your consideration:

#1 - re: A brain single photon emission computed tomography (SPECT) or FDG-PET scan has not been obtained for the same indication;

Comment #1 - please consider establishing a reasonable time frame that would allow patients that have had an inconclusive SPECT study to have a FDG-PET scan. (e.g. within twelve (12) months of the effective date of coverage)
reason: FDG-PET availability and questionable technical and/or interpretive quality of SPECT studies

#2 re: The referring and billing provider(s) have documented the appropriate evaluation of the Medicare beneficiary. Medicare contractors will verify that the conditions for coverage described above have been met, and that providers have established the medical necessity of an FDG-PET scan by collecting the following information: ä- date of onset of symptoms; ä- mini mental status exam (MMSE) or similar test score; ä- neuropsychological testing; ä- diagnosis of clinical syndrome; ä- presumptive cause (possible, probable, uncertain AD); ä- results of structural imaging (MRI, CT); ä- relevant laboratory tests (B12, thyroid hormone); ä- number and name of prescribed medications; In addition, the billing provider must furnish a copy of the FDG-PET scan result for use by CMS and its contractors in Medicare quality assessment and improvement.

Comment #2: For the purpose of timely, accurate and electronic claims filing for FDG-PET Scans for Alzheimer's disease (AD)/Dementia, please consider the use of modifiers, similar to the modifiers used in the first FDG-PET covered indications in 1998 and 1999, to report appropriate information to CMS contracted Carriers and Fiscal Intermediaries. (e.g. one modifier would validate that the referring physician has documented in the patient medical

record all requisite information has been collected that would establish the medical necessity for the FDG-PET scan and one modifier would be used to report the result of the FDG-PET scan.)

reason: Timely and accurate data collection by CMS contracted Carriers and Fiscal Intermediaries and continued use of electronic claims format.

Thank you providing this valuable electronic service.

Comment #18:
Submitter: Denise Merlino
Organization: The Society of Nuclear Medicine
Date: Thu, Jul 15, 2004 8:09 AM
Comment:
We have already submitted comments for the SNM. But did notice one Typo which you may already know about, but just in case you did not see it. I believe there is a typo in IV Timeline of recent activities November 10, 2004 should be November 10, 2003.

Comment #19:
Submitter: Sidney Wolfe
Organization: Public Citizen's Health Research Group
Date: Thu, July 15, 2004, 4:07 PM
Comment:
The proposal by CMS to reimburse, in certain instances, for Positive Emission Tomography (PET) diagnostic tests for people suspected of having Alzheimer's Disease (AD)is a sharp refutation of the widely-espoused principle of evidence-based medicine. Within HHS, neither the National Institute on Aging nor AHRQ has found that that there is sufficient evidence for the accuracy of PET scans in definitively making the diagnosis of AD and that, combined with the lack of significant treatments for AD, this does not justify the expenditure of what will surely be tens if not hundreds of millions of scarce Medicare dollars within a short amount of time. I hope you will reconsider this decision and, instead, spend money on diagnostic and therapeutic modalities that actually are effective.
Comment #20: Submitter: James H. Scully, Jr., M.D. Organization: American Psychiatric Asociation Date: Thu, July 15, 2004 4:10 PM Comment:

The American Psychiatric Association (APA), a medical specialty society representing more than 35,000 psychiatrists nationwide, takes this opportunity to submit comments in response to the Draft Decision Memo for Positron Emission Tomography (FDG) and Other Neuroimaging Devices for Suspected Dementia (CAG-00088R). APA appreciates the Centers for Medicare and Medicaid ServicesÆ (CMS) outreach to all interested parties as the agency begins its process of review and possible revision of these important rules. Our comments are detailed below.

The APA understands the complexity of Medicare coverage of PET scans for patients with suspected dementia. The APA believes that the restrictive coverage criteria imposed by the draft decision memorandum recognizes the concerns that less restrictive Medicare coverage criteria for PET scans for patients with suspected dementia could result in Medicare overpayments resulting from indiscriminate use of PET scans, especially until more specific treatments are available. We support CMSÆ conclusion that Medicare coverage of PET scans for patients with suspected dementia should be restricted to patients with a recent diagnosis of dementia and documented cognitive decline of at least six months, who meet diagnostic criteria for both AlzheimerÆs disease (AD) and fronto-temporal dementia (FTD), who have been evaluated for specific alternate neurodegenerative diseases or causative factors, and for whom the cause of the clinical symptoms

remains uncertain.

We agree with the recommendation that Medicare coverage of PET scans in diagnosing dementia be limited to specific instances of real diagnostic uncertainty, with documentation of the diagnostic dilemma, with consideration given to the impact of more precise diagnosis on clinical care, with review of the rationale, and with no repeat scans. We believe that the proposed conditions for coverage are consistent with this recommendation.

APA also recommends that, before coverage is instituted throughout the Medicare system, CMS implement this coverage decision through a one- year demonstration project to gauge its impact on diagnosis, clinical care, and cost to the system.

We appreciate the opportunity to offer these comments and we look forward to working with you in the future.

Comment #21:
Submitter: Peter S. Conti, M.D., Ph.D., FACR, FACNP
Organization: PET Center of Excellence
Date: July 15, 2004
Comment:
The Society of Nuclear Medicine (SNM) representing more than 14,000 physicians, physicists, scientists, pharmacists and nuclear medicine technologists, appreciates the opportunity to supply this supplemental comment on the June 15, 2004 draft decision memorandum for Positron Emission Tomography (FDG) and other Neuroimaging Devices for Suspected Dementia (CAG-00088R).

These comments will focus on training and evidence of physician, technologist and technology (facility) capability to perform and interpret PET brain studies.

CMSs draft decision memo states:

The evaluation has been conducted by a physician experienced in the diagnosis and assessment of dementia;

• The FDG-PET scan is performed in facilities that have all the accreditation necessary to operate such equipment. The reading of the scan should be done by an expert in nuclear medicine, radiology, neurology, or psychiatry with experience interpreting such scans in the presence of dementia; The SNM agrees with the CMS current language in the proposed draft regarding encouraging appropriate training and accreditation of the physician, technologist, and technology (facility) which are no doubt important in providing diagnostic patient care. We do caution CMS regarding developing more specific and restrictive requirements in this area for reimbursement of these studies. There currently is no evidence to ensure that any one or combination of available programs will or will not meet the desired results. That said, SNM continues to provide exceptional educational and accreditation services for the nuclear medicine and PET community. For your information, the SNM has established the PET Center of Excellence (COE) as an educational forum for all aspects of the delivery of clinical PET services, including training and credentialing, coding and reimbursement, and practice standards. Regarding development of practice standards, training materials and symposia, the Center has direct input from the SNM's Brain Imaging Council whose membership comprises some the world's leading experts in SPECT and PET brain imaging.

The SNM provides formal guidelines for acquisition and interpretation of nuclear medicine procedures through their Practice Guidelines Committee. Currently the PET Learning Center, a component of the PET COE, has multiple course offerings such as NeuroPET imaging (see additional list below and attached), which includes extensive training and education in image interpretation in multiple areas including Alzheimer's Disease, at their three training centers in the US and as part of period symposia offered to the community. Attached is list of COE educational programs and materials. We would like to highlight the following symposia and educational materials which are detailed in the attachments:

PET COR Web site:
http://interactive.snm.org/index.cfm?PageID=1407&RPID=10
PET Learning Center for Physicians and Technologists
PET and PET/CT Physics, Instrumentation, and Radiation
RadioPharmaceutical PET and PET for NMT Educators
Advances in Clinical PET: Oncology and Neurology
PET Educational Program CDs
PET SNM Online Teaching Files:
PET Reference CDs:

In additional to these programs the SNM has offered a PET/CT supplement which was intended to stimulate debate and encourage the kind of research which can lead to answering questions about cost-effectiveness and optimal imaging protocols.

The SNM Technologist Section (SNMTS) develops and supports numerous educational programs. The SNMTS is very active and works collaboratively with nuclear medicine certification and accreditation bodies such as the Nuclear Medicine Technology Certification Board (NMTCB) and the American Registry of Radiologic Technologists (ARRT) as well as supporting the CARE Act. The SNMTS has recently approved and adopted a PET/CT Curriculum which is the product of a multi-organizational effort to define the educational needs of imaging technologists and radiation therapists and establish a pathway for producing competent qualified technologists to operate new technologies.

The SNM believes appropriately qualified and trained nuclear medicine physicians, or other physicians certified to handle and administer radioactive materials as well as interpret diagnostic imaging studies, are the appropriate experts to supervise and conduct such examinations. The SNM also offers facility accreditation through a partnership with ICANL. The SNM recommends that facilities consider obtaining accreditation for delivery of such services, although as mentioned above this **should not be a requisite** for providing diagnostic patient care or obtaining reimbursement for such studies at this time.

Again, the SNM appreciates the opportunity to comment on this proposed expanded coverage for Alzheimer's disease and other suspected dementia.

Comment #22:
Submitter: Carmella A. Bocchino, MBA, RN
Organization: America's Health Insurance Plans
Date: July 15, 2004
Comment:
America's Health Insurance Plans (AHIP) is pleased to submit comments on the Centers for Medicare & Medicaid Services' (CMS) draft decision memorandum on *Positron Emission Tomography (FDG) and Other Neuroimaging Devices for Suspected Dementia*. AHIP is the national trade association representing the private sector in health care. AHIP's member companies provide health benefits to more than 200 million Americans.

We have reviewed the draft memorandum and offer the following comments for consideration in your final decision.

First, we would like to thank CMS for the thorough evaluation on positron emission tomography (PET) technology for the diagnosis of Alzheimer's disease (AD) and frontotemporal dementia. We feel that the draft decision memorandum outlines specific criteria to be followed prior to ordering a PET and, if adhered to, will result in clinically appropriate usage based on what limited evidence is currently available. However, we do have several concerns regarding the challenges translating into medical practice the coverage of PET for indications specified in the memorandum.

We understand that AD as a source of dementia is traditionally a challenging, labor intensive, and (in some cases) impossible condition to diagnose. While we appreciate the efforts put forth by CMS to establish specific criteria to reach diagnosis, we do not feel that there is adequate evidence to utilize PET in the diagnosis of AD. We recommend further study to establish a consensus-supported process for diagnosis of AD.

Another important issue is the oversight of providers to determine adherence to the criteria set out in the decision memorandum. Given the extensive criteria to be followed prior to conducting PET (i.e., documented cognitive decline of at least six months, extensive clinical testing, and histories from patients and families), there appears to be a significant risk that providers will not consistently adhere to the required criteria for appropriate use of PET. The increased demand for this service by families who believe it is a covered service and fail to recognize its stringent application will further pressure providers to provide PET inappropriately. An administrative structure to monitor provider practice to ensure that all of the criteria are met does not appear to exist in the current memorandum, nor does a public education campaign to inform stakeholders on its proper application. This could result in a proliferation of inappropriate and costly PET for patients.

Recent evidence that suggests there is not a clear indication that adding PET technology to the diagnosis process is as effective as current clinical evaluation standards. In one recent study, the efficacy of PET in diagnosis of Alzheimer's disease compared to routine clinical evaluation has been challenged.[1] In another, the authors recommend PET as a future application for early and pre-symptomatic diagnosis of individuals at risk for Alzheimer's disease, if an effective neuroprotective agent becomes available. It is also recommended for *atypical* cases of parkinsonian syndromes and dementia.[2] We believe that there is not sufficient research demonstrating differential treatment considerations and improved health outcomes as a result of PET for those suffering from dementia. It is possible that Medicare would incur increased costs of this service associated with AD while providing little to no improvement in health outcomes. Therefore, we remain concerned that there is not sufficient evidence to establish PET as a covered benefit and support further research to determine its effectiveness more conclusively.

AHIP appreciates the opportunity to provide comment on the *Positron Emission Tomography (FDG) and Other Neuroimaging Devices for Suspected Dementia* draft decision memorandum.

Comment #23:
Submitter: Saty Satya-Murti, MD, FAAN
Organization: Blue Cross and Blue Shield of Kansas
Date: June 24, 2004
Comment:
I thank the CMS and the coverage group for allowing me to send the following response to your invitation for comments with regard to PET scans in the diagnosis of dementia. Please permit me to divide my comments into 3 sections.

1. The first shares some of my concerns in translating the intent of the Decision Memo to the bedside.
2. The second is a request not to forget to include newer behavioral-cognitive tests also in practical clinical trials.
3. The last is a brief comment on the ultimate value of PET derived information.

First Comment:

You indicate that, "… (FDG-PET) scan is reasonable and necessary in patients <u>with a recent diagnosis</u> of dementia and documented cognitive decline of at least six months, who meet diagnostic criteria for both Alzheimer's disease (AD) and fronto-temporal dementia (FTD), who have been evaluated for specific alternate neurodegenerative diseases or causative factors, and for whom the cause of the clinical symptoms remains <u>uncertain</u>."

May I state that I have some difficulty in understanding this complex sentence? Does it assume the existence of two potential opposites in a given patient at the same time, namely both a

criteria-based diagnosis and uncertainty about the, "cause of the clinical symptoms?" At the bedside, I am fairly confident that I could diagnose dementia in a given patient.

- On this person, if I have some doubts as to a causation of clinical symptoms, nature, detail and degree unspecified, then would this doubt allow me to perform a PET scan?
- Could it be any uncertainty, or should it be an uncertainty about the differential diagnosis between AD and FTD only?
- If there is such uncertainty, how would this patient have already met the diagnostic criteria for AD or FTD?
- Is this "uncertainty," then the qualifying and enabling filter before performing a PET scan?

The expert panel had expressed some concerns about, "potential overuse." The overuse is likely to occur because the only forward door to gaining entry for a PET scan is that of a, "thorough workup," and "uncertainty." May I state, respectfully but with some degree of conviction, that this is a very permissive one? I say this based on what typical encounters are like in a general neurology or geriatric setup. The type of workup that you envision is the approximately-8-part list that is included in the Decision memorandum. This type of thorough workup is quite common, and nearly always, and readily and easily met in most medical offices, rural or urban clinics, academic or entrepreneurial centers, regardless of the specialty of the provider. Perhaps, the only item that may not have been carried out is a "neuropsychological testing." This is time consuming and expensive. The listing that is now given in the Memo does encourage performance of this test, if only to remove the last barrier to ordering a PET scan. Having thus passed the listed requirements, it is not at all difficult to raise doubts and uncertainties about the differential diagnosis of dementia. Please allow me to explain.
a. The spectrum of daily life experiences are sufficiently rich and variegated that anamneses, during history and review, would raise the issue of uncertainty easily. Here lies a potential for overuse.
b. Patients' own report may be readily reconstructed to either support or refute that of their caregivers, or vice-versa. Patients may admit to a six month history of forgetfulness whereas the family or co-workers may date this back to a few years.

c. It is difficult to isolate executive dysfunction from other cognitive and emotional symptoms.
d. A case could be made to be inclusive or exclusive of any symptom reported in passing (for instance parking lot confusion, or irritability, or requesting clarification or repetition during ordinary conversations). Depending on its value to add support to the planned course of action (here, qualifying to order a PET scan) the provider may maximize or marginalize the significance of a narration.

Thus, FTD as an alternative diagnosis to AD is easy enough to invoke, but hard enough to prove ante-mortem. In the absence of distinct clinical cordons between the two, there is no barrier to invoking this uncertainty among various FTDs and AD. This is all that I need to document before asking for a PET scan.

Either at a post-pay review stage, or at an Administrative appeals level, few if any, instances would be found where medical necessity did not exist to justify diagnostic uncertainty. In summary then, it is my arguable contention that in spite of the long, cogent and well-described Decision Memorandum, the qualifying threshold for PET scans is low and flush at the floor level.

Second Comment:

A practical clinical trial would be most welcome. May I suggest inclusion of two other testing modalities, in this connection?

Both behavioral testing, such as semantic-phonemic fluency testing, and functional MRI should be

incorporated in some arm of the anticipated trial. (1-4) We have to find out if clinical testing or fMRI would provide equally valid information as does the PET scan. (4-6) A comparative study of the capabilities of the three diagnostic modalities would be desirable. The PET scan may or may not perform as well as the others. Exactly which neuroradiological modality provides the best differentiating information among dementing illnesses is still not clear. One editorialist comments as follows. "*Not surprisingly, all of these techniques have their advocates, but clinical overlap between these methodologies is significant and abnormalities in structure, neurochemistry, and metabolism tend to develop in parallel. Indeed, even after decades of study it is still difficult to say which of these techniques is the most powerful diagnostic tool*."(7)
Third Comment:

The benefit of any diagnostic procedure is that it should have an application in disease management. Unless a new diagnostic test has been evaluated using the STARD criteria, its benefit to improving dementia patients' status remains unproven.(8) The technology assessment by Duke Center finds that there were no studies that could have predicted a response to treatment based on PET scan derived information. (http://www.cms.hhs.gov/coverage/download/id104b.pdf) (p67/94).

The same group of researchers also comments, perhaps obliquely, that the current PET scan data collection has not adhered to STARD recommendations.(6) (page 79) They also write, "*the test should be evaluated in patients from a variety of clinical settings with suspected dementia as opposed to patients from specialty clinics with evident dementia and nonimpaired control subjects*."(6))page 80).

If these, "variety of clinical settings," were registered and enrolled in a prospective clinical trial then the true merits of PET, or any other modality, would emerge. If PET scan performance were to be assessed outside of such a trial, in a fee-for-service milieu, it is doubtful that these settings would adhere to STARD standards in.

These, then, are my projections:

I. In a non-trial situation, the access to PET scan will be available to any Medicare beneficiary. It is unlikely that the qualifiers the Memo proposes to erect will disqualify any patient.

II. I hope that the value PET scans would be thoroughly evaluated exclusively and only in a clinical trial.

I thank you for reading through my comments.

1. Cummings JL. The one-minute mental status examination. Neurology 2004;62(4):534-5.
2. Rosen HJ, Hartikainen KM, Jagust W, et al. Utility of clinical criteria in differentiating frontotemporal lobar degeneration (FTLD) from AD. Neurology 2002;58(11):1608-15.
3. Canning SJ, Leach L, Stuss D, Ngo L, Black SE. Diagnostic utility of abbreviated fluency measures in Alzheimer disease and vascular dementia. Neurology 2004;62(4):556-62.
4. Kantarci K, Clifford R. Jack J. Quantitative Magnetic Resonance Techniques as Surrogate Markers of Alzheimer's Disease. NeuroRx 2004;1(2):196-205.
5. Machulda MM, Ward HA, Borowski B, et al. Comparison of memory fMRI response among normal, MCI, and Alzheimer's patients. Neurology 2003;61(4):500-6.
6. Patwardhan MB, McCrory DC, Matchar DB, Samsa GP, Rutschmann OT. Alzheimer disease: operating characteristics of PET--a meta-analysis. Radiology 2004;231(1):73-80.
7. Miller BL. Past glory and future promise: maximizing and improving understanding of atrophy patterns in the diagnosis of degenerative dementias. AJNR Am J Neuroradiol 2002;23(1):33-4.
8. Bossuyt PM, Reitsma JB, Bruns DE, et al. Towards complete and accurate reporting of studies of diagnostic accuracy: the STARD initiative. Bmj 2003;326(7379):41-4.

July 12, 2004

Steve Phurrough, MD, MPA
Director, Coverage and Analysis Group
Office of Clinical Standards and Quality
Centers for Medicare & Medicaid Services
Attn: Public Comments, S3-02-01
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Draft Decision Memo for Positron Emission Tomography (FDG) and Other Neuroimaging Devices for Suspected Dementia (CAG-00088R)

Dear Dr. Phurrough:

On behalf of the American Association for Geriatric Psychiatry (AAGP), I am pleased to submit these comments on the Draft Decision Memo for Positron Emission Tomography (FDG) and Other Neuroimaging Devices for Suspected Dementia (CAG-00088R). The AAGP is a professional membership organization dedicated to promoting the mental health and well-being of older people and improving the care of those with late-life mental disorders. Our membership consists of about 2,000 geriatric psychiatrists as well as other health care professionals who focus on the mental health problems faced by senior citizens.

The AAGP commends CMS for its careful review and analysis of the complex issue of Medicare coverage of PET scans for patients with suspected dementia. We support your conclusion that Medicare coverage of PET scans for patients with suspected dementia should be restricted to patients with a recent diagnosis of dementia and documented cognitive decline of at least six months, who meet diagnostic criteria for both Alzheimer's disease (AD) and fronto-temporal dementia (FTD), who have been evaluated for specific alternate neurodegenerative diseases or causative factors, and for whom the cause of the clinical symptoms remains uncertain.

Your conclusion is generally consistent with the opinions of AAGP that were presented on April 5, 2004 during a joint expert panel meeting of CMS and the National Institute on Aging (NIA). During the meeting and in our subsequent written responses to several questions that were posed to the meeting participants, we expressed our concern about the drain on resources that could result from indiscriminate use of PET scans, especially until more specific treatments are available.

We also recommended that Medicare coverage of PET scans in diagnosing dementia be limited to specific instances of real diagnostic uncertainty, with documentation of the diagnostic dilemma, with consideration given to the

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impact of more precise diagnosis on clinical care, with review of the rationale, and with no repeat scans. We are pleased to note that your proposed conditions for coverage (copy attached) are generally consistent with our recommendations.

AAGP endorses your proposed coverage conditions but recommends the following minor revisions that we believe will strengthen the final policy:

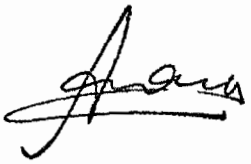
- The requirement for a comprehensive clinical evaluation should be expanded to include a behavioral assessment. The second and seventh items on the proposed conditions should be revised as follows, with the underlined phrases representing our recommended changes:
  - The patient has had a comprehensive clinical evaluation (as defined by the American Academy of Neurology (AAN)) encompassing a medical history from the patient and a well-acquainted informant (including assessment of activities of daily living), physical and mental status examination aided by cognitive scales or neuropsychological testing, laboratory tests, <u>a comprehensive behavioral assessment to determine the presence or absence of non-cognitive behavioral manifestations such as agitation, depression, psychosis and wandering</u>, and structural imaging such as magnetic resonance imaging (MRI) or computed tomography (CT).
  - The referring and billing provider(s) have documented the appropriate evaluation of the Medicare beneficiary. Medicare contractors will verify that the conditions for coverage described above have been met, and that providers have established the medical necessity of an FDG-PET scan by collecting the following information:
    - date of onset of symptoms;
    - mini mental status exam (MMSE) or similar test score;
    - neuropsychological testing;
    - diagnosis of clinical syndrome, <u>including non-cognitive behavioral manifestations</u>;
    - presumptive cause (possible, probable, uncertain AD);
    - results of structural imaging (MRI, CT);
    - relevant laboratory tests (B12, thyroid hormone);
    - number and name of prescribed medications.
- While we support the proposed requirement that Medicare contractors verify that the conditions for coverage described above have been met, we are concerned that a lack of specificity in the instructions could result in marked variation across carriers and the collection of an unnecessary amount of information. For example, the complete results of neuropsychological testing could involve ten or more pages of documentation, which we believe would be excessive. We recommend that the final instructions be revised to require the submission of a single document to the appropriate Medicare contractor that addresses each of the required points in a single two-three page summary.
- Consistent with the proposed requirement that the evaluation of the patient be conducted by a physician experienced in the diagnosis and assessment of dementia, we recommend that CMS require the review of the submitted

documentation by the Medicare contractor be performed by a physician who also is experienced in the diagnosis and assessment of dementia.

AAGP also suggests that, before coverage is instituted throughout the Medicare system, it may be useful to implement this coverage decision through a one-year demonstration project to gauge its impact on diagnosis, clinical care, and cost to the system.

We appreciate the opportunity to offer these comments and we look forward to working with you in the future as new and improved treatments for Alzheimer's disease become available. If you have any questions about our comments and recommendations, please contact Christine deVries, Executive Director, 301-654-7850 x103, cdevries@aagponline.org, or Stephanie Reed, Associate Director of Government Affairs, 301-654-7850 x101, sreed@aagponline.org.

Sincerely,



Anand Kumar, M.D.
President

Enclosure

Attachment: CMS Proposed Conditions for Coverage FDG-PET in the Diagnosis and Treatment of Mild Cognitive Impairment (MCI) and Early Dementia in Elderly Patients[1]

- The onset, clinical presentation, or course of cognitive impairment is aberrant for AD, and FTD is suspected as an alternative neurodegenerative cause of the cognitive decline;
- The patient has had a comprehensive clinical evaluation (as defined by the American Academy of Neurology (AAN)) encompassing a medical history from the patient and a well-acquainted informant (including assessment of activities of daily living), physical and mental status examination aided by cognitive scales or neuropsychological testing, laboratory tests, and structural imaging such as magnetic resonance imaging (MRI) or computed tomography (CT);
- The evaluation has been conducted by a physician experienced in the diagnosis and assessment of dementia;
- The evaluation did not clearly determine a specific neurodegenerative disease or cause for the clinical symptoms, and information available through FDG-PET is reasonably expected to help clarify the diagnosis and/or help guide future treatment;
- The FDG-PET scan is performed in facilities that have all the accreditation necessary to operate such equipment. The reading of the scan should be done by an expert in nuclear medicine, radiology, neurology, or psychiatry with experience interpreting such scans in the presence of dementia;
- A brain single photon emission computed tomography (SPECT) or FDG-PET scan has not been obtained for the same indication;
- The referring and billing provider(s) have documented the appropriate evaluation of the Medicare beneficiary. Medicare contractors will verify that the conditions for coverage described above have been met, and that providers have established the medical necessity of an FDG-PET scan by collecting the following information:
  - date of onset of symptoms;
  - mini mental status exam (MMSE) or similar test score;
  - neuropsychological testing;
  - diagnosis of clinical syndrome;
  - presumptive cause (possible, probable, uncertain AD);
  - results of structural imaging (MRI, CT);
  - relevant laboratory tests (B12, thyroid hormone);
  - number and name of prescribed medications;

In addition, the billing provider must furnish a copy of the FDG-PET scan result for use by CMS and its contractors in Medicare quality assessment and improvement.

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[1] Draft Decision Memo for Positron Emission Tomography (FDG) and Other Neuroimaging Devices for Suspected Dementia (CAG-00088R). http://www.cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?id=104.