

December 6, 2007

THE ACQUISITION, UTILIZATION PARAMETERS AND REPORTING OF POSITRON EMISSION TOMOGRAPHY (PET)

1. PURPOSE: This Veterans Health Administration (VHA) Directive defines the policy for acquisition of new Positron Emission Tomography (PET) capacity, the application of established utilization parameters, centralized reporting requirements for modality usage, and the identification of professional and technical staff qualifications for on-site operations.

2. BACKGROUND

a. In 1992, the Under Secretary of Health placed a moratorium on the acquisition of additional Department of Veterans Affairs (VA) PET capacity until its clinical utility in the veteran population could be demonstrated. Following formal technology assessments and the report of a VHA Special PET Advisory Group, an Executive Decision Memorandum (EDM) was presented to the National Leadership Board (NLB) on March 26, 2004. The moratorium was lifted in October 2005 by VHA Directive 2005-046, The Acquisition, Utilization Parameters, and Reporting of Positron Emission Tomography, that imposed certain conditions and restrictions on the purchase of PET equipment that have been in effect for the past 2 years. During this interval the impact of PET on clinical decision-making has grown, necessitating a review and modification of policy to allow improved access to PET through local facilities and Veterans Integrated Service Network (VISN) control of strategic planning and resource management.

b. Contemporary PET scanners are hybrid devices that include Computed Tomography (CT) to combine “functional” PET and simultaneous CT “anatomic” imaging. The complexity of CT necessary to complement PET varies, but most applications are of lesser capacity (4 to 6 slice capacity).

c. While VA is not required to comply in states where Certificate of Need legislation controls the purchase of medical devices, facilities are cautioned that the sale of excess capacity to potential non-VA clients could be problematic.

3. POLICY: It is VHA policy that each medical facility Director is responsible for managing PET resources and capacity in complying with the conditions and restrictions stated in this Directive in accordance with National Health Physics Program (NHPP) guidelines and Nuclear Regulatory Commission (NRC) regulations.

4. ACTION

a. **VISN Director.** Each VISN Director must ensure that the following considerations are addressed in the acquisition of PET Capacity:

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(1) The decision to purchase PET scanners, or contract for PET services is to be made by each VISN based upon referral patterns, clinical needs, and local and VISN strategic plans.

(2) Placement of scanners purchased should be based upon facility mission, referral patterns and VISN strategic plans to provide PET in a manner that is in accordance with sound business principles and is cognizant of industry performance as a basis for placement of PET capacity.

(3) Requests to purchase a PET scanner must be approved by the VISN Director.

(4) Purchases must be funded from VISN equipment funds and prioritized with other high-cost equipment. Those purchases greater than \$1 million require the preparation of a capital investment proposal (CIP).

NOTE: As the radiopharmaceutical for clinical PET scans (F-18 FDG) is readily available from commercial sources nationwide, the purchase of cyclotron equipment is not addressed in this Directive.

(5) The Centers for Medicare and Medicaid (CMS) National Coverage Determination (NCD) is used as the source for approved indications for the clinical use of PET which are available on the Nuclear Medicine and Radiation Safety Service website at: <http://vaww1.va.gov/nuclearmedicineservice/>. The list of approved indications is updated as CMS approves conditions. Clinical PET studies are to be limited to those conditions covered by CMS with exceptions for non-approved indications that are justified by contemporary literature and with assent from local higher authority, e.g., the Chief of Staff or designee.

b. **Facility Director.** The facility Director is responsible for ensuring:

(1) PET resources and capacity are managed in compliance with the conditions and restrictions stated in this Directive.

(2) An existing framework exists within each medical center for planning, implementing, and operating any in-house nuclear medicine device.

(3) NHPP guidelines are followed to ensure that accreditation and/or regulatory requirements are met. *NOTE: Generally, the radiomaterials utilized have very short half-lives and do not create a voluminous radioactive waste disposal concern.*

(4) The receipt, handling, and storage of radioactive materials adheres to proscribed NRC regulations. *NOTE: In the dual modality PET-CT devices, the radiographic portion has certain operational requirements and inspections to ensure proper functioning.*

(5) Clinical utilization of approved and non-approved PET applications is recorded and centrally compiled through use of the Current Procedure Terminology (CPT) codes in the Veterans Health Information and Technology Architecture (VistA) reporting system. **NOTE:** *Guidance for the use of these codes has been distributed by the Program Director, Nuclear Medicine and Radiation Safety Service. Coding changes occur frequently, and updates are posted on the Nuclear Medicine and Radiation Safety Service website at: <http://vaww1.va.gov/nuclearmedicineservice/>*

(6) Research projects on human subjects performed on VA-owned equipment are reported in a registry that identifies demographic information about the subject, site, disease process studied, tracer employed, and other data.

(7) The research PET Registry (see Att. B) requirement is factored into the research project's resource requirements and is summarized annually by the researcher and is submitted to the facility Chief, Nuclear Medicine Imaging, who reports the information to the Program Director, Nuclear Medicine and Radiation Safety Service. **NOTE:** *VA Form 10-0434, PET Research Individual Project Registry, can be found in Attachment B.*

(8) Professional medical staff providing PET interpretations (reading) are credentialed and privileged.

(a) Technical expertise is to be determined by the nature of the PET device, i.e. PET versus dual modality PET-CT.

(b) On the joint recommendation of the appropriate certifying bodies, the American Society of Radiologic Technologists (ASRT) and the Society of Nuclear Medicine Technology Section (SNMITS), any registered radiographer with the credential of R.T.(R), registered radiation therapist with the credential of R.T.(T), or registered certified nuclear medicine technologist with the credentials R.T.(N), or certified nuclear medicine technologist (CNMT) may operate PET-CT equipment after obtaining additional education or training and demonstrating competency.

(c) Varying amounts of education, depending upon the practitioner's existing background, skills, and knowledge, are required. **NOTE:** *The ASRT and SNMITS have developed an educational gap analysis that identifies the component parts of the necessary educational program.*

(9) A plan to have several technical staff educated to safely operate the modality is developed, once a decision to purchase in-house PET capacity is implemented. **NOTE:** *Additional information concerning the PET-CT curriculum is available on the Society of Nuclear Medicine website: <http://interactive.snm.org/>*

5. REFERENCES: None.

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6. FOLLOW-UP RESPONSIBILITY: The Program Director, Nuclear Medicine and Radiation Safety Service (115B), is responsible for the contents of this Directive. Questions should be directed to the Associate Director, Nuclear Medicine and Radiation Safety Service, at (734) 761-7885.

7. RESCISSION: None. This VHA Directive expires on December 31, 2012.

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Attachments

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ATTACHMENT A

**CENTERS FOR MEDICARE AND MEDICAID NATIONAL COVERAGE
DETERMINATION**

This Table shows the Centers for Medicare and Medicaid National Coverage Determination, as of April 2005. The table has not been updated since this date however; providers need to be cognizant that these are anticipated to change in the future. For full text, additional restrictions and updates see the CMS website: <http://www.cms.gov/>

Clinical Condition	Coverage
1. Solitary Pulmonary Nodules (SPNs)	Characterization
2. Lung Cancer (Non Small Cell)	Diagnosis, staging, restaging.
3. Esophageal Cancer	Diagnosis, staging, restaging.
4. Colorectal Cancer	Diagnosis, staging, restaging.
5. Lymphoma	Diagnosis, staging, restaging.
6. Melanoma	Diagnosis, staging, restaging. Evaluating recurrence prior to surgery as an alternative to a Gallium scan.
7. Breast Cancer	Staging of distant metastasis or restaging patients with locoregional recurrence or metastasis. Monitoring tumor response to treatment when a change in therapy is anticipated (Not covered for diagnosis or initial staging of axillary lymph nodes).
8. Head and Neck Cancers (excluding Central Nervous System (CNS) and thyroid)	Diagnosis, staging and restaging.
9. Thyroid Cancer	Restaging of recurrent or residual follicular thyroid cancers that have been previously treated by thyroidectomy and radioiodine ablation and have a serum thyroglobulin greater than 10 nanograms per milliliter (>10ng/mL) and negative I-131 when the whole body scan is performed.
10. Cervical	Staging as an adjunct to conventional imaging.
11. Myocardial Viability	Metabolic assessment of myocardial viability following an inconclusive single photon electron computerized tomography (SPECT).

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Clinical Condition	Coverage
12. Perfusion of the heart using Rubidium 82 tracer	Perfusion of the heart performed at rest or with pharmacological stress used for noninvasive imaging of the perfusion of the heart for the diagnosis and management of patients with known or suspected coronary artery disease.
13. Perfusion of the heart using ammonia N-13 tracer	Perfusion of the heart performed at rest or with pharmacological stress for the diagnosis and management of patients with known or suspected coronary artery disease.
14. Refractory Seizures	Pre-surgical evaluation for the purpose of localization of a focus of refractory seizure activity.
15. Alzheimer's Disease	Differential diagnosis of fronto-temporal dementia (FTD) and Alzheimer's disease.

ATTACHMENT B

VA FORM 10-0434, PET RESEARCH INDIVIDUAL PROJECT REGISTRY

Below is an imbedded copy of Department of Veterans Affairs (VA) Form 10-0434, PET Research Individual Project Registry. This form can also be found on the VA Forms web site at: <http://vaww.va.gov/vaforms>.



10-0434-fill.pdf