



Medicare Indications for PET and PETCT

PET and PETCT scans have been approved for reimbursement under Medicare for the following:

Clinical Condition FDG-PET and PETCT	Coverage - is subject to additional guidelines set forth below and in the conditions and requirements of the CMS National Coverage Determination described below.
Breast Cancer*	Staging*, restaging*, and monitoring response to therapy*
Colorectal Cancer	Diagnosis*, staging* and restaging*
Esophageal Cancer	Diagnosis*, staging* and restaging*
Head & Neck Cancers (excluding CNS and thyroid)	Diagnosis*, staging* and restaging*
Lung Cancer (Non-Small Cell)	Diagnosis*, staging* and restaging*
Lymphoma	Diagnosis*, staging* and restaging*
Melanoma (Excludes evaluation of regional nodes)	Diagnosis*, staging* and restaging*
Myocardial Viability*	Primary or initial diagnosis, or following an inconclusive SPECT prior to revascularization*
Refractory Seizures	Covered for pre-surgical evaluation only
Solitary Pulmonary Nodule	Characterization of indeterminate single pulmonary nodule
Thyroid Cancer*	Restaging
Cervical Cancer*	Staging as an adjunct to conventional imaging
Dementia	Differential diagnosis of fronto-temporal dementia (FTD) and Alzheimer's disease (AD) - or - CMS approved practical clinical trial
Clinical Condition NON FDG-PET	Coverage - is subject to additional guidelines set forth below and in the conditions and requirements of the CMS National Coverage Determination described below
Perfusion of the heart using Rubidium 82 tracer*	Covered for noninvasive imaging of the perfusion of the heart*
Perfusion of the heart using ammonia N-13 tracer*	Covered for noninvasive imaging of the perfusion of the heart*

* Approved under certain conditions outlined below

Approved Under the Following Conditions:

For all uses of PET relating to malignancies the following conditions apply:

***Diagnosis:** PET is covered only in clinical situations in which: (1) the PET results may assist in avoiding an invasive diagnostic procedure, or in which, (2) the PET results may assist in determining the optimal anatomical location to perform an invasive diagnostic procedure. In general, for most solid tumors, a tissue diagnosis is made prior to the performance of PET scanning. PET scans following a tissue diagnosis are generally performed for staging rather than diagnosis.

PET is not covered as a screening test (i.e. testing of patients without specific signs and symptoms of disease).

***Staging:** PET is covered for staging in clinical situations in which: (1)(a) the stage of the cancer remains in doubt after completion of a standard diagnostic workup, including conventional imaging (computed tomography(CT), magnetic resonance imaging(MRI), or ultrasound), or (1)(b) if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient; and (2) clinical management of the patient would differ depending on the stage of the cancer identified.

***Restaging:** PET is covered for restaging: (1) after completion of treatment for the purpose of detecting residual disease, (2) for detecting suspected recurrence or metastasis, (3) to determine the extent of a known recurrence, or (4) if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient. Restaging applies to testing after a course of treatment is completed, and is covered subject to the conditions above.

Monitoring: This refers to the use of PET to monitor tumor response to treatment during the planned course of therapy (i.e., when a change in therapy is anticipated)

***Breast Cancer:** Medicare covers FDG PET as an adjunct to standard imaging modalities for staging patients with distant metastasis, or restaging patients with locoregional recurrence or metastasis. Monitoring treatment of a breast cancer tumor when a change in therapy is contemplated is also covered as an adjunct to other imaging modalities.

***Thyroid Cancer:** Medicare covers the use of FDG PET for thyroid cancer only for restaging of recurrent or residual thyroid cancers of follicular cell origin that have been previously treated by thyroidectomy and radioiodine ablation and have a serum thyroglobulin >10ng/ml and negative I-131 whole body scan performed.

***Myocardial Viability:** Medicare covers FDG PET for the determination of myocardial viability as a primary or initial diagnostic study prior to revascularization, or following an inconclusive SPECT. SPECT may not be used following an inconclusive PET scan.

***Cervical:** Medicare covers FDG-PET as an adjunct test for the detection of pre-treatment metastases (i.e. staging) in newly diagnosed cervical cancer subsequent to conventional imaging that is negative for extra-pelvic metastasis.

***Dementia:** Medicare covers FDG-PET scans for either the differential diagnosis of fronto-temporal dementia (FTD) and Alzheimer's disease (AD) under specific requirements. Medicare has established specific requirements for coverage of the differential diagnosis of FTD and AD. These requirements are detailed in the NCD for Dementia and Neurodegenerative Diseases (220.6.1) below and summarized in the Alzheimer's Order Form in the Forms and Resources section.

***Myocardial Perfusion:** PET scans performed at rest or stress (exercise or pharmacological) used for noninvasive imaging of the perfusion of the heart for the diagnosis and management of patients with known or suspected coronary artery disease using the FDA-approved radiopharmaceutical Ammonia N-13 or Rubidium 82 (Rb 82).

General Conditions: Regardless of any other terms or conditions, all uses of FDG PET scans, in order to be covered by the Medicare program, must meet the following general conditions as of July 1,2001:

1. The provider of the PET scan should maintain on file the doctor's referral and documentation that the procedure involved only FDA approved drugs and devices, as is normal business practice.
2. The ordering physician is responsible for documenting the medical necessity of the study and that it meets the conditions specified in the instructions. The physician should have documentation in the beneficiary's medical record to support the referral to the PET scan provider.

National Coverage

PET scans are covered by the Centers for Medicare and Medicaid Services (CMS), Medicare, for specific clinical conditions under a National Coverage Determination (NCD).

What is a National Coverage Determination (NCD)?

"CMS makes NCDs granting, limiting, or excluding Medicare coverage for a specific medical service, procedure, or device. NCDs are made under section 1862(a) (1) of the Social Security Act (the Act) or other applicable provisions of the Act. The national coverage decisions apply nationwide and are binding on all Medicare carriers, fiscal intermediaries, quality improvement organizations, health maintenance organizations, competitive medical plans, and health care prepayment plans for purposes of Medicare coverage."