

Covered Indications for PET Scans in South Africa and Limitations/Requirements for Usage (SAPUA protocol task group)

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

A. 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 patients without specific signs and symptoms of disease).

B. 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) 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.

C. 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.

D. Monitoring

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

Clinical records documenting the medical necessity of the study must be available at the provider of the PET study or the referring physician.

A) Positron emission tomography done with coincidence gamma cameras.

Technical specifications

These coincidence systems must have all the following features:

- Crystal at least **5/8-inch** thick;
- Techniques to minimize or correct for scatter and/or randoms; and
- Digital detectors and iterative reconstruction.

Scans performed with gamma camera PET systems with crystals thinner than 5/8" should not be covered. In addition, scans performed with systems with crystals greater than or equal to 5/8" in thickness, but that do not meet the other listed design characteristics should not be covered.

Indications

- Characterization of single pulmonary nodules. (Requires diagnostic evidence of primary tumor prior to PET. Tumor must be 1- 4cm. Not covered if prior negative PET within 90 days.
- Initial staging of lung cancer (non small cell)
- Determining location of colorectal tumors if rising CEA level suggests recurrence (once per year)
- Staging or restaging of lymphoma only when used as alternative to gallium scan (up to four times per year)
- Evaluating recurrence of melanoma prior to surgery (once per year)

B) Indications for PET/CT and dedicated PET systems (Full and partial ring)

1) Absolute indications

	Indications for 2005/2006	Frequency of scan
Oncology applications		
Parotid	Identification of metastatic disease in the neck from a diagnosed malignancy	1/year
Malignancies of the oropharynx	Diagnosis, Initial staging, Restaging	up to 4/year
Larynx	Diagnosis, Initial staging, Restaging	up to 4/year

Thyroid	<p>1) Assessment of patients with elevated thyroglobulin (or suspected false negative value) and negative iodine scans for recurrent disease. Applicable only in patients who did have a thyroidectomy and I-131 treatment.</p> <p>2) Assessment of tumour recurrence in medullary carcinoma of the thyroid</p>	<p>up to 2/year</p> <p>up to 2/year</p>
Lung	<p>1) Differentiation of benign versus malignant lesions where anatomical imaging or biopsy is inconclusive or there is a relative contraindication to biopsy. The lesion must be 1-4cm in size.</p> <p>2) Preoperative staging of non small cell primary lung tumours.</p> <p>3) Assessment of recurrent disease in previously treated areas where anatomical imaging is unhelpful.</p> <p>4) Assessment of response to treatment</p>	<p>Not more than every 90 days</p> <p>1/year</p> <p>up to 4/year</p>
Oesophagus	<p>1) Staging of primary cancer</p> <p>2) Assessment of disease recurrence in previously treated cancers</p> <p>3) Assessment of neoadjuvant chemotherapy</p>	<p>up to 4/year</p>
Breast cancer	<p>1) Assessment of the extent of disseminated disease</p> <p>2) Assessment of multifocal disease</p> <p>3) Suspected local recurrence</p> <p>4) Assessment of chemotherapy response</p>	<p>up to 4/year</p>
Colon and rectum	<p>Diagnosis, Initial staging and restaging</p>	<p>Up to 4/year: Intervals not less than 12 months with no rising CEA levels</p>

Lymphoma

1) Staging of Hodgkin's lymphoma.
 2) Staging of NonHodgkins lymphoma
 3) Assessment of residual masses for active disease
 4) Identification of disease sites when there is suspicion of relapse from clinical assessment
 5) Response to chemotherapy

Up to 4/ year

6) Assessment of remission from lymphoma

Every 12 months

Melanoma

Initial staging and restaging(not for evaluating regional nodes)

Up to 1/ year

Cardiac applications

Diagnosis of hibernating myocardium in patients with ischemic heart disease following an inconclusive SPECT

Up to 1/year

Neuropsychiatry applications

1) Presurgical evaluation of epilepsy.
 2) Early diagnosis of dementia, (especially younger patients) (particularly Alzheimer's disease) when MR or CT is either normal, marginally abnormal or equivocally abnormal

Up to 1/year

Up to 1/year

2) Relative indications**Oncology**

Liver: Secondary lesion

1) Equivocal diagnostic imaging (CT, MRI, Ultrasound)

1/year

2) Exclude other metastatic disease prior to metastectomy

1/year

Renal and adrenal

Assessment of possible adrenal metastases

1/year

Testicle	1)Assessment of recurrent disease from seminomas and teratomas 2)Assessment of residual masses	1/year
Ovary	Initial staging(In stage 1A disease where adjuvant therapy is not contemplated) and restaging	Up to 4/year
Uterus: cervix	In difficult situations to define the extent of disease with accompanying image registration(staging and restaging)	Up to 4/year
Metastases from unknown primary	Determining the site of an unknown primary when this influences management	Up to 1/year

Miscellaneous applications

Fever of unknown origin	Identifying source of the fever of unknown origin when conventional diagnostic workout remains unequivocal
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3) Future indications subject to evidence development

Oncology applications

Brain and spinal cord	1)Suspected tumour recurrence when anatomical imaging is difficult or equivocal and management will be affected. Often a combination of methionine and FDG PET scans will need to be performed 2)Benign versus malignant lesions, where there is uncertainty on anatomical imaging and a relative contraindication to biopsy 3) Investigation of the extent of tumour within the brain or spinal cord. 4) Secondary tumours in the brain. 5) Assess tumour response to therapy.
Parathyroid Pancreas	Localization of parathyroid adenomas with methionine when other investigations are negative 1) Staging a known primary. 2)Differentiation of chronic pancreatitis from pancreatic carcinoma 3)Assessment of pancreatic masses to determine benign or malignant status

Musculoskeletal tumors

- 1) Soft tissue primary mass assessment to distinguish high grade malignancy from low or benign disease
- 2) Staging of primary soft tissue malignancy to assess nonskeletal metastases
- 3) Assessment of recurrent abnormalities in operative sites
- 4) Assessment of osteogenic sarcomas for metastatic disease
- 5) Follow up to detect recurrence or metastases

Assessment of bone metastases

When bone scan or other imaging is equivocal

Assessment of tumour recurrence in the pituitary

Identifying recurrent functional pituitary tumours when anatomical imaging has not been successful.

Cardiac applications

Diagnosis of coronary artery disease or assessment of known coronary stenosis where other investigations (SPECT, ECG etc.) remain equivocal.

Miscellaneous applications

Disease assessment in HIV and other immunosuppressed patients

- 1) Identifying sites to biopsy in patients with pyrexia
- 2) Differentiating benign from malignant cerebral pathology
- 3) Routine assessment of weight loss where malignancy is suspected.

Assessment of bone infection

Assessment of spinal infection or problematic cases of infection.