

GENERAL:

CareImaging provides the following guidelines – both recommendations and the requirements – for referral for PET and for this trial. Within the requirements, in all cases determination of the medical necessity for a PET scan is with the referring physician.

To refer patients to the study the physician must be enrolled and agree with the terms of the trial. As is normal practice, documentation should be maintained in the patient's medical file at the referring physician's office to support the medical necessity of the procedure.

Patient must be at least age 18, male or female, not more than 275 lbs. They must be willing to adhere to protocol requirements, and sign a consent form. Females must not be lactating or pregnant, and if of reproductive age must have a negative urine pregnancy test. Patients must have normal fasting blood glucose levels or controlled diabetes mellitus that is not insulin dependent. They must not have known concurrent inflammatory conditions (such as rheumatoid arthritis, sarcoidosis, tuberculosis, or fungal infections). Patient must not have other known medical or psychological (e.g. history of claustrophobia) conditions, which in the opinion of the investigator make the patient unable to tolerate or complete the procedure. They must not have known or suspected hypersensitivity to diazepam or lorazepam. Patients must be able to undergo biopsy.

Trial personnel will obtain in advance from the enrolled physician patient information including results of conventional diagnostic methods, and description of the treatment plan. The diagnostics can include patient history, result of conventional imaging (e.g. x-ray, CT, MRI, ultrasound, planar x-ray, and nuclear medicine), blood test and pathology. Completion of conventional diagnostic methods must be within five weeks of the PET scan.

The PET scan is to be used for staging (and restaging), not for initial diagnosis, for five cancer indications – lung (small cell and non-small cell), breast, colorectal, (non-Hodgkin's) lymphoma, and malignant melanoma. For all tumours, tissue diagnosis (histopathologic proof) must be made prior to the PET scan. The one exception is diagnosis of solitary pulmonary nodule (and must be at least one cm to less than three cm), for which PET may be used for differentiation of benign and malignant lung nodules.

For staging, PET is recommended following standard diagnostic workup such as conventional imaging with CT, MRI or ultrasound, when the stage of the cancer is unclear. Or it may be used to replace one or more conventional imaging tests when other tests may not provide sufficient information for the clinical management of the patient. In either case PET is recommended when the clinical management of the patient would differ depending on the stage of the cancer identified from the PET scan.

For restaging, PET scan is recommended after completion of treatment, for detecting residual disease, suspected recurrence, or extent of known recurrence. PET is usually done after a course of treatment is completed. Although available, PET is not usually used to monitor tumour response during a planned course of therapy – that is, when no change in therapy is being considered.

LUNG CANCERS AND SOLITARY PULMONARY NODULE

FDG PET may be used for staging and restaging of lung cancers, and for diagnosis of solitary pulmonary nodules.

Solitary Pulmonary Nodule (SPN)

PET chest scans are useful for characterization of SPNs, primarily to determine the likelihood of malignancy, to plan management and treatment. For best results, referral for regional PET for SPNs should include the evidence for the initial detection of a primary lung nodule, usually by CT. This includes a report on the results of the CT or other detection method (for additional anatomic information). For this trial, a CT scan should show an indeterminate or possible malignant lesion that is at least one cm to less than three cm in diameter.

In cases of serial evaluation of SPNs using both x-ray CT and regional PET chest scanning, after a negative PET scan it is not recommended to repeat it within 12 months. In cases of negative PET scan for characterization of SPNs biopsy is not recommended, since the patient is presumed not to have a malignant lesion based on the PET scan results.

Lung Cancer (non small cell carcinoma (NSCLC) and small cell carcinoma (SCLC))

PET scans may be used for staging and restaging of lung cancers. The primary cancerous lung tumour must be pathologically confirmed. Referrals should include evidence of the detection of the primary lung tumour, such as the result of a thoracic CT; (and necessary for anatomic information), and the results of any lymph node biopsy, to determine if the patient will be a surgical candidate.

If the patient is considered a surgical candidate, a lymph node biopsy is not indicated if there is a negative CT and negative PET, unless medically necessary. A lymph node biopsy is recommended in all other cases – positive CT and PET, negative CT and positive PET, positive CT and negative PET.

BREAST CANCER

PET is recommended as an adjunct to conventional imaging for staging distant metastases, for restaging patients with local/regional recurrence of metastasis, for monitoring treatment of a locally advanced breast cancer tumour, and for evaluating metastatic breast cancer when a change in therapy is considered. At this time PET is not recommended for initial staging of axillary lymph nodes.

COLORECTAL CANCER

PET is done for staging and restaging of colorectal carcinomas for patients with recurrence, as suggested by rising levels of tumour marker CEA, or other clinical signs or symptoms. Recent medical evidence also supports the usefulness of FDG PET to determine the presence of hepatic/extrahepatic metastases in the primary staging of colorectal carcinoma, prior to selecting a treatment regimen. Referrals for PET should include evidence of previous colorectal tumour.

Frequency: Whole-body PET scans for assessment of recurrence of colorectal cancer should not be ordered more than once every twelve months, unless a separate re-evaluation of CEA within this period occurs.

NON-HODGKIN'S LYMPHOMA

PET is done only for staging or follow up restaging of lymphoma, as an alternative to a Gallium scan. PET should usually be performed as an alternative; however, the treating physician may conclude that previously performed Gallium scans are either inconclusive or not sufficiently reliable for proper patient care.

When used as an alternative, referrals should be based on evidence of previous diagnosis of lymphoma. To PET is properly coordinated with other diagnostic modalities, referrals should include the results of recent or concurrent CT and/or these other modalities and for additional anatomic information.

Frequency: PET scans usually should be performed for restaging no sooner than 50 days after the last staging PET or Gallium scan, unless there is evidence to suggest earlier restaging is necessary. Since PET scans for restaging are generally done following cycles of chemotherapy, and since such cycles usually are at least eight weeks, it is felt that this screen adequately prevents unnecessary scans while allowing some adjustments for unusual cases. However, in all cases the determination of medical necessity for a PET scan for restaging lymphoma is the prerogative of the referring physician.

MALIGNANT MELANOMA

PET is recommended for evaluating recurrent melanoma prior to surgery, as an alternative to a Gallium scan. PET is recommended for the staging and restaging of malignant melanoma. Pet is recommended as an alternative to a Gallium scan; however, the treating physician may conclude that previously performed Gallium scans are either inconclusive or not sufficiently reliable for proper patient care. PET is available but not recommended for evaluation of regional nodes in melanoma patients. PET is available but not recommended for evaluation of regional nodes in melanoma patients.

Frequency: Whole-body PET scans should not be ordered more than once every twelve months, unless there is a specific need for anatomic localization of possible recurrent tumour within this period.