

CHANGES TO MEDICARE COVERAGE CRITERIA – PET/CT

(Implementation Oct. 19th)

Framework:

CMS has replaced the original 4-part system (diagnosis, staging, restaging, and chemotherapy monitoring) with a new 2-part system: Initial Treatment Strategy, and Subsequent Treatment Strategy. The new framework, in essence, combines diagnosis and staging into one new category and combines restaging and treatment monitoring into another. All PET will be ordered under one or the other of these two new categories.

Initial Treatment Strategy:

CMS has extending coverage for an initial PET to virtually all solid tumors (with only a few exclusions)

- PET will not be allowed in the initial staging of adenocarcinoma of the Prostate.
- PET will still not be allowed in the diagnosis of Breast Cancer (i.e. the evaluation of s suspicious mass in the breast) – Classic Staging and Restaging are still allowed.
- PET for Initial Staging of Cervical Cancer remains covered only after traditional imagery has been done, **and** was negative for extra-pelvic mets. PET is not covered if extra-pelvic mets were already found.
- PET’s intended solely and specifically for the evaluation of sentinel lymph nodes in Breast Cancer or Melanoma will still not be allowed. Traditional Staging and Restaging uses are still allowed.

All other solid tumors, which are either biopsy proven or strongly suspected based on other diagnostic testing, will be covered for an initial PET if the treating physician decides that FDG-PET is needed to determine the location and/or extent of the tumor for the following therapeutic purposes related to the initial treatment strategy:

- To determine whether or not the patient is an appropriate candidate for an invasive diagnostic or therapeutic procedure (i.e.: to see if a biopsy or other surgical procedure is necessary)
- To determine the optimal anatomical location for an invasive procedure (i.e.: to help guide a biopsy or other surgical procedure)
- To determine the anatomic extent of tumor when the recommended anti-tumor treatment reasonably depends on the extent of the tumor (classic initial staging)

Myeloma: While not strictly a solid tumor, PET is now approved for the Initial Treatment Strategy in cases of Myeloma under the same guidelines as solid tumors.

Subsequent Treatment Strategy:

The coverage for “Restaging” PET’s has been left largely unchanged but CMS has added three new indications. In addition to the previously covered cancers:

Breast	Colorectal	Esophagus	Head & Neck
Lymphoma	Melanoma	Non-Small Cell Lung	Thyroid

CMS has added coverage for PET in Subsequent Treatment Strategy for three new cancer types:

Ovarian	Cervical	Myeloma
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Therefore, CMS will not reimburse for a classic “restaging” PET’s on most of the new indications for which it has now approved initial staging PET’s (Renal Cell, Liver, Brain, etc.). The National Oncologic PET Registry (NOPR) will continue to accept restaging PET’s for all indications not listed above.

As a side bonus: In combining “restaging” and “therapy monitoring” into one category, CMS has, in effect, expanded PET for chemotherapy monitoring to all of the above eleven indications. Previously, there was only coverage for chemotherapy monitoring in Breast Cancer.

Appendix A: Effect of Coverage Changes on Oncologic Uses of FDG PET
See NCD Manual for specific coverage language.

Solid Tumor Type	Final Framework	
	Initial Treatment Strategy*	Subsequent Treatment Strategy**
Colorectal	Cover	Cover
Esophagus	Cover	Cover
Head & Neck (not thyroid or CNS)	Cover	Cover
Lymphoma	Cover	Cover
Non-small cell lung	Cover	Cover
Ovary	Cover	Cover
Cervix	(1) or NOPR	Cover
Breast (female and male)	(2)	Cover
Melanoma	(3)	Cover
Thyroid	Cover	(4) or NOPR
Brain	Cover	NOPR
Small cell lung	Cover	NOPR
Soft Tissue Sarcoma	Cover	NOPR
Pancreas	Cover	NOPR
Testes	Cover	NOPR
Prostate	Not Covered	NOPR
All other solid tumors	Cover	NOPR
Myeloma	Cover	Cover
All other cancers not listed herein	NOPR	NOPR

* Formerly “diagnosis” and “staging”

** Formerly “restaging” and “therapy monitoring”

NOPR = National Oncologic PET Registry

- (1) Cervix: Covered for the detection of pre-treatment metastases (i.e., initial staging) in newly diagnosed cervical cancer subsequent to conventional imaging that is negative for extra-pelvic metastasis. All other uses are NOPR.
- (2) Breast: Non-covered for diagnosis. Also non-covered if ordered solely and specifically for the evaluation of the axillary lymph nodes. Covered for traditional initial staging of metastatic disease.
- (3) Melanoma: Non-covered if ordered solely and specifically for the evaluation of regional lymph nodes. All other uses for initial staging are covered.
- (4) Thyroid: Covered for subsequent treatment strategy of recurrent or residual thyroid cancer of follicular cell origin previously treated by thyroidectomy and radioiodine ablation and have a serum thyroglobulin >10ng/ml and have a negative I-131 whole body scan. All other uses for subsequent treatment strategy are NOPR.