

CMS Revises Medicare PET Coverage Guidelines and Billing Instructions and Makes Them Retroactive

In April, CMS issued a Decision Memo setting new Medicare coverage guidelines for positron emission tomography (PET) scans for solid tumors. The memo announced a new coverage framework that would replace the old coverage policy's four categories of diagnosis, staging, restaging and monitoring. Under the new framework, coverage would be based upon whether the scan was performed for initial or subsequent treatment strategy.

Although CMS issued the Decision Memo in April, the agency did not release a revised National Coverage Determination (NCD) until July 17. On that date CMS issued Transmittals 104 and 1772, which revised the Medicare National Coverage Determinations Manual and the Medicare Claims Processing Manual to reflect the new coverage policy.

You can find the transmittals on the CMS Web site at:

- http://www.cms.hhs.gov/transmittals/downloads/R104_NCD.pdf
- http://www.cms.hhs.gov/transmittals/downloads/R1772_CP.pdf

The new coverage provisions are retroactive to April 6, 2009. The expansion of PET coverage applies to Medicare Advantage plans as well as traditional Medicare.

New Framework

The new NCD applies to all oncologic PET and PET-CT studies performed using FDG. Studies are divided into two categories:

1. Initial treatment
2. Subsequent treatment

Initial Treatment: These studies are performed to determine the physician's initial treatment strategy when the patient has a solid tumor that is biopsy proven or strongly suspected based on other diagnostic testing. The physician must order the study for one of the following purposes:

- To determine whether the patient is a candidate for an invasive procedure (either diagnostic or therapeutic);
- To determine the optimal anatomic location for an invasive procedure; or
- To determine the anatomic extent of the tumor when the treatment recommendations depend on the extent.

Under the old coverage framework, these studies would have fallen into the Diagnosis or Staging categories.

Subsequent Treatment: These studies are performed to guide the physician's subsequent treatment strategies after the completion of initial treatment. Under the old framework, these studies would have fallen into the Restaging or Monitoring categories.

New Coverage Provisions

The table on the following page shows the new coverage parameters. The highlighted cells represent coverage changes from the previous NCD. Medicare will cover studies designated as "CED" (Coverage with Evidence Development) only as part of a prospective clinical study (for example, the National Oncologic PET Registry, or NOPR).

Under the new NCD, Medicare will cover FDG PET or PET-CT studies for **initial treatment** of certain common tumor types, including colorectal, non-small cell and small cell lung, etc. Only one initial treatment scan will be covered per patient, per tumor. After the first scan, Medicare will not cover any additional scans for initial treatment strategies of the same tumor.

Note that CMS has added coverage for initial treatment scans for tumors of the brain, small cell lung, soft tissue sarcoma, pancreas, testicle, other solid tumors and myeloma, all of which were previously paid only under CED.

CMS has not changed the restrictions that were in place under the old coverage policy for initial treatment scans for cervical cancer, breast cancer and melanoma.

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- **Cervical cancer:** Medicare will cover initial treatment scans when used to detect pretreatment metastasis in newly diagnosed cervical cancers following conventional imaging that is negative for extra-pelvic metastasis. Other initial treatment scans will be paid only under CED.
- **Breast cancer:** Initial treatment scans are covered when used in staging distant metastasis. Medicare will not cover initial treatment scans when used for diagnosing breast cancer or for initial staging of axillary nodes.
- **Melanoma:** Initial treatment scans are noncovered when used for evaluation of regional lymph nodes. Medicare, however, will cover other initial treatment uses.

Initial treatment scans for prostate cancer are now **noncovered**. Medicare will not pay for these scans even if the scan is reported to the National Oncologic PET Registry (NOPR).

Scans performed for **subsequent treatment** strategy are covered for the 10 tumor types listed in the table as “Covered.” Note that CMS has added coverage for subsequent treatment scans for ovarian and cervical cancer and myeloma. Previously, these scans were paid only under CED.

Subsequent treatment scans for tumor types other than the 10 shown in the table continue to be paid only under CED.

CMS has not changed the restrictions that were in place under the old policy for subsequent treatment scans of thyroid cancer. Medicare will continue to cover these scans only for recurrent or residual follicular cell thyroid cancer previously treated by thyroidectomy and radioactive iodine ablation. The

patient must have a serum thyroglobulin greater than 10 ng/ml and a negative I-131 whole body scan. If the patient does not meet these criteria, the scan will be paid only under CED.

Modifiers

CMS has issued two new modifiers that all health care providers (hospitals, imaging centers and physicians) should use to distinguish initial treatment strategy scans from subsequent treatment strategy scans:

Modifier	Definition
PI	Positron Emission Tomography (PET) or PET/Computed Tomography (CT) to inform the initial treatment strategy of tumors that are biopsy proven or strongly suspected of being cancerous based on other diagnostic testing
PS	Positron Emission Tomography (PET) or PET/Computed Tomography (CT) to inform the subsequent treatment strategy of cancerous tumors when the beneficiary’s treating physician determines that the PET study is needed to inform subsequent anti-tumor strategy

Note that modifier PI contains the letter “I” rather than the numeral “1.” Modifier P1 is an anesthesia modifier that is not valid on claims for imaging services.

Tumor Type	Initial Treatment Strategy	Subsequent Treatment Strategy
Colorectal	Covered	Covered
Esophagus	Covered	Covered
Head and neck (except thyroid and CNS)	Covered	Covered
Lymphoma	Covered	Covered
Non-small cell lung cancer	Covered	Covered
Ovary	Covered	Covered
Brain	Covered	CED
Cervix	Restricted coverage	Covered
Small cell lung cancer	Covered	CED
Soft tissue sarcoma	Covered	CED
Pancreas	Covered	CED
Testicular	Covered	CED
Breast (female and male)	Restricted coverage	Covered
Melanoma	Restricted coverage	Covered
Prostate	Noncovered	CED
Thyroid	Covered	Restricted coverage
All other solid tumors	Covered	CED
Myeloma	Covered	Covered
All other cancers	CED	CED

Medicare contractors will accept these modifiers beginning on July 6, and providers may use the modifiers on claims with dates of service back to April 6, 2009, when the new coverage policy took effect. Beginning Oct. 5, 2009, Medicare contractors will return all oncologic FDG PET claims with date of service on or after April 6 to providers unless they include modifier PI or PS.

As noted previously, Medicare will pay for only one scan for initial treatment strategy and will deny additional scans with modifier PI for the same tumor type.

In addition to modifiers PI and PS, scans submitted to NOPR and covered under CED must also be submitted with modifier Q0 (Investigational clinical service provided in a clinical research study that is in an approved clinical research study). And hospital claims must include diagnosis code V70.7 and condition code 30.

For example, an imaging center performs a PET-CT scan, skull base to mid thigh, for restaging of small cell lung cancer. This service is paid only under CED, so the center submits the case to NOPR. The facility should submit code 78815-PS-Q0 on its Medicare claim. Modifier PS indicates that the facility performed the scan for subsequent treatment strategy (restaging), and modifier Q0 indicates that it was submitted to NOPR.

ICD-9-CM Diagnosis Codes

CMS has indicated that the ICD-9-CM cancer codes 140.XX through 239.XX are appropriate for oncologic PET and PET-CT studies. Additionally, the local Medicare contractors can choose to cover “alternate ICD-9 diagnosis codes.”

Presumably, these alternate codes will include V codes or other non-cancer codes that providers can use when they strongly suspect a patient has a malignancy, but that malignancy has not yet been confirmed by tissue diagnosis. For example, local Medicare contractors may designate code 518.89 as a covered code for patients with solitary pulmonary nodules that are presumed to be cancerous but not yet proven by biopsy. Be sure to watch your local contractor’s newsletter and coverage policies for guidance about how to code these cases.

When a PET or PET-CT claim includes one of these “alternate” diagnosis codes and does not include a cancer code from the range 140.XX-239.XX, providers must submit an additional modifier on the claim:

Modifier	Definition
KX	Requirements specified in the medical policy have been met

Modifier KX must be used together with modifier PI or PS.

For example, a hospital performs a PET-CT scan, skull base to mid thigh, for initial treatment strategy of lung cancer in a patient with a solitary pulmonary nodule that has not yet been biopsied. If the local Medicare contractor has designated 518.89 as an alternate code, the hospital should submit

procedure code 78815-PI-KX and diagnosis code 518.89 on its Medicare claim. Modifier PI indicates that the scan was performed for initial treatment strategy, and KX indicates that it was performed for an alternate diagnosis code approved by the local contractor.

Non-Oncologic Studies

The new oncologic PET NCD does not affect the existing Medicare National Coverage Determinations for non-oncologic studies. For example, there has been no change to the coverage and billing guidelines for PET myocardial perfusion studies, PET brain studies for dementia or seizures, etc.

Noncovered Studies

Remember to use the appropriate HCPCS code when submitting a claim to Medicare for a noncovered PET or PET-CT scan. The available codes are:

Modifier	Definition
G0219	PET imaging whole body; melanoma for non-covered indications
G0235	PET imaging, any site, not otherwise specified
G0252	PET imaging, full or partial ring PET scanners only, for initial diagnosis of breast cancer and/or surgical planning for breast cancer (e.g. initial staging of axillary lymph nodes)

Providers should issue Advance Beneficiary Notices (ABNs) for these noncovered scans.

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