Medlearn Matters
Information for Medicare Providers

Related Change Request (CR) #: 3741
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Expanded Coverage for PET Scans for Cervical and Other Cancers, New Coding for PET Scans, and Billing Requirements for PET Scans for Specific Indications of Cervical and Other Cancers

Provider Types Affected

Physicians, providers, and suppliers billing Medicare carriers and Fiscal Intermediaries (FIs) for the subject PET scans

Provider Action Needed

CR 3741, as summarized by this instruction, changes the national coverage for the use of 2-[F-18] Fluoro-D-Glucose Positron Emission Tomography scans (FDG-PET) for certain cancer indications.

Effective for services performed on or after January 28, 2005, the Centers for Medicare & Medicaid Services (CMS) expands national coverage of FDG-PET to include:

- Specific indications in patients with cervical cancer;
- Indications not previously specified in 5 other cancer diagnoses; brain, ovarian, pancreatic, small cell lung, and testicular (but only when you and your patients are participating in specifically defined prospective clinical studies/trials);
- Monitoring response to treatment when a change in therapy is indicated in a number of cancers that are already covered for diagnosis, staging, and restaging; and,
- A broad range of other cancers not previously specified (but only when you and your patients are participating in specifically defined prospective clinical studies/trials).

Note: For the coverage of specific indications, see table 1 below.

Background

Positron Emission Tomography (PET) is a noninvasive diagnostic imaging procedure that assesses the level of metabolic activity and perfusion in various organ systems. In this procedure, a positron camera produces cross-sectional tomographic images obtained from intravenous positron emitting radioactive

tracer substances (radiopharmaceuticals), such as 2-[F-18] Fluoro-D-Glucose (FDG). In general, FDG PET is covered in the following clinical situations:

Diagnosis

When the results may help avoid an invasive diagnostic procedure, or help determine the best anatomic location for an invasive diagnostic procedure.

Staging

When a cancer's stage remains in doubt after completion of a standard diagnostic workup, including conventional imaging (computed tomography, magnetic resonance imaging, or ultrasound); when using PET could potentially replace one or more conventional imaging studies if it is expected that conventional study information is not sufficient for the patient's clinical management, and when the patient's clinical management would differ depending on the cancer's stage.

Restaging

After the completion of treatment for the purpose of detecting residual disease, for detecting suspected recurrence, or metastasis, to determine the extent of a known recurrence, or if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is not adequate to determine the extent of a known recurrence, or if study information is not sufficient for the patient's clinical management. Restaging applies to testing after a course of treatment is completed and is covered subject to the above conditions.

Monitoring

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

CR 3741 expands the FDG PET national coverage policy (by revisions to the National Coverage Determinations (NCD) Manual – CMS Publication (Pub.) 100-03 and the Medicare Claims Processing Manual – CMS Pub. 100-04) by providing general Medicare coverage and billing requirements for FDG PET usage for brain, cervical, ovarian, pancreatic, small cell lung, testicular, and other cancer indications both previously specified and not previously specified.

In newly diagnosed and locally advanced cervical cancer (after negative conventional imaging for extra-pelvic metastasis) CMS determines that the evidence is adequate to conclude that FDG PET to detect pre-treatment metastases (staging) is reasonable and necessary as an adjunct test.

In addition, for brain, ovarian, pancreatic, small cell lung, and testicular cancers, CMS determines that the evidence is sufficient to conclude that FDG PET is reasonable and necessary only when the provider is participating in, and patients are enrolled in, one of the following types of prospective clinical studies:

- A clinical trial of FDG PET that meets the requirements of the Food and Drug Administration (FDA) category B investigational device exemption (42 CFR 405.201); or
- A FDG PET clinical study that is designed to collect additional information at the time of the scan to assist in patient management. Qualifying clinical studies must ensure that specific hypotheses are

addressed; appropriate data elements are collected; hospitals and providers are qualified to provide the PET scan and interpret the results; participating hospitals and providers accurately report data on all enrolled patients not included in other qualifying trials through adequate auditing mechanisms; and, all patient confidentiality, privacy, and other Federal laws must be followed.

In addition, coverage is also expanded under clinical studies (as defined above) for certain indications of brain, cervical, colorectal, esophageal, head and neck, lymphoma, melanoma, non-small cell lung, ovarian, pancreatic, small-cell lung, soft tissue sarcoma, thyroid, testicular, and other cancers not previously identified. Monitoring response to treatment when a change in therapy is indicated is now covered in a number of cancers (cervical, colorectal, esophageal, head and neck, lymphoma, melanoma, non-small cell lung, and thyroid) only in the context of a clinical study. Lastly, this guidance expands coverage in the context of a clinical study for a broad range of other cancers not previously specified. You can find these changes in the following table.

Table 1

Coverage of FDG PET for Cancer Indications

Effective January 28, 2005

Indication	Covered [1]	Nationally Non-covered [2]	Coverage with Evidence Development [3]
Brain			X
Breast			
-Diagnosis		X	
-Initial staging of axillary nodes		X	
-Staging of distant metastasis	X		
-Restaging, monitoring *	X		
Cervical			
-Staging as adjunct to conventional imaging	X		
-Other staging			X
-Diagnosis, restaging, monitoring *			X
Colorectal			
-Diagnosis, staging, restaging	X		
-Monitoring *			X
Esophagus			
-Diagnosis, staging, restaging	X		
-Monitoring *			X

Indication	Covered [1]	Nationally Non-covered [2]	Coverage with Evidence Development [3]
Head and Neck (non-CNS/thyroid)			
-Diagnosis, staging, restaging	X		
-Monitoring *			X
Lymphoma			
-Diagnosis, staging, restaging	X		
-Monitoring *			X
Melanoma			
-Diagnosis, staging, restaging	X		
-Monitoring *			X
Non-Small Cell Lung			
-Diagnosis, staging, restaging	X		
-Monitoring *			X
Ovarian			X
Pancreatic			X
Small Cell Lung			X
Soft Tissue Sarcoma			X
Solitary Pulmonary Nodule (characterization)	X		
Thyroid			
-Staging of follicular cell tumors	X		
-Restaging of medullary cell tumors			X
-Diagnosis, other staging & restaging			X
-Monitoring *			X
Testicular			X
All other cancers not listed herein (all indications)			X

[1] Covered nationally based on evidence of benefit. Refer to National Coverage Determination Manual Section 220.6 in its entirety for specific coverage language and limitations for each indication.

[2] Non-covered nationally based on evidence of harm or no benefit

[3] Covered only in specific settings discussed above if certain patient safeguards are provided. Otherwise, non-covered nationally based on lack of evidence sufficient to establish either benefit or harm or no prior decision addressing this cancer. Medicare will notify providers and beneficiaries where these services can be accessed, as they become available, via Federal Register Notice and the CMS coverage Web site at: http://www.cms.hhs.gov/coverage

* Monitoring = monitoring response to treatment when a change in therapy is anticipated.

Perhaps a quick review of the term National Coverage Determination (NCD) would be helpful at this point. NCDs grant, limit, or exclude Medicare coverage for a specific medical item/service. They apply nationwide and are binding on all Medicare carriers, FIs, quality improvement organizations, health maintenance organizations, competitive medical plans, and health care prepayment plans for purposes of Medicare coverage. Moreover, an administrative law judge may not review an NCD.

Here are some specific details about the NCD issued as part of CR 3741 of which you should be aware:

- A particular use of FDG PET scans is not covered unless the NCD Manual specifically provides coverage of that use.
- All currently non-covered FDG PET indications based on lack of evidence or benefit remain in effect (i.e., HCPCS G0219 and G0252 remain in effect as non-covered PET indications).
- For all other currently non-covered FDG PET indications (not based on lack of evidence or benefit), Medicare will cover FDG PET scans meeting the clinical study/trial criteria outlined in this NCD.
- Effective for claims with dates of service on or after January 28, 2005, all HCPCS codes listed in Table 2 (below) will be used for all covered PET scan indications specified, and those listed in Table 3 (below) will become invalid. Additionally, a new HCPCS code (G0235 – PET not otherwise specified) has been added for non-coverage of PET scan indications not otherwise specified.

Note: While G0336 for Coverage of PET Scans for Dementia and Neurodegenerative Diseases will be replaced with a CPT code for services on or after January 28, 2005, all other limiting conditions and indications for coverage apply. Refer to the National Coverage Determinations Manual, section 220.6.13, for complete coverage conditions for PET scans for dementia and neurodegenerative diseases.

Table 2

CPT Codes for Covered PET scan Indications

Effective for dates of service on or after January 28, 2005

CPT Code	Description
78459	Myocardial imaging, positron emission tomography (PET), metabolic evaluation
78491	Myocardial imaging, positron emission tomography (PET), perfusion, single study at rest or stress
78492	Myocardial imaging, positron emission tomography (PET), perfusion, multiple studies at rest and/or stress
78608	Brain imaging, positron emission tomography (PET); metabolic evaluation
78609	Brain imaging, positron emission tomography (PET); perfusion evaluation
78811	Tumor imaging, positron emission tomography (PET); limited area (eg, chest, head/neck)

CPT Code	Description
78812	Tumor imaging, positron emission tomography (PET); base to mid thigh
78813	Tumor imaging, positron emission tomography (PET); whole body
78814	Tumor imaging, positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization; limited area (eg chest, head/neck)
78815	Tumor imaging, positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization; skull base to mid thigh
78816	Tumor imaging, positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization; whole body

Table 3

HCPCS Codes Not Valid for Medicare for dates of service on or after January 28, 2005

G0030	G0046	G0223
G0031	G0047	G0224
G0032	G0125	G0225
G0033	G0210	G0226
G0034	G0211	G0227
G0035	G0212	G0228
G0036	G0213	G0229
G0037	G0214	G0230
G0038	G0215	G0231
G0039	G0216	G0232
G0040	G0217	G0233
G0041	G0218	G0234
G0042	(this space intentionally left blank)	G0253
G0043	G0220	G0254
G0044	G0221	G0296
G0045	G0222	G0336

Additional Information

You can find more information about the billing requirements for FDG PET scans for brain, cervical, ovarian, pancreatic, small cell lung, soft tissue sarcoma, testicular, and all other cancer Indications by going to:

http://www.cms.hhs.gov/manuals/transmittals/comm_date_dsc.asp

From that web page, look for CR 3741 in the CR NUM column on the right, and click on the file for that CR. Please note that there will be two transmittals with CR 3741, one for the NCD issuance itself and the other for the changes to Medicare claims processing as a result of the NCD. The revised portion of the NCD Manual will be attached to CR 3741, transmittal number 31. The billing/claims processing changes to the Medicare Claims Processing Manual will be attached to CR 3741, transmittal number 518.

Finally, if you have questions, please contact your carrier/intermediary at their toll-free number, which may be found at:

http://www.cms.hhs.gov/medlearn/tollnums.asp