



Related MLN Matters Article #: MM3741

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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

Key Words

CR3741, MM3741, R31NCD, R527CP, FDG, PET, MM5124, CR5124, R956CP, Scan, Cancer, Cervical, Dementia, Neurodegenerative

Provider Types Affected

Physicians, providers and suppliers billing Medicare Carriers and Fiscal Intermediaries (FIs) for Positron Emission Tomography (PET) scans

Key Points

- The effective date for instruction is January 28, 2005.
- The implementation date is April 18, 2005.
- Change Request (CR) 3741 changes the national coverage for the use of 2-[F-18] Fluoro-D-Glucose PET 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 the provider and their 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

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- A broad range of other cancers not previously specified (**but only when the provider and their patients are participating in specifically defined prospective clinical studies/trials**).

Coverage

- 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 - Restaging applies to testing after a course of treatment is completed and is covered subject to the following conditions:
 - 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;
 - 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.
 - Monitoring - Monitoring refers to evaluating tumor response to treatment during the planned course of therapy (i.e., when a change in therapy is anticipated).

Expanded Coverage

- CR3741 expands the FDG-PET national coverage policy 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 Code of Federal Regulations 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.
- 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.
- This guidance expands coverage in the context of a clinical study for a broad range of other cancers not previously specified. Providers can find these changes in Table 1 that starts on page 3 of MLN Matters article MM3741.

Review of the National Coverage Determination (NCD)

- 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.
- 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 providers 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., Healthcare Common Procedure Coding System (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 on page 6 of MM3741 will be used for all covered PET scan indications specified.
 - Effective for claims with dates of service on or after January 28, 2005, all HCPCS codes listed in Table 3 on page 7 of MM3741 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.

Important Links

The related MLN Matters article can be found at

<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM3741.pdf> on the CMS website.

Please note that there are two transmittals with CR3741, 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 CR3741, transmittal number 31

(<http://www.cms.hhs.gov/Transmittals/downloads/R31NCD.pdf>). The billing/claims processing changes to the *Medicare Claims Processing Manual* will be attached to CR3741, transmittal number 527

(<http://www.cms.hhs.gov/Transmittals/downloads/R527CP.pdf>) on the CMS website.

Note: CR5124 revised CR3741 (effective for services on or after January 28, 2005) to require that providers use the appropriate Common Procedural Terminology (CPT) code and the QR modifier, rather than the QV modifier on carrier claims for services for dementia and neurodegenerative diseases, and a broad range of cancer indications listed as “coverage with evidence development.”

Providers can find more information about FDG PET scans in patients undergoing Medicare approved clinical trials by going to CR5124, located at

<http://www.cms.hhs.gov/Transmittals/downloads/R956CP.pdf> on the CMS website. The related article (MM5124) may be found at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/mm5124.pdf> on the CMS website.

CMS Coverage web page is at <http://www.cms.hhs.gov/CoverageGenInfo/> on the CMS website.

National Coverage Determinations Manual and the *National Claims Processing Manual* may be found at <http://www.cms.hhs.gov/Manuals/IOM/list.asp> on the CMS website.