

MLN Matters Number: MM5124 **Revised**

Related Change Request (CR) #: 5124

Related CR Release Date: May 19, 2006

Effective Date: January 28, 2005

Related CR Transmittal #: R956CP

Implementation Date: June 19, 2006

Payment for Positron Emission Tomography Scans in CMS-Approved Clinical Trials and Coverage with Evidence Development - Use of QR and QV Modifiers

Note: Important new information regarding PET Scans in clinical trials and on clinical trial modifiers is available in the MLN Matters® articles at

<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6753.pdf> and at

<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6431.pdf> on the CMS website.

Provider Types Affected

Physicians and other providers who bill Medicare carriers and fiscal intermediaries (FI) for the use of FDG PET scans for oncology and dementia/neurodegenerative diseases.

Provider Action Needed



STOP – Impact to You

Effective January 28, 2005, for certain FDG PET indications (listed in the *Background* section below), rather than the **QV** modifier previously required, you must use the **QR** modifier on all carrier claims to identify that this service is provided in a Medicare-specified study.



CAUTION – What You Need to Know

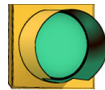
CR5124 revises Transmittal 527 (CR 3741) to require that you use the appropriate CPT code and the **QR** modifier (item or service provided in a Medicare-specified study), rather than the **QV** modifier (other than inpatient), on carrier claims for

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services for dementia and neurodegenerative diseases, and a broad range of cancer indications listed as “coverage with evidence development.”

Claims submitted to FIs must contain the principal diagnosis code, the appropriate CPT code, and V70.7 diagnosis code. In addition, CMS has entered into an agreement with the Academy of Molecular Imaging (AMI) in which AMI collects data for a broad range of cancers through the National Oncologic PET Registry (NOPR). The NOPR, which began accepting patients on May 8, 2006, satisfies Medicare’s requirement that the FDG PET provider and Medicare beneficiary participate in a prospective clinical study in order for the services to be considered reasonable and necessary. NOPR information and registration materials are available at its website, provided in the *Additional Information* section below.



GO – What You Need to Do

Make sure that your billing staffs are aware of these coding changes for FDG PET services in your Medicare claims.

Background

Positron Emission Tomography (PET)

Positron emission tomography (PET) is a noninvasive imaging procedure that assesses perfusion and the level of metabolic activity in various organ systems of the human body. A positron camera (tomograph) is used to produce cross-sectional tomographic images obtained by detecting radioactivity from a radioactive tracer substance (radionuclide), 2-[F-18] Fluoro-D-Glucose (FDG).

Refer to Publication 100-03, the *National Coverage Determinations (NCD) Manual*, section 220.6, for coverage instructions that indicate conditions under which a PET scan is performed. The manual is available at <http://www.cms.hhs.gov/Manuals/IOM/list.asp#TopOfPage> on the CMS website.

Covered FDG PET Scans

For cancers listed as “coverage with evidence development” in section 220.6 of the NCD Manual, CMS has determined that (effective for services performed on or after January 28, 2005) FDG PET scans are reasonable and necessary only when the provider is participating in, and patients are enrolled in:

- A clinical trial that meets the requirements of Food and Drug Administration (FDA) category B investigational device exemption (42 CFR 405.201); or

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- An FDG PET clinical study that is designed to collect additional information at the time of the scan to assist in patient management.

CR3741, released April 15, 2005, indicated that there is adequate evidence to conclude that an FDG PET scan for the detection of pre-treatment metastases (i.e., staging) in newly-diagnosed cervical cancer (after conventional imaging that is negative for extra-pelvic metastasis), is reasonable and necessary as an adjunct test, and it expanded coverage to include FDG PET for certain indications of cervical cancer.

CR3741 also designated **QV** as the correct modifier to be used in carrier claims for beneficiaries participating in CMS-approved clinical trials utilizing FDG PET scans for dementia and neurodegenerative diseases.

CR5124, upon which this article is based, revises CR3741 to provide that (effective for services on or after January 28, 2005) you will be reimbursed for the use of FDG PET services for:

- Dementia and neurodegenerative disease (see NCD Manual (100.03) section 220.6.13);
- Certain indications for cancers of the cervix, lung (including small cell), esophagus, colon and rectum, head and neck, breast, thyroid, brain, ovary, pancreas, and testes; and lymphoma, melanoma, and soft tissue sarcoma (as listed in sections 220.6.2-220.6.7 and 220.6.10-220.6.14); and
- All other cancer indications not previously specified (as listed in section 220.6.15);
- **Only** if these scans were performed as part of a Centers for Medicare & Medicaid Services (CMS)-approved clinical trial.

In fact, be aware that FDG PET scans for all cancer indications listed in section 220.6 as “coverage with evidence development” remain nationally non-covered unless they are performed in conjunction with a CMS-approved clinical trial.

Using Appropriate CPT Code and QR Modifier

In line with the requirement for including these patients in clinical trials, you must submit all (other than inpatient) FDG PET claims to your carriers using the appropriate CPT code and the **QR** modifier, which was created for use on Part B claims (and other outpatient claims) to identify items/services that are covered when provided in a Medicare-specified study.

You may no longer use the **QV** modifier when a beneficiary undergoes an FDG PET scan in a facility participating in a Medicare-approved study specified by the above-referenced NCDs.

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National Oncologic PET Registry (NOPR)

You should also be aware that CMS contracted with the Academy of Molecular Imaging (AMI) to establish the NOPR, a national, internet-based data registry that reports on oncologic FDG PET scans received by Medicare beneficiaries as outlined in the NCD.

Reporting data to the NOPR for the oncologic FDG PET scan indications listed in section 220.6 as “coverage with evidence development” is a requirement of Medicare coverage. Without appropriately reported data, Medicare may be unable to approve claims and/or may be required to take action to recoup payments already made if data reporting discrepancies are discovered through post-payment claims analysis.

Remember that you are responsible for ensuring that data is accurately reported to the NOPR and that claims are accurately submitted. CMS recommends that you contact NOPR so that your facility may provide expanded oncologic FDG PET benefits under the NCD.

When submitting such claims to your FIs, you should use the appropriate principal diagnosis code, the appropriate CPT code, and ICD-9 code V70.7 in the second diagnosis position on the CMS-1450 (UB-92), or the electronic equivalent.

Finally, note that effective for PET scan claims with dates of service on or after January 28, 2005 until implementation of CR5124 on June 19, 2006, your carriers and FIs do not need to search their files to either retract erroneous payment for claims already paid or to retroactively pay claims incorrectly processed, unless you bring those claims to their attention.

Additional Information

You 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.

Additionally, you might want to look at the *National Coverage Determinations (NCD) Manual*, sections 220.6, 220.6.2 - 220.6.7, 220.6.10 - 220.6.12, 220.6.14, and 220.6.15 for important information regarding FDG PET for oncology.

The transmittal that conveyed the above NCD is available at <http://www.cms.hhs.gov/Transmittals/downloads/R31NCD.pdf> on the CMS website.

A related Medicare Claims Processing Manual transmittal is available at <http://www.cms.hhs.gov/Transmittals/downloads/R527CP.pdf> on the CMS website.

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A related MLN Matters article appears at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM3741.pdf> on the same site.

Information and registration materials are available at NOPR's website: <http://www.cancerPETregistry.org>. A regularly updated list of NOPR's Medicare approved facilities is located at <http://www.cms.hhs.gov/MedicareApprovedFacilitie/NOPR/list.asp#TopOfPage> on the CMS website.

NOPR can also be reached at 800-227-5463, extension 4859, or 215-717-0859. If you have any questions, please contact your carrier or FI at their toll-free number, which may be found at <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip> on the CMS website.

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