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MLN Matters® Number: MM6753 **Revised**

Related Change Request (CR) #: 6753

Related CR Release Date: January 6, 2010

Effective Date: November 10, 2009

Related CR Transmittal #: R1888CP and R110NCD Implementation Date: January 4, 2010

Positron Emission Tomography (PET) (FDG) for Cervical Cancer

Note: This article was revised on January 7, 2010, to reflect a revised CR 6753 that was issued on January 6, 2010. In the article, the CR release date, transmittal numbers (see above), and the Web addresses for accessing the transmittals were changed. All other information remains the same.

Provider Types Affected

Physicians, hospitals, and other providers who provide F-18 flouro-D-glucose (FDG) Positron Emission Tomography (PET) imaging services should be aware of this article if they bill Medicare carriers, Fiscal Intermediaries (FIs) or Medicare Administrative Contractors (MACs) for those services provided to Medicare beneficiaries with cervical cancer.

What You Need to Know

CR 6753, from which this article is taken, announces a National Coverage Determination (NCD) regarding F-18 flouro-D-glucose (FDG) Positron Emission Tomography (PET) imaging for cervical cancer.

Specifically, (effective for claims with dates of service on and after November 10, 2009) the Centers for Medicare & Medicaid Services (CMS) ends the coverage

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with evidence development (CED) requirements for FDG PET for cervical cancer; and will cover only one FDG PET for cervical cancer for staging in beneficiaries with biopsy-proven tumors when the treating physician determines that the study is needed to determine the location and/or extent of the tumor for specific therapeutic purposes related to initial treatment strategy (as outlined in the Medicare *National Coverage Determination Manual*, Section 220.6.17 (FDG PET for Oncologic Conditions (Various Effective Dates)).

Background

CR 6753 announces an NCD regarding FDG PET imaging for cervical cancer (including FDG PET/CT). It provides that, effective November 10, 2009 (as the result of a reconsideration request), CMS:

- Ended CED prospective data collection requirements for the use of FDG PET imaging in the initial staging of cervical cancer related to initial treatment strategy;
- Determined that there is no credible evidence that the results of FDG PET imaging are useful in making the initial diagnoses of cervical cancer; or in improving health outcomes; and
- Announced that FDG PET is not reasonable and necessary under section 1862(a)(1)(A) of the Social Security Act (the Act) and, therefore, CMS non-covers FDG PET imaging for initial diagnosis of cervical cancer related to initial treatment strategy.

As a result, CR 6753 provides that (effective for claims with dates of service on and after November 10, 2009), CMS will cover only one initial FDG PET study for staging in beneficiaries who have biopsy-proven cervical cancer when the treating physician determines that the FDG PET study is needed to determine the location and/or extent of the tumor for the following therapeutic purposes related to initial treatment strategy:

- To determine whether or not the beneficiary is an appropriate candidate for an invasive diagnostic or therapeutic procedure; or,
- To determine the optimal anatomic location for an invasive procedure; or
- To determine the anatomic extent of the tumor when the recommended anti-tumor treatment reasonably depends on the extent of the tumor.

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NOTE the exception to this policy: CMS continues to non-cover FDG PET for the initial diagnosis of cervical cancer related to initial treatment strategy.

Billing Changes

Effective for claims with dates of service on or after November 10, 2009, your carrier, FI, or MAC will accept FDG PET oncologic claims that you bill to inform initial treatment strategy; specifically for staging in beneficiaries who have biopsy-proven cervical cancer when the beneficiary's treating physician determines the FDG PET study is needed to determine the location and/or extent of the tumor as specified above. **Please note that for these claims, the –Q0 modifier (investigational clinical service provided in a clinical research study that is in an approved clinical research study) is no longer necessary for FDG PET services for cervical cancer.**

In addition, your carrier, FI, or MAC will "return as unprocessable/return to provider" your claims for FDG PET for cervical cancer billed to inform initial treatment if all the following are not present:

- PET or PET/CT Current Procedural Terminology (CPT) code (78608, 78811, 78812, 78813, 78814, 78815, or 78816), AND
- -PI modifier (PET Tumor initial treatment strategy), AND
- ICD-9 cervical cancer diagnosis code.

Failure to use the correct codes will result in the following messages:

- Claim Adjustment Reason Code 4 – The procedure code is inconsistent with the modifier used or a required modifier is missing.
- Remittance Advice Remark Code (RARC) MA130 - Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable. Submit a new claim with the complete/correct information.
- RARC M16 - Alert: See our Web site, mailings, or bulletins for more details concerning this policy/procedure/decision.

You should be aware that while your carrier, FI, or MAC will not search their files for FDG PET oncologic cervical cancer claims for initial treatment strategy, for dates of service November 10, 2009, through January 3, 2010, they will adjust such claims that you bring to their attention.

Additional Information

The official CR 6753 was issued in two transmittals, one announcing the NCD as added to the *Medicare NCD Manual* and the other transmittal providing the revised *Medicare Claims Processing Manual* instructions. You can find these transmittals

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at <http://www.cms.hhs.gov/Transmittals/downloads/R110NCD.pdf> and <http://www.cms.hhs.gov/Transmittals/downloads/R1888CP.pdf>, respectively, on the CMS website.

If you have any questions, please contact your carrier, FI, or MAC 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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