



Positron Emission Tomography (PET) F-18 flouro-D-glucose (FDG) for Cervical Cancer – JA6753

Note: MLN Matters® article MM6753 was revised to reflect a revised Change Request (CR) 6753 that was issued on January 7, 2010. The CR release date, transmittal numbers (see below), and the Web addresses for accessing the transmittals were changed. All other information remains the same.

Related CR Release Date: January 6, 2010 **Revised**

Date Job Aid Revised: January 21, 2010

Effective Date: November 10, 2009

Implementation Date: January 4, 2010

Key Words	MM6753, CR6753, R1888CP, R110NCD, Positron, Emission, Tomography, PET, FDG, Cervical, Cancer
Contractors Affected	<ul style="list-style-type: none"> • Medicare Carriers • Fiscal Intermediaries (FIs) • Part A/B Medicare Administrative Contractors (A/B MACs)
Provider Types Affected	Provider types affected are physicians, hospitals, and other providers who bill Medicare Carriers, FIs or A/B MACs for FDG PET imaging services provided to Medicare beneficiaries with cervical cancer.



- CR6753 announces a National Coverage Determination (NCD), regarding FDG PET imaging for cervical cancer.
- Effective for claims with dates of service on and after November 10, 2009, the Centers for Medicare & Medicaid Services (CMS) ends the coverage 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))).

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- CR6753 announces a NCD regarding FDG PET imaging for cervical cancer (including FDG PET/Computed Tomography (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. Therefore, CMS non-covers FDG PET imaging for initial diagnosis of cervical cancer related to initial treatment strategy.
 - As a result, CR6753 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.

Provider Needs to Know...

Note: The exception to this policy is that 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, carriers, FIs, or A/B MACs will accept FDG PET oncologic claims 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. **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, carriers, FIs, or A/B MACs will "return as unprocessable/return to provider" 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**
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- International Classification of Diseases, Ninth Revision 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.
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Background

CMS generated a request to reconsider Section 220.6 of the *NCD Manual* to end the prospective data collection requirements FDG PET imaging for the initial anti-tumor treatment strategy for cervical cancer under certain circumstances.

**Operational
Impact**

Providers should be aware that while their carrier, FI, or A/B 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 are brought to their attention.

**Reference
Materials**

The related MLN Matters® article can be found at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6753.pdf> on the CMS website.

The official instruction (CR6753) issued regarding this change may be found at <http://www.cms.hhs.gov/Transmittals/downloads/R1888CP.pdf> on the CMS website.

The transmittal announcing the NCD regarding this change may be found at <http://www.cms.hhs.gov/Transmittals/downloads/R110NCD.pdf> on the CMS website.
