DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

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MLN Matters® Number: MM8739 Revised

Related Change Request (CR) #: CR 8739

Related CR Release Date: January 8, 2015

Effective Date: June 11, 2013

Related CR Transmittal #: R3162CP, R168NCD

Implementation Dates: May 19, 2014 - MAC Non-Shared System Edits; July 7, 2014 - CWF development/testing, FISS requirement development; October 6, 2014 - CWF, FISS, MCS Shared System Edits

Fluorodeoxyglucose (FDG) Positron Emission Tomography (PET) for Solid Tumors (This Change Request (CR) rescinds and fully replaces MM 8468, dated February 6, 2014.)

Note: This article was revised on January 12, 2015, to reflect the revised CR8739 issued on January 8. In the article, reference to an attachment at the bottom of page 2 has been replaced with a Web link to the list of appropriate diagnosis codes. Note that 793.11 has been added to that list. Also, the CR release date, transmittal number, and the Web address for accessing the CR are revised. All other information remains the same.

Provider Types Affected

This MLN Matters® Article is intended for physicians, providers and suppliers submitting claims to Medicare Administrative Contractors (MACs) for services to Medicare beneficiaries.

Provider Action Needed

This article is based on Change Request (CR) 8739, which advises MACs, effective for dates of service on or after June 11, 2013, to cover three FDG PET scans when used to guide subsequent management of anti-tumor treatment strategy after completion of initial anti-cancer therapy for the same cancer diagnosis. Coverage of any additional FDG PET scans (that is, beyond three) used to guide subsequent management of anti-tumor treatment strategy after completion of initial anti-cancer therapy for the same diagnosis will be determined by your MAC. Make sure your billing staffs are aware of these changes.

Background

The Centers for Medicare & Medicaid Services (CMS) has reconsidered Section 220.6, of the "National Coverage Determinations (NCD) Manual" to end the prospective data collection requirements across all oncologic indications of FDG PET in the context of CR8739. The term FDG PET includes PET/computed tomography (CT) and PET/magnetic resonance (MRI).

CMS is revising the "NCD Manual", Section 220.6, to reflect that CMS has ended the coverage with evidence development (CED) requirement for (2-[F18] fluoro-2-deoxy-D-glucose) FDG PET, PET/CT, and PET/MRI for all oncologic indications contained in Section 220.6.17 of the "NCD Manual". This removes the current requirement for prospective data collection by the National Oncologic PET Registry (NOPR) for oncologic indications for FDG (Healthcare Common Procedure Coding System (HCPCS) Code A9552) only.

NOTE: For clarification purposes, as an example, each different cancer diagnosis is allowed one (1) initial treatment strategy (-PI modifier) FDG PET Scan and three (3) subsequent treatment strategy (-PS modifier) FDG PET Scans without the -KX modifier. The fourth FDG PET Scan and beyond for subsequent treatment strategy for the same cancer diagnosis will always require the -KX modifier. If a different cancer diagnosis is reported, whether reported with a -PI modifier or a -PS modifier, that cancer diagnosis will begin a new count for subsequent treatment strategy for that beneficiary. A beneficiary's file may or may not contain a claim for initial treatment strategy with a -PI modifier. The existence or non-existence of an initial treatment strategy claim has no bearing on the frequency count of the subsequent treatment strategy (-PS) claims.

Providers may refer to **http://cms.gov/medicare/coverage/determinationprocess/downloads/petforsolidtumorsoncologicdxcodesattachment_NCD220_6_17.pdf** for a list of appropriate diagnosis codes.

Effective for claims with dates of service on or after June 11, 2013, Medicare will accept and pay for FDG PET oncologic claims billed to inform initial treatment strategy or subsequent treatment strategy for suspected or biopsy proven solid tumors for all oncologic conditions without requiring the following:

- Q0 modifier: Investigational clinical service provided in a clinical research study that is in an approved clinical research study (institutional claims only);
- Q1 modifier: routine clinical service provided in a clinical research study that is in an approved clinical research study (institutional claims only);
- V70.7: Examination of participant in clinical research; or
- Condition code 30 (institutional claims only).

Effective for dates of service on or after June 11, 2013, MACs will use the following messages when denying claims in excess of **three** for PET FDG scans for subsequent treatment strategy when the –KX modifier is not included, identified by CPT codes 78608, 78811, 78812, 78813, 78814, 78815, or 78816, modifier –PS, HCPCS A9552, and the same cancer diagnosis code:

- Claim Adjustment Reason Code (CARC) 96: "Non-Covered Charge(s). Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present."
- Remittance Advice Remarks Code (RARC) N435: "Exceeds number/frequency approved/allowed within time period without support documentation."
- Group Code PR assigning financial liability to the beneficiary, if a claim is received with a GA modifier indicating a signed ABN is on file.
- Group Code CO assigning financial liability to the provider, if a claim is received with a GZ modifier indicating no signed ABN is on file.

MACs will not search their files to adjust claims processed prior to implementation of CR8739. However, if you have such claims and bring them to the attention of your MAC, the MAC will adjust such claims if appropriate.

Synopsis of Coverage of FDG PET for Oncologic Conditions

Effective for claims with dates of service on and after June 11, 2013, the chart below summarizes national FDG PET coverage for oncologic conditions:

FDG PET for Cancers **Tumor Type**	**Initial Treatment Strategy** (formerly "diagnosis" & "staging"	**Subsequent Treatment Strategy** (formerly "restaging" & "monitoring response to treatment"
Colorectal	Cover	Cover
Esophagus	Cover	Cover
Head and Neck (not thyroid, CNS)	Cover	Cover
Lymphoma	Cover	Cover
Non-small cell lung	Cover	Cover
Ovary	Cover	Cover
Brain	Cover	Cover
Cervix	Cover with exceptions *	Cover
Small cell lung	Cover	Cover
Soft tissue sarcoma	Cover	Cover
Pancreas	Cover	Cover
Testes	Cover	Cover
Prostate	**Non-cover**	Cover
Thyroid	Cover	Cover
Breast (male and female)	Cover with exceptions *	Cover
Melanoma	Cover with exceptions *	Cover
All other solid tumors	Cover	Cover
Myeloma	Cover	Cover
All other cancers not listed	Cover	Cover

*Cervix: Nationally non-covered for the initial diagnosis of cervical cancer related to initial anti-tumor treatment strategy. All other indications for initial anti-tumor treatment strategy for cervical cancer are nationally covered.

*Breast: Nationally non-covered for initial diagnosis and/or staging of axillary lymph nodes. Nationally covered for initial staging of metastatic disease. All other indications for initial anti-tumor treatment strategy for breast cancer are nationally covered.

*Melanoma: Nationally non-covered for initial staging of regional lymph nodes. All other indications for initial anti-tumor treatment strategy for melanoma are nationally covered.

Additional Information

The official instruction, CR 8739, issued to your MAC regarding this change, is available at in two transmittals at **http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3162CP.pdf** and **http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R168NCD.pdf** on the CMS website.