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MLN Matters® Number: MM6861 **Revised**

Related Change Request (CR) #: 6861

Related CR Release Date: March 26, 2010

Effective Date: February 26, 2010

Related CR Transmittal #: R1937CP and R119NCD

Implementation Date: July 6, 2010

Positron Emission Tomography (PET) (NaF-18) to Identify Bone Metastasis of Cancer

Note: This article was updated on November 30, 2012, to reflect current Web addresses. This article was previously revised on February 23, 2011, to add a reference to MLN Matters® article MM7125, which is available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM6861.pdf>, which amends the instructions in MM6861. It explains the specific claims handling instructions for claims submitted for each of the professional, technical or global components. All other information is unchanged.

Provider Types Affected

This article is for physicians and other providers who bill Medicare Carriers, fiscal intermediaries (FIs), or Medicare Administrative Contractors (A/B MACs) when providing NaF-18 PET Scans to identify bone metastasis of cancer for Medicare beneficiaries.

Provider Action Needed

This article is based on Change Request (CR) 6861 and states that effective for claims with dates of service on and after February 26, 2010, be aware that NaF-18 PET oncologic claims to inform initial treatment strategy (PI) or subsequent treatment strategy (PS) for suspected or biopsy proven bone metastasis **are covered, BUT ONLY IN THE CONTEXT OF A CLINICAL STUDY**. All other claims for NaF-18 PET oncology claims are non-covered.

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Background

On June 4, 2009, the Centers for Medicare & Medicaid Services (CMS) opened a reconsideration of section 220.6 of the National Coverage Determinations (NCD) Manual to review evidence on the use of NaF-18 (sodium fluoride-18) imaging (NaF-18 PET) to identify bone metastasis of cancer. CMS proposes that the evidence is not sufficient to determine that the results of NaF-18 PET imaging to identify bone metastases improve health outcomes of beneficiaries with cancer. Therefore this use is not reasonable and necessary under Section 1862(a)(1)(A) of the Social Security Act (the Act).

However, CMS proposes that the available evidence is sufficient to determine that NaF-18 PET imaging, to identify symptomatic or strongly suspected bone metastasis of cancer to inform the initial antitumor treatment strategy or to guide subsequent antitumor treatment strategy after the completion of initial treatment, is reasonable and necessary under Section 1862(a)(1)(E) through Coverage with Evidence Development (CED) when the beneficiary's treating physician determines that the NaF-18 PET study is needed, and when the beneficiary is enrolled in, and the NaF-18 PET provider is participating in, specific types of prospective clinical studies as outlined in section 220.6 of the NCD Manual.

Key Points of CR 6861

NaF-18 PET oncologic claims:

- With dates of service on or after February 26, 2010, Medicare Contractors will accept and pay the claims as specified in the revised section 220.6.19 of the NCD Manual, to inform initial treatment strategy or subsequent treatment strategy for suspected or biopsy proven bone metastasis **ONLY IN THE CONTEXT OF A CLINICAL STUDY**. **NOTE:** NaF-18 PET also applies to NaF-18 PET/CT.
- With dates of service on or after February 26, 2010, contractors will **return as unprocessable (professional) or return to provider (institutional)** the claims to inform the initial treatment strategy or subsequent treatment strategy for bone metastasis that do not include **ALL** of the following are present on the claim:
 - -PI or -PS modifier; **AND**
 - PET or PET/CT CPT code (78608, 78811, 78812, 78813, 78814, 78815, 78816); **AND**
 - ICD-9 cancer diagnosis code; **AND**
 - HCPCS A9580 (sodium fluoride F-18, diagnostic, per study dose, up

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to 30 millicuries); **AND**

- -Q0 modifier - Investigational clinical service provided in a clinical research study that is in an approved clinical research study.

NOTE: For institutional claims, continue to include diagnosis code V70.7 and condition code 30 to denote a clinical study.

- Effective for claims with dates of service on or after February 26, 2010, when returning NaF-18 PET claims to providers, they will use the following messages depending on the reason for return:
 - Claims returned for not having the Q0 and either the PI or PS modifier will reflect Claim Adjustment Reason Code (CARC) 4 (The procedure 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.), and RARC M16 (Alert: See our Web site, mailings, or bulletins for more details concerning this policy/procedure/decision.);
 - Such claims submitted without HCPCS A9580 will be returned with RARC M20 (Missing/incomplete/invalid HCPCS); and
 - Such claims submitted without an ICD-9 cancer diagnosis code will contain CARC 167 (This (these) diagnosis(es) is (are) not covered).
- Although this coverage decision is effective February 26, 2010, it will not be fully implemented until a clinical study is ready to enroll providers and patients. Medicare will notify providers and beneficiaries where these services can be accessed, as they become available, via the CMS coverage page at <http://www.cms.gov/Center/Special-Topic/Medicare-Coverage-Center.html> on the CMS website.

Additional Information

If you have questions, please contact your Medicare MAC, FI or carrier at their toll-free number which may be found at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html> on the CMS website.

The official instruction, CR6861, was issued to your Medicare MAC, FI or carrier regarding this change via two transmittals. The first modifies the Medicare NCD Manual and is at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R119NCD.pdf> on the CMS website. The second revises the Medicare Claims Processing Manual and it may

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be viewed at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1937CP.pdf> on the CMS website. Attached to the NCD Transmittal is the revised Section 220.6.19 of the NCD Manual.

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