MLN Matters®
Information for Medicare Fee-for-Service Health Care Professionals

News Flash – Flu Season is upon us! CMS encourages providers to begin taking advantage of each office visit to encourage your patients with Medicare to get a seasonal flu shot; it's their best defense against combating seasonal flu this season. (*Medicare beneficiaries may receive the seasonal influenza vaccine without incurring any out-of-pocket costs. No deductible or copayment/coinsurance applies.*) For more information about Medicare's coverage of the seasonal influenza vaccine and its administration as well as related educational resources for health care professionals, please go to *http://www.cms.hhs.gov/MLNProducts/35_PreventiveServices.asp* on the CMS website.

MLN Matters® Number: MM6632 Revised

Related Change Request (CR) #: 6632

Related CR Release Date: October 16, 2009

Effective Date: April 3, 2009

Related CR Transmittal #: R1833CP and R108NCD

Implementation Date: October 30, 2009

FDG PET for Solid Tumors and Myeloma

Note: This article was revised on October 22, 2009, to clarify the language in the "What You Need to Know" and "Background" sections. All other information remains 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 F-18 flouro-D-glucose (FDG) Positron Emission Tomography (PET) Scans to Medicare beneficiaries. Note that the term FDG PET includes FDG PET/CT (Computed Tomography).

What You Need to Know

CR 6632, from which this article is taken, announces that the Centers for Medicare & Medicaid Services (CMS) is revising the *Medicare National Coverage Determinations Manual,* Section 220.6: Positron Emission Tomography (PET) Scans. Specifically, in CR 6632, CMS announces (effective April 3, 2009) a National Coverage Determination (NCD) that adopts a two-part framework which differentiates the use of F-18 flouro-D-glucose (FDG) PET imaging in the initial antitumor treatment strategy, from its other uses related to guiding subsequent antitumor treatment strategies after the

completion of initial treatment. This framework replaces the previous, **four-part** framework that contained the diagnosis, staging, restaging, and monitoring response to treatment.

Background

The NCD that CR 6632 announces requires the replacement of the four-part framework (mentioned in the previous paragraph) with a two-part one that differentiates FDG PET imaging used for initial antitumor treatment strategy from subsequent antitumor treatment strategies after the completion of initial treatment. In so doing, it provides that (effective for services provided on or after April 3, 2009) the terms "diagnosis" and "staging" are to be replaced with "Initial Treatment Strategy," and the terms "restaging" and "monitoring" are to be replaced with "Subsequent Treatment Strategy."

NCD Requirements

Initial Antitumor Treatment Strategy

CMS will cover one FDG PET study for beneficiaries who have solid tumors that are biopsy proven or strongly suspected based on other diagnostic testing when the beneficiary's 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 the initial treatment strategy:

- Whether or not the beneficiary is an appropriate candidate for an invasive diagnostic or therapeutic procedure; or
- The optimal anatomic location for an invasive procedure; or
- The anatomic extent of tumor when the recommended antitumor treatment reasonably depends on the extent of the tumor.

There are some exceptions to this initial treatment strategy:

- CMS will nationally non-cover the use of FDG PET imaging to determine initial treatment strategy in patients with adenocarcinoma of the prostate.
- CMS will continue to cover FDG PET imaging for the initial treatment strategy for male and female breast cancer when used in staging distant metastasis. FDG PET imaging for diagnosis and initial staging of axillary nodes will remain non-covered.
- CMS will continue non-coverage of FDG PET for the evaluation of regional lymph nodes in melanoma. Other uses to determine initial treatment strategy remain covered.
- CMS will continue to cover FDG PET imaging as an adjunct test for the detection of pre-treatment metastasis (i.e., staging) in newly diagnosed cervical cancers following conventional imaging that is negative for extra-pelvic metastasis. All other uses of FDG PET for the initial treatment strategy for beneficiaries diagnosed with cervical cancer will only continue to be covered through Coverage with Evidence Development (CED).

Specifically, CMS will cover one initial FDG PET study for patients with newly diagnosed cervical cancer (when not used as an adjunct test to detect pre-treatment metastases following conventional imaging that is negative for extra-pelvic metastasis) only when the beneficiary's treating physician determines that the FDG PET study is needed to inform the initial antitumor treatment strategy, and the beneficiary is enrolled in, and the FDG PET provider is participating in, an FDG PET clinical study that is designed to collect additional information at the time of the scan to assist in patient management. Clinical studies for which CMS will provide coverage must answer one or more of the following three questions:

Prospectively, in Medicare beneficiaries with newly diagnosed cervical cancer who have not been found following conventional imaging to be negative for extra-pelvic metastases and whose treating physician determines that the FDG PET study is needed to inform the initial antitumor treatment strategy, does the addition of FDG PET imaging lead to:

- A change in the likelihood of appropriate referrals for palliative care;
- Improved quality of life; or,
- Improved survival?

The study must adhere to the standards of scientific integrity and relevance to the Medicare population as described in the following section on Subsequent Antitumor Strategy (items a through m, below).

Subsequent Antitumor Treatment Strategy

For tumor types other than breast, colorectal, esophagus, head and neck (non-CNS/thyroid), non-small cell lung, and thyroid cancers, lymphoma, and melanoma, CMS has determined that FDG PET imaging for subsequent antitumor treatment strategy may be covered as research through CED.

However, CMS will cover a subsequent FDG PET study for tumor types other than breast, colorectal, esophagus, head and neck (non-CNS/thyroid), non-small cell lung, and thyroid cancers, lymphoma, and melanoma, when the beneficiary's treating physician determines that the FDG PET study is needed to inform the subsequent antitumor treatment strategy and the beneficiary is enrolled in, and the FDG PET provider is participating in, the following types of prospective clinical study:

- A FDG PET clinical study that is designed to collect additional information at the time of the scan to assist in patient management. Qualifying clinical studies must ensure that specific hypotheses are addressed; appropriate data elements are collected; hospitals and providers are qualified to provide the PET scan and interpret the results; participating hospitals and providers accurately report data on all enrolled patients not included in other qualifying trials through adequate auditing mechanisms; and all patient confidentiality, privacy, and other Federal laws must be followed.

The clinical studies for which CMS will provide coverage must answer one or more of the following three questions:

Prospectively, in Medicare beneficiaries whose treating physician determines that the FDG PET study is needed to inform the subsequent antitumor treatment strategy, does the addition of FDG PET imaging lead to:

- A change in the likelihood of appropriate referrals for palliative care;
- Improved quality of life; or
- Improved survival?

The study must adhere to the following standards of scientific integrity and relevance to the Medicare population

a. The principal purpose of the research study is to test whether a particular intervention improves the participant's health outcomes.

b. The research study is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.

c. The research study does not unjustifiably duplicate existing studies.

d. The research study design is appropriate to answer the research question being asked in the study.

e. The research study is sponsored by an organization or individual capable of executing the proposed study successfully.

f. The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found in the Code of Federal Regulations (CFR) at 45 CFR 46. If a study is regulated by the Food and Drug Administration (FDA), it also must be in compliance with 21 CFR Parts 50 and 56.

g. All aspects of the research study are conducted according to the appropriate standards of scientific integrity.

h. The research study has a written protocol that clearly addresses, or incorporates by reference, the Medicare standards.

i. The clinical research study is not designed to exclusively test toxicity or disease pathophysiology in health individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard only if the disease or condition being studied is life-threatening as defined in 21 CFR 312.81(a) and the patient has no other viable treatment options.

j. The clinical research study is registered on the *http://www.clinicaltrials.gov* website by the principal sponsor/investigator prior to the enrollment of the first study subject.

k. The research study protocol specifies the method and timing of public release of all pre-specified outcomes to be measured including release of outcomes if such are negative or the study is terminated early. The results must be made public within 24 months of the end of data collection. If a report is planned to be published in a peer-reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors. However, a full report of the outcomes must be made no later than 3 years after the end of data collection.

l. The research study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria enrollment of these populations, and a plan for the retention and reporting of said populations on the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.

m. The research study protocol explicitly discusses how the results are or are not expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability, or Medicaid eligibility.

Consistent with Section 1142 of the Social Security Act, the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions.

As exceptions to the subsequent treatment strategy section above:

- CMS has determined that FDG PET for subsequent treatment strategy in Medicare beneficiaries with ovarian cancer is nationally covered.
- CMS has determined that FDG PET for subsequent treatment strategy in Medicare beneficiaries with cervical cancer is nationally covered.

Myeloma

CMS has determined that FDG PET for initial treatment strategy and subsequent treatment strategy in Medicare beneficiaries with myeloma is nationally covered.

Further Exceptions

CMS will continue to cover FDG PET for subsequent treatment strategy for specific indications in the following nine tumor types:

- Breast
- Cervix
- Colorectal
- Esophagus
- Head and Neck (non-CNS/thyroid)

- Lymphoma
- Melanoma
- Non-small cell lung
- Thyroid

The CMS has transitioned the prior framework—diagnosis, staging, restaging, and monitoring response to treatment—into the initial treatment strategy and subsequent treatment strategy framework while maintaining current coverage.

The chart below summarizes section 220.6.1:

Table 1
FDG PET Coverage for Solid Tumors and Myeloma

Tumor Type	Initial Treatment Strategy (formerly "diagnosis" & "staging")	Subsequent Treatment Strategy (formerly "restaging" & "monitoring response to treatment")
Colorectal	Cover	Cover
Esophagus	Cover	Cover
Head & Neck (not Thyroid, CNS)	Cover	Cover
Lymphoma	Cover	Cover
Non-Small Cell Lung	Cover	Cover
Ovary	Cover	Cover
Brain	Cover	CED
Cervix	See note (1) below or CED	Cover
Small Cell Lung	Cover	CED
Soft Tissue Sarcoma	Cover	CED
Pancreas	Cover	CED
Testes	Cover	CED
Breast (female and male)	See note (2)	Cover
Melanoma	See note (3)	Cover
Prostate	Non-Cover	CED
Thyroid	Cover	See note (4) or CED
All Other Solid Tumors	Cover	CED
Myeloma	Cover	Cover
All other cancers not listed herein	CED	CED

Notes:
(1) Cervix: Covered for the detection of pre-treatment metastases (i.e., staging) in newly diagnosed cervical cancer subsequent to conventional imaging that is negative for extra-pelvic metastasis. All other uses are CED.
(2) Breast: Non-covered for initial diagnosis and/or staging of axillary lymph nodes. Covered for initial staging of metastatic disease.
(3) Melanoma: Non-covered for initial staging of regional lymph nodes. All other uses for initial staging are covered.
(4) Thyroid: Covered for subsequent treatment strategy of recurrent or residual thyroid cancer of follicular cell origin previously treated by thyroidectomy and radioiodine ablation and have a serum thyroglobulin >10ng/ml and have a negative I-131 whole body scan. All other uses for subsequent treatment strategy are CED.

Coding and Billing Requirements

CR 6632 also announces new modifiers for PET imaging, effective for services provided on or after April 3, 2009.

PI - Positron Emission Tomography (PET) or PET/Computed Tomography (CT) to inform the initial treatment strategy of tumors that are biopsy proven or strongly suspected of being cancerous based on other diagnostic testing. Short descriptor: PET tumor init tx strat

PS - Positron Emission Tomography (PET) or PET/Computed Tomography (CT) to inform the subsequent treatment strategy of cancerous tumors when the beneficiary's treating physician determines that the PET study is needed to inform subsequent antitumor strategy. Short descriptor: PET tumor subsq tx strategy

Note: *The two new FDG PET oncologic modifiers are included in the July quarterly update of the Integrated Outpatient Code Editor (IOCE) with an effective date of April 1, 2009. As of October 30, 2009, all FDG PET oncologic-related claims for dates of service on or after April 3, 2009, MUST include one of these 2 new modifiers in order for the claim to be processed correctly.*

Medicare claims processing requirements in CR 6632 are as follows:

- For claims with dates of service on or after April 3, 2009, Medicare will accept and pay for FDG PET claims as specified in the CR 6632 NCD to inform initial treatment strategy or subsequent treatment strategy for suspected or biopsy proven solid tumors.

Claims that your carrier, FI, or A/B MAC receive after October 30, 2009 (for dates of service on or after April 3, 2009), will return as unprocessable (professional claims) or as return to provider (institutional claims) if they do not include the -PI modifier with one of the following PET or PET/CT CPT codes when billing to inform the initial treatment strategy for solid tumors: 78608, 78811, 78812, 78813, 78814, 78815, or 78816.

- Your carrier or A/B MAC will return as unprocessable those professional claims for the **subsequent treatment strategy** without the -PS modifier AND a CPT code of 78608, 78811, 78812, 78813, 78814, 78815, or 78816, AND an ICD-9 cancer diagnosis code.

Should your carrier, FI, or A/B MAC return your claim that does not contain the –PI or – PS modifier, they will use 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 MA-130 - Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information.
- Remittance Advice Remark Code M16 - Alert: Please see our web site, mailings, or bulletins for more details concerning this policy/procedure/decision.

For claims with dates of service on or after April 3, 2009, Medicare will accept and pay for FDG PET oncologic claims billed for **initial or subsequent treatment strategy** when performed under CED only when billed **with the following:**

- PET/PET/CT CPT code in 6632.1.1 AND
- PI modifier OR
- PS modifier AND an ICD-9 cancer code diagnosis code AND
- Q0 modifier.

For claims with dates of service on or after April 3, 2009, Medicare will return as unprocessable, return to provider, FDG PET oncologic claims for **initial or subsequent treatment strategy** when performed under CED billed **without:**

- PET/PET/CT CPT code in 6632.1.1 AND
- PI modifier OR
- PS modifier AND an ICD-9 cancer code diagnosis code AND
- Q0 modifier.

You should also be aware that your carrier, FI, or A/B MAC will not search their files for FDG PET oncologic-related claims with dates of service April 3, 2009, through October 29, 2009, processed prior to October 30, 2009. However, they may adjust claims that you bring to their attention.

Additional Information

CR6632 was issued in two transmittals. One transmittal conveys the revisions to the *Medicare National Coverage Determinations Manual*, and the other conveys the changes to the *Medicare Claims Processing Manual.* These transmittals are at *http://www.cms.hhs.gov/Transmittals/downloads/R108NCD.pdf* and *http://www.cms.hhs.gov/Transmittals/downloads/R1833CP.pdf*, respectively.

If you have any questions, please contact your carrier, FI, or A/B MAC at their toll-free number, which may be found at *http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip* on the CMS website.