



F-18 flouro-D-glucose (FDG) Positron Emission Tomography (PET) for Solid Tumors and Myeloma – JA6632

Related CR Release Date: October 16, 2009 **Revised**

Date Job Aid Revised: November 17, 2010

Effective Date: April 3, 2009

Implementation Date: October 30, 2009

Note: JA6632 was revised to add a reference to MLN Matters® article MM7148 (<http://www.cms.gov/MLN MattersArticles/downloads/MM7148.pdf>), which states that Medicare contractors have discretion to cover (or not cover), within their jurisdictions, any additional FDG PET scans for therapeutic purposes related to the initial treatment strategy. All other information is unchanged

Key Words CR6632, MM6632, R1833CP, R120NCD, FDG, PET, Tumors, Myeloma

Contractors Affected

- Fiscal Intermediaries (FIs)
- Part A/B Medicare Administrative Contractors (A/B MACs)
- Medicare Carriers

Provider Types Affected

The physicians and other providers affected are those that bill Medicare Carriers, FIs, or A/B MACs when providing FDG PET scans to Medicare beneficiaries. Note that the term FDG PET includes FDG PET/Computed Tomography (CT).



CR6632 announces (effective April 3, 2009) a NCD that replaces the previous, four-part framework that contained the oncologic diagnosis, staging, restaging, and monitoring response to treatment **with a two-part framework**, which differentiates the use of F-18 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.

NCD Requirements – Two-Part Framework

Initial Antitumor Treatment Strategy

- The Centers for Medicare & Medicaid Services (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.

Exceptions to 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).

Provider Needs to Know...

Coverage of Initial FDG PET Study

- 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 three questions stated in the following section.

Questions Study Must Answer

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

1. Does the addition of FDG PET imaging lead to a change in the likelihood of appropriate referrals for palliative care;
2. Does the addition of FDG PET imaging lead to improved quality of life; or
3. Does the addition of FDG PET imaging lead to improved survival?

Study Standards

- 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.
- 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 types of prospective clinical study described in the Prospective Clinical Study section below, CMS will cover a subsequent FDG PET study for tumor types other than the following:
 - Breast,
 - Colorectal,
 - Esophagus,
 - Head and neck (non-CNS/thyroid),
 - Non-small cell lung, and thyroid cancers, and
 - Lymphoma, and melanoma.

Prospective Clinical Study

- An FDG PET clinical study must be designed to collect additional information at the time of the scan to assist in patient management. Qualifying clinical studies must ensure the following:
 - 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**:
 1. Does the addition of FDG PET imaging lead to a change in the likelihood of appropriate referrals for palliative care;
 2. Does the addition of FDG PET imaging lead to Improved quality of life; or
 3. Does the addition of FDG PET imaging lead to improved survival?

Study Standards

- 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, 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 healthy 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
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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.

- I. 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 affect 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 supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions.

Exceptions to the Subsequent Treatment Strategy

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

Myeloma

- 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.

Summary of Section 220.6.1

- 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 table on page 6 of MM6632 summarizes Section 220.6.1.

Coding and Billing Requirements

New Modifiers for PET Imaging

- The following new modifiers for PET imaging are effective for services provided on or after April 3, 2009.
 - **PI** - PET or PET/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** - PET or PET/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 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.

Claims Processing Requirements

- 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 CR6632 NCD to inform initial treatment strategy or subsequent treatment strategy for suspected or biopsy proven solid tumors.
 - Claims that the 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 Current Procedural Terminology (CPT) codes when billing to inform the initial treatment strategy for solid tumors: 78608, 78811, 78812, 78813, 78814, 78815, or 78816.
 - 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 the carrier, FI, or A/B MAC return 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
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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:
 - 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.

Background

CMS is revising the *Medicare National Coverage Determinations Manual*, Section 220.6 (Positron Emission Tomography (PET) Scans).

**Operational
Impact**

Carriers, FIs, or A/B MACs 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.

**Reference
Materials**

The related MLN Matters® article can be found at <http://www.cms.gov/MLN MattersArticles/downloads/MM6632.pdf> on the CMS website.

The official instruction (CR6632) issued regarding this change is available at <http://www.cms.gov/Transmittals/downloads/R120NCD.pdf> (*Medicare National Coverage Determinations Manual*), and <http://www.cms.gov/Transmittals/downloads/R1833CP.pdf> (*Medicare Claims Processing Manual*).