

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services



REVISED products from the Medicare Learning Network® (MLN)

- ["The Medicare Coverage of Imaging Services,"](#) Fact Sheet, ICN 907164, Downloadable only.

MLN Matters® Number: MM8381

Related Change Request (CR) #: CR 8381

Related CR Release Date: August 2, 2013

Effective Date: March 7, 2013

Related CR Transmittal #: R2750CP and R156NCD

Implementation Date: September 3, 2013

Positron Emission Tomography (PET)

Provider Types Affected

This MLN Matters® Article is intended for physicians, other providers, and suppliers who submit claims to Medicare contractors (carriers, Fiscal Intermediaries (FIs), and/or A/B Medicare Administrative Contractors (A/B MACs)) for services provided to Medicare beneficiaries.

Provider Action Needed

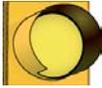


STOP – Impact to You

This article is based on Change Request (CR) 8381 which announces that on July 11, 2012, the Centers for Medicare & Medicaid Services (CMS) opened a reconsideration of the Medicare National Coverage Determinations (NCD) Manual (Publication (Pub) 100-03, Section 220.6 (Positron Emission Tomography (PET) Scans -Effective April 6, 2009)), to review coverage of PET for oncologic imaging. The new policy appears below.

Disclaimer

This article was prepared as a service to the public and is not intended to grant rights or impose obligations. This article may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations and other interpretive materials for a full and accurate statement of their contents. CPT only copyright 2012 American Medical Association.



CAUTION – What You Need to Know

CMS has determined that (unless there is a specific NCD to the contrary) local MACs may determine coverage or noncoverage for PET (within their respective jurisdictions) using new, proprietary radiopharmaceuticals for their Food and Drug Administration (FDA)-approved labeled indications ***for oncologic imaging only***. This is effective for dates of service on or after March 7, 2013, and includes those radiopharmaceuticals that may be approved by the FDA in the future. This decision does not change coverage for any uses of PET using the following four radiopharmaceuticals: FDG (2-deoxy-2-[F-18] fluoro-D-Glucose (fluorodeoxyglucose)); NaF-18 (fluorine-18 labeled sodium fluoride); ammonia N-13; or rubidium-82 (Rb-82)). In addition, this decision does not prevent CMS from determining national coverage for any uses of any radiopharmaceuticals in the future, and if such determinations are made, a future determination would supersede local MAC determination(s).



GO – What You Need to Do

See the Background and Additional Information Sections of this article for further details, and make sure that your billing staff is aware of these changes.

Background

PET is a minimally-invasive diagnostic imaging procedure used to evaluate normal tissue as well as in diseased tissues in conditions such as cancer, ischemic heart disease, and some neurologic disorders.

On July 11, 2012, CMS opened a reconsideration of the NCD Manual" Pub 100-03, Section 220.6 PET Scans, to review coverage of PET for oncologic conditions. See

http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part4.pdf on the CMS Website.

The Medicare NCD Section 220.6 currently identifies the following radiopharmaceuticals as the only nationally covered radiopharmaceuticals (also known as radioisotopes or tracers) for certain defined uses in PET:

1. FDG (2-deoxy-2-[F-18] fluoro-D-Glucose (fluorodeoxyglucose)),
2. NaF-18 (fluorine-18 labeled sodium fluoride),
3. Ammonia N-13, and,
4. Rubidium-82 (Rb-82)

All remaining uses of PET are nationally non-covered.

Effective March 7, 2013, CMS subsequently decided that (unless there is a specific NCD to the contrary) local MACs may determine coverage or non-coverage for PET (within their respective jurisdictions) using new, proprietary radiopharmaceuticals for their FDA-approved labeled

Disclaimer

This article was prepared as a service to the public and is not intended to grant rights or impose obligations. This article may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations and other interpretive materials for a full and accurate statement of their contents. CPT only copyright 2012 American Medical Association.

indications for oncologic imaging only, and includes those radiopharmaceuticals that may be approved by the FDA in the future.

This decision does not:

1. Change coverage for any uses of PET using the four radiopharmaceuticals listed above (i.e., FDG (2-deoxy-2-[F-18] fluoro-D-Glucose (fluorodeoxyglucose)), NaF-18 (fluorine-18 labeled sodium fluoride), Ammonia N-13, or Rubidium-82 (Rb-82)); or
2. Prevent CMS from determining national coverage for any uses of any radiopharmaceuticals in the future, and if such determinations are made, a future determination would supersede local contractor determination.

For claims with dates of service on or after March 7, 2013, Medicare contractors will not search their files, but contractors will adjust claims brought to their attention.

CR8381 revised the Medicare NCD Manual, Pub 100-03, Section 220.6 (Positron Emission Tomography (PET) Scans (Effective April 6, 2009)) as follows:

We emphasize each of the following points:

1. Changing the 'restrictive' language of prior PET decisions will not by itself suffice to expand Medicare coverage to new PET radiopharmaceuticals.
2. The scope of this change extends only to FDA-approved indications for oncologic uses of PET tracers.
3. This change does not include screening uses of PET scanning.

CR8381 also revises the "Medicare Claims Processing Manual," Chapter 13, Radiology Services and Other Diagnostic Procedures, and adds Section 60.19 (Local Local Coverage Determination for PET Using New, Proprietary Radiopharmaceuticals for their FDA-Approved Labeled Indications for Oncologic Imaging Only) as follows:

- Effective for dates of service on or after March 7, 2013, MACs may determine coverage within their respective jurisdictions for PET using radiopharmaceuticals for their FDA-approved labeled indications for oncologic imaging. When the local MAC determines that a claim is non-covered, the following messages apply:
 1. Claim Adjustment Reason Code (CARC) 167: This (these) diagnosis(es) is(are) not covered. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.
 2. If an Advance Beneficiary Notice (ABN) is provided with a GA modifier indicating there is a signed ABN on file, the liability falls to the beneficiary. However, if an ABN is provided with a GZ modifier indicating no ABN was provided, the liability falls to the provider.

Disclaimer

This article was prepared as a service to the public and is not intended to grant rights or impose obligations. This article may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations and other interpretive materials for a full and accurate statement of their contents. CPT only copyright 2012 American Medical Association.

Additional Information

The official instruction, CR8381, issued to your Medicare contractor regarding contained two transmittals. The first updates the "Medicare Claims Processing Manual" and is available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2750CP.pdf> on the CMS website. The second updates the NCD Manual and is at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R156NCD.pdf> on the CMS website.

If you have any questions, please contact your carriers, FIs, or A/B MACs 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.

Disclaimer

This article was prepared as a service to the public and is not intended to grant rights or impose obligations. This article may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations and other interpretive materials for a full and accurate statement of their contents. CPT only copyright 2012 American Medical Association.