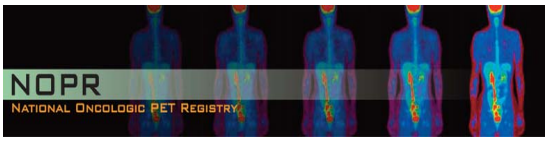

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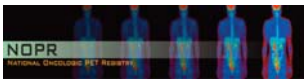

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Positron Emission Tomography for Solid Tumors Post CMS Final Decision (CAG-00181R4)

Denise A. Merlino, CNMT, CPC

Barry A. Siegel, M.D.

June 19, 2013

Jointly Sponsored by:
The National Oncologic PET Registry
Merlino Healthcare Consulting Corp.
The Society of Nuclear Medicine & Molecular Imaging

PET Imaging for Solid Tumors Post CMS Final Decision (CAG-00181R4)

This webinar is being recorded and will:

- Review the CMS Final Coverage Decision (CAG-00181R4)
- Discuss coding, billing, implementation and logistics for:
  - NOPR PET studies with dates of service (DOS) prior to the CMS Final Decision
  - FDG-PET studies with DOS immediately post the CMS Final Decision
  - NOPR (NaF-PET) Registry
- Address participants' questions

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Detailed Agenda

- Brief Review of PET Reimbursement History
- Review of the Final Decision (CAG-00181R4)
- NOPR Logistics – Transition Items
- Medicare Claims Processing Logistics and Updates
  - Transition Items
    - NOPR and MACs
  - Advanced Beneficiary Notice
  - Medicare Administrative Contractors
- NOPR (NaF-PET) Registry

3

Medicare Coverage Decisions

- National Coverage Decisions (NCDs)
  - National Coverage (positive decision)
    - Coverage with Evidence Development (CED)
  - National Non-coverage (negative decision)
    - Not medically necessary
- No National Coverage Decision
  - Left to contractor (MAC) discretion
    - Local Coverage Determinations (LCDs)

4

Changes in National Coverage for PET 2013 CMS Decisions

1. **Final Decision March 7, 2013**
   - **MITA Request – FDA-approved PET Tracers**
2. **Final June 11, 2013**
   - **NOPR Request – Expand coverage and end CED for FDG-PET**
3. **Draft decision due July 9, 2013**
   Final decision due October 2013
   - **Lilly Request- Amyloid PET Imaging**

5

PET NCD – Exclusionary Policy

The NCD states in part,

- Except as set forth below in cancer indications listed as "coverage with evidence development", **a particular use of PET scans is not covered unless this manual specifically provides that such use is covered.** Although this **section 220.6** lists some non-covered uses of PET scans, it does not constitute an exhaustive list of all non-covered uses.

Use G0235 for non-covered PET studies.

6

March 7, 2013 – Final Decision
CMS Expands Local Coverage Options

- Unless there is a specific national coverage determination, local Medicare Administrative Contractors (MACs) may determine coverage within their respective jurisdictions for PET using radiopharmaceuticals for their **FDA-approved labeled indications for oncologic imaging for products approved by the FDA after September 1, 2012.**
  - **C-11 Choline (FDA approved 9/12/12)**
  - Potentially could apply to:
    - FLT, F-DOPA, Ga-68 DOTATOC/DOTATATE

7

March 7, 2013 – Final Decision
CMS Expands Local Coverage Options

- The effect of this decision is to remove the national non-coverage for FDA-approved (post September 1,2012) labeled oncologic uses of radiopharmaceuticals that are not more specifically determined nationally.
- This decision does not change coverage for any use of PET with F-18 FDG, NaF-18 sodium fluoride, ammonia N-13, or rubidium-82 (Rb-82).
- 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 contractor determination.

8

History of Medicare Coverage Oncologic PET

1998	Evaluation of solitary pulmonary nodules and initial staging of NSCLC (non small cell lung cancer)
1999	Suspected recurrent colorectal cancer, lymphoma, melanoma (covered after public meeting, with considerable restrictions)
2001	Further expanded coverage for six prevalent cancers (PET must either resolve inconclusive results of standard test or replace standard test)

9

History of Medicare Coverage Oncologic PET

2002	Individual requests submitted and some approved for several other cancers
2004	Proposed mechanism for expanded coverage (CED)
2006	National Oncologic PET Registry
2009	Expanded Coverage and New Structure (April 3, 2009)
2009	Initial Staging Cervical Cancer (Correction-November 10, 2009)

10

History of Medicare Coverage Oncologic PET

2010 Single-scan limit for initial treatment strategy evaluation (08/04/2010)

RT planning, Evolving cancer / delay in treatment, CMS Final Decision to leave to contractor discretion

2011 Final Decision for ^{18}F-NaF Bone PET

2010 Limited coverage with CED (02/26/10 CMS notification)

2011 NOPR Opened the NaF Registry 02/07/2011

2013 **PET for Solid Tumors (CAG-00181R4)** (6/11/13)

11

Covered, CED & Non-Covered Oncologic PET Indications on or before June 11, 2013

Cancers and Indications Eligible for Entry in the NOPR

Cancers and indications that are reimbursable by Medicare are NOT eligible for entry in the NOPR. Cancers and indications that are specifically excluded for Medicare reimbursement are also not eligible for entry in the NOPR.

C = covered – Not eligible for entry in the NOPR
NC = non-covered nationally – Not eligible for entry in the NOPR
NOPR = covered only with entry in the NOPR

Indications	Initial Treatment Strategy (formerly Diagnosis and Initial Staging)	Subsequent Treatment Strategy (includes Treatment Monitoring, Restaging and Detection of Suspected Recurrence)
Lip, Oral Cavity, and Pharynx (140-149)	C	C
Esophagus (150)	C	C
Stomach (151)	C	NOPR
Small Intestine (152)	C	NOPR
Colon (153) and Rectum (154)	C	C
Anus (154)	C	NOPR[1]
Liver and intrahepatic bile ducts (155)	C	NOPR
Gallbladder & extrahepatic bile ducts (156)	C	NOPR
Pancreas (157)	C	NOPR
Retroperitoneum and peritoneum (158)	C	NOPR
Nasal cavity, ear, and sinuses (160)	C	C
Larynx (161)	C	C
Lung, non-small cell (162)	C	C
Lung, small cell (162)	C	NOPR
Pleura (163)	C	NOPR
Thymus, heart, mediastinum (164)	C	NOPR
Bone/cartilage (170)	C	NOPR
Connective/other soft tissue (171)	C	NOPR
Melanoma (172)	C / NC[2]	C
Non-melanoma skin (173)	C	NOPR
Female breast (174)	C / NC[2,3]	C
Male breast (175)	C / NC[2,3]	C
Kaposi's sarcoma (176)	C	NOPR
Uterus, unspecified (179)	C	NOPR
Cervix (180)	C / NC[4]	C
Uterus, body (182)	C	NOPR
Placenta (181)	C	NOPR
Ovary (183.0)	C	C
Uterine adnexa (183.2-183.9)	C	NOPR
Other and unspecified female genitalia (184)	C	NOPR
Prostate (185)	NC	NOPR
Testis (186)	C	NOPR
Penis and other male genitalia (187)	C	NOPR
Bladder (188)	C	NOPR
Kidney and other urinary tract (189)	C	NOPR
Eye (190)	C	NOPR
Primary Brain (191)	C	NOPR
Other and unspecified nervous system (192)	C	NOPR
Thyroid (193)	C	C / NOPR[5]
Other endocrine glands and related structures (194)	C	NOPR
Metastatic cancer / unknown primary origin (196-199)	C	NOPR
Lymphoma (200-202)	C	C
Myeloma (203)	C	C
Leukemia (204-208)	NOPR	NOPR
Neuroendocrine tumor (209)	C	NOPR
All other solid tumors	C	NOPR
All other cancers not listed herein	NOPR	NOPR

FOOTNOTES:

1. Some Medicare contractors include anal cancer in their local coverage of "colorectal cancer"; for PET facilities served by those carriers, PET for subsequent treatment evaluation of anal cancer would be a covered indication.
2. PET is non-covered for initial staging for axillary lymph nodes in patients with breast cancer and of regional lymph nodes in patients with melanoma, but is covered for detection of distant metastatic disease in high-risk patients with breast cancer or melanoma.
3. PET is non-covered for "diagnosis" of breast cancer to evaluate a suspicious breast mass. However, PET is covered for initial treatment strategy evaluation of a patient with axillary nodal metastasis of unknown primary origin or with a paraneoplastic syndrome potentially caused by an occult breast cancer.
4. PET is non-covered for "diagnosis" of cervical cancer. However, PET is covered for initial staging of cervical cancer.
5. To qualify as a covered indication for subsequent treatment strategy evaluation, thyroid cancer must be of follicular cell origin, must have been previously treated by thyroidectomy and radioiodine ablation, and the patient must have a serum thyroglobulin > 10ng/mL and a negative whole-body I-131 scan. Patients who do not qualify for this covered indication (e.g., because tumor is of other than follicular cell origin, the thyroglobulin is not elevated, or I-131 whole-body imaging was not performed or is positive) can be entered on NOPR.

IMPORTANT NOTES:

- The scientific evidence concerning the clinical utility of FDG-PET is generally less robust for cancers and indications that are currently covered by Medicare only in the NOPR than for cancers and indications that are currently covered without the requirement for clinical data submission to the NOPR. For this reason, Medicare has conditioned coverage of FDG-PET under the NOPR on the collection of clinical data. These data will be used to help determine the clinical utility of FDG-PET for conditionally covered cancers and indications. The billing physician remains responsible for documenting medical necessity, which is required for the coding and billing of both covered and NOPR-eligible PET studies. Eligibility for the NOPR does not constitute a clinical management recommendation for the use of PET for the conditionally covered cancers and indications, by either the Medicare program or NOPR investigators. Referring and interpreting physicians are thus advised to refer to the published literature to better understand the potential limitations of FDG-PET for NOPR-eligible uses.
- The ICD-9-CM® codes in the table above are provided for reference purposes only and for guidance in completion of the cancer type on the pre-PET form for cases included in the NOPR. Each provider should refer to the coverage policy of its respective Medicare contractor to determine which ICD-9-CM® codes are indicative of medical necessity. Note also that, although PET is covered to aid in the diagnosis of strongly suspected cancers, claims submitted with the appropriate non-cancer ICD-9-CM® code(s) may not be paid without medical necessity appeal.
- PET imaging of the brain with CPT code 78608 is covered for those cancers and indications designated by "C" in the table above and is covered only under NOPR for those cancers and indications indicated by "NOPR" in the table above.

12

FDG-PET (CAG-00181R4) Final Decision Summary

CMS is ending the requirement for Coverage with Evidence Development (CED) for oncologic indications contained in section 220.6.17 of the Medicare National Coverage Manual.

- "CMS is adopting a coverage framework that ends the prospective data collection requirements by NOPR under CED for all oncologic uses of FDG-PET imaging."

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FDG-PET (CAG-00181R4) Final Decision Summary

Effective Date for Ending Data Collection:

- Effective for claims with dates of service **(DOS) on or after June 11, 2013**

  Because of late afternoon announcement by CMS, NOPR will complete data collection for all scans done on June 11, 2013.

- CED for NaF-PET is not affected and continues.

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FDG-PET (CAG-00181R4) Final Decision Summary

Limitation on Coverage:

- Three (3) FDG-PET scans will be nationally covered for oncologic indications when used to guide ***subsequent*** physician management of anti-tumor strategy after initial anticancer therapy.
- Additional scans will be permitted at MAC or MA Plan Contractor discretion.

15

FDG-PET (CAG-00181R4) Final Decision Summary

Coverage of Prostate Cancer:

- Use of FDG-PET/CT "when used to guide ***subsequent*** anti-tumor treatment strategy for patients with cancer of the **prostate** **is** reasonable and necessary under § 1862(a)(1)(A)."
  - MACs are likely to monitor for appropriate patient use

16

FDG-PET (CAG-00181R4) Final Decision Summary

Use of PET for Surveillance:

- CMS acknowledged that "we are now aware that many patients may expect to undergo **more than one** FDG-PET scan **during later phases** of their medical treatment."
- By nationally covering three scans, the Final Decision provides "administrative flexibility to **enhance patient access** to needed medical care, and **reduce potential overutilization** of FDG-PET scans that would not be found to be reasonable and necessary."

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FDG-PET (CAG-00181R4) Final Decision Summary

Scanner Technology:

- CMS clarified that "we **include integrated FDG-PET/computerized tomography** (FDG-PET/CT) and **integrated FDG-PET/magnetic resonance imaging** (FDG-PET/MRI) in the **term *FDG-PET*** as used in this decision unless context indicates otherwise."
- "However, we [CMS] are not with this reconsideration determining any change in coverage either for CT or for MRI."

18

FDG-PET (CAG-00181R4) Final Decision Summary

Anti-Tumor Treatment Strategy (ATS):

- The completion of initial anticancer therapy (that is, the conclusion or termination of all anticancer therapies in the ***initially*** intended (combination) treatment regimen) marks, in time, the starting point of ***subsequent*** ATS planning (and the completion of initial ATS planning).
- 'Watchful waiting' represents a widespread clinical approach for patients with certain cancers, we (CMS) do not intend that it is a 'therapy' to be included in an initial treatment regimen.

This definition differs from that CMS used previously.
Language in Manual now will stand!

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CMS Decision Framework

Framework differentiates PET imaging into use for:

- **Anti-tumor treatment strategy (ATS)**
  - **<u>Initial treatment strategies (ITS)</u>** (formerly diagnosis and initial staging)
  - **<u>Subsequent treatment strategies (STS)</u>** (formerly treatment monitoring and restaging/ detection of suspected recurrence)

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Identifier for CMS PET Claims HCPCS Modifier

PET Oncology Modifiers		
HCPCS Modifier	**Descriptor**	**Effective October 30, 2009 on Claims With DOS April 3, 2009 for covered FDG-PET Oncologic-Related Claims NaF-18 Claims DOS February 7, 2011**
PI (eye)	Positron emission tomography (PET) or PET / computed tomography initial treatment strategy of tumors that are biopsy proven or suspected of being cancerous based on other diagnostic testing	***PET tumor initial treatment strategy*** "Diagnosis" or "initial staging"
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 anti-tumor strategy.	***PET tumor subsequent treatment strategy*** "Restaging" or "monitoring"

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Initial ATS Nationally Covered Effective June 11, 2013

- CMS continues to **nationally cover one FDG-PET** study for beneficiaries who have cancers 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 anti-tumor treatment strategy:
- To determine whether or not the beneficiary is an appropriate candidate for an invasive diagnostic or therapeutic procedure; or
- To determine the optimal anatomic location for an invasive procedure; or
- To determine the anatomic extent of tumor when the recommended anti-tumor treatment reasonably depends on the extent of the tumor.

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CMS *NON-Covered* Indications for FDG-PET

Initial Treatment Strategy

- Breast cancer diagnosis (to determine if mass on physical examination or mammography is benign or malignant)
- Detection of axillary nodal metastasis in newly diagnosed breast cancer
- Detection of regional nodal metastasis in newly diagnosed malignant melanoma
- Diagnosis of cervical cancer
- Diagnosis and initial staging of prostate cancer

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Medicare Non-Covered PET Procedures

HCPCS Level II	Description
G0219	PET imaging whole body; melanoma for non-covered indications *Initial staging regional lymph nodes*
G0235	PET imaging, any site, not otherwise specified
G0252	PET imaging, full and partial-ring PET scanners only, for initial diagnosis of breast cancer and/or surgical planning for breast cancer (e.g. initial staging of axillary lymph nodes)

For PET examinations that do not correspond to any Medicare-covered conditions, providers may choose to obtain a signed ABN from the patient.

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Subsequent ATS Nationally Covered Effective June 11, 2013

- Three (3) FDG-PET scans are nationally covered when used to guide subsequent management of anti-tumor treatment strategy after completion of initial anti-tumor therapy.
- Coverage of more than three FDG-PET scans to guide subsequent management of anti-tumor treatment strategy after completion of initial anti-tumor therapy **shall be determined by the local Medicare Administrative Contractors.**

The "count" for this provision starts on June 11, 2013.

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Achieving Favorable Outcomes of Coverage at MAC Discretion

Reporting Guidance for Oncologic ^{18}F-FDG PET/CT Imaging

Ryan D. Niederkohr[1], Bennett S. Greenspan[2], John O. Prior[3], Heiko Schöder[4], Marc A. Seltzer[5], Katherine A. Zukotynski[6,7], and Eric M. Rohren[8]

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Learning Objectives: On successful completion of this activity, participants should be able to discuss (1) the elements of a concise and complete oncologic ^{18}F-FDG PET/CT report; (2) the importance of obtaining and including in the report a focused history of the patient malignancy and treatments; and (3) the importance of interpreting both the ^{18}F-FDG PET and the CT findings of PET/CT and of integrating both the metabolic and the anatomic components in the report.

J Nucl Med 2013; 54:756-761

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National FDG PET for Solid Tumors and Myeloma effective June 11, 2013

Tumor Type	Initial Treatment Strategy (formerly "diagnosis" & "staging")	Subsequent Treatment Strategy (formerly "restaging" and "monitoring response to treatment")
Colorectal	Cover	Cover
Esophagus	Cover	Cover
Head and Neck (not thyroid or 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

Leukemia

Nationally Covered Effective June 11, 2013
Monitored by MAC

Prostate Cancer for Subsequent Treatment Strategy:

- CMS reversed its position in proposed decision.
- Will provide coverage for FDG-PET for subsequent treatment strategy in prostate cancer.

- "CMS anticipates that post-coverage analysis (PCA) will confirm the NOPR public comments noting that **physicians selectively employed FDG-PET for subsequent anticancer treatment planning in appropriate patients."**

28

National Coverage Change
Effective June 11, 2013

Thyroid Cancers for Subsequent Treatment Strategy:

- **Prior to June 11, 2013:** FDG-PET covered for thyroid cancer of follicular cell origin, previously treated by thyroidectomy and radioiodine ablation, with current serum thyroglobulin > 10 ng/mL and negative whole-body I-131 scan.
- Other patients could be entered into NOPR.
- **On or after June 11, 2013: this qualification is removed.**

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National Coverage Important Notes
Effective June 11, 2013

Check your Medicare or Third Party Payer local medical coverage policy for specific ICD 9 or ICD 10 codes:

- The billing physician remains responsible for documenting medical necessity, which is required for the coding and billing of all covered PET studies. Referring and interpreting physicians are thus advised to refer to the published literature to better understand the potential limitations of FDG-PET.
- **We strongly advise conversations between referring MD and radiologist to determine usefulness of FDG-PET.**

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FDG-PET NOPR Logistics
Claims DOS on/or prior to June 11, 2013

- These claims were entered into NOPR prior to the CMS Final Decision.
  - Facilities should continue through the entire process of data collection and entry within the required time frame.
  - Data entry for "open" NOPR-2009 cases will no longer be possible after **July 10, 2013** (end of the 30-day window for entering post-PET form after scan).

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FDG-PET NOPR Logistics
Claims DOS on or after June 11, 2013

- Any case registered on or before the close of business on June 11, 2013 **without scan completion on or before June 11, 2013** will be cancelled and the $50 case registration fee will be automatically refunded to the site's escrow account.
- **NOPR-2009 is closed for new FDG-PET patient registration for scans performed after June 11.**

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How do we get a refund of balance in our escrow account, now that NOPR-2009 has ended?

Those sites no longer wishing to participate in NOPR may submit a request to withdraw from the NOPR and have the balance in its escrow account refunded*; alternatively, balance can be used for NaF-PET.*

- If your site wants to end its participation, send request to the following:

  OPTOUT_NOPR@acr.org

  Please ensure that the request includes the following information:
  NOPR facility ID number
  NOPR facility name
  Name of person submitting request
  Phone number of the person submitting request
  Date of request
  Payee information (i.e., name and address)
  NOPR will acknowledge receipt of your request and send a refund check to the payee as indicated in the request with 7-10 days.

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General Claims Processing Questions: Ending Data Collection

- **Question:** Today, on June 19, 2013, I tried to enter a patient into NOPR-2009 but the web site does not seem to work. Is the system down? Can I enter the data later?
- **Answer:** NOPR-2009 is closed to new patients because of the June 11, 2013 NCD publication. You can locate the detailed decision at:
- **http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=263**

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General Claims Processing Questions: Ending Data Collection

- **Question:** Should I still append the Q0 (zero) modifier for my claims with DOS on or after **June 12, 2013** that used to be ***covered under CED***, but now are ***covered***?
- **Answer:** No, appending the Q0 modifier signifies that subject participated in a clinical trial, such as NOPR. Since NOPR-2009 closed EOB **June 11, 2013** for new patients, we do not believe appending the modifier is appropriate or consistent with correct coding principles.
  - ***(Answer continued on next slide.)***

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General Claims Processing Questions: Interim Claims Processing

- **Question:** Should I still append the Q0 (zero) modifier for my claims with DOS on or after **June 12, 2013** that used to be covered under CED, but now are covered?
- **Answer continued:** No; Pending CMS Transmittal & MAC / MA Plan Implementation, claims will very likely deny
  - Q0 modifier, or other NOPR claims processing items such as V70.7 and condition code – no longer appropriate
  - MACs given 30 to 60 day time period to get systems ready
  - Alternatively, you may want to consider **holding** those newly covered indication claims and wait for your MAC instructions
  - **To be clear providers should NOT hold claims that were covered prior to the June 11th. NCD.**

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Limitation on Coverage Questions:

Three (3) FDG-PET scans used to guide *subsequent* physician management of anti-tumor strategy after initial anticancer therapy.

- **Question:** If a patient had two PS studies prior to June 11, 2013, are those counted?
- **Answer: No,** the counting begins with the NCD publication on June 11, 2013.

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Limitation on Coverage Questions:

Three (3) FDG-PET scans used to guide *subsequent* physician management of anti-tumor strategy after initial anticancer therapy.

- **Question:** What if the patient or referring physician tells us that patient has not previously had ≥ 3 PET studies, but we later find out had 3? Will Medicare deny coverage? Can we appeal to the local Medicare contractor?
- **Answer:** The NCD allows for medically necessary scans beyond 3; specifically, if there is medical necessity for more than 3 PET scans, appeal to the local MAC providing documentation. Without documentation of medical necessity, claim likely will not be paid on appeal.

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Limitation on Coverage Questions:

Three (3) FDG-PET scans used to guide *subsequent* physician management of anti-tumor strategy after initial anticancer therapy.

- **Question:** Can you please clarify if the limitations that are referenced in the NCD are per cancer or per patient?
- **Answer:** The limits are per patient per cancer.

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Limitation on Coverage Questions:

Three (3) FDG-PET scans used to guide *subsequent* physician management of anti-tumor strategy after initial anticancer therapy.

- **Question:** Is there a time limit for a recurrence of a cancer specified in the NCD? Is the limit of three PS scans per year or per patient lifetime?
- **Answer:** The limits are per patient per cancer over the patient's lifetime (with the count beginning on June 11, 2013).
- A time limit is not referenced in the NCD.

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Medicare Advantage Plan "NOPR-2009" Cases: Whom do we bill?

- For claims DOS prior to June 12, 2013, bill the MAC
- For claims DOS **on or after June 12, 2013, continue to bill the MAC (pending further instructions from CMS)**
  - Providers should obtain preauthorization / precertification as usual, you may or may not get approval. If the study clearly meets the new NCD guidelines, perform the study.
    - Expect claim denials for interim until CMS transmittal is out with instructions and timing.
  - Alternatively hold the claim.

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Resources
SNMMI Payer Relations Kit

- How to Deal with Denials
- Understand Reasons for Denials
  - Unaware of local coverage determinations
  - Clerical errors
- Dealing with Denials
- Tips to Regular Contact with Payers
  - Attend CAC meeting
  - Attend local educational seminars
  - Send new guidelines & literature to Medical Director

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Resources
Example Re-Determination Request

WPS Medicare Part B
ATTN: Appeals Department
P. O. Box 14260
Madison, WI 53708-0123

Date: 11/12/09

TO THE MEDICARE CLAIMS **APPEALS REVIEW UNIT**:

A "RE-DETERMINATION IS REQUESTED" on the following claim. Please see all attached information, documentation and EOB for correct information.

__X__ Letter of Medical Necessity attached

__X__ Operative/Office notes attached. Please review Procedure Code for payment of service provided to Patient Name ID#9999999999A on Date of Service. We feel that the attached information shows that procedure was medically necessary.

_____ Coding/bundling issue.

_____ Other-

Please see attachments.

MIR Rep Name
Appeals Unit Representative
Telephone: (314) 747-9999
Fax: (314) 747-9999

- Place on provider letterhead
- Attach report alone, (if report contains details history)
- If report does not contain detailed history, additionally attach Letter of Medical Necessity including a detailed history, or progress notes (or other medical documentation) from phone calls or directly from the referring physician.

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Advance Beneficiary Notice (ABN)
Form CMS-R-131 (03/11) - Effective Jan 1, 2012

Form Number & Date
(CMS-R-131 3/11)

Form OMB No. 0938-0566

A. Notifier:
B. Patient Name: C. Identification Number:

Advance Beneficiary Notice of Noncoverage (ABN)

NOTE: If Medicare doesn't pay for **D.** _____ below, you may have to pay. Medicare does not pay for everything, even some care that you or your health care provider have good reason to think you need. We expect Medicare may not pay for the **D.** _____ below.

D.	E. Reason Medicare May Not Pay:	F. Estimated Cost

WHAT YOU NEED TO DO NOW:
- Read this notice, so you can make an informed decision about your care.
- Ask us any questions that you may have after you finish reading.
- Choose an option below about whether to receive the **D.** _____ listed above.

Note: If you choose Option 1 or 2, we may help you to use any other insurance that you might have, but Medicare cannot require us to do this.

G. OPTIONS: Check only one box. We cannot choose a box for you.

☐ **OPTION 1.** I want the **D.** _____ listed above. You may ask to be paid now, but I also want Medicare billed for an official decision on payment, which is sent to me on a Medicare Summary Notice (MSN). I understand that if Medicare doesn't pay, I am responsible for payment, but **I can appeal to Medicare** by following the directions on the MSN. If Medicare does pay, you will refund any payments I made to you, less co-pays or deductibles.

☐ **OPTION 2.** I want the **D.** _____ listed above, but do not bill Medicare. You may ask to be paid now as I am responsible for payment. **I cannot appeal if Medicare is not billed.**

☐ **OPTION 3.** I don't want the **D.** _____ listed above. I understand with this choice I am not responsible for payment, and **I cannot appeal to see if Medicare would pay.**

H. Additional Information:

This notice gives our opinion, not an official Medicare decision. If you have other questions on this notice or Medicare billing, call **1-800-MEDICARE** (1-800-633-4227/**TTY:** 1-877-486-2048). Signing below means that you have received and understand this notice. You also receive a copy.

I. Signature:	J. Date:

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0566. The time required to complete this information collection is estimated to average 7 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.

Form CMS-R-131 (03/11) Form Approved OMB No. 0938-0566

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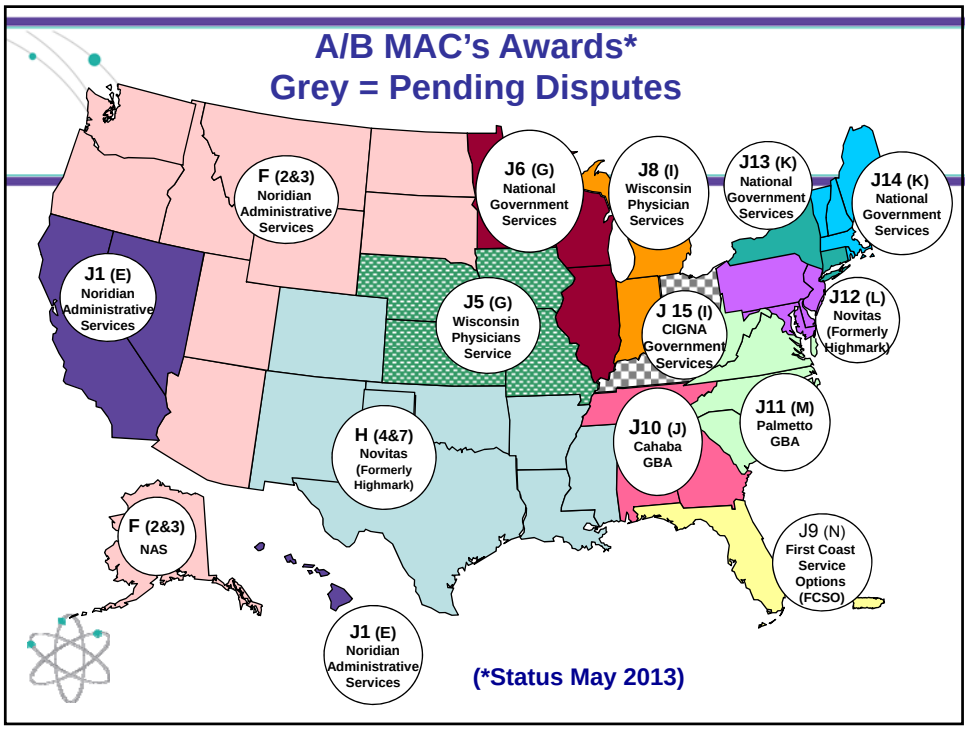
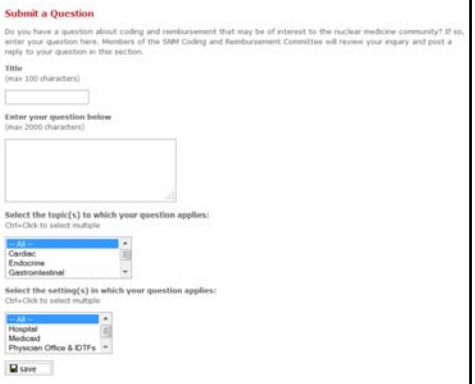


Medicare Administrative Contractors (MAC) A/B Consolidations Status May 2013

Jurisdiction #	States Included in Jurisdiction	Awarded / Imp. Date
1 (E)	American Samoa, California, Guam, Hawaii, Nevada, & Northern Mariana Islands	Palmetto GBA - Current MAC Noridian Awarded Sep 2012; Protest Denied Apr 2013. Implement Sep 2013
F (2 & 3)	Alaska, Arizona, Idaho, Montana, North Dakota, Oregon, South Dakota, Utah, Washington and Wyoming	Noridian (NAS) - Fully Implemented)
H (4 & 7)	Arkansas, Colorado, Louisiana, Mississippi, New Mexico, Oklahoma, Texas	Novitas (Formerly Highmark) Fully Implemented
5 (G)	Iowa, Kansas, Missouri, and Nebraska	WPS - New Contract Jul 2012
6 (G)	Illinois, Minnesota, and Wisconsin	NGS - A (IL, WI) & NAS-A (MN), WPS-B NGS - Part A/B Awarded Sep 2012 Protest Filed, GAO denied Implementation (in process) by Sep
8 (I)	Indiana and Michigan	WPS - Awarded Sep 2011 (NGS Dispute Denied by GAO) (Implementation Completed)
9 (N)	Florida, Puerto Rico, and U.S. Virgin Islands	First Coast Service Options, Inc (FCSO) - Fully Implemented Recompete in progress as of Feb 2013
10 (J)	Alabama, Georgia, and Tennessee	Cahaba GBA - Fully Implemented Recompete in progress as of Feb 2013
11 (M)	North Carolina, South Carolina, Virginia and West Virginia	Palmetto GBA - Fully Implemented
12 (L)	Delaware, District of Columbia, Maryland, New Jersey, and Pennsylvania For part B services A/B MAC J 12 includes counties of Arlington and Fairfax in Virginia with City of Alexandria.	Novitas (Formerly Highmark) New Contract Sep 2012 – Protest resolved. Implement by Jul 2103
K (13)	Connecticut and New York	NGS - Current J13 A/B MAC NGS - A/B Cutover (Jun 1, 2013)
K (14)	Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont	NHIC - Current J14 A/B MAC NGS - A/B Cutover (Oct 18/25, 2013)
15 (I)	Kentucky and Ohio	CIGNA Gov Svcs - Fully Implemented

Questions Post Webinar

- Contact your local MAC or payer for specific guidance.
- SNMMI Members
  - Practice management, coding corner, submit a question to the C&R SNMMI committee.
  - **HPRA@snmmi.org**



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NOPR
NATIONAL ONCOLOGIC PET REGISTRY

NOPR (NaF-PET)

- The June 11, 2013 NCD does not change the coverage policy for NaF-PET bone imaging, which is still covered by Medicare only under CED.
- NORP remains open for NaF-PET Registry data submissions.
- *NOPR will be asking all sites **to opt in or out** of NaF-PET registry and to provide updated site information if opting in.*

48 June 19, 2013 CANCERPETREGISTRY.ORG

Continuing Education Credits Live Session

This program is approved for **three type** of credits:

- **Post the Webinar Look for an E-mail and complete the evaluation, select the type of CEU**
- **SNMMI- Contact:** jschoolnik@snmmi.org
  - Nuclear Medicine Technologists – VOICE
  - Physicians, Nurses, etc – CME
- **Merlino Healthcare Consulting Corp.**
  - Billers and Coders – AAPC
    - **For Live Credits e-mail**: training@merlinohccc.com

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Continuing Education Credits Recorded Instructions

This program is approved for **three type** of credits:

- **SNMMI- Contact:** jschoolnik@snmmi.org
- **Recording Link:** http://interactive.snm.org/index.cfm?PageID=12734
  - Nuclear Medicine Technologists – VOICE
  - Physicians, Nurses, etc – CME
- **Merlino Healthcare Consulting Corp.**
  - Billers and Coders – AAPC
    - **For On Demand AAPC Credits** http://www.merlinohccc.com/presentations.html
- **National Oncologic PET Registry-**
  - www.CancerPETRegistry.org
  - Handouts and Recording ONLY no credits available.

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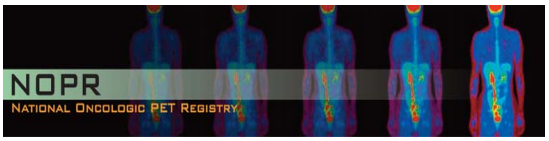

Merlino Healthcare Consulting Corp.

SNMMI SOCIETY OF NUCLEAR MEDICINE AND MOLECULAR IMAGING

CONTACT:

1850 Samuel Morse Drive, Reston, VA 20190
Submit Coding Questions to coding corner, log in and send question, or e-mail: **HPRA@SNMMI.org**
HPRA@SNMMI.org
Phone: (703) 326-1187

SNMMI SOCIETY OF NUCLEAR MEDICINE AND MOLECULAR IMAGING

Questions

CONTACT:

address: P.O. Box 5569, Magnolia, MA 01930
voice: 888-606-4222
fax: 888-606-4223
e-mail: denise@merlinohccc.com

Merlino Healthcare Consulting Corp.

PET Resources – CMS, SNMMI & NOPR Websites

- **CMS Coverage Database:**
  http://www.cms.gov/mcd/search.asp?from2=search.asp&
- **PET PROS:**
  http://interactive.snm.org/index.cfm?PageID=9273
- **NOPR:**
  www.cancerpetregistry.org

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PET PROS
PET Professional Resources and Outreach Source

http://interactive.snm.org/index.cfm?PageID=9273

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Important PET Transmittals

- For information on FDG-PET **for solid tumors and myeloma new framework**, see Transmittal R120NCD (CR 6632, May 6, 2010) at *http://www.cms.hhs.gov/transmittals/Downloads/R120NCD.pdf*
  - PI, PS and Exclusionary language
- For information on FDG-PET for **Initial Treatment Strategy (PI) in Solid Tumors and Myeloma,** see Transmittal 124 (CR 7148 September 24, 2010) at *http://www.cms.gov/transmittals/downloads/R124NCD.pdf and http://www.cms.gov/MLNMattersArticles/downloads/MM7148.pdf*
  - Allows local contractor discretion when more then one PET study is needed and identified as (PI) initial treatment strategy
- For information on **Billing Clarification for (NaF-18) PET (Sodium Fluoride - 18) PET for Identify Bone Metastasis of Cancer in Context of a Clinical Trial,** see Transmittal 2096 (CR 7125, November 19, 2010) at http://www.cms.gov/transmittals/downloads/R2096CP.pdf
  - PET Bone Imaging Billing Guidance

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Advance Beneficiary Notice of Noncoverage (ABN) Important URLs

Advanced Beneficiary Notices (BNI)
http://www.cms.gov/Medicare/Medicare-General-Information/BNI/index.html

Revised ABN CMS-R-131 Form and Instructions
http://www.cms.gov/Medicare/Medicare-General-Information/BNI/Downloads/ABNFormInstructions.zip

Revised ABN Manual Instructions - Transmittal 2480 (CR 7821) Jun 1, 2012
http://www.cms.gov/Medicare/Medicare-General-Information/BNI/Downloads/RevABNManualInstructions.pdf

Revised ABN CMS-R-131 Implementation Announcement
http://www.cms.gov/Medicare/Medicare-General-Information/BNI/Downloads/ABNAnnouncementFAQs.pdf

Advance Beneficiary Notice of Non-Coverage (ABN) MedLearn Booklet
http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/ABN_Booklet_ICN006266.pdf

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REVISED Advance Beneficiary Notices (ABNs) **Effective January 1, 2012**

- New Form CMS-R-131 (March 2011) continues to combine the ABN-G (General), ABN-L (Laboratory) and NEMB (Notice of Exclusion from Medicare Benefits used in voluntary situations) Forms
- **Physicians and other providers must use the new form for claims submitted as of January 1, 2012**
- *Original implementation dates: September 1st and November 1st were extended:*
  - *To allow more time for transition*
  - *To use up leftover copies of old forms*
- Form CMS-R-131 – release date, March 2011 printed in lower left corner
- ABNs with release date, March 2008 used for claims with date of service (DOS) on or after January 1, 2012 are invalid

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Advance Beneficiary Notice (ABN) Non-Coverage Modifiers*

GA - Waiver of Liability Statement Issued as Required by Payer Policy, Individual Case

Use this modifier to report when you issue a mandatory ABN for a service as required and it is on file. You do not need to submit a copy of the ABN, but you must have it available upon request.

GX - Notice of Liability Issued, Voluntary Under Payer Policy

Use this modifier to report when you issue a voluntary ABN for a service that Medicare never covers because it is statutorily excluded or is not a Medicare benefit.

GY - Item or Service Statutorily Excluded, Does Not Meet the Definition Medicare Benefit

Use this modifier to report that Medicare statutorily excludes the item or service or the item or service does not meet the definition of any Medicare benefit.

GZ - Item or Service Expected to Be Denied as Not Reasonable and Necessary

Use this modifier to report when you expect Medicare to deny payment of the item or service due to a lack of medical necessity and no ABN was issued.

*Note: **See Medicare Claims Processing Manual, Chapter 1, Section 60 for specific instructions on filing claims associated with ABNs)**

http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c01.pdf

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Positron Emission Tomography Imaging for Solid Tumors Post CMS Final Decision (CAG-00181R4)

Wednesday, June 19, 2013

Noon to 1 PM EDT

Speakers: Denise A. Merlino, CPC, CNMT and Barry A. Siegel, MD

Sponsored by: NOPR/SNMMI/Merlino HCCC

This course is designed for PET professionals including coders, billers, technologists and physicians involved with PET imaging for oncologic indications and are also responsible for administration and billing activities related to providing PET services (especially those done under the National Oncologic PET Registry). This session will focus on the most current Medicare national coverage policy. Attendees will understand how new policy changes, to become effective on or after June 11, 2013, will impact their coding, coverage and provider practices. Practical implementation strategies will be discussed to limit administrative billing issues, with special attention to transition to a new coverage policy. References and resources will be provided so the participants understand where the most current information can be located.

Upon completion of this session, attendees will be able to:

1. Discuss and implement the new Medicare National Coverage Policy for FDG-PET services.

2. Implement the revised and transitional claims processing procedures for FDG-PET studies performed before and after the change in national coverage policy.

3. Identify national and local reimbursement policy via web sites for authoritative coding and billing information pertinent to FDG-PET services.

LEARNER OUTCOMES/ Desired Results - Please list what learner can expect to do in his/her practice

- PET providers will be able to update front-end FDG-PET registration and scheduling consistent with the revised FDG-PET National coverage policy, inducing potential updates to Charge Description Masters necessary as a result of the new coverage policy.
- Update and explain claims processing options for the PET imaging facility/center regarding the FDG-PET changes and how they will effect payment for the services in both the short and long term.
- Easily locate current authoritative reimbursement web-based or hard copy references important for oncologic FDG-PET nuclear medicine services.

Continuing Medical Education:

The Society of Nuclear Medicine and Molecular Imaging (SNMMI) is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. SNMMI designates this live internet activity for a maximum of 1.0 AMA PRA Category 1 Credits™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Nuclear Medicine Technologists (VOICE):

The SNMMI, through its Verification of Involvement in Continuing Education (VOICE) program, has approved this meeting for a maximum of 1.0 continuing education hours (CEHs). VOICE-approved credit is recognized by most licensure states and by the NMTCB and ARRT as Category A credit. Participants will receive CE credit for those sessions at which they were present a minimum of 80%. This session is approved as VOICE+ (Category A+) credit, CA Scope (NI).

Financial Disclosures

Denise Merlino, MBA, FSNMTS, CNMT, CPC

- President, Merlino Healthcare Consulting Corp.
- Society of Nuclear Medicine, Coding Advisor
- Consultant/Advisor: American Society of Nuclear Cardiology; Bracco; IBA Molecular; Jazz

Barry Alan Siegel, MD

- Professor of Radiology and Medicine at Washington University School of Medicine,
- Director of the Division of Nuclear Medicine at Mallinckrodt Institute of Radiology,
- Physician, Alvin J. Siteman Cancer Center
- Consultant/Advisor: GE Healthcare
- Board Member/Officer/Trustee: Radiology Corporation of America (RCOA)
- Investment Interest: Radiology Corporation of America (RCOA)

Terms of Use Agreement

Additional Information:

This live internet activity requires connection to the following website, and may require additional software to be downloaded: https://www2.gotomeeting.com/join/916832410/106553826

Please contact the Education Department of the SNMMI with any questions relating to this program: 703-326-1184 or education@snmmi.org.