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Department of Health & Human Services (DHHS)
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CHANGE REQUEST 3304

I. SUMMARY OF CHANGES: This instruction manualizes transmittal AB-03-092, dated June 20, 2003 (Change Request 2687) - Expanded Coverage of Positron Emission Tomography (PET) Scans and Related Claims Processing Requirements-for Thyroid Cancer and Perfusion of the Heart Using Ammonia N-13. Additional material has been added which was inadvertently left out of the new Internet Only Manual.

MANUALIZATION - EFFECTIVE DATE: Not Applicable IMPLEMENTATION DATE: Not Applicable

Disclaimer for manual changes only: The revision date and transmittal number apply only to the red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will only receive the new/revised information, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (R = REVISED, N = NEW, D = DELETED)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	13/60/Table of Contents - PET Scans
R	13/60/Positron Emission Tomography (PET) Scans – General Information
N	13/60.1/Billing Instructions
N	13/60.2/Use of Gamma Cameras and Full Ring and Partial Ring PET Scanners
	for PET Scans
N	13/60.3/PET Scan Qualifying Conditions and HCPCS Code Chart
N	13/60.4/PET Scans for Imaging of the Perfusion of the Heart Using Rubidium
	82 (Rb82)
N	13/60.5/Expanded Coverage of PET Scans for Solitary Pulmonary Nodules
	(SPNs)
N	13/60.6/ Expanded Coverage of PET Scans Effective for Services on or after
	July 1, 1999
N	13/60.7/ Expanded Coverage of PET Scans Effective for Services on or after
	July 1, 2001
N	13/60.8/ Expanded Coverage of PET Scans for Breast Cancer Effective for
	Dates of Service on or After October 1, 2002
N	13/60.9/Coverage of PET Scans for Myocardial Viability
N	13/60/10 /Coverage of PET Scans for Thyroid Cancer
N	13/60/11/ Coverage of PET Scans for Perfusion of the Heart Using Ammonia
	N-13

III. FUNDING: *Medicare contractors only:

These instructions should be implemented within your current operating budget.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

Medicare Claims Processing Manual

Chapter 13 - Radiology Services and Other Diagnostic Procedures

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(Rev. 223, Issued: 07-02-04) (Effective/Implementation: Not Applicable)

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60 - Positron Emission Tomography (PET) Scans – General Information

(Rev. 223, Issued: 07-02-04) (Effective/Implementation: Not Applicable)

Positron emission tomography (PET) is a noninvasive imaging procedure that assesses perfusion and the level of metabolic activity in various organ systems of the human body. A positron camera (tomograph) is used to produce cross-sectional tomographic images which are obtained by detecting radioactivity from a radioactive tracer substance (radiopharmaceutical) that emits a radioactive tracer substance (radiopharmaceutical FDG) such as 2 –[F-18] flouro-D-glucose FDG, that is administered intravenously to the patient.

The Medicare National Coverage Determinations Manual, Chapter 1, §220.6, contains additional coverage instructions to indicate the conditions under which a PET scan is performed.

A – Definitions

For all uses of PET, excluding Rubidium 82 for perfusion of the heart, myocardial viability and refractory seizures, the following definitions apply:

- Diagnosis: PET is covered only in clinical situations in which the PET results may assist in avoiding an invasive diagnostic procedure, or in which the PET results may assist in determining the optimal anatomical location to perform an invasive diagnostic procedure. In general, for most solid tumors, a tissue diagnosis is made prior to the performance of PET scanning. PET scans following a tissue diagnosis are performed for the purpose of staging, not diagnosis. Therefore, the use of PET in the diagnosis of lymphoma, esophageal and colorectal cancers, as well as in melanoma, should be rare. PET is not covered for other diagnostic uses, and is not covered for screening (testing of patients without specific signs and symptoms of disease).
- Staging and/or Restaging: PET is covered in clinical situations in which (1) (a) the stage of the cancer remains in doubt after completion of a standard diagnostic workup, including conventional imaging (computed tomography, magnetic resonance imaging, or ultrasound) or, (b) the use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient and, (2) clinical management of the patient would differ depending on the stage of the cancer identified. PET will be covered for restaging after the completion of treatment for the purpose of detecting residual disease, for detecting suspected recurrence, or to determine the extent of a known recurrence.
- Monitoring: Use of PET to monitor tumor response during the planned course of therapy (i.e., when no change in therapy is being contemplated) is NOT covered. Restaging only occurs after a course of treatment is completed, and this is covered, subject to the conditions above.

B - Limitations

For staging and restaging: PET is covered in either/or both of the following circumstances:

- The stage of the cancer remains in doubt after completion of a standard diagnostic workup, including conventional imaging (computed tomography, magnetic resonance imaging, or ultrasound); and/or
- The clinical management of the patient would differ depending on the stage of the cancer identified. PET will be covered for restaging after the completion of treatment for the purpose of detecting residual disease, for detecting suspected recurrence, or to determine the extent of a known recurrence. Use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient.

PET is not covered for other diagnostic uses, and is not covered for screening (testing of patients without specific symptoms). Use of PET to monitor tumor response during the planned course of therapy (i.e. when no change in therapy is being contemplated) is not covered

60.1 - Billing Instructions

(Rev. 223, Issued: 07-02-04) (Effective/Implementation: Not Applicable)

A - Billing and Payment Instructions or Responsibilities for Carriers

Claims for PET scan services must be billed on orm-CMS 1500 or the electronic equivalent with the appropriate HCPCS and diagnosis codes to the local carrier. **Effective for claims received on or after July 1, 2001, PET modifiers were discontinued and are no longer a claims processing requirement for PET scan claims.** Therefore, July 1, 2001, and after the MSN messages regarding the use of PET modifiers can be discontinued. The type of service (TOS) for the new PET scan procedure codes is TOS 4, Diagnostic Radiology. Payment is based on the Medicare Physician Fee Schedule.

B - Billing and Payment Instructions or Responsibilities for FIs

Claims for PET scan procedures must be billed to the FI on Form CMS0-1450 (UB-92) or the electronic equivalent with the appropriate diagnosis *and* HCPCS "G" codes to indicate the conditions under which a PET scan was done. These codes represent the technical component costs associated with these procedures when furnished to hospital and SNF outpatients. They are paid under the Outpatient Prospective Payment System to hospitals and under the Medicare Physician Fee schedule when billed by a SNF. Institutional providers bill these codes under Revenue Code 0404 (PET Scan).

C - Frequency

In the absence of national frequency limitations, for all indications covered on and after July 1, 2001, contractors can, if necessary, develop frequency limitations on any or all covered PET scan services.

D - Post-Payment Review for PET Scans

As with any claim, but particularly in view of the limitations on this coverage, Medicare may decide to conduct post-payment reviews to determine that the use of PET scans is consistent with coverage instructions. Pet scanning facilities must keep patient record information on file for each Medicare patient for whom a PET scan claim is made. These medical records can be used in any post-payment reviews and must include the information necessary to substantiate the need for the PET scan. These records must include standard information (e.g., age, sex, and height) along with sufficient patient histories to allow determination that the steps required in the coverage instructions were followed. Such information must include, but is not limited to, the date, place and results of previous diagnostic tests (e.g., cytopathology and surgical pathology reports, CT), as well as the results and reports of the PET scan(s) performed at the center. If available, such records should include the prognosis derived from the PET scan, together with information regarding the physician or institution to which the patient proceeded following the scan for treatment or evaluation. The ordering physician is responsible for forwarding appropriate clinical data to the PET scan facility.

Effective for claims received on or after July 1, 2001, CMS will no longer requires *paper documentation to be submitted up front with PET scan claims*. Documentation requirements such as physician referral and medical necessity determination are to be maintained by the provider as part of the beneficiary's medical record. This information must be made available to the carrier or FI upon request of additional documentation to determine appropriate payment of an individual claim.

60.2 - Use of Gamma Cameras and Full Ring and Partial Ring PET Scanners for PET Scans

(Rev. 223, Issued: 07-02-04) (Effective/Implementation: Not Applicable)

See the Medicare National Coverage Determinations Manual, Section 220.6, concerning 2-[F-18] Fluoro-D-Glucose (FDG) PET scanners and details about coverage.

On July 1, 2001, HCPCS codes G0210 - G0230 were added to allow billing for all currently covered indications for FDG PET. Although the codes do not indicate the type of PET scanner, these codes were used until January 1, 2002, by providers to bill for services in a manner consistent with the coverage policy.

Effective January 1, 2002, HCPCS codes G0210 – G0230 were updated with new descriptors to properly reflect the type of PET scanner used. In addition, four new HCPCS codes became effective for dates of service on and after January 1, 2002, (G0231, G0232, G0233, G0234) for covered conditions that may be billed if a gamma camera is used for the PET scan. As of January 1, 2002, providers should bill using the revised HCPCS codes G0210 - G0234.

60.3 - PET Scan Qualifying Conditions and HCPCS Code Chart (Rev. 223, Issued: 07-02-04) (Effective/Implementation: Not Applicable)

Below is a summary of all covered PET Scan conditions, with effective dates.

Conditions	Coverage Effective Date	HCPCS Code
*Myocardial perfusion imaging (following previous PET G0030-G0047) single study, rest or stress (exercise and/or pharmacologic)	3/14/95	G0030
*Myocardial perfusion imaging (following previous PET G0030-G0047) multiple studies, rest or stress (exercise and/or pharmacologic)	3/14/95	G0031
*Myocardial perfusion imaging (following rest SPECT, 78464); single study, rest or stress (exercise and/or pharmacologic)	3/14/95	G0032
*Myocardial perfusion imaging (following rest SPECT 78464); multiple studies, rest or stress (exercise and/or pharmacologic)	3/14/95	G0033
*Myocardial perfusion (following stress SPECT 78465); single study, rest or stress (exercise and/or pharmacologic)	3/14/95	G0034
*Myocardial Perfusion Imaging (following stress SPECT 78465); multiple studies, rest or stress (exercise and/or pharmacologic)	3/14/95	G0035
*Myocardial Perfusion Imaging (following coronary angiography 93510-93529); single study, rest or stress (exercise and/or pharmacologic)	3/14/95	G0036

Conditions	Coverage Effective Date	HCPCS Code
*Myocardial Perfusion Imaging, (following coronary angiography), 93510-93529); multiple studies, rest or stress (exercise and/or pharmacologic)	3/14/95	G0037
*Myocardial Perfusion Imaging (following stress planar myocardial perfusion, 78460); single study,	3/14/95	G0038

rest or stress (exercise and/or pharmacologic)		
*Myocardial Perfusion Imaging (following stress planar myocardial perfusion, 78460); multiple studies, rest or stress (exercise and/or pharmacologic)	3/14/95	G0039
*Myocardial Perfusion Imaging (following stress echocardiogram 93350); single study, rest or stress (exercise and/or pharmacologic)	3/14/95	G0040
*Myocardial Perfusion Imaging (following stress echocardiogram, 93350); multiple studies, rest or stress (exercise and/or pharmacologic)	3/14/95	G0041
*Myocardial Perfusion Imaging (following stress nuclear ventriculogram 78481 or 78483); single study, rest or stress (exercise and/or pharmacologic)	3/14/95	G0042
*Myocardial Perfusion Imaging (following stress nuclear ventriculogram 78481 or 78483); multiple studies, rest or stress (exercise and/or pharmacologic)	3/14/95	G0043
*Myocardial Perfusion Imaging (following stress ECG, 93000); single study, rest or stress (exercise and/or pharmacologic)	3/14/95	G0044
*Myocardial perfusion (following stress ECG, 93000), multiple studies; rest or stress (exercise and/or pharmacologic)	3/14/95	G0045

Conditions	Coverage Effective Date	HCPCS Code
*Myocardial perfusion (following stress ECG, 93015), single study; rest or stress (exercise and/or pharmacologic)	3/14/95	G0046
*Myocardial perfusion (following stress ECG, 93015); multiple studies, rest or stress (exercise and/or pharmacologic)	3/14/95	G0047

PET imaging regional or whole body; single pulmonary nodule	1/1/98	G0125
Lung cancer, non-small cell - (PET imaging whole body) Diagnosis, Initial Staging, Restaging	7/1/01	G0210 G0211 G0212
Melanoma - (PET imaging whole body) Diagnosis, Initial Staging, Restaging	7/1/01	G0216 G0217 G0218
Melanoma for non-covered indications	7/1/01	G0219
Lymphoma - (PET imaging whole body) Diagnosis, Initial Staging, Restaging	7/1/01	G0220 G0221 G0222
Head and neck cancer; excluding thyroid and CNS cancers - (PET imaging whole body or regional) Diagnosis, Initial staging, Restaging	7/1/01	G0223 G0224 G0225

Conditions	Coverage Effective Date	HCPCS Code
Esophageal cancer - (PET imaging whole body) Diagnosis, Initial, Restaging	7/1/01	G0226 G0227 G0228
Metabolic brain imaging for pre-surgical evaluation of refractory seizures	7/1/01	G0229
Metabolic assessment for myocardial viability	7/1/01	G0230

following inconclusive SPECT study		
Recurrence of colorectal or colorectal metastatic cancer (PET whole body, gamma cameras only)	1/1/02	G0231
Staging and characterization of lymphoma - (PET whole body, gamma cameras only)	1/1/02	G0232
Recurrence of melanoma or melanoma metastatic cancer - (PET whole body, gamma cameras only)	1/1/02	G0233
Regional or whole body, for solitary pulmonary nodule following CT, or for initial staging of non-small cell lung cancer – (gamma cameras only)	1/1/02	G0234
Non-Covered Service Initial diagnosis of breast cancer and/or surgical planning for breast cancer (e.g., initial staging of axillary lymph nodes), not covered (Full and partial-ring PET scanners only)	10/1/02	G0252
Breast cancer, staging/restaging of local regional recurrence or distant metastases, i.e., staging/restaging after or prior to course of treatment (Full and partial-ring PET scanners only)	10/1/02	G0253

Conditions	Coverage Effective Date	HCPCS Code
Breast cancer, evaluation of responses to treatment, performed during course of treatment (Full and partial-ring PET scanners only)	10/1/02	G0254
Myocardial imaging, positron emission tomography (PET), metabolic evaluation)	10/1/02	78459
Restaging or previously treated thyroid cancer of follicular cell origin following negative I-131 whole body scan - (Full and partial-ring PET scanner only)	10/1/03	G0296

Tracer Rubidium**82 (Supply of Radiopharmaceutical Diagnostic Imaging Agent) (This is only billed through Outpatient Perspective Payment System, OPPS.) (Carriers must use HCPCS Code A4641).	10/1/03	Q3000
Supply of Radiopharmaceutical Diagnostic Imaging Agent, Ammonia N-13	01/01/04	A9526

*NOTE: Carriers must report A4641 for the tracer Rubidium 82 when used with PET scan codes G0030 through G0047.

**NOTE: Not FDG PET

***NOTE: For dates of service October 1 2003 through December 31, 2003, use temporary code Q4078 for billing this radiopharmaceutical.

60.4 -PET Scans for Imaging of the Perfusion of the Heart Using Rubidium 82 (Rb 82)

(Rev. 223, Issued: 07-02-04) (Effective/Implementation: Not Applicable)

For dates of service on or after March 14, 1995, Medicare covers one PET scan for imaging of the perfusion of the heart using Rubidium 82 (Rb 82), provided that the following conditions are met:

- The PET is done at a PET imaging center with a PET scanner that has been approved by the FDA;
- The PET scan is a rest alone or rest with pharmacologic stress PET scan, used for noninvasive imaging of the perfusion of the heart for the diagnosis and management of patients with known or suspected coronary artery disease, using Rb 82; and
- Either the PET scan is used in place of, but not in addition to, a single photon emission computed tomography (SPECT) or the PET scan is used following a SPECT that was found inconclusive.

60.5 - Expanded Coverage of PET Scan for Solitary Pulmonary Nodules (SPNs)

(Rev. 223, Issued: 07-02-04) (Effective/Implementation: Not Applicable)

For dates of service on or after January 1, 1998, Medicare expanded PET scan coverage to include characterization of solitary pulmonary nodules (SPNs).

60.6 - Expanded Coverage of PET Scans Effective for Services on or after July 1, 1999

(Rev. 223, Issued: 07-02-04) (Effective/Implementation: Not Applicable)

Effective *for services performed on or after* July 1, 1999, Medicare expanded coverage of PET scans to include the evaluation of recurrent colorectal cancer in patients with rising levels of carinoembryonic antigen (CEA), for the staging of lymphoma (both Hodgkins and non-Hodgkins) when the PET scan substitutes for a gallium scan or lymphangiogram, and for the staging of recurrent melanoma prior to surgery, provided certain conditions are met. All three indications are covered only when using the radiopharmaceutical FD*G*- (2-[flourine-18]-fluoro-2-deoxy-D-glucose), and are further predicated on the legal availability of FDG for use in such scans.

60.7 - Expanded Coverage of PET Scans Effective for Services on or After July 1, 2001

(Rev. 223, Issued: 07-02-04) (Effective/Implementation: Not Applicable)

See the Medicare National Coverage Determinations Manual, Section 220.6, for specific coverage criteria for PET Scans. Coverage is expanded for PET scans to include the following effective July 1, 2001:

- Scans performed with dedicated full-ring scanners will be covered. Gamma camera systems with at least a 1 inch thick crystal are eligible for coverage in addition to those already approved by CMS (FDA approved);
- The provider must maintain on file the doctor's referral and documentation that the procedure involved:
 - o Only FDA approved drugs and devices and,
 - o Did not involve investigational drugs, or procedures using investigational drugs, as determined by the FDA;
- The ordering physician is responsible for certifying the medical necessity of the study according to the conditions. The physician must have documentation in the beneficiary's medical record to support the referral supplied to the PET scan provider.

The following is a brief summary of the expanded coverage as of July 1, 2001:

- PET is covered for diagnosis, initial staging and restaging of non-small cell lung cancer (NSCLC).
- Usage of PET for colorectal cancer has been expanded to include diagnosis, staging, and restaging.
- Usage of PET for the initial staging, and restaging of both Hodgkin's and non-Hodgkin's disease.
- Usage of PET for the diagnosis, initial staging, and restaging of melanoma. (PET Scans are NOT covered for the evaluation of regional nodes.)

- Medicare covers PET for the diagnosis, initial staging, and restaging of esophageal cancer.
- Usage of PET for Head and Neck Cancers. (**PET scans for head and neck cancer is NOT covered for central nervous system or thyroid cancers.**)
- Usage of PET following an inconclusive single photon emission computed tomography (SPECT) only for myocardial viability. In the event that a patient has received a SPECT and the physician finds the results to be inconclusive, only then may a PET scan be ordered utilizing the proper documentation.
- Usage of PET for pre-surgical evaluation for patients with refractory seizures.

NOTE: Effective January 1, 2002, the definitions of HCPCS Codes G0210 through G0230 have been updated to properly reflect the type of PET scanner used.

60.8 - Expanded Coverage of PET Scans for Breast Cancer Effective for Dates of Service on or After October 1, 2002

(Rev. 223, Issued: 07-02-04) (Effective/Implementation: Not Applicable)

Effective for dates of service on or after October 1, 2002, Medicare will cover FDG PET as an adjunct to other imaging modalities for staging and restaging for locoregional, recurrence or metastasis of *breast cancer*. Monitoring treatment of a locally advanced breast cancer tumor and metastatic breast cancer when a change in therapy is contemplated is also covered as an adjunct to other imaging modalities. The baseline PET study for monitoring should be done under the code for staging or restaging.

Medicare continues to have a national non-coverage determination for initial diagnosis of breast cancer and initial staging of axillary lymph nodes. Medicare coverage now includes PET as an adjunct to standard imaging modalities for staging patients with distant metastasis or restaging patients with locoregional recurrence or metastasis of breast cancer; as an adjunct to standard imaging modalities for monitoring for women with locally advanced and metastatic breast cancer when a change in therapy is contemplated.

HCPCS Codes for PET Scans Performed on or After October 1, 2002 for Breast Cancer

G0252 through G0254 are applicable codes for billing breast cancer PET scans performed on or after October 1, 2002.

NOTE: The National Coverage Determinations Manual contains a description of coverage. FDG Positron Emission Tomography is a minimally invasive diagnostic procedure using positron camera [tomograph] to measure the decay of radioisotopes such as FDG. The CMS determined that the benefit category for the requested indications fell under §1861(s)(3) of the Act diagnostic service.).

60.9 - Coverage of PET Scans for Myocardial Viability

(Rev. 223, Issued: 07-02-04) (Effective/Implementation: Not Applicable)

FDG PET is covered for the determination of myocardial viability following an inconclusive single photon computed tomography test (SPECT) from July 1, 2001, through September 30, 2002. Only full ring scanners are covered as the scanning medium for this service from July 1, 2001, through December 31, 2001. However, as of January 1, 2002, full and partial ring scanners are covered for myocardial viability following an inconclusive SPECT.

Beginning October 1, 2002, Medicare will cover FDG PET for the determination of myocardial viability as a primary or initial diagnostic study prior to revascularization, and will continue to cover FDG PET when used as a follow-up to an inconclusive SPECT. However, if a patient received a FDG PET study with inconclusive results, a follow-up SPECT is not covered. FDA full and partial ring PET scanners are covered. In the event that a patient receives a SPECT with inconclusive results, a PET scan may be performed and covered by Medicare. However, a SPECT is not covered following a FDG PET with inconclusive results. See the Medicare National Coverage Determinations Manual, Section 220.6 for specific frequency limitations for Myocardial Viability following an inconclusive SPECT.

Documentation that these conditions are met should be maintained by the referring provider as part of the beneficiary's medical record.

HCPCS Code for PET Scan for Myocardial Viability

78459 - Myocardial imaging, positron emission tomography (PET), metabolic evaluation

60.10 - Coverage of PET Scans for PET Scan for Thyroid Cancer

(Rev. 223, Issued: 07-02-04) (Effective/Implementation: Not Applicable)

For services furnished on or after October 1, 2003, Medicare covers the use of FDG PET for thyroid cancer only for restaging of recurrent or residual thyroid cancers of follicular cell origin that have previously been treated by thyroidectomy and radioiodine ablation and have a serum thyroglobulin > 10ng/ml and negative I-131 whole body scan. All other uses of FDG PET in the diagnosis and treatment of thyroid cancer remain non-covered. See the Medicare National Coverage Determinations Manual, Section 220.6 for further coverage information.

HCPCS Code for Thyroid Cancer

G0296 - PET imaging, full and partial ring PET scanner only, for restaging of previously treated thyroid cancer of follicular cell origin following negative I-131 whole body scan.

60.11 - Coverage of PET Scans for Perfusion of the Heart Using Ammonia N-13

(Rev. 223, Issued: 07-02-04) (Effective/Implementation: Not Applicable)

Effective for service performed on or after October 1, 2003, PET scans performed at rest or with pharmacological stress used for noninvasive imaging of the perfusion of the heart for the diagnosis and management of patients with known or suspected coronary artery disease using the FDA-approved radiopharmaceutical ammonia N-13 are covered, provided the following requirements are met.

- Limitations:

--The PET scan, whether at rest alone, or rest with stress, is performed in place of, but not in addition to, a single photon emission computed tomography (SPECT); or

--The PET scan, whether at rest alone or with stress, is used following a SPECT that was found to be inconclusive. In these cases, the PET scan must have been considered necessary in order to determine what medical or surgical intervention is required to treat the patient. (For purposes of this requirement, an inconclusive test is a test(s), whose results are equivocal, technically uninterpretable, or discordant with a patient's other clinical data and must be documented in the beneficiary's file.)

HCPCS Codes for PET Scan for Perfusion of the Heart Using Ammonia N-13

Effective October 1, 2003, only two tracers, HCPCS Q3000 and Q4078, shall be covered for PET scans for the perfusion of the heart for use with G0030 through G0047. HCPCS Q3000 identifies the tracer Rubidium 82 and Q4078 identifies the tracer Ammonia N-13. Temporary HCPCS Q4078 is effective for dates of service October 1, 2003 through December 31, 2003. For dates of service on or after January 1, 2004, HCPCS A9526 must be used instead of HCPCS Q4078.