

## **Billing and Coding Guidelines for Radiopharmaceutical Agents (RAD-026)**

### **National Coverage**

Title XVIII of the Social Security Act section 1862(a) (1) (A). This section allows coverage and payment of those services that are considered medically reasonable and necessary.

Title XVIII of the Social Security Act section 1862(a) (7). This section excludes routine physical examinations and services.

Title XVIII of the Social Security Act section 1833(e). This section prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

### **Medicare Regulation Excerpts:**

#### **PUB 100-4 Medicare Claims Processing Manual- Chapter 12 - Physicians/Nonphysician Practitioners**

##### **20.4.4 - Supplies (Rev. 1, 10-01-03) B3-15900.2**

*Carriers make a separate payment for supplies furnished in connection with a procedure only when one of the two following conditions exists:*

*The supply is a pharmaceutical or radiopharmaceutical diagnostic imaging agent (including codes A4641 through A4647); pharmacologic stressing agent (code J1245); or therapeutic radionuclide (CPT code 79900). Other agents may be used which do not have an assigned HCPCS code. The procedures performed are:*

- Diagnostic radiologic procedures (including diagnostic nuclear medicine) requiring pharmaceutical or radiopharmaceutical contrast media and/or pharmacologic stressing agent;*
- Other diagnostic tests requiring a pharmacologic stressing agent;*
- Clinical brachytherapy procedures (other than remote after-loading high intensity brachytherapy procedures (CPT codes 77781 through 77784) for which the expendable source is included in the TC RVUs); or*
- Therapeutic nuclear medicine procedures.*

*Drugs are not supplies, and may be paid incidental to physicians' services as described in Chapter 17.*

#### **PUB 100-04 Medicare Claims Processing Manual- Chapter 17 Drugs and Biologicals**

##### **90.2 - Drugs, Biologicals, and Radiopharmaceuticals**

**(Rev. 1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)**

##### **A. General Billing and Coding for Hospital Outpatient Drugs, Biologicals, and Radiopharmaceuticals**

*Hospitals should report charges for all drugs, biologicals, and radiopharmaceuticals, regardless of whether the items are paid separately or packaged, using the correct HCPCS codes for the items used. It is also of great importance that hospitals billing for these products make certain that the reported units of service of the reported HCPCS code are consistent with the quantity of a drug, biological, or radiopharmaceutical that was used in the care of the patient. Payment for drugs, biologicals and radiopharmaceuticals under the OPDS is inclusive of both the acquisition cost and the associated pharmacy overhead or nuclear medicine handling cost. Hospitals should include these costs in their line-item charges for drugs, biologicals, and radiopharmaceuticals.*

### **C. Pass-Through Drugs, Biologicals, and Radiopharmaceuticals**

*Payment for drugs, biologicals, and radiopharmaceuticals may be made under the pass-through provision which provides additional payments for drugs, biologicals, and radiopharmaceuticals that meet certain requirements relating to newness and relative costs. According to section 1833(t) of the Social Security Act, transitional pass-through payments can be made for at least 2 years, but no more than 3 years.*

### **E. Radiopharmaceuticals**

#### **1. General**

*Beginning in CY 2008, the OPSS divides radiopharmaceuticals into two groups for payment purposes: diagnostic and therapeutic. Diagnostic radiopharmaceuticals function effectively as products that enable the provision of an independent service, specifically, a diagnostic nuclear medicine scan. Therapeutic radiopharmaceuticals are themselves the primary therapeutic modality.*

*Beginning January 1, 2008, the I/OCE requires claims with separately payable nuclear medicine procedures to include a radiolabeled product (i.e., diagnostic radiopharmaceutical, therapeutic radiopharmaceutical, or brachytherapy source). Hospitals are required to submit the HCPCS code for the radiolabeled product on the same claim as the HCPCS code for the nuclear medicine procedure. Hospitals are also instructed to submit the claim so that the services on the claim each reflect the date the particular service was provided. Therefore, if the nuclear medicine procedure is provided on a different date of service from the radiolabeled product, the claim will contain more than one date of service. More information regarding these edits is available on the OPSS Web site at <http://www.cms.gov/HospitalOutpatientPPS/>.*

*There are rare situations where a hospital provides a radiolabeled product to an inpatient, and then the patient is discharged and later returns to the outpatient department for a nuclear medicine imaging procedure but does not require additional radiolabeled product. In these situations, hospitals are to include HCPCS code C9898 (Radiolabeled product provided during a hospital inpatient stay) with a token charge (of less than \$1.01) on the same claim as the nuclear medicine procedure in order to receive payment for the nuclear medicine procedure. HCPCS code C9898 should only be reported under the circumstances described above and the date of service for C9898 should be the same as the date of service for the diagnostic nuclear medicine procedure.*

#### **2. Diagnostic Radiopharmaceuticals**

*Beginning in CY 2008, payment for nonpass-through diagnostic radiopharmaceuticals is packaged into the payment for the associated nuclear medicine procedure.*

#### **3. Therapeutic Radiopharmaceuticals**

*The OPSS will continue to pay for therapeutic radiopharmaceuticals at charges adjusted to cost from January 1, 2008 through December 31, 2009.*

#### **Coding Guidelines:**

1. The radiopharmaceutical and the procedure code should be billed on the same claim. If the procedure code and radiopharmaceutical are not billed on the same claim, it could result in payment delays or unnecessary denials. The injection of the radiopharmaceutical agent should only be billed when it is accompanied by the agent and the procedure.

2. The ordering or referring physician's name and NPI must be indicated in item 17 and 17a of the CMS 1500 form, respectively or 2310A or 2420F loop NM1 & REF segments for EMC.
3. Codes 78000-79999 can be billed with the modifiers -26 and -TC.  
In the inpatient and outpatient hospital setting- the technical (TC) portion is only payable when submitted by the hospital to the Part A fiscal intermediary/MAC A.  
  
Global and technical services are not payable by the Carrier /MAC B in the inpatient and outpatient setting.
4. Similarly, agent codes (e.g., A4641, A4642, A9500-A9507, A9600) administered in an in patient or outpatient hospital are billed by the hospital to the Part A Intermediary/MAC A.
5. 78804 may only be reported once, no matter how many scans are reported. This code represents the administration of radiopharmaceutical and performance and interpretation of all scans.
6. Rituximab prior to the administration of Zevalin is separately payable.
7. **Coding radiopharmaceuticals**  
Check the radiopharmaceuticals current HCPC's code description. The codes description defines **one** unit of service.
  - A. Most radiopharmaceuticals that have their own code include in the code's description "per study dose" **and include a range of mCi's**. These radiopharmaceutical agents should be billed as **one** unit of service per study. It is **not** appropriate to bill per mCi for the codes that include per study dose in its HCPC's description. It would be unusual to have more than 2 units of service for most of the agents with a per study dose or per treatment in its description.  
  
**Example:** A9503 is defined as Technetium Tc 99m, Medronate, (MDP), diagnostic, **per study dose, up to 30 mCi's**). Per study dose, up to 30 millicuries is **one unit of service**. If the provider administers **one to 30mCi** of this agent for a study, it should be billed as **one** unit of service.
  - B. Some radiopharmaceutical code descriptions are defined as **per millicurie** (mCi). These agents should be billed per millicurie. The number of mCi's that were administered to the patient should be the same as the number of services listed in the unit field on the claim.  
  
**Example:** A9512 is defined as Technetium Tc-99m-Per technetate, Diagnostic, **per mCi**. If you administer 5 mCi of this agent to your patient then 5 would be listed in the units' field of the claim.
  - C. NOC radiopharmaceutical codes (A4641, A9699) should be billed with one unit of service. The claim must include the name and total dosage of the agent in item 19 of the CMS 1500 form, or the electronic equivalent for EMC.
8. There are several kits that can be used for both myocardial infarct imaging and blood pool imaging tests. Examples of these kits include CIS-PRO, Technescan and Phosphotec. The kits are prepared/mixed differently depending on the test that is performed. The radiopharmaceutical code billed should correspond to the test performed.

9. **Cardiac blood pool imaging,**

There are two types of studies: first pass studies and equilibrium studies.

**A. First pass Studies** (CPT codes 78481 and 78483)

First pass studies utilize rapidly acquired images of a bolus of a radiopharmaceutical agent as it moves through the heart. The first pass technique only views the initial flow of the radiopharmaceutical as it moves through the heart.

78481 is a single first pass study at rest **or** stress, requiring a single injection. The radiopharmaceutical may be any product that has enough photons packed into the bolus to provide adequate counting statistics from which assessment and measurements of ejection fraction and wall motion can be derived.

78483 is a multiple first pass study at rest and stress, and requires two injections of appropriate radiopharmaceutical agent(s).

The radiopharmaceuticals used for these studies are A9512 and A9539.

A9512 Technetium Tc-99m-Per technetate, Diagnostic, per mCi

A9539 Technetium Tc-99m Pentetate, Diagnostic, per study dose, up to 25 mCi's

**B. Gated Equilibrium studies** (78472, 78473, 78494, and 78496).

Unlike the first pass technique, gated blood pool imaging studies are assessed over multiple cardiac cycles. This procedure involves binding /tagging the red blood cells with Technetium tc99m.

A9560 Technetium Tc-99m Labeled Red Blood Cell's (RBC's), Diagnostic, per study dose, up to 30 mCi's,

A9560 is the radiopharmaceutical code that should be used for tagging red blood cells. It should be used for both the invitro (UltraTag) and invivo (non-radioactive "cold" pyrophosphate (PYP) followed by an injection of 99m technetium) methods. Regardless of the method used to tag the red blood cells, invitro or invivo, the correct code to use is A9560.

**Invitro**-whole blood is withdrawn from the patient and transferred to a sterile UltraTag bag or vial. Tc 99m Per technetate is added to the bag or vial and incubated at room temperature for approximately 25 minutes. The patient is then injected with labeled RBCs.

**invivo**- Pt is injected with "non-radioactive" "cold" Pyrophosphate (PYP) reconstituted with normal saline followed 20 minutes later by an injection of Tc 99m Per technetate.

**Note:** Per technetate is a commonly used radiopharmaceutical given during a nuclear scan to allow imaging with specialized equipment. The cost for the per technetate, in this instance, is considered part of the payment for A9560 and thus not separately payable. The individual components of preparing tagged red blood cells will not be paid for separately. A9512 will not be paid when billed with A9560. Invoices will not be necessary for reimbursement of A9560.

10. **Myocardial Infarct Imaging - CPT codes 78466-78469.**

A9538 Technetium Tc-99m pyrophosphate, diagnostic, per study dose up to 25 mCi's is used for these procedures. This code is used for Pyrophosphate (PYP) compounded /prepared with technetium Tc99m per technetate. It is prepared external to the patient and is then administered

intravenously for cardiac “hot spot” imaging.

Do not use HCPCS A9538 when administering "non-radioactive" Pyrophosphate with saline followed by a second administration of Tc99m pertechnetate. A9512 will not be paid separately when billed with A9538. Invoices will not be necessary for reimbursement of A9538.

11. **Myocardial Perfusion imaging studies (78451-78454)**

Radiopharmaceuticals commonly used for these studies include A9500 and A9502.

A9500 Technetium Tc-99m, Sestamibi, diagnostic, per study dose,

A9502 Technetium Tc 99m tetrofosmin, diagnostic, per study dose

If two (2) per study doses of these agents are used, one for rest and one for the stress portion of the study, it would be billed as two (2) units.

**Example:** A9500 is defined as Technetium Tc 99m sestamibi, diagnostic, **per study dose**. When multiple studies (rest and stress) nuclear medicine procedures are performed using this agent for two studies it would be appropriate to bill for 2 units.

12. Electronic submitters should indicate they have additional documentation or an **invoice**, which Medicare may require, by indicating “DOCUMENTATION AVAILABLE UPON REQUEST” in the electronic equivalent of item 19. If the additional documentation or an invoice you have is needed for Medicare to make its payment determination, a development letter will be sent requesting the information. If you do not indicate the availability of the additional documentation, or the information is not returned timely, the claim will be returned as unprocessable.

13. Invoices must clearly indicate the name of the radiopharmaceutical and the dosage billed must correspond to the HCPC’s code description.

- a. HCPC’s descriptions with a specified unit of measure such as mCi :

A9512 is defined as Technetium Tc-99m-Pertechnetate, Diagnostic, **per mCi**. The invoice must indicate the number of mCi in a dose. The number of mCi’s would match the number of units billed on the claim. If the invoice lists a dose price, you must indicate the number of mCi’s in the dose. This can be added to the manufacturer’s invoice and must be signed or initialed to indicate information was added.

- b. HCPC’s descriptions that state per study dose, up to a specified number of millicuries:

A9539 Technetium Tc-99m Pentetate, Diagnostic, **per study dose, up to 25 mCi’s**, Per study dose, up to 25 millicuries is **one unit of service**. If the provider administers **one to 25mCi** of this agent for a study, it should be billed as **one** unit of service. The invoice should indicate the cost of the radiopharmaceutical dosage given for the study.

14. A9547 Indium-IN-111 Oxyquinoline, will not be paid when billed with A9570 Indium-111 labeled autologous white blood cells, or A9571 Indium in-111 labeled autologous platelets.

A9547 Indium-IN-111 Oxyquinoline, Diagnostic, per 0.5 mCi,  
Leukocyte labeling (CPT 78805-78807, 78185)  
Platelet labeling. (CPT 78190-78191, 78199)

A9570 Indium-111 labeled autologous white blood cells, diagnostic, per study dose  
Leukocyte labeling (CPT 78805-78807, 78185)

A9571 Indium in-111 labeled autologous platelets, diagnostic, per study dose (A9571)  
Platelet labeling. (CPT 78190-78191, 78199)

**Source of Information:**

FDA Website

Society of Nuclear Medicine (SNM):

Practice Management Coding Corner:

1. Cardiac Blood Pool Imaging Radiopharmaceutical Codes  
<http://interactive.snm.org/index.cfm?PageID=2437&RPID=1995>

2. Gastrointestinal Bleed Imaging Radiopharmaceutical Codes

<http://interactive.snm.org/index.cfm?PageID=5018&RPID=1995>

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