

## Comment and Response Document

### LCD Database ID Number

DL31361

### LCD Title

Radiopharmaceutical Agents

### Contractor's Determination Number

RAD-026

**Comments:** We received the following requests to add the specific procedure codes/ tests to the agents below. The policy was updated as follows:

#### **Section A. Technetium (Tc) labeled radiopharmaceuticals:**

6. Technetium Tc-99m Pentetate, Diagnostic, per study dose, up to 25 mCi's, A9539  
Vascular flow study (CPT 78445)  
Cardiac Shunt detection (78428)
15. Technetium Tc-99m Macroaggregated Albumin (MAA), Diagnostic, per study dose, up to 10 mCi's, A9540  
Peritoneal cavity imaging prior to intraperitoneal chemotherapy (78800, 78801, 78803)  
Liver imaging (SPECT) (CPT 78201, 78205, 78215)
20. Technetium Tc-99m-Pertechnetate, Diagnostic, per mCi, A9512  
Peritoneal-Venous Shunt Study (CPT 78291)  
Cerebrospinal Fluid study (CPT 78630-78650)
22. Technetium Tc-99m Labeled Red Blood Cell's (RBC's) Diagnostic, per study dose, up to 30 mCi's, A9560 (Ultra Tag ® or cold pyrophosphate (pyp) +99m technetium),  
Liver scan (for Hemangioma) (CPT 78206)
25. Technetium Tc 99m tetrofosmin, diagnostic, per study dose, A9502 (Myoview)  
Trade name added and Parathyroid study (CPT 78070, 78803)

#### **Section B. Iodine labeled radiopharmaceuticals**

2. I 125
  - c. Iodine- 125 Sodium Iodide solution, Therapeutic, per millicurie A9527  
Intracavitary radiation source application, simple (77761)
3. I 131
  - e. Iodine I-131 Sodium Iodide **capsule(s), Diagnostic**, per mCi, A9528  
Thyroid uptake and imaging (78020, 78803)
  - f. Iodine I-131 Sodium Iodide **solution, Diagnostic**, per mCi, A9529  
Thyroid uptake and imaging (78020, 78803)

- g. Iodine I-131 Sodium Iodide, Diagnostic, per microcurie (up to 100 microcuries)  
A9531  
Thyroid uptake and imaging (78020, 78803)

**Section C. Indium labeled Radiopharmaceuticals:**

Added brand name (MPI INDIUM DTPA IN 111)

Removed CPT 78800-78803. The following tests were added to A9548:

- 3. Indium IN-111 Pentetate Diagnostic, per 0.5 mCi A9548 (MPI INDIUM DTPA IN 111)  
Cisternogram (cerebrospinal fluid flow) (CPT 78630)  
Cerebrospinal ventriculography (CPT 78635)  
CSF Shunt evaluation (CPT 78645)  
Cerebrospinal fluid scan (CPT 78647)  
CSF Leakage detection and localization (CPT 78650)  
Radiopharmaceutical dacryocystography (CPT 78660)

**Section D. Miscellaneous Radiopharmaceuticals**

- 9. Thallous Chloride TL-201, diagnostic, per mCi, A9505  
Brain imaging (CPT 78607)

**Comment:**

A request to add additional tumor imaging codes 78800-78803 to the use of Iodine I-131 Tositumomab, (Bexxar®) Diagnostic, per study dose, A9544.

**Response:**

This agent covered is covered for whole body imaging, requiring 2 or more days imaging (CPT 78804). This instruction was issued in One time Notification -change request 3007.

**Comment:**

A few physicians noted that the some of the agents were no longer marketed / available in the United States.

**Response:**

We reviewed the agents on the FDA web site and checked with some of our Carrier Advisory Committee members to verify that these agents were no longer available. We have moved the discontinued agents to a new section of the LCD with the following information:

F. The following agents are no longer marketed in the United States and will be denied.  
Coverage will be added if the agent(s) become available in the future.

- 1. A9501 Technetium Tc-99m Teboroxime (Cardiotec)
- 2. A9504 Technetium Tc 99m Apcitide (Acu Tect®),
- 3. A9536 Technetium Tc-99M Depreotide, (Neotect®)
- 4. A9550 Technetium Tc-99m Sodium Glucoptate (Glucoheptonate®)
- 5. A9566 Technetium Tc-99m Fanolesomab, (NeuroSpec®)
- 6. A9546 Cobalt CO-57-/58 Cyanocobalamin
- 7. A9559 Cobalt CO-57 Cyanocobalamin, oral

**Comment:**

Request received that WPS add HCPCS codes A9699 and C9399 to the list of radiopharmaceuticals that may be reported

**Response:**

Providers may use NOC codes when no true code exists. We are not aware of any radiopharmaceutical NOC codes or otherwise unclassified agents that are currently being used. No information was submitted with this request to indicate an agent that would be billed using one of these NOC codes. A9699 and C9399 were not added to the LCD.

**Comment:**

We received a request to add CPT 38792 sentinel lymph node injection to this LCD.

**Response:** The administration /injection codes of the radiopharmaceuticals are not included in the LCD. This LCD links the radiopharmaceutical with the diagnostic test and/or procedure to ensure appropriate usage of the agent. Radiopharmaceutical diagnostic imaging agents are considered a supply and are addressed in the National Internet Only Manuals(IOM), Claims Processing Manual -100-04 Chapter 12, Section 20.4.4. Payment for the radiopharmaceutical agent/supply can only be made in connection with the diagnostic radiological/nuclear medicine procedure. The radiopharmaceutical agent will only be paid when it is billed with the diagnostic testing procedure. The sentinel lymph node injection procedure is addressed in our Sentinel Lymph Node Biopsy LCD (L30475).

**Comment:**

The Billing and coding article contain a typo. Number 12 contains the same information as #14.

**Response:**

Thank you, we have removed the duplicate information.

**Comment:**

The language in the Draft LCD under the heading "Utilization Guidelines" states: Data reviewed and showed incorrect coding /utilization for A9500 and A9502, A9503. These agents are to be billed once per study. Codes were being billed per mCi...Up to 2 units of service will be allowed for A9500 and A9502. One unit of service will be allowed for A9503.

This language is unclear regarding whether providers may bill for two doses when a rest/stress myocardial perfusion imaging (MPI) study is performed and two doses are administered to the patient- one dose during the rest phase of the study and a second dose during the stress phase of the study). Thus, we recommend WPS clarify the language to make clear that providers may properly bill for two doses in such instances when two doses are administered.

The Draft LCD states that only a single dose should be billed for A9500 and A9502, which are the codes used for MPI studies. Presumably, the rationale for limiting payment of the radiopharmaceuticals – if that is what WPS intends -- is that WPS considers both the "rest" and "stress" portion of a myocardial perfusion imaging study to be "one" test and therefore asserts that only one radiopharmaceutical should be billed for a test for one patient.

It is important to understand why and how the doses for myocardial imaging are ordered from the nuclear pharmacy. When a rest/stress myocardial perfusion study utilizing Technetium Tc99m Sestamibi or Technetium Tc99m Tetrofosmin is ordered for a patient, the physician orders two

separate patient-specific unit doses for the patient study that are filled pursuant to a prescription – one dose to be administered during the rest portion of the exam, and a second dose for the stress portion of the study.

Importantly, the stress portion of the dose may be administered (if medically appropriate for a given patient) hours after the rest portion of the exam. Thus, consistent with good clinical practice and hospital and pharmacy standards, when the physician orders the myocardial imaging test, the nuclear pharmacy prepares two separate prescription doses based on the order. These two doses are then dispensed to the provider for that patient study. The provider is invoiced for the two prescription doses that were ordered and dispensed, which creates an audit trail for each patient specific unit dose based on prescription number.

Contrary to these best clinical practices, this interpretation of the Draft LCD essentially limits the billing for a rest/stress myocardial perfusion study to a single dose for a given patient.

**1. Practical Implications of the Policy Are Inconsistent with Standards for Recordkeeping and Product Labeling, and with Federal and State Law**

The Draft LCD should be clarified or changed to allow providers to bill appropriately for radiopharmaceuticals that are administered, consistent with Medicare HCPCS coding guidelines, clinical standards, and product labeling standards. Unfortunately, if the Draft LCD limits billing to a single dose, this approach is inconsistent with the clinical standards of practice for Technetium-based (Tc99m) myocardial perfusion imaging studies and creates significant problems that are in juxtaposition to applicable law and standards, and which are antithetical to patient safety, accreditation agency standards, state and federal laws for drug labeling, ALARA standards, and USP compendia requirements.

For example, we are concerned that if the Draft LCD is not clarified/changed, providers may try to order a single “large” dose of the radiopharmaceutical, and try to split this large dose into two separate doses in house so that they may administer the stress dose at a later time. If providers try to adopt this practice, the unused portion for the stress portion of the study could remain stored in a syringe without proper labeling and could become non-sterile. This practice of dose-splitting results in unlabeled syringes that conflict with:

- (1) Federal law on the labeling of radioactive materials;
- (2) State laws for labeling of legend drugs;
- (3) The Joint Commission standards for the labeling of dispensed medications in healthcare facilities; and
- (4) Applicable compendia standards, including USP General Chapter 797, which pertains to the proper methods for labeling sterile medications.

In addition, most radioactive medications supplied by nuclear pharmacies include a medication bar code that is utilized in the nuclear medicine department to provide for certain safeguards. The ability to accurately track the utilization, storage, and handling of radiopharmaceuticals is critical to the safe and secure use of these products. Use of a barcode ensures: (1) compliance with proper documentation of patient dosages; (2) compliance with Radioactive Materials License conditions; and (3) safe drug administration. This safeguard ensures that the right dose is administered to the right patient, that the material is stored securely and accounted for, and become part of the patient’s health record.

We are especially concerned that the Draft LCD (limiting to “one” dose) may lead to partial doses being stored, handled and/or administered without a proper barcode on the product. Further, this practice makes the original pharmacy label moot and, thus, prevents the use of the bar code or additional labeling that the healthcare system may use in the patient’s health record.

## **2. Inevitable Dose Splitting Resulting from the Policy Threatens the Safe Handling and Safe Administration to Patients**

The practical implications of the Draft LCD, if not clarified, reach beyond issues of storage, handling and compliance with law. The Draft LCD also results in an increased risk to patient safety, as evidenced by a multiple problems inherent if providers need to split a “large” dose into two separate doses. We note that subversion of the safeguards discussed above also results in a significantly increased risk to patient safety (*e.g.*, ensuring the correct patient is getting the correct drug).

### **(a) Excessive Radiation Exposure**

Similar to the problems with sterility, the potential dose splitting practice spurred by the Draft LCD may result in unintended or excessive radiation exposure. Although personnel administering the radiologic material are trained to conduct the study, they are not trained in the manipulation of radiopharmaceutical drug similar to that of personnel at a nuclear pharmacy. Even if they were trained properly, further manipulation of sterile, radioactive medications leads to unnecessary radiation exposure of healthcare workers. This increased exposure to radiation conflicts with the ALARA requirements of the Radioactive Materials License for the healthcare facility.

### **(b) Sterility Concerns and Heightened Risk for General Medication Errors**

The additional step of breaking out the stress dose, and the corresponding handling and storage problems, create the potential for microbial contamination of the drug. In fact, this practice violates the compendia standard directly related to this issue. USP General Chapter 797 standards provide for specific procedures for manipulation of sterile dosages outside of a controlled environment, and use of non-sterile technique in a patient care environment in close proximity to blood-borne pathogens. Furthermore, the personnel that will be splitting the doses are not trained in aseptic technique for the manipulation of sterile dosages in an ambient environment.

In addition, dose-splitting may result in patient dosing that is over or under the prescribed amount. Due to the difficulty in transfer of a sterile, radioactive medication from one syringe to another, there is potential for loss of medication or excessive medication in one syringe or another. Manipulation of a properly labeled radioactive medication into 2 dosages that are either not labeled (the “new split dose”) or labeled improperly (the source dose) violates patient safety standards.

## **Response:**

The agents (A9500, A9502, and A9503) are to be billed once per study is referring to the actual description of the HCPC’s codes and to alert the providers that they should not be billing the agents per MCI. Data indicated this was a problem.

Regarding comments on myocardial perfusion imaging billing: Our billing and coding document clearly states that if the agent was given at rest and stress that they may bill 2 doses.

The following information is in our billing and coding document:

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.

We have not received any questions from providers asking for clarification on the billing of these agents. The LCD will remain as written.