

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 3911	Date: November 9, 2017
	Change Request 10319

SUBJECT: New Positron Emission Tomography (PET) Radiopharmaceutical/Tracer Unclassified Codes

I. SUMMARY OF CHANGES: To help alleviate inordinate spans of time between when a coverage determination is made and when it can be fully implemented via valid claims processing, the Centers for Medicare & Medicaid Services has created two new PET radiopharmaceutical unclassified tracer codes that can be used temporarily pending the creation/approval/implementation of permanent Current Procedural Terminology (CPT) codes that would later specifically define their function.

EFFECTIVE DATE: January 1, 2018

**Unless otherwise specified, the effective date is the date of service.*

IMPLEMENTATION DATE: December 11, 2017 - A/B MAC; April 2, 2018 - FISS

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

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	13/60/3.2 Tracer Codes Required for PET Scans

III. FUNDING:

For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

**Business Requirements
Manual Instruction**

Attachment - Business Requirements

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I. GENERAL INFORMATION

A. Background: Positron emission tomography (PET) is a nuclear medicine imaging study used to detect normal and abnormal tissues. All PET scan services are billed using PET or PET/computed tomography (CT) Current Procedural Terminology (CPT) codes 78459, 78491, 78492, 78608, and 78811 through 78816. Each of these CPT codes always requires the use of a radiopharmaceutical code, also known as a tracer code. Therefore, an applicable tracer code, along with an applicable CPT code, is necessary for claims processing of any PET scan services.

While there are a number of PET tracers already billable for a diverse number of medical indications, there have been, and may be in the future, additional PET indications that might require a new PET tracer. Under those circumstances, the process to request/approve/implement a new tracer code could be time-intensive. To help alleviate inordinate spans of time between when a coverage determination is made and when it can be fully implemented via valid claims processing, the Centers for Medicare & Medicaid Services (CMS) has created two new PET radiopharmaceutical unclassified tracer codes that can be used temporarily pending the creation/approval/implementation of permanent CPT tracer codes that would later specifically define their function.

B. Policy: Effective for claims with dates of service on or after January 1, 2018, the following Healthcare Common Procedure Coding System (HCPCS) codes shall be used **ONLY AS NECESSARY FOR AN INTERIM PERIOD OF TIME** under the circumstances explained above. Specifically, there are two circumstances that would warrant use of the below codes: (1) After Food and Drug Administration (FDA) approval of a PET oncologic indication, or (2) after CMS approves coverage of a new PET indication, and **ONLY** if either of those situations requires the use of a dedicated PET radiopharmaceutical/tracer code that is currently non-existent. This change request (CR) implements the use of the below 2 PET HCPCS tracer codes for an interim period of time until a dedicated tracer code is later approved by the FDA and found reasonable and necessary by CMS for a particular indication and fully implemented in the CMS systems. Once permanent replacement PET tracer codes are implemented via a subsequent CMS CR, that subsequent CR will also discontinue use of the temporary tracer code A9597 or A9598 for that specified indication. The following two PET tracer codes were effective as of January 1, 2017, with the January 2017 quarterly HCPCS update.

A9597 - Positron emission tomography radiopharmaceutical, diagnostic, for tumor identification, not otherwise classified

A9598 - Positron emission tomography radiopharmaceutical, diagnostic, for non-tumor identification, not otherwise classified

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility							
		A/B MAC		D M E	Shared- System Maintainers				Other
		A	B		H H H	M I S S	V C S	C M W F	
	Part B, PET claims for A9597 or A9598: Remittance Advice Remark Codes (RARC) N386 Claim Adjustment Reason Code (CARC) 50, 96, 16, and/or 119. Group Code CO (Contractual Obligation) assigning financial liability to the provider.								
10319.4	Contractors shall not search for claims but shall adjust any claims that are brought to their attention.	X	X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility					
		A/B MAC			D M E	C M E D I	Other
		A	B	H H H			
10319.5	MLN Article: A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within 5 business days after receipt of the notification from CMS announcing the availability of the article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X	X				

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
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Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Pat Brocato-Simons, 410-786-0261 or patricia.brocato-simons@cms.hhs.gov (Coverage) , Stuart Caplan, 410-786-8564 or stuart.caplan@cms.hhs.gov (Coverage) , Wanda Belle, 410-786-7491 or wanda.belle@cms.hhs.gov (Coverage)

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0

60.3.2 - Tracer Codes Required for *Positron Emission Tomography (PET)* Scans

(Rev.3911, Issued: 11-09-17, Effective: 01-01-18, Implementation: 12-11-17)

An applicable tracer/radiopharmaceutical code, along with an applicable Current Procedural Technology (CPT) code, is necessary for claims processing of any Positron Emission Tomography (PET) scan services. While there are a number of PET tracers already billable for a diverse number of medical indications, there have been, and may be in the future, additional PET indications that might require a new PET tracer. Under those circumstances, the process to request/approve/implement a new code could be time-intensive. To help alleviate inordinate spans of time between when a national coverage determination is made, or when the Food and Drug Administration (FDA) approves a particular radiopharmaceutical for an oncologic indication already approved by the Centers for Medicare & Medicaid Services (CMS), and when it can be fully implemented via valid claims processing, CMS has created two new PET radiopharmaceutical unclassified tracer codes that can be used temporarily. This time period would be pending the creation/approval/implementation of permanent CPT codes that would later specifically define their function by CMS in official instructions.

Effective with dates of service on or after January 1, 2018, the following Healthcare Common Procedure Coding System (HCPCS) codes shall be used ONLY AS NECESSARY FOR AN INTERIM PERIOD OF TIME under the circumstances explained here. Specifically, there are two circumstances that would warrant use of the below codes: (1) After FDA approval of a PET oncologic indication, or, (2) after CMS approves coverage of a new PET indication, and ONLY if either of those situations requires the use of a dedicated PET radiopharmaceutical/tracer that is currently non-existent. Once permanent replacement codes are officially implemented by CMS, use of the temporary code for that particular indication will simultaneously be discontinued.

NOTE: The following two codes were effective as of January 1, 2017, with the January 2017 quarterly HCPCS update.

A9597 - Positron emission tomography radiopharmaceutical, diagnostic, for tumor identification, not otherwise classified

A9598 - Positron emission tomography radiopharmaceutical, diagnostic, for non-tumor identification, not otherwise classified

Effective for claims with dates of service on and after January 1, 2018, when PET tracer code A9597 or A9598 are present on a claim, that claim must also include:

-an appropriate PET HCPCS code, either 78459, 78491, 78492, 78608, 78811, 78812, 78813, 78814, 78815, or 78816,

-if tumor-related, either the -PI or -PS modifier as appropriate,

-if clinical trial, registry, or study-related outside of NCD220.6.17, PET for Solid Tumors, clinical trial modifier -Q0,

-if clinical trial, registry, or study-related, all claims require the 8-digit clinical trial number,

-if Part A OP and clinical trial, registry, or study-related outside of NCD220.6.17, PET for Solid Tumors, also include condition code 30 and ICD-10 diagnosis Z00.6.

Effective for claims with dates of service on and after January 1, 2018, A/Medicare Administrative Contractors (MACs) shall line-item deny, and B/MACs shall line-item reject, PET claims for A9597 or A9598 that don't include the elements noted above as appropriate.

Contractors shall use the following messaging when line-item denying (Part A) or line-item rejecting (Part B) PET claims containing HCPCS A9597 or A9598:

Remittance Advice Remark Codes (RARC) N386

Claim Adjustment Reason Code (CARC) 50, 96, and/or 119.

Group Code CO (Contractual Obligation) assigning financial liability to the provider (if a claim is received with a GZ modifier indicating no signed ABN is on file).

(The above new verbiage will supersede any existing verbiage in chapter 13, section 60.3.2.)