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| CMS Manual System | Department of Health & Human Services (DHHS) |
| Pub 100-04 Medicare Claims Processing | Centers for Medicare & Medicaid Services (CMS) |
| Transmittal 2915 | Date: March 27, 2014 |
| | Change Request 8526 |

Transmittal 2871, dated February 6, 2014 is being rescinded and replaced by Transmittal 2915, dated March 27, 2014 to update the reference to the correct CPM, chapter 13 on the transmittal. All other information remains the same.

SUBJECT: Medicare National Coverage Determination (NCD) for Beta Amyloid Positron Emission Tomography (PET) in Dementia and Neurodegenerative Disease

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is that effective for claims with dates of service on or after, September 27, 2013, Medicare will only allow coverage for PET A β imaging (one PET A β scan per patient) through coverage with evidence development (CED) to: (1) develop better treatments or prevention strategies for AD, or, as a strategy to identify subpopulations at risk for developing AD, or (2) resolve clinically difficult differential diagnoses (e.g., frontotemporal dementia (FTD) versus AD) where the use of PET A β imaging appears to improve health outcomes, when the patient is enrolled in an approved clinical study under CED.

EFFECTIVE DATE: September 27, 2013

IMPLEMENTATION DATE: July 7, 2014

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 | 13/60.12/ Coverage for PET Scans for Dementia and Neurodegenerative Diseases |

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 obliged 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

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

Attachment - Business Requirements

| | | | |
|-------------|-------------------|----------------------|----------------------|
| Pub. 100-04 | Transmittal: 2915 | Date: March 27, 2014 | Change Request: 8526 |
|-------------|-------------------|----------------------|----------------------|

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SUBJECT: Medicare National Coverage Determination (NCD) for Beta Amyloid Positron Emission Tomography (PET) in Dementia and Neurodegenerative Disease

EFFECTIVE DATE: September 27, 2013

IMPLEMENTATION DATE: July 7, 2014

I. GENERAL INFORMATION

A. Background: CMS does not currently cover Positron Emission Tomography (PET) beta amyloid (also referred to as PET amyloid-beta ($A\beta$)) imaging, based on a longstanding general non-coverage of PET except where specifically covered nationally. Another radiopharmaceutical used in PET neuroimaging, fluoro-D-glucose F18 (FDG) PET, is nationally covered for either the differential diagnosis of frontotemporal dementia (FTD) versus Alzheimer's disease (AD) under specific requirements; or, its use in a CMS-approved practical clinical trial focused on the utility of FDG PET in the diagnosis or treatment of dementing neurodegenerative diseases.

Lilly USA, LLC, manufacturer of the radiopharmaceutical florbetapir (Amyvid™) that was approved by the Food and Drug Administration (FDA) in April 2012, requested that CMS reconsider its non-coverage decision of PET $A\beta$ imaging. Lilly asked that CMS provide coverage of PET $A\beta$ imaging as a diagnostic test to “estimate amyloid neuritic plaque density in adult patients with documented cognitive impairment who are being evaluated for AD and other causes of cognitive impairment” (quoting the Amyvid™ FDA-approved label). The label states that a negative florbetapir scan “is inconsistent with a neuropathological diagnosis of AD,” and “reduces the likelihood that a patient’s cognitive impairment is due to AD.” However, a positive scan “does not establish a diagnosis of AD or other cognitive disorder.” A Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) meeting was convened on the role of PET $A\beta$ imaging in dementia and neurodegenerative disease on January 30, 2013. The MEDCAC highlighted the paucity of evidence on the actual impact of PET $A\beta$ scanning on patients.

B. Policy: After careful consideration, effective for claims with dates of service on or after, September 27, 2013, CMS believes that the evidence is insufficient to conclude that the use of PET $A\beta$ imaging improves health outcomes for Medicare beneficiaries with dementia or neurodegenerative disease. However, there is sufficient evidence that the use of PET $A\beta$ imaging could be promising in certain scenarios. Therefore, Medicare will only allow coverage for PET $A\beta$ imaging (one PET $A\beta$ scan per patient) through coverage with evidence development (CED) to: (1) develop better treatments or prevention strategies for AD, or, as a strategy to identify subpopulations at risk for developing AD, or (2) resolve clinically difficult differential diagnoses (e.g., frontotemporal dementia (FTD) versus AD) where the use of PET $A\beta$ imaging appears to improve health outcomes, when the patient is enrolled in an approved clinical study under CED.

Health outcomes may include: avoidance of unnecessary or potentially harmful treatment or tests; improving, or slowing the decline of, quality of life (to include maintenance of independence) and cognitive and functional status; and survival. Outcomes may be short term (e.g., related to meaningful changes in clinical management) or long term (e.g., related to dementia outcomes).

NOTE: Please note each new beta amyloid radiopharmaceutical will require a separate code. Therefore, for the interim period, HCPCS code (A9599) - Radiopharmaceutical for beta-amyloid positron emission

tomography (PET) imaging, diagnostic, per study dose shall be used with an effective date of January 1, 2014. After a new beta amyloid radiopharmaceutical is approved for a separate, individual HCPCS code, a subsequent CR will be issued to update this NCD policy.

NOTE: Contractors should refer to the business requirements below as well as general clinical trial billing requirements at Pub. 100-03, chapter 1, section 310, and Pub. 100-04, chapter 32, section 69. See Pub. 100-03, NCD Manual, chapter 1, section 220.6.20, for the coverage of Beta Amyloid PET in Neurodegenerative Disease and Dementia, and Pub. 100-04, Claims Processing Manual, chapter 13, section 60.12, for claims processing instructions.

II. BUSINESS REQUIREMENTS TABLE

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

| Number | Requirement | Responsibility | | | | | | | | Other |
|-----------|---|----------------|---|-------------|----------------------------|----------------------------------|-------------|-------------|-------------|-------|
| | | A/B MAC | | | D M E M A C | Shared- System Maintainers | | | | |
| | | A | B | H H H | | F I S S | M C S | V M S | C W F | |
| 8526-04.1 | <p>Effective for claims with dates of service on and after September 27, 2013, Medicare will only allow coverage with evidence development (CED) for Positron Emission Tomography (PET) beta amyloid (also referred to as amyloid-beta (Aβ)) imaging (HCPCS A9586) or (HCPCS A9599) (one PET Aβ scan per patient).</p> <p>Note: Please note that effective January 1, 2014 the following code A9599 will be updated in the IOCE and HCPCS update. This code will be contractor priced.</p> | X | X | | | X | | | | IOCE |
| 8526-04.2 | <p>Effective for claims with dates of service on or after September 27, 2013, contractors shall return to provider/return as unprocessable claims for PET Aβ imaging, through CED during a clinical trial, not containing the following:</p> <ul style="list-style-type: none"> • Condition code 30, (for institutional claims only) • Modifier Q0 and/or modifier Q1 as appropriate • ICD-9 dx code V70.7/ICD-10 dx code Z00.6 (on either the primary/secondary position) • A PET HCPCS code (78811 or 78814), • Dx codes (see Attachment A), and | X | X | | | X | X | | | |

| Number | Requirement | Responsibility | | | | | | | | |
|-------------|--|----------------|---|-------------|----------------------------|----------------------------------|-------------|-------------|-------------|-------|
| | | A/B MAC | | | D M E M A C | Shared- System Maintainers | | | | Other |
| | | A | B | H H H | | F I S S | M C S | V M S | C W F | |
| | Aß HCPCS code A9586 or A9599 | | | | | | | | | |
| 8526-04.2.1 | <p>Contractors shall return as unprocessable claims for PET Aß imaging using the following messages:</p> <p>-Claim Adjustment Reason Code 4 – the procedure code is inconsistent with the modifier used or a required modifier is missing.</p> <p>Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.</p> <p>-Remittance Advice Remark Code N517 - Resubmit a new claim with the requested information.</p> <p>-Remittance Advice Remark Code N519 - Invalid combination of HCPCS modifiers.</p> | | X | | | | X | | | |
| 8526-04.3 | <p>For claims with dates of service on or after September 27, 2013, CWF shall deny/reject claims for more than one PET Aß scan, HCPCS code A9586 or A9599, in a patient’s lifetime.</p> <p>Note: This edit shall be overridable</p> | X | X | | | X | X | | X | |
| 8526-04.3.1 | <p>Contractors shall line-item deny claims for PET Aß, HCPCS code A9586 or A9599, where a previous PET Aß, HCPCS code A9586 or A9599 is paid in history using the following messages:</p> <ul style="list-style-type: none"> • CARC 149: “Lifetime benefit maximum has been reached for this service/benefit category.” • RARC N587: “Policy benefits have been exhausted”. • MSN 20.12: “This service was denied because Medicare only covers this service | X | X | | | | | | | |

| Number | Requirement | Responsibility | | | | | | | | |
|-----------|---|----------------|---|-------------|----------------------------|---------------------------|-------------|-------------|-------------|-------|
| | | A/B MAC | | | D M E M A C | Shared-System Maintainers | | | | Other |
| | | A | B | H H H | | F I S S | M C S | V M S | C W F | |
| | <p>once a lifetime.”</p> <ul style="list-style-type: none"> Spanish Version: “Este servicio fue negado porque Medicare sólo cubre este servicio una vez en la vida.” Group Code: PR, if a claim is received with a GA modifier. <p>Group Code: CO, if a claim is received with a GZ modifier.</p> | | | | | | | | | |
| 8526-04.4 | CWF shall identify claims with TOB 85X when revenue code is 096X, 097X, or 098X as professional claims. | X | | | | | | | X | |
| 8526-04.5 | For PET Aβ claims with dates of service on or after September 27, 2013, contractors shall not search their files. However, contractors shall adjust claims brought to their attention. | X | X | | | | | | | |

III. PROVIDER EDUCATION TABLE

| Number | Requirement | Responsibility | | | | |
|-----------|---|----------------|---|-------------|----------------------------|------------------|
| | | A/B MAC | | | D M E M A C | C E D I |
| | | A | B | H H H | | |
| 8526-04.6 | 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 one week of the availability of the provider education 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: |
|---------------------------------|---|
|---------------------------------|---|

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Patricia Brocato-Simons, 410-786-0261 or patricia.brocatosimons@cms.hhs.gov (Coverage) , William Ruiz, 410-786-9283 or william.ruiz@cms.hhs.gov (Institutional claims processing) , William Ruiz, 410-786-9283 or william.ruiz@cms.hhs.gov (Institutional claims processing) , Chanelle Jones, 410-786-9668 or chanelle.jones@cms.hhs.gov (practitioner claims processing) , Brijet Burton, 410-786-7364 or brijet.burtoncoachman@cms.hhs.gov (Coverage)

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR) or Contractor Manager, as applicable.

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 do 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.

60.12 - Coverage for PET Scans for Dementia and Neurodegenerative Diseases *(Rev.2915, Issued: 03-27-14, Effective: 09-27- 13, Implementation: 07-07-14)*

Effective for dates of service on or after September 15, 2004, Medicare will cover FDG PET scans for a differential diagnosis of fronto-temporal dementia (FTD) and Alzheimer's disease OR; its use in a CMS-approved practical clinical trial focused on the utility of FDG-PET in the diagnosis or treatment of dementing neurodegenerative diseases. Refer to Pub. 100-03, NCD Manual, section 220.6.13, for complete coverage conditions and clinical trial requirements and section 60.15 of this manual for claims processing information.

A. Carrier and FI Billing Requirements for PET Scan Claims for FDG-PET for the Differential Diagnosis of Fronto-temporal Dementia and Alzheimer's Disease:

- CPT Code for PET Scans for Dementia and Neurodegenerative Diseases

Contractors shall advise providers to use the appropriate CPT code from section 60.3.1 for dementia and neurodegenerative diseases for services performed on or after January 28, 2005.

- Diagnosis Codes for PET Scans for Dementia and Neurodegenerative Diseases

The contractor shall ensure one of the following appropriate diagnosis codes is present on claims for PET Scans for AD:

- 290.0, 290.10 - 290.13, 290.20 - 290, 21, 290.3, 331.0, 331.11, 331.19, 331.2, 331.9, 780.93

Medicare contractors shall use an appropriate Medicare Summary Notice (MSN) message such as 16.48, "Medicare does not pay for this item or service for this condition" to deny claims when submitted with an appropriate CPT code from section 60.3.1 and with a diagnosis code other than the range of codes listed above. Also, contractors shall use an appropriate Remittance Advice (RA) such as 11, "The diagnosis is inconsistent with the procedure."

Medicare contractors shall instruct providers to issue an Advanced Beneficiary Notice to beneficiaries advising them of potential financial liability prior to delivering the service if one of the appropriate diagnosis codes will not be present on the claim.

- Provider Documentation Required with the PET Scan Claim

Medicare contractors shall inform providers to ensure the conditions mentioned in the NCD Manual, section 220.6.13, have been met. The information must also be maintained in the beneficiary's medical record:

- Date of onset of symptoms;
- Diagnosis of clinical syndrome (normal aging, mild cognitive impairment or MCI: mild, moderate, or severe dementia);
- Mini mental status exam (MMSE) or similar test score;
- Presumptive cause (possible, probably, uncertain AD);
- Any neuropsychological testing performed;
- Results of any structural imaging (MRI, CT) performed;
- Relevant laboratory tests (B12, thyroid hormone); and,
- Number and name of prescribed medications.

B. Billing Requirements for Beta Amyloid Positron Emission Tomography (PET) in Dementia and Neurodegenerative Disease:

Effective for claims with dates of service on and after September 27, 2013, Medicare will only allow coverage with evidence development (CED) for Positron Emission Tomography (PET) beta amyloid (also referred to as amyloid-beta (A β)) imaging (HCPCS A9586) or (HCPCS A9599) (one PET A β scan per patient).

Note: Please note that effective January 1, 2014 the following code A9599 will be updated in the IOCE and HCPCS update. This code will be contractor priced.

Medicare Summary Notices, Remittance Advice Remark Codes, and Claim Adjustment Reason Codes

Effective for dates of service on or after September 27, 2013, contractors shall **return as unprocessable/return to provider** claims for PET Aβ imaging, through CED during a clinical trial, not containing the following:

- Condition code 30, (FI only)
- Modifier Q0 and/or modifier Q1 as appropriate
- ICD-9 dx code V70.7/ICD-10 dx code Z00.6 (on either the primary/secondary position)
- A PET HCPCS code (78811 or 78814)
- At least, one Dx code from the table below,

| ICD-9 Codes | Corresponding ICD-10 Codes |
|---|---|
| 290.0 Senile dementia, uncomplicated | F03.90 Unspecified dementia without behavioral disturbance |
| 290.10 Presenile dementia, uncomplicated | F03.90 Unspecified dementia without behavioral disturbance |
| 290.11 Presenile dementia with delirium | F03.90 Unspecified dementia without behavioral disturbance |
| 290.12 Presenile dementia with delusional features | F03.90 Unspecified dementia without behavioral disturbance |
| 290.13 Presenile dementia with depressive features | F03.90 Unspecified dementia without behavioral disturbance |
| 290.20 Senile dementia with delusional features | F03.90 Unspecified dementia without behavioral disturbance |
| 290.21 Senile dementia with depressive features | F03.90 Unspecified dementia without behavioral disturbance |
| 290.3 Senile dementia with delirium | F03.90 Unspecified dementia without behavioral disturbance |
| 290.40 Vascular dementia, uncomplicated | F01.50 Vascular dementia without behavioral disturbance |
| 290.41 Vascular dementia with delirium | F01.51 Vascular dementia with behavioral disturbance |
| 290.42 Vascular dementia with delusions | F01.51 Vascular dementia with behavioral disturbance |
| 290.43 Vascular dementia with depressed mood | F01.51 Vascular dementia with behavioral disturbance |
| 294.10 Dementia in conditions classified elsewhere without behavioral disturbance | F02.80 Dementia in other diseases classified elsewhere without behavioral disturbance |
| 294.11 Dementia in conditions classified elsewhere with behavioral disturbance | F02.81 Dementia in other diseases classified elsewhere with behavioral disturbance |
| 294.20 Dementia, unspecified, without behavioral disturbance | F03.90 Unspecified dementia without behavioral disturbance |
| 294.21 Dementia, unspecified, with behavioral disturbance | F03.91 Unspecified dementia with behavioral disturbance |
| 331.11 Pick's Disease | G31.01 Pick's disease |

| | |
|---|--|
| <i>331.19 Other Frontotemporal dementia</i> | <i>G31.09 Other frontotemporal dementia</i> |
| <i>331.6 Corticobasal degeneration</i> | <i>G31.85 Corticobasal degeneration</i> |
| <i>331.82 Dementia with Lewy Bodies</i> | <i>G31.83 Dementia with Lewy bodies</i> |
| <i>331.83 Mild cognitive impairment, so stated</i> | <i>G31.84 Mild cognitive impairment, so stated</i> |
| <i>780.93 Memory Loss</i> | <i>R41.1 Anterograde amnesia R41.2 Retrograde amnesia R41.3 Other amnesia (Amnesia NOS, Memory loss NOS)</i> |
| <i>V70.7 Examination for normal comparison or control in clinical</i> | <i>Z00.6 Encounter for examination for normal comparison and control in clinical research program</i> |

and

- Aβ HCPCS code A9586 or A9599*

Contractors shall return as unprocessable claims for PET Aβ imaging using the following messages:

-Claim Adjustment Reason Code 4 – the procedure code is inconsistent with the modifier used or a required modifier is missing.

Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

- Remittance Advice Remark Code N517 - Resubmit a new claim with the requested information.

- Remittance Advice Remark Code N519 - Invalid combination of HCPCS modifiers.

*Contractors shall line-item **deny** claims for PET Aβ , HCPCS code A9586 or A9599 , where a previous PET Aβ, HCPCS code A9586 or A9599 is paid in history using the following messages:*

- CARC 149: “Lifetime benefit maximum has been reached for this service/benefit category.”*
- RARC N587: “Policy benefits have been exhausted”.*
- MSN 20.12: “This service was denied because Medicare only covers this service once a lifetime.”*
- Spanish Version: “Este servicio fue negado porque Medicare sólo cubre este servicio una vez en la vida.”*
- Group Code: PR, if a claim is received with a GA modifier*
- Group Code: CO, if a claim is received with a GZ modifier*

Attachment A

Beta Amyloid for Dementia and Neurodegenerative Diseases

ICD-9 Codes

Corresponding ICD-10 Codes

| | |
|---|---|
| 290.0 Senile dementia, uncomplicated | F03.90 Unspecified dementia without behavioral disturbance |
| 290.10 Presenile dementia, uncomplicated | F03.90 Unspecified dementia without behavioral disturbance |
| 290.11 Presenile dementia with delirium | F03.90 Unspecified dementia without behavioral disturbance |
| 290.12 Presenile dementia with delusional features | F03.90 Unspecified dementia without behavioral disturbance |
| 290.13 Presenile dementia with depressive features | F03.90 Unspecified dementia without behavioral disturbance |
| 290.20 Senile dementia with delusional features | F03.90 Unspecified dementia without behavioral disturbance |
| 290.21 Senile dementia with depressive features | F03.90 Unspecified dementia without behavioral disturbance |
| 290.3 Senile dementia with delirium | F03.90 Unspecified dementia without behavioral disturbance |
| 290.40 Vascular dementia, uncomplicated | F01.50 Vascular dementia without behavioral disturbance |
| 290.41 Vascular dementia with delirium | F01.51 Vascular dementia with behavioral disturbance |
| 290.42 Vascular dementia with delusions | F01.51 Vascular dementia with behavioral disturbance |
| 290.43 Vascular dementia with depressed mood | F01.51 Vascular dementia with behavioral disturbance |
| 294.10 Dementia in conditions classified elsewhere without behavioral disturbance | F02.80 Dementia in other diseases classified elsewhere without behavioral disturbance |
| 294.11 Dementia in conditions classified elsewhere with behavioral disturbance | F02.81 Dementia in other diseases classified elsewhere with behavioral disturbance |
| 294.20 Dementia, unspecified, without behavioral disturbance | F03.90 Unspecified dementia without behavioral disturbance |
| 294.21 Dementia, unspecified, with behavioral disturbance | F03.91 Unspecified dementia with behavioral disturbance |
| 331.11 Pick's Disease | G31.01 Pick's disease |
| 331.19 Other Frontotemporal dementia | G31.09 Other frontotemporal dementia |
| 331.6 Corticobasal degeneration | G31.85 Corticobasal degeneration |
| 331.82 Dementia with Lewy Bodies | G31.83 Dementia with Lewy bodies |
| 331.83 Mild cognitive impairment, so stated | G31.84 Mild cognitive impairment, so stated |
| 780.93 Memory Loss | R41.1 Anterograde amnesia |

| | |
|--|---|
| | R41.2 Retrograde amnesia R41.3 Other amnesia (Amnesia NOS, Memory loss NOS) |
| V70.7 Examination for normal comparison or control in clinical | Z00.6 Encounter for examination for normal comparison and control in clinical research program |