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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 3478 | Date: March 11, 2016 |
| | Change Request 9557 |

SUBJECT: April 2016 Update of the Ambulatory Surgical Center (ASC) Payment System

I. SUMMARY OF CHANGES: This Recurring Update Notification describes changes to billing instructions for various payment policies implemented in the April 2016 ASC payment system update. This Recurring Update Notification applies to chapter 14, section 10. As appropriate, this notification also includes updates to the Healthcare Common Procedure Coding System (HCPCS).

EFFECTIVE DATE: April 1, 2016

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

IMPLEMENTATION DATE: April 4, 2016

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/revise 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 |
|--------------|---|
| N/A | N/A |

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:

Recurring Update Notification

Attachment - Recurring Update Notification

| | | | |
|-------------|-------------------|----------------------|----------------------|
| Pub. 100-04 | Transmittal: 3478 | Date: March 11, 2016 | Change Request: 9557 |
|-------------|-------------------|----------------------|----------------------|

SUBJECT: April 2016 Update of the Ambulatory Surgical Center (ASC) Payment System

EFFECTIVE DATE: April 1, 2016

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

IMPLEMENTATION DATE: April 4, 2016

I. GENERAL INFORMATION

A. Background: Included in this notification are updates to the ASC payment system, payment rates for separately payable drugs and biologicals, including descriptors for newly created Level II HCPCS codes for drugs and biologicals (ASC DRUG files), and the CY 2016 ASC payment rates for covered surgical and ancillary services (ASCFS file).

Many ASC payment rates under the ASC payment system are established using payment rate information in the Medicare Physician Fee Schedule (MPFS). The payment files associated with this transmittal reflect the most recent changes to CY 2016 MPFS payment.

B. Policy: 1. HCPCS Code C1822 and C1820

As described in the January 2016 Update of the Ambulatory Surgical Center (ASC) Payment System (January 2016 ASC Update) (Change Request 9484, Transmittal 3430), HCPCS code C1822 (Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system) was added to the ASC list as a new pass-through device effective January 1, 2016. HCPCS code C1822 is based on a clinical trial that demonstrated that a high frequency spinal cord stimulator operated at 10,000 Hz and paresthesia-free provides a substantial clinical improvement in pain management versus a low-frequency spinal cord stimulator. No changes are being introduced to C1822 but this information is being announced as the descriptor is closely related to C1820.

In the January 2016 ASC Recurring Update Notification (Change Request 9484, Transmittal 3430, dated December 29, 2015), we added the words “non-high-frequency” to the descriptor of C1820. We are revising the descriptor for C1820 back to its original language and deleting “non-high-frequency” from the descriptor such that the descriptor again states the following: *Generator, neurostimulator (implantable), with rechargeable battery and charging system*. Neurostimulator generators that are not high frequency are to be reported with C1820. It should also be noted that C1820, in the ASC payment system, is a packaged code. ASCs do not report packaged codes, but with the change in the descriptor for HCPCS code C1820, it is important to announce the differentiation between HCPCS code C1822 and C1820.

The latest short and long descriptor for HCPCS code C1820 can be found on the CMS HCPCS website at <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update.html>

2. Drugs, Biologicals, and Radiopharmaceuticals

a. Drugs and Biologicals with Payments Based on Average Sales Price (ASP) Effective April 1, 2016

For CY 2016, payment for nonpass-through drugs, biologicals and therapeutic radiopharmaceuticals is made at a single rate of ASP + 6 percent, which provides payment for both the acquisition cost and pharmacy overhead costs associated with the drug, biological or therapeutic radiopharmaceutical. In CY 2016, a single payment of ASP + 6 percent for pass-through drugs, biologicals and radiopharmaceuticals is made to provide payment for both the acquisition cost and pharmacy overhead costs of these pass-through items. Payments for drugs and biologicals based on ASPs will be updated on a quarterly basis as later quarter ASP

submissions become available. Updated payment rates effective April 1, 2016 can be found in the April 2016 ASC Addendum BB on the CMS Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/11_Addenda_Updates.html .

b. Separately Payable CY 2016 HCPCS Codes and Dosage Descriptors for Certain Drugs, Biologicals, and Radiopharmaceuticals Effective April 1, 2016

For April 2016, nine new HCPCS codes have been created for reporting drugs and biologicals in the ASC setting. Additionally, one existing code, J7503, is now separately payable. These codes, their descriptors, and payment indicator are listed in Table 1. (see Attachment A: Policy Section Tables)

c. Revised ASC Payment Indicator for HCPCS Codes

Effective April 1, 2016, the payment indicator for HCPCS code J0130 (Injection abciximab, 10 mg) will change from ASC PI= K2 (Drugs and biologicals paid separately when provided integral to a surgical procedure on ASC list; payment based on OPPS rate.) to ASC PI=N1 (Packaged service/item; no separate payment made.).

Effective April 1, 2016, the payment indicator for HCPCS code J0583 (Injection, bivalirudin, 1 mg) will change from ASC PI= K2 (Drugs and biologicals paid separately when provided integral to a surgical procedure on ASC list; payment based on OPPS rate.) to ASC PI=N1 (Packaged service/item; no separate payment made.).

d. Drugs and Biologicals Based on ASP Methodology with Restated Payment Rates

Some drugs and biologicals based on ASP methodology may have payment rates that are corrected retroactively. These retroactive corrections typically occur on a quarterly basis. The list of drugs and biologicals with corrected payments rates will be accessible on the CMS Web site on the first date of the quarter at <http://cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/index.html>

Suppliers who think they may have received an incorrect payment for drugs and biologicals impacted by these corrections may request contractor adjustment of the previously processed claims.

3. Coverage Determinations

The fact that a drug, device, procedure or service is assigned a HCPCS code and a payment rate under the ASC payment system does not imply coverage by the Medicare program, but indicates only how the product, procedure, or service may be paid if covered by the program. Medicare Administrative Contractors (MACs) determine whether a drug, device, procedure, or other service meets all program requirements for coverage. For example, MACs determine that it is reasonable and necessary to treat the beneficiary's condition and whether it is excluded from payment.

4. Attachments

Attachment A: POLICY SECTION TABLES

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 A C | F I S S | M C S | V M S | C W F | |
|----------|---|---|---|-------------|-------------|------------------|-------------|-------------|-------------|------|
| 9557.1 | <p>Medicare contractors shall download and install the April 2016 ASC DRUG file.</p> <p>FILENAME: MU00.@BF12390.ASC.CY16.DRUG.APRA.V0325</p> <p>NOTE: Date of retrieval will be provided in a separate email communication from CMS.</p> | | X | | | | | | | VDCs |
| 9557.2 | <p>Medicare contractors shall download and install the April 2016 ASC PI file.</p> <p>FILENAME: MU00.@BF12390.ASC.CY16.PI.APRA.V0311</p> <p>NOTE: Date of retrieval will be provided in a separate email communication from CMS.</p> | | X | | | | | | | VDCs |
| 9557.3 | <p>If released by CMS, Medicare contractors shall download and install the revised January 2016 ASC DRUG file.</p> <p>FILENAME: MU00.@BF12390.ASC.CY16.DRUG.JANB.V0325</p> <p>NOTE: Date of retrieval will be provided in a separate email communication from CMS.</p> | | X | | | | | | | VDCs |
| 9557.3.1 | <p>Medicare contractors shall adjust as appropriate claims brought to their attention that:</p> <p>1) Have dates of service January 1, 2016- March 31, 2016 and ;</p> <p>2) Were originally processed prior to the installation of the revised January 2016 ASC DRUG File.</p> | | X | | | | | | | |
| 9557.4 | <p>If released by CMS, Medicare contractors shall download and install the revised October 2015 ASC DRUG file.</p> <p>FILENAME: MU00.@BF12390.ASC.CY15.DRUG.OCTC.V0325</p> <p>NOTE: Date of retrieval will be provided in a separate email communication from CMS.</p> | | X | | | | | | | VDCs |
| 9557.4.1 | <p>Medicare contractors shall adjust as appropriate claims brought to their attention that:</p> <p>1) Have dates of service October 1, 2015- December</p> | | 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 | |
| | 31, 2015 and ; 2) Were originally processed prior to the installation of the revised October 2015 ASC DRUG File. | | | | | | | | | |
| 9557.5 | If released by CMS, Medicare contractors shall download and install the revised July 2015 ASC DRUG file. FILENAME: MU00.@BF12390.ASC.CY15.DRUG.JULC.V0325 NOTE: Date of retrieval will be provided in a separate email communication from CMS. | | X | | | | | | VDCs | |
| 9557.5.1 | Medicare contractors shall adjust as appropriate claims brought to their attention that: 1) Have dates of service July 1, 2015- September 30, 2015 and ; 2) Were originally processed prior to the installation of the revised July 2015 ASC DRUG File. | | X | | | | | | | |
| 9557.6 | If released by CMS, Medicare contractors shall download and install the revised April 2015 ASC DRUG file. FILENAME: MU00.@BF12390.ASC.CY15.DRUG.APRC.V0325 NOTE: Date of retrieval will be provided in a separate email communication from CMS. | | X | | | | | | VDCs | |
| 9557.6.1 | Medicare contractors shall adjust as appropriate claims brought to their attention that: 1) Have dates of service April 1, 2015- June 30, 2015 and ; 2) Were originally processed prior to the installation of the revised April 2015 ASC DRUG File. | | X | | | | | | | |
| 9557.7 | Contractors and CWF shall add TOS F, as appropriate, for HCPCS included in attachment A, table 1, effective for services April 1, 2016 and later payable | | 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 | |
| | in the ASC setting. | | | | | | | | | |
| 9557.8 | Contractors and CWF shall add/revise descriptors, as appropriate, for HCPCS included in attachment A, table 1, and C1820, effective for services April 1, 2016 and later payable in the ASC setting. | | 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 | | |
| 9557.9 | 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 | | | |

IV. SUPPORTING INFORMATION

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

"Should" denotes a recommendation.

| X-Ref Requirement Number | Recommendations or other supporting information: |
|--------------------------|--|
| 2 | Attachment A: POLICY SECTION TABLES |
| 1 | Attachment A: POLICY SECTION TABLES |

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

V. CONTACTS

Pre-Implementation Contact(s): Chuck Braver, 410-786-6719 or chuck.braver@cms.hhs.gov (ASC Payment Policy) , Yvette Cousar, 410-786-2160 or yvette.cousar@cms.hhs.gov (Carrier/ AB MAC Claims Processing Issues) , Mark Baldwin, 410-786-8139 or mark.baldwin@cms.hhs.gov (Carrier/ AB MAC Claims Processing Issues)

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: 1

POLICY SECTION TABLES

Table 1 – Separately Payable CY 2016 HCPCS Codes and Dosage Descriptors for Certain Drugs, Biologicals, and Radiopharmaceuticals Effective April 1, 2016

| HCPCS Code | Short Descriptor | Long Descriptor | ASC PI |
|-------------------|------------------------------|---|---------------|
| C9137 | Adynovate Factor VIII recom | Injection, Factor VIII (antihemophilic factor, recombinant) PEGylated, 1 I.U. | K2 |
| C9138 | Nuwiq Factor VIII recomb | Injection, Factor VIII (antihemophilic factor, recombinant) (Nuwiq), 1 I.U. | K2 |
| C9461 | Choline C 11, diagnostic | Choline C 11, diagnostic, per study dose | K2 |
| C9470 | Aripiprazole lauroxil im | Injection, aripiprazole lauroxil, 1 mg | K2 |
| C9471 | Hymovis, 1 mg | Hyaluronan or derivative, Hymovis, for intra-articular injection, 1 mg | K2 |
| C9472 | Inj talimogene laherparepvec | Injection, talimogene laherparepvec, 1 million plaque forming units (PFU) | K2 |
| C9473 | Injection, mepolizumab | Injection, mepolizumab, 1 mg | K2 |
| C9474 | Inj, irinotecan liposome | Injection, irinotecan liposome, 1 mg | K2 |
| C9475 | Injection, necitumumab | Injection, necitumumab, 1 mg | K2 |
| J7503 | Tacrol envarsus ex rel oral | Tacrolimus, extended release, (envarsus xr), oral, 0.25 mg | K2 |