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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 4125 | Date: August 31, 2018 |
| | Change Request 10932 |

SUBJECT: October 2018 Update of the Ambulatory Surgical Center (ASC) Payment System

I. SUMMARY OF CHANGES: This Recurring Update Notification describes policy and billing changes to the October 2018 ASC payment system update.

EFFECTIVE DATE: October 1, 2018

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

IMPLEMENTATION DATE: October 1, 2018

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 |
|--------------|---|
| 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: 4125 | Date: August 31, 2018 | Change Request: 10932 |
|-------------|-------------------|-----------------------|-----------------------|

SUBJECT: October 2018 Update of the Ambulatory Surgical Center (ASC) Payment System

EFFECTIVE DATE: October 1, 2018

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

IMPLEMENTATION DATE: October 1, 2018

I. GENERAL INFORMATION

A. Background: This Recurring Update Notification describes changes to and billing instructions for various payment policies implemented in the October 2018 ASC payment system update. As appropriate, this notification also includes updates to the Healthcare Common Procedure Coding System (HCPCS).

Included in this notification are calendar year (CY) 2018 payment rates for separately payable drugs and biologicals, including descriptors for newly created Level II HCPCS codes for drugs and biologicals (ASC DRUG) files. We are also including an update file for the Ambulatory Surgical Center Fee Schedule (ASCFS), and an Ambulatory Surgical Center Payment Indicator (ASC PI) File. No ASC Code Pair file is being issued.

B. Policy: 1. New Separately Payable Procedure Code Effective October 1, 2018

Effective October 1, 2018, HCPCS code C9750 has been created as described in Table 1, (see Attachment A: Policy Section Tables). This procedure was previously described by Category III CPT code 0302T which was deleted December 31, 2017.

2. Drugs and Biologicals

a. Drugs and Biologicals with Payments Based on Average Sales Price (ASP) Effective October 1, 2018

For CY 2018, payment for nonpass-through drugs and biologicals continues to be 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 or biological. In addition, in CY 2018, a single payment of ASP + 6 percent continues to be made for OPSS pass-through drugs, and biologicals 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 October 1, 2018, can be found in the October 2018 update of ASC Addendum BB on the CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/11_Addenda_Updates.html.

b. HCPCS Codes and Dosage Descriptors for Certain Drugs and Biologicals Effective October 1, 2018

Two (2) new HCPCS codes have been created for reporting drugs and biologicals in the ASC payment system effective October 1, 2018, where there have not previously been specific codes available. These new codes are listed in Table 2 (see Attachment A: Policy Section Tables).

c. HCPCS Code Payment Indicator Changes to Separately Payable Status Effective October 1, 2018

Four (4) HCPCS codes will have their ASC PI change from ASC PI=N1 (Packaged service/item; no separate payment made.) to ASC PI= K2 (Drugs and biologicals paid separately when provided integral to a surgical procedure on ASC list; payment based on OPPS rate.) effective October 1, 2018. The HCPCS codes, their July 2018 ASC PI, and their new ASC PI effective October 1, 2018 are listed in Table 3 (see Attachment A: Policy Section Tables).

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 payment rates will be accessible on the CMS Web site on the first date of the quarter at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Restated-Payment-Rates.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.

e. New Biosimilar HCPCS Code Effective July 12, 2018

HCPCS code Q5108, listed in Table 4, (see Attachment A: Policy Section Tables), is a biosimilar with the trade name Fulphila that will be paid separately in the ASC payment system. The code will be included in the ASC payment system with an effective date retroactive to July 12, 2018, per CR 10834 which states that HCPCS code is payable for Medicare for claims with a date of service on or after July 12, 2018.

3. Reassignment of Skin Substitute Product from the Low Cost Group to the High Cost Group

The payment for skin substitute products that do not qualify for hospital outpatient prospective payment system (OPPS) pass-through status are packaged into the OPSS payment for the associated skin substitute application procedure. This policy is also implemented in the ASC payment system. The skin substitute products are divided into two groups: 1) high cost skin substitute products and 2) low cost skin substitute products for packaging purposes. Table 4, (see Attachment A: Policy Section Tables), lists the skin substitute product and its assignment as either a high cost or a low cost skin substitute product, when applicable. ASCs should not separately bill for packaged skin substitutes (ASC PI=N1). High cost skin substitute products should only be utilized in combination with the performance of one of the skin application procedures described by CPT codes 15271-15278. Low cost skin substitute products should only be utilized in combination with the performance of one of the skin application procedures described by HCPCS code C5271-C5278. All OPSS pass-through skin substitute products (ASC PI=K2) should be billed in combination with one of the skin application procedures described by CPT code 15271-15278.

The skin substitute product listed in Table 5 has been reassigned from the low cost skin substitute group to the high cost skin substitute group based on updated pricing information. Please note that this skin substitute product is packaged and should not be separately billed by ASCs.

4. 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.

5. Attachment

II. BUSINESS REQUIREMENTS TABLE

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

| 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 | |
| 10932.1 | <p>Medicare contractors shall download the October 2018 ASCFS from the CMS mainframe.</p> <p>FILENAME: MU00.@BF12390.ASC.CY18.FS.OCTA.V0904</p> <p>NOTE: The October 2018 ASCFS is a partial update.</p> <p>NOTE: Date of retrieval will be provided in a separate email communication from CMS.</p> | | X | | | | | | VDC |
| 10932.2 | <p>Medicare contractors shall download and install the October 2018 ASC DRUG file.</p> <p>FILENAME: MU00.@BF12390.ASC.CY18.DRUG.OCTA.V0921</p> <p>NOTE: Date of retrieval will be provided in a separate email communication from CMS.</p> | | X | | | | | | VDC |
| 10932.3 | <p>Medicare contractors shall download and install the October 2018 ASC PI file.</p> <p>FILENAME: MU00.@BF12390.ASC.CY18.PI.OCTA.V0907</p> <p>NOTE: Date of retrieval will be provided in a separate email communication from CMS.</p> | | X | | | | | | VDC |
| 10932.4 | <p>Contractors and CWF shall add TOS F for HCPCS included in attachment A, table 1-2, effective for services October 1, 2018 and later payable in the ASC</p> | | X | | | | | X | |

| Number | Requirement | Responsibility | | | | | | | | |
|-----------|---|----------------|---|-------------|----------------------------|----------------------------------|-------------|-------------|-------------|-------|
| | | A/B MAC | | H H H | D M E M A C | Shared- System Maintainers | | | | Other |
| | | A | B | | | F I S S | M C S | V M S | C W F | |
| | setting. | | | | | | | | | |
| 10932.5 | Contractors and CWF shall add TOS F for HCPCS included in attachment A, table 4, effective for services July 12, 2018 and later payable in the ASC setting. | | X | | | | | | X | |
| 10932.6 | If released by CMS, Medicare contractors shall download and install the revised July 2018 ASC DRUG file. FILENAME: MU00.@BF12390.ASC.CY18.DRUG.JULB.V0921 NOTE: Date of retrieval will be provided in a separate email communication from CMS. | | X | | | | | | VDC | |
| 10932.6.1 | Medicare contractors shall adjust as appropriate claims brought to their attention that: 1) Have dates of service July 1, 2018 - September 30, 2018; and 2) Were originally processed prior to the installation of the revised July 2018 ASC DRUG File. | | X | | | | | | | |
| 10932.7 | If released by CMS, Medicare contractors shall download and install the revised April 2018 ASC DRUG file. FILENAME: MU00.@BF12390.ASC.CY18.DRUG.APRB.V0921 NOTE: Date of retrieval will be provided in a separate email communication from CMS. | | X | | | | | | VDC | |
| 10932.7.1 | Medicare contractors shall adjust as appropriate claims brought to their attention that: | | X | | | | | | | |

| Number | Requirement | Responsibility | | | | | | | | | |
|-----------|---|----------------|---|-------------|----------------------------|----------------------------------|-------------|-------------|-------------|-------|--|
| | | A/B MAC | | H H H | D M E M A C | Shared- System Maintainers | | | | Other | |
| | | A | B | | | F I S S | M C S | V M S | C W F | | |
| | <p>1) Have dates of service April 1, 2018 - June 30, 2018; and</p> <p>2) Were originally processed prior to the installation of the revised April 2018 ASC DRUG File.</p> | | | | | | | | | | |
| 10932.8 | <p>If released by CMS, Medicare contractors shall download and install the revised January 2018 ASC DRUG file.</p> <p>FILENAME: MU00.@BF12390.ASC.CY18.DRUG.JANB.V0921</p> <p>NOTE: Date of retrieval will be provided in a separate email communication from CMS.</p> | | X | | | | | | | VDC | |
| 10932.8.1 | <p>Medicare contractors shall adjust as appropriate claims brought to their attention that:</p> <p>1) Have dates of service January 1, 2018 - March 31, 2018; and</p> <p>2) Were originally processed prior to the installation of the revised January 2018 ASC DRUG File.</p> | | X | | | | | | | | |
| 10932.9 | <p>If released by CMS, Medicare contractors shall download and install the revised October 2017 ASC DRUG file.</p> <p>FILENAME: MU00.@BF12390.ASC.CY17.DRUG.OCTC.V0921</p> <p>NOTE: Date of retrieval will be provided in a separate email communication from CMS.</p> | | X | | | | | | | VDC | |
| 10932.9.1 | <p>Medicare contractors shall adjust as appropriate claims brought to their attention that:</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 | | |
| | <p>1) Have dates of service October 1, 2017 - December 31, 2017; and</p> <p>2) Were originally processed prior to the installation of the revised October 2017 ASC DRUG File.</p> | | | | | | | | | | |
| 10932.10 | Contractors shall make October 2018 ASCFS fee data for their ASC payment localities available on their web sites. | | X | | | | | | | | |
| 10932.11 | Contractors shall notify CMS of successful receipt via e-mail to price_file_receipt@cms.hhs.gov stating the name of the file received, (e.g., CLAB, ASP, etc.) and the entity for which it was received (i.e., include states, carrier numbers, quarter, and if Part A, Part B, or both). | | X | | | | | | | VDC | |

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 | | | | |
| 10932.12 | MLN Article: CMS will make available an MLN Matters provider education article that will be marketed through the MLN Connects weekly newsletter shortly after the CR is released. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1, instructions for distributing MLN Connects information to providers, posting the article or a direct link to the article on your website, and including the article or a direct link to the article in your bulletin or newsletter. You may supplement MLN Matters articles with localized information benefiting your provider community in billing and administering the Medicare program correctly. Subscribe to the “MLN Matters” listserv to get article release notifications, or review them in the MLN Connects weekly newsletter. | | 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: |
|--------------------------|--|
| 1-5 | Attachment A: POLICY SECTION TABLES |

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

V. CONTACTS

Pre-Implementation Contact(s): Yvette Cousar, 410-786-2160 or yvette.cousar@cms.hhs.gov (Part B MAC Claims Processing) , Chuck Braver, 410-786-6719 or chuck.braver@cms.hhs.gov (ASC Payment Policy)

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

Attachment A – Policy Section Tables

Table 1. – New Separately Payable Procedure Code Effective October 1, 2018

| HCPCS Code | Short Descriptor | Long Descriptor | ASC PI |
|------------|----------------------------|--|--------|
| C9750 | Ins/rem-replace compl iims | Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation and peri-operative interrogation and programming; complete system (includes device and electrode) | G2 |

Table 2. – HCPCS Codes and Dosage Descriptors for Certain Drugs and Biologicals Effective October 1, 2018

| HCPCS Code | Short Descriptor | Long Descriptor | ASC PI |
|------------|-----------------------------|--|--------|
| C9033 | Inj, akynzeo | Injection, fosnetupitant 235 mg and palonosetron 0.25 mg | K2 |
| C9034 | Injection, dexamethasone 9% | Injection, dexamethasone 9%, intraocular, 1 mcg | K2 |

Table 3. – HCPCS Code Payment Indicator Changes to Separately Payable Status Effective October 1, 2018

| HCPCS Code | Short Descriptor | ASC PI Effective July 1, 2018 | ASC PI Effective October 1, 2018 |
|------------|------------------------------|-------------------------------|----------------------------------|
| A9586 | Florbetapir f18 | N1 | K2 |
| C9447 | Inj, phenylephrine ketorolac | N1 | K2 |
| Q4172 | Puraply or puraply am | N1 | K2 |
| Q9950 | Inj sulf hexa lipid microsph | N1 | K2 |

Table 4. – New Biosimilar HCPCS Code Effective July 12, 2018

| HCPCS Code | Short Descriptor | Long Descriptor | ASC PI | Effective Date |
|-------------------|-------------------------|---|---------------|-----------------------|
| Q5108 | Injection, fulphila | Injection, pegfilgrastim-jmdb, biosimilar, (fulphila), 0.5 mg | K2 | 07/12/2018 |

Table 5. – Reassignment of Skin Substitute Product from the Low Cost Group to the High Cost Group

| HCPCS Code | Short Descriptor | ASC PI | Low/High Cost Skin Substitute |
|-------------------|----------------------------|---------------|--------------------------------------|
| Q4181 | Amnio wound, per square cm | N1 | High |