



January 2018 Update of the Ambulatory Surgical Center (ASC) Payment System

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Related Change Request (CR) Number: 10441

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Related CR Transmittal Number: R3939CP Implementation Date: January 2, 2018

PROVIDER TYPE AFFECTED

This MLN Matters Article is intended for Ambulatory Surgical Centers (ASCs) billing Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

WHAT YOU NEED TO KNOW

Change Request (CR) 10441 informs MACs about updates to the ASC payment system for January 2018. Be sure your billing staffs are aware of these changes.

BACKGROUND

CR10441 includes changes to and billing instructions for various payment policies implemented in the January 2018 ASC payment system update and also includes updates to the Healthcare Common Procedure Coding System (HCPCS).

This notification includes 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), and the CY 2018 ASC Payment Rates for Covered Surgical and Ancillary Services (ASCFS file). No ASC Code Pair file is being issued with this notice.

ASC payment rates under the ASC payment system are generally established using payment rate information in the hospital Outpatient Prospective Payment System (OPPS) or the Medicare Physician Fee Schedule (MPFS). The payment files associated with CR10441 reflect the most recent changes to CY 2018 OPPS and CY 2018 MPFS payments.

The changes in CR10441 are as follows:

1. a. New Device Pass-Through Policies

Section 1833(t)(6)(B) of the Social Security Act (the Act) requires that, under the OPPS,

categories of devices be eligible for transitional pass-through payments for at least two (2), but not more than three (3) years. Section 1833(t)(6)(B)(ii)(IV) of the Act requires that the Centers for Medicare & Medicaid Services (CMS) creates additional categories for transitional pass-through payment of new medical devices not described by existing or previously existing categories of devices. This policy was implemented in the 2008 revised ASC payment system. Therefore, additional payments may be made to the ASC for covered ancillary services, including certain implantable devices with pass-through status under the Outpatient Prospective Payment System (OPPS).

Effective January 1, 2018, there are no device categories eligible for pass-through payment. However, an existing device described by HCPCS code C2623 (*Catheter, transluminal angioplasty, drug coated, non laser*) was recently approved by Food and Drug Administration (FDA) for a new indication, specifically the treatment of patients with Dysfunctional Arteriovenous (AV) fistulae.

Accordingly, in this January 2018 update, devices described by HCPCS code C2623 are eligible for pass-through status retroactive to August 25, 2017, when the device is billed with Current Procedural Terminology (CPT) code 36902 (*Introduction of needle(s) and/or catheter(s), dialysis circuit, with diagnostic angiography of the dialysis circuit, including all direct puncture(s) and catheter placement(s), injection(s) of contrast, all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava, fluoroscopic guidance, radiological supervision and interpretation and image documentation and report; with transluminal balloon angioplasty, peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty*) or CPT code 36903 (*Insertion of needle and/or catheter into dialysis circuit and insertion of stent in dialysis segment, with imaging including radiological supervision and interpretation*). This device pass through status will be applied retroactively from August 25, 2017, through December 31, 2017.

1. b. Device Offset from Payment for Device Category

Section 1833(t)(6)(D)(ii) of the Act requires that CMS deduct from pass-through payments for devices an amount that reflects the portion of the Ambulatory Payment Classifications (APC) payment amount. With respect to device code C2623, CMS has previously determined that the costs associated with C2623 are not reflected in the APC payment amount. Therefore, CMS is not applying a device offset to the retroactive pass-through payments for C2623. Retroactive pass-through payments for services furnished on August 25, 2017, through December 31, 2017, without deduction, will only apply when HCPCS code C2623 is billed with CPT codes 36902 or 36903.

2. New Separately Payable Procedure Code, Effective January 1, 2018

Effective January 1, 2018, new HCPCS code C9748 has been created as described in Table 1.

Table 1 – New Separately Payable Procedure Code, Effective January 1, 2018

| HCPCS Code | Short Descriptor | Long Descriptor | ASC PI |
|-------------------|-----------------------------|---|---------------|
| C9748 | Prostatic rf water vapor tx | Transurethral destruction of prostate tissue; by radiofrequency water vapor (steam) thermal therapy | G2 |

3. Drugs, Biologicals, and Radiopharmaceuticals

a. New CY 2018 HCPCS Codes and Dosage Descriptors for Certain Drugs, Biologicals, and Radiopharmaceuticals

For CY 2018, several new HCPCS codes have been created for reporting drugs and biologicals in the ASC payment system, where there have not previously been specific codes available. These new codes are listed in Table 2.

Table 2 – New CY 2018 HCPCS Codes and Dosage Descriptors for Certain Drugs, Biologicals, and Radiopharmaceuticals

| HCPCS Code | Short Descriptor | Long Descriptor | ASC PI |
|-------------------|------------------------------|--|---------------|
| C9014 | Injection, cerliponase alfa | Injection, cerliponase alfa, 1 mg | K2 |
| C9015 | C-1 esterase, haegarda | Injection, c-1 esterase inhibitor (human), Haegarda, 10 units | K2 |
| C9016 | Inj, triptorelin ext rel | Injection, triptorelin extended release, 3.75 mg | K2 |
| C9024 | Inj, daunorubicin-cytarabine | Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine | K2 |
| C9028 | Inj. inotuzumab ozogamicin | Injection, inotuzumab ozogamicin, 0.1 mg | K2 |
| C9029 | Injection, guselkumab | Injection, guselkumab, 1 mg | K2 |
| J0606 | Inj, etelcalcetide, 0.1 mg | Injection, etelcalcetide, 0.1 mg | K2 |

| HCPCS Code | Short Descriptor | Long Descriptor | ASC PI |
|------------|------------------------------|--|--------|
| J1555 | Inj cuvitru, 100 mg | Injection, immune globulin (cuvitru), 100 mg | K2 |
| J7211 | Inj, kovaltry, 1 i.u. | Injection, factor viii, (antihemophilic factor, recombinant), (kovaltry), 1 i.u. | K2 |
| J7345 | Aminolevulinic acid, 10% gel | Aminolevulinic acid hcl for topical administration, 10% gel, 10 mg | K2 |
| J9203 | Gemtuzumab ozogamicin 0.1 mg | Injection, gemtuzumab ozogamicin, 0.1 mg | K2 |
| Q2040 | Tisagenlecleucel car-pos t | Tisagenlecleucel, up to 250 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per infusion | K2 |

b. Other Changes to CY 2018 HCPCS and CPT Codes for Certain Drugs, Biologicals, and Radiopharmaceuticals

Many HCPCS and CPT codes for drugs, biologicals, and radiopharmaceuticals have undergone changes in their HCPCS and CPT code descriptors that will be effective in CY 2018. In addition, several temporary HCPCS C-codes have been deleted, effective December 31, 2017, and replaced with permanent HCPCS codes in CY 2018. ASCs should pay close attention to accurate billing for units of service consistent with the dosages contained in the long descriptors of the CY 2018 HCPCS and CPT codes.

Table 3 notes those drugs, biologicals, and radiopharmaceuticals that have undergone changes in their HCPCS/CPT code, their long descriptor, or both. Each product's CY 2017 HCPCS/CPT code and long description is included.

Table 3 – Other CY 2018 HCPCS and CPT Code Changes for Certain Drugs, Biologicals, and Radiopharmaceuticals

| CY 2017 HCPCS Code | CY 2017 Long Descriptor | CY 2018 HCPCS Code | CY 2018 Long Descriptor |
|--------------------|--------------------------------|--------------------|--------------------------------|
| C9490 | Injection, bezlotoxumab, 10 mg | J0565 | Injection, bezlotoxumab, 10 mg |

| CY 2017 HCPCS Code | CY 2017 Long Descriptor | CY 2018 HCPCS Code | CY 2018 Long Descriptor |
|--------------------|---|--------------------|---|
| C9484 | Injection, eteplirsen, 10 mg | J1428 | Injection, eteplirsen, 10 mg |
| C9486 | Injection, granisetron extended release, 0.1 mg | J1627 | Injection, granisetron, extended-release, 0.1 mg |
| Q9986 | Injection, hydroxyprogesterone caproate (Makena), 10 mg | J1726 | Injection, hydroxyprogesterone caproate (Makena), 10 mg |
| C9489 | Injection, nusinersen, 0.1 mg | J2326 | Injection, nusinersen, 0.1 mg |
| C9494 | Injection, ocrelizumab, 1 mg | J2350 | Injection, ocrelizumab, 1 mg |
| Q9989 | Ustekinumab, for Intravenous Injection, 1 mg | J3358 | Ustekinumab, for intravenous injection, 1 mg |
| C9140 | Injection, Factor VIII (antihemophilic factor, recombinant) (Afstyla), 1 I.U. | J7210 | Injection, factor viii, (antihemophilic factor, recombinant), (Afstyla), 1 i.u. |
| C9483 | Injection, atezolizumab, 10 mg | J9022 | Injection, atezolizumab, 10 mg |
| C9491 | Injection, avelumab, 10 mg | J9023 | Injection, avelumab, 10 mg |
| C9485 | Injection, olaratumab, 10 mg | J9285 | Injection, olaratumab, 10 mg |

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

For CY 2018, payment for non-pass-through drugs, biologicals and therapeutic radiopharmaceuticals 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, biological or therapeutic radiopharmaceutical. In addition, in CY 2018, a single payment of ASP + 6 percent continues to be made 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.

Effective January 1, 2018, payment rates for many drugs and biologicals have changed from the

values published in the CY 2018 OPPS/ASC final rule with comment period as a result of the new ASP calculations based on sales price submissions from the third quarter of CY 2017. In cases where adjustments to payment rates are necessary, CMS is not publishing the updated payment rates in CR10441.

However, all ASC payable drugs and biologicals, effective January 1, 2018, including those that were updated as a result of the new ASP calculations are in the January 2018 ASC Addendum BB at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/11_Addenda_Updates.html.

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 first date of the quarter at <http://www.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.

e. Biosimilar Biological Product Payment Policy

Effective January 1, 2018, the payment rate for biosimilars approved for payment in the ASC payment system will be the same as the payment rate in the OPPS and physician office setting, calculated as the ASP of the biosimilar(s) described by the HCPCS code + 6 percent of the ASP of the reference product. Payment will be made at the single ASP + 6 percent rate.

As a reminder, ASC claims for separately paid biosimilar biological products are required to include the modifier that identifies the manufacturer of the specific product. The modifier does not affect payment determination, but is used to distinguish between biosimilar products that appear in the same HCPCS code, but are made by different manufacturers. Any changes to the billing requirements for biosimilar biological products will be issued to ASCs in a future transmittal.

f. Skin-Substitute Assignments to High-Cost and Low-Cost Groups for CY 2018

The payment for skin-substitute products that do not qualify for hospital OPPS pass-through status are packaged into the OPPS 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 lists the skin-substitute products and their 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). Note that:

- High-cost skin-substitute products should only be used 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 used 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.

Note: All of the skin substitute products listed in this table are packaged and should not be separately billed by ASCs.

Table 4 – Skin-Substitute Assignments to High-Cost and Low-Cost Groups for CY 2018

| HCPCS Code | 2018 Short Descriptor | ASC PI | CY 2018 High/Low Assignment |
|------------|------------------------------|--------|-----------------------------|
| C9363 | Integra meshed bil wound mat | N1 | High |
| Q4100 | Skin substitute, nos | N1 | Low |
| Q4101 | Apligraf | N1 | High |
| Q4102 | Oasis wound matrix | N1 | Low |
| Q4103 | Oasis burn matrix | N1 | High |
| Q4104 | Integra bmwd | N1 | High |
| Q4105 | Integra drt or omnigraft | N1 | High |
| Q4106 | Dermagraft | N1 | High |
| Q4107 | Graftjacket | N1 | High |
| Q4108 | Integra matrix | N1 | High |
| Q4110 | Primatrix | N1 | High |
| Q4111 | Gammagraft | N1 | Low |

| HCPCS Code | 2018 Short Descriptor | ASC PI | CY 2018 High/Low Assignment |
|------------|------------------------------|--------|-----------------------------|
| Q4115 | Alloskin | N1 | Low |
| Q4116 | Alloderm | N1 | High |
| Q4117 | Hyalomatrix | N1 | Low |
| Q4121 | Theraskin | N1 | High |
| Q4122 | Dermacell | N1 | High |
| Q4123 | Alloskin | N1 | High |
| Q4124 | Oasis tri-layer wound matrix | N1 | Low |
| Q4126 | Memoderm/derma/tranz/integup | N1 | High |
| Q4127 | Talymed | N1 | High |
| Q4128 | Flexhd/allopachhd/matrixhd | N1 | High |
| Q4131 | Epifix or epicord | N1 | High |
| Q4132 | Grafix core, grafixpl core | N1 | High |
| Q4133 | Grafix prime grafix pl prime | N1 | High |
| Q4134 | Hmatrix | N1 | Low |
| Q4135 | Mediskin | N1 | Low |
| Q4136 | Ezderm | N1 | Low |
| Q4137 | Amnioexcel or biodexcel, 1cm | N1 | High |
| Q4138 | Biodfence dryflex, 1cm | N1 | High |
| Q4140 | Biodfence 1cm | N1 | High |
| Q4141 | Alloskin ac, 1cm | N1 | High |
| Q4143 | Repriza, 1cm | N1 | High |
| Q4146 | Tensix, 1 cm | N1 | High |
| Q4147 | Architect ecm px fx 1 sq cm | N1 | High |
| Q4148 | Neox rt or clarix cord | N1 | High |

| HCPCS Code | 2018 Short Descriptor | ASC PI | CY 2018 High/Low Assignment |
|-------------------|-------------------------------|---------------|------------------------------------|
| Q4150 | Allowrap ds or dry 1 sq cm | N1 | High |
| Q4151 | Amnioband, guardian 1 sq cm | N1 | High |
| Q4152 | Dermapure 1 square cm | N1 | High |
| Q4153 | Dermavest, plurivest sq cm | N1 | High |
| Q4154 | Biovance 1 square cm | N1 | High |
| Q4156 | Neox 100 or clarix 100 | N1 | High |
| Q4157 | Revitalon 1 square cm | N1 | High |
| Q4158 | Neox 100 or clarix 100 | N1 | High |
| Q4159 | Neox 100 or clarix 100 | N1 | High |
| Q4160 | Neox 100 or clarix 100 | N1 | High |
| Q4161 | Bio-Connekt per square cm | N1 | High |
| Q4163 | Woundex, bioskin, per sq cm | N1 | High |
| Q4164 | Helicoll, per square cm | N1 | High |
| Q4165 | Keramatrix, per square cm | N1 | Low |
| Q4166 | Cytal, per square cm | N1 | Low |
| Q4167 | Truskin, per square cm | N1 | Low |
| Q4169 | Artacent wound, per square cm | N1 | High |
| Q4170 | Cygnus, per square cm | N1 | Low |
| Q4172* | Puraply or puraply am | N1 | High |
| Q4173 | Palingen or palingen xplus | N1 | High |
| Q4175 | Miroderm | N1 | High |
| Q4176* | Neopatch, per sq centimeter | N1 | Low |
| Q4178* | Floweramniopatch, per sq cm | N1 | Low |
| Q4179* | Flowerderm, per sq cm | N1 | Low |

| HCPCS Code | 2018 Short Descriptor | ASC PI | CY 2018 High/Low Assignment |
|------------|------------------------------|--------|-----------------------------|
| Q4180* | Revita, per sq cm | N1 | Low |
| Q4181* | Amnio wound, per square cm | N1 | Low |
| Q4182* | Transcyte, per sq centimeter | N1 | Low |

Note: HCPCS codes Q4176, Q4178, Q4179, Q4180, Q4181, and Q4182 were assigned to the low-cost group in CY 2018 OPPS/ASC final rule with comment period. Pass-through status for HCPCS code Q4172 ended on December 31, 2017.

4. Section 4011 of the 21st Century Cures Act

Section 4011 of the 21st Century Cures Act created a new subsection (t) in Section 1834 of the Act that requires CMS to make available to the public a searchable Internet website that compares estimated payment and beneficiary liability for an appropriate number of items and services paid under the OPPS and the ASC Payment System. Consistent with this statute, CMS plans to first make this website available during CY 2018.

CMS believes that making available a comparison for all services that receive separate payment under both the OPPS and ASC payment system would be most useful to the public, with regards to displaying the comparison for an “appropriate number of such items and services.” CMS believes that displaying the national unadjusted payments and copayment amounts will allow the user to make a meaningful comparison between the systems for items and services paid under both systems. CMS may consider providing payment and copayment comparisons at the locality or provider level for future years.

Along with the comparison information that CMS will make available to the public in accordance with the requirements of Section 4011, CMS also plans to include a disclaimer statement that notes some of the payment policy differences in each care setting and describes the limitations of the comparison tool, to provide users with some context for why there might be potential differences. In the case of the OPPS copayments, CMS plans to include an additional indicator where the service is likely to be capped at the Part A inpatient deductible, based on the unadjusted copayments, under the OPPS coinsurance rules.

5. July ASCFS Technical Record Correction CMS is including a revised July ASCFS record to provide a technical correction to the record for 0474T, position 38, on the ASCFS record layout. The original indicator was incompatible with this code. No additional instructions are being provided to MACs at this time.

6. 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. 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.

ADDITIONAL INFORMATION

The official instruction, CR10441, issued to your MAC regarding this change is available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R3939CP.pdf>.

If you have any questions, please contact your MAC at their toll-free number. That number is available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/>.

DOCUMENT HISTORY

| Date of Change | Description |
|-----------------|---------------------------|
| January 2, 2017 | Initial article released. |

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