DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

MLN Matters® Number: MM9923 **Related Change Request (CR) #: CR 9923**

Related CR Release Date: December 22, 2016 **Effective Date: January 1, 2017**

Related CR Transmittal #: R3683CP **Implementation Date: January 3, 2017**

January 2017 Update of the Ambulatory Surgical Center (ASC) Payment System

Provider Types Affected

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

Provider Action Needed

Change Request (CR) 9923 updates the ASC payment system, the payment rates for separately payable drugs and biologicals, including descriptors for newly created Level II HCPCS codes for drugs and biologicals (ASC DRUG files), the ASC Payment Indicator (PI) file, and the CY 2017 ASC payment rates for covered surgical and ancillary services (ASCFS file). Make sure that your billing staffs are aware of these changes that are effective on January 1, 2017.

Background

CR9923 describes changes to, and billing instructions for, various payment policies implemented in the January 2017 ASC payment system update, including:

1. The CY 2017 payment rates for separately payable drugs and biologicals along with descriptors for newly created Level II HCPCS codes for drugs and biologicals (ASC DRUG files), and
2. The CY 2017 ASC payment rates for covered surgical and ancillary services (ASCFS file). It also includes the CY2017 ASC Code pair file, and as appropriate, also includes updates to the Healthcare Common Procedure Coding System (HCPCS).

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 provided in CR9923 reflect the most recent changes to CY 2017 MPFS payment.

Key Updates

1. New Device Pass-Through Policies

Section 1833(t)(6)(B) of the Social Security Act (the Act) requires that, under the Outpatient Prospective Payment System (OPPS), categories of devices are eligible for transitional pass-through payments for at least 2, but not more than 3 years. Section 1833(t)(6)(B)(ii)(IV) of the Act requires that the Centers for Medicare & Medicaid Services (CMS) create additional categories for transitional pass-through payment of new medical devices not described by existing (or previously existing) categories of devices.

Medicare implemented this policy 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 OPPS.

In the CY2017 OPPS/ASC final rule with comment period that was published in the Federal Register on November 14, 2016, CMS adopted a policy to revise the pass-through payment time period by having the pass-through start date begin with the date of first payment and by allowing pass-through status to expire on a quarterly basis, such that the duration of device pass-through payment will be as close to 3 years as possible. This policy is applicable in both the OPPS and ASC payment systems. Refer to the CY 2017 OPPS/ASC final rule with comment period at **https://www.gpo.gov/fdsys/pkg/FR-2016-11-14/pdf/2016-26515.pdf** for complete details about these policy changes for device pass-through that will become effective on January 1, 2017.

The three device categories that are currently eligible for pass-through payment in the OPPS and ASC payment systems are: (1) HCPCS code C2623 (Catheter, transluminal angioplasty, drug-coated, non-laser); (2) HCPCS code C2613 (Lung biopsy plug with delivery system); and (3) HCPCS code C1822 (Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system). These codes and their ASC payment indicator are listed in Addendum BB at **http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/11_Addenda_Updates.html**.

2. Argus Retinal Prosthesis Add-on Code (C1842)

Effective October 1, 2013, and expiring December 31, 2015, one device, listed in Table 1 (C1841 - Retinal prosthesis, includes all internal and external components) was eligible for pass-through payment in the OPPS and ASC payment systems. After pass-through status expires for a medical device, the payment for the device is packaged into the payment for the associated procedure.

Effective January 1, 2016, in the OPPS and ASC payment systems, payment for the device described by HCPCS code C1841 is packaged into payment for CPT code 0100T. Due to current ASC systems limitations, CMS cannot implement the identical policy in ASCs. As an administrative workaround to the field limit on ASC payments equal to or greater than $100,000, CMS is creating a second device code; HCPCS code C1842, and splitting payments in half across C1841 and C1842. Therefore, effective January 1, 2017, HCPCS code C1842 (Long descriptor -Retinal prosthesis, includes all internal and external components; add on to C1841; short descriptor - Retinal prosth, add-on) must be reported with both C1841 and 0100T when a retinal prosthesis is implanted in the ASC (see Table 1 below).

Since CMS's device payment will be equally split between C1841 and C1842. ASCs must split the submitted device charges equally between C1841 and C1842, to ensure that Medicare pays what they intended to pay. Likewise, when appropriate, the use of the FB modifier (Item provided without cost to provider, supplier or practitioner (examples, but not limited to: covered under warranty, replaced due to defect, free samples)) and FC modifier (Partial credit received for replaced device) would apply to both C1841 and C1842.

Table 1 – Argus Retinal Prosthesis Add-on Code (C1842)

CY 2017 HCPCS Code	CY 2017 Long Descriptor	CY 2017 Short Descriptor	ASC PI
C1842	Retinal prosthesis, includes all internal and external components; add on to C1841	Retinal prosth, add-on	J7

3. Drugs, Biologicals, and Radiopharmaceuticals

a. New CY 2017 HCPCS Codes and Dosage Descriptors for Certain Drugs, Biologicals, and Radiopharmaceuticals

For CY 2017, 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, below.

Table 2
New CY 2017 HCPCS Codes Effective for Certain Drugs, Biologicals, and Radiopharmaceuticals

CY 2017 HCPCS Code	CY 2017 Long Descriptor	CY 2017 Short Descriptor	ASC PI
A9587	Gallium ga-68, dotatate, diagnostic, 0.1 millicurie	Gallium ga-68	K2
A9588	Fluciciovine f-18, diagnostic, 1 millicurie	Fluciclovine f-18	K2
C9140	Injection, Factor VIII (antihemophilic factor, recombinant) (Afstyla), 1 I.U.	Afstyla factor viii recomb	K2
J0570	Buprenorphine implant, 74.2 mg	Buprenorphine implant 74.2mg	K2
J7175	Injection, factor x, (human), 1 i.u.	Inj, factor x, (human), 1iu	K2
J7179	Injection, von willebrand factor (recombinant), (Vonvendi), 1 i.u. vwf:rco	Vonvendi inj 1 iu vwf:rco	K2
J9034	Injection, bendamustine hcl (Bendeka), 1 mg	Inj., bendeka 1 mg	K2

b. Other Changes to CY 2017 HCPCS and CPT Codes for Certain Drugs, Biologicals, and Radiopharmaceuticals

Many HCPCS and CPT codes for drugs, biologicals, and radiopharmaceuticals have changes in their HCPCS and CPT code descriptors that will be effective in CY 2017. In addition, several temporary HCPCS C-codes have been deleted effective December 31, 2016, and replaced with permanent HCPCS codes in CY 2017. ASCs should pay close attention to accurate billing for units of service consistent with the dosages contained in the long descriptors of the CY 2017 HCPCS and CPT codes.

Table 3, below, notes those drugs, biologicals, and radiopharmaceuticals that have changes in their HCPCS/CPT code, their long descriptor, or both. Each product's CY 2016 HCPCS/CPT code and long descriptor are noted in the two left hand columns and the CY 2017 HCPCS/CPT code and long descriptor are noted in the adjacent right hand columns.

Table 3
Other CY 2017 HCPCS Changes for Certain Drugs, Biologicals, and Radiopharmaceuticals

CY 2016 HCPCS Code	CY 2016 Long Descriptor	CY 2017 HCPCS Code	CY 2017 Long Descriptor
C9461	Choline C 11, diagnostic, per study dose	A9515	Choline c-11, diagnostic, per study dose up to 20 millicuries
C9121	Injection, argatroban, per 5 mg	J0883	Injection, argatroban, 1 mg (for non-esrd use)
C9137	Injection, Factor VIII (antihemophilic factor, recombinant) PEGylated, 1 I.U.	J7207	Injection, factor viii, (antihemophilic factor, recombinant), pegylated, 1 i.u.
C9138	Injection, Factor VIII (antihemophilic factor, recombinant) (Nuwiq), 1 I.U.	J7209	Injection, factor viii, (antihemophilic factor, recombinant), (nuwiq), 1 i.u.
C9139	Injection, factor ix, albumin fusion protein (recombinant), idelvion, 1 i.u.	J7202	Injection, factor ix, albumin fusion protein, (recombinant), idelvion, 1 i.u.
C9349	Puraply, and puraply antimicrobial, any type, per square centimeter	Q4172	Puraply or puraply am, per square centimeter
C9470	Injection, aripiprazole lauroxil, 1 mg	J1942	Injection, aripiprazole lauroxil, 1 mg
C9471	Hyaluronan or derivative, Hymovis, for intra-articular injection, 1 mg	J7322	Hyaluronan or derivative, hymovis, for intra-articular injection, 1 mg
C9472	Injection, talimogene laherparepvec, 1 million plaque forming units (PFU)	J9325	Injection, talimogene laherparepvec, per 1 million plaque forming units
C9473	Injection, mepolizumab, 1 mg	J2182	Injection, mepolizumab, 1 mg
C9474	Injection, irinotecan liposome, 1 mg	J9205	Injection, irinotecan liposome, 1 mg
C9475	Injection, necitumumab, 1 mg	J9295	Injection, necitumumab, 1 mg
C9476	Injection, daratumumab, 10 mg	J9145	Injection, daratumumab, 10 mg
C9477	Injection, elotuzumab, 1 mg	J9176	Injection, elotuzumab, 1 mg
C9478	Injection, sebelipase alfa, 1 mg	J2840	Injection, sebelipase alfa, 1 mg
C9479	Instillation, ciprofloxacin otic suspension, 6 mg	J7342	Installation, ciprofloxacin otic suspension, 6 mg
C9480	Injection, trabectedin, 0.1 mg	J9352	Injection, trabectedin, 0.1 mg

CY 2016 HCPCS Code	CY 2016 Long Descriptor	CY 2017 HCPCS Code	CY 2017 Long Descriptor
C9481	Injection, reslizumab, 1 mg	J2786	Injection, reslizumab, 1 mg
J3357	Injection, ustekinumab, 1 mg	J3357	Ustekinumab, for subcutaneous injection, 1 mg
J1745	Injection, infliximab, 10 mg	J1745	Injection, infliximab, excludes biosimilar, 10 mg
J7201	Injection, factor ix, fc fusion protein (recombinant), per iu	J7201	Injection, factor ix, fc fusion protein (recombinant), Alprolix, per iu
J7340	Carbidopa 5 mg/levodopa 20 mg enteral suspension	J7340	Carbidopa 5 mg/levodopa 20 mg enteral suspension, 100 ml
Q9981	Rolapitant, oral, 1 mg	J8670	Rolapitant, oral, 1 mg
Q4105	Integra dermal regeneration template (drt), per square centimeter	Q4105	Integra dermal regeneration template (drt) or integra omnigraft dermal regeneration matrix, per square centimeter

c. Drugs and Biologicals with Payments Based on Average Sales Price (ASP) Effective January 1, 2017

For CY 2017, payment for nonpass-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 2017, 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, 2017, payment rates for many drugs and biologicals have changed from the values published in the CY 2017 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 2016. In cases where adjustments to payment rates are necessary, CMS is not publishing the updated payment rates in this Change Request. However, all ASC payable drugs and biologicals effective January 1, 2017, including those that were updated as a result of the new ASP calculations, can be found in the January 2017 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://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 their MAC to adjust the previously processed claims.

e. Biosimilar Biological Product Payment Policy

Effective January 1, 2017, 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 Average Sales Price (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.

You should remember that ASC claims for separately paid biosimilar biological products are required to include a modifier (see table 4, below) that identifies the specific product's manufacturer. 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.

Table 4
Biosimilar Biological Product Payment and Required Modifiers

HCPCS Code	Short Descriptor	Long Descriptor	ASC PI	FDA Approval Date	Modifier	Modifier Effective Date
Q5101	Inj filgrastim g-csf biosim	Injection, Filgrastim (G-CSF), Biosimilar, 1 microgram	K2	03/06/2015	ZA-Novartis/Sandoz	01/01/2016
Q5102	Inj., infliximab biosimilar	Injection, Infliximab, Biosimilar, 10 mg	K2	04/05/2016	ZB-Pfizer/Hospira	04/05/2016

f. Billing and Payment for New Drugs, Biologicals, or Radiopharmaceuticals Approved by the Food and Drug Administration (FDA) but Before Assignment of a Product-Specific HCPCS Code

As in the OPPS, ASCs are allowed to bill for new drugs, biologicals, and therapeutic radiopharmaceuticals that are approved by the Food and Drug Administration (FDA) on or after January 1, 2004, for which OPPS pass-through status has not been approved and a C-code and APC payment have not been assigned using the "unclassified" drug/biological HCPCS code C9399 (Unclassified drugs or biological). Drugs, biologicals, and therapeutic radiopharmaceuticals that are assigned to HCPCS code C9399 are MAC priced.

Diagnostic radiopharmaceuticals and contrast agents are policy packaged under both the OPPS and ASC payment system unless they have been granted pass-through status. Therefore, new diagnostic radiopharmaceuticals and contrast agents are an exception to the above policy and should not be billed with C9399 prior to the approval of pass-through status but, instead, are packaged in the ASC setting with payment already included in the surgical procedure performed, and are not billed.

g. Skin Substitute Procedure Edits

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 5, below, 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). 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 OPPS 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.

Table 5
Skin Substitute Product Assignment to High Cost/Low Cost Status for CY 2016

CY 2017 HCPCS Code	CY 2017 Short Descriptor	CY 2017 SI	Low/High Cost Skin Substitute
C9363	Integra Meshed Bil Wound Mat	N1	High
Q4100	Skin Substitute, NOS	N1	Low
Q4101	Apligraf	N1	High
Q4102	Oasis Wound Matrix	N1	Low

CY 2017 HCPCS Code	CY 2017 Short Descriptor	CY 2017 SI	Low/High Cost Skin Substitute
Q4103	Oasis Burn Matrix	N1	High
Q4104	Integra BMWD	N1	High
Q4105	Integra DRT	N1	High
Q4106	Dermagraft	N1	High
Q4107	GraftJacket	N1	High
Q4108	Integra Matrix	N1	High
Q4110	Primatrix	N1	High
Q4111	Gammagraft	N1	Low
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/Allopatchhd/Matrixhd	N1	High
Q4131	Epifix	N1	High
Q4132	Grafix Core	N1	High
Q4133	Grafix 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

CY 2017 HCPCS Code	CY 2017 Short Descriptor	CY 2017 SI	Low/High Cost Skin Substitute
Q4143*	Repriza, 1cm	N1	High
Q4146*	Tensix, 1CM	N1	High
Q4147	Architect ecm, 1cm	N1	High
Q4148	Neox 1k, 1cm	N1	High
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 1 square cm	N1	High
Q4154	Biovance 1 square cm	N1	High
Q4156	Neox 100 1 square cm	N1	High
Q4157*	Revitalon 1 square cm	N1	High
Q4158*	MariGen 1 square cm	N1	High
Q4159	Affinity 1 square cm	N1	High
Q4160	NuShield 1 square cm	N1	High
Q4161	Bio-Connekt per square cm	N1	Low
Q4162	Amnio bio and woundex flow	N1	Low
Q4163*	Amnion bio and woundex 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
Q4168*	Amnioband, 1 mg	N1	Low
Q4169*	Artacent wound, per square cm	N1	Low
Q4170*	Cygnus, per square cm	N1	Low
Q4171*	Interfyl, 1 mg	N1	Low
Q4172	PuraPly, PuraPly antimic	K2	High
Q4173*	Palingen or palingen xplus, per sq cm	N1	Low
Q4175*	Miroderm, per square cm	N1	Low

*HCPCS codes Q4166, Q4167, Q4168, Q4169, Q4170, Q4171, Q4173, and Q4175 were assigned to the low cost group in the CY 2017 OPPS/ASC final rule with comment period. Upon submission of updated pricing information, Q4143, Q4146, Q4157, Q4158, and Q4163 are assigned to the high cost group for CY 2017.

h. Reassignment of Skin Substitute Products from the Low Cost Group to the High Cost Group – Retroactive Change

One existing skin substitute product has been reassigned from the low cost skin substitute group to the high cost skin substitute group based on updated pricing information. The start date on this change is retroactive to October 1, 2016. ASCs should not separately bill for packaged skin substitutes (ASC PI=N1). The product is listed in Table 6 below.

Table 6

Updated Skin Substitute Product Assignment to High Cost Status Retroactive to October 1, 2016

HCPCS Code	Short Descriptor	ASC PI	Low/High Cost Status
Q4158	MariGen 1 square cm	N1	High

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. CY 2017 Wage Index

In the CY2017 OPPS/ASC final rule with comment period, we informed readers that generally, the Office of Management and Budget (OMB) issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses. On July 15, 2015, OMB issued OMB Bulletin No. 15–01, which provides updates to and supersedes OMB Bulletin No. 13–01 that was issued on February 28, 2013. The attachment to OMB Bulletin No. 15–01 provides detailed information on the update to statistical areas since February 28, 2013. The updates provided in OMB Bulletin No. 15–01 are based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2012 and July 1, 2013. Please refer to page 79562 of the final rule for

more details. OMB Bulletin No. 15–01 made the following changes that are relevant to the ASC wage index:

- Garfield County, OK, with principal city Enid, OK, which was a Micropolitan (geographically rural) area, now qualifies as an urban new Core Based Statistical Area (CBSA) 21420 called Enid, OK.

- The county of Bedford City, VA, a component of the Lynchburg, VA CBSA 31340, changed to town status and is added to Bedford County. Therefore, the county of Bedford City (SSA State county code 49088, FIPS State County Code 51515) is now part of the county of Bedford, VA (SSA State county code 49090, FIPS State County Code 51019). However, the CBSA remains Lynchburg, VA, 31340.

- The name of Macon, GA, CBSA 31420, as well as a principal city of the Macon-Warner Robins, GA combined statistical area, is now Macon-Bibb County, GA. The CBSA code remains as 31420.

These changes are effective January 1, 2017. For CY 2017, the final CY 2017 ASC wage indexes fully reflect the new OMB labor market area delineations. The final CY2017 ASC wage indices are included in Attachment B of CR 9923.

Additional Information

The official instruction, CR9923, issued to your MAC regarding this change is available at **https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3683CP.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/**.