

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-04 Medicare Claims Processing</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 11004</b>	<b>Date: September 17, 2021</b>
	<b>Change Request 12451</b>

**SUBJECT: October 2021 Update of the Ambulatory Surgical Center [ASC] Payment System**

**I. SUMMARY OF CHANGES:** This recurring update notification provides changes to and billing instructions for various payment policies implemented in the October 2021 ASC payment system update. As appropriate, this notification also includes updates to the Healthcare Common Procedure Coding System (HCPCS).

**EFFECTIVE DATE: October 1, 2021**

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

**IMPLEMENTATION DATE: October 4, 2021**

*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.

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
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: 11004	Date: September 17, 2021	Change Request: 12451
-------------	--------------------	--------------------------	-----------------------

**SUBJECT: October 2021 Update of the Ambulatory Surgical Center [ASC] Payment System**

**EFFECTIVE DATE: October 1, 2021**

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

**IMPLEMENTATION DATE: October 4, 2021**

## **I. GENERAL INFORMATION**

**A. Background:** This recurring update notification provides changes to and billing instructions for various payment policies implemented in the October 2021 Ambulatory Surgical Center (ASC) payment system update. As appropriate, this notification also includes updates to the Healthcare Common Procedure Coding System (HCPCS).

Included in this transmittal are Calendar Year (CY) 2021 payment rates for separately payable procedures/services, drugs and biologicals, including descriptors for newly created Current Procedural Terminology (CPT) and Level II HCPCS codes. An October 2021 Ambulatory Surgical Center Fee Schedule (ASCFS) File, an October 2021 Ambulatory Surgical Center Payment Indicator (ASC PI) File, an October 2021 Ambulatory Surgical Center Drug File, a July 2021 ASC Code Pair file, and an October 2021 ASC Code Pair file will be issued in this transmittal.

## **B. Policy: 1. a. Device Pass-Through Categories**

Section 1833(t)(6)(B) of the Social Security Act requires that, under the Hospital Outpatient Prospective Payment System (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 we create additional categories for transitional pass-through payment of new medical devices not described by existing or previously existing categories of devices. The OPPS payment policies for device pass-through categories are also implemented in ASCs. We are establishing one new OPPS device pass-through category that is also paid in ASCs. HCPCS code C1831 (Personalized interbody cage) is effective October 1, 2021. We are also updating the device information for the device category described by HCPCS code C1761 (Catheter, transluminal intravascular lithotripsy, coronary). Table 1 lists the coding and descriptor information as well as the device offset information, described in the section below, for these device categories (see Attachment A: Policy Section Tables).

### **b. Device Offset from Payment**

Section 1833(t)(6)(D)(ii) of the Act requires that we deduct from OPPS pass-through payments for devices an amount that reflects the device portion of the Ambulatory Payment Classification (APC) payment amount. This deduction is known as the device offset, or the portion(s) of the APC amount that is associated with the cost of the pass-through device. This device offset policy is also implemented in ASCs. The device offset represents a deduction from the ASC procedure payment for the applicable passthrough device.

i. We have determined that the offsets are associated with costs of the device category described by HCPCS code C1831 (Personalized, anterior and lateral interbody cage (implantable)). The device(s) in the category described by HCPCS code C1831 should always be billed in the ASC setting with Current Procedural Terminology (CPT) code 22612. Refer to Table 1 for the codes descriptors and offset pairings. The codes, along with their short descriptors, status indicators, APC assignments, and payment rates are also listed in the October 2021 Update of the OPSS Addendum B. (see Attachment A: Policy Section Tables).

ii. In the July 2021 Update of the Ambulatory Surgical Center [ASC] Payment System (Transmittal 10858, dated June 25, 2021), we stated that the device in the category described by HCPCS C1761 should always be billed with either CPT code 92928 (Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch) or HCPCS code C9600 (Percutaneous transcatheter placement of drug eluting intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch). We are updating this list to add the following 2 CPT codes: HCPCS code C9602 (Percutaneous transluminal coronary atherectomy, with drug eluting intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch), and HCPCS code C9607 (Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty; single vessel). This change is retroactive to July 1, 2021. These changes, as well as the two HCPCS codes that were included in the July 2021 ASC CR, are also reflected in Table 1. (see Attachment A: Policy Section Tables).

Therefore, the device in the category described by HCPCS code C1761 should always be billed with one of the following Current Procedural Terminology (CPT) codes listed below.

- HCPCS code C9602 (Percutaneous transluminal coronary atherectomy, with drug eluting intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch), which is assigned to OPSS APC 5194 for Calendar Year (CY) 2021
- HCPCS code C9607 (Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty; single vessel), which is assigned to OPSS APC 5194 for Calendar Year (CY) 2021
- CPT code 92928 (Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch), which is assigned to OPSS APC 5193 for Calendar Year (CY) 2021;
- HCPCS code C9600 (Percutaneous transcatheter placement of drug eluting intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch), which is assigned to OPSS APC 5193 for Calendar Year (CY) 2021

## **2. Drugs and Biologicals**

### **a. New Separately Payable and Expiring HCPCS Codes and Dosage Descriptors for Certain Drugs and Biologicals in ASCs effective October 1, 2021**

Fourteen (14) new HCPCS codes have been created for reporting drugs and biologicals in the ASC setting, where there have not previously been specific codes available starting on October 1, 2021. Seven (7) of those new HCPCS codes replace expiring ones. The expiring HCPCS codes for these drugs and biologicals will be deleted on October 1, 2021.

The new and old HCPCS codes as well as the descriptors and ASC PIs are listed in Table 2, (see Attachment A: Policy Section Tables).

#### **b. HCPCS Codes for Drugs and Biologicals with Revised Long Descriptor as of October 1, 2021**

The long descriptors for HCPCS code J1443 and HCPCS code J2407 will be revised on October 1, 2021. These long descriptor changes are reported in Table 3, (see Attachment A: Policy Section Tables).

#### **c. Drugs and Biologicals with Payments Based on Average Sales Price (ASP)**

For CY 2021, 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 2021, a single payment of ASP + 6 percent continues to be made for the Outpatient Prospective Payment System (OPPS) 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, 2021, can be found in the July 2021 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](https://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 with payment rates based on the ASP methodology may have their payment rates 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 website 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.

### **3. Skin Substitutes**

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. 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 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. New skin substitute HCPCS codes are assigned into the low-cost skin substitute group unless CMS has OPPS pricing data that demonstrates that the cost of the product is above either the mean unit cost of \$48 or per day cost of \$949 for CY 2021.







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	
	<p>NOTE: The revised ASC Drug file is a full replacement file.</p> <p><b>NOTE: Date of retrieval will be provided in a separate email communication from CMS.</b></p>									
12451.8.1	<p>Medicare contractors shall adjust as appropriate claims brought to their attention that:</p> <p>1) Have dates of service April 1, 2021- June 30, 2021 and ;</p> <p>2) Were originally processed prior to the installation of the revised April 2021 ASC DRUG File.</p>		X							
12451.9	<p>Medicare contractors shall download and install the revised January 2021 ASC DRUG file, if released by CMS.</p> <p>FILENAME: MU00.@BF12390.ASC.CY21.DRUG.JAND.V0917</p> <p>NOTE: The revised ASC Drug file is a full replacement file.</p> <p><b>NOTE: Date of retrieval will be provided in a separate email communication from CMS.</b></p>		X						VDC	
12451.9.1	<p>Medicare contractors shall adjust as appropriate claims brought to their attention that:</p> <p>1) Have dates of service January 1, 2021- March 31, 2021 and ;</p>		X							

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	
	2) Were originally processed prior to the installation of the revised January 2021 ASC DRUG File.									
12451.10	<p>Medicare contractors shall download and install the revised October 2020 ASC DRUG file, if released by CMS.</p> <p>FILENAME: MU00.@BF12390.ASC.CY20.DRUG.OCTE.V0917</p> <p>NOTE: The revised ASC Drug file is a full replacement file.</p> <p><b>NOTE: Date of retrieval will be provided in a separate email communication from CMS.</b></p>		X							VDC
12451.10.1	<p>Medicare contractors shall adjust as appropriate claims brought to their attention that:</p> <p>1) Have dates of service October 1, 2020- December 31, 2020 and ;</p> <p>2) Were originally processed prior to the installation of the revised October 2020 ASC DRUG File.</p>		X							
12451.11	<p>Medicare contractors shall download and install the July 2021 ASC Code Pair file.</p> <p>FILENAME: MU00.@BF12390.ASC.CY21.CP.JULB.V0910</p> <p><b>NOTE: Date of retrieval will be provided in a separate email communication from CMS.</b></p>		X							VDC



### III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			D M E	C E D I
		A	B	H H H	M A C	
12451.16	Medicare Learning Network® (MLN): CMS will market provider education content through the MLN Connects® newsletter shortly after CMS releases the CR. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 instructions for distributing the MLN Connects newsletter information to providers and link to relevant information on your website. You may supplement MLN content with your local information after we release the MLN Connects newsletter. Subscribe to the “MLN Connects” listserv to get MLN content notifications. You don’t need to separately track and report MLN content releases when you distribute MLN Connects newsletter content per the manual section referenced above.		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:
1-6	Attachment A: Policy Section Tables

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

### V. CONTACTS

**Pre-Implementation Contact(s):** Chuck Braver, [chuck.braver@cms.hhs.gov](mailto:chuck.braver@cms.hhs.gov) (ASC Payment Policy) , Yvette Cousar, [yvette.cousar@cms.hhs.gov](mailto:yvette.cousar@cms.hhs.gov) (B 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**

## Attachment A – Policy Section Tables

**Table 1. – Device Pass-Through Categories**

<b>HCPCS code</b>	<b>Effective Date</b>	<b>ASC PI</b>	<b>Short Descriptor</b>	<b>Long Descriptor</b>	<b>Device Offset Code(s)</b>
C1831	10/1/2021	J7	Personalized interbody cage	Personalized, anterior and lateral interbody cage (implantable)	CPT code 22612
C1761	7/1/2021	J7	Cath, trans intra litho/coro	Catheter, transluminal intravascular lithotripsy, coronary	CPT code C9602 CPT code C9607

**Table 2. – New Separately Payable and Expiring HCPCS Codes and Dosage Descriptors for Certain Drugs and Biologicals in ASCs effective October 1, 2021**

<b>New HCPCS Code</b>	<b>Old HCPCS Code</b>	<b>New HCPCS Code Short Descriptor</b>	<b>New HCPCS Code Long Descriptor</b>	<b>ASC PI</b>
J2406	N/A	Injection, oritavancin 10 mg	Injection, oritavancin (kimyrsa), 10 mg	K2
C9082	N/A	Inj Dostarlimab-gxly, 100 mg	Injection, dostarlimab-gxly, 100 mg	K2
C9083	N/A	Inj, amivantamab-vmjw, 10 mg	Injection, amivantamab-vmjw, 10 mg	K2

<b>New HCPCS Code</b>	<b>Old HCPCS Code</b>	<b>New HCPCS Code Short Descriptor</b>	<b>New HCPCS Code Long Descriptor</b>	<b>ASC PI</b>
A9593	N/A	Gallium ga-68 psma-11 ucsf	Gallium ga-68 psma-11, diagnostic, (ucsf), 1 millicurie	K2
A9594	N/A	Gallium ga-68 psma-11, ucla	Gallium ga-68 psma-11, diagnostic, (ucla), 1 millicurie	K2
C9084	N/A	loncastuximab-lpyl, 0.1 mg	Injection, loncastuximab tesirine-lpyl, 0.1 mg	K2
J0699	N/A	Inj, cefiderocol, 10 mg	Injection, cefiderocol, 10 mg	K2
J0741	C9077	Inj, cabote rilpivir 2mg 3mg	Injection, cabotegravir and rilpivirine, 2mg/3mg	K2
J1305	C9079	Inj, evinacumab-dgnb, 5 mg	Injection, evinacumab-dgnb, 5mg	K2
J1426	C9075	Injection, casimersen, 10 mg	Injection, casimersen, 10 mg	K2
J1448	C9078	Injection, trilaciclib, 1mg	Injection, trilaciclib, 1mg	K2
J9247	C9080	Inj, melphalan flufenami 1mg	Injection, melphalan flufenamide, 1mg	K2
J9318	C9065	Inj romidepsin non-lyo 0.1mg	Injection, romidepsin, non-lyophilized, 0.1 mg	K2

New HCPCS Code	Old HCPCS Code	New HCPCS Code Short Descriptor	New HCPCS Code Long Descriptor	ASC PI
J9319	J9315	Inj romidepsin lyophil 0.1mg	Injection, romidepsin, lyophilized, 0.1 mg	K2

NOTE: Old HCPCS Codes, if applicable, are deleted September 30, 2021.

**Table 3. – HCPCS Codes for Drugs and Biologicals with Revised Long Descriptor as of October 1, 2021**

July 2021 HCPCS Code	July 2021 Long Descriptor	October 2021 HCPCS Code	October 2021 Long Descriptor
J1443	Injection, ferric pyrophosphate citrate solution (triferic), 0.1 mg of iron	J1443	Injection, ferric pyrophosphate citrate powder, 0.1 mg of iron
J2407	Injection, oritavancin, 10 mg	J2407	Injection, oritavancin (orbactiv), 10 mg

**Table 4. – New Skin Substitute Products Low Cost Group/High Cost Group Assignment Effective October 1, 2021**

HCPCS Code	Short Descriptor	Long Descriptor	ASC PI	Low/High Cost Skin Substitute
Q4251	Vim, per square centimeter	Vim, per square centimeter	N1	Low
Q4252	Vendaje, per square centimet	Vendaje, per square centimeter	N1	Low
Q4253	Zenith amniotic membrane psc	Zenith amniotic membrane, per square centimeter	N1	Low

NOTE: ASCs should not separately bill for packaged skin substitutes (ASC PI=N1) since packaged codes are not reportable under the ASC payment system.

**Table 5. – Skin Substitute Products Deleted as of October 1, 2021**

<b>HCPCS Code</b>	<b>Short Descriptor</b>	<b>ASC PI through 9/30/2021</b>	<b>New ASCPI Eff. 10/1/2021</b>
Q4228	Bionextpatch, per sq cm	N1	D5
Q4236	Carepatch per sq cm	N1	D5

NOTE: ASCs should not separately bill for packaged skin substitutes (ASC PI=N1) since packaged codes are not reportable under the ASC payment system.