

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 12229	Date: August 31, 2023
	Change Request 13353

SUBJECT: October 2023 Update of the Ambulatory Surgical Center (ASC) Payment System

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to provide changes to and billing instructions for various payment policies implemented in the October 2023 ASC payment system update.

EFFECTIVE DATE: October 1, 2023

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

IMPLEMENTATION DATE: October 2, 2023

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: 12229	Date: August 31, 2023	Change Request: 13353
-------------	--------------------	-----------------------	-----------------------

SUBJECT: October 2023 Update of the Ambulatory Surgical Center (ASC) Payment System

EFFECTIVE DATE: October 1, 2023

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

IMPLEMENTATION DATE: October 2, 2023

I. GENERAL INFORMATION

A. Background: The purpose of this recurring update notification change request (CR) is to provide changes to and billing instructions for various payment policies implemented in the October 2023 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) 2023 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 2023 Ambulatory Surgical Center Fee Schedule (ASCFS) File, an October 2023 Ambulatory Surgical Center Payment Indicator (ASC PI) File, and an October 2023 Ambulatory Surgical Center Drug File are being issued. As appropriate, restated ASC Drug files, and a revised October 2023 ASC Code Pair file may also be issued this quarter.

B. Policy: 1. New HCPCS Procedure Code Describing the Instillation of an Anti-neoplastic Pharmacologic / Biologic Agent into the Renal Pelvis

CMS is establishing a new HCPCS procedure code, C9789, to describe the instillation of an anti-neoplastic pharmacologic/biologic agent into the renal pelvis. Table 1 lists the long and short descriptors, and ASC PI. This code, along with its short descriptor, ASC PI, and payment rate, is also included in the October 2023 ASC Addendum AA (see Attachment A: Policy Section Tables).

2. New HCPCS Code for Renal/Kidney Histotripsy

The clinical study associated with HistoSonic's Edison Histotripsy System for kidney histotripsy was approved by CMS for Medicare coverage on June 15, 2023, as a Category B IDE study. Currently, there is no specific HCPCS code to describe the service. We are establishing HCPCS code C9790 to enable Medicare to track and pay appropriately for this IDE study effective October 1, 2023.

Information associated with the clinical study is posted on the CMS approved IDE studies website at: <https://www.cms.gov/Medicare/Coverage/IDE/Approved-IDE-Studies>.

Table 2 lists the descriptors and ASC PI for HCPCS code C9790. (see Attachment A: Policy Section Tables).

3. Drugs and Biologicals

a. Newly Established HCPCS Codes for Drugs and Biologicals Effective October 1, 2023

Fourteen (14) new separately payable HCPCS codes have been established in the ASC setting effective October 1, 2023. These HCPCS codes, as well as their descriptors, and ASC PIs are listed in Table 3 (see Attachment A: Policy Section Tables). HCPCS code C9151 is deleted effective September 30, 2023 and is replaced by HCPCS code J2781 effective October 1, 2023. Also, HCPCS code J0800 is deleted effective September 30, 2023 and is replaced by HCPCS code J0801 and HCPCS code J0802 effective October 1, 2023.

b. Existing HCPCS Codes for Certain Diagnostic Radiopharmaceuticals with OPPS Pass-Through Status Ending on September 30, 2023

There are two (2) HCPCS codes for diagnostic radiopharmaceuticals that will have their OPPS pass-through status end on September 30, 2023 at which point payment for these codes will be packaged into the payment for their respective primary procedures. These codes will also be packaged in the ASC setting. The codes are listed in Table 4 and are also included in the October 2023 ASC addenda. (see Attachment A: Policy Section Tables).

c. HCPCS Code J0174 Previously Established Retroactive to July 6, 2023

HCPCS code J0174 (Injection, lecanemab-irmb, 1 mg) was established retroactive to July 6, 2023 and is separately payable in the ASC setting. The information for HCPCS code J0174 is listed in Table 5 (see Attachment A: Policy Section Tables).

d. HCPCS Code for Drug Deleted as of September 30, 2023

Two (2) drug HCPCS codes will be deleted on September 30, 2023. These HCPCS codes are listed in Table 6 (see Attachment A: Policy Section Tables).

e. HCPCS Code for Drug with Descriptor Change as of October 1, 2023

One (1) drug HCPCS code has a descriptor change as of October 1, 2023. This HCPCS code is listed in Table 7 (see Attachment A: Policy Section Tables).

f. HCPCS Code for Drug with Descriptor Change as of July 1, 2023

One (1) drug, biological, and radiopharmaceutical HCPCS code has a descriptor change as of July 1, 2023. This new July 2023 descriptor is unchanged for October 2023. This HCPCS code is listed in Table 8 (see Attachment A: Policy Section Tables).

g. Drugs and Biologicals with Payments Based on Average Sales Price (ASP)

For CY 2023, payment for the majority of OPPS pass-through and nonpass-through drugs and biologicals is generally made in the ASC setting at a single rate of ASP plus 6 percent (or ASP plus 6 or 8 percent of the

reference product for biosimilars), which provides payment for both the acquisition cost and pharmacy overhead costs of these items. Payments for drugs and biologicals based on ASPs will be updated on a quarterly basis as later quarter ASP submissions become available.

Effective October 1, 2023, payment rates for many drugs and biologicals have changed from the values published in the CY 2023 OPSS/ASC final rule with comment period as a result of the new ASP calculations based on sales price submissions from the second quarter of CY 2023. In cases where adjustments to payment rates are necessary, changes to the payment rates will be incorporated in the October 2023 ASC drug file. The updated payment rates effective October 1, 2023, can be found in the October 2023 update of the ASC addenda, specifically, ASC Addendum BB on the CMS website at https://www.cms.gov/medicare/medicare-fee-for-service-payment/ascpayment/11_addenda_updates.

i. 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.

4. Skin Substitutes

The payment for skin substitute products that do not qualify for hospital OPSS 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. 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 codes 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 codes 15271-15278. New skin substitute HCPCS codes are assigned into the low-cost skin substitute group unless CMS has OPSS pricing data that demonstrates that the cost of the product is above either the mean unit cost of \$47 or the per day cost of \$837 for CY 2023.

a. New Skin Substitute Products as of October 1, 2023

There are four (4) new skin substitute HCPCS codes that will be active as of October 1, 2023. These codes are listed in Table 9 (see Attachment A: Policy Section Tables).

b. Skin Substitute Product Reassigned to the High Cost Skin Substitute Group as of October 1, 2023

There is one (1) skin substitute HCPCS code that will be reassigned from the low cost skin substitute group to the high cost skin substitute group as of October 1, 2023. The code is listed in Table 10 (see Attachment A: Policy Section Tables).

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	
13353.7	Contractors and CWF, as appropriate, shall end date as appropriate, HCPCS included in table 6 attachment A in their systems, effective September 30, 2023.		X						X	
13353.8	CWF, as appropriate, shall remove the TOS F records for the HCPCS included in table 6 attachment A, effective September 30, 2023.								X	
13353.9	Contractors shall reprocess claims, as appropriate, for HCPCS J0174 with dates of services July 6, 2023 and later, when brought to your attention.		X							
13353.10	If released by CMS, Medicare contractors shall download and install the revised July 2023 ASC DRUG file. FILENAME: <u>MU00.@BF12390.ASC.CY23.DRUG.JULB.V0915</u> NOTE: Date of retrieval will be provided in a separate email communication from CMS.		X							VDC
13353.10.1	Medicare contractors shall adjust as appropriate claims brought to their attention that: 1) Have dates of service July 1, 2023 - October 31, 2023 and; 2) Were originally processed prior to the installation of the revised July 2023 ASC DRUG File.		X							
13353.11	If released by CMS, Medicare contractors shall download and install the revised April 2023 ASC DRUG file.		X							VDC

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>FILENAME:</p> <p><u>MU00.@BF12390.ASC.CY23.DRUG.APRC.V0915</u></p> <p>NOTE: Date of retrieval will be provided in a separate email communication from CMS.</p>										
13353.11.1	<p>Medicare contractors shall adjust as appropriate claims brought to their attention that:</p> <p>1) Have dates of service April 1, 2023 - June 30, 2023 and;</p> <p>2) Were originally processed prior to the installation of the revised April 2023 ASC DRUG File.</p>		X								
13353.12	<p>Medicare contractors shall download and install the revised January 2023 ASC DRUG file.</p> <p>FILENAME:</p> <p><u>MU00.@BF12390.ASC.CY23.DRUG.JAND.V0915</u></p> <p>NOTE: Date of retrieval will be provided in a separate email communication from CMS.</p>		X							VDC	
13353.12.1	<p>Medicare contractors shall adjust as appropriate claims brought to their attention that:</p> <p>1) Have dates of service January 1, 2023 - March 31, 2023 and;</p> <p>2) Were originally processed prior to the installation of the revised January 2023 ASC DRUG File.</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	
13353.13	<p>Medicare contractors shall download and install the revised October 2023 ASC DRUG file.</p> <p>FILENAME:</p> <p><u>MU00.@BF12390.ASC.CY22.DRUG.OCTE.V0915</u></p> <p>NOTE: Date of retrieval will be provided in a separate email communication from CMS.</p>		X								VDC
13353.13.1	<p>Medicare contractors shall adjust as appropriate claims brought to their attention that:</p> <p>1) Have dates of service October 1, 2022 - December 31, 2022 and;</p> <p>2) Were originally processed prior to the installation of the revised October 2022 ASC DRUG File.</p>		X								
13353.14	Contractors shall make October 2023 ASCFS fee data for their ASC payment localities available on their web sites.		X								
13353.15	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 D I	C E D I
		A	B	H H H		
13353.16	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:
1-3,5-9	Attachment A: Policy Section Tables

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

V. CONTACTS

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 HCPCS Procedure Code Describing the Instillation of an Anti-neoplastic Pharmacologic / Biologic Agent into the Renal Pelvis

HCPCS Code	Short Descriptor	Long Descriptor	ASC PI
C9789	Instill pharm renal pelvis	Instillation of anti-neoplastic pharmacologic/biologic agent into renal pelvis, any method, including all imaging guidance, including volumetric measurement if performed	G2

Table 2. – New HCPCS Code for Renal/Kidney Histotripsy

HCPCS Code	Short Descriptor	Long Descriptor	ASC PI
C9790	Kidney histotripsy w/image	Histotripsy (ie, non-thermal ablation via acoustic energy delivery) of malignant renal tissue, including image guidance	G2

Table 3. – Newly Established HCPCS Codes for Drugs and Biologicals Effective October 1, 2023

CY 2023 HCPCS Code	Short Descriptor	Long Descriptor	ASC PI
C9152	Inj, abilify asimtuftii, 1 mg	Injection, aripiprazole, (abilify asimtuftii), 1 mg	K2
C9153	Inj, amisulpride, 1 mg	Injection, amisulpride, 1 mg	K2
C9154	Inj buprenorph (brixadi) 1mg	Injection, buprenorphine extended-release (brixadi), 1 mg	K2
C9155	Inj epcoritamab-bysp, 0.16 mg	Injection, epcoritamab-bysp, 0.16 mg	K2
C9156	Flotufolastat f18, dia 1 mci	Flotufolastat F 18, diagnostic, 1 millicurie	K2
C9157	Inj, tofersen, 1 mg	Injection, tofersen, 1 mg	K2
C9158	Inj, uzedy, 1 mg	Injection, risperidone, (uzedy), 1 mg	K2
J7214	Altuviiiio per factor viii iu	Injection, factor viii/von willebrand factor complex, recombinant (altuviiiio), per factor viii i.u.	K2
J0349	Inj, rezafungin, 1 mg	Injection, rezafungin, 1 mg	K2

CY 2023 HCPCS Code	Short Descriptor	Long Descriptor	ASC PI
J0801	Inj. acthar gel to 40 units	Injection, corticotropin (acthar gel), up to 40 units	K2
J0802	Inj. (ani), up to 40 units	Injection, corticotropin (ani), up to 40 units	K2
J2781	Inj, pegcetacoplan, 1mg	Injection, pegcetacoplan, intravitreal, 1 mg	K2
J7519	Inj. mycophenolate mofetil	Injection, mycophenolate mofetil, 10 mg	K2
J9345	Inj, retifanlimab-dlwr, 1 mg	Injection, retifanlimab-dlwr, 1 mg	K2

Table 4. – HCPCS Codes for Certain Diagnostic Radiopharmaceuticals with OPPS Pass-Through Status Ending Effective September 30, 2023

CY 2023 HCPCS Code	Short Descriptor	October 2023 ASC PI
A9591	Fluoroestradiol F 18	N1
C9067	Gallium ga-68 Dotatoc	N1

Table 5. – HCPCS Code J0174 Previously Established Retroactive to July 6, 2023

New HCPCS Code	Short Descriptor	Long Descriptor	ASC PI Effective July 6, 2023
J0174	Inj, lecanemab-irmb	Injection, lecanemab-irmb, 1 mg	K2

Table 6. – HCPCS Code for Drug Deleted as of September 30, 2023

CY 2023 HCPCS Code	Short Descriptor	Replacement HCPCS Code Effective October 1, 2023
J0800	Corticotropin injection	J0801; J0802
C9151	Inj, pegcetacoplan 1 mg	J2781

Table 7. – HCPCS Code for Drug with Descriptor Changes as of October 1, 2023

CY 2023 HCPCS Code	July 2023 Long Descriptor	October 2023 Long Descriptor
J1921	Injection, labetalol hydrochloride (hikma) not therapeutically equivalent to J1820, 5 mg	Injection, labetalol hydrochloride (hikma) not therapeutically equivalent to J1920, 5 mg

Table 8. – HCPCS Code for Drug with Descriptor Change as of July 1, 2023

CY 2023 HCPCS Code	April 2023 Long Descriptor	July 2023 Long Descriptor
J2426	Injection, paliperidone palmitate extended release, 1 mg	Injection, paliperidone palmitate extended release (invega sustenna), 1 mg

Table 9. – New Skin Substitute Products as of October 1, 2023

CY 2023 HCPCS Code	Short Descriptor	CY 2023 ASC PI	Low/High-Cost Skin Substitute
A2022	Innovabrnl/innovamatx xl sqcm	N1	High
A2024	Resolve matrix per sq cm	N1	High
Q4285	Nudyn dl or dl mesh pr sq cm	N1	Low
Q4286	Nudyn sl or slw, per sq cm	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 10. – Skin Substitute Products Reassigned to the High-Cost Skin Substitute Group as of October 1, 2023

HCPCS Code	Short Descriptor	ASC PI	Prior Low/High-Cost Skin Substitute Group	October 2023 Low/High-Cost Skin Substitute Group
Q4282	Cygnus dual per sq cm	N1	Low	High

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