CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 4410	Date: October 4, 2019
	Change Request 11457

Transmittal 4389, dated September 6, 2019, is being rescinded and replaced by Transmittal 4410, dated, October 4, 2019 to correct table 1 attachment A to reinstate C9043 rather than delete it effective October 1, 2019, revise corresponding footnote 1, and delete footnote 2. Filenames have been corrected for BR11457.1 and BR11457.2. All other information remains the same.

SUBJECT: October 2019 Update of the Ambulatory Surgical Center (ASC) Payment System

I. SUMMARY OF CHANGES: This Recurring Update Notification (RUN) provides instructions for the quarterly update to the Ambulatory Surgical Center (ASC) Payment System.

EFFECTIVE DATE: October 1, 2019

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

IMPLEMENTATION DATE: October 7, 2019

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: 4410 Date: October 4, 2019 Change Request: 11457

Transmittal 4389, dated September 6, 2019, is being rescinded and replaced by Transmittal 4410, dated, October 4, 2019 to correct table 1 attachment A to reinstate C9043 rather than delete it effective October 1, 2019, revise corresponding footnote 1, and delete footnote 2. Filenames have been corrected for BR11457.1 and BR11457.2. All other information remains the same.

SUBJECT: October 2019 Update of the Ambulatory Surgical Center (ASC) Payment System

EFFECTIVE DATE: October 1, 2019

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

IMPLEMENTATION DATE: October 7, 2019

I. GENERAL INFORMATION

A. Background: This Recurring Update Notification describes changes to and billing instructions for various payment policies implemented in the October 2019 ASC payment system update. As appropriate, this notification also includes updates to the Healthcare Common Procedure Coding System (HCPCS).

Calendar year (CY) 2019 payment rates for separately payable procedures/services, drugs and biologicals, including descriptors for newly created CPT and Level II HCPCS codes for drugs and biologicals (ASC DRUG) files, are included in this notification. An October 2019 Ambulatory Surgical Center Payment Indicator (ASC PI) File will be issued. However, no October 2019 Ambulatory Surgical Center Fee Schedule (ASCFS) or ASC Code Pair file is being issued in this transmittal.

B. Policy: 1. Drugs and Biologicals

a. Drugs and Biologicals with Payments Based on Average Sales Price (ASP) Effective October 1, 2019

For CY 2019, 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 2019, a single payment of ASP + 6 percent continues to be made for 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, 2019, can be found in the October 2019 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. New Established HCPCS Codes for Separately Payable Drugs and Biologicals as of October 1, 2019

There are 20 new drug and biological HCPCS codes that will be established on October 1, 2019. The codes that are displayed in the old HCPCS code column are deleted September 30, 2019. The new and old codes are listed in Table 1, attachment A (see Attachment A: Policy Section Tables).

c. Separately Payable Drugs and Biologicals with Retroactive Payment Indicator Change for the Period of April 1, 2019 Through June 30, 2019

The ASC PI for HCPCS code C9042 (Injection, bendamustine hcl (belrapzo), 1 mg) for the period of April 1, 2019 through June 30, 2019 will be changed retroactively from ASC PI = Y5 to status indicator = K2. This drug is reported in Table 2, attachment A (see Attachment A: Policy Section Tables).

d. Separately Payable Drug and Biological with Retroactive Payment Indicator Change for the Period of July 18, 2019 through September 30, 2019

The payment indicator for HCPCS code Q5107 (Injection, bevacizumab-awwb, biosimilar, (mvasi), 10 mg) for the period of July 18, 2019 through September 30, 2019 will be changed retroactively from ASC PI = Y5 to APC PI = K2. This drug is reported in Table 3, attachment A (see Attachment A: Policy Section Tables).

e. 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 Web site on the first date of the quarter at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/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.

2. 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.

3. Attachment

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
			A/B MA(D M		Sys	red- tem		Other
		A D		TT	Е	Main		aine V	_	
		A	В	H H	M	F I	$\begin{array}{ c c }\hline MI \\ C\end{array}$			
				Н	A C	S S	S	S	F	
11457.1	Medicare contractors shall download and install the October 2019 ASC DRUG file.		X							VDC
	FILENAME: MU00.@BF12390.ASC.CY19.DRUG.OCTA.V0930									
	NOTE: Date of retrieval will be provided in a separate email communication from CMS.									
11457.2	Medicare contractors shall download and install the October 2019 ASC PI file.		X							VDC
	FILENAME:									
	MU00.@BF12390.ASC.CY19.PI.OCTA.V0930									
	NOTE: Date of retrieval will be provided in a separate email communication from CMS.									
11457.3	Contractors and Common Working File (CWF) shall add the procedure codes to the system's procedure code file [Type of Service (TOS) F] for HCPCS included in attachment A, table 1, effective for services October 1, 2019 and later payable in the ASC setting.		X						X	
11457.3.1	Contractors and CWF shall end date as appropriate, the CY 2019 HCPCS/CPT codes in table 1 in their systems, effective September 30, 2019.		X						X	
	NOTE: The impacted table 1 codes appear in the 'Old HCPCS Codes' column.									

Number	er Requirement Responsibility									
Number	Requirement						Sha	d		Othor
			А/В ИА(D M					Other
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11457.00	CWE 1 II 4 TOO E 1				C	S			37	
11457.3.2	CWF shall remove the TOS F records, as appropriate, for the CY 2019 HCPCS/CPT codes in tables 1, effective September 30, 2019.								X	
11457.4	Contractors and Common Working File (CWF) shall add the procedure code to the system's procedure code file [Type of Service (TOS) F] for HCPCS C9042 included in attachment A, table 2, effective for services April 1, 2019 and later payable in the ASC		X						X	
11.457.4.1	setting.		***						***	
11457.4.1	Contractors and CWF shall end date as appropriate, C9042 in table 2 in their systems, effective June 30, 2019.		X						X	
11457.4.2	CWF, as appropriate, shall remove the TOS F record for the CY 2019 HCPCS/CPT code C9042 in table 2, effective June 30, 2019.								X	
11457.5	Contractors and Common Working File (CWF) shall add the procedure code to the system's procedure code file [Type of Service (TOS) F] for HCPCS Q5107 included in attachment A, table 3, effective for services July 18, 2019 and later payable in the ASC setting.		X						X	
11457.6	If released by CMS, Medicare contractors shall download and install the revised July 2019 ASC DRUG file.		X							VDC
	FILENAME: MU00.@BF12390.ASC.CY19.DRUG.JULB.V0917									
	NOTE: Date of retrieval will be provided in a separate email communication from CMS.									

Number	Requirement	nt Responsibility												
			A/B		D		Sha	red-		Other				
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11457.6.1	Medicare contractors shall adjust as appropriate claims brought to their attention that:		X											
	1) Have dates of service July 1, 2019 - September 30, 2019; and													
	2) Were originally processed prior to the installation of the revised July 2019 ASC DRUG File.													
11457.7	If released by CMS, Medicare contractors shall download and install the revised April 2019 ASC DRUG file.		X							VDC				
	FILENAME: MU00.@BF12390.ASC.CY19.DRUG.APRB.V0917													
	NOTE: Date of retrieval will be provided in a separate email communication from CMS.													
11457.7.1	Medicare contractors shall adjust as appropriate claims brought to their attention that:		X											
	1) Have dates of service April 1, 2019 - June 30, 2019; and													
	2) Were originally processed prior to the installation of the revised April 2019 ASC DRUG File.													
11457.8	If released by CMS, Medicare contractors shall download and install the revised January 2019 ASC DRUG file.		X							VDC				

Number	Requirement	Responsibility													
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	FILENAME:														
	MU00.@BF12390.ASC.CY19.DRUG.JANB.V0917														
	NOTE: Date of retrieval will be provided in a														
	separate email communication from CMS.														
11457.8.1	Medicare contractors shall adjust as appropriate claims		X												
111071011	brought to their attention that:		11												
	1) Have dates of service January 1, 2019 - March 31,														
	2019; and														
	2) Were originally processed prior to the installation of the revised January 2019 ASC DRUG File.														
	of the fevised failuary 2019 ASC DROG File.														
11457.9	If released by CMS, Medicare contractors shall		X							VDC					
	download and install the revised October 2018 ASC DRUG file.														
	DRUG IIIC.														
	EH ENJAME.														
	FILENAME: MU00.@BF12390.ASC.CY18.DRUG.OCTD.V0917														
	NOTE: Date of retrieval will be provided in a														
	separate email communication from CMS.														
11457.9.1	Medicare contractors shall adjust as appropriate claims		X												
	brought to their attention that:														
	<u> </u>	1]							

Number	Requirement	Re	espo	nsi	bilit	v						
	•		A/B		D	T T				Other		
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					Е			E Maintainers				
				Н		F	M		C			
					M		C					
				Н	A C	S	S	S	F			
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	1) Have dates of service October 1, 2018 - December 31, 2018; and											
	2) Were originally processed prior to the installation of the revised October 2018 ASC DRUG File.											
11457.10	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	Re	ility			
		N	D M E	E D		
		A	В	H H H	M A C	Ι
11457.11	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	Recommendations or other supporting information:
Requirement	
Number	
1-7	Attachment A: POLICY SECTION TABLES

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

V. CONTACTS

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

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 Established HCPCS Codes for Separately Payable Drugs and Biologicals Effective October 1, 2019

New HCPCS Code	Old HCPCS Code	Short Descriptor	Long Descriptor			
J1943	C9035	Inj., aristada initio, 1 mg	Injection, aripiprazole lauroxil (aristada initio), 1 mg	K2		
J0222	C9036	Inj., patisiran, 0.1 mg	Injection, Patisiran, 0.1 mg	K2		
J2798	C9037	Inj., perseris, 0.5 mg	Injection, risperidone, (perseris), 0.5 mg	K2		
J9204	C9038	Inj mogamulizumab-kpkc, 1 mg	Injection, mogamulizumab-kpkc, 1 mg	K2		
J0291	C9039	Inj., plazomicin, 5 mg	Injection, plazomicin, 5 mg	K2		
J3031	C9040	Inj., fremanezumab-vfrm 1 mg	Injection, fremanezumab-vfrm, 1 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)	K2		
J0641 ⁽¹⁾		Inj levoleucovorin nos 0.5mg	Injection, levoleucovorin, not otherwise specified, 0.5mg	K2		
J9119	C9044	Inj., cemiplimab-rwlc, 1 mg	Injection, cemiplimab-rwlc, 1 mg	K2		
J9313	C9045	Inj., lumoxiti, 0.01 mg	Injection, moxetumomab pasudotox-tdfk, 0.01 mg	K2		
J1096	C9048	Dexametha opth insert 0.1 mg	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg	K2		
J9269	C9049	Inj. tagraxofusp-erzs 10 mcg	Injection, tagraxofusp-erzs, 10 micrograms	K2		
J9210	C9050	Inj., emapalumab-lzsg, 1 mg	Injection, emapalumab-lzsg, 1 mg	K2		
J0121	C9051	Inj., omadacycline, 1 mg	Injection, omadacycline, 1 mg	K2		
J1303	C9052	Inj., ravulizumab-cwvz 10 mg	Injection, ravulizumab-cwvz, 10 mg	K2		
J1097	C9447	Phenylep ketorolac opth soln	phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml	K2		
J0122		Inj., eravacycline, 1 mg	Injection, eravacycline, 1 mg	K2		
J0593		Inj., lanadelumab-flyo, 1 mg	Injection, lanadelumab-flyo, 1 mg (code may be used for Medicare when drug administered under direct supervision of a physician, not for use when drug is self-administered)	K2		
J1944	J1942	aripiprazole lauroxil 1 mg	Injection, aripiprazole lauroxil, (aristada), 1 mg	K2		
J3111		Inj. romosozumab-aqqg 1 mg	Injection, romosozumab-aqqg, 1 mg	K2		
J7314		Inj., yutiq, 0.01 mg	Injection, fluocinolone acetonide, intravitreal implant (Yutiq), 0.01 mg	K2		
Q5117		Inj., kanjinti, 10 mg	Injection, trastuzumab-anns, biosimilar, (kanjinti), 10 mg	K2		

⁽¹⁾ HCPCS J0641 is not new for October 1, 2019, but please note that the short and long descriptors have changed for J0641, effective October 1, 2019.

Table 2. — Separately Payable Drugs and Biologicals with Retroactive Payment Indicator Change for the Period of April 1, 2019 Through June 30, 2019

HCPCS Code	Short Descriptor	Long Descriptor	Old ASC PI	New ASC PI
C9042	Inj., belrapzo 1 mg	Injection, bendamustine hcl (belrapzo), 1 mg	Y5	K2

Table 3. — Separately Payable Drug and Biological with Retroactive Payment Indicator Change for the Period of July 18, 2019 through September 30, 2019

HCPCS Code	Short Descriptor	Long Descriptor	Old ASC PI	New ASC PI
Q5107	Inj mvasi 10 mg	Injection, bevacizumab-awwb, biosimilar, (mvasi), 10 mg	Y5	K2