CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 4123	**Date: August 24, 2018**
	Change Request 10923

SUBJECT: October 2018 Update of the Hospital Outpatient Prospective Payment System (OPPS)

I. SUMMARY OF CHANGES: This recurring update notification describes changes to and billing instructions for various payment policies implemented in the October 2018 OPPS update. The October 2018 Integrated Outpatient Code Editor (I/OCE) will reflect the Healthcare Common Procedure Coding System (HCPCS), Ambulatory Payment Classification (APC), HCPCS Modifier, and Revenue Code additions, changes, and deletions identified in this Change Request (CR). This recurring update notification applies to chapter 4, section 50.8.

The October 2018 revisions to I/OCE data files, instructions, and specifications are provided in the forthcoming October 2018 I/OCE CR.

EFFECTIVE DATE: October 1, 2018
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: October 1, 2018

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: 4123	Date: August 24, 2018	Change Request: 10923

SUBJECT: October 2018 Update of the Hospital Outpatient Prospective Payment System (OPPS)

EFFECTIVE DATE: October 1, 2018
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: October 1, 2018

I. GENERAL INFORMATION

A. Background: This recurring update notification describes changes to billing instructions for various payment policies implemented in the October 2018 OPPS update. The October 2018 I/OCE will reflect the HCPCS, APC, HCPCS modifier, and revenue code additions, changes, and deletions identified in this CR. This recurring update notification applies to chapter 4, section 50.8.

The October 2018 revisions to I/OCE data files, instructions, and specifications are provided in the forthcoming October 2018 I/OCE CR.

B. Policy: 1. New Separately Payable Procedure Code

Effective October 1 2018, HCPCS code C9750 has been created as described in Table 1, attachment A, and assigned to APC 5223 (Level 3 Pacemaker and Similar Procedures) with a payment rate of $9,747.99. This procedure was previously described by Category III Current Procedural Terminology (CPT) code 0302T, which was deleted December 31, 2017.

2. Drugs, Biologicals, and Radiopharmaceuticals

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

For Calendar (CY) 2018, payment for separately payable, nonpass-through drugs, biologicals and therapeutic radiopharmaceuticals that were not acquired through the 340B Program is made at a single rate of ASP + 6 percent (or ASP - 22.5 percent if acquired under the 340B Program), which provides payment for both the acquisition cost and pharmacy overhead costs associated with the drug, biological or therapeutic radiopharmaceutical. In CY 2018, a single payment of ASP + 6 percent 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. Updated payment rates effective October 1, 2018 and drug price restatements can be found in the October 2018 update of the OPPS Addendum A and Addendum B on the CMS website at http://www.cms.gov/HospitalOutpatientPPS/.

b. Drugs and Biologicals Based on ASP Methodology with Restated Payment Rates

Some drugs and biologicals based on ASP methodology will 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 CMS website on the first date of the quarter at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/OPPS-Restated-Payment-Rates.html.

c. Drugs and Biologicals with OPPS Pass-Through Status Effective October 1, 2018

Eight (8) drugs and biologicals have been granted OPPS pass-through status effective October 1, 2018. These drugs and biologicals are described in section 2b. and 2c. of this transmittal and can be found in

Tables 2 and 3, attachment A.

Four drugs and biologicals have been granted new OPPS pass-through status effective October 1, 2018. CMS received a completed pass-through application for these drugs, which passed both the newness and cost criteria to receive pass-through payment. These items, along with their descriptors and APC assignments, are identified in Table 2, attachment A.

Providers may resubmit claims that were impacted by adjustments to previous quarter's payment files.

d. Proposed Drugs, Biologicals, and Radiopharmaceuticals with Pass-Through Status as a Result of Section 1301 of the Consolidated Appropriations Act of 2018 (Publication (Pub.) L. 115-141)

Section 1301(a)(1) of the Consolidated Appropriations Act of 2018 (Pub. L. 115-141) amended section 1833(t)(6) of the Act and added a new section 1833(t)(6)(G), which provides that for drugs or biologicals whose period of pass-through payment status ended on December 31, 2017 and for which payment was packaged into a covered hospital outpatient service furnished beginning January 1, 2018, such pass-through payment status shall be extended for a 2-year period beginning on October 1, 2018 through September 30, 2020. There are four products whose period of drug and biological pass-through payment status ended on December 31, 2017; these four drugs and biologicals will have pass-through status reinstated effective October 1, 2018. These products are listed in Table 3, attachment A.

Beginning in CY 2019, we proposed to continue pass-through payment status for these drugs and biologicals (83 FR 37114).

Section 1301(a)(1) of Pub. L. 115-141 also added a new subparagraph (H) to section 1833(t)(6) to the Act, which provides for a temporary payment rule for drugs and biologicals whose period of pass-through payment ended on December 31, 2017. Under this provision, the payment amount for such drugs or biologicals furnished during the period beginning on October 1, 2018 and ending on March 31, 2019, shall be the greater of the payment amount that would otherwise apply under subparagraph (D)(i) for such drug or biological or the payment amount that applied under subparagraph (D)(i) for such drug or biological on December 31, 2017. In addition, section 1301(a)(1) of Pub. L. 115-141 added a new subparagraph (I) to section 1833(t)(6) to require that, for any drug or biological whose period of pass-through payment ended on December 31, 2017, and for which payment under this subsection is packaged into a payment amount for a covered hospital Outpatient Department (OPD) service (or group of services) furnished during the period beginning on October 1, 2018, and ending on December 31, 2018, the Secretary shall remove the packaged costs of such drug or biological from the payment amount for the covered OPD service with which it is packaged. Finally, section 1301(a)(3) of Pub. L. 115-141 permits the Secretary to implement the amendments made by section 1301(a)(1) and (2) by program instruction or otherwise. This change request implements the requirement in section 1833(t)(6)(I)(i) to remove the packaged costs of the drugs or biologicals listed in Table 3 below from the payment amounts for the covered OPD services (or groups of services) with which they are packaged.

As explained above, these drugs and biologicals will be receiving separate payment under the OPPS instead of having their costs packaged into the payment amount for associated procedures for the period beginning October 1, 2018 through December 31, 2018. Therefore, CMS updated the CY 2018 payment rates to reflect the separate payment for the drugs and biologicals listed in Table 3, attachment A, and found the payment rates for the 10 APCs listed in Table 4, attachment A, were affected by the separate payment for these drugs and biologicals, and therefore, we removed the costs of the drugs and biologicals from the payment amounts for these APCs. The updated payment rates for these APCS, which are effective October 1, 2018 through December 31, 2018, can be found in the October 2018 update of the OPPS Addendum A and Addendum B on the CMS website at http://www.cms.gov/HospitalOutpatientPPS/.

e. New Biosimilar HCPCS Code

HCPCS code Q5108, listed in table 5, attachment A, is a biosimilar with the trade name Fulphila that will be paid separately in the OPPS. The code will be included in the OPPS with an effective date retroactive to July 12, 2018, per CR 10834, which states that HCPCS code is payable for Medicare for claims with a date of service on or after July 12, 2018.

3. Reassignment of Skin Substitute Product from the Low Cost Group to the High Cost Group

One skin substitute product, HCPCS code Q4181, has been reassigned from the low cost skin substitute group to the high cost skin substitute group based on updated pricing information. The product is listed in Table 6, attachment A.

4. Changes to OPPS Pricer Logic

a. New OPPS payment rates and copayment amounts will be effective October 1, 2018. All copayment amounts will be limited to a maximum of 40 percent of the APC payment rate. Copayment amounts for each service cannot exceed the CY 2018 inpatient deductible of $1,340. For most OPPS services, copayments are set at 20 percent of the APC payment rate.

b. Effective October 1, 2018, there will be one contrast agent, Q9950, receiving pass-through payment in the OPPS Pricer logic. For APCs containing nuclear medicine procedures, the I/OCE will send the off-set amount of the pass-through for the contrast agent, then Pricer will reduce the amount of the pass-through contrast agent payment by the wage-adjusted offset for the APC with the highest offset amount when the contrast agent with pass-through appears on a claim with a nuclear procedure. The offset will cease to apply when the contrast agent expires from pass-through status. The offset amounts for diagnostic radiopharmaceuticals are the “policy-packaged” portions of the CY 2018 APC payments for nuclear medicine procedures and may be found on the CMS website.

5. Coverage Determinations

As a reminder, the fact that a drug, device, procedure or service is assigned a HCPCS code and a payment rate under the OPPS 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.

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
10923.1	Medicare contractors shall install the October 2018 OPPS Pricer.	X		X		X				
10923.2	Medicare contactors shall manually add the following codes to their systems:	X		X						

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	• HCPCS code C9750, listed in table 1, attachment A, effective October 1, 2018, • HCPCS codes C9033-C9034 listed in table 2, attachment A, effective October 1, 2018, • HCPCS code Q5108, listed in table 5, attachment A, effective July 12, 2018, and • HCPCS codes G9978-G9987 listed in the upcoming October 2018 I/OCE CR, effective October 1, 2018. **Note:** These HCPCS codes will be included with the October 2018 I/OCE update. Status and payment indicators for these HCPCS codes will be listed in the October 2018 update of the OPPS Addendum A and Addendum B on the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html									
10923.3	Medicare contractors shall adjust, as appropriate, claims brought to their attention with any retroactive changes that were processed prior to implementation of the October 2018 I/OCE.	X		X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
10923.4	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	X		X		

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
	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.					

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

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

V. CONTACTS

Pre-Implementation Contact(s): Marina Kushnirova, marina.kushnirova@cms.hhs.gov

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 − Tables for the Policy Section

Table 1. ─ New Separately Payable Procedure Code Effective October 1, 2018

HCPCS Code	Short Descriptor	Long Descriptor	SI	APC	Payment Rate
C9750	Ins/rem-replace compl iims	Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation and peri-operative interrogation and programming; complete system (includes device and electrode)	J1	5223	$9,747.99

Table 2. – Drugs and Biologicals with OPPS Pass-Through Status Effective October 1, 2018

HCPCS Code	Long Descriptor	SI	APC
C9033	Injection, fosnetupitant 235 mg and palonosetron 0.25 mg	G	9099
C9034	Injection, dexamethasone 9%, intraocular, 1 mcg	G	9172
Q5105	Injection, epoetin alfa, biosimilar, (Retacrit) (for esrd on dialysis), 100 units	G	9096
Q5106	Injection, epoetin alfa, biosimilar, (Retacrit) (for non-esrd use), 1000 units	G	9097

Table 3. – Drugs and Biologicals Receiving Pass-Through Status in Accordance with Public Law 115-141 Effective October 1, 2018

HCPCS Code	Long Descriptor	SI	APC
A9586	Florbetapir f18, diagnostic, per study dose, up to 10 millicuries	G	9084
C9447	Injection, phenylephrine and ketorolac, 4 ml vial	G	9083
Q4172	PuraPly, and PuraPly Antimicrobial, any type, per square centimeter	G	9082

Q9950	Injection, sulfur hexafluoride lipid microsphere, per ml	G	9085

Table 4. – APCs with New Payment Rates because of the Separate Payment for Certain Drugs and Biologicals Receiving Pass-Through Status in Accordance with Public Law 115-141 Effective October 1, 2018 through December 31, 2018

Long Descriptor	SI	APC
Level 5 Intraocular Procedures	J1	5495
Level 1 Intraocular Procedures	J1	5491
Level 3 Imaging with Contrast	S	5573
Level 4 Nuclear Medicine and Related Services	S	5594
Level 3 Intraocular Procedures	J1	5493
Level 2 Intraocular Procedures	J1	5492
Level 3 ENT Procedures	T	5163
Level 2 Imaging with Contrast	S	5572
Pulmonary Treatment	S	5791
Level 4 Extraocular, Repair, and Plastic Eye Procedures	J1	5504

Table 5. ─ New Biosimilar HCPCS Code Effective July 12, 2018

HCPCS Code	Long Descriptor	SI	APC	Effective Date
Q5108	Injection, pegfilgrastim-jmdb, biosimilar, (fulphila), 0.5 mg	K	9173	07/12/2018

Table 6. – Reassignment of Skin Substitute Product from the Low Cost Group to the High Cost Group Effective October 1, 2018

HCPCS Code	Short Descriptor	SI	Low/High Cost Skin Substitute
Q4181	Amnio wound, per square cm	N	High