CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 4064	**Date: June 1, 2018**
	Change Request 10781

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

I. SUMMARY OF CHANGES: This recurring update notification describes changes to billing instructions for various payment policies implemented in the July 2018 OPPS update. The July 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 July 2018 revisions to I/OCE data files, instructions, and specifications are provided in the forthcoming July 2018 I/OCE CR.

EFFECTIVE DATE: July 1, 2018
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: July 2, 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: 4064	Date: Date: June 1, 2018	Change Request: 10781

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

EFFECTIVE DATE: July 1, 2018
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: July 2, 2018

I. GENERAL INFORMATION

A. Background: This recurring update notification describes changes to billing instructions for various payment policies implemented in the July 2018 OPPS update. The July 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 July 2018 revisions to I/OCE data files, instructions, and specifications are provided in the forthcoming July 2018 I/OCE CR.

B. Policy: 1. Multianalyte Assays with Algorithmic Analyses (MAAA) CPT Coding Changes Effective April 1, 2018

The American Medical Association (AMA) Current Procedural Terminology (CPT) Editorial Panel established two new MAAA codes, specifically, 0012M and 0013M, effective April 1, 2018. Because the codes were released on March 1, 2018, it was too late to include them in the April 2018 OPPS update. Instead, the codes are being included in the July 2018 update with an effective date of April 1, 2018. Table 1, attachment A, lists the long descriptor and status indicator for CPT codes 0012M and 0013M.

2. Proprietary Laboratory Analyses (PLA) CPT Coding Changes Effective April 1, 2018

The AMA CPT Editorial Panel established 10 new PLA CPT codes, specifically, CPT codes 0035U through 0044U effective April 1, 2018. Because the codes were released on February 22, 2018, it was too late to include them in the January 2018 OPPS update. Instead, they are being included in the July 2018 update with an effective date of April 1, 2018.

Table 2, attachment A, lists the long descriptors and status indicators for CPT codes 0035U through 0044U. For more information on OPPS status indicators “A” and “Q4”, refer to OPPS Addendum D1 of the Calendar Year (CY) 2018 OPPS/Ambulatory Surgical Center (ASC) final rule. CPT codes 0035U through 0044U have been added to the July 2018 I/OCE with an effective date of April 1, 2018. These codes, along with their short descriptors and status indicators, are also listed in the July 2018 OPPS Addendum B.

3. Category III CPT Codes Effective July 1, 2018

The AMA releases Category III CPT codes twice per year: in January, for implementation beginning the following July, and in July, for implementation beginning the following January.

For the July 2018 update, CMS is implementing four Category III CPT codes that the AMA released in January 2018 for implementation on July 1, 2018. The status indicators and APC assignments for these codes are shown in Table 3, attachment A. Payment rates for these services can be found in Addendum B of the July 2018 OPPS update that is posted on the CMS website.

4. Bilateral Indicator for HCPCS Code C9749

In the April 2018 OPPS update CR (Transmittal 4005, CR 10515 dated March 20, 2018), we announced the establishment of HCPCS code C9749 (Repair of nasal vestibular lateral wall stenosis with implant(s)) effective April 1, 2018. We are clarifying that this code describes an inherently bilateral procedure, and that for unilateral procedures, hospital outpatient departments need to report either modifier 73 or 74. We note that modifiers 73 and 74 are only used to indicate discontinued procedures for which anesthesia is planned or provided.

5. Packaging of CPT code 01402 when reported with Total Knee Arthroplasty (CPT code 27447)

CPT code 01402 describes anesthesia for open or surgical arthroscopic procedures on knee joint; total knee arthroplasty. For CY 2018, the status indicator assigned to this code is "C", which indicates that this is an inpatient procedure that is not paid for under the OPPS. For the July 2018 update, when CPT code 01402 is reported with CPT code 27447, Arthroplasty, knee, condyle and plateau; medical and lateral compartments with or without patella resurfacing (total knee arthroplasty), this code is paid under the OPPS and payment for this service is packaged into the payment for CPT code 27447. If the code is not reported with CPT code 27447, the code is treated as an inpatient procedure that is not paid for under the OPPS. This change is retroactive to January 1, 2018.

6. Drugs, Biologicals, and Radiopharmaceuticals

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

For CY 2018, payment for 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 July 1, 2018 and drug price restatements can be found in the July 2018 update of the OPPS Addendum A and Addendum B on the CMS website at http://www.cms.gov/HospitalOutpatientPPS/.

b. **Drugs and Biologicals with OPPS Pass-Through Status Effective July 1, 2018**

Six drugs and biologicals have been granted OPPS pass-through status effective July 1, 2018. These items, along with their descriptors and APC assignments, are identified in Table 4, attachment A.

c. **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.

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

d. Other Changes to CY 2018 HCPCS Codes for Certain Drugs, Biologicals, and Radiopharmaceuticals

Effective July 1, 2018, HCPCS code Q9993 (Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg) will replace HCPCS code C9469 (Injection, triamcinolone

acetonide, preservative-free, extended-release, microsphere formulation, 1 mg). The status indicator will remain G, “Pass-Through Drugs and Biologicals”. Table 5, attachment A, describes the HCPCS code change and effective date.

e. Change to Status Indicator for CPT Code 90739

Hepatitis B vaccine associated with CPT code 90739 (Hepatitis b vaccine (hepb), adult dosage, 2 dose schedule, for intramuscular use) was approved by the Food and Drug Administration (FDA) on November 09, 2017. Therefore, we are changing the status indicator for 90739 from SI=E1 (Not paid by Medicare when submitted on outpatient claims (any outpatient bill type) to SI=F (Not paid under OPPS. Paid at reasonable cost.) effective April 1, 2018 in the July 2018 I/OCE update. Table 6, attachment A, describes the status indicator change and effective date.

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

One skin substitute product, HCPCS code Q4178, 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 7, attachment A.

8. Allow HCPCS Code Q4116 (Alloderm, per square centimeter) to Be Billed with Either Revenue Code 0278 (Other implants) or Revenue Code 0636 (Drugs requiring detailed coding)

HCPCS code Q4116 (Alloderm, per square centimeter) may be billed with either revenue code 0278 (Other implants) or revenue code 0636 (Drugs requiring detailed coding). HCPCS code Q4116 is used both as an applied skin substitute and as an implanted biologic used in breast reconstruction, and these procedures are reported with two different revenue codes. This request is described in Table 8, attachment A.

9. 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 MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
10781.1	Medicare contractors shall manually update the HCPCS file for Q4116 to allow both revenue codes 0278 or 0636.	X		X		X				
10781.2	Medicare contractors shall manually add the following codes to their systems:	X		X		X				

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	• CPT codes 0012M and 0013M listed in table 1, attachment A, effective April 1, 2018; and • CPT code 0035U - 0044U listed in table 2, attachment A, effective April 1, 2018; and • CPT codes 0505T – 0508T listed in table 3, attachment A, effective July 1, 2018; and • All HCPCS codes in table 4, Attachment A, effective July 1, 2018; and • HCPCS code Q9993 listed in table 5, attachment A, effective July 1, 2018; and **NOTE:** These HCPCS codes will be included with the July 2018 I/OCE update. Status and payment indicators for these HCPCS codes will be listed in the July 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									
10781.3	Medicare contractors shall manually add termination dates for the following HCPCS codes to their systems: • CPT code 0008M listed in the upcoming July 2018 I/OCE CR, effective January 1, 2018. • HCPCS code C9469 listed in table 5, attachment A, effective June 30, 2018. **NOTE:** These deletions will be reflected in the July 2018 I/OCE update and in the July 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	X		X		X				

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
10781.4	Medicare contractors shall adjust, as appropriate, claims brought to their attention with any retroactive changes that were processed prior to implementation of the July 2018 I/OCE.	X		X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
10781.5	MLN Article: A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within 5 business days after receipt of the notification from CMS announcing the availability of the article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X		X		

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. ─ Multianalyte Assays with Algorithmic Analyses (MAAA) CPT Coding Changes Effective April 1, 2018

CPT Code	Long Descriptor	OPPS SI	OPPS APC APC
0012M	Oncology (urothelial), mRNA, gene expression profiling by real-time quantitative PCR of five genes (MDK, HOXA13, CDC2 [CDK1], IGFBP5, and XCR2), utilizing urine, algorithm reported as a risk score for having urothelial carcinoma	A	N/A
0013M	Oncology (urothelial), mRNA, gene expression profiling by real-time quantitative PCR of five genes (MDK, HOXA13, CDC2 [CDK1], IGFBP5, and CXCR2), utilizing urine, algorithm reported as a risk score for having recurrent urothelial carcinoma	A	N/A

Table 2. ─ Proprietary Laboratory Analyses (PLA) CPT Coding Changes Effective April 1, 2018

CPT Code	Long Descriptor	OPPS SI	OPPS APC
0035U	Neurology (prion disease), cerebrospinal fluid, detection of prion protein by quaking-induced conformational conversion, qualitative	Q4	N/A
0036U	Exome (ie, somatic mutations), paired formalin-fixed paraffin-embedded tumor tissue and normal specimen, sequence analyses	A	N/A
0037U	Targeted genomic sequence analysis, solid organ neoplasm, DNA analysis of 324 genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden	A	N/A
0038U	Vitamin D, 25 hydroxy D2 and D3, by LC-MS/MS, serum microsample, quantitative	Q4	N/A
0039U	Deoxyribonucleic acid (DNA) antibody, double stranded, high avidity	Q4	N/A
0040U	BCR/ABL1 (t(9;22)) (eg, chronic myelogenous leukemia) translocation analysis, major breakpoint, quantitative	A	N/A
0041U	Borrelia burgdorferi, antibody detection of 5 recombinant protein groups, by immunoblot, IgM	Q4	N/A
0042U	Borrelia burgdorferi, antibody detection of 12 recombinant protein groups, by immunoblot, IgG	Q4	N/A
0043U	Tick-borne relapsing fever Borrelia group, antibody detection	Q4	N/A

	to 4 recombinant protein groups, by immunoblot, IgM		
0044U	Tick-borne relapsing fever Borrelia group, antibody detection to 4 recombinant protein groups, by immunoblot, IgG	Q4	N/A

Table 3. — Category III CPT Codes Effective July 1, 2018

CPT Code	Long Descriptor	OPPS SI	OPPS APC
0505T	Endovenous femoral-popliteal arterial revascularization, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed, with crossing of the occlusive lesion in an extraluminal fashion	J1	5193
0506T	Macular pigment optical density measurement by heterochromatic flicker photometry, unilateral or bilateral, with interpretation and report	Q1	5733
0507T	Near-infrared dual imaging (ie, simultaneous reflective and trans-illuminated light) of meibomian glands, unilateral or bilateral, with interpretation and report	Q1	5733
0508T	Pulse-echo ultrasound bone density measurement resulting in indicator of axial bone mineral density, tibia	S	5522

Table 4. — Drugs and Biologicals with OPPS Pass-Through Status Effective July 1, 2018

HCPCS Code	Long Descriptor	Status Indicator	APC
C9030	Injection, copanlisib, 1 mg	G	9030
C9031	Lutetium Lu 177, dotatate, therapeutic, 1 mCi	G	9067
C9032	Injection, voretigene neparvovec-rzyl, 1 billion vector genome	G	9070
Q9991	Injection, buprenorphine extended-release (Sublocade), less than or equal to 100 mg	G	9073

Q9992	Injection, buprenorphine extended-release (Sublocade), greater than 100 mg	G	9239
Q9995	Injection, emicizumab-kxwh, 0.5 mg	G	9257

Table 5. – Other Changes to CY 2018 HCPCS Codes for Certain Drugs, Biologicals, and Radiopharmaceuticals

HCPCS Code	Long Descriptor	Status Indicator	APC	Effective Date	Termination Date
C9469	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg	G	9469	04/01/2018	06/30/2018
Q9993	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg	G	9469	07/01/2018	

Table 6. – Change to Status Indicator for CPT Code 90739

CPT Code	Long Descriptor	Status Indicator	Effective Date
90739	Hepatitis b vaccine (hepb), adult dosage, 2 dose schedule, for intramuscular use	E1	January 1, 2013 – March 31, 2018
90739	Hepatitis b vaccine (hepb), adult dosage, 2 dose schedule, for intramuscular use	F	April 1, 2018

Table 7. – Reassignment of Skin Substitute Product from the Low Cost Group to the High Cost Group Effective July 1, 2018

CY 2018 HCPCS Code	CY 2018 Short Descriptor	CY 2018 SI	Low/High Cost Skin Substitute
Q4178	Floweramniopatch, per sq cm	N	High

Table 8. – Allow HCPCS Code Q4116 (Alloderm, per square centimeter) to Be Billed with Either Revenue Code 0278 (Other implants) or Revenue Code 0636 (Drugs requiring detailed coding)

CY 2018 HCPCS Code	CY 2018 Short Descriptor	CY 2018 SI	Allowed Revenue Codes for Billing
Q4116	Alloderm, per square centimeter	N	0278, 0636