CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 3853	**Date: August 25, 2017**
	Change Request 10236

SUBJECT: October 2017 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 2017 OPPS update. The October 2017 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 10.9.

The October 2017 revisions to I/OCE data files, instructions, and specifications are provided in the forthcoming October 2017 I/OCE CR.

EFFECTIVE DATE: October 1, 2017
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: October 2, 2017

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: 3853	Date: August 25, 2017	Change Request: 10236

SUBJECT: October 2017 Update of the Hospital Outpatient Prospective Payment System (OPPS)

EFFECTIVE DATE: October 1, 2017
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IMPLEMENTATION DATE: October 2, 2017

I. GENERAL INFORMATION

A. Background: This Recurring Update Notification describes changes to and billing instructions for various payment policies implemented in the October 2017 OPPS update. The October 2017 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 10.9.

The October 2017 revisions to I/OCE data files, instructions, and specifications are provided in the forthcoming October 2017 I/OCE CR.

B. Policy:
1. Proprietary Laboratory Analyses (PLA) CPT Codes 0006U through 0017U Effective August 1, 2017

The AMA CPT Editorial Panel established 12 new PLA CPT codes, specifically, CPT codes 0006U through 0017U effective August 1, 2017. The long descriptors for the codes are listed in table 1, Attachment A. Because the codes will be effective August 1, 2017, they were not included in the July 2017 OPPS Update and are instead being including in the October 2017 Update with an effective date of August 1, 2017.

Table 1, attachment A, lists the long descriptors and status indicators for CPT codes 0006U through 0017U. For more information on OPPS status indicators “A” and “Q4”, refer to OPPS Addendum D1 of the CY 2017 OPPS/ASC final rule for the latest definitions.

CPT codes 0006U through 0017U have been added to the October 2017 I/OCE with an effective date of August 1, 2017. These codes, along with their short descriptors and status indicators, are also listed in the October 2017 OPPS Addendum B.

2. Billing for Peripheral Artery Disease (PAD) Rehabilitation

Effective May 25, 2017, CMS will pay for supervised exercised therapy (SET) for beneficiaries with intermittent claudication for the treatment of symptomatic peripheral artery disease. To implement this NCD, CMS will pay separately for CPT code 93668 under the hospital OPPS.

For purposes of Medicare coverage, services must meet all of the following eligibility criteria:

- consist of sessions lasting 30-60 minutes comprising a therapeutic exercise-training program for PAD in patients with claudication;

- be conducted in a hospital outpatient setting, or a physician’s office;

- be delivered by qualified auxiliary personnel necessary to ensure benefits exceed harms, and who are trained in exercise therapy for PAD; and

- be under the direct supervision of a physician (as defined in 1861(r)(1)), physician assistant, or nurse practitioner/clinical nurse specialist (as identified in 1861(aa)(5)) who must be trained in both basic and advanced life support techniques.

Beneficiaries must have a face-to-face visit with the physician responsible for PAD treatment to obtain the referral for SET. At this visit, the beneficiary must receive information regarding cardiovascular disease and PAD risk factor reduction, which could include education, counseling, behavioral interventions, and outcome assessments.

1. Medicare Administrative Contractors (MACs) have the discretion to cover SET beyond 36 sessions over 12 weeks and may cover an additional 36 sessions over an extended period of time. A second referral is required for these additional sessions.

2. SET is non-covered for beneficiaries with absolute contraindications to exercise as determined by their primary physician.

For more information on this recent national coverage determination, refer to the "Decision Memo on Supervised Exercise Therapy (SET) for Symptomatic Peripheral Artery Disease (PAD) (CAG-00449N)," which can be found on the CMS website, specifically, at https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=287.

Table 2, attachment A, lists the long descriptor, status indicator, and APC assignment for CPT code 93668. The payment amount for CPT code 93668 can be found in the October 2017 OPPS Addendum B.

3. New Procedures Requiring the Insertion of a Device

Since January 1, 2017, all new procedures requiring the insertion of an implantable medical device will be assigned a default device offset percentage of at least 41%, and thereby assigned device intensive status, until claims data is available. In certain rare instances, we may temporarily assign a higher offset percentage if warranted by additional information. In accordance with our current policy the following code requiring the insertion of a device (listed in Table 3, attachment A) will be assigned device intensive status effective October 1, 2017. We note that although HCPCS code C9747, was effective under the OPPS as of July 1, 2017, its device intensive designation is not effective until October 1, 2017.

4. Drugs, Biologicals, and Radiopharmaceuticals

a. Drugs and Biologicals with Payments Based on Average Sales Price (ASP) Effective October 1, 2017

Payment for separately payable non pass-through drugs, biologicals and therapeutic radiopharmaceuticals (status indicator "K") is 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, biological or therapeutic radiopharmaceutical. In addition, a single payment of ASP + 6 percent for pass-through drugs, biologicals and radiopharmaceuticals (status indicator "G") 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 ASP submissions become available. Updated payment rates effective October 1, 2017 and drug price restatements can be found in the October 2017 update of the OPPS Addendum A and Addendum B on the CMS Web site at http://www.cms.gov/HospitalOutpatientPPS/.

b. Drugs and Biologicals Based on ASP Methodology with Restated PaymentRates

Some drugs and biologicals paid based on the 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 Web site 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.

c. Drugs and Biologicals with OPPS Pass-Through Status Effective October 1, 2017

Four drugs and biologicals have been granted OPPS pass-through status effective October 1, 2017. These items, along with their descriptors and APC assignments, are identified in table 4, attachment A.

d. New Modifier for Biosimilar Biological Product

Q5102 can be reported with either the existing modifier ZB or new modifier ZC effective July 1, 2017, see table 5, attachment A.

e. New Flu Vaccine

The existing influenza vaccine CPT code 90674 (Cciiv4 vaccine, no preservative, 0.5 ml, intramuscular) with trade name Flucelvax Quadrivalent was effective January 1, 2017 and is a preservative-free and antibiotic-free vaccine. A new preservative, antibiotic-free influenza vaccine CPT code with the same trade name, Flucelvax Quadrivalent, will be effective on January 1, 2018. For the period between August 1, 2017 and December 31, 2017, Flucelvax Quadrivalent Preservative should be reported as Q2039. The permanent CPT code for the Flucelvax Quadrivalent preservative influenza vaccine will be released on a later date, see table 6, attachment A.

5. Upper Eyelid Blepharoplasty and Blepharoptosis Repair

As indicated in Chapter VIII of the CY 2017 National Correct Coding Initiative (NCCI) Policy Manual for Medicare Services, CMS payment policy does not allow separate payments for a blepharoptosis procedure (CPT code 67901-67908) and a blepharoplasty procedure (CPT codes 15822-15823) on the ipsilateral upper eyelid. Under this policy, any removal of upper eyelid skin in the context of an upper eyelid blepharoptosis surgery was considered a part of the blepharoptosis surgery. This instruction was clarified in the July 2016 Hospital Outpatient Prospective Payment System (OPPS) Update Change Request (Transmittal 3557, Change Request 9658 dated July 1, 2016) and the July 2016 OPPS MLN Matters Article MM9658.

However, effective October 1, 2017, CMS is revising this policy to allow either cosmetic or medically necessary blepharoplasty to be performed in conjunction with a medically necessary upper eyelid blepharoptosis surgery. Specifically, physicians may receive payment for a medically necessary upper eyelid blepharoptosis from Medicare even when performed with (non-covered) cosmetic blepharoplasty on the same eye during the same visit. Since cosmetic procedures are not covered by Medicare, advanced beneficiary notice of noncoverage (ABN) instructions would apply for cosmetic blepharoplasty. However, medically necessary blepharoplasty will continue to be bundled into the payment for blepharoptosis when performed with and as a part of a blepharoptosis surgery.

Other aspects of the July 2016 OPPS Update CR and MLN guidance on upper eyelid blepharoplasty and blepharoptosis remain unchanged. Specifically, we note that Medicare does not allow separate payment for the following:

* Operating on the left and right eyes on different days when the standard of care is bilateral eyelid surgery

* Charging the beneficiary an additional amount for removing orbital fat when a blepharoplasty or a blepharoptosis repair is performed

* Performing a medically necessary blepharoplasty on a different date of service than the blepharoptosis procedure for the purpose of unbundling the medically necessary blepharoplasty

* Performing blepharoplasty as a staged procedure, either by one or more surgeons (note that under certain circumstances a blepharoptosis procedure could be a staged procedure)

* Billing for two procedures when two surgeons divide the work of a medically necessary blepharoplasty performed with a blepharoptosis repair

* Using modifier 59 to unbundle a medically necessary blepharoplasty from the ptosis repair on the claim form; this applies to both physicians and facilities.

* Treating medically necessary surgery as cosmetic for the purpose of charging the beneficiary for a cosmetic surgery

* In the rare event that a blepharoplasty is performed on one eye and a blepharoptosis repair is performed on the other eye, the services must each be billed with the appropriate RT or LT modifier.

6. 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	
10236.1	Medicare contactors shall manually add the following codes to their systems: • All CPT codes listed in table 1, attachment A, effective August 1, 2017; and • All HCPCS codes, listed in table 4, attachment A, effective October 1, 2017; **Note:** These HCPCS codes will be included with the October 2017 I/OCE update. Status and payment indicators for these HCPCS codes will be listed in the October 2017 update of the OPPS Addendum A and Addendum B on the CMS Web site at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html	X		X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
10236.2	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. – Proprietary Laboratory Analyses (PLA) CPT Codes Effective August 1, 2017

CPT Code	Long Descriptor	OPPS SI	OPPS APC
0006U	Prescription drug monitoring, 120 or more drugs and substances, definitive tandem mass spectrometry with chromatography, urine, qualitative report of presence (including quantitative levels, when detected) or absence of each drug or substance with description and severity of potential interactions, with identified substances, per date of service	Q4	N/A
0007U	Drug test(s), presumptive, with definitive confirmation of positive results, any number of drug classes, urine, includes specimen verification including DNA authentication in comparison to buccal DNA, per date of service	Q4	N/A
0008U	Helicobacter pylori detection and antibiotic resistance, DNA, 16S and 23S rRNA, gyrA, pbp1, rdxA and rpoB, next generation sequencing, formalin-fixed paraffin embedded or fresh tissue, predictive, reported as positive or negative for resistance to clarithromycin, fluoroquinolones, metronidazole, amoxicillin, tetracycline and rifabutin	A	N/A
0009U	Oncology (breast cancer), ERBB2 (HER2) copy number by FISH, tumor cells from formalin fixed paraffin embedded tissue isolated using image-based dielectrophoresis (DEP) sorting, reported as ERBB2 gene amplified or non-amplified	Q4	N/A
0010U	Infectious disease (bacterial), strain typing by whole genome sequencing, phylogenetic-based report of strain relatedness, per submitted isolate	A	N/A
0011U	Prescription drug monitoring, evaluation of drugs present by LCMS/MS, using oral fluid, reported as a comparison to an estimated steady-state range, per date of service including all drug compounds and metabolites	Q4	N/A
0012U	Germline disorders, gene rearrangement detection by whole genome next-generation sequencing, DNA, whole blood, report of specific gene rearrangement(s)	A	N/A
0013U	Oncology (solid organ neoplasia), gene rearrangement detection by whole genome next-generation sequencing, DNA, fresh or frozen tissue or cells, report of specific gene rearrangement(s)	A	N/A
0014U	Hematology (hematolymphoid neoplasia), gene rearrangement detection by whole genome nextgeneration sequencing, DNA, whole blood or bone marrow, report of specific gene rearrangement(s)	A	N/A

CPT Code	Long Descriptor	OPPS SI	OPPS APC
0015U	Drug metabolism (adverse drug reactions), DNA, 22 drug metabolism and transporter genes, real-time PCR, blood or buccal swab, genotype and metabolizer status for therapeutic decision support	Q4	N/A
0016U	Oncology (hematolymphoid neoplasia), RNA, BCR/ABL1 major and minor breakpoint fusion transcripts, quantitative PCR amplification, blood or bone marrow, report of fusion not detected or detected with quantitation	A	N/A
0017U	Oncology (hematolymphoid neoplasia), JAK2 mutation, DNA, PCR amplification of exons 12-14 and sequence analysis, blood or bone marrow, report of JAK2 mutation not detected or detected	A	N/A

Table 2. ─ Peripheral Artery Disease (PAD) Rehabilitation

CPT Code	Long Descriptor	OPPS SI	OPPS APC
93668	Peripheral arterial disease (pad) rehabilitation, per session	S	5733

Table 3. ─ New Procedures Requiring the Insertion of a Device

HCPCS Code	Long Descriptor	Effective Date	October 2017 OPPS SI	October 2017 OPPS APC	CY 2017 OPPS Payment Rate	CY 2017 Device Offset
C9747	Ablation of prostate, transrectal, high intensity focused ultrasound (HIFU), including imaging guidance	10-01-2017	J1	5376	$7,452.66	$3,055.60

Table 4. – Drugs and Biologicals with OPPS Pass-Through Status Effective October 1, 2017

HCPCS Code	Short Description	Long Description	Oct 2017 OPPS SI	Oct 2017 OPPS APC
C9491	Injection, avelumab	Injection, avelumab, 10 mg	G	9491
C9492	Injection, durvalumab	Injection, durvalumab, 10 mg	G	9492
C9493	Injection, edaravone	Injection, edaravone, 1 mg	G	9493
C9494	Injection, ocrelizumab	Injection, ocrelizumab, 1 mg	G	9494

Table 5. – Biosimilar Biological Product Payment and Required Modifiers

HCPCS Code	Short Descriptor	Long Descriptor	SI	APC	HCPCS Code Effective Date	Modifier	Modifier Effective Date
Q5102	Injection, infliximab biosimilar	Injection, Infliximab, Bio similar, 10 mg	K	1847	04/05/2016	ZB – Pfizer/Hospira	04/01/2016
Q5102	Injection, infliximab biosimila	Injection, Infliximab, Biosimilar, 10 mg	K	1847	04/05/2016	ZC – Merck/Samsung Bioepis	07/01/2017

Table 6. – Billing for Preservative and Preservative-Free Flucelvax Quadrivalent Influenza Vaccine

Vaccine Type	HCPCS Code	Short Descriptor	Long Descriptor	OPPS SI

Flucelvax Quadrivalent Preservative-Free and Antibiotic-Free Flu Vaccine	90674	Cciiv4 vaccine, no preservative, 0.5 ml, intramuscular	Influenza virus vaccine, quadrivalent (ccIIV4), derived from cell cultures, subunit, preservative and antibiotic free, 0.5 mL dosage, for intramuscular	L
Flucelvax Quadrivalent Preservative Flu Vaccine	Q2039	Cciiv4 vaccine, nos, intramuscular	Influenza virus vaccine, not otherwise specified	L