



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

MLN Matters Number: MM10236 **Revised**

Related Change Request (CR) Number: 10236

Related CR Release Date: September 15, 2017

Effective Date: October 1, 2017

Related CR Transmittal Number: R3864CP

Implementation Date: October 2, 2017

The article was revised on September 15, 2017, to reflect an updated Change Request (CR) that updated the policy section (added Transurethral Waterjet Prostate Ablation Procedure) that also includes information on the revised OPPS status indicator and APC for CPT code 0421T. It also corrected an error to the OPPS status indicator for Q5102 in Table 5. In addition, a new Table 7 was added. All other information remains the same

### PROVIDER TYPES AFFECTED

This MLN Matters® Article is intended for providers and suppliers that submit claims to Medicare Administrative Contractors (MACs), including Home Health and Hospice (HH&H) MACs, for services provided to Medicare beneficiaries and paid under the Outpatient Prospective Payment System (OPPS).

### PROVIDER ACTION NEEDED

Change Request (CR) 10236 which describes changes to the OPPS to be implemented in the July 2017 update. Make sure your billing staffs are aware of these changes.

### 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 CR 10236. This Recurring Update Notification applies to Chapter 4, section 10.9.

Key changes to and billing instructions for various payment policies implemented in the October 2017 Outpatient Prospective Payment System (OPPS) updates are as follows:

#### ***Proprietary Laboratory Analyses (PLA) CPT Codes 0006U through 0017U Effective August 1, 2017***

The American Medical Association CPT Editorial Panel established 12 new PLA CPT codes,

specifically, CPT codes 0006U through 0017U effective August 1, 2017. Because the codes will be effective August 1, 2017, they were not included in the July 2017 OPSS Update and are instead being including in the October 2017 Update with an effective date of August 1, 2017.

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

**Table 1 – Proprietary Laboratory Analyses (PLA) CPT Codes Effective August 1, 2017**

CPT Code	Long Descriptor	OPSS SI	OPSS 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

CPT Code	Long Descriptor	OPPS SI	OPPS APC
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
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

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.

### ***Billing for Peripheral Artery Disease (PAD) Rehabilitation***

Effective May 25, 2017, the Centers for Medicare & Medicaid Services (CMS) will pay for supervised exercised therapy (SET) for beneficiaries with intermittent claudication for the treatment of symptomatic peripheral artery disease. To implement this National Coverage Determination (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
- 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. 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 NCD, refer to the "Decision Memo on Supervised Exercise Therapy (SET) for Symptomatic Peripheral Artery Disease (PAD) (CAG-00449N)," which is available at <https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=287>.

Table 2 lists the long descriptor, status indicator, and APC assignment for CPT code 93668. The payment amount for CPT code 93668 is available in the October 2017 OPPS Addendum B.

**Table 2 – Peripheral Artery Disease (PAD) Rehabilitation**

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

### ***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, CMS may temporarily assign a higher offset percentage if warranted by additional information. In accordance with current Medicare policy, the following code requiring the insertion of a device (listed in Table 3) will be assigned device intensive status effective October 1, 2017. CMS notes that although HCPCS code C9747, was effective under the OPPTS as of July 1, 2017, its device intensive designation is not effective until October 1, 2017.

**Table 3 – New Procedures Requiring the Insertion of a Device**

HCPCS Code	Long Descriptor	Effective Date	October 2017 OPPTS SI	October 2017 OPPTS APC	CY 2017 OPPTS 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

### ***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 are available in the October 2017 update of the OPPTS Addendum A and Addendum B at <http://www.cms.gov/HospitalOutpatientPPS/>.

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

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 first date of the quarter at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/OPPTS-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.

**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

### 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. **CMS is also instructing MACs that the ZC modifier will become effective, that is, valid for claims submitted beginning October 1, 2017, and applies retroactively to dates of service on or after July 24, 2017.**

**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	G	1847	04/05/2016	ZB – Pfizer/Hospira	04/01/2016

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

#### 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 can 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.

**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 (ccIV4), derived from cell cultures, subunit, preservative and antibiotic free, 0.5 mL dosage, for intramuscular use	L
Flucelvax Quadrivalent Preservative Flu Vaccine	Q2039	Cciiv4 vaccine, nos, intramuscular	Influenza virus vaccine, not otherwise specified	L

#### ***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 OPSS Update Change Request (Transmittal 3557, Change Request 9658 dated July 1, 2016) and the July 2016 OPSS MLN Matters Article MM9658, available at <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9658.pdf>.

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, advance 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 OPSS Update CR and MLN guidance on upper eyelid blepharoplasty and blepharoptosis remain unchanged. Specifically, CMS notes 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 blepharoplasty on a different date of service than the blepharoptosis procedure for the purpose of unbundling the 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 blepharoplasty performed with a blepharoptosis repair
- Using modifier 59 to unbundle the 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.

### ***Transurethral Waterjet Prostate Ablation Procedure***

On June 5, 2017, the Investigational Device Exemption (IDE) study associated with the “Waterjet Ablation Therapy for Endoscopic Resection of Prostate Tissue II” met CMS’s standards for coverage. The procedure associated with this study is currently described by CPT code 0421T. Based on the recent Medicare coverage of the IDE study, CMS is revising the

OPPS status indicator (SI) for CPT code 0421T from “E1” (Not paid by Medicare when submitted on outpatient claims (any outpatient bill type)) to “J1” (Hospital Part B services paid through a comprehensive APC) and assigning the code to APC 5374 (Level 4 Urology and Related Services).

The SI and APC revision will be added to the January 2018 IOCE release with an effective date of June 5, 2017, which is the date of the Medicare approval for coverage of the IDE study.

Table 7 (below) lists the long descriptor, status indicator, and APC assignment for CPT code 0421T. The October 2017 national payment rate for APC 5374 is \$2,542.56. However, as previously stated, payment for claims involving CPT code 0421T will not begin to be processed until January 1, 2018.

For more information on this approved Medicare IDE study, refer to study title “Waterjet Ablation Therapy for Endoscopic Resection of Prostate Tissue II” which can be found on the CMS IDE Studies website at: <https://www.cms.gov/Medicare/Coverage/IDE/Approved-IDE-Studies.html>.

For more information on Medicare’s coverage related to IDE studies, refer to this CMS website: <https://www.cms.gov/Medicare/Coverage/IDE/index.html>.

**Table 7 - Transurethral Waterjet Prostate Ablation Procedure**

CPT Code	Long Description	OPPS SI	OPPS APC
0421T	Transurethral waterjet ablation of prostate, including control of post-operative bleeding, including ultrasound guidance, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included when performed)	J1	5374

### **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.

## ADDITIONAL INFORMATION

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The official instruction, CR10236, issued to your MAC regarding this change is available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R3864CP.pdf>.

If you have any questions, please contact your MAC at their toll-free number. That number is available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/>.

## DOCUMENT HISTORY

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Date of Change	Description
September 15, 2017	The article was revised to reflect an updated Change Request (CR) that updated the policy section (added Transurethral Waterjet Prostate Ablation Procedure) that also includes information on the revised OPPS status indicator and APC for CPT code 0421T. It also corrected an error to the OPPS status indicator for Q5102 in Table 5. In addition, a new Table 7 was added.
August 29, 2017	Initial article released.

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