



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

MLN Matters Number: MM10781 Revised

Related Change Request (CR) #: 10781

Related CR Release Date: June 15, 2018

Effective Date: July 1, 2018

Related CR Transmittal Number: R4075CP

Implementation Date: July 2, 2018

Note: This article was revised on June 19, 2018, to reflect an updated Change Request (CR). That update added new Retacrit codes Q5105 and Q5106 and new PLACodes 0045U - 0061U. Code Q9994 was also added for In-Line Cartridge Containing Digestive Enzyme(s). These codes are effective July 1, 2018. CMS is also changing status indicators for two drug codes, The status indicator for J9216 and Q2049 were also changed from SI "K" to SI "E2" effective July 1, 2018. The CR release date, transmittal number and link to the transmittal also changed. All other information remains the same.

PROVIDERS TYPE AFFECTED

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

PROVIDER ACTION NEEDED

CR10781 describes changes to and billing instructions for various payment policies implemented in the July 2018 OPPS update. Make sure your billing staffs are aware of these changes.

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.

Key Changes in CR 10781

Key changes and billing instructions for various payment policies implemented in July 2018 OPPS updates are as follows:

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 lists the long descriptor and status indicator (SI) for CPT codes 0012M and 0013M.

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

CPT Code	Long Descriptor	OPPS Status Indicator (SI)	OPPS Ambulatory Payment Classification (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

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 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](#).

**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 (i.e., 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)) (e.g., 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 to 4 recombinant protein groups, by immunoblot, IgM	Q4	N/A
0044U	Tick-borne relapsing fever Borrelia group, antibody detection to 4 recombinant protein groups, by immunoblot, IgG	Q4	N/A

Proprietary Laboratory Analysis (PLA) CPT Coding Changes Effective July 1, 2018

Effective July 1, 2018, the AMA CPT Editorial Panel established 17 new PLA codes, specifically, CPT codes 0045U through 0061U. Table 3, lists the long descriptors and status indicators for these codes. For more information on OPSS status indicators “A” and “Q4”, refer to OPSS Addendum D1 of the Calendar Year (CY) 2018 OPSS/Ambulatory Surgical Center (ASC) final rule. These codes, along with their short descriptors and status indicators, are also listed in the July 2018 OPSS Addendum B.

Table 3 – PLA CPT Coding Changes Effective July 1, 2018

CPT Code	Long Descriptor	OPSS SI	OPSS APC
0045U	Oncology (breast ductal carcinoma in situ), mRNA, gene expression profiling by real-time RT-PCR of 12 genes (7 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as recurrence score	A	N/A
0046U	<i>FLT3</i> (fms-related tyrosine kinase 3) (eg, acute myeloid leukemia) internal tandem duplication (ITD) variants, quantitative	A	N/A
0047U	Oncology (prostate), mRNA, gene expression profiling by real-time RT-PCR of 17 genes (12 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a risk score	A	N/A
0048U	Oncology (solid organ neoplasia), DNA, targeted sequencing of protein-coding exons of 468 cancer-associated genes, including interrogation for somatic mutations and microsatellite instability, matched with normal specimens, utilizing formalin-fixed paraffin-embedded tumor tissue, report of clinically significant mutation(s)	A	N/A
0049U	<i>NPM1</i> (nucleophosmin) (eg, acute myeloid leukemia) gene analysis, quantitative	A	N/A
0050U	Targeted genomic sequence analysis panel, acute myelogenous leukemia, DNA analysis, 194 genes, interrogation for sequence variants, copy number variants or rearrangements	A	N/A
0051U	Prescription drug monitoring, evaluation of drugs present by LC-MS/MS, urine, 31 drug panel, reported as quantitative results, detected or not detected, per date of service	Q4	N/A

CPT Code	Long Descriptor	OPPS SI	OPPS APC
0052U	Lipoprotein, blood, high resolution fractionation and quantitation of lipoproteins, including all five major lipoprotein classes and subclasses of HDL, LDL, and VLDL by vertical auto profile ultracentrifugation	Q4	N/A
0053U	Oncology (prostate cancer), FISH analysis of 4 genes (ASAP1, HDAC9, CHD1 and PTEN), needle biopsy specimen, algorithm reported as probability of higher tumor grade	A	N/A
0054U	Prescription drug monitoring, 14 or more classes of drugs and substances, definitive tandem mass spectrometry with chromatography, capillary blood, quantitative report with therapeutic and toxic ranges, including steady-state range for the prescribed dose when detected, per date of service	Q4	N/A
0055U	Cardiology (heart transplant), cell-free DNA, PCR assay of 96 DNA target sequences (94 single nucleotide polymorphism targets and two control targets), plasma	A	N/A
0056U	Hematology (acute myelogenous leukemia), DNA, whole genome next-generation sequencing to detect gene rearrangement(s), blood or bone marrow, report of specific gene rearrangement(s)	A	N/A
0057U	Oncology (solid organ neoplasia), mRNA, gene expression profiling by massively parallel sequencing for analysis of 51 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a normalized percentile rank	A	N/A
0058U	Oncology (Merkel cell carcinoma), detection of antibodies to the Merkel cell polyoma virus oncoprotein (small T antigen), serum, quantitative	Q4	N/A
0059U	Oncology (Merkel cell carcinoma), detection of antibodies to the Merkel cell polyoma virus capsid protein (VP1), serum, reported as positive or negative	Q4	N/A
0060U	Twin zygosity, genomic targeted sequence analysis of chromosome 2, using circulating cell-free fetal DNA in maternal blood	A	N/A

CPT Code	Long Descriptor	OPPS SI	OPPS APC
0061U	Transcutaneous measurement of five biomarkers (tissue oxygenation [StO ₂], oxyhemoglobin [ctHbO ₂], deoxyhemoglobin [ctHbR], papillary and reticular dermal hemoglobin concentrations [ctHb1 and ctHb2]), using spatial frequency domain imaging (SFDI) and multi-spectral analysis	Q4	N/A

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 4. Payment rates for these services can be found in [Addendum B of the July 2018 OPPS Update](#).

Table 4 – 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 road mapping 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 (i.e., 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

Bilateral Indicator for HCPCS Code C9749

In the April 2018 OPPS update CR (Transmittal 4005, CR 10515 dated March 20, 2018), CMS announced the establishment of HCPCS Code C9749 (Repair of nasal vestibular lateral wall stenosis with implant(s), effective April 1, 2018. CMS is also 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. Modifiers 73 and 74 are only used to indicate discontinued procedures for which anesthesia is planned or provided.

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.

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](#).

B. Drugs and Biologicals with OPSS Pass-Through Status Effective July 1, 2018

Six drugs and biologicals have been granted OPSS pass-through status, effective July 1, 2018. These items, along with their descriptors and APC assignments, are identified in Table 5.

**Table 5 – Drugs and Biologicals with OPPS Pass-Through Status
Effective July 1, 2018**

HCPCS Code	Long Descriptor	OPPS Status Indicator	OPPS 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

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 6 describes the HCPCS code change and effective date.

Table 6 – Other Changes to CY 2018 HCPCS Codes for Certain Drugs, Biologicals, and Radiopharmaceuticals

HCPCS Code	Long Descriptor	OPPS SI	OPPS 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	

Note: HCPCS code Q9994 (In-line cartridge containing digestive enzyme(s) for enteral feeding, each) will also be added and is listed in the upcoming July 2018 I/OCE CR, effective July 1, 2018.

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, CMS is 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 OPSS. Paid at reasonable cost.), effective April 1, 2018, in the July 2018 I/OCE update. Table 7 describes the status indicator change and effective date.

Table 7 – Change to Status Indicator for CPT Code 90739

CPT Code	Long Descriptor	OPPS SI	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

F. Drugs and Biologicals with a change in Status Indicator

Two drugs, specifically, HCPCS codes J9216 and Q2049, listed in Table 8 have a change in status indicator from “K” to “E2” effective July 1, 2018, to indicate that CMS has no pricing information for both drug codes.

Table 8 – Drugs and Biologicals with a Change in Status Indicator

HCPCS Code	Long Descriptor	Old SI	New SI	Effective Date
J9216	Injection, interferon, gamma 1-b, 3 million units	K	E2	07/01/2018
Q2049	Injection, doxorubicin hydrochloride, liposomal, imported lipodox, 10 mg	K	E2	07/01/2018

G. New Biosimilar Biological Products Effective July 1, 2018

Two new HCPCS codes will be created for reporting Retacrit, (epoetin alfa-epbx) as a biosimilar to Epogen/Procrit (epoetin alfa) for the treatment of anemia caused by chronic kidney disease, chemotherapy, or use of zidovudine in patients with HIV infection. Retacrit is also approved for use before and after surgery to reduce the chance that red blood cell transfusions will be needed because of blood loss during surgery. Both codes are assigned to status indicator “K”. These codes are listed in Table 9 and are effective for services furnished on or after July 1, 2018. Payment for each of these codes may be found in the July 2018 update of the OPBS Addendum B at <http://www.cms.gov/HospitalOutpatientPPS/>.

Table 9 – New HCPCS Drug Codes for Retacrit Effective July 1, 2018

HCPCS Code	Short Descriptor	Long Descriptor	OPPS SI	OPPS APC
Q5105	Inj Retacrit esrd on dialysi	Injection, epoetin alfa, biosimilar, (Retacrit) (for esrd on dialysis), 100 units	K	9096
Q5106	Inj Retacrit non-esrd use	Injection, epoetin alfa, biosimilar, (Retacrit) (for non-esrd use), 1000 units	K	9097

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 10.

Table 10 – Reassignment of Skin Substitute Product from the Low Cost Group to the High Cost Group Effective July 1, 2018

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

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 11.

Table 11 – 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	Short Descriptor	OPP SI	Allowed Revenue Codes for Billing
Q4116	Alloderm, per square centimeter	N	0278, 0636

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 OPSS 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

The official instruction, CR10781, issued to your MAC regarding this change, is available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R4075CP.pdf>.

If you have questions, your MACs may have more information. Find their website at <http://go.cms.gov/MAC-website-list>.

DOCUMENT HISTORY

Date of Change	Description
June 19, 2018	This article was revised to reflect an updated Change Request (CR). That update added new Retacrit codes Q5105 and Q5106 and new PLACodes 0045U - 0061U. Code Q9994 was also added for In-Line Cartridge Containing Digestive Enzyme(s). These codes are effective July 1, 2018. CMS is also changing status indicators for two drug codes, The status indicator for J9216 and Q2049 were also changed from SI "K" to SI "E2" effective July 1, 2018. The CR release date, transmittal number and link to the transmittal also changed.
June 5, 2018	Initial article released.

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