



October 2019 Update of the Hospital Outpatient Prospective Payment System (OPPS)

MLN Matters Number: MM11451 **Revised** Related Change Request (CR) Number: 11451
Related CR Release Date: **October 4, 2019** Effective Date: October 1, 2019
Related CR Transmittal Number: **R4411CP** Implementation Date: October 7, 2019

Note: We revised this article on October 7, 2019, to reflect the revised CR 11451, issued on October 4, 2019. CMS revised the CR to correct Table 7 to reinstate C9043 rather than delete it effective October 1, 2019. CR 11451 also added a new HCPCS code J0642, which is effective October 1, 2019, and revised the descriptor for J0641. The CR release date, transmittal number, and the web address of the CR are changed. All other information remains the same.

PROVIDER TYPES AFFECTED

This MLN Matters article is for hospital outpatient facilities, physicians, providers, including home health and hospice providers, and suppliers billing Medicare Administrative Contractors (MACs) for hospital outpatient services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

CR 11451 describes changes to and billing instructions for various payment policies that Medicare is implementing in the October 2019 Outpatient Prospective Payment System (OPPS) update. Make sure your billing staffs are aware of these changes.

BACKGROUND

The October 2019 Integrated Outpatient Code Editor (I/OCE) will reflect the HCPCS, Ambulatory Payment Classification (APC), HCPCS Modifier, and Revenue Code additions, changes, and deletions identified in CR 11451.

The October 2019 revisions to I/OCE data files, instructions, and specifications are provided in the October 2019 I/OCE CR, which will be available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2019Downloads/R4383CP.pdf>.

1. CPT Proprietary Laboratory Analyses (PLA) Coding Changes Effective Oct 1, 2019

The American Medical Association (AMA) CPT Editorial Panel deleted one PLA code (0104U) and established 34 new PLA codes (CPT codes 0105U-0138U), effective October 1, 2019. Table 1 lists the long descriptors and status indicators for the codes.

For more information on OPPS status indicators "A," "D," "E1," "N," and "Q4," refer to OPPS [Addendum D1](#) of the Calendar Year (CY) 2019 OPPS/ASC final rule for the latest definitions. CPT codes 0105U-0138U are in the October 2019 I/OCE with an effective date of October 1, 2019.

Table 1: Newly Established PLA Codes

CPT Code	Long Descriptor	OPPS SI	OPPS APC
0104U	Hereditary pan cancer (eg, hereditary breast and ovarian cancer, hereditary endometrial cancer, hereditary colorectal cancer), genomic sequence analysis panel utilizing a combination of NGS, Sanger, MLPA, and array CGH, with mRNA analytics to resolve variants of unknown significance when indicated (32 genes [sequencing and deletion/duplication], EPCAM and GREM1 [deletion/duplication only])	D	N/A
0105U	Nephrology (chronic kidney disease), multiplex electrochemiluminescent immunoassay (ECLIA) of tumor necrosis factor receptor 1A, receptor superfamily 2 (TNFR1, TNFR2), and kidney injury molecule-1 (KIM-1) combined with longitudinal clinical data, including APOL1 genotype if available, and plasma (isolated fresh or frozen), algorithm reported as probability score for rapid kidney function decline (RKFD)	Q4	N/A
0106U	Gastric emptying, serial collection of 7 timed breath specimens, non-radioisotope carbon-13 (¹³ C) spirulina substrate, analysis of each specimen by gas isotope ratio mass spectrometry, reported as rate of ¹³ CO ₂ excretion	Q4	N/A
0107U	Clostridium difficile toxin(s) antigen detection by immunoassay technique, stool, qualitative, multiple-step method	Q4	N/A

CPT Code	Long Descriptor	OPPS SI	OPPS APC
0108U	Gastroenterology (Barrett's esophagus), whole slide–digital imaging, including morphometric analysis, computer-assisted quantitative immunolabeling of 9 protein biomarkers (p16, AMACR, p53, CD68, COX-2, CD45RO, HIF1a, HER-2, K20) and morphology, formalin-fixed paraffin-embedded tissue, algorithm reported as risk of progression to high-grade dysplasia or cancer	Q4	N/A
0109U	Infectious disease (Aspergillus species), real-time PCR for detection of DNA from 4 species (A. fumigatus, A. terreus, A. niger, and A. flavus), blood, lavage fluid, or tissue, qualitative reporting of presence or absence of each species	A	N/A
0110U	Prescription drug monitoring, one or more oral oncology drug(s) and substances, definitive tandem mass spectrometry with chromatography, serum or plasma from capillary blood or venous blood, quantitative report with steady-state range for the prescribed drug(s) when detected	Q4	N/A
0111U	Oncology (colon cancer), targeted KRAS (codons 12, 13, and 61) and NRAS (codons 12, 13, and 61) gene analysis, utilizing formalin-fixed paraffin-embedded tissue	A	N/A
0112U	Infectious agent detection and identification, targeted sequence analysis (16S and 18S rRNA genes) with drug-resistance gene	A	N/A
0113U	Oncology (prostate), measurement of PCA3 and TMPRSS2-ERG in urine and PSA in serum following prostatic massage, by RNA amplification and fluorescence-based detection, algorithm reported as risk score	A	N/A
0114U	Gastroenterology (Barrett's esophagus), VIM and CCNA1 methylation analysis, esophageal cells, algorithm reported as likelihood for Barrett's esophagus	A	N/A
0115U	Respiratory infectious agent detection by nucleic acid (DNA and RNA), 18 viral types and subtypes and 2 bacterial targets, amplified probe technique, including multiplex reverse transcription for RNA targets, each analyte reported as detected or not detected	A	N/A

CPT Code	Long Descriptor	OPPS SI	OPPS APC
0116U	Prescription drug monitoring, enzyme immunoassay of 35 or more drugs confirmed with LC-MS/MS, oral fluid, algorithm results reported as a patient-compliance measurement with risk of drug to drug interactions for prescribed medications	Q4	N/A
0117U	Pain management, analysis of 11 endogenous analytes (methylmalonic acid, xanthurenic acid, homocysteine, pyroglutamic acid, vanilmandelate, 5-hydroxyindoleacetic acid, hydroxymethylglutarate, ethylmalonate, 3-hydroxypropyl mercapturic acid (3-HPMA), quinolinic acid, kynurenic acid), LC-MS/MS, urine, algorithm reported as a pain-index score with likelihood of atypical biochemical function associated with pain	Q4	N/A
0118U	Transplantation medicine, quantification of donor-derived cell-free DNA using whole genome next-generation sequencing, plasma, reported as percentage of donor-derived cell-free DNA in the total cell-free DNA	A	N/A
0119U	Cardiology, ceramides by liquid chromatography–tandem mass spectrometry, plasma, quantitative report with risk score for major cardiovascular events	Q4	N/A
0120U	Oncology (B-cell lymphoma classification), mRNA, gene expression profiling by fluorescent probe hybridization of 58 genes (45 content and 13 housekeeping genes), formalin-fixed paraffin-embedded tissue, algorithm reported as likelihood for primary mediastinal B-cell lymphoma (PMBCL) and diffuse large B-cell lymphoma (DLBCL) with cell of origin subtyping in the latter	A	N/A
0121U	Sickle cell disease, microfluidic flow adhesion (VCAM-1), whole blood	Q4	N/A
0122U	Sickle cell disease, microfluidic flow adhesion (P-Selectin), whole blood	Q4	N/A
0123U	Mechanical fragility, RBC, shear stress and spectral analysis profiling	Q4	N/A
0124U	Fetal congenital abnormalities, biochemical assays of 3 analytes (free beta-hCG, PAPP-A, AFP), time-resolved fluorescence immunoassay, maternal dried-blood spot, algorithm reported as risk scores for fetal trisomies 13/18 and 21	E1	N/A

CPT Code	Long Descriptor	OPPS SI	OPPS APC
0125U	Fetal congenital abnormalities and perinatal complications, biochemical assays of 5 analytes (free beta-hCG, PAPP-A, AFP, placental growth factor, and inhibin-A), time-resolved fluorescence immunoassay, maternal serum, algorithm reported as risk scores for fetal trisomies 13/18, 21, and preeclampsia	Q4	N/A
0126U	Fetal congenital abnormalities and perinatal complications, biochemical assays of 5 analytes (free beta-hCG, PAPP-A, AFP, placental growth factor, and inhibin-A), time-resolved fluorescence immunoassay, includes qualitative assessment of Y chromosome in cell-free fetal DNA, maternal serum and plasma, predictive algorithm reported as a risk scores for fetal trisomies 13/18, 21, and preeclampsia	Q4	N/A
0127U	Obstetrics (preeclampsia), biochemical assays of 3 analytes (PAPP-A, AFP, and placental growth factor), time-resolved fluorescence immunoassay, maternal serum, predictive algorithm reported as a risk score for preeclampsia	Q4	N/A
0128U	Obstetrics (preeclampsia), biochemical assays of 3 analytes (PAPP-A, AFP, and placental growth factor), time-resolved fluorescence immunoassay, includes qualitative assessment of Y chromosome in cell-free fetal DNA, maternal serum and plasma, predictive algorithm reported as a risk score for preeclampsia	Q4	N/A
0129U	Hereditary breast cancer–related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer), genomic sequence analysis and deletion/duplication analysis panel (ATM, BRCA1, BRCA2, CDH1, CHEK2, PALB2, PTEN, and TP53)	A	N/A
0130U	Hereditary colon cancer disorders (eg, Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatous polyposis), targeted mRNA sequence analysis panel (APC, CDH1, CHEK2, MLH1, MSH2, MSH6, MUTYH, PMS2, PTEN, and TP53) (List separately in addition to code for primary procedure)	N	N/A
0131U	Hereditary breast cancer–related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer), targeted mRNA sequence analysis panel (13 genes) (List separately in addition to code for primary procedure)	N	N/A

CPT Code	Long Descriptor	OPPS SI	OPPS APC
0132U	Hereditary ovarian cancer–related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer), targeted mRNA sequence analysis panel (17 genes) (List separately in addition to code for primary procedure)	N	N/A
0133U	Hereditary prostate cancer–related disorders, targeted mRNA sequence analysis panel (11 genes) (List separately in addition to code for primary procedure)	N	N/A
0134U	Hereditary pan cancer (eg, hereditary breast and ovarian cancer, hereditary endometrial cancer, hereditary colorectal cancer), targeted mRNA sequence analysis panel (18 genes) (List separately in addition to code for primary procedure)	N	N/A
0135U	Hereditary gynecological cancer (eg, hereditary breast and ovarian cancer, hereditary endometrial cancer, hereditary colorectal cancer), targeted mRNA sequence analysis panel (12 genes) (List separately in addition to code for primary procedure)	N	N/A
0136U	ATM (ataxia telangiectasia mutated) (eg, ataxia telangiectasia) mRNA sequence analysis (List separately in addition to code for primary procedure)	N	N/A
0137U	PALB2 (partner and localizer of BRCA2) (eg, breast and pancreatic cancer) mRNA sequence analysis (List separately in addition to code for primary procedure)	N	N/A
0138U	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) mRNA sequence analysis (List separately in addition to code for primary procedure)	N	N/A

2. New CPT Category II Codes Effective October 1, 2019

For the October 2019 update, the Centers for Medicare & Medicaid Services (CMS) is implementing five new CPT Category II codes that the AMA released on July 8, 2019, for implementation on October 1, 2019. New CPT codes 2023F, 2025F, 2033F, 3051F, and 3052F are in the October 2019 I/OCE with an effective date of October 1, 2019.

Also, the AMA is revising the code descriptors for CPT codes 2022F, 2024F, 2026F, and deleting 3045F on September 30, 2019. The status indicators and APC assignments for the codes are shown in Table 2. These codes, along with their short descriptors, status indicators, and payment rates are listed in the October 2019 OPSS Addendum B that is posted at

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html>. For information on the OPSS status indicator "M", refer to OPSS Addendum D1 of the CY 2019 OPSS/ASC final rule for the latest definition.

Table 2: New, Revised, and Deleted CPT Category II Codes

CPT Code	Status	Long Descriptor	OPSS SI	OPSS APC
2022F	REVISE	Dilated retinal eye exam with interpretation by an ophthalmologist or optometrist documented and reviewed; <u>with evidence of retinopathy</u> (DM) ²	M	N/A
2023F	NEW	Dilated retinal eye exam with interpretation by an ophthalmologist or optometrist documented and reviewed; without evidence of retinopathy (DM) ²	M	N/A
2024F	REVISE	7 standard field stereoscopic <u>retinal</u> photos with interpretation by an ophthalmologist or optometrist documented and reviewed; <u>with evidence of retinopathy</u> (DM) ²	M	N/A
2025F	NEW	7 standard field stereoscopic retinal photos with interpretation by an ophthalmologist or optometrist documented and reviewed; without evidence of retinopathy (DM) ²	M	N/A
2026F	REVISE	Eye imaging validated to match diagnosis from 7 standard field stereoscopic <u>retinal</u> photos results documented and reviewed; <u>with evidence of retinopathy</u> (DM) ²	M	N/A
2033F	NEW	Eye imaging validated to match diagnosis from 7 standard field stereoscopic retinal photos results documented and reviewed; without evidence of retinopathy (DM) ²	M	N/A
3045F	DELETE	Most recent hemoglobin A1c (HbA1c) level 7.0–9.0% (DM)	D	N/A
3051F	NEW	Most recent hemoglobin A1c (HbA1c) level greater than or equal to 7.0% and less than 8.0% (DM)	M	N/A
3052F	NEW	Most recent hemoglobin A1c (HbA1c) level greater than or equal to 8.0% and less than or equal to 9.0% (DM) ²	M	N/A

3. Advanced Diagnostic Laboratory Tests (ADLT) Under the Clinical Lab Fee Schedule (CLFS)

On May 17, 2019, CMS announced the approval of three laboratory tests as ADLTs under paragraph (1) of the definition of an ADLT in 42 CFR Section 414.502. CMS notes that under the OPSS, tests that receive ADLT status under Section 1834A(d)(5)(A) of the Social Security Act (the Act) are assigned to status indicator "A." These laboratory tests are listed in Table 3.

Based on the ADLT designation, CMS revised the OPSS status indicator for HCPCS codes 0080U and 81599 to "A" (Not paid under OPSS. Paid by MACs under a fee schedule or payment system other than OPSS) effective July 1, 2019. However, because the ADLT designation was made in May 2019, it was too late to include this change in the July 2019 I/OCE Release and the July 2019 OPSS update; therefore, we are including this change in the October 2019 I/OCE Release with an effective date of July 1, 2019.

Note that the DecisionDx-UM test, as described by HCPCS code 0081U, was also approved for ADLT status on May 17, 2019, however it was already assigned OPSS SI "A" based on being a molecular pathology test.

The latest list of ADLTs under the CLFS is available at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/List-of-Approved-ADLTs.pdf>. For more information on the OPSS status indicator "A", refer to OPSS Addendum D1 of the CY 2019 OPSS/ASC final rule for the latest definitions.

Table 3: ADLT Codes and Long Descriptors

Lab Name	Test Name	CPT Code	CPT Code Long Descriptor
Biodesix	BDX-XL2	0080U	Oncology (lung), mass spectrometric analysis of galectin-3-binding protein and scavenger receptor cysteine-rich type 1 protein M130, with five clinical risk factors (age, smoking status, nodule diameter, nodule-spiculation status and nodule location), utilizing plasma, algorithm reported as a categorical probability of malignancy
Castle BioSciences, Inc.	DecisionDX-Melanoma	81599*	Unlisted multianalyte assay with algorithmic analysis

Lab Name	Test Name	CPT Code	CPT Code Long Descriptor
Castle BioSciences Inc.	DecisionDx-UM	0081U	Oncology (uveal melanoma), mRNA, gene-expression profiling by real-time RT-PCR of 15 genes (12 content and 3 housekeeping genes), utilizing fine needle aspirate or formalin-fixed paraffin-embedded tissue, algorithm reported as risk of metastasis.

* DecisionDx-Melanoma is currently described by HCPCS codes 81599 and identifier ZB1D4.

4. Drugs, Biologicals, and Radiopharmaceuticals

a. HCPCS Codes and Dosage Descriptors for Certain Drugs, Biologicals, and Radiopharmaceuticals with Pass-through Status

For October 2019, two HCPCS codes have received pass-through status for reporting drugs and biologicals in the hospital outpatient setting. These new codes are in Table 4.

Table 4: Codes Receiving Pass-Through Status

HCPCS Code	Long Descriptor	SI	APC
J3111	Injection, romosozumab-aqqg, 1 mg	G	9327
J9356	Injection, trastuzumab, 10 mg and Hyaluronidase-oysk	G	9314

b. Separately Payable Drugs and Biologicals that Will Receive Pass-Through Status (Status Indicator = "G") for the Period of April 1, 2019, Through June 30, 2019

The status indicator for HCPCS code C9042 (Injection, bendamustine hcl (belrapzo), 1 mg) for the period of April 1, 2019, through June 30, 2019, will be changed retroactively from status indicator = "E2" to status indicator = "G." This drug is in Table 5.

Table 5: C9042 Updated Status Indicator

HCPCS Code	Long Descriptor	Old SI	New SI	APC
C9042	Injection, bendamustine hcl (belrapzo), 1 mg	E2	G	9313

c. Drugs and Biologicals that Will Change from Non-Payable Status (Status Indicator = "E2") to Separately Payable Status (Status Indicator = "K") for the Period of July 18, 2019, through September 30, 2019

The status indicator for HCPCS code Q5107 (Injection, bevacizumab-awwb, biosimilar, (mvasi),

10 mg) for the period of July 18, 2019, through September 30, 2019, will be changed retroactively from status indicator = “E2” to status indicator = “K”. This drug is in Table 6.

Table 6: Q5107 Updated Status Indicator

HCPSC Code	Long Descriptor	Old SI	New SI	APC
Q5107	Injection, bevacizumab-awwb, biosimilar, (mvasi), 10 mg	E2	K	9329

d. New Established HCPCS Codes for Drugs, Biologicals, and Radiopharmaceuticals as of October 1, 2019

There are 45 new drug, biological, and radiopharmaceutical HCPCS codes that will be established on October 1, 2019. The new codes are in Table 7.

Table 7: New Drug, Biological, and Radiopharmaceutical Codes to be Established on October 1, 2019

New HCPCS Code	Old HCPCS Code	Long Descriptor	SI	APC
J1943	C9035	Injection, aripiprazole lauroxil (aristada initio), 1 mg	G	9179
J0222	C9036	Injection, Patisiran, 0.1 mg	G	9180
J2798	C9037	Injection, risperidone, (perseris), 0.5 mg	G	9181
J9204	C9038	Injection, mogamulizumab-kpkc, 1 mg	G	9182
J0291	C9039	Injection, plazomicin, 5 mg	G	9183
J3031	C9040	Injection, fremanezumab-vfrm, 1 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)	G	9197
J0641 ⁽¹⁾		Injection, levoleucovorin, not otherwise specified, 0.5 mg	K	1236
J0642		Injection, Levoleucovorin (khapzory), 0.5 mg	B	N/A
J9119	C9044	Injection, cemiplimab-rwlc, 1 mg	G	9304
J9313	C9045	Injection, moxetumomab pasudotox-tdfk, 0.01 mg	G	9305
J1096	C9048	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg	G	9308
J9269	C9049	Injection, tagraxofusp-erzs, 10 micrograms	G	9309
J9210	C9050	Injection, emapalumab-lzsg, 1 mg	G	9310
J0121	C9051	Injection, omadacycline, 1 mg	G	9311
J1303	C9052	Injection, ravulizumab-cwvz, 10 mg	G	9312
J1097	C9447	phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml	G	9324

New HCPCS Code	Old HCPCS Code	Long Descriptor	SI	APC
J0122		Injection, eravacycline, 1 mg	K	9325
J0593		Injection, lanadelumab-flyo, 1 mg (code may be used for Medicare when drug administered under direct supervision of a physician, not for use when drug is self-administered)	K	9326
J1944	J1942	Injection, aripiprazole lauroxil, (aristada), 1 mg	K	9470
J7314		Injection, fluocinolone acetonide, intravitreal implant (Yutiq), 0.01 mg	K	9328
J7331		Hyaluronan or derivative, synojoynt, for intra-articular injection, 1 mg	E2	N/A
J7332		Hyaluronan or derivative, triluron, for intra-articular injection, 1 mg	E2	N/A
J9118		Injection, calaspargase pegol-mknl, 10 units	E2	N/A
Q4205		Membrane graft or membrane wrap, per square centimeter	N	N/A
Q4206		Fluid flow or fluid GF, 1 cc	N	N/A
Q4208		Novafix, per square centimeter	N	N/A
Q4209		Surgraft, per square centimeter	N	N/A
Q4210		Axolotl graft or axolotl dualgraft, per square centimeter	N	N/A
Q4211		Amnion bio or Axobiomembrane, per square centimeter	N	N/A
Q4212		Allogen, per cc	N	N/A
Q4213		Ascent, 0.5 mg	N	N/A
Q4214		Cellesta cord, per square centimeter	N	N/A
Q4215		Axolotl ambient or axolotl cryo, 0.1 mg	N	N/A
Q4216		Artacent cord, per square centimeter	N	N/A
Q4217		Woundfix, BioWound, Woundfix Plus, BioWound Plus, Woundfix Xplus or BioWound Xplus, per square centimeter	N	N/A
Q4218		Surgicord, per square centimeter	N	N/A
Q4219		Surgigraft-dual, per square centimeter	N	N/A
Q4220		BellaCell HD or Surederm, per square centimeter	N	N/A
Q4221		Amniowrap2, per square centimeter	N	N/A
Q4222		Progenamatrix, per square centimeter	N	N/A
Q4226		MyOwn skin, includes harvesting and preparation procedures, per square centimeter	N	N/A
Q5107		Injection, bevacizumab-awwb, biosimilar, (mvasi), 10 mg	K	9329

New HCPCS Code	Old HCPCS Code	Long Descriptor	SI	APC
Q5116		Injection, trastuzumab-qyyp, biosimilar, (trazimera), 10 mg	E2	N/A
Q5117		Injection, trastuzumab-anns, biosimilar, (kanjinti), 10 mg	K	9330
Q5118		Injection, bevacizumab-bvcr, biosimilar, (Zirabev), 10 mg	E2	N/A
J7401	S1090	Mometasone furoate sinus implant, 10 micrograms	N	N/A

(1) HCPCS J0641 is not new for October 1, 2019, but please note that the long descriptor has changed for J0641, effective October 1, 2019.

e. Ambulatory Payment Classification (APC) Assignment Change for HCPCS code J9030, BCG live intravesical instillation, 1 mg, Effective July 1, 2019, in the October 2019 I/OCE Release

See Table 8 for the APC assignment change for HCPCS code, J9030, effective July 1, 2019, in the October 2019 I/OCE Release.

Table 8: J9030 – APC Assignment Change

HCPCS Code	Long Descriptor	Old APC Assignment	New APC Assignment	Effective Date
J9030	BCG live intravesical instillation, 1 mg	0809	9322	07/01/19

f. Drugs and Biologicals with Payments Based on Average Sales Price (ASP)

For CY 2019, 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 2019, 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. Effective October 1, 2019, payment rates for some drugs and biologicals have changed from the values published in the July 2019 update of the OPSS Addendum A and Addendum B. CMS is not publishing the updated payment rates in this CR implementing the October 2019 update of the OPSS. However, the updated payment rates effective October 1, 2019, can be found in the October 2019 update of the OPSS

Addendum A and Addendum B on the CMS website at <http://www.cms.gov/HospitalOutpatientPPS/>.

g. 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.

5. Clarification on the Guidance for Intraocular or Periocular Injections of Combinations of Anti- Inflammatory Drugs and Antibiotics

On September 15, 2015, CMS issued CR 9298 (Transmittal R3352CP), which provided guidance for "dropless cataract surgery." (See related MLN Matters article at <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9298.pdf>. CR 11451 is a clarification to CR 9298 on "dropless cataract surgery." Intraocular or periocular injections of combinations of anti-inflammatory drugs and antibiotics are being used with increased frequency in ocular surgery (primarily cataract surgery). One example of combined or compounded drugs includes, triamcinolone and moxifloxacin with or without vancomycin. Such combinations may be administered as separate injections or as a single combined injection. Because such injections may obviate the need for post-operative anti-inflammatory and antibiotic eye drops, some have referred to cataract surgery with such injections as "dropless cataract surgery." However, nothing in this CR is intended to preclude physicians or other professionals from discussing the potential benefits and drawbacks of dropless therapy with their patients and prescribing it if the patient so elects.

6. OPSS Pricer logic and data changes for October

There are no OPSS PRICER logic or data changes for October; therefore, there is no OPSS PRICER release for October.

7. 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, CR 11451, issued to your MAC regarding this change is available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2019Downloads/R4411CP.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
October 7, 2019	We revised this article to reflect the revised CR 11451, issued on October 4, 2019. CMS revised the CR to correct Table 7 to reinstate C9043 rather than delete it effective October 1, 2019. CR11451 also added a new HCPCS code J0642, which is effective October 1, 2019, and revised the descriptor for J0641. The CR release date, transmittal number, and the web address of the CR are changed. All other information remains the same.
September 3, 2019	Initial article released.

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