



## July 2020 Update of the Hospital Outpatient Prospective Payment System (OPPS)

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Related Change Request (CR) Number: 11814

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**Note: We revised this article on July 16, 2020, to reflect a revised CR 11814. In the article:**

- We updated the section on "Covid-19 Laboratory Tests and Services and Other Laboratory Tests Coding Update".
- Table 1 has also been updated to add 3 new COVID-19 codes: 87426, 0223U, and 0224U.
- We are also changing payment status indicator for HCPCS code Q5112 from SI=E2 to SI=K, effective April 15, 2020 through September 30, 2020 and are updating section 9 "Drugs, Biologicals, and Radiopharmaceuticals" by adding new subsections j and k to reflect this change.
- Therefore, we are re-numbering all other subsequent sub-sections, and Tables 19 and 20 have been added to reflect payment status indicator change for Q5112. All other subsequent tables have been re-numbered.
- We also revised the CR release date, transmittal number and the web address of the CR. All other information remains the same.

### PROVIDER TYPE AFFECTED

This MLN Matters® Article is for physicians, hospitals, and other providers submitting claims to Medicare Administrative Contractors (MACs), including Home Health & Hospice MACs for services to Medicare beneficiaries.

### PROVIDER ACTION NEEDED

This article informs you about the changes to and billing instructions for various payment policies implemented in the July 2020 Outpatient Prospective Payment System (OPPS) update. The July 2020 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 11814. The July 2020 revisions to I/OCE data files, instructions, and specifications are provided in CR 11792. The article related to that CR, MM11792, is available at <https://www.cms.gov/files/document/mm11792.pdf>.

Make sure that your billing staffs are aware of these changes.

## BACKGROUND

Here is a summary of the main topics covered by CR 11814:

### 1. COVID-19 Laboratory Tests and Services and Other Laboratory Tests Coding Update

Since February 2020, the Centers for Medicare and Medicaid Services (CMS) has recognized several COVID-19 laboratory tests and related services. The codes are listed in Table 1 along with their OPPS status indicators (SI). The codes, along with their short descriptors and status indicators are also listed in the July 2020 OPPS [Addendum B](#) that is posted on the CMS website. For information on the OPPS status indicator definitions, refer to OPPS Addendum D1 of the Calendar Year (CY) 2020 OPPS/Ambulatory Surgical Center (ASC) final rule.

**Table 1. – COVID-19 Laboratory Tests and Services and Other Laboratory Tests Codes**

HCPCS Code	Long Descriptor	Add Date	OPPS SI	OPPS APC
U0001	CDC 2019 Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel	02/04/2020	A	N/A
U0002	2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC	02/04/2020	A	N/A
C9803	Hospital outpatient clinic visit specimen collection for severe acute respiratory syndrome coronavirus 2 (sars-cov-2) (coronavirus disease [covid-19]), any specimen source	03/01/2020	Q1	5731
G2023	Specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), any specimen source	03/01/2020	B	N/A
G2024	Specimen collection for severe acute respiratory syndrome coronavirus 2 (sars-cov-2) (coronavirus disease [covid-19]) from an individual in a SNF or by a laboratory on behalf of a HHA, any specimen source	03/01/2020	B	N/A
87635	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique	03/13/2020	A	N/A
86328	Immunoassay for infectious agent antibody, qualitative or semiquantitative, single step method (eg., reagent strip); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])	04/10/2020	A	N/A

HCPCS Code	Long Descriptor	Add Date	OPPS SI	OPPS APC
86769	Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])	04/10/2020	A	N/A
*87426	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative, multiple-step method; severe acute respiratory syndrome coronavirus (eg, SARS-CoV, SARS-CoV-2 [COVID-19])	06/25/2020	A	N/A
U0003	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique, making use of high throughput technologies as described by CMS-2020-01-R	04/14/2020	A	N/A
U0004	2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC, making use of high throughput technologies as described by CMS-2020-01-R	04/14/2020	A	N/A
0202U	Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 22 targets including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), qualitative RT-PCR, nasopharyngeal swab, each pathogen reported as detected or not detected	5/20/2020	A	N/A
*0223U	Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 22 targets including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), qualitative RT-PCR, nasopharyngeal swab, each pathogen reported as detected or not detected	06/25/2020	A	N/A
*0224U	Antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), includes titer(s), when performed	06/25/2020	A	N/A

HCPCS Code	Long Descriptor	Add Date	OPPS SI	OPPS APC
0014M	Liver disease, analysis of 3 biomarkers (hyaluronic acid [ha], procollagen iii amino terminal peptide [piiinp], tissue inhibitor of metalloproteinase 1 [timp-1]), using immunoassays, utilizing serum, prognostic algorithm reported as a risk score and risk of liver fibrosis and liver-related clinical events within 5 years	04/01/2020	Q4	N/A

**\*CPT codes 87426, 0202U, 0223U and 0224U were not included in the July I/OCE update but are still active codes based on their effective dates.**

## 2. Status Indicator Changes for Certain Virtual Services

In accordance with interim final rule changes adopted in light of the COVID-19 Public Health Emergency, CMS is recognizing payment for several additional virtual services including those related to telephone assessment and management services, remote evaluation of a prerecorded video or image and a virtual check-in.

Specifically, CMS is changing the following HCPCS codes to status indicator “A” retroactive to March 1, 2020, in the July I/OCE update since they are payable as therapy services under the Physician Fee schedule.

- Current Procedural Terminology (CPT) codes 98966 through 98968, which describe telephone assessment and management service provided by a qualified nonphysician health care professional
- HCPCS codes G2010 and G2012 describe a remote evaluation of a prerecorded video or image and a virtual check-in, respectively

The following HCPCS codes have been changed to status indicator “B” in the April re-release of the I/OCE retroactive to March 1, 2020, to be in line with the waivers so Critical Access Hospitals (CAHs) that chose Method II can bill the waiver services.

- CPT codes 99421-99423, which describe online digital evaluation and management service, for an established patient
- CPT codes 99441-99443, which describe telephone assessment and management services furnished by a physician or other qualified health care professional who may report evaluation and management services
- CPT code 99457 – 99458\*, which describe remote physiologic monitoring treatment management services, by clinical staff/physician/other qualified health care professional
- CPT code 99474, which describes self-measured blood pressure using a device validated for clinical accuracy; separate self-measurements of two readings one minute apart, twice daily over a 30-day period (minimum of 12 readings), collection of data reported by the patient and/or caregiver to the physician or other qualified health care professional, with

report of average systolic and diastolic pressures and subsequent communication of a treatment plan to the patient.

**\* CPT code 99458 was inadvertently missed in the July I/OCE update but will still have a SI =B based on stated policy.**

The following rehabilitation HCPCS codes have been assigned to status indicator “A” in the April re-release of the I/OCE retroactive to March 1, 2020, since they are payable under the Physician Fee schedule.

- HCPCS codes G2061-G2063 which describe qualified nonphysician healthcare professional online assessment, for an established patient.

The codes, along with their long descriptors, are listed in Table 2.

**Table 2. – Status Indicator Changes for Certain Virtual Services that are Effective March 1, 2020**

HCPCS	Long Descriptor	Status Indicator
98966	Telephone assessment and management service provided by a qualified nonphysician health care professional to an established patient, parent, or guardian not originating from a related assessment and management service provided within the previous 7 days nor leading to an assessment and management service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion	A
98967	Telephone assessment and management service provided by a qualified nonphysician health care professional to an established patient, parent, or guardian not originating from a related assessment and management service provided within the previous 7 days nor leading to an assessment and management service or procedure within the next 24 hours or soonest available appointment; 11-20 minutes of medical discussion	A
98968	Telephone assessment and management service provided by a qualified nonphysician health care professional to an established patient, parent, or guardian not originating from a related assessment and management service provided within the previous 7 days nor leading to an assessment and management service or procedure within the next 24 hours or soonest available appointment; 21-30 minutes of medical discussion	A
99421	Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 5-10 minutes	B
99422	Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 11-20 minutes	B

HCPCS	Long Descriptor	Status Indicator
99423	Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 21 or more minutes	B
99441	Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related e/m service provided within the previous 7 days nor leading to an e/m service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion	B
99442	Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related e/m service provided within the previous 7 days nor leading to an e/m service or procedure within the next 24 hours or soonest available appointment; 11-20 minutes of medical discussion	B
99443	Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related e/m service provided within the previous 7 days nor leading to an e/m service or procedure within the next 24 hours or soonest available appointment; 21-30 minutes of medical discussion	B
99457	Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; first 20 minutes	B
99458	Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; each additional 20 minutes (list separately in addition to code for primary procedure)	B
99474	Self-measured blood pressure using a device validated for clinical accuracy; separate self-measurements of two readings one minute apart, twice daily over a 30-day period (minimum of 12 readings), collection of data reported by the patient and/or caregiver to the physician or other qualified health care professional, with report of average systolic and diastolic pressures and subsequent communication of a treatment plan to the patient	B

HCPCS	Long Descriptor	Status Indicator
G2010	Remote evaluation of recorded video and/or images submitted by an established patient (e.g., store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related e/m service provided within the previous 7 days nor leading to an e/m service or procedure within the next 24 hours or soonest available appointment	A
G2012	Brief communication technology-based service, e.g. virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related e/m service provided within the previous 7 days nor leading to an e/m service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion	A
G2061	Qualified nonphysician healthcare professional online assessment, for an established patient, for up to seven days, cumulative time during the 7 days; 5-10 minutes	A
G2062	Qualified nonphysician healthcare professional online assessment service, for an established patient, for up to seven days, cumulative time during the 7 days; 11-20 minutes	A
G2063	Qualified nonphysician qualified healthcare professional assessment service, for an established patient, for up to seven days, cumulative time during the 7 days; 21 or more minutes	A

### 3. a. New Telehealth Code for a Telehealth Distant Site Service Furnished by a Rural Health Clinic (RHC) or Federally Qualified Health Center (FQHC) Only

Effective January 27, 2020, CMS established new HCPCS code G2025 which is recognized for payment for a telehealth distant site service furnished by a RHC or FQHC only. See Table 3. This code is assigned to status indicator "A" retroactive to January 27, 2020, in the July OPSS Addendum B.

**Table 3. – New Telehealth Code for a Telehealth Distant Site Service Furnished by a Rural Health Clinic (RHC) or Federally Qualified Health Center (FQHC) Only**

HCPCS Code	Long Descriptor	Short Descriptor	Add Date	OPPS SI
G2025	Payment for a telehealth distant site service furnished by a rural health clinic (RHC) or federally qualified health center (FQHC) only	Dis site tele svcs RHC/FQHC	01/27/2020	A

### b. Other Telehealth Distant Site Codes for RHCs and FQHCs in the OPSS Addendum B and I/OCE

CMS added other codes for RHCs and FQHCs that are currently included in the I/OCE and the OPSS Addendum B for RHCs and FQHCs that are assigned to status indicator "A" with various effective dates in Table 4.

**Table 4. — Other Telehealth Distant Site Codes for RHCs and FQHCs in the OPPS Addendum B and I/OCE**

HCPSC Code	Long Descriptor	Short Descriptor	Effective Date	OPPS SI
G0071	Payment for communication technology-based services for 5 minutes or more of a virtual (non-face-to-face) communication between an rural health clinic (rhc) or federally qualified health center (fqhc) practitioner and rhc or fqhc patient, or 5 minutes or more of remote evaluation of recorded video and/or images by an rhc or fqhc practitioner, occurring in lieu of an office visit; rhc or fqhc only	Comm svcs by rhc/fqhc 5 min	01/01/2019	A
G0466	Federally qualified health center (fqhc) visit, new patient; a medically-necessary, face-to-face encounter (one-on-one) between a new patient and a fqhc practitioner during which time one or more fqhc services are rendered and includes a typical bundle of medicare-covered services that would be furnished per diem to a patient receiving a fqhc visit	Fqhc visit new patient	10/01/2014	A
G0467	Federally qualified health center (fqhc) visit, established patient; a medically-necessary, face-to-face encounter (one-on-one) between an established patient and a fqhc practitioner during which time one or more fqhc services are rendered and includes a typical bundle of medicare-covered services that would be furnished per diem to a patient receiving a fqhc visit	Fqhc visit, estab pt	10/01/2014	A
G0468	Federally qualified health center (fqhc) visit, ippe or awv; a fqhc visit that includes an initial preventive physical examination (ippe) or annual wellness visit (awv) and includes a typical bundle of medicare-covered services that would be furnished per diem to a patient receiving an ippe or awv	Fqhc visit, ippe or awv	10/01/2014	A

HCPCS Code	Long Descriptor	Short Descriptor	Effective Date	OPPS SI
G0469	Federally qualified health center (fqhc) visit, mental health, new patient; a medically-necessary, face-to-face mental health encounter (one-on-one) between a new patient and a fqhc practitioner during which time one or more fqhc services are rendered and includes a typical bundle of medicare-covered services that would be furnished per diem to a patient receiving a mental health visit	Fqhc visit, mh new pt	10/01/2014	A
G0470	Federally qualified health center (fqhc) visit, mental health, established patient; a medically-necessary, face-to-face mental health encounter (one-on-one) between an established patient and a fqhc practitioner during which time one or more fqhc services are rendered and includes a typical bundle of medicare-covered services that would be furnished per diem to a patient receiving a mental health visit	Fqhc visit, mh estab pt	10/01/2014	A
G0511	Rural health clinic or federally qualified health center (rhc or fqhc) only, general care management, 20 minutes or more of clinical staff time for chronic care management services or behavioral health integration services directed by an rhc or fqhc practitioner (physician, np, pa, or cnm), per calendar month	Ccm/bhi by rhc/fqhc 20min mo	01/01/2018	A
G0512	Rural health clinic or federally qualified health center (rhc/fqhc) only, psychiatric collaborative care model (psychiatric cocm), 60 minutes or more of clinical staff time for psychiatric cocm services directed by an rhc or fqhc practitioner (physician, np, pa, or cnm) and including services furnished by a behavioral health care manager and consultation with a psychiatric consultant, per calendar month	Cocm by rhc/fqhc 60 min mo	01/01/2018	A

#### 4. New CPT Category III Codes Effective July 1, 2020

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

For the July 2020 update, CMS is implementing 25 CPT Category III codes that the AMA released in January 2020 for implementation on July 1, 2020. The status indicators and APC assignments for these codes are shown in Table 5. CPT codes 0594T through 0619T have been added to the July 2020 I/OCE with an effective date of July 1, 2020. These codes, along with their short descriptors, status indicators, and payment rates (where applicable) are also listed in the July 2020 OPSS Addendum B that is posted on the CMS website. For information on the OPSS status indicators, refer to OPSS Addendum D1 of the CY 2020 OPSS/ASC final rule for the latest definitions.

**Table 5. – CPT Category III Codes Effective July 1, 2020**

<b>CPT Code</b>	<b>Long Descriptor</b>	<b>OPSS SI</b>	<b>OPSS APC</b>
0594T	Osteotomy, humerus, with insertion of an externally controlled intramedullary lengthening device, including intraoperative imaging, initial and subsequent alignment assessments, computations of adjustment schedules, and management of the intramedullary lengthening device	J1	5114
0596T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); initial insertion, including urethral measurement	T	5372
0597T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); replacement	T	5372
0598T	Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; first anatomic site (eg, lower extremity)	T	5722
0599T	Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; each additional anatomic site (eg, upper extremity) (List separately in addition to code for primary procedure)	N	N/A
0600T	Ablation, irreversible electroporation; 1 or more tumors per organ, including imaging guidance, when performed, percutaneous	J1	5361
0601T	Ablation, irreversible electroporation; 1 or more tumors, including fluoroscopic and ultrasound guidance, when performed, open	J1	5361
0602T	Glomerular filtration rate (GFR) measurement(s), transdermal, including sensor placement and administration of a single dose of fluorescent pyrazine agent	Q4	N/A
0603T	Glomerular filtration rate (GFR) monitoring, transdermal, including sensor placement and administration of more than one dose of fluorescent pyrazine agent, each 24 hours	Q4	N/A

CPT Code	Long Descriptor	OPPS SI	OPPS APC
0604T	Optical coherence tomography (OCT) of retina, remote, patient-initiated image capture and transmission to a remote surveillance center unilateral or bilateral; initial device provision, set-up and patient education on use of equipment	V	5012
0605T	Optical coherence tomography (OCT) of retina, remote, patient-initiated image capture and transmission to a remote surveillance center unilateral or bilateral; remote surveillance center technical support, data analyses and reports, with a minimum of 8 daily recordings, each 30 days	Q1	5741
0606T	Optical coherence tomography (OCT) of retina, remote, patient-initiated image capture and transmission to a remote surveillance center unilateral or bilateral; review, interpretation and report by the prescribing physician or other qualified health care professional of remote surveillance center data analyses, each 30 days	M	N/A
0607T	Remote monitoring of an external continuous pulmonary fluid monitoring system, including measurement of radiofrequency-derived pulmonary fluid levels, heart rate, respiration rate, activity, posture, and cardiovascular rhythm (eg, ECG data), transmitted to a remote 24-hour attended surveillance center; set-up and patient education on use of equipment	V	5012
0608T	Remote monitoring of an external continuous pulmonary fluid monitoring system, including measurement of radiofrequency-derived pulmonary fluid levels, heart rate, respiration rate, activity, posture, and cardiovascular rhythm (eg, ECG data), transmitted to a remote 24-hour attended surveillance center; analysis of data received and transmission of reports to the physician or other qualified health care professional	S	5741
0609T	Magnetic resonance spectroscopy, determination and localization of discogenic pain (cervical, thoracic, or lumbar); acquisition of single voxel data, per disc, on biomarkers (ie, lactic acid, carbohydrate, alanine, laal, propionic acid, proteoglycan, and collagen) in at least 3 discs	E1	N/A
0610T	Magnetic resonance spectroscopy, determination and localization of discogenic pain (cervical, thoracic, or lumbar); transmission of biomarker data for software analysis	E1	N/A
0611T	Magnetic resonance spectroscopy, determination and localization of discogenic pain (cervical, thoracic, or lumbar); postprocessing for algorithmic analysis of biomarker data for determination of relative chemical differences between discs	E1	N/A

CPT Code	Long Descriptor	OPPS SI	OPPS APC
0612T	Magnetic resonance spectroscopy, determination and localization of discogenic pain (cervical, thoracic, or lumbar); interpretation and report	E1	N/A
0613T	Percutaneous transcatheter implantation of interatrial septal shunt device, including right and left heart catheterization, intracardiac echocardiography, and imaging guidance by the proceduralist, when performed	E1	N/A
0614T	Removal and replacement of substernal implantable defibrillator pulse generator	J1	5231
0615T	Eye-movement analysis without spatial calibration, with interpretation and report	Q1	5734
0616T	Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; without removal of crystalline lens or intraocular lens, without insertion of intraocular lens	J1	5491
0617T	Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with removal of crystalline lens and insertion of intraocular lens	J1	5492
0618T	Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with secondary intraocular lens placement or intraocular lens exchange	J1	5492
0619T	Cystourethroscopy with transurethral anterior prostate commissurotomy and drug delivery, including transrectal ultrasound and fluoroscopy, when performed	J1	5375

### 5. CPT Proprietary Laboratory Analyses (PLA) Coding Changes Effective July 1, 2020

The AMA CPT Editorial Panel deleted five PLA codes, specifically, CPT codes 0124U through 0128U, and established 30 new PLA codes, specifically, CPT codes 0172U through 0201U, effective July 1, 2020. Table 6 lists the long descriptors and status indicators for the newly created codes as well as the deleted codes.

CPT codes 0172U through 0201U have been added to the July 2020 I/OCE with an effective date of July 1, 2020. These codes, along with their short descriptors, status indicators, and payment rates (where applicable) are also listed in the July 2020 OPSS Addendum B that is posted on the CMS website. As noted in Table 6, several of the new codes are assigned to either status indicator "Q4" to indicate that the laboratory tests are conditionally packaged or status indicator "A" to indicate that the laboratory tests are paid under a different Medicare payment system other than the OPSS. For a complete list of the OPSS status indicators, refer to OPSS Addendum D1 of the CY 2020 OPSS/ASC final rule for the latest definitions.

Table 6. – PLA Coding Changes Effective July 1, 2020

CPT Code	Long Descriptor	OPPS SI	OPPS APC
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	D	N/A
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	D	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	D	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	D	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	D	N/A
0172U	Oncology (solid tumor as indicated by the label), somatic mutation analysis of <i>BRCA1</i> ( <i>BRCA1</i> , <i>DNA repair associated</i> ), <i>BRCA2</i> ( <i>BRCA2</i> , <i>DNA repair associated</i> ) and analysis of homologous recombination deficiency pathways, DNA, formalin-fixed paraffin-embedded tissue, algorithm quantifying tumor genomic instability score	A	N/A
0173U	Psychiatry (ie, depression, anxiety), genomic analysis panel, includes variant analysis of 14 genes	A	N/A
0174U	Oncology (solid tumor), mass spectrometric 30 protein targets, formalin-fixed paraffin-embedded tissue, prognostic and predictive algorithm reported as likely, unlikely, or uncertain benefit of 39 chemotherapy and targeted therapeutic oncology agents	Q4	N/A

CPT Code	Long Descriptor	OPPS SI	OPPS APC
0175U	Psychiatry (eg, depression, anxiety), genomic analysis panel, variant analysis of 15 genes	A	N/A
0176U	Cytolethal distending toxin B (CdtB) and vinculin IgG antibodies by immunoassay (ie, ELISA)	Q4	N/A
0177U	Oncology (breast cancer), DNA, <i>PIK3CA</i> (phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha) gene analysis of 11 gene variants utilizing plasma, reported as <i>PIK3CA</i> gene mutation status	A	N/A
0178U	Peanut allergen-specific quantitative assessment of multiple epitopes using enzyme-linked immunosorbent assay (ELISA), blood, report of minimum eliciting exposure for a clinical reaction	Q4	N/A
0179U	Oncology (non-small cell lung cancer), cell-free DNA, targeted sequence analysis of 23 genes (single nucleotide variations, insertions and deletions, fusions without prior knowledge of partner/breakpoint, copy number variations), with report of significant mutation(s)	A	N/A
0180U	Red cell antigen (ABO blood group) genotyping (ABO), gene analysis Sanger/chain termination/conventional sequencing, <i>ABO</i> ( <i>ABO, alpha 1-3-N-acetylgalactosaminyltransferase and alpha 1-3-galactosyltransferase</i> ) gene, including subtyping, 7 exons	A	N/A
0181U	Red cell antigen (Colton blood group) genotyping (CO), gene analysis, <i>AQP1</i> ( <i>aquaporin 1 [Colton blood group]</i> ) exon 1	A	N/A
0182U	Red cell antigen (Cromer blood group) genotyping (CROM), gene analysis, <i>CD55</i> ( <i>CD55 molecule [Cromer blood group]</i> ) exons 1-10	A	N/A
0183U	Red cell antigen (Diego blood group) genotyping (DI), gene analysis, <i>SLC4A1</i> ( <i>solute carrier family 4 member 1 [Diego blood group]</i> ) exon 19	A	N/A
0184U	Red cell antigen (Dombrock blood group) genotyping (DO), gene analysis, <i>ART4</i> ( <i>ADP-ribosyltransferase 4 [Dombrock blood group]</i> ) exon 2	A	N/A
0185U	Red cell antigen (H blood group) genotyping (FUT1), gene analysis, <i>FUT1</i> ( <i>fucosyltransferase 1 [H blood group]</i> ) exon 4	A	N/A
0186U	Red cell antigen (H blood group) genotyping (FUT2), gene analysis, <i>FUT2</i> ( <i>fucosyltransferase 2</i> ) exon 2	A	N/A
0187U	Red cell antigen (Duffy blood group) genotyping (FY), gene analysis, <i>ACKR1</i> ( <i>atypical chemokine receptor 1 [Duffy blood group]</i> ) exons 1-2	A	N/A

CPT Code	Long Descriptor	OPPS SI	OPPS APC
0188U	Red cell antigen (Gerbich blood group) genotyping (GE), gene analysis, <i>GYP C</i> ( <i>glycophorin C [Gerbich blood group]</i> ) exons 1-4	A	N/A
0189U	Red cell antigen (MNS blood group) genotyping (GYPA), gene analysis, <i>GYP A</i> ( <i>glycophorin A [MNS blood group]</i> ) introns 1, 5, exon 2	A	N/A
0190U	Red cell antigen (MNS blood group) genotyping (GYPB), gene analysis, <i>GYP B</i> ( <i>glycophorin B [MNS blood group]</i> ) introns 1, 5, pseudoexon 3	A	N/A
0191U	Red cell antigen (Indian blood group) genotyping (IN), gene analysis, <i>CD44</i> ( <i>CD44 molecule [Indian blood group]</i> ) exons 2, 3, 6	A	N/A
0192U	Red cell antigen (Kidd blood group) genotyping (JK), gene analysis, <i>SLC14A1</i> ( <i>solute carrier family 14 member 1 [Kidd blood group]</i> ) gene promoter, exon 9	A	N/A
0193U	Red cell antigen (JR blood group) genotyping (JR), gene analysis, <i>ABCG2</i> ( <i>ATP binding cassette subfamily G member 2 [Junior blood group]</i> ) exons 2-26	A	N/A
0194U	Red cell antigen (Kell blood group) genotyping (KEL), gene analysis, <i>KEL</i> ( <i>Kell metallo-endopeptidase [Kell blood group]</i> ) exon 8	A	N/A
0195U	<i>KLF1</i> ( <i>Kruppel-like factor 1</i> ), targeted sequencing (ie, exon 13)	A	N/A
0196U	Red cell antigen (Lutheran blood group) genotyping (LU), gene analysis, <i>BCAM</i> ( <i>basal cell adhesion molecule [Lutheran blood group]</i> ) exon 3	A	N/A
0197U	Red cell antigen (Landsteiner-Wiener blood group) genotyping (LW), gene analysis, <i>ICAM4</i> ( <i>intercellular adhesion molecule 4 [Landsteiner-Wiener blood group]</i> ) exon 1	A	N/A
0198U	Red cell antigen (RH blood group) genotyping (RHD and RHCE), gene analysis Sanger/chain termination/conventional sequencing, <i>RHD</i> ( <i>Rh blood group D antigen</i> ) exons 1-10 and <i>RHCE</i> ( <i>Rh blood group CcEe antigens</i> ) exon 5	A	N/A
0199U	Red cell antigen (Scianna blood group) genotyping (SC), gene analysis, <i>ERMAP</i> ( <i>erythroblast membrane associated protein [Scianna blood group]</i> ) exons 4, 12	A	N/A
0200U	Red cell antigen (Kx blood group) genotyping (XK), gene analysis, <i>XK</i> ( <i>X-linked Kx blood group</i> ) exons 1-3	A	N/A
0201U	Red cell antigen (Yt blood group) genotyping (YT), gene analysis, <i>ACHE</i> ( <i>acetylcholinesterase [Cartwright blood group]</i> ) exon 2	A	N/A

## 6. Hemodialysis Arteriovenous Fistula (AVF) Procedures: Replacement Codes for HCPCS Codes C9754 and C9755

For CY 2019, based on two separate new technology applications received for hemodialysis arteriovenous fistula creation, CMS established two new HCPCS codes to describe the procedures. Specifically, CMS established HCPCS code C9754 for the Ellipsys System and C9755 for the WavelinQ System effective January 1, 2019. These codes were listed in the OPPS Addendum B that was released with the CY 2019 OPPS/ASC Final Rule. In addition, we listed the codes in the January 2019 OPPS quarterly update (Transmittal 4186, CR 11099) that was published on December 21, 2018.

For the July 2020 update, we are deleting HCPCS codes C9754 and C9755 since they will be replaced with HCPCS codes G2170 and G2171, respectively, effective July 1, 2020. We note that the replacement G-codes have been assigned to the same APC and status indicator as the predecessor HCPCS C-codes. Table 7 lists the HCPCS codes and long descriptors.

The codes, along with their short descriptors, APC assignment, status indicators, and payment rates are also listed in the July 2020 OPPS Addendum B that is posted on the CMS website. For information on the OPPS status indicator definitions, refer to OPPS Addendum D1 of the CY 2020 OPPS/ASC final rule.

**Table 7. – Replacement Codes for HCPCS Codes C9754 and C9755**

HCPCS Code	Long Descriptor	Add Date	Term Date	Replacement Code
C9754	Creation of arteriovenous fistula, percutaneous; direct, any site, including all imaging and radiologic supervision and interpretation, when performed and secondary procedures to redirect blood flow (e.g., transluminal balloon angioplasty, coil embolization, when performed)	1/1/2019	6/30/2020	G2170
G2170	Percutaneous arteriovenous fistula creation (AVF), direct, any site, by tissue approximation using thermal resistance energy, and secondary procedures to redirect blood flow (e.g., transluminal balloon angioplasty, coil embolization) when performed, and includes all imaging and radiologic guidance, supervision and interpretation, when performed	7/1/2020	N/A	N/A

HCPCS Code	Long Descriptor	Add Date	Term Date	Replacement Code
C9755	Creation of arteriovenous fistula, percutaneous using magnetic-guided arterial and venous catheters and radiofrequency energy, including flow-directing procedures (e.g., vascular coil embolization with radiologic supervision and interpretation, when performed) and fistulogram(s), angiography, venography, and/or ultrasound, with radiologic supervision and interpretation, when performed	1/1/2019	6/30/2020	G2171
G2171	Percutaneous arteriovenous fistula creation (AVF), direct, any site, using magnetic-guided arterial and venous catheters and radiofrequency energy, including flow-directing procedures (e.g., vascular coil embolization with radiologic supervision and interpretation, when performed) and fistulogram(s), angiography, enography, and/or ultrasound, with radiologic supervision and interpretation, when performed	7/1/2020	N/A	N/A

### 7. a. New Device Pass-Through Categories

Section 1833(t)(6)(B) of the Social Security Act (the Act) requires that, under the OPSS, categories of devices be eligible for transitional pass-through payments for at least 2, but not more than 3 years. Section 1833(t)(6)(B)(ii)(IV) of the Act requires that we create additional categories for transitional pass-through payment of new medical devices not described by existing or previously existing categories of devices.

We are establishing one new device pass-through category as of July 1, 2020. Table 8 provides a listing of new coding and payment information concerning the new device categories for transitional pass-through payment.

**Table 8. – New Device Pass-Through Code Effective July 1, 2020**

HCPCS Code	SI	APC	Short Descriptor	Long Descriptor
C1748	H	2029	Endoscope, single, UGI	Endoscope, single-use (i.e. disposable), upper gi, imaging/illumination device (insertable)

**b. Device Offset from Payment:**

Section 1833(t)(6)(D)(ii) of the Act requires that we deduct from pass-through payments for devices an amount that reflects the portion of the APC payment amount. This deduction is known as the device offset, or the portion(s) of the APC amount that is associated with the cost of the pass-through device. The device offset from payment represents a deduction from pass-through payments for the applicable pass-through device.

i. We have determined the device offset amounts, or the portion of the APC payment amounts for APC 5303 (Level 3 Upper GI Procedures) and APC 5331 (Complex GI Procedures) that are associated with the costs of the device category described by HCPCS code C1748.

The device in the category described by HCPCS code C1748 should always be billed with one of the CPT codes listed in Table 9. The table also includes the device offset associated with each code.

**Table 9. – CPT Codes Reportable with HCPCS Code C1748 Effective July 1, 2020**

CPT Code	Short Descriptor	CY 2020 OPPS SI	CY 2020 OPPS APC	Device Offset Amount
43260	Ercp w/specimen collection	J1	5303	\$376.68
43261	Endo cholangiopancreatograph	J1	5303	\$320.30
43262	Endo cholangiopancreatograph	J1	5303	\$382.68
43263	Ercp sphincter pressure meas	J1	5303	\$128.36
43264	Ercp remove duct calculi	J1	5303	\$376.38
43265	Ercp lithotripsy calculi	J1	5331	\$816.09
43274	Ercp duct stent placement	J1	5331	\$1,287.96
43275	Ercp remove forgn body duct	J1	5303	\$323.30
43276	Ercp stent exchange w/dilate	J1	5331	\$1,392.66
43277	Ercp ea duct/ampulla dilate	J1	5303	\$483.45
43278	Ercp lesion ablate w/dilate	J1	5303	\$452.56

ii. **Application of Offset to C1734:** On January 1, 2020, we determined that an offset would apply to C1734 because APC 5115 (Level 5 Musculoskeletal Procedures) and APC 5116 (Level 6 Musculoskeletal Procedures) already contain costs associated with the device described by C1734. C1734 should always be billed with CPT codes 27870, 28715, 28725 (which are assigned to APC 5115 for CY 2020) and 28705 (which is assigned to APC 5116 for CY 2020). The device offset is a deduction from pass-through payments for C1734. After further review, we have determined that the costs associated with C1734 are not already reflected in APCs 5115 or 5116. Therefore, we are not applying an offset to C1734. This determination to not

apply the device offset from payment will be retroactive to January 1, 2020. See 68 FR 63438-9 for further discussion about the device offset policy.

Also, refer to [https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough\\_payment.html](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html) for the most current device pass-through information.

### **c. Transitional Pass-Through Payments for Designated Devices**

Certain designated new devices are assigned to APCs and identified by the OCE as eligible for payment based on the reasonable cost of the new device reduced by the amount included in the APC for the procedure that reflects the packaged payment for device(s) used in the procedure. OCE will determine the proper payment amount for these APCs as well as the coinsurance and any applicable deductible. All related payment calculations will be returned on the same APC line and identified as a designated new device. We refer readers to Addendum P of the CY 2020 final rule with comment period for the most current OPFS HCPCS Offset file. Addendum P is available on the CMS website.

### **d. Alternative Pathway for Devices That Have a Food and Drug Administration (FDA) Breakthrough Designation**

For devices that have received FDA marketing authorization and a Breakthrough Devices designation from the FDA, CMS provided an alternative pathway to qualify for device pass-through payment status, under which devices would not be evaluated in terms of the substantial clinical improvement criterion for the purposes of determining device pass-through payment status. The devices would still need to meet the other criteria for pass-through status. This applies to devices that receive pass-through payment status effective on or after January 1, 2020.

## **8. Changes to Certain Device Offsets for 2020**

For CY 2020, in the absence of claims data, we applied a default device offset percentage of 31 percent for CPT codes 0548T and 0549T. Under existing policy, the associated claims data used for purposes of determining whether or not to apply the default device offset are the associated claims data for either the new HCPCS code or any predecessor code, as described by CPT coding guidance, for the new HCPCS code. Additionally, in limited instances where a new HCPCS code does not have a predecessor code as defined by CPT, but describes a procedure that was previously described by an existing code, we use clinical discretion to identify HCPCS codes that are clinically related or similar to the new HCPCS code, but are not officially recognized as a predecessor code by CPT, and to use the claims data of the clinically related or similar code(s) for purposes of determining whether or not to apply the default device offset to the new HCPCS code.

After further review, we have determined that the device offset percentage for C9746, the predecessor code to CPT code 0548T which was deleted June 30, 2019, would be a more appropriate, and clinically similar, device offset percentage for CPT codes 0548T and 0549T. For CY 2020, the device offset percentage of C9746 based on CY 2018 claims data was 63.56 percent. For CPT codes 0548T and 0549T, a device offset percentage of 63.56 percent results in device offset amounts of \$5,127.98 for CPT code 0548T and \$2,689.62 for CPT code 0549T for CY 2020. The device offset percentage of 63.56 percent and device offset amounts are now

displayed in Addendum P to the CY 2020 OPPTS/ASC final rule. This determination to apply the device offset percentage for C9746 to CPT codes 0548T and 0549T is retroactive to January 1, 2020.

## 9. Drugs, Biologicals, and Radiopharmaceuticals

### a. New CY 2020 HCPCS Codes and Dosage Descriptors for Certain Drugs, Biologicals, and Radiopharmaceuticals Receiving Pass-Through Status

Eleven new HCPCS codes have been created for reporting drugs and biologicals in the hospital outpatient setting, where there have not previously been specific codes available starting on July 1, 2020. These drugs and biologicals will receive drug pass-through status starting July 1, 2020. These new codes are listed in Table 10.

**Table 10. – New CY 2020 HCPCS Codes Effective July 1, 2020, for Certain Drugs, Biologicals, and Radiopharmaceuticals Receiving Pass-Through Status**

CY 2020 HCPCS Code	CY 2020 Long Descriptor	CY 2020 SI	CY 2020 APC
C9059	Injection, meloxicam, 1 mg	G	9371
J9358	Injection, fam-trastuzumab deruxtecan-nxki, 1 mg	G	9353
J7204	Injection, factor viii, antihemophilic factor (recombinant), (esperoct), glycopegylated-exei, per iu	G	9354
J9177	Injection, enfortumab vedotin-ejfv, 0.25 mg	G	9364
J0742	Injection, imipenem 4 mg, cilastatin 4 mg and relebactam 2 mg	G	9362
Q5119	Injection, rituximab-pvvr, biosimilar, (ruxience), 10 mg	G	9367
C9061	Injection, teprotumumab-trbw, 10 mg	G	9355
J1429	Injection, golodirsen, 10 mg	G	9356
C9063	Injection, eptinezumab-jjmr, 1 mg	G	9357
C9122	Mometasone furoate sinus implant, 10 micrograms (sinuva)	G	9346
J0896	Injection, luspatercept-aamt, 0.25 mg	G	9347

### b. Currently Existing HCPCS Codes for Certain Drugs, Biologicals, and Radiopharmaceuticals That Will Start to Receive Pass-Through Status

There are two existing HCPCS codes for certain drugs, biologicals, and radiopharmaceuticals in the outpatient setting that will start to receive pass-through status beginning on July 1, 2020.

These new codes are listed in Table 11.

**Table 11. – Currently Existing HCPCS Codes for Certain Drugs, Biologicals, and Radiopharmaceuticals Receiving Pass-Through Status Effective July 1, 2020**

CY 2020 HCPCS Code	CY 2020 Long Descriptor	April 2020 SI	July 2020 SI	CY 2020 APC
Q5116	Injection, trastuzumab-qyyp, biosimilar, (trazimera), 10 mg	E2	G	9350
Q5118	Injection, bevacizumab-bvzr, biosimilar, (zirabev), 10 mg	K	G	9348

**c. Currently Existing HCPCS Codes for Certain Drugs, Biologicals, and Radiopharmaceuticals with Pass-Through Status Ending on June 30, 2020**

There are two HCPCS codes for certain drugs, biologicals, and radiopharmaceuticals in the outpatient setting that will have their pass-through status end on June 30, 2020. These codes are listed in Table 12.

**Table 12. – HCPCS Codes for Certain Drugs, Biologicals, and Radiopharmaceuticals with Pass-Through Status Ending Effective June 30, 2020**

CY 2020 HCPCS Code	CY 2020 Long Descriptor	April 2020 SI	July 2020 SI	CY 2020 APC
J0565	Injection, bezlotoxumab, 10 mg	G	K	9490
J2326	Injection, nusinersen, 0.1 mg	G	K	9489

**d. Drugs and Biologicals that Will Change from Non-Payable Status (Status Indicator = “E2”) to Separately Payable Status (Status Indicator = “K”) for the Period of February 23, 2020, through June 30, 2020**

The status indicator for HCPCS code Q5116 (Injection, trastuzumab-qyyp, biosimilar, (trazimera), 10 mg) for the period of February 23, 2020, through June 30, 2020, will be changed retroactively from status indicator = “E2” to status indicator = “K.” This drug or biological is reported in Table 13.

**Table 13. — CY 2020 HCPCS and CPT Code Changes for Certain Drugs, Biologicals, and Radiopharmaceuticals Retroactive for the Period of February 23, 2020, through June 30, 2020**

HCPCS Code	Long Descriptor	Old SI	New SI	APC	Effective Date
Q5116	Injection, trastuzumab-qyyp, biosimilar, (trazimera), 10 mg	E2	K	9350	02/23/2020

**e. Drugs and Biologicals that Will Change from Non-Payable Status (Status Indicator = “E2”) to Separately Payable Status (Status Indicator = “K”) Retroactive for the Period of March 16, 2020, through June 30, 2020**

The status indicator for HCPCS code Q5113 (Injection, trastuzumab-pkrb, biosimilar, (herzuma), 10 mg) will be changed from status indicator = “E2” to status indicator = “K” retroactively for the period of March 16, 2020, through June 30, 2020. This drug or biological is reported in Table 14.

**Table 14. — CY 2020 HCPCS and CPT Code Changes for Certain Drugs, Biologicals, and Radiopharmaceuticals Retroactive for the Period of March 16, 2020, through June 30, 2020**

HCPCS Code	Long Descriptor	Old SI	New SI	APC	Effective Date
Q5113	Injection, trastuzumab-pkrb, biosimilar, (herzuma), 10 mg	E2	K	9349	03/16/2020

**f. Drugs and Biologicals that Will Be Separately Payable (Status Indicator = “K”) Retroactively for the Period of February 3, 2020, through June 30, 2020**

HCPCS code Q5119 (Injection, rituximab-pvvr, biosimilar, (ruxience), 10 mg) will have its effective date changed to February 3, 2020. Furthermore, HCPCS code Q5119 will be retroactively separately payable with a status indicator of “K” for the period of February 3, 2020, through June 30, 2020. This drug or biological is reported in Table 15.

**Table 15. — CY 2020 HCPCS and CPT Code Changes for Certain Drugs, Biologicals, and Radiopharmaceuticals Retroactive for the Period of February 3, 2020, through June 30, 2020**

HCPCS Code	Long Descriptor	SI	APC	Effective Date
Q5119	Injection, rituximab-pvvr, biosimilar, (ruxience), 10 mg	K	9367	02/03/2020

**g. Drugs and Biologicals that Will Be Separately Payable (Status Indicator = “K”) Retroactively for the Period of November 15, 2019, through March 31, 2020**

We are changing the effective date of HCPCS code C9058 (Injection, pegfilgrastim-bmez, biosimilar, (Ziextenzo) 0.5 mg) to November 15, 2019. Furthermore, HCPCS code C9058 will be retroactively separately payable with a status indicator of “K” for the period of November 15, 2019, through March 31, 2020. This drug or biological is reported in Table 16.

**Table 16. – CY 2020 HCPCS and CPT Code Changes for Certain Drugs, Biologicals, and Radiopharmaceuticals that Are Separately Payable Retroactive for the Period of November 15, 2019, through March 31, 2020**

HCPCS Code	Long Descriptor	SI	APC	Effective Date	End Date
C9058	Injection, pegfilgrastim-bmez, biosimilar, (Ziextenzo) 0.5 mg	K	9345	11/15/2019	03/31/2020

**h. HCPCS Codes for Drugs and Biologicals that Are Not Recognized in the OPSS (Status Indicator = “B”) Retroactively for the Period of November 15, 2019 through June 30, 2020**

We are changing the effective date of HCPCS code Q5120 (Injection, pegfilgrastim-bmez, biosimilar, (ziextenzo), 0.5 mg) to November 15, 2019. However, this drug is already described by HCPCS code C9058 which is a separately payable code for the period of November 15, 2019, until June 30, 2020. Therefore, HCPCS code Q5120 will be assigned to status indicator = “B” (Code Not Recognized by the OPSS when submitted on an outpatient hospital Part B bill type (12x and 13x)) retroactively for the period of November 15, 2019, through June 30, 2020. Starting on July 1, 2020, HCPCS code Q5120 will be assigned to status indicator = “G” until June 30, 2023. This drug or biological is reported in Table 17.

**Table 17. – CY 2020 HCPCS and CPT Code Changes for Certain Drugs, Biologicals, and Radiopharmaceuticals that Are Not Recognized in the OPSS Retroactive for the Period of November 15, 2019, through June 30, 2020**

HCPCS Code	Long Descriptor	SI	APC	Effective Date	End Date
Q5120	Injection, pegfilgrastim-bmez, biosimilar, (ziextenzo), 0.5 mg	B	N/A	11/15/2019	06/30/2020
Q5120	Injection, pegfilgrastim-bmez, biosimilar, (ziextenzo), 0.5 mg	G	9345	07/01/2020	06/30/2023

**i. Existing HCPCS Codes for Drugs, Biologicals, and Radiopharmaceuticals with a Change from Non-Payable Status (Status Indicator = “E1”) to Vaccine Not Payable in the OPSS (Status Indicator = “L”)**

The status indicator for CPT code 90694 (Influenza virus vaccine, quadrivalent (aiiv4), inactivated, adjuvanted, preservative free, 0.5 ml dosage, for intramuscular use) changes from SI = “E1” to SI = “L” on July 1, 2020, as the vaccine described by CPT code 90694 may be covered by Medicare, but is payable outside of the OPSS. See Table 18.

**Table 18. – Existing HCPCS Codes for Drugs, Biologicals, and Radiopharmaceuticals with a Change from SI=E1 to SI=L, Effective July 1, 2020**

HCPCS Code	Long Descriptor	Old SI	New SI	APC	Effective Date
90694	Influenza virus vaccine, quadrivalent (aiiv4), inactivated, adjuvanted, preservative free, 0.5 ml dosage, for intramuscular use	E1	L	N/A	07/01/2020

**j. Drugs and Biologicals that Will Change from Non-Payable Status (Status Indicator = “E2”) to Separately Payable Status (Status Indicator = “K”) Retroactive for the Period of April 15, 2020 through June 30, 2020**

The status indicator for HCPCS code Q5112 (Injection, trastuzumab-dttb, biosimilar, (ontruzant), 10 mg) will be changed from status indicator = “E2” to status indicator = “K” retroactively for the period of April 15, 2020 through June 30, 2020. This drug/biological is reported in Table 19.

**Table 19. – CY 2020 HCPCS and CPT Code Changes for Certain Drugs, Biologicals, and Radiopharmaceuticals Retroactive for the Period of April 15, 2020 through June 30, 2020**

HCPCS Code	Long Descriptor	Old SI	New SI	APC	Effective Date
Q5112	Injection, trastuzumab-dttb, biosimilar, (ontruzant), 10 mg	E2	K	9382	04/15/2020

**k. HCPCS code Q5112 to Have a Separately Payable Status (Status Indicator = “K”) for the Period of July 1, 2020 through September 30, 2020**

The status indicator for HCPCS code Q5112 (Injection, trastuzumab-dttb, biosimilar, (ontruzant), 10 mg) will continue to be status indicator = “K” for the period of July 1, 2020 through September 30, 2020. This drug/biological is reported in Table 20.

**Table 20. – HCPCS Code Q5112 Continues to be Separately Payable for the Period of July 1, 2020 through September 30, 2020**

HCPCS Code	Long Descriptor	SI	APC	Effective Dates
Q5112	Injection, trastuzumab-dttb, biosimilar, (ontruzant), 10 mg	K	9382	07/01/2020 – 09/30/2020

**I. Newly Established HCPCS Codes for Drugs, Biologicals, and Radiopharmaceuticals as of July 1, 2020**

42 new drug, biological, and radiopharmaceutical HCPCS codes will be established on July 1, 2020. The new codes are listed in Table 19.

**Table 21. – Other CY 2020 HCPCS and CPT Code Changes for Certain Drugs, Biologicals, and Radiopharmaceuticals Effective July 1, 2020**

New HCPCS Code	Old HCPCS Code	Long Descriptor	SI	APC
J7169	C9041	Injection, coagulation factor xa (recombinant), inactivated-zhzo (andexxa), 10 mg	G	9198
J0791	C9053	Injection, crizanlizumab-tmca, 5 mg	G	9359
J0691	C9054	Injection, lefamulin, 1 mg	G	9332
J0223	C9056	Injection, givosiran, 0.5 mg	G	9343
J1201	C9057	Injection, cetirizine hydrochloride, 0.5 mg	G	9361
Q5120	C9058	Injection, pegfilgrastim-bmez, biosimilar, (ziextenzo), 0.5 mg	G	9345
J7204		Injection, factor viii, antihemophilic factor (recombinant), (esperoct), glycopegylated-exei, per iu	G	9354
C9059		Injection, meloxicam, 1 mg	G	9371
C9061		Injection, teprotumumab-trbw, 10 mg	G	9355

New HCPCS Code	Old HCPCS Code	Long Descriptor	SI	APC
C9063		Injection, eptinezumab-jjmr, 1 mg	G	9357
C9122		Mometasone furoate sinus implant, 10 micrograms (sinuva)	G	9346
J0591		Injection, deoxycholic acid, 1 mg	E1	N/A
J0742		Injection, imipenem 4 mg, cilastatin 4 mg and relebactam 2 mg	G	9362
J0896		Injection, luspatercept-aamt, 0.25 mg	G	9347
J1429		Injection, golodirsen, 10 mg	G	9356
J1558		Injection, immune globulin (xembify), 100 mg	K	9372
J3399		Injection, onasemnogene abeparvovec-xioi, per treatment, up to 5x10 <sup>15</sup> vector genomes	K	9373
J7333		Hyaluronan or derivative, visco-3, for intraarticular injection, per dose	N	N/A
J9177		Injection, enfortumab vedotin-ejfv, 0.25 mg	G	9364
J9198		Injection, Gemcitabine hydrochloride, (Infugem), 100 mg	N	N/A
J9246		Injection, melphalan (evomela), 1 mg	K	9375
J9358		Injection, fam-trastuzumab deruxtecan-nxki, 1 mg	G	9353
Q4227		Amniocore, per square centimeter	N	N/A
Q4228		Bionextpatch, per square centimeter	N	N/A
Q4229		Cogenex amniotic membrane, per square centimeter	N	N/A
Q4230		Cogenex flowable amnion, per 0.5 cc	N	N/A

New HCPCS Code	Old HCPCS Code	Long Descriptor	SI	APC
Q4231		Corplex p, per cc	N	N/A
Q4232		Corplex, per square centimeter	N	N/A
Q4233		Surfactor or nudyn, per 0.5 cc	N	N/A
Q4234		Xcellerate, per square centimeter	N	N/A
Q4235		Amniorepair or altiply, per square centimeter	N	N/A
Q4236		Carepatch, per square centimeter	N	N/A
Q4237		Cryo-cord, per square centimeter	N	N/A
Q4238		Derm-maxx, per square centimeter	N	N/A
Q4239		Amnio-maxx or amnio-maxx lite, per square centimeter	N	N/A
Q4240		Corecyte, for topical use only, per 0.5 cc	N	N/A
Q4241		Polycyte, for topical use only, per 0.5 cc	N	N/A
Q4242		Amniocyte plus, per 0.5 cc	N	N/A
Q4244		Procenta, per 200 mg	N	N/A
Q4245		Amniotext, per cc	N	N/A
Q4246		Coretext or protext, per cc	N	N/A
Q4247		Amniotext patch, per square centimeter	N	N/A
Q4248		Dermacyte amniotic membrane allograft, per square centimeter	N	N/A
Q5121		Injection, infliximab-axxq, biosimilar, (avsola), 10 mg	E2	N/A

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

For CY 2020, payment for the majority of 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 + 6 percent of the reference product for biosimilars). Payment for

nonpass-through drugs, biologicals and therapeutic radiopharmaceuticals that were acquired under the 340B program is made at the single rate of ASP - 22.5 percent (or ASP - 22.5 percent of the biosimilar's ASP if a biosimilar is 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 2020, 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 (or ASP + 6 percent of the reference product for biosimilars). Payments for drugs and biologicals based on ASPs will be updated on a quarterly basis as later quarter ASP submissions become available. Effective July 1, 2020, payment rates for many drugs and biologicals have changed from the values published in the CY 2020 OPPS/ASC final rule with comment period as a result of the new ASP calculations based on sales price submissions from the fourth quarter of CY 2019. In cases where adjustments to payment rates are necessary, changes to the payment rates will be incorporated in the July 2020 FISS release. CMS is not publishing the updated payment rates in CR 11814 implementing the July 2020 update of the OPPS. However, the updated payment rates effective July 1, 2020, are in the July 2020 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>.

#### **n. 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 payment 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.

#### **10. Skin Substitutes – New Products**

The payment for skin substitute products that do not qualify for pass-through status will be packaged into the payment for the associated skin substitute application procedure. The skin substitute products are divided into two groups: 1) high cost skin substitute products and 2) low cost skin substitute products for packaging purposes.

There are 13 new skin substitute HCPCS codes that will be active as of July 1, 2020. New skin substitute HCPCS codes are assigned into the low-cost skin substitute group unless CMS has pricing data that demonstrates that the cost of the product is above either the mean unit cost (MUC) of \$48 or per day cost (PDC) of \$790 for CY 2020. These codes are listed in [Table 22](#).

**Table 22. – New Skin Substitute Products Low Cost Group/High Cost Group Assignment Effective July 1, 2020**

CY 2020 HCPCS Code	CY 2020 Short Descriptor	CY 2020 SI	Low/High Cost Skin Substitute
C1849	Skin substitute, synthetic	N	High
Q4227	Amniocore per sq cm	N	Low
Q4228	Bionextpatch, per sq cm	N	Low
Q4229	Cogenex amnio memb per sq cm	N	Low
Q4232	Corplex, per sq cm	N	Low
Q4234	Xcellerate, per sq cm	N	Low
Q4235	Amniorepair or altiply sq cm	N	Low
Q4236	Carepatch per sq cm	N	Low
Q4237	cryo-cord, per sq cm	N	Low
Q4238	Derm-maxx, per sq cm	N	Low
Q4239	Amnio-maxx or lite per sq cm	N	Low
Q4247	Amniotext patch, per sq cm	N	Low
Q4248	Dermacyte Amn mem allo sq cm	N	Low

**11. New Separately Payable Procedure Codes – Surgical Procedures**

Effective July 1, 2020, two new HCPCS codes have been created as described in Table 21.

C9760 was inappropriately assigned to APC 1591 in the July I/OCE. The correct APC for C9760 should be APC 1589, which is listed in [Table 23](#).

**Table 23. – New Surgical Procedure Effective July 1, 2020**

HCPSC Code	Short Descriptor	Long Descriptor	APC	SI
C9759	Transcath intraop microinf	Transcatheter intraoperative blood vessel microinfusion(s) (e.g., intraluminal, vascular wall and/or perivascular) therapy, any vessel, including radiological supervision and interpretation, when performed	N/A	N
C9760	Non-blind interatrial shunt	Non-randomized, non-blinded procedure for NYHA Class II, III, IV heart failure; transcatheter implantation of interatrial shunt or placebo control, including right and left heart catheterization, transeptal puncture, trans-esophageal echocardiography (TEE)/intracardiac echocardiography (ICE), and all imaging with or without guidance (e.g., ultrasound, fluoroscopy), performed in an approved investigational device exemption (IDE) study	1589	T

### 12. New HCPCS Codes Describing Strain-Encoded Cardiac Magnetic Resonance Imaging (MRI)

For the July 2020 Update, CMS is establishing two new codes to describe the technology associated with strain-encoded cardiac magnetic resonance imaging. Specifically, CMS is establishing HCPCS codes C9762 and C9763 to describe the strain imaging and stress imaging associated with strain-encoded cardiac MRI. [Table 24](#) lists the long descriptors, status indicator, and APC assignment for both codes. For more information on OPSS status indicator “Q3”, refer to OPSS Addendum D1 of the Calendar Year 2020 OPSS/ASC final rule for the latest definition. These codes, along with their short descriptors, status indicator, and payment rates are also listed in the July 1, 2020, OPSS Addendum B.

**Table 24.—New Strain-Encoded Cardiac MRI HCPCS Codes Effective July 1, 2020**

HCPCS Code	Long Descriptor	OPSS SI	OPSS APC
C9762	Cardiac magnetic resonance imaging for morphology and function, quantification of segmental dysfunction; with strain imaging	Q3	5524
C9763	Cardiac magnetic resonance imaging for morphology and function, quantification of segmental dysfunction; with stress imaging	Q3	5524

### 13. New HCPCS Codes Describing Peripheral Intravascular Lithotripsy

For the July 2020 Update, CMS is establishing four new codes to describe the technology

associated with peripheral intravascular lithotripsy. CMS is establishing HCPCS codes C9764, C9765, C9766, and C9767 to describe procedures utilizing peripheral intravascular lithotripsy catheter. **Table 25** lists the long descriptors, status indicators, and APC assignment for all four codes. For more information on OPPS status indicator “J1”, refer to OPPS Addendum D1 of the CY 2020 OPPS/ASC final rule for the latest definition. These codes, along with their short descriptors, status indicator, and payment rates are also listed in the July 1, 2020, OPPS Addendum B.

**Table 25. New Peripheral Intravascular Lithotripsy HCPCS Codes Effective July 1, 2020**

HCPCS Code	Long Descriptor	OPPS SI	OPPS APC
C9764	Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy, includes angioplasty within the same vessel (s), when performed	J1	5192
C9765	Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed	J1	5193
C9766	Revascularization, endovascular, open or percutaneous, any vessel (s); with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel (s), when performed	J1	5193
C9767	Revascularization, endovascular, open or percutaneous, any vessel (s); with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel (s), when performed	J1	5194

#### 14. Supervision of Outpatient Therapeutic Services

On March 13, 2020, the President of the United States declared the COVID-19 outbreak a national emergency, and the Secretary declared the existence of a public health emergency (PHE). Subsequently, CMS implemented an interim final rule with comment period on April 6, 2020, to provide physician and hospital providers flexibilities in the administration of care retroactive to March 1, 2020. The goal of the interim final rule was to reduce burden on providers, suppliers, and practitioners during this public health emergency including avoiding exposure risks to COVID-19, and to expand the facilities where medical care may be provided and the available personnel who can provide that care. These policies are only in effect for the duration of the COVID-19 PHE.

In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61359 through 61363), we changed the generally applicable minimum required level of supervision for most hospital outpatient therapeutic services from direct supervision to general supervision for hospitals and CAHs. Given the circumstances of the PHE for the COVID-19 pandemic, we believed it was critical that hospitals have the most flexibility possible to provide the services Medicare beneficiaries need during this challenging time. One of the policies in the April 6, 2020, interim final rule with comment period related to hospital outpatient hospital care was changing the

minimum default level of physician supervision for non-surgical extended duration therapeutic services (NSEDTS) to general supervision for the entire service including the initiation portion of the service that had previously required direct supervision. Changing the minimum default level of supervision to general supervision for NSEDTS during the initiation of the service gives providers additional flexibility they will need to handle the burdens created by the PHE for the COVID-19 pandemic.

Therefore, we assigned, on an interim basis, all outpatient hospital therapeutic services that fall under §410.27(a)(1)(iv)(E) (that is, NSEDTS), a minimum level of general supervision to be consistent with the minimum default level of general supervision that applies for most outpatient hospital therapeutic services. General supervision, as defined in our regulation at §410.32(b)(3)(i) means that the procedure is furnished under the physician's overall direction and control, but that the physician's presence is not required during the performance of the procedure. In addition, we adopted, on an interim final basis, a change to the direct supervision requirement for outpatient hospital therapeutic services for pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services. During the duration of the PHE, the direct supervision requirement may be satisfied by the virtual presence of the physician through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider. We revised §410.27(a)(1)(iv)(D), to reflect this change to allow the direct supervision requirement to be met by virtual presence.

## 15. Changes to the Wage Index

As noted in the January 2020 OPSS CR, in the CY 2020 OPSS we finalized changes to the CY 2020 OPSS wage index to remove urban to rural reclassifications from the calculation of the rural floor, increase the wage index values for hospitals with a wage index value below the 25th percentile wage index value of 0.8457 across all hospitals, and apply a 5 percent cap for CY 2020 on any wage index values that decreased relative to CY 2019. While we developed a table of 2019 wages for the payment systems to automatically calculate whether the 5 percent cap on decreases applied, some providers, such as those that are new in 2020, were not included on the list.

## 16. Inadvertent Deletion of CPT code 0126T

CPT code 0126T was inadvertently deleted from the July I/OCE update but will remain an active code during claims processing. The I/OCE will be corrected in October 2020 to correct the inadvertent deletion of 0126T and to match claims processing.

## 17. 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. 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 11814, issued to your MAC regarding this change is available at <https://www.cms.gov/files/document/r10224CP.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
July 16, 2020	We revised this article to reflect a revised CR 11814. In the article, we updated the section on "Covid-19 Laboratory Tests and Services and Other Laboratory Tests Coding Update". Table 1 has also been updated to add 3 new COVID-19 codes: 87426, 0223U, and 0224U. We are also changing payment status indicator for HCPCS code Q5112 from SI=E2 to SI=K, effective April 15, 2020 through September 30, 2020 and are updating section 9 "Drugs, Biologicals, and Radiopharmaceuticals" by adding new subsections j and k to reflect this change. Therefore, we are re-numbering all other subsequent sub-sections, and Tables 19 and 20 have been added to reflect payment status indicator change for Q5112. All other subsequent tables have been re-numbered. We also revised the CR release date, transmittal number and the web address of the CR. All other information remains the same.

Date of Change	Description
July 2, 2020	<p>Note: We revised this article due to an updated Change Request. The updated CR:</p> <ul style="list-style-type: none"> <li>• Added CPT code 99458 with status indicator "B".</li> <li>• "New Separately Payable Procedure Codes – Surgical Procedures" has been updated with corrected APC assignment for HCPCS code C9760.</li> <li>• "OPPS PRICER Logic and Data Changes for the July 2020 Update" has been removed. There is also a new, "Inadvertent Deletion of CPT code 0126T" added.</li> <li>• Therefore, the existing section 16 "Changes to the Wage Index" has become section 15. Table 1 has been updated by adding a new PLA COVID-19 code, 0202U.</li> <li>• Table 2 has been updated by adding CPT code 99458 with status indicator "B".</li> <li>• Table 21 has been updated by changing APC number for HCPCS code C9760 from APC 1591 to APC 1589. All other information remains the same. We also changed the CR release date, transmittal number and link to the transmittal. All other information is unchanged.</li> </ul>
June 8, 2020	Initial article released.

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