

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-04 Medicare Claims Processing</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 10013</b>	<b>Date: March 25, 2020</b>
	<b>Change Request 11691</b>

**Transmittal 4544, dated March 6, 2020, is being rescinded and replaced by Transmittal 10013, dated, March 25, 2020 to revise section I.B.3 to add new Coronavirus CPT codes U0002 and 87635, and to add a new section I.B.4.f. to revise a status indicator for Q5118, (Injection, bevacizumab-bvzr, biosimilar, (zirabev), 10 mg) from status indicator "E2" (Not paid by Medicare when submitted on outpatient claims (any outpatient bill type)) to status indicator = "K" (Paid under OPPTS; separate APC payment). We are also updating table 3 and adding new table 7 to the Attachment A. All other information remains the same.**

**SUBJECT: April 2020 Update of the Hospital Outpatient Prospective Payment System (OPPS)**

**I. SUMMARY OF CHANGES:** This Recurring Update Notification describes changes to and billing instructions for various payment policies implemented in the April 2020 OPPTS update. The April 2020 Integrated Outpatient Code Editor (I/OCE) will reflect the Healthcare Common Procedure Coding System (HCPCS), Ambulatory Payment Classification (APC), HCPCS Modifier, and Revenue Code additions, changes, and deletions identified in this Change Request (CR). This Recurring Update Notification applies to Chapter 4, section 50.7.

The April 2020 revisions to I/OCE data files, instructions, and specifications are provided in the forthcoming April 2020 I/OCE CR.

**EFFECTIVE DATE: April 1, 2020**

*\*Unless otherwise specified, the effective date is the date of service.*

**IMPLEMENTATION DATE: April 6, 2020**

*Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.*

**II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)**

R=REVISED, N=NEW, D=DELETED-Only One Per Row.

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
N/A	N/A

**III. FUNDING:**

**For Medicare Administrative Contractors (MACs):**

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions

regarding continued performance requirements.

**IV. ATTACHMENTS:**

**Recurring Update Notification**

# Attachment - Recurring Update Notification

Pub. 100-04	Transmittal: 10013	Date: March 25, 2020	Change Request: 11691
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**SUBJECT: April 2020 Update of the Hospital Outpatient Prospective Payment System (OPPS)**

**EFFECTIVE DATE: April 1, 2020**

*\*Unless otherwise specified, the effective date is the date of service.*

**IMPLEMENTATION DATE: April 6, 2020**

## **I. GENERAL INFORMATION**

**A. Background:** This Recurring Update Notification describes changes to and billing instructions for various payment policies implemented in the April 2020 OPSS update. The April 2020 Integrated Outpatient Code Editor (I/OCE) will reflect the Healthcare Common Procedure Coding System (HCPCS), Ambulatory Payment Classification (APC), HCPCS Modifier, and Revenue Code additions, changes, and deletions identified in this Change Request (CR). This Recurring Update Notification applies to Chapter 4, section 50.7.

The April 2020 revisions to I/OCE data files, instructions, and specifications are provided in the forthcoming April 2020 I/OCE CR.

## **B. Policy:**

### **1. CPT Proprietary Laboratory Analyses (PLA) Coding Changes Effective April 1, 2020**

For the April 2020 update, the AMA CPT Editorial Panel made several changes to the PLA codes. Specifically, CPT code 0006U was deleted, the descriptors for CPT codes 0154U and 0155U were revised, and 9 new PLA codes were established, specifically, CPT codes 0163U through 0171U, effective April 1, 2020. Table 1 attachment A, lists the long descriptors and status indicators for the codes.

For more information on OPSS status indicators "A," "D," "E1," and "Q4", refer to OPSS Addendum D1 of the Calendar Year 2020 OPSS/ASC final rule for the latest definitions. CPT codes 0163U through 0171U have been added to the April 2020 I/OCE with an effective date of April 1, 2020. These codes, along with their short descriptors and status indicators, are also listed in the April 1, 2020 OPSS Addendum B.

### **2. New Medicare National Coverage Determination for Acupuncture and Dry Needling Services**

Effective January 21, 2020, Medicare will cover acupuncture and dry needling for patients with chronic low back pain. Information on this new coverage determination can be found on the CMS website at: <https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=295>

Based on this recent coverage determination, we revised the OPSS status indicator and APC assignment for the CPT codes describing acupuncture and dry needling services from "E1" (Not paid by Medicare when submitted on outpatient claims (any outpatient bill type) to "S" (Paid under OPSS; separate APC payment) and "N" (Paid under OPSS; payment is packaged into payment for other services. Therefore, there is no separate APC payment.). Table 2, attachment A, lists the long descriptors and status indicators for the codes.

For more information on OPSS status indicators "E1," "N," and "S", refer to OPSS Addendum D1 of the Calendar Year 2020 OPSS/ASC final rule for the latest definitions. These codes, along with their short descriptors and status indicators, are also listed in the April 1, 2020 OPSS Addendum B.

### **3. New Corona Virus Lab Tests HCPCS Codes U0001, U0002, and 87635**

Medicare covers medically necessary and reasonable clinical diagnostic laboratory tests when ordered by a physician or non-physician practitioner who is treating the patient. HCPCS codes U0001, U0002, and 87635, which are listed in table 3, attachment A, will be added to the national HCPCS file and therefore do not need to be manually added to the HCPCS files by the MACs. The codes have been assigned to status indicator "A" (Not paid under OPSS. Paid by MACs under a fee schedule or payment system other than OPSS). Table 3, Attachment A, lists the HCPCS codes, descriptors, effective dates, and status indicator for the codes.

### **4. Drugs, Biologicals, and Radiopharmaceuticals**

#### **a. New CY 2020 HCPCS Codes and Dosage Descriptors for Certain Drugs, Biologicals, and Radiopharmaceuticals**

Four 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 April 1, 2020. These new codes are listed in Table 4, attachment A.

#### **b. Currently Existing HCPCS Codes for Certain Drugs, Biologicals, and Radiopharmaceuticals receiving pass-through status**

In addition to the four new HCPCS drug codes which have been assigned drug-pass-through status effective April 1, 2020, four additional existing HCPCS codes for certain drugs, biologicals, and radiopharmaceuticals in the outpatient setting have received pass-through beginning on April 1, 2020. These codes are listed in Table 5, attachment A.

#### **c. Currently Existing HCPCS Codes for Certain Drugs, Biologicals, and Radiopharmaceuticals with pass-through status ending on March 31, 2010**

Seven HCPCS code for certain drugs, biologicals, and radiopharmaceuticals in the outpatient setting will have their pass-through status end on March 31, 2020. These codes are listed in Table 6, attachment A.

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

For CY 2020, 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 + 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 April 1, 2020, payment rates for many drugs and biologicals have changed from the values published in the CY 2020 OPSS/ASC final rule with comment period as a result of the new ASP calculations based on sales price submissions from the third quarter of CY 2019. In cases where adjustments to payment rates are necessary, changes to the payment rates will be incorporated in the April 2020 FISS release. CMS is not publishing the updated payment rates in this Change Request implementing the April 2020 update of the OPSS. However, the

updated payment rates effective April 1, 2020 can be found in the April 2020 update of the OPSS Addendum A and Addendum B on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS>

**e. 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/OPSS-Restated-Payment-Rates>

Providers may resubmit claims that were impacted by adjustments to previous quarter’s payment files.

**f. Drugs and Biologicals that Will Change from Status Indicator = “E2” (Not paid by Medicare when submitted on outpatient claims (any outpatient bill type)) to Status Indicator = “K” (Paid under OPSS; separate APC payment) Effective January 13, 2020**

The status indicator for HCPCS code Q5118 (Injection, bevacizumab-bvzr, biosimilar, (zirabev), 10 mg) will be changed retroactively from status indicator =”E2” to status indicator = “K”, Effective January 13, 2020. This drug is reported in Table 7, attachment A.

**5. OPSS Pricer Logic and Data Changes for the April 2020 Update**

There are no OPSS PRICER logic or data changes for the April 2020 update; therefore, there is no OPSS PRICER release for April 2020.

**6. Coverage Determinations**

As a reminder, the fact that a drug, device, procedure or service is assigned a HCPCS code and a payment rate under the 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.

**II. BUSINESS REQUIREMENTS TABLE**

*"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.*

Number	Requirement	Responsibility								
		A/B MAC			D M E	Shared-System Maintainers				Other
		A	B	H H H		F M V C	I C M	S S S	S W F	
11691.1	Medicare contractors shall adjust, as appropriate, claims brought to their attention with any retroactive changes that were received prior to implementation of April 2020 I/OCE.	X		X						

### III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			D M E M A C	C E D I
		A	B	H H H		
11691.2	MLN Article: CMS will make available an MLN Matters provider education article that will be marketed through the MLN Connects weekly newsletter shortly after the CR is released. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1, instructions for distributing MLN Connects information to providers, posting the article or a direct link to the article on your website, and including the article or a direct link to the article in your bulletin or newsletter. You may supplement MLN Matters articles with localized information benefiting your provider community in billing and administering the Medicare program correctly. Subscribe to the “MLN Matters” listserv to get article release notifications, or review them in the MLN Connects weekly newsletter.	X		X		

### IV. SUPPORTING INFORMATION

**Section A: Recommendations and supporting information associated with listed requirements: N/A**

*"Should" denotes a recommendation.*

X-Ref Requirement Number	Recommendations or other supporting information:

**Section B: All other recommendations and supporting information: N/A**

### V. CONTACTS

**Pre-Implementation Contact(s):** Marina Kushnirova, marina.kushnirova@cms.hhs.gov

**Post-Implementation Contact(s):** Contact your Contracting Officer's Representative (COR).

### VI. FUNDING

**Section A: For Medicare Administrative Contractors (MACs):**

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**ATTACHMENTS: 1**

## Attachment A – Tables for the Policy Section

**Table 1. – PLA Coding Changes Effective April 1, 2020**

CPT Code	Long Descriptor	OPPS SI	OPPS APC
0006U	Detection interacting medications, substances, supplements and foods, 120 or more analytes, definitive chromatography with mass spectrometry, urine, description and severity of each interaction identified, per date of service	D	N/A
0154U	Oncology (urothelial cancer), RNA, analysis by real-time RT-PCR of the FGFR3 (fibroblast growth factor receptor 3) gene analysis (ie, p.R248C [c.742C>T], p.S249C [c.746C>G], p.G370C [c.1108G>T], p.Y373C [c.1118A>G], FGFR3-TACC3v1, and FGFR3-TACC3v3) utilizing formalin-fixed paraffin-embedded urothelial cancer tumor tissue, reported as FGFR gene alteration status	A	N/A
0155U	Oncology (breast cancer), DNA, PIK3CA (phosphatidylinositol-4,5-bisphosphate 3-kinase, catalytic subunit alpha) (eg, breast cancer) gene analysis (ie, p.C420R, p.E542K, p.E545A, p.E545D [g.1635G>T only], p.E545G, p.E545K, p.Q546E, p.Q546R, p.H1047L, p.H1047R, p.H1047Y), utilizing formalin-fixed paraffin-embedded breast tumor tissue, reported as PIK3CA gene mutation status	A	N/A
0163U	Oncology (colorectal) screening, biochemical enzyme-linked immunosorbent assay (ELISA) of 3 plasma or serum proteins (teratocarcinoma derived growth factor-1 [TDGF-1, Cripto-1], carcinoembryonic antigen [CEA], extracellular matrix protein [ECM]), with demographic data (age, gender, CRC-screening compliance) using a proprietary algorithm and reported as likelihood of CRC or advanced adenomas	E1	N/A
0164U	Gastroenterology (irritable bowel syndrome [IBS]), immunoassay for anti-CdtB and anti-vinculin antibodies, utilizing plasma, algorithm for elevated or not elevated qualitative results	Q4	N/A
0165U	Peanut allergen-specific IgE and quantitative assessment of 64 epitopes using enzyme-linked immunosorbent assay (ELISA), blood, individual epitope results and interpretation	Q4	N/A
0166U	Liver disease, 10 biochemical assays ( $\alpha$ 2-macroglobulin, haptoglobin, apolipoprotein A1, bilirubin, GGT, ALT, AST, triglycerides, cholesterol, fasting glucose) and biometric and demographic data, utilizing serum, algorithm reported as scores for fibrosis, necroinflammatory activity, and steatosis with a summary interpretation	Q4	N/A
0167U	Gonadotropin, chorionic (hCG), immunoassay with direct optical observation, blood	Q4	N/A
0168U	Fetal aneuploidy (trisomy 21, 18, and 13) DNA sequence analysis of selected regions using maternal plasma without fetal fraction cutoff, algorithm reported as a risk score for each trisomy	Q4	N/A
0169U	NUDT15 (nudix hydrolase 15) and TPMT (thiopurine S-methyltransferase) (eg, drug metabolism) gene analysis, common variants	A	N/A
0170U	Neurology (autism spectrum disorder [ASD]), RNA, next-generation sequencing, saliva, algorithmic analysis, and results reported as predictive probability of ASD diagnosis	A	N/A

<b>CPT Code</b>	<b>Long Descriptor</b>	<b>OPPS SI</b>	<b>OPPS APC</b>
0171U	Targeted genomic sequence analysis panel, acute myeloid leukemia, myelodysplastic syndrome, and myeloproliferative neoplasms, DNA analysis, 23 genes, interrogation for sequence variants, rearrangements and minimal residual disease, reported as presence/absence	A	N/A

**Table 2. — Acupuncture and Dry Needling CPT Codes Newly Covered by Medicare**

<b>CPT Code</b>	<b>Long Descriptor</b>	<b>OPPS SI</b>	<b>OPPS APC</b>	<b>Effective Date</b>
20560	Needle insertion(s) without injection(s); 1 or 2 muscle(s)	S	5731	01/21/20
20561	Needle insertion(s) without injection(s); 3 or more muscles	S	5731	01/21/20
97810	Acupuncture, 1 or more needles; without electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient	S	5731	01/21/20
97811	Acupuncture, 1 or more needles; without electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with re-insertion of needle(s) (list separately in addition to code for primary procedure)	N	N/A	01/21/20
97813	Acupuncture, 1 or more needles; with electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient	S	5731	01/21/20
97814	Acupuncture, 1 or more needles; with electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with re-insertion of needle(s) (list separately in addition to code for primary procedure)	N	N/A	01/21/20

**Table 3. — New Corona Virus Lab Tests HCPCS Codes U0001, U0002, and 87635**

<b>HCPCS Code</b>	<b>Short Descriptor</b>	<b>Long Descriptor</b>	<b>Effective Date</b>	<b>OPPS SI</b>
U0001	2019 –nCoV diagnostic P	CDC 2019 Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel	02/04/2020	A
U0002	COVID-19 lab test non-CDC	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
87635	Sars-cov-2 covid-19 amp prb	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

**Table 4. – New CY 2020 HCPCS Codes Effective April 1, 2020 for Certain Drugs, Biologicals, and Radiopharmaceuticals**

CY 2020 HCPCS Code	CY 2020 Long Descriptor	CY 2020 SI	CY 2020 APC
C9053	Injection, crizanlizumab-tmca, 1 mg	G	9342
C9056	Injection, givosiran, 0.5 mg	G	9343
C9057	Injection, cetirizine hydrochloride, 1 mg	G	9344
C9058	Injection, pegfilgrastim-bmez, biosimilar, (Ziextenzo) 0.5 mg	G	9345

**Table 5. – Currently Existing HCPCS Codes for Certain Drugs, Biologicals, and Radiopharmaceuticals receiving pass-through status Effective April 1, 2020**

CY 2020 HCPCS Code	CY 2020 Long Descriptor	January 2020 SI	April 2020 SI	CY 2020 APC
J0179	Injection, brolocizumab-dbl, 1 mg	K	G	9340
Q5114	Injection, trastuzumab-dkst, biosimilar, (ogivri), 10 mg	K	G	9341
J7331	Hyaluronan or derivative, synojoynt, for intra-articular injection, 1 mg	K	G	9337
Q5115	Injection, rituximab-abbs, biosimilar, (truxima), 10 mg	K	G	9336

**Table 6. – HCPCS Codes for Certain Drugs, Biologicals, and Radiopharmaceuticals with Pass-Through Status Ending Effective March 31, 2020**

CY 2020 HCPCS Code	CY 2020 Long Descriptor	January 2020 SI	April 2020 SI	CY 2020 APC
C9488	Injection, conivaptan hydrochloride, 1 mg	G	K	9488
J1428	Injection, eteplirsen, 10 mg	G	K	9484
J1627	Injection, granisetron extended release, 0.1 mg	G	N	N/A
J3358	Ustekinumab, for Intravenous Injection, 1 mg	G	K	9487
J7328	Hyaluronan or derivative, gelsyn-3, for intra-articular injection, 0.1 mg	G	K	1862
J9285	Injection, olaratumab, 10 mg	G	K	9485
Q5103	Injection, infliximab-dyyb, biosimilar, (inflectra), 10 mg	G	K	1847

**Table 7. – Other CY 2020 HCPCS and CPT Code Changes for Certain Drugs, Biologicals, and Radiopharmaceuticals Effective January 13, 2020**

HCPCS Code	Long Descriptor	Old SI	New SI	APC	Effective Date
Q5118	Injection, bevacizumab-bvzr, biosimilar, (zirabev), 10 mg	E2	K	9348	01/13/2020