

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 4005	Date: March 20, 2018
	Change Request 10515

Transmittal 3988, dated March 2, 2018, is being rescinded and replaced by Transmittal 4005, dated March 20, 2018 to correct the policy section 5.b. to update number of drugs and biologicals with OPPS pass-through status effective April 1, 2018, from twelve to eleven and to remove HCPCS code J0606, Injection, etelcalcetide, 0.1 mg, from table 5, Attachment A since its status indicator remains "K" for the April update. All other information remains the same.

SUBJECT: April 2018 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 2018 OPSS update. The April 2018 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 50.8.

The April 2018 revisions to I/OCE data files, instructions, and specifications are provided in the forthcoming April 2018 I/OCE CR.

EFFECTIVE DATE: April 1, 2018

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

IMPLEMENTATION DATE: April 2, 2018

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/revise 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.

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
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: 4005	Date: March 20, 2018	Change Request: 10515
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SUBJECT: April 2018 Update of the Hospital Outpatient Prospective Payment System (OPSS)

EFFECTIVE DATE: April 1, 2018

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

IMPLEMENTATION DATE: April 2, 2018

I. GENERAL INFORMATION

A. Background: This Recurring Update Notification describes changes to and billing instructions for various payment policies implemented in the April 2018 OPSS update. The April 2018 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 50.8.

The April 2018 revisions to I/OCE data files, instructions, and specifications are provided in the forthcoming April 2018 I/OCE CR.

B. Policy: 1. New Separately Payable Procedure Code

Effective April 1, 2018, HCPCS code, C9749 have been created as described in Table 1, attachment A.

2. Multianalyte Assays with Algorithmic Analyses (MAAA) CPT Coding Change Effective January 1, 2018

The AMA CPT Editorial Panel established one new MAAA code, specifically, 0011M, effective January 1, 2018. Because the code was released on December 1, 2017, it was too late to include in the January 2018 OPSS Update. Instead, this code is being included in the April 2018 Update with an effective date of January 1, 2018. Table 2, attachment A, lists the long descriptor and status indicator for CPT code 0011M.

3. Proprietary Laboratory Analyses (PLA) CPT Coding Changes Effective January 1, 2018

The AMA CPT Editorial Panel established eleven new PLA CPT codes, specifically, CPT codes 0024U through 0034U and deleted two PLA codes, specifically, CPT codes 0004U and 0015U, effective January 1, 2018. Because the codes were released on December 1, 2017, it was too late to include them in the January 2018 OPSS Update. Instead, they are being included in the April 2018 Update with an effective date of January 1, 2018.

Table 3, attachment A, lists the long descriptors and status indicators for CPT codes 0024U through 0034U. For more information on OPSS status indicators "A" and "Q4", refer to OPSS Addendum D1 of the CY 2018 OPSS/ASC final rule. CPT codes 0024U through 0034U have been added to the April 2018 I/OCE with an effective date of January 1, 2018. These codes, along with their short descriptors and status indicators, are also listed in the April 2018 OPSS Addendum B.

4. Reassignment of Skin Substitute Product from the Low Cost Group to the High Cost Group

One skin substitute product, HCPCS code Q4180, has been reassigned from the low cost skin substitute group to the high cost skin substitute group based on updated pricing information. The product is listed in Table 4, attachment A.

5. Drugs, Biologicals, and Radiopharmaceuticals

a. Drugs and Biologicals with Payments Based on Average Sales Price (ASP) Effective April 1, 2018

For CY 2018, payment for nonpass-through drugs, biologicals and therapeutic radiopharmaceuticals that were not acquired through the 340B Program is made at a single rate of ASP + 6 percent (or ASP - 22.5 percent if acquired under the 340B Program), which provides payment for both the acquisition cost and pharmacy overhead costs associated with the drug, biological or therapeutic radiopharmaceutical. In CY 2018, a single payment of ASP + 6 percent for pass-through drugs, biologicals and radiopharmaceuticals is made to provide payment for both the acquisition cost and pharmacy overhead costs of these pass-through items. Payments for drugs and biologicals based on ASPs will be updated on a quarterly basis as later quarter ASP submissions become available. Updated payment rates effective April 1, 2018 and drug price restatements can be found in the April 2018 update of the OPSS Addendum A and Addendum B on the CMS Web site at <http://www.cms.gov/HospitalOutpatientPPS/>.

b. Drugs and Biologicals with OPSS Pass-Through Status Effective April 1, 2018

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

c. Drugs and Biologicals Based on ASP Methodology with Restated Payment Rates

Some drugs and biologicals based on ASP methodology will have payment rates that are corrected retroactively. These retroactive corrections typically occur on a quarterly basis. The list of drugs and biologicals with corrected payments rates will be accessible on the CMS Web site on the first date of the quarter at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/OPSS-Restated-Payment-Rates.html>.

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

d. Changes to Biosimilar Biological Product HCPCS Codes and Modifiers

Effective April 1, 2018, CMS is revising the long and short descriptors for HCPCS code Q5101. Table 6, attachment A, displays the revised descriptors.

In addition, effective April 1, 2018, HCPCS codes Q5103, Injection, infliximab-dyyb, biosimilar, (inflectra), 10 mg, and Q5104, Injection, infliximab-abda, biosimilar, (renflexis), 10 mg will replace HCPCS code Q5102, Inj., infliximab biosimilar. Table 7, attachment A, describes coding changes, status indicator, APC assignments, and effective dates for biosimilar biological product HCPCS codes.

The new biosimilar payment policy also makes the use of modifiers that describe the manufacturer of a biosimilar product unnecessary. Therefore, modifiers ZA, ZB, and ZC will be discontinued for dates of service on or after April 1, 2018. However, please note that HCPCS code Q5102 and the requirement to use applicable biosimilar modifiers remain in effect for dates of service prior to April 1, 2018.

6. Use of Modifier "FY"

As stated in the CY 2018 OPSS/ASC final rule, section 502 of Division O, title V of the Consolidated Appropriations Act, 2016 (Pub. L. 114-113), which was enacted on December 18, 2015, contains provisions

to incentivize the transition from traditional X-ray imaging to digital radiography. As permitted by section 1833(t)(16)(F)(iv) of the Act, we implemented modifier “FY” (*X-ray taken using computed radiography technology/cassette-based imaging*) to enable providers under the OPSS to appropriately report computed radiography services. Effective January 1, 2018, hospital outpatient facilities are required to use this modifier with the applicable HCPCS code(s) to describe an imaging service that is an X-ray taken using computed radiography technology.

In this same final rule, we also stated that section 1833(t)(16)(F)(ii) of the Act provides for a phased-in reduction in payment in the case of an imaging service that is an X-ray taken using computed radiography technology (as defined in section 1848(b)(9)(C) of the Act). Payment for such a service (including the X-ray component of a packaged service) furnished during CY 2018, 2019, 2020, 2021, or 2022, that would otherwise be determined under section 1833(t) of the Act (without application of subparagraph (F)(ii) and before application of any other adjustment), will be reduced by 7 percent, and if such a service is furnished during CY 2023 or a subsequent year, by 10 percent. For purposes of this reduction, computed radiography technology is defined in section 1848(b)(9)(C) of the Act as cassette-based imaging which utilizes an imaging plate to create the image involved.

We note that section 1833(t)(16)(F)(ii) refers to *an* imaging service that *is* an X-ray taken using computed radiography technology. Where the imaging service is comprised of multiple images that include both X-rays taken using computed radiography technology and images taken using digital radiography, we do not believe the payment reduction would apply to that service. Instead, the payment adjustment applies to an imaging service that is an X-ray taken using computed radiography technology where the X-ray taken using computed radiography technology is not combined with digital radiography in the same imaging service.

7. Coverage Determinations

As a reminder, the fact that a drug, device, procedure or service is assigned a HCPCS code and a payment rate under the OPSS does not imply coverage by the Medicare program, but indicates only how the product, procedure, or service may be paid if covered by the program. Medicare Administrative Contractors (MACs) determine whether a drug, device, procedure, or other service meets all program requirements for coverage. For example, MACs determine that it is reasonable and necessary to treat the beneficiary’s condition and whether it is excluded from payment.

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	M I C S	V M S	C W F			
10515.1	<p>Medicare contactors shall manually add the following codes to their systems:</p> <ul style="list-style-type: none"> HCPCS code C9749 listed in table 1, attachment A, effective April 1, 2018. CPT code 0011M listed in table 2, attachment A, effective January 1, 2018; and CPT codes 0024U – 0034U listed in table 3, attachment A, effective January 1, 2018; 	X		X								

Number	Requirement	Responsibility								
		A/B MAC			D M E	Shared-System Maintainers				Other
		A	B	H H H		F I S S	M C S	V M S	C W F	
	<ul style="list-style-type: none"> HCPCS codes C9462-C9469 and HCPCS code Q2041 listed in table 5, attachment A, effective April 1, 2018, HCPCS codes Q5103 and Q5104 listed in table 7, attachment A, effective April 1, 2018 K0903 listed in the upcoming April 2018 I/OCE CR effective April 1, 2018 G9873-G9885 and G9890-G9891 listed in the upcoming April 2018 I/OCE CR effective April 1, 2018. Note: These HCPCS codes will be included with the April 2018 I/OCE update. Status and payment indicators for these HCPCS codes will be listed in the April 2018 update of the OPPS Addendum A and Addendum B on the CMS Web site at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html 									
10515.2	<p>Medicare contactors shall manually add termination dates to the following HCPCS codes in their systems:</p> <ul style="list-style-type: none"> CPT codes 0004U and 0015U listed in table 3, attachment A, effective December 31, 2017. Q5102 listed in table 7, attachment A, effective March 31, 2018 G9976 and G9977 listed in the upcoming April 2018 I/OCE CR, effective January 1, 2018. <p>Note: These deletions will be reflected in the April 2018 I/OCE update and in the April 2018 Update of the OPPS Addendum A and Addendum B on the CMS Web site at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html</p>	X		X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility
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		A/B MAC			D M E M A C	C E D I
		A	B	H H H		
10515.3	MLN Article: A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within 5 business days after receipt of the notification from CMS announcing the availability of the article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	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):

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.

ATTACHMENTS: 1

Attachment A – Tables for the Policy Section

Table 1. – New Separately Payable Procedure Code

HCPCS Code	Short Descriptor	Long Descriptor	OPPS SI	OPPS APC	OPPS Payment Rate
C9749	Repair nasal stenosis w/imp	Repair of nasal vestibular lateral wall stenosis with implant(s)	J1	5164	\$2,199.06

Table 2. – Multianalyte Assays with Algorithmic Analyses (MAAA) CPT Coding Change Effective January 1, 2018

CPT Code	Long Descriptor	OPPS SI	OPPS APC
0011M	Oncology, prostate cancer, mRNA expression assay of 12 genes (10 content and 2 housekeeping), RT-PCR test utilizing blood plasma and/or urine, algorithms to predict high-grade prostate cancer risk	A	N/A

Table 3. – Proprietary Laboratory Analyses (PLA) CPT Coding Changes Effective January 1, 2018

CPT Code	Long Descriptor	OPPS SI	OPPS APC
0004U	Infectious disease (bacterial), DNA, 27 resistance genes, PCR amplification and probe hybridization in microarray format (molecular detection and identification of AmpC, carbapenemase and ESBL coding genes), bacterial culture colonies, report of genes detected or not detected, per isolate	D	N/A
0015U	Drug metabolism (adverse drug reactions), DNA, 22 drug metabolism and transporter genes, real-time PCR, blood or buccal swab, genotype and metabolizer status for therapeutic decision support	D	N/A
0024U	Glycosylated acute phase proteins (GlycA), nuclear magnetic resonance spectroscopy, quantitative	Q4	N/A
0025U	Tenofovir, by liquid chromatography with tandem mass spectrometry (LC-MS/MS), urine, quantitative	Q4	N/A
0026U	Oncology (thyroid), DNA and mRNA of 112 genes, next-generation sequencing, fine needle aspirate of thyroid nodule, algorithmic analysis reported as a categorical result ("Positive,	A	N/A

CPT Code	Long Descriptor	OPPS SI	OPPS APC
	high probability of malignancy" or "Negative, low probability of malignancy")		
0027U	JAK2 (Janus kinase 2) (eg, myeloproliferative disorder) gene analysis, targeted sequence analysis exons 12-15	A	N/A
0028U	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism) gene analysis, copy number variants, common variants with reflex to targeted sequence analysis	A	N/A
0029U	Drug metabolism (adverse drug reactions and drug response), targeted sequence analysis (ie, CYP1A2, CYP2C19, CYP2C9, CYP2D6, CYP3A4, CYP3A5, CYP4F2, SLCO1B1, VKORC1 and rs12777823)	A	N/A
0030U	Drug metabolism (warfarin drug response), targeted sequence analysis (ie, CYP2C9, CYP4F2, VKORC1, rs12777823)	A	N/A
0031U	CYP1A2 (cytochrome P450 family 1, subfamily A, member 2)(eg, drug metabolism) gene analysis, common variants (ie, *1F, *1K, *6, *7)	A	N/A
0032U	COMT (catechol-O-methyltransferase)(drug metabolism) gene analysis, c.472G>A (rs4680) variant	A	N/A
0033U	HTR2A (5-hydroxytryptamine receptor 2A), HTR2C (5-hydroxytryptamine receptor 2C) (eg, citalopram metabolism) gene analysis, common variants (ie, HTR2A rs7997012 [c.614-2211T>C], HTR2C rs3813929 [c.-759C>T] and rs1414334 [c.551-3008C>G])	A	N/A
0034U	TPMT (thiopurine S-methyltransferase), NUDT15 (nudix hydroxylase 15)(eg, thiopurine metabolism), gene analysis, common variants (ie, TPMT *2, *3A, *3B, *3C, *4, *5, *6, *8, *12; NUDT15 *3, *4, *5)	A	N/A

Table 4. — Reassignment of Skin Substitute Product from the Low Cost Group to the High Cost Group Effective April 1, 2018

CY 2018 HCPCS Code	CY 2018 Short Descriptor	CY 2018 SI	Low/High Cost Skin Substitute
Q4180	Revita, per sq cm	N	High

Table 5. — Drugs and Biologicals with OPSS Pass-Through Status Effective April 1, 2018

HCPCS Code	Long Descriptor	APC	Status Indicator
C9462	Injection, delafloxacin, 1 mg	9462	G
C9463	Injection, aprepitant, 1 mg	9463	G
C9464	Injection, rolapitant, 0.5 mg	9464	G
C9465	Hyaluronan or derivative, Durolane, for intra-articular injection, per dose	9465	G
C9466	Injection, benralizumab, 1 mg	9466	G
C9467	Injection, rituximab and hyaluronidase, 10 mg	9467	G
C9468	Injection, factor ix (antihemophilic factor, recombinant), glycopegylated,	9468	G

HCPCS Code	Long Descriptor	APC	Status Indicator
	Rebinyn, 1 i.u..		
C9469	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg	9469	G
Q2040	Tisagenlecleucel, up to 250 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per infusion	9081	G
Q2041	Axicabtagene Ciloleucel, up to 200 Million Autologous Anti-CD19 CAR T Cells, Including Leukapheresis And Dose Preparation Procedures, Per Infusion	9035	G
Q5104	Injection, infliximab-abda, biosimilar, (renflexis), 10 mg	9036	G

Table 6. – Revised Descriptors for Q5101

HCPCS Code	Short Descriptor	Long Descriptor	APC	Status Indicator	Added Date
Q5101	Injection, zarxio	Injection, filgrastim-sndz, biosimilar, (zarxio), 1 microgram	1822	G	07/01/2015

Table 7. – Changes to Biosimilar Biological Product HCPCS Codes

HCPCS Code	Short Descriptor	Long Descriptor	APC	Status Indicator	Added Date	Termination Date
Q5102	Inj., infliximab biosimilar	Injection, infliximab, biosimilar, 10 mg	1847	G	07/01/2016	03/31/2018
Q5103	Injection, inflectra	Injection, infliximab-dyyb, biosimilar, (inflectra), 10 mg	1847	G	04/01/2018	
Q5104	Injection, renflexis	Injection, infliximab-abda, biosimilar, (renflexis), 10 mg	9036	G	04/01/2018	