CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 3352	Date: September 15, 2015
	Change Request 9298

Transmittal 3333, dated August 21, 2015, is being rescinded and replaced by Transmittal 3352 to change the status indicator for the HCPCS code Q5101, *Injection, Filgrastim (G-CSF)*, *Biosimilar*, 1 *microgram*, from E to K and to assign APC 1822 in the October update of the I/OCE. We are adding section I.B.4.g, and a new business requirement #9298.4 to this Recurring Update Notification, and table 6 to the attachment A. All other information remains the same.

SUBJECT: October 2015 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 October 2015 OPPS update. The October 2015 Integrated Outpatient Code Editor (I/OCE) and OPPS Pricer 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.

The October 2015 revisions to I/OCE data files, instructions, and specifications are provided in the forthcoming October 2015 I/OCE CR.

EFFECTIVE DATE: October 1, 2015

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

IMPLEMENTATION DATE: October 5, 2015

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.

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
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: 3352 Date: September 15, 2015 Change Request: 9298

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SUBJECT: October 2015 Update of the Hospital Outpatient Prospective Payment System (OPPS)

EFFECTIVE DATE: October 1, 2015

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

IMPLEMENTATION DATE: October 5, 2015

I. GENERAL INFORMATION

A. Background: This Recurring Update Notification describes changes to and billing instructions for various payment policies implemented in the October 2015 OPPS update. The October 2015 Integrated Outpatient Code Editor (I/OCE) and OPPS Pricer 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.

The October 2015 revisions to I/OCE data files, instructions, and specifications are provided in the forthcoming October 2015 I/OCE CR.

B. Policy: 1. New Separately Payable Procedure Code

Effective October 1, 2015 a new HCPCS code C9743 has been created. Table 1, attachment A, provides the short and long descriptors and the APC placement for this new code.

2. Compounded Drugs

Effective June 30, 2015, modifier JF (Compounded drug) was discontinued and replaced with HCPCS code Q9977 (Compounded Drug, Not Otherwise Classified) effective July 1, 2015. HCPCS code Q9977 should be used to report compounded drug combinations.

3. Revised Coding Guidance for Intraocular or Periocular Injections of Combinations of Anti-Inflammatory Drugs and Antibiotics

Intraocular or periocular injections of combinations of anti-inflammatory drugs and antibiotics are being used with increased frequency in ocular surgery (primarily cataract surgery). One example of combined or compounded drugs includes triamcinolone and moxifloxacin with or without vancomycin. Such combinations may be administered as separate injections or as a single combined injection. Because such injections may obviate the need for post-operative anti-inflammatory and antibiotic eye drops, some have referred to cataract surgery with such injections as "dropless cataract surgery."

As stated in Chapter VIII, section D, item 20 of the CY 2015 NCCI Policy Manual, injection of a drug during a cataract extraction procedure or other ophthalmic procedure is not separately reportable. Specifically, no separate procedure code may be reported for any type of injection during surgery or in the

perioperative period. Injections are a part of the ocular surgery and are included as a part of the ocular surgery and the HCPCS code used to report the surgical procedure.

According to Pub.100-04, the Medicare Claims Processing Manual, Chapter 17, section 90.2, the compounded drug combinations described above and similar drug combinations should be reported with HCPCS code Q9977 (Compounded Drug, Not Otherwise Classified), regardless of the site of service of the surgery, and are packaged as surgical supplies in both the HOPD and the ASC. Although these drugs are a covered part of the ocular surgery, no separate payment will be made. In addition, these drugs and drug combinations may not be reported with HCPCS code C9399. According to the Medicare Claims Processing Manual, Chapter 30, section 40.3.6, physicians or facilities should not give Advance Beneficiary Notices (ABNs) to beneficiaries for either these drugs or for injection of these drugs because they are fully covered by Medicare. Physicians or facilities are not permitted to charge the patient an extra amount (beyond the standard copayment for the surgical procedure) for these injections or the drugs used in these injections because they are a covered part of the surgical procedure. Also, physicians or facilities cannot circumvent packaged payment in the HOPD or ASC for these drugs by instructing beneficiaries to purchase and bring these drugs to the facility for administration.

4. Drugs, Biologicals, and Radiopharmaceuticals

a. Drugs and Biologicals with Payments Based on Average Sales Price (ASP) Effective October 1, 2015

For CY 2015, payment for nonpass-through drugs, biologicals and therapeutic radiopharmaceuticals is made at a single rate of ASP + 6 percent, which provides payment for both the acquisition cost and pharmacy overhead costs associated with the drug, biological or therapeutic radiopharmaceutical. In CY 2015, 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 October 1, 2015 and drug price restatements can be found in the October 2015 update of the OPPS Addendum A and Addendum B on the CMS Web site at http://www.cms.gov/HospitalOutpatientPPS/.

b. 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 http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html?redirect=/HospitalOutpatientPPS/01 overview.asp

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

c. Drugs and Biologicals with OPPS Pass-Through Status Effective October 1, 2015

Two drugs and biologicals have been granted OPPS pass-through status effective October 1, 2015. These items, along with their descriptors and APC assignments, are identified in Table 2, attachment A.

d. New HCPCS Codes and Dosage Descriptors for Certain Drugs, Biologicals, and Biosimilar Biological Products

Effective October 1, 2015 a new HCPCS code has been created for reporting drugs and biologicals in the hospital outpatient setting, where there have not previously been specific codes available. This new code is listed in Table 3, attachment A.

e. Corrected Dosage Descriptor for HCPCS Code Q9976

The correct dosage descriptor for Q9976 is 0.1 mg of iron. The short and long descriptor are included in table 4, attachment A.

f. Reassignment of Skin Substitute Products from the Low Cost Group to the High Cost Group

One existing skin substitute product has been reassigned from the low cost skin substitute group to the high cost skin substitute group based on updated pricing information. This product is listed in Table 5, attachment A.

g. Revised Status Indicator for HCPCS Code Q5101

Effective September 3, 2015, the status indicator for HCPCS code Q5101 (Injection, Filgrastim (G-CSF), Biosimilar, 1 microgram) will change from SI=E (Not paid by Medicare when submitted on outpatient claims (any outpatient bill type)) to SI=K (Paid under OPPS; separate APC payment). The APC assignment is listed in Table 6, attachment A.

5. Coverage Determinations

The fact that a drug, device, procedure or service is assigned a HCPCS code and a payment rate under the OPPS 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	Re	Responsibility							
		A/		A/B			Sha	red-		Other
		1	MAC M		MAC M System					
						M	aint	aine	ers	
		A	В	Н		F	M	V	C	
				Н		I	C	M	W	
				Н		S	S	S	F	
					C	S				
9298.1	Medicare contractors shall install the October 2015 OPPS Pricer.	X		X		X				BCRC
9298.2	Medicare contactors shall manually add the following HCPCS codes to their systems:	X		X						BCRC
	• HCPCS codes listed in tables 1, 2, and 3, effective October 1, 2015.									
	Note: These HCPCS codes will be included with the									
	October 2015 I/OCE update. Status and payment									
	indicators for these HCPCS codes will be listed in the									
	October 2015 update of the OPPS Addendum A and									

Number	Requirement	Re	espo	nsi	bilit	y									
		A/B MAC						MAC N							Other
		A	В	H H H	M A C	F	M C S		С						
	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														
9298.3	Medicare contractors shall adjust, as appropriate, claims brought to their attention with any retroactive changes that were received prior to implementation of October 2015 OPPS Pricer.	X		X						BCRC					
9298.4	 Medicare contractors shall adjust, as appropriate, claims brought to their attention that: Contain HCPCS code Q5101, listed in table 6 of Attachment A in this transmittal; and Have dates of service that fall on or after September 3, 2015; and Were originally processed prior to the installation of the October 2015 OPPS Pricer. 	X		X						BCRC					

III. PROVIDER EDUCATION TABLE

Number	Requirement	Re	spo	nsib	ility	
			A/B MA(D M E	C E D
		A	В	H H H	M A C	I
9298.5	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	Recommendations or other supporting information:
Requirement	
Number	

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

Policy Section Tables

Table 1 – New Separately Payable Procedure Code Effective October 1, 2015

HCPCS Code	Short Descriptor	Long Descriptor	OPPS SI	OPPS APC	Effective Date
C9743	Bulking/spacer material impl	Injection/implantation of bulking or spacer material (any type) with or without image guidance (not to be used if a more specific code applies)	S	0310	10/01/2015

Table 2 – Drugs and Biologicals with OPPS Pass-Through Status Effective October 1, 2015

HCPCS			Status
Code	Long Descriptor	APC	Indicator
C9456	Injection, isavuconazonium sulfate, 1 mg	9456	G
C9457	Injection, sulfur hexafluoride lipid microsphere, per ml	9457	G

Table 3 – New HCPCS Code Effective for Certain Drugs, Biologicals, and Radiopharmaceuticals

CY 2015 HCPCS Code	CY 2015 Long Descriptor	CY 2015 SI	CY 2015 APC
Q9979	Injection, alemtuzumab, 1 mg	K	1809

Table 4 - Corrected Dosage Descriptor for HCPCS Code Q9976

HCPCS Code	Revised Short Descriptor	Revised Long Descriptor
Q9976	Inj Ferric Pyrophosphate Cit	Injection, Ferric Pyrophosphate Citrate
		Solution, 0.1 mg of iron

Table 5 – Updated Skin Substitute Product Assignment to High Cost Status Effective October 1, 2015

	October 1, 2013		
			Low/High
HCPCS		Status	Cost
Code	Short Descriptor	Indicator	Status
Q4151	AmnioBand, guardian 1 sq cm	N	High

Table 6 – Drug and Biological with Revised Status Indicator Effective September 3, 2015

HCPCS Code	Long Descriptor	APC	Status Indicator
Q5101	Injection, Filgrastim (G-CSF), Biosimilar, 1 microgram	1822	K