

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 3523	Date: May 13, 2016
	Change Request 9658

SUBJECT: July 2016 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 July 2016 OPPS update. The July 2016 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 200.3.1.

The July 2016 revisions to I/OCE data files, instructions, and specifications are provided in the forthcoming July 2016 I/OCE CR.

EFFECTIVE DATE: July 1, 2016

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

IMPLEMENTATION DATE: July 5, 2016

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
R	4/Table of Contents
R	4/200.3.1/Billing Instructions for IMRT Planning and Delivery

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: 3523	Date: May 13, 2016	Change Request: 9658
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SUBJECT: July 2016 Update of the Hospital Outpatient Prospective Payment System (OPPS)

EFFECTIVE DATE: July 1, 2016

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

IMPLEMENTATION DATE: July 5, 2016

I. GENERAL INFORMATION

A. Background: This Recurring Update Notification describes changes to and billing instructions for various payment policies implemented in the July 2016 OPPS update. The July 2016 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 200.3.1.

The July 2016 revisions to I/OCE data files, instructions, and specifications are provided in the forthcoming July 2016 I/OCE CR.

B. Policy: 1. Billing Instructions for IMRT Planning

These revised IMRT planning billing instructions that were also included in the April 2016 Update of the Hospital Outpatient Prospective Payment System (OPPS) (Transmittal 3471, Change Request 9549) replace the instructions discussed in the 2016 OPPS final rule at 80 FR 70401-70402 and in the January 2016 Update of the Hospital Outpatient Prospective Payment System (OPPS) (Transmittal 3425, Change Request 9486). The effective date of these instructions is January 1, 2016.

Payment for the services identified by CPT codes 77014, 77280, 77285, 77290, 77295, 77306 through 77321, 77331, and 77370 are included in the APC payment for CPT code 77301 (IMRT planning). These codes should not be reported in addition to CPT code 77301 when provided prior to or as part of the development of the IMRT plan.

2. Upper Eyelid Blepharoplasty and Blepharoptosis Repair

CMS payment policy does not allow separate payment for a blepharoplasty procedure (CPT codes 15822, 15823) in addition to a blepharoptosis procedure (CPT codes 67901-67908) on the ipsilateral upper eyelid. Any removal of upper eyelid skin in the context of an upper eyelid blepharoptosis surgery is considered a part of the blepharoptosis surgery. A blepharoplasty cannot be billed to Medicare and the beneficiary cannot be separately charged for a cosmetic surgery regardless of the amount of upper eyelid skin that is removed on a patient receiving a blepharoptosis repair because removal of (any amount) of upper eyelid skin is part of the blepharoptosis repair. In addition, the following are not permitted:

- Operating on the left and right eyes on different days when the standard of care is bilateral eyelid surgery;
- Charging the beneficiary an additional amount for a cosmetic blepharoplasty when a blepharoptosis repair is performed;

- Charging the beneficiary an additional amount for removing orbital fat when a blepharoplasty or a blepharoptosis repair is performed;
- Performing a blepharoplasty on a different date of service than the blepharoptosis procedure for the purpose of unbundling the blepharoplasty or charging the beneficiary for a cosmetic surgery;
- Performing blepharoplasty as a staged procedure, either by one or more surgeons (note that under certain circumstances a blepharoptosis procedure could be a staged procedure);
- Billing for two procedures when two surgeons divide the work of a blepharoplasty performed with a blepharoptosis repair;
- Using modifier 59 to unbundle the blepharoplasty from the ptosis repair on the claim form; this applies to both physicians and facilities;
- Treating medically necessary surgery as cosmetic for the purpose of charging the beneficiary for a cosmetic surgery;
- Using an Advance Beneficiary Notice of Noncoverage for a service that would be bundled into another service if billed to Medicare.
- In the rare event that a blepharoplasty is performed on one eye and a blepharoptosis repair is performed on the other eye, the services must each be billed with the appropriate RT or LT modifier.

3. Revised Status Indicators for Pathology CPT Codes

The status indicator for CPT code 85396 (Clotting assay whole blood) will change from SI=Q4 (Conditionally packaged laboratory tests) to SI=N (Paid under OPPS; payment is packaged into payment for other services) in the July 2016 update.

The status indicator for CPT code 88141 (Cytopath c/v interpret) will change from SI=Q4 (Conditionally packaged laboratory tests) to SI=N (Paid under OPPS; payment is packaged into payment for other services) in the July 2016 update.

The status indicator for CPT code 88174 (Cytopath c/v auto in fluid) will change from SI=N (Paid under OPPS; payment is packaged into payment for other services) to SI=Q4 (Conditionally packaged laboratory tests) in the July 2016 update.

The status indicator for CPT code 88175 (Cytopath c/v auto fluid redo) will change from SI=N (Paid under OPPS; payment is packaged into payment for other services) to SI=Q4 (Conditionally packaged laboratory tests) in the July 2016 update.

These codes are listed in Table 1, attachment A, along with the effective dates for the revised status indicators.

4. Reporting for Certain Outpatient Department Services (That Are Similar to Therapy Services) (“Non-Therapy Outpatient Department Services”) That Are Adjunctive to Comprehensive APC Procedures

Effective for claims received on or after July 1, 2016 with dates of service on or after January 1, 2015, non-therapy outpatient department services (that are similar to therapy services) that are adjunctive to a comprehensive APC procedure (status indicator (SI) = J1 procedure) (*see* 80 FR 70326) or the specific combination of services assigned to the Observation Comprehensive APC 8011 (SI = J2), should not be reported with therapy CPT codes. This includes services described at 1833(a)(8), namely outpatient physical therapy, outpatient speech-language pathology and outpatient occupational therapy furnished either by

therapists or non-therapists and included on the same claim as a comprehensive APC procedure. Non-therapy outpatient department services that are adjunctive to J1 or J2 procedures should be reported without a CPT code and instead should be reported with Revenue Code 0940 (Other Therapeutic Services). The status indicator for this revenue code will be changed from SI=B to SI=N, indicating that the payment for these services will be packaged into the C-APC payment.

5. Category III CPT Codes Effective July 1, 2016

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

For the July 2016 update, CMS is implementing in the OPPS nine (9) Category III CPT codes that the AMA released in January 2016 for implementation on July 1, 2016. The status indicators and APCs for these codes are shown in Table 2, attachment A. Payment rates for these services can be found in Addendum B of the July 2016 OPPS Update that is posted on the CMS website. We note that HCPCS code C9743 will be deleted June 30, 2016 since it will be replaced with Category III CPT code 0438T effective July 1, 2016. CPT code 0438T will be assigned to the same status indicator and APC assignment as its predecessor HCPCS code C9743 effective July 1, 2016.

6. Drugs, Biologicals, and Radiopharmaceuticals

a. Drugs and Biologicals with Payments Based on Average Sales Price (ASP) Effective July 1, 2016

For CY 2016, 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 2016, 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 July 1, 2016 and drug price restatements can be found in the July 2016 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 paid based on the 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 July 1, 2016

Five drugs and biologicals have been granted OPPS pass-through status effective July 1, 2016. These items, along with their descriptors and APC assignments, are identified in Table 3, attachment A.

d. New Drug HCPCS Code

Effective July 1, 2016, one 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 4, attachment A.

e. Biosimilar Biological Product Payment and Required Modifiers

As a reminder, OPPS claims for separately paid biosimilar biological products are required to include a modifier that identifies the manufacturer of the specific product. The modifier does not affect payment determination, but is used to distinguish between biosimilar products that appear in the same HCPCS code but are made by different manufacturers.

On April 5, 2016, the second biosimilar biological product, Inflectra®, was approved by the FDA.

Table 5 in Attachment A lists the biosimilar HCPCS codes and required modifiers.

f. Reassignment of Skin Substitute Product 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 6, attachment A.

g. Other Changes to CY 2016 HCPCS Codes for Certain Drugs, Biologicals, and Radiopharmaceuticals

Effective July 1, 2016, HCPCS code Q9982, flutemetamol f18 diagnostic, will replace HCPCS code C9459, Flutemetamol f18. The status indicator will remain G, “Pass-Through Drugs and Biologicals”.

Effective July 1, 2016, HCPCS code Q9983, florbetaben f18 diagnostic, will replace HCPCS code C9458, Florbetaben f18. The status indicator will remain G, “Pass-Through Drugs and Biologicals”.

Table 7, Attachment A describes the HCPCS codes changes and effective dates.

h. Changes to OPPS Pricer Logic

Effective July 1, 2016, there will be four diagnostic radiopharmaceuticals (2 with new Q-codes replacing the previously used C-codes (as described above in section 6.g.)) and one contrast agent receiving pass-through payment in the OPPS Pricer logic. For APCs containing nuclear medicine procedures, Pricer will reduce the amount of the pass-through diagnostic radiopharmaceutical or contrast agent payment by the wage-adjusted offset for the APC with the highest offset amount when the radiopharmaceutical or contrast agent with pass-through appears on a claim with a nuclear procedure. The offset will cease to apply when the diagnostic radiopharmaceutical or contrast agent expires from pass-through status. The offset amounts for diagnostic radiopharmaceuticals and contrast agents are the “policy-packaged” portions of the CY 2016 APC payments for nuclear medicine procedures and may be found on the CMS Web site.

7. Addition of C1713 and C1817 to the List of Devices Allowed for the Device Intensive Procedure Edit

We will be adding C1713 (Anchor/screw for opposing bone-to-bone or soft tissue-to-bone (implantable)) and C1817 (Septal defect implant system, intracardiac) to the list of devices allowed for the device intensive procedure edit in the July 2016 release and make it retroactive to January 2016.

8. 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	Responsibility								
		A/B MAC			D M E M A C	Shared- System Maintainers				Other
		A	B	H H H		F I S S	M C S	V M S	C W F	
9658.1	Medicare contractors shall install the July 2016 OPPS Pricer.	X		X		X				BCRC
9658.2	<p>Medicare contractors shall manually add the following codes to their systems:</p> <ul style="list-style-type: none"> CPT codes 0437T – 0445T, listed in table 2, attachment A, effective July 1, 2016; HCPCS codes C9476 – C9480, listed in table 3, attachment A, effective July 1, 2016; HCPCS code Q9981, listed in table 4, attachment A, effective July 1, 2016; HCPCS code Q5102, listed in table 5, attachment A, effective April 5, 2016; HCPCS codes Q9982 and Q9983, listed in table 7, attachment A, effective July 1, 2016; <p>Note: These HCPCS codes will be included with the July 2016 I/OCE update. Status and payment indicators for these HCPCS codes will be listed in the July 2016 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						BCRC
9658.3	<p>Medicare contractors shall manually delete the following HCPCS codes from their systems:</p> <ul style="list-style-type: none"> HCPCS code C9743 listed in table 2, attachment A, effective June 30, 2015. HCPCS codes C9458 and C9459, listed in table 7, attachment A, effective June 30, 2015. <p>Note: These deletions will be reflected in the July 2016 I/OCE update and in the July 2016 Update of the</p>	X		X						BCRC

Number	Requirement	Responsibility									
		A/B MAC			D M E M A C	Shared- System Maintainers				Other	
		A	B	H H H		F I S S	M C S	V M S	C W F		
	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										
9658.4	Medicare contractors shall adjust, as appropriate, claims brought to their attention with any retroactive changes that were received prior to implementation of July 2016 OPPS Pricer.	X		X						BCRC	

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		
9658.5	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:

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
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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

Medicare Claims Processing Manual
Chapter 4 - Part B Hospital
(Including Inpatient Hospital Part B and OPPS)
(Rev.3523, Issued: 05-13-16)

200.3.1 - Billing Instructions for IMRT Planning *and Delivery*

200.3.1 - Billing Instructions for IMRT Planning *and Delivery*
(Rev.3523, Issued: 05-13-16, Effective: 07-01-16, Implementation; 07-05- 16)

Payment for the services identified by CPT codes 77014, 77280, *77285, 77290, 77295, 77306* through 77321, 77331, and 77370 *are* included in the APC payment for CPT code 77301 (IMRT planning). These codes should not be reported in addition to CPT code 77301 *when provided prior to or as part of the development of the IMRT plan.*

Attachment A – Tables for the Policy Section
Table 1 – Pathology CPT Codes with Revised Status Indicators

HCPCS Code	Long Descriptor	Status Indicator	Effective Date
85396	Coagulation/fibrinolysis assay, whole blood (eg, viscoelastic clot assessment), including use of any pharmacologic additive(s), as indicated, including interpretation and written report, per day	N	1/1/2016
88141	Cytopathology, cervical or vaginal (any reporting system), requiring interpretation by physician	N	1/1/2016
88174	Cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation; screening by automated system, under physician supervision	Q4	1/1/2016
88175	Cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation; with screening by automated system and manual rescreening or review, under physician supervision	Q4	1/1/2016

Table 2 - Category III CPT Codes Effective July 1, 2016

CPT Code	Long Descriptor	Add Date	Term Date	July 2016 OPPI SI	July 2016 OPPI S APC
0437T	Implantation of non-biologic or synthetic implant (eg, polypropylene) for fascial reinforcement of the abdominal wall (List separately in addition to primary procedure)	07/01/2016		N	N/A
0438T	Transperineal placement of biodegradable material, peri-prostatic (via needle), single or multiple, includes image guidance	07/01/2016		T	5374
0439T	Myocardial contrast perfusion echocardiography; at rest or with stress, for assessment of myocardial ischemia or viability (List separately in addition to primary procedure)	07/01/2016		N	N/A
0440T	Ablation, percutaneous, cryoablation, includes imaging guidance; upper extremity distal/peripheral nerve	07/01/2016		J1	5361
0441T	Ablation, percutaneous, cryoablation, includes imaging guidance; lower extremity distal/peripheral nerve	07/01/2016		J1	5361
0442T	Ablation, percutaneous, cryoablation, includes imaging guidance; nerve plexus or other truncal nerve (eg, brachial	07/01/2016		J1	5361

CPT Code	Long Descriptor	Add Date	Term Date	July 2016 OPPS SI	July 2016 OPPS APC
	plexus, pudendal nerve)				
0443T	Real time spectral analysis of prostate tissue by fluorescence spectroscopy	07/01/2016		T	5373
0444T	Initial placement of a drug-eluting ocular insert under one or more eyelids, including fitting, training, and insertion, unilateral or bilateral	07/01/2016		N	N/A
0445T	Subsequent placement of a drug-eluting ocular insert under one or more eyelids, including re-training, and removal of existing insert, unilateral or bilateral	07/01/2016		N	N/A
C9743	Injection/implantation of bulking or spacer material (any type) with or without image guidance (not to be used if a more specific code applies)	10/01/2015	06/30/2016	T	5374

Table 3 – Drugs and Biologicals with OPPS Pass-Through Status Effective July 1, 2016

HCPCS Code	Long Descriptor	SI	APC
C9476	Injection, daratumumab, 10 mg	G	9476
C9477	Injection, elotuzumab, 1 mg	G	9477
C9478	Injection, sebelipase alfa, 1 mg	G	9478
C9479*	Instillation, ciprofloxacin otic suspension, 6 mg	G	9479
C9480	Injection, trabectedin, 0.1 mg	G	9480

*Note on reporting C9479: Each vial of C9479 contains 60 mg, or 10 doses. If one single use vial is used for both patient's ears with the remainder of the drug in the vial unused, then two units of C9479 should be reported as administered to the patient; any discarded amount should be reported with the JW modifier according to the Medicare Claims Processing Manual, Chapter 17 - Drugs and Biologicals, Section 40 - Discarded Drugs and Biologicals.

Table 4 – New Drug HCPCS Codes Effective July 1, 2016

HCPCS Code	Short Descriptor	Long Descriptor	SI	APC
Q9981	rolapitant, oral, 1mg	Rolapitant, oral, 1 mg	K	1761

Table 5 – Biosimilar Biological Product Payment and Required Modifiers

HCPCS Code	Short Descriptor	Long Descriptor	SI	APC	HCPCS Code Effective Date	Modifier	Modifier Effective Date
Q5101	Inj	Injection,	G	1822	03/06/2015	ZA-	01/01/2016

	filgrastim g-csf biosim	Filgrastim (G-CSF), Biosimilar, 1 microgram				Novartis/Sandoz	
Q5102	Inj., infliximab biosimilar	Injection, Infliximab, Biosimilar, 10 mg	K	1761	04/05/2016	ZB – Pfizer/Hospira	04/01/2016

**Table 6 – Reassignment of Skin Substitute Product from the Low Cost Group to the High Cost Group
Effective July 1, 2016**

HCPCS Code	Short Descriptor	Status Indicator	Low/High Cost Status
Q4164	Helicoll, per square cm	N	High

**Table 7 – Other Changes to CY 2016 HCPCS Codes for Certain Drugs, Biologicals, and
Radiopharmaceuticals Effective July 1, 2016**

HCPCS Code	Short Descriptor	Long Descriptor	Status Indicator	APC	Added Date	Termination Date
C9459	Flutemetamol f18	Flutemetamol f18, diagnostic, per study dose, up to 5 millicuries	G	9459	01/01/2016	06/30/2016
Q9982	flutemetamol f18 diagnostic	Flutemetamol F18, diagnostic, per study dose, up to 5 millicuries	G	9459	07/01/2016	
C9458	Florbetaben f18	Florbetaben f18, diagnostic, per study dose, up to 8.1 millicuries	G	9458	01/01/2016	06/30/2016
Q9983	florbetaben f18 diagnostic	Florbetaben f18, diagnostic, per study dose, up to 8.1 millicuries	G	9458	07/01/2016	