CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 3531	**Date: May 27, 2016**
	Change Request 9668

SUBJECT: July 2016 Update of the Ambulatory Surgical Center (ASC) Payment System

I. SUMMARY OF CHANGES: This Recurring Update Notification describes changes to billing instructions for various payment policies implemented in the July 2016 ASC payment system update. This Recurring Update Notification applies to chapter 14, section 10. As appropriate, this notification also includes updates to the Healthcare Common Procedure Coding System (HCPCS).

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
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: 3531	Date: May 27, 2016	Change Request: 9668

SUBJECT: July 2016 Update of the Ambulatory Surgical Center (ASC) Payment System

EFFECTIVE DATE: July 1, 2016
**Unless otherwise specified, the effective date is the date of service.*
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I. GENERAL INFORMATION

A. Background: Included in this notification are updates to the ASC payment system, payment rates for separately payable drugs and biologicals, including descriptors for newly created Level II HCPCS codes for drugs and biologicals (ASC DRUG files), ASC billing edits, and the CY 2016 ASC payment rates for covered surgical and ancillary services (ASCFS file).

B. Policy: 1. Billing Instructions for IMRT Planning

Payment for the services identified by CPT codes 77280, 77285, 77290, 77295, 77306 through 77321, 77331, and 77370 are already included in the ASC payment for CPT code 77301 (IMRT planning). Effective, July 1, 2016, these codes should not be reported by ASCs in addition to CPT code 77301 when provided as part of the development of the IMRT plan.

2. Upper Eyelid Blepharoplasty and Blepharoptosis Repair

CMS payment policy does not allow ASCs to bill for 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 and is already be included in the payment rate. Also ASCs cannot bill a blepharoplasty 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.

3. 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 ASC Payment System five (5) Category III CPT codes that the AMA released in January 2016 for implementation on July 1, 2016. The long and short descriptors, and ASC payment indicators for these codes are shown in Table 1. (see Attachment A: Policy Section Tables). Payment rates for these services can be found in Addendum AA of the July 2016 ASC Update that is posted on the CMS website. Of note, HCPCS code C9743 will be deleted June 30, 2016 since it will be replaced with Category III CPT code 0438T effective July 1, 2016

4. 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 can be found in the July 2016 ASC Addendum BB on the CMS Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/11_Addenda_Updates.html .

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

Some drugs and biologicals based on ASP methodology may 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://cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/index.html

Suppliers who think they may have received an incorrect payment for drugs and biologicals impacted by these corrections may request contractor adjustment of the previously processed claims.

c. New CY 2016 HCPCS Codes and Dosage Descriptors for Certain Drugs, Biologicals, and Radiopharmaceuticals

Seven new HCPCS codes have been created for reporting drugs and biologicals in the ASC setting. These new codes, their descriptors, and payment indicator and their effective dates are listed in Table 2. (see Attachment A: Policy Section Tables).

d. Biosimilar Biological Product Payment and Required Modifiers

ASC claims for separately paid biosimilar biological products are now 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.

Q5101: This is a reminder that for claims with dates of service January 1, 2016 and later, Q5101 must be submitted with a modifier to identify the manufacturer of the biosimilar product. Currently, the ZA modifier is the only manufacturer/modifier that may be submitted with Q5101. Claims submitted without the modifier cannot be processed.

Q5102: Effective April 5, 2016, Q5102 (Inj., infliximab biosimilar) is payable in the ASC setting, where there has not previously been a specific code available. Also effective April 5, 2016, Q5102 must be submitted with a modifier to identify the manufacturer of the biosimilar product. Currently, the ZB modifier is the only manufacturer/modifier that may be submitted with this HCPCS. Claims submitted without the modifier cannot be processed.

The biosimilar HCPCS codes and required modifiers are listed in table 3.
(see Attachment A: Policy Section Tables).

e. 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 ASC payment indicator will remain K2, “Pass-Through Drugs and Biologicals”.

Effective July 1, 2016, HCPCS code Q9983, florbetaben f18 diagnostic, will replace HCPCS code C9458, Florbetaben f18. The ASC payment indicator will remain K2, “Pass-Through Drugs and Biologicals”.

Both C9458 and C9459 have a termination date of 6/30/2016.

As stated previously in this transmittal, C9743 has a termination date of 6/30/2016 and is being included in table 4 as a reference to contractors.

Table 4 describes the HCPCS codes changes and effective dates. (see Attachment A: Policy Section Tables).

5. Coverage Determinations

The fact that a drug, device, procedure or service is assigned a HCPCS code and a payment rate under the ASC payment system 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	DME	Shared-System Maintainers	Other

		A	B	H H H	M A C	F I S S	M C S	V M S	C W F	
9668.1	Medicare contractors shall download and install the July 2016 ASCFS from the CMS mainframe. FILENAME: MU00.@BF12390.ASC.CY16.FS.JULA.V0603 **NOTE: Date of retrieval will be provided in a separate email communication from CMS.**		X							VDCs
9668.2	Medicare contractors shall download and install the July 2016 ASC DRUG file. FILENAME: MU00.@BF12390.ASC.CY16.DRUG.JULA.V0624 **NOTE: Date of retrieval will be provided in a separate email communication from CMS.**		X							VDCs
9668.3	Medicare contractors shall download and install the July 2016 ASC PI file. FILENAME: MU00.@BF12390.ASC.CY16.PI.JULA.V0610 **NOTE: Date of retrieval will be provided in a separate email communication from CMS.**		X							VDCs
9668.4	Contractors and CWF shall add TOS F for HCPCS that are included in attachment A, tables 1-2 except Q5102, and as appropriate, table 4, effective for services July 1, 2016 and later payable in the ASC setting.		X						X	
9668.4.1	Contractors and CWF shall add TOS F for HCPCS Q5102 included in attachment A, table 2, effective for services April 5, 2016 and later payable in the ASC setting.		X						X	
9668.5	Contractors and CWF shall end date as appropriate, the C9458, C9459, and C9743, in their systems effective June 30, 2016.		X						X	
9668.5.1	CWF, as appropriate, shall remove the TOS F records as appropriate, for C9458, C9459, and C9743, in their systems effective June 30, 2016.								X	
9668.6	Effective April 5, 2016, Medicare contractors shall return as unprocessable claim lines for Q5102 that do not include the “ZB” modifier.		X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
9668.6.1	Contractors shall use the following messages when returning these claims: • Claim Adjustment Reason Code (CARC) 4 – The procedure code is inconsistent with the modifier used or a required modifier is missing. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present. • Remittance Advice Remark Code (RARC) MA-130- Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable.Please submit a new claim with the complete/correct information. • Group Code: CO (Contractual Obligation)		X							
9668.7	If released by CMS, Medicare contractors shall download and install the revised April 2016 ASC DRUG file. FILENAME: MU00.@BF12390.ASC.CY16.DRUG.APRB.V0624 **NOTE: Date of retrieval will be provided in a separate email communication from CMS.**		X							VDCs
9668.7.1	Medicare contractors shall adjust as appropriate claims brought to their attention that: 1) Have dates of service April 1, 2016- June 30, 2016 and ; 2) Were originally processed prior to the installation of the revised April 2016 ASC DRUG File.		X							
9668.8	If released by CMS, Medicare contractors shall download and install the revised January 2016 ASC DRUG file. FILENAME: MU00.@BF12390.ASC.CY16.DRUG.JANC.V0624 **NOTE: Date of retrieval will be provided in a separate email communication from CMS.**		X							VDCs

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
9668.8.1	Medicare contractors shall adjust as appropriate claims brought to their attention that: 1) Have dates of service January 1, 2016- March 31, 2016 and ; 2) Were originally processed prior to the installation of the revised January 2016 ASC DRUG File.		X							
9668.9	If released by CMS, Medicare contractors shall download and install the revised October 2015 ASC DRUG file. FILENAME: MU00.@BF12390.ASC.CY15.DRUG.OCTD.V0624 **NOTE: Date of retrieval will be provided in a separate email communication from CMS.**		X							VDCs
9668.9.1	Medicare contractors shall adjust as appropriate claims brought to their attention that: 1) Have dates of service October 1, 2015- December 31, 2015 and ; 2) Were originally processed prior to the installation of the revised October 2015 ASC DRUG File.		X							
9668.10	If released by CMS, Medicare contractors shall download and install the revised July 2015 ASC DRUG file. FILENAME: MU00.@BF12390.ASC.CY15.DRUG.JULD.V0624 **NOTE: Date of retrieval will be provided in a separate email communication from CMS.**		X							VDCs
9668.10.1	Medicare contractors shall adjust as appropriate claims brought to their attention that: 1) Have dates of service July 1, 2015- September 30, 2015 and ; 2) Were originally processed prior to the installation of the revised July 2015 ASC DRUG File.		X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
9668.11	Contractors shall make July 2016 ASCFS fee data for their ASC payment localities available on their web sites.		X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
9668.12	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			

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:
5	Attachment A: POLICY SECTION TABLES
5.1	Attachment A: POLICY SECTION TABLES
6	Attachment A: POLICY SECTION TABLES
6.1	Attachment A: POLICY SECTION TABLES

X-Ref Requirement Number	Recommendations or other supporting information:
4.1	Attachment A: POLICY SECTION TABLES
1	Attachment A: POLICY SECTION TABLES
2	Attachment A: POLICY SECTION TABLES
4	Attachment A: POLICY SECTION TABLES

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

V. CONTACTS

Pre-Implementation Contact(s): Chuck Braver, 410-786-6719 or chuck.braver@cms.hhs.gov (ASC Payment Policy) , Yvette Cousar, 410-786-2160 or yvette.cousar@cms.hhs.gov (Carrier/ AB MAC Claims Processing Issues) , Mark Baldwin, 410-786-8139 or mark.baldwin@cms.hhs.gov (Carrier/ AB MAC Claims Processing Issues)

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

POLICY SECTION TABLES

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

CPT Code	Long Descriptor	Short Descriptor	ASC PI
0438T	Transperineal placement of biodegradable material, peri-prostatic (via needle), single or multiple, includes image guidance	Tprnl plmt biodegrdabl matrl	G2
0440T	Ablation, percutaneous, cryoablation, includes imaging guidance; upper extremity distal/peripheral nerve	Abltj perc uxtr/perph nrv	G2
0441T	Ablation, percutaneous, cryoablation, includes imaging guidance; lower extremity distal/peripheral nerve	Abltj perc lxtr/perph nrv	G2
0442T	Ablation, percutaneous, cryoablation, includes imaging guidance; nerve plexus or other truncal nerve (eg, brachial plexus, pudendal nerve)	Abltj perc plex/trncl nrv	G2
0443T	Real time spectral analysis of prostate tissue by fluorescence spectroscopy	R-t spctrl alys prst8 tiss	G2

Table 2 – New CY 2016 HCPCS Codes and Dosage Descriptors for Certain Drugs, Biologicals, and Radiopharmaceuticals

HCPCS Code	Long Descriptor	Short Descriptor	ASC PI	Effective Date
C9476	Injection, daratumumab, 10 mg	Injection, daratumumab	K2	7/1/2016
C9477	Injection, elotuzumab, 1 mg	Injection, elotuzumab	K2	7/1/2016
C9478	Injection, sebelipase alfa, 1 mg	Injection, sebelipase alfa	K2	7/1/2016
C9479*	Instillation, ciprofloxacin otic suspension, 6 mg	Instill, ciprofloxacin otic	K2	7/1/2016
C9480	Injection, trabectedin, 0.1 mg	Injection, trabectedin	K2	7/1/2016
Q9981	Rolapitant, oral, 1 mg	Rolapitant, oral, 1mg	K2	7/1/2016
Q5102**	Injection, infliximab, biosimilar, 10 mg	Inj., infliximab biosimilar	K2	4/5/2016

*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.

**Note on Q5102: the effective date of Q5102 is 4/5/2016.

Table 3 – Biosimilar Biological Product Payment and Required Modifiers

HCPCS Code	Short Descriptor	ASC PI	FDA Approval Date	Modifier	Modifier Effective Date
Q5101	Inj filgrastim g-csf biosim	K2	03/06/2015	ZA-Novartis/Sandoz	01/01/2016
Q5102	Inj., infliximab biosimilar	K2	04/05/2016	ZB – Pfizer/Hospira	04/05/2016

Table 4 – Other Changes to CY 2016 HCPCS Codes for Certain Drugs, Biologicals, and Radiopharmaceuticals Effective July 1, 2016

HCPCS Code	Short Descriptor	Long Descriptor	ASC PI	Added Date	Termination Date
C9459	Flutemetamol f18	Flutemetamol f18, diagnostic, per study dose, up to 5 millicuries	K2	01/01/2016	06/30/2016
Q9982	flutemetamol f18 diagnostic	Flutemetamol F18, diagnostic, per study dose, up to 5 millicuries	K2	07/01/2016	
C9458	Florbetaben f18	Florbetaben f18, diagnostic, per study dose, up to 8.1 millicuries	K2	01/01/2016	06/30/2016
Q9983	florbetaben f18 diagnostic	Florbetaben f18, diagnostic, per study dose, up to 8.1 millicuries	K2	07/01/2016	
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)	G2		06/30/2016