CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 2045	**Date: September 10, 2010**
	Change Request 7147

SUBJECT: October 2010 Update of the Ambulatory Surgical Center (ASC) Payment System

I. SUMMARY OF CHANGES: This Recurring Update Notification (RUN) describes changes to, and billing instructions for, payment policies implemented in the October 2010 ASC payment system update. This RUN applies to Chapter 14, section 20.

EFFECTIVE DATE: *October 1, 2010
IMPLEMENTATION DATE: October 4, 2010

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 Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:
No additional funding will be provided by CMS; Contractor activities are to be carried out within their operating budgets.

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

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

Attachment – Recurring Update Notification

Pub. 100-04	Transmittal: 2045	Date: September 10, 2010	Change Request: 7147

SUBJECT: October 2010 Update of the Ambulatory Surgical Center (ASC) Payment System

EFFECTIVE DATE: October 1, 2010

IMPLEMENTATION DATE: October 4, 2010

I. GENERAL INFORMATION

A. Background:

This Recurring Update Notification describes changes to, and billing instructions for, payment policies implemented in the October 2010 ASC payment system update. Final policy under the revised ASC payment system, as set forth in Medicare Program; Revised Payment System Policies for Services Furnished in Ambulatory Surgical Centers (ASCs), beginning in CY 2008 (72 FR 42470), requires that ASC payment rates for covered separately payable drugs and biologicals be consistent with the payment rates under the Medicare hospital outpatient prospective payment system (OPPS). Those rates are updated quarterly. Therefore, beginning with Transmittal 1488 (CR5994), issued April 9, 2008, CMS has issued quarterly updates to ASC payment rates for separately paid drugs and biologicals. CMS also updates the lists of covered surgical procedures and covered ancillary services to include newly created HCPCS codes, as appropriate. This instruction provides information on one newly created pass-through device HCPCS codes, five newly created drug HCPCS codes, and six newly created HCPCS codes describing imaging services that will be added to the ASC list of covered ancillary services effective October 1, 2010.

In this Change Request, we are issuing instructions to contractors to modify their systems to accept the October 2010 ASC Fee Schedule (ASCFS), the October 2010 ASC Payment Indicator (PI) file, the October 2010 ASC DRUG file, an updated April 2010 ASC DRUG file, and updated July 2010 ASC DRUG file, and to ensure that the updated files properly interface with all other ASC module programming. The October 2010 ASCFS is an updated file only. The October 2010 ASC PI file is an updated file only and will contain all PI updates impacted by this CR. All of the ASC DRUG files are full replacement files that include payment rates for all separately payable drugs and biologicals applicable to the calendar quarter. Additionally, we will also be providing contractors with a special new June 3, 2010 ASCFS to implement a recent NCD.

B. Policy:

1. Billing for Drugs and Biologicals

ASCs are strongly encouraged to report charges for all separately payable drugs and biologicals, using the correct HCPCS codes for the items used. ASCs billing for these products must make certain that the reported units of service for the reported HCPCS codes are consistent with the quantity of the drug or biological that was used in the care of the patient. ASCs should not report HCPCS codes and separate charges for drugs and biologicals that receive packaged payment through the payment for the associated covered surgical procedure.

We remind ASCs that under the ASC payment system if two or more drugs or biologicals are mixed together to facilitate administration, the correct HCPCS codes should be reported separately for each product used in the care of the patient. The mixing together of two or more products does not constitute a "new" drug as regulated by the Food and Drug Administration (FDA) under the New Drug Application (NDA) process. In these situations, ASCs are reminded that it is not appropriate to bill HCPCS code C9399. HCPCS code C9399,

Unclassified drug or biological, is for new drugs and biologicals that are approved by the FDA on or after January 1, 2004, for which a HCPCS code has not been assigned.

Unless otherwise specified in the long description, HCPCS descriptions refer to the non-compounded, FDA-approved final product. If a product is compounded and a specific HCPCS code does not exist for the compounded product, the ASC should include the charge for the compounded product in the charge for the surgical procedure performed. Instructions for downloading the ASC DRUG file updates are included in the business requirements section below.

HCPCS payment updates are posted to the CMS website quarterly at:
http://www.cms.hhs.gov/ASCPayment/11_Addenda_Updates.asp#TopOfPage

Correct Reporting of Drugs and Biologicals When Used As Implantable Devices
When billing for a biological for which the HCPCS code describes a product that is solely surgically implanted or inserted, and that is separately payable under the ASC payment system, the ASC should report the HCPCS code for the product. If the implanted biological is packaged, that is, not eligible for separate payment under the ASC payment system, the ASC should not report the biological product HCPCS code. Units should be reported in multiples of the units included in the HCPCS descriptor. ASCs should not bill the units based on the way the implantable biological is packaged, stored, or stocked. The HCPCS short descriptors are limited to 28 characters, including spaces, so short descriptors do not always capture the complete description of the implantable biological. Therefore, before submitting Medicare claims for biologicals that are used as implantable devices, it is extremely important to review the complete long descriptors for the applicable HCPCS codes.

When billing for a biological for which the HCPCS code describes a product that may be either surgically implanted or inserted or otherwise applied in the care of a patient, ASCs should not report the HCPCS code for the product when the biological is used as an implantable device (including as a scaffold or an alternative to human or nonhuman connective tissue or mesh used in a graft) during surgical procedures. Under the ASC payment system, ASCs are provided a packaged payment for surgical procedures that includes the cost of supportive items. When using biologicals during surgical procedures as implantable devices, ASCs may include the charges for these items in their charge for the procedure.

Correct Reporting of Units for Drugs
ASCs are reminded to ensure that units of drugs administered to patients are accurately reported in terms of the dosage specified in the full HCPCS code descriptor. That is, units should be reported in multiples of the units included in the HCPCS descriptor. For example, if the description for the drug code is 6 mg, and 6 mg of the drug was administered to the patient, the units billed should be 1. As another example, if the description for the drug code is 50 mg, but 200 mg of the drug was administered to the patient, the units billed should be 4. ASCs should not bill the units based on the way the drug is packaged, stored, or stocked. That is, if the HCPCS descriptor for the drug code specifies 1 mg and a 10 mg vial of the drug was administered to the patient, hospitals should bill 10 units, even though only 1 vial was administered. The HCPCS short descriptors are limited to 28 characters, including spaces, so short descriptors do not always capture the complete description of the drug. Therefore, before submitting Medicare claims for drugs and biologicals, it is extremely important to review the complete long descriptors for the applicable HCPCS codes.

As discussed in Chapter 17, Section 40 of the Medicare Claims Processing Manual, Pub.100-04, we encourage ASCs to use drugs efficiently and in a clinically appropriate manner. However, we also recognize that ASCs may discard some drug and biological product when administering from a single use vial or package. In that circumstance, Medicare pays for the amount of drug or biological discarded as well as the dose administered, up to the amount of the drug or biological as indicated on the vial or package label. Multi-use vials are not subject to payment for discarded amounts of drug or biological.

a. New HCPCS Codes for Drugs and Biologicals Separately Payable under the ASC Payment System Effective October 1, 2010

Five new HCPCS codes have been created for drugs that are payable as covered ancillary services for dates of service on and after October 1, 2010. The new HCPCS codes, the short descriptors, the long descriptors, and payment indicators are identified in Table 1 below.

The new separately payable drug and biological codes and their payment rates are included in the October 2010 ASC DRUG file.

Table 1 – New Drugs and Biologicals Separately Payable under the ASC Payment System Effective October 1, 2010

HCPCS Code	LongDescriptor	Short Descriptor	Payment Indicator Effective 10/01/10
C9269	Injection, C-1 esterase inhibitor (human), Berinert, 10 units	C-1 esterase, berinert	K2
C9270	Injection, immune globulin (Gammaplex), intravenous, non-lyophilized (e.g. liquid), 500 mg	Gammaplex IVIG	K2
C9271	Injection, velaglucerase alfa, 100 units	Velaglucerase alfa	K2
C9272	Injection, denosumab, 1 mg	Inj, denosumab	K2
C9273	Sipuleucel-T, minimum of 50 million autologous CD54+ cells activated with PAP-GM-CSF in 250 mL of Lactated Ringer's, including leukapheresis and all other preparatory procedures, per infusion	Sipuleucel-T, per infusion	K2

b. Supplemental Information for HCPCS Code C9273

CMS has opened a national coverage determination analysis (NCD) for HCPCS code C9273, Provenge (Sipuleucel-T, minimum of 50 million autologous CD54+ cells activated with PAP-GM-CSF in 250mL of Lactated Ringer's, including leukapheresis and all other preparatory procedures, per infusion). A final decision on coverage is forthcoming in 2011. As with other drugs and biologicals, at this time, local contractors will retain the discretion to make individual claim determinations for Provenge based on the medical necessity of the service(s) being provided.

Additionally, we clarify that the language given in the long descriptor of Provenge states that "all other preparatory procedures" refers to the transportation process of collecting immune cells from a patient during a non-therapeutic leukapheresis procedure, subsequently sending the immune cells to the manufacturing facility, and then transporting the immune cells back to the site of service to be administered to the patient.

c. Updated Payment Rate for HCPCS Code 90476 Effective April 1, 2010 through June 30, 2010

The payment rate for one HCPCS code was incorrect in the April 2010 ASC DRUG file. The corrected payment rate is listed in Table 2 below and has been included in the revised April 2010 ASC DRUG file effective for services furnished on April 1, 2010 through implementation of the July 2010 update. Suppliers who think they may have received an incorrect payment between April 1, 2010 and June 30, 2010 may request contractor adjustment of the previously processed claims.

Table 2-Updated Payment Rates for Certain HCPCS Codes Effective April 1, 2010 through June 30, 2010

HCPCS Code	Short Descriptor	ASC Payment Rate	ASC PI
90476	Adenovirus vaccine, type 4	$72.17	K2

d. Updated Payment Rates for Certain HCPCS Codes Effective July 1, 2010 through September 30, 2010

The payment rates for two HCPCS codes were incorrect in the July 2010 ASC DRUG file. The corrected payment rates are listed in Table 3 below and have been included in the revised July 2010 ASC DRUG file effective for services furnished on July 1, 2010 through implementation of the October 2010 update. Suppliers who think they may have received an incorrect payment between July 1, 2010 and September 30, 2010 may request contractor adjustment of the previously processed claims.

Table 3-Updated Payment Rates for Certain HCPCS Codes Effective July 1, 2010 through September 30, 2010

HCPCS Code	Short Descriptor	ASC Payment Rate	ASC PI
J9264	Paclitaxel protein bound	$9.22	K2
C9268	Capsaicin patch	$25.55	K2

e. Payment for Vaccine CPT Code 90670 Effective April 1, 2010

CPT code 90670 (Pneumococcal conjugate vaccine, 13 valent, for intramuscular use) was erroneously assigned ASC PI=K2 (Drugs and biologicals paid separately when provided integral to a surgical procedure on ASC list; payment based on OPPS rate) in the July 2010 ASC update (CR 7008), effective April 1, 2010. Effective April 1, 2010, the payment for CPT code 90670 will change from ASC PI=K2 to ASC PI=L1 (Influenza vaccine; pneumococcal vaccine. Packaged item/service; no separate payment made). As a result, CPT code 90670 does not appear in the revised April 2010 and revised July 2010 ASC DRUG files.

f. Payment for Vaccine CPT Code 90662

CPT code 90662 (Long Descriptor: Influenza virus vaccine, split virus, preservative free, enhanced immunogenicity via increased antigen content, for intramuscular use; Short Descriptor: Flu vacc prsv free inc antig) has been assigned ASC PI=Y5. However, 90662 received approval from the FDA on December 23, 2009. Therefore, effective December 23, 2009, CPT code 90662 is assigned ASC PI=L1 (Influenza vaccine; pneumococcal vaccine. Packaged item/service; no separate payment made).

2. New Device Pass-Through Category

Additional payments may be made to the ASC for covered ancillary services, including certain implantable devices with pass-through status under the outpatient prospective payment system (OPPS). Section 1833(t)(6)(B) of the Social Security Act requires that, under the OPPS, categories of devices be eligible for transitional pass-through payments for at least 2, but not more than 3 years. Section 1833(t)(6)(B)(ii)(IV) of

the Act requires that we create additional categories for transitional pass-through payment of new medical devices not described by existing or previously existing categories of devices.

The OPPS has established one new pass-through device category as of October 1, 2010. The ASC payment system is also establishing the same device pass-through code for separate payment effective October 1, 2010. We have determined that we are not able to identify a portion of the OPPS procedure payment amount associated with the cost of the device; therefore, we will not reduce the ASC procedure payment to remove the costs of related predecessor devices packaged into the base procedure's OPPS payment weight. Table 4 provides a listing of new ASC coding and payment information concerning the new device category for transitional pass-through payment. HCPCS code C1749 is assigned ASC PI=J7 (OPPS pass-through device paid separately when provided integral to a surgical procedure on ASC list; payment contractor-priced).

Table 4-New ASC Device Pass-Through HCPCS Code Effective October 1, 2010

HCPCS	Short Descriptor	Long Descriptor	ASC PI
C1749	Endo, colon, retro imaging	Endoscope, retrograde imaging/illumination colonoscope device (implantable)	J7

3. Coding and Payment for Magnetic Resonance Angiography (MRA)

Effective for claims with dates of service on and after June 3, 2010, CMS permits local Medicare contractors to cover (or not cover) all indications of MRA that are not specifically nationally covered or nationally non-covered. CMS has created the six Level II HCPCS codes in Table 5 below to allow ASCs to bill for certain MRA services that were previously non-covered but may now be covered at local Medicare contractor discretion. These HCPCS codes are assigned ASC PI=Z2 (Radiology service paid separately when provided integral to a surgical procedure on ASC list; payment based on OPPS relative payment weight) with the update to the Medicare physician fee schedule authorized for June 1 through November 30, 2010, under the Preservation of Access to Care for Medicare Beneficiaries and Pension Relief Act of 2010. The six Level II HCPCS codes must be used in place of existing CPT codes for the previously non-covered MRA procedures due to a statutory requirement that the OPPS provide payment for imaging services provided with contrast and without contrast through separate payment groups. Specifically, HCPCS codes C8931, C8932, and C8933 replace CPT code 72159 (Magnetic resonance angiography, spinal canal and contents, with or without contrast material(s)), while HCPCS codes C8934, C8935, and C8936 replace CPT code 73225 (Magnetic resonance angiography, upper extremity, with or without contrast material(s)).

Further information on billing and coverage for MRA is available to contractors in Transmittal 123 (CR7040), issued July 9, 2010.

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Table 5 – Carrier Determination MRA Codes Effective June 3, 2010

HCPCS Code	Long Descriptor	Short Descriptor	Payment Indicator Effective 06/03/10
C8931	Magnetic resonance angiography with contrast, spinal canal	MRA, w/dye, spinal canal	Z2

	and contents		
C8932	Magnetic resonance angiography without contrast, spinal canal and contents	MRA, w/o dye, spinal canal	Z2
C8933	Magnetic resonance angiography without contrast followed by with contrast, spinal canal and contents	MRA, w/o&w/dye, spinal canal	Z2
C8934	Magnetic resonance angiography with contrast, upper extremity	MRA, w/dye, upper extremity	Z2
C8935	Magnetic resonance angiography without contrast, upper extremity	MRA, w/o dye, upper extr	Z2
C8936	Magnetic resonance angiography without contrast followed by with contrast, upper extremity	MRA, w/o&w/dye, upper extr	Z2

4. 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. Carriers/Medicare Administrative Contractors (MACs) determine whether a drug, device, procedure, or other service meets all program requirements for coverage. For example, Carriers/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

Use"Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
7147.1	Medicare contractors shall download the October 2010 ASCFS from the CMS mainframe.	X			X						All EDCs

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	FILENAME: MU00.@BF12390.ASC.CY10.FS.OCT.M.V0901 **Date of retrieval will be provided in a separate email communication from CMS**										
7147.2	Medicare contractors shall download and install the October 2010 ASC PI file FILENAME: MU00.@BF12390.ASC.CY10.IND.OCT.M.V0907 **Date of retrieval will be provided in a separate email communication from CMS**	X			X						
7147.3	Medicare contractors shall download and install the October 2010 ASC DRUG file FILENAME: MU00.@BF12390.ASC.CY10.DRUG.OCT.M.V0922 **Date of retrieval will be provided in a separate email communication from CMS**	X			X						
7147.4	Medicare contractors shall download and install the revised July 2010 ASC DRUG file. FILENAME: MU00.@BF12390.ASC.CY10.DRUG.JUL.M.V0922 **Date of retrieval will be provided in a separate email communication from CMS**	X			X						All EDCs
7147.4.1	Medicare contractors shall adjust as appropriate claims brought to their attention that: 1) Have dates of service on or after July 1, 2010 prior to October 1, 2010 and ; 2) Were originally processed prior to the installation of the revised July 2010 ASC DRUG File.	X			X						
7147.5	Medicare contractors shall download and install a revised April 2010 ASC DRUG file. FILENAME: MU00.@BF12390.ASC.CY10.DRUG.APR.M.V0922	X			X						All EDCs

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	Confirmation and date of retrieval will be provided in a separate email communication from CMS										
7147.5.1	Medicare contractors shall adjust as appropriate claims brought to their attention that: 1) Have dates of service on or after April 1, 2010 prior to July 1, 2010; and, 2) Were originally processed prior to the installation of the revised April 2010 ASC DRUG File.	X			X						
7147.6	Contractors shall make October 2010 ASCFS fee data for their ASC payment localities available on their web sites.	X			X						
7147.7	Medicare contractors shall download a special June 3, 2010 effective date ASCFS from the CMS mainframe. FILENAME: MU00.@BF12390.ASC.CY10.FS.JUN.M.V0901 **Date of retrieval will be provided in a separate email communication from CMS**	X			X						All EDCs
7147.8	Contractors shall modify the procedure code file and TOS tables for HCPCS code C1749, C8931-C8936, C9269-C9273.	X			X						
7147.8.1	Contractors shall accept C8931-C8936 for claims with a DOS on or after June 3, 2010.	X			X						
7147.8.2	Contractors shall accept C1749, C9269-C9273 for claims with a DOS on or after October 1, 2010.	X			X						
7147.9	CWF shall assign TOS F for C8931-C8936 for claims with DOS on or after June 3, 2010.									X	
7147.10	CWF shall assign TOS F for C1749, C9269-C9273 for claims with DOS on or after October 1, 2010.									X	
7147.11	Medicare contractors shall send notification of successful receipt via email to price_file_receipt@cms.hhs.gov stating the name of the file received and the entity for which it was received (e.g., carrier name and number).	X			X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
7147.12	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/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 site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your 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: For any recommendations and supporting information associated with listed requirements, use the box below: N/A

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: For all other recommendations and supporting information, use this space: N/A

V. CONTACTS

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

Post-Implementation Contact(s): Appropriate Regional Office

VI. FUNDING

Section A: For *Carriers:*
No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

Section B: *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.