

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-04 Medicare Claims Processing</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 1702</b>	<b>Date: March 13, 2009</b>
	<b>Change Request 6416</b>

**SUBJECT: April 2009 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 2009 OPPS update. It affects Chapter 4, Sections 60.4, 61.1, 230.2, and 231. CMS is revising these sections.

The April 2009 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.

April 2009 revisions to the I/OCE data files, instructions, and specifications are provided in Change Request (CR) 6413, April 2009 Integrated Outpatient Code Editor (I/OCE) Specifications Version 10.1.

**New / Revised Material**

**Effective Date: April 1, 2009**

**Implementation Date: April 6, 2009**

*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	3/90.3.3/Billing for Stem Cell Transplantation
R	4/Table of Contents
R	4/60.4/General Coding and Billing Instructions and Explanations
R	4/61.1/Requirement that Hospitals Report Device Codes on Claims on Which They Report Specified Procedures
R	4/230.2/Coding and Payment for Drug Administration
R	4/231/Billing and Payment for Blood, Blood Products, and Stem Cells and Related Services Under the Hospital Outpatient Prospective Payment System (OPPS)
R	4/231.1/When a Provider Paid Under the OPPS Does Not Purchase the Blood

	or Blood Products That It Procures from a Community Blood Bank, or When a Provider Paid Under the OPSS Does Not Assess a Charge for Blood or Blood Products Supplied by the Provider's Own Blood Bank Other Than Blood Processing and Storage
R	4/231.2/When a Provider Paid Under the OPSS Purchases Blood or Blood Products from a Community Blood Bank or When a Provider Paid Under the OPSS Assesses a Charge for Blood or Blood Products Collected By Its Own Blood Bank That Reflects More Than Blood Processing and Storage
R	4/231.10/Billing for Autologous Stem Cell Transplants
N	4/231.11/Correct Coding Initiative (CCI) Edits

### III. FUNDING:

#### SECTION A: For Fiscal Intermediaries and 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.

### IV. ATTACHMENTS:

#### Recurring Update Notification

#### Manual Instruction

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

# Attachment – Recurring Update Notification

Pub. 100-04	Transmittal: 1702	Date: March 13, 2009	Change Request: 6416
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**SUBJECT: April 2009 Update of the Hospital Outpatient Prospective Payment System (OPPS)**

**Effective Date:** April 1, 2009

**Implementation Date:** April 6, 2009

## I. GENERAL INFORMATION

**A. Background:** This Recurring Update Notification describes changes to and billing instructions for various payment policies implemented in the April 2009 OPSS update. The April 2009 Integrated Outpatient Code Editor (I/OCE) and OPSS 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).

April 2009 revisions to the I/OCE data files, instructions, and specifications are provided in CR 6413, April 2009 Integrated Outpatient Code Editor (I/OCE) Specifications Version 10.1.”

## B. Policy:

### 1. Pass-Through Devices and Non Pass-Through Devices Included in Kits

Manufacturers frequently package a number of individual items used with a device in a particular procedure in a kit. Generally, to avoid complicating the device pass-through category list unnecessarily and to avoid the possibility of double coding, CMS has not established HCPCS codes for such kits. However, hospitals may purchase and use such kits. If the kits contain individual items that separately qualify for transitional pass-through payments, these items should be separately billed using applicable HCPCS codes. Hospitals may not bill for transitional pass-through payments for supplies that may be contained in kits. This information can also be found in the Medicare Claims Processing Manual, Pub.100-04, Chapter 4, §60.4 (General Coding and Billing Instructions and Explanations).

In cases of devices that are described by device category HCPCS codes whose pass-through status has expired, or HCPCS codes that describe devices without pass-through status and that are packaged in kits with other items used in a particular procedure, hospitals may consider all kit costs in their line-item charge for the associated device/device category HCPCS code that is assigned status indicator “N” for packaged payment. That is, hospitals may report the total charge for the whole kit with the associated device/device category HCPCS code. Payment for device/device category HCPCS codes without pass-through status is packaged into payment for the procedures in which they are used, and these codes are assigned status indicator “N.” In the case of a device kit, should a hospital choose to report the device charge alone under a device/ device category HCPCS code with status indicator “N,” the hospital should report charges for other items that may be included in the kit on a separate line on the claim. Hospitals may use the same revenue code to report all components of the kit. This information can also be found in the Medicare Claims Processing Manual, Pub.100-04, Chapter 4, §61.1 (Requirement that Hospitals Report Device Codes on Claims on Which They Report Specified Procedures).

Hospitals are advised to continue to report all HCPCS codes that describe packaged items and services that were provided, unless CPT instructions or CMS provide other guidance. Further, hospitals should include

charges for packaged items or services described and reported by those HCPCS codes with status indicator “N” on their claims when those codes can be appropriately reported, so that the costs associated with the packaged items or services can then be added to the costs of separately payable procedures on the same claims when establishing the annual payment rates for the separately payable services under the OPSS.

## **2. Further Clarification Related to Billing for Medical and Surgical Supplies**

When medical and surgical supplies (other than prosthetic and orthotic devices as described in the Medicare Benefit Policy Manual, Pub. 100-02, Chapter 15, §120 and §130, and take-home surgical dressings) described by HCPCS codes with status indicators other than “H” or “N,” are provided incident to a physician's service by a hospital outpatient department, the HCPCS codes for these items should not be reported because these items represent supplies. Claims containing charges for medical and surgical supplies used in providing hospital outpatient services are submitted to the Medicare contractor providing OPSS payment for the services in which they are used. The hospital should include charges associated with these medical and surgical supplies on claims so their costs are incorporated in rate setting, and payment for the supplies is packaged into payment for the associated procedures under the OPSS in accordance with 42 CFR 419.2(b)(4).

For example, if the hospital staff in the emergency department initiate the intravenous administration of a drug through an infusion pump described by HCPCS code E0781 (Ambulatory infusion pump, single or multiple channels, electric or battery operated, with administrative equipment, worn by patient), complete the drug infusion, and discontinue use of the infusion pump before the patient leaves the hospital outpatient department, HCPCS code E0781 should not be reported because the infusion pump was used as a supply and would be paid through OPSS payment for the drug administration service. The hospital should include the charge associated with the infusion pump on the claim.

In another example, if hospital outpatient staff perform a surgical procedure on a patient in which temporary bladder catheterization is necessary and use a catheter described by HCPCS code A4338 (Indwelling catheter; Foley type, two-way latex with coating (Teflon, silicone, silicone elastomer, or hydrophilic, etc.), each), the hospital should not report A4338 because the catheter was used as a supply and would be paid through OPSS payment for the surgical procedure. The hospital should include the charge associated with the urinary catheter on the claim.

When hospital outpatient staff provide a prosthetic or orthotic device, and the HCPCS code that describes that device includes the fitting, adjustment, or other services necessary for the patient's use of the item, the hospital should not bill a visit or procedure HCPCS code to report the charges associated with the fitting, adjustment, or other related services. Instead, the HCPCS code for the device already includes the fitting, adjustment or other similar services. For example, if the hospital outpatient staff provides the orthotic device described by HCPCS code L1830 (KO, immobilizer, canvas longitudinal, prefabricated, includes fitting and adjustment), the hospital should only bill HCPCS code L1830 and should not bill a visit or procedure HCPCS code to describe the fitting and adjustment.

## **3. Billing for Inherently Bilateral Procedures**

Inherently bilateral procedures represent services that are performed bilaterally. Oftentimes the word “bilateral” appears in the HCPCS code long descriptor. Since the implementation of the OPSS on August 1, 2000, inherently bilateral procedure codes have been included in the I/OCE as a table that is used in applying edit 17 (inappropriate specification of bilateral procedure). The I/OCE edit 17 occurs when a bilateral procedure code appears on the claim form more than once per day on the same date for the same patient. Recently, CMS received reports of a clinical scenario where a bilateral procedure may be performed more than once per day on the same date for the same patient. For only those instances that involve more than one bilateral procedure and are medically necessary and appropriate, hospitals are advised to report the procedure code with a modifier -76 (repeat procedure or service by same physician) in order for the claim to process correctly. Appending modifier

-76 to one of the reported bilateral HCPCS code indicates that the bilateral procedure or service was repeated on the same day for the same patient. CMS expects these types of claims to be uncommon and will be monitoring claims to ensure that this is the case.

#### **4. Billing for Processing and Storage of Blood and Blood Products**

CMS updated the Medicare Claims Processing Manual, Pub. 100-04, Chapter 4, §231.1 and §231.2, to include Revenue Code 0392 (Blood Processing/Storage; Processing and Storage) as an acceptable revenue code for billing blood processing and storage charges. Most OPPS providers obtain blood or blood products from community blood banks that charge only for processing and storage, and not for the blood itself. These hospitals should follow the instructions outlined in §231.1, which require using Revenue Code 0390 (Blood Processing/Storage), 0392 (Blood Processing/Storage; Processing and Storage), or 0399 (Blood Processing /Storage; Other Processing and Storage), along with the appropriate blood HCPCS code, the number of units transfused, and the line item date of service (LIDOS).

The OPPS providers that incur a charge for the blood or blood product itself in addition to the charge for processing and storage, should follow the coding requirements outlined in §231.2, which instructs hospitals to report charges for the blood or blood product itself using Revenue Code series 038X (excluding 0380) with the LIDOS, the number of units transfused, and the appropriate blood product HCPCS code and HCPCS modifier BL. The OPPS provider also should report charges for processing and storage services on a separate line using Revenue Code 0390, 0392, or 0399 with the LIDOS, the number of units transfused, and the appropriate blood product HCPCS code and HCPCS modifier BL. The same LIDOS, the same number of units, the same HCPCS code, and HCPCS modifier BL must be reported on both lines.

#### **5. Billing for Autologous Stem Cell Transplant Procedures**

CMS updated the Medicare Claims Processing Manual, Pub. 100-04, Chapter 3, §90.3.3 to clarify billing for allogeneic stem cell transplant acquisition services, which are billed and payable under Part A, and to clarify billing for autologous stem cell transplant procedures, which may be billed and payable under either Part A or Part B. CMS also added §231.10 on billing for autologous stem cell transplant procedures to Chapter 4.

#### **6. Billing for Drugs, Biologicals, and Radiopharmaceuticals**

Hospitals are strongly encouraged to report charges for all drugs, biologicals, and radiopharmaceuticals, regardless of whether the items are paid separately or packaged, using the correct HCPCS codes for the items used. It is also of great importance that hospitals billing for these products make certain that the reported units of service of the reported HCPCS codes are consistent with the quantity of a drug, biological, or radiopharmaceutical that was used in the care of the patient.

CMS reminds hospitals that under the OPPS, 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, hospitals 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 hospital should report an appropriate unlisted code such as J9999 or J3490.

##### **a. Drugs and Biologicals with Payments Based on Average Sales Price (ASP) Effective April 1, 2009**

For CY 2009, payment for nonpass-through drugs and biologicals is made at a single rate of ASP+4 percent, which provides payment for both the acquisition cost and pharmacy overhead costs associated with the drug or biological. In CY 2009, a single payment of ASP+6 percent for pass-through drugs and biologicals is made to provide payment for both the acquisition cost and pharmacy overhead costs of these pass-through items. We note that for the second quarter of CY 2009, payment for drugs and biologicals with pass-through status is not made at the Part B Drug Competitive Acquisition Program (CAP) rate, as the CAP program is suspended beginning January 1, 2009. Should the Part B Drug CAP program be reinstated sometime during CY 2009, we would again use the Part B drug CAP rate for pass-through drugs and biologicals if they are a part of the Part B drug CAP program, as required by the statute.

In the CY 2009 OPSS/ASC final rule with comment period, it was stated that payments for drugs and biologicals based on ASPs will be updated on a quarterly basis as later quarter ASP submissions become available. In cases where adjustments to payment rates are necessary based on the most recent ASP submissions, CMS will incorporate changes to the payment rates in the April 2009 release of the OPSS PRICER. The updated payment rates, effective April 1 2009, will be included in the April 2009 update of the OPSS Addendum A and Addendum B, which will be posted on the CMS Web site.

**b. Drugs and Biologicals with OPSS Pass-Through Status Effective April 1, 2009**

Three drugs and one diagnostic radiopharmaceutical have been granted OPSS pass-through status effective April 1, 2009. These items, along with their descriptors and APC assignments, are identified in Table 1 below.

**Table 1- Drugs and Biologicals with OPSS Pass-Through Status Effective April 1, 2009**

<b>HCPCS Code</b>	<b>Long Descriptor</b>	<b>APC</b>	<b>Status Indicator Effective 4/1/09</b>
C9247	Iobenguane, I-123, diagnostic, per study dose, up to 10 millicuries	9247	G
C9249*	Injection, certolizumab pegol, 1 mg	9249	G
J0641	Injection, levoleucovorin calcium, 0.5 mg	1236	G
J8705	Topotecan, oral, 0.25 mg	1238	G

**NOTE:** The HCPCS code identified with an “\*” indicates that this is a new code effective April 1, 2009.

**c. Adjustment to Status Indicator for HCPCS Code J3300 For CY 2009**

As stated in the CY 2009 OPSS/ASC correction notice, CMS erroneously assigned a packaged status indicator (SI = “N”) to HCPCS code J3300, Injection, triamcinolone acetonide, preservative free, 1 mg, for CY 2009. To correct this error, CMS is updating the payment rate in the OPSS PRICER retroactively to January 1, 2009, to reflect the updated separately payable status of HCPCS code J3300 (SI = “K”) for CY 2009. The HCPCS code J3300 is assigned to APC 1253 (Triamcinolone A inj PRS-free) with a payment rate of \$3.18 for the first quarter of CY 2009. If this payment rate changes for the second quarter of CY 2009, CMS will include the pricing update for HCPCS code J3300 in the corresponding update for other separately payable drugs and biologicals for the April 2009 OPSS PRICER.

**d. Recognition of Multiple HCPCS Codes For Drugs**

Prior to January 1, 2008, the OPSS generally recognized only the lowest available administrative dose of a drug if multiple HCPCS codes existed for the drug; for the remainder of the doses, the OPSS assigned a status indicator “B” indicating that another code existed for OPSS purposes. For example, if drug X has two HCPCS codes, one for a 1 ml dose and another for a 5 ml dose, the OPSS would assign a payable status indicator to the 1 ml dose and status indicator “B” to the 5 ml dose. Hospitals then were required to bill the appropriate number of units for the 1 ml dose in order to receive payment under the OPSS. However, beginning January 1, 2008, the OPSS has recognized each HCPCS code for a Part B drug, regardless of the units identified in the drug descriptor. Hospitals may choose to report multiple HCPCS codes for a single drug, or to continue billing the HCPCS code with the lowest dosage descriptor available.

**e. Correct Reporting of Drugs and Biologicals When Used As Implantable Devices**

When billing for biologicals where the HCPCS code describes a product that is solely surgically implanted or inserted, whether the HCPCS code is identified as having pass-through status or not, hospitals are to report the appropriate HCPCS code for the product. In circumstances where the implanted biological has pass-through status, a separate payment for the biological is made. In circumstances where the implanted biological does not have pass-through status, the OPSS payment for the biological is packaged into the payment for the associated procedure.

When billing for biologicals where the HCPCS code describes a product that may either be surgically implanted or inserted or otherwise applied in the care of a patient, hospitals should not separately report the biological HCPCS codes, with the exception of biologicals with pass-through status, when using these items as implantable devices (including as a scaffold or an alternative to human or nonhuman connective tissue or mesh used in a graft) during surgical procedures. Under the OPSS, hospitals are provided a packaged APC payment for surgical procedures that includes the cost of supportive items, including implantable devices without pass-through status. When using biologicals during surgical procedures as implantable devices, hospitals may include the charges for these items in their charge for the procedure, report the charge on an uncoded revenue center line, or report the charge under a device HCPCS code (if one exists) so these costs would appropriately contribute to the future median setting for the associated surgical procedure.

**f. Correct Reporting of Units for Drugs**

Hospitals and providers 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. Providers and hospitals 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, 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.

**g. Introduction of Payment Offset for Pass-Through Diagnostic Radiopharmaceuticals**

Effective April 1, 2009, diagnostic radiopharmaceutical HCPCS code C9247, Iobenguane, I-123, diagnostic, per study dose, up to 10 millicuries, has been granted pass-through status under the OPSS and will be assigned status indicator “G.” As finalized in the CY 2009 OPSS/ASC final rule with

comment period, payment for diagnostic radiopharmaceuticals with pass-through status during CY 2009 will be made according to the established ASP methodology. Therefore, beginning April 1, 2009, payment for HCPCS code C9247 will be made at 106 percent of ASP if ASP data are submitted by the manufacturer. Otherwise, payment will be made based on the product's wholesale acquisition cost (WAC). Further, if WAC data are not available, payment will be made at 95 percent of the average wholesale price (AWP).

Effective for nuclear medicine services furnished on and after April 1, 2009, when HCPCS code C9247 is billed on the same claim with a nuclear medicine procedure, CMS will reduce the amount of payment for the pass-through diagnostic radiopharmaceutical reported with HCPCS code C9247 by the corresponding nuclear medicine procedure's portion of its APC payment associated with "policy packaged" drugs (offset amount) so no duplicate radiopharmaceutical payment is made. The "policy packaged" portions of the CY 2009 APC payments may be found on the CMS Web site at: [http://www.cms.hhs.gov/HospitalOutpatientPPS/06\\_Annual\\_Policy\\_File.asp#TopOfPage](http://www.cms.hhs.gov/HospitalOutpatientPPS/06_Annual_Policy_File.asp#TopOfPage) in the download file labeled 2009 OPSS Offset Amounts by APC. Pass-through payment for the diagnostic radiopharmaceutical is the difference between the payment for the pass-through product and the payment for the predecessor product that, in the case of diagnostic radiopharmaceuticals, is packaged into the payment for the nuclear medicine procedure in which the diagnostic radiopharmaceutical is used. Therefore, effective for services furnished on and after April 1, 2009, but before the date that HCPCS code C9247 expires from pass-through status, CMS will reduce the payment for HCPCS code C9247 by the estimated amount of payment that is attributable to the predecessor radiopharmaceutical that is packaged into payment for the associated nuclear medicine procedure reported on the same claim as HCPCS code C9247.

When HCPCS code C9247 is billed on a claim with one or more nuclear medicine procedures, the OPSS Pricer will identify the offset amount or amounts that apply to the nuclear medicine procedures that are reported on the claim. Where there is a single nuclear medicine procedure reported on the claim with a single occurrence of C9247, the OPSS Pricer will identify a single offset amount for the procedure billed and adjust the offset by the wage index that applies to the hospital submitting the bill. Where there are multiple nuclear medicine procedures on the claim with a single occurrence of the pass-through radiopharmaceutical, the OPSS Pricer will select the nuclear medicine procedure with the single highest offset amount, and will adjust the selected offset amount by the wage index of the hospital submitting the claim. When a claim has more than one occurrence of C9247, the OPSS Pricer will rank potential offset amounts associated with the units of nuclear medicine procedures on the claim and identify a total offset amount that takes into account the number of occurrences of the pass-through radiopharmaceutical on the claim and adjust the total offset amount by the wage index of the hospital submitting the claim. The adjusted offset will be subtracted from the APC payment for the pass-through diagnostic radiopharmaceutical reported with HCPCS code C9247. The offset will cease to apply when the diagnostic radiopharmaceutical expires from pass-through status.

## **7. OPSS Pricer Changes**

New Pass-Through Diagnostic Radiopharmaceutical Offset logic will be added (see section "I.B.6.g." above) along with the April Average Sales Pricer (ASP) APC updates.

## **8. Coverage Determinations**

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. Fiscal Intermediaries (FIs)/Medicare Administrative Contractors (MACs) determine whether a drug, device, procedure, or other service meets all program requirements for

coverage. For example, FIs/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  M A C	D M E  M A C	F I  R I E R	C A R R I E R	R H I  I E R	Shared-System Maintainers				OTHER
						F I S S	M C S	V M S	C W F		
6416.1	Medicare contractors shall install the April 2009 OPPS Pricer.	X		X		X	X				COBC

## III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B  M A C	D M E  M A C	F I  R I E R	C A R R I E R	R H I  I E R	Shared-System Maintainers				OTHER
						F I S S	M C S	V M S	C W F		
6416.2	A provider education article related to this instruction will be available at <a href="http://www.cms.hhs.gov/MLNMattersArticles/">http://www.cms.hhs.gov/MLNMattersArticles/</a> 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		X					COBC

## IV. SUPPORTING INFORMATION

**Section A: For any recommendations and supporting information associated with listed requirements, use the box below:**

Use "Should" to denote a recommendation.

<b>X-Ref Requirement Number</b>	<b>Recommendations or other supporting information:</b>
CR 6413	April 2009 Integrated Outpatient Code Editor (I/OCE) Specifications Version 10.1” for supporting information.

**Section B: For all other recommendations and supporting information, use this space:**

## V. CONTACTS

**Pre-Implementation Contact(s):** Marina Kushnirova at [marina.kushnirova@cms.hhs.gov](mailto:marina.kushnirova@cms.hhs.gov)

**Post-Implementation Contact(s):** Regional Office

## VI. FUNDING

**Section A: For *Fiscal Intermediaries (FIs)*, *Regional Home Health Intermediaries (RHHIs)*, and/or *Carriers*, use only one of the following statements:**

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)*, include the following statement:**

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.

### **90.3.3 - Billing for Stem Cell Transplantation**

*(Rev.1702, Issued: 03-13-09, Effective: 04-01-09, Implementation: 04-06-09)*

#### **A. Billing for *Allogeneic Stem Cell Transplants***

##### *1. Definition of Acquisition Charges for Allogeneic Stem Cell Transplants*

*Acquisition charges for allogeneic stem cell transplants include, but are not limited to, charges for the costs of the following services:*

- National Marrow Donor Program fees, if applicable, for stem cells from an unrelated donor;*
- Tissue typing of donor and recipient;*
- Donor evaluation;*
- Physician pre-admission/pre-procedure donor evaluation services;*
- Costs associated with harvesting procedure (e.g., general routine and special care services, procedure/operating room and other ancillary services, apheresis services, etc.);*
- Post-operative/post-procedure evaluation of donor; and*
- Preparation and processing of stem cells.*

*Payment for these acquisition services is included in the MS-DRG payment for the allogeneic stem cell transplant. The Medicare contractor does not make separate payment for these acquisition services, because hospitals may bill and receive payment only for services provided to the Medicare beneficiary who is the recipient of the stem cell transplant and whose illness is being treated with the stem cell transplant. Unlike the acquisition costs of solid organs for transplant (e.g., hearts and kidneys), which are paid on a reasonable cost basis, acquisition costs for allogeneic stem cells are included in prospective payment.*

*Acquisition charges for stem cell transplants apply only to allogeneic transplants, for which stem cells are obtained from a donor (other than the recipient himself or herself). Acquisition charges do not apply to autologous transplants (transplanted stem cells are obtained from the recipient himself or herself), because autologous transplants involve services provided to the beneficiary only (and not to a donor), for which the hospital may bill and receive payment (see paragraph B of this section).*

## 2. *Billing for Acquisition Services*

*The hospital identifies stem cell acquisition charges for allogeneic bone marrow/stem cell transplants separately in FL 42 of Form CMS-1450 (or electronic equivalent) by using revenue code 0819 (Other Organ Acquisition). Revenue code 0819 charges should include all services required to acquire stem cells from a donor, as defined above.*

*On the recipient's transplant bill, the hospital reports the acquisition charges, cost report days, and utilization days for the donor's hospital stay (if applicable) and/or charges for other encounters in which the stem cells were obtained from the donor. The donor is covered for medically necessary inpatient hospital days of care or outpatient care provided in connection with the allogeneic stem cell transplant under Part A. Expenses incurred for complications are paid only if they are directly and immediately attributable to the stem cell donation procedure. The hospital reports the acquisition charges on the billing form for the recipient, as described in the first paragraph of this section. It does not charge the donor's days of care against the recipient's utilization record. For cost reporting purposes, it includes the covered donor days and charges as Medicare days and charges.*

*The transplant hospital keeps an itemized statement that identifies the services furnished, the charges, the person receiving the service (donor/recipient), and whether this is a potential transplant donor or recipient. These charges will be reflected in the transplant hospital's stem cell/bone marrow acquisition cost center. For allogeneic stem cell acquisition services in cases that do not result in transplant, due to death of the intended recipient or other causes, hospitals include the costs associated with the acquisition services on the Medicare cost report.*

*The hospital shows charges for the transplant itself in revenue center code 0362 or another appropriate cost center. Selection of the cost center is up to the hospital.*

### **B. Billing for *Autologous* Stem Cell Transplants**

*The hospital bills and shows all charges for autologous stem cell harvesting, processing, and transplant procedures based on the status of the patient (i.e., inpatient or outpatient) when the services are furnished. It shows charges for the actual transplant, described by the appropriate ICD-9-CM procedure or CPT codes, in revenue center code 0362 or another appropriate cost center.*

*The CPT codes describing autologous stem cell harvesting procedures may be billed and are separately payable under the Outpatient Prospective Payment System (OPPS) when provided in the hospital outpatient setting of care. Autologous harvesting procedures are distinct from the acquisition services described in section A. above for allogeneic stem cell transplants, which include services provided when stem cells are obtained from a donor and not from the patient undergoing the stem cell transplant. The CPT codes describing autologous stem cell processing procedures also may be billed and are separately payable under the OPPS when provided to hospital outpatients.*

*Payment for stem cell harvesting procedures performed in the hospital inpatient setting of care, with transplant also occurring in the inpatient setting of care, is included in the MS-DRG payment for the autologous stem cell transplant.*

# Medicare Claims Processing Manual

## Chapter 4 - Part B Hospital

### (Including Inpatient Hospital Part B and OPPS)

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*(Rev.1702, 03-13-09)*

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## 60.4 - General Coding and Billing Instructions and Explanations

*(Rev.1702, Issued: 03-13-09, Effective: 04-01-09, Implementation: 04-06-09)*

### Explanations of Terms

#### *Device Kits*

Manufacturers frequently package a number of individual items used *with a device* in a particular procedure in a kit. Generally, to avoid complicating the *device pass-through* category list unnecessarily and to avoid the possibility of double coding, CMS has not established HCPCS codes for such kits. However, hospitals may purchase and use such kits. If the kits contain individual items that separately qualify for transitional pass-through payments, these items should be separately billed using applicable *HCPCS* codes. Hospitals may not bill for transitional pass-through payments for supplies that may be contained in kits.

#### *Reporting Multiple Units of Pass-Through Device Categories*

Hospitals must bill for multiple units of items that qualify for transitional pass-through payments when such items are used with a single procedure by entering the number of units used on the bill.

#### *Reporting of Multiple Device Categories*

For items with multiple component devices that fall in more than one category (e.g., kits or systems other than those explicitly identified in the long descriptors), hospitals should code the appropriate category separately for each component. For example, the “Rotablator Rotational Angioplasty System (with catheter and advancer)” consists of both a catheter and an advancer/sheath. Hospitals should report category C1724 for the catheter and C1894 for the advancer/sheath.

Also, for items packaged as kits that contain a catheter and an introducer, hospitals should report both appropriate categories. For example, the “Clinicath 16G Peripherally Inserted Central Catheter (PICC) Dual-Lumen PolyFlow Polyurethane” contains a catheter and an introducer. To appropriately bill for this item, hospitals should report category C1751 for the catheter and C1894 for the introducer. (Please note that the device categories C1724, C1894 and C1751 are no longer eligible for pass-through payments, but are used here for illustrative purposes for reporting multiple categories. However, hospitals should continue to report devices on claims in this manner even after the category is no longer eligible for pass-through payment.)

#### *Reprocessed Devices*

Hospitals may bill for transitional pass-through payments only for those devices that are “single use.” Reprocessed devices may be considered “single use” if they are reprocessed in compliance with enforcement guidance of the Food and Drug Administration (FDA) relating to the reprocessing of devices applicable at the time the service is delivered. The FDA phased in new enforcement guidance relating to reprocessing during 2001 and 2002. For further information, see FDA’s guidance document entitled “Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals,” published August 14, 2000, or any later FDA guidance or enforcement documents currently in effect. For a complete list of currently and previously payable device categories related to pass-through payments and

specific definitions of such device categories, refer to [http://www.cms.hhs.gov/HospitalOutpatientPPS/Downloads/DeviceCats\\_OPSSUpdate.pdf](http://www.cms.hhs.gov/HospitalOutpatientPPS/Downloads/DeviceCats_OPSSUpdate.pdf)

## **61.1 - Requirement that Hospitals Report Device Codes on Claims on Which They Report Specified Procedures**

*(Rev.1702, Issued: 03-13-09, Effective: 04-01-09, Implementation: 04-06-09)*

Effective January 1, 2005, hospitals paid under the OPSS (bill types 12X and 13X) that report procedure codes that require the use of devices must also report the applicable HCPCS codes and charges for all devices that are used to perform the procedures where such codes exist and are designated with a status indicator of “N” (for packaged payment) or “H” (for pass-through device payment) in the OPSS Addendum B that applies to the date of service. If there are device HCPCS codes with status indicators other than “N” or “H” that describe devices that are used to perform the procedure or that are furnished because they are necessary for the function of an implanted device, hospitals should report the charges for those other devices on an uncoded revenue code line, but should not report the HCPCS codes for those items. Typically, payment for the costs of all internal and external components required for the function of a nonpass-through device is packaged into the APC payment for the associated procedure in which the device is used. Accurate reporting of HCPCS codes and charges for these internal and external device components is necessary so that the OPSS payment for the associated procedures will be correct in future years in which the claims are used to set the APC payment rates.

*Manufacturers frequently package a number of individual items used with a device in a particular procedure. In cases of devices that are described by device category HCPCS codes whose pass-through status has expired, or HCPCS codes that describe devices without pass-through status, and that are packaged in kits with other items used in a particular procedure, hospitals may consider all kit costs in their line-item charge for the associated device/device category HCPCS code that is assigned status indicator “N” for packaged payment. That is, hospitals may report the total charge for the whole kit with the associated device/device category HCPCS code. Payment for device/device category HCPCS codes without pass-through status is packaged into payment for the procedures in which they are used, and these codes are assigned status indicator “N.” In the case of a device kit, should a hospital choose to report the device charge alone under a device/device category HCPCS code with SI=“N,” the hospital should report charges for other items that may be included in the kit on a separate line on the claim. Hospitals may use the same revenue code to report all components of the kit.*

## **230.2 - Coding and Payment for Drug Administration**

*(Rev.1702, Issued: 03-13-09, Effective: 04-01-09, Implementation: 04-06-09)*

### **A. Overview**

Drug administration services furnished under the Hospital Outpatient Prospective Payment System (OPPS) during CY 2005 were reported using CPT codes 90780, 90781, and 96400-96459.

Effective January 1, 2006, some of these CPT codes were replaced with more detailed CPT codes incorporating specific procedural concepts, as defined and described by the CPT manual, such as initial, concurrent, and sequential.

Hospitals are instructed to use the full set of CPT codes, including those codes referencing concepts of initial, concurrent, and sequential, to bill for drug administration services furnished in the hospital outpatient department beginning January 1, 2007. In addition, hospitals are instructed to continue billing the HCPCS codes that most accurately describe the service(s) provided.

Hospitals are reminded to bill a separate Evaluation and Management code (with modifier 25) only if a significant, separately identifiable E/M service is performed in the same encounter with OPPS drug administration services.

### **B. Billing for Infusions and Injections**

Beginning in CY 2007, hospitals were instructed to use the full set of drug administration CPT codes (90760-90779; 96401-96549), (96413-96523 beginning in CY 2008) *(96360-96549 beginning in CY 2009)* when billing for drug administration services provided in the hospital outpatient department. In addition, hospitals are to continue to bill HCPCS code C8957 (Intravenous infusion for therapy/diagnosis; initiation of prolonged infusion (more than 8 hours), requiring use of portable or implantable pump) when appropriate. Hospitals are expected to report all drug administration CPT codes in a manner consistent with their descriptors, CPT instructions, and correct coding principles. Hospitals should note the conceptual changes between CY 2006 drug administration codes effective under the OPPS and the CPT codes in effect beginning January 1, 2007, in order to ensure accurate billing under the OPPS. Hospitals should report all HCPCS codes that describe the drug administration services provided, regardless of whether or not those services are separately paid or their payment is packaged.

Medicare's general policy regarding physician supervision within hospital outpatient departments meets the physician supervision requirements for use of CPT codes 90760-90779, 96401-96549, (96413-96523 beginning in CY 2008). (Reference: Medicare Benefit Policy Manual, Pub.100-02, Chapter 6, §20.4.1.)

*Drug administration services are to be reported with a line item date of service on the day they are provided. In addition, only one initial drug administration service is to be reported per vascular access site per encounter, including during an encounter where observation services span more one calendar day.*

### **C. Payments For Drug Administration Services**

For CY 2007, OPSS drug administration APCs were restructured, resulting in a six-level hierarchy where active HCPCS codes have been assigned according to their clinical coherence and resource use. Contrary to the CY 2006 payment structure that bundled payment for several instances of a type of service (non-chemotherapy, chemotherapy by infusion, non-infusion chemotherapy) into a per-encounter APC payment, structure introduced in CY 2007 provides a separate APC payment for each reported unit of a separately payable HCPCS code.

Hospitals should note that the transition to the full set of CPT drug administration codes provides for conceptual differences when reporting, such as those noted below.

- In CY 2006, hospitals were instructed to bill for the first hour (and any additional hours) by each type of infusion service (non-chemotherapy, chemotherapy by infusion, non-infusion chemotherapy). Beginning in CY 2007, the first hour concept no longer exists. CPT codes in CY 2007 and beyond allow for only one initial service per encounter, for each vascular access site, no matter how many types of infusion services are provided; however, hospitals will receive an APC payment for the initial service and separate APC payment(s) for additional hours of infusion or other drug administration services provided that are separately payable .
- In CY 2006, hospitals providing infusion services of different types (non-chemotherapy, chemotherapy by infusion, non-infusion chemotherapy) received payment for the associated per-encounter infusion APC even if these infusions occurred during the same time period. Beginning in CY 2007, CPT instructions allow reporting of only one initial drug administration service, including infusion services, per encounter for each distinct vascular access site, with other services through the same vascular access site being reported via the sequential, concurrent or additional hour codes.

**(NOTE:** This list above provides a brief overview of a limited number of the conceptual changes between CY 2006 OPSS drug administration codes and CY 2007 OPSS drug administration codes - this list is not comprehensive

and does not include all items hospitals will need to consider during this transition)

For APC payment rates, refer to the most current quarterly version of Addendum B on the CMS Web site at <http://www.cms.hhs.gov/HospitalOutpatientPPS/>.

#### **D. Infusions Started Outside the Hospital**

Hospitals may receive Medicare beneficiaries for outpatient services who are in the process of receiving an infusion at their time of arrival at the hospital (e.g., a patient who arrives via ambulance with an ongoing intravenous infusion initiated by paramedics during transport). Hospitals are reminded to bill for all services provided using the HCPCS code(s) that most accurately describe the service(s) they provided. This includes hospitals reporting an initial hour of infusion, even if the hospital did not initiate the infusion, and additional HCPCS codes for additional or sequential infusion services if needed.

#### **231 - Billing and Payment for Blood, Blood Products, *and Stem Cells and Related Services* Under the Hospital Outpatient Prospective Payment System (OPPS)**

*(Rev.1702, Issued: 03-13-09, Effective: 04-01-09, Implementation: 04-06-09)*

#### **231.1 - When a Provider Paid Under the OPPS Does Not Purchase the Blood or Blood Products That It Procures from a Community Blood Bank, or When a Provider Paid Under the OPPS Does Not Assess a Charge for Blood or Blood Products Supplied by the Provider's Own Blood Bank Other Than Blood Processing and Storage**

*(Rev.1702, Issued: 03-13-09, Effective: 04-01-09, Implementation: 04-06-09)*

When an OPPS provider furnishes blood or a blood product collected by its own blood bank for which only processing and storage costs are assessed, or when an OPPS provider procures blood or a blood product from a community blood bank for which it is charged only the processing and storage costs incurred by the community blood bank, the OPPS provider bills the processing and storage charges using Revenue Code 0390 (Blood Processing/Storage), *0392 (Blood Processing/Storage; Processing and Storage)*, or 0399 (Blood Processing /Storage; Other Processing and Storage), along with the appropriate blood HCPCS code, the number of units transfused, and the line item date of service (LIDOS). Processing and storage costs may include blood product collection, safety testing, retyping, pooling, irradiating, leukocyte-reducing, freezing, and thawing blood products, along with the costs of blood delivery, monitoring, and storage. In general,

such categories of processing costs are not patient-specific. There are specific blood HCPCS codes for blood products that have been processed in varying ways, and these codes are intended to make payment for the variable resource costs of blood products that have been processed differently.

*Most OPPS providers obtain blood or blood products from community blood banks that charge only for processing and storage, and not for the blood itself. These hospitals should follow the instructions outlined in this section. Those OPPS providers that incur a charge for the blood product itself, in addition to the charge for processing and storage, should follow the coding requirements outlined in §231.2.*

### **231.2 - When a Provider Paid Under the OPSS Purchases Blood or Blood Products from a Community Blood Bank or When a Provider Paid Under the OPSS Assesses a Charge for Blood or Blood Products Collected By Its Own Blood Bank That Reflects More Than Blood Processing and Storage**

*(Rev.1702, Issued: 03-13-09, Effective: 04-01-09, Implementation: 04-06-09)*

If an OPSS provider pays for the actual blood or blood product itself, in addition to paying for processing and storage costs when blood or blood products are supplied by either a community blood bank or the OPSS provider's own blood bank, the OPSS provider must separate the charge for the unit(s) of blood or blood product(s) from the charge for processing and storage services. The OPSS provider reports charges for the blood or blood product itself using Revenue Code series 038X (excluding 0380, which is not a valid revenue code for Medicare billing) with the LIDOS, the number of units transfused, and the appropriate blood product HCPCS code and HCPCS modifier BL. The OPSS provider reports charges for processing and storage services on a separate line using Revenue Code 0390, *0392*, or 0399 with the LIDOS, the number of units transfused, and the appropriate blood product HCPCS code and HCPCS modifier BL. The same LIDOS, the same number of units, the same HCPCS code, and HCPCS modifier BL must be reported on **both** lines. This requirement applies to all OPSS providers that transfuse blood *and incur charges for both the blood itself and processing and storage.*

Effective for services furnished on or after July 1, 2005, the I/OCE will return to providers any claim that reports a charge for blood or blood products using Revenue Code 038X without a separate line for processing and storage services using Revenue Code 0390, *0392*, or 0399. Moreover, in order to process to payment, both lines must report the same line item date of service, the same number of units, and the same HCPCS code accompanied by modifier BL. Payment for blood and blood products is based on the Ambulatory Payment Classification (APC) Group to which its HCPCS code is assigned, multiplied by the number of units transfused.

Units of whole blood or packed red cells for which only processing and storage charges are reported are not subject to the blood deductible. The Medicare blood deductible is applicable only if the OPPS provider purchases whole blood or packed red cells from a community blood bank or if the OPPS provider assesses a charge that reflects more than blood processing and storage for whole blood or packed red cells collected by its own blood bank. If the beneficiary has not already fulfilled the annual blood deductible or replaced the blood, OPPS payment will be made for processing and storage costs only. The beneficiary is liable for the blood portion of the payment as the blood deductible. In order to ensure correct application of the Medicare blood deductible, providers should report charges for whole units of packed red cells using Revenue Code 381 (Packed red cells), and should report charges for whole units of whole blood using Revenue Code 382 (Whole blood). Revenue Codes 381 and 382 should be used only to report charges for packed red cells and whole blood, respectively.

Please note that *most hospitals obtain blood or blood products from community blood banks that charge only for processing and storage, rather than for the blood itself*. The blood coding requirements discussed in this section do not apply to blood and blood products carrying only a processing and storage fee; when billing only for blood processing and storage, OPPS providers should follow the coding requirements outlined in §231.1.

**EXAMPLE:** An OPPS provider purchases 2 units of leukocyte-reduced red blood cells from a community blood bank and incurs a charge for the red cells themselves, and a charge for the blood bank's processing and storage of the red blood cell unit. The OPPS provider further incurs costs related to additional processing and storage of the red blood cell units after the OPPS provider has received the 2 units. A Medicare beneficiary is transfused the two units of leukocyte-reduced red blood cells.

The OPPS provider should report the charges for 2 units of P9016 by separately billing the red blood cell charges and the total processing and storage charges incurred. The charges for the red blood cell units are to be reported on one line with the date the blood was transfused, Revenue Code series 038X (excluding 380), 2 units, HCPCS code P9016, and modifier BL. The total charges for processing and storage are to be reported on the same claim, on a separate line, showing the date the blood was transfused, Revenue Code 390, *0392*, or 399, 2 units, HCPCS code P9016, and modifier BL. Note that HCPCS modifier BL is reported on both lines.

### ***231.10 - Billing for Autologous Stem Cell Transplants***

***(Rev.1702, Issued: 03-13-09, Effective: 04-01-09, Implementation: 04-06-09)***

*The hospital bills and shows all charges for autologous stem cell harvesting, processing, and transplant procedures based on the status of the patient (i.e., inpatient or outpatient) when the services are furnished. It shows charges for the actual transplant, described by*

*the appropriate ICD-9-CM procedure or CPT codes, in revenue center code 0362 or another appropriate cost center.*

*The CPT codes describing autologous stem cell harvesting procedures may be billed and are separately payable under the Outpatient Prospective Payment System (OPPS) when provided in the hospital outpatient setting of care. Autologous harvesting procedures are distinct from the acquisition services described in Pub. 100-04, Chapter 3, §90.3.3 for allogeneic stem cell transplants, which include services provided when stem cells are obtained from a donor and not from the patient undergoing the stem cell transplant.*

*The CPT codes describing autologous stem cell processing procedures also may be billed and are separately payable under the OPPS when provided to hospital outpatients.*

### ***231.11 - Correct Coding Initiative (CCI) Edits***

***(Rev.1702, Issued: 03-13-09, Effective: 04-01-09, Implementation: 04-06-09)***

*The OPPS providers should be aware that certain CCI edits may apply when billing for blood and blood product services. The OPPS providers should consult the most current list of CCI edits to determine whether they apply to the services or HCPCS blood product codes being reported. A file with the most current list of CCI edits applicable to Medicare Part B services paid by fiscal intermediaries under the OPPS is available at: <http://www.cms.hhs.gov/NationalCorrectCodInitEd/NCCIEHOPPS/list.asp>*