

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services



News Flash – The Centers for Medicare & Medicaid Services (CMS) is pleased to announce the scheduled release of modifications to the Healthcare Common Procedure Coding System (HCPCS) code set. These changes have been posted at http://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS_Quarterly_Update.html on the HCPCS website. Changes are effective on the date indicated on the update.

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Related Change Request (CR) #: CR 7847

Related CR Release Date: June 8, 2012

Effective Date: July 1, 2012

Related CR Transmittal #: R2483CP and R157BP

Implementation Date: July 2, 2012

July 2012 Update of the Hospital Outpatient Prospective Payment System

Provider Types Affected

This MLN Matters® Article is intended for providers and suppliers who submit claims to Medicare contractors (Fiscal Intermediaries (FIs), A/B Medicare Administrative Contractors (A/B MACs), and/or Regional Home Health Intermediaries (RHHIs)) for services provided to Medicare beneficiaries and paid under the Outpatient Prospective Payment System (OPPS).

Provider Action Needed

This article is based on Change Request (CR) 7847 which describes changes to and billing instructions for various payment policies implemented in the July 2012 OPPS update. Be sure your billing staffs are aware of these changes.

Background

CR7847 describes changes to and billing instructions for various payment policies implemented in the July 2012 OPPS update. The July 2012 Integrated Outpatient Code Editor (I/OCE) and OPPS Pricer will reflect the Healthcare Common Procedure Coding System (HCPCS), Ambulatory Payment Classification (APC), HCPCS Modifier, and Revenue Code additions, changes, and deletions identified in this Change Request (CR).

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The July 2012 revisions to I/OCE data files, instructions, and specifications are provided in CR7841, "July 2012 Integrated Outpatient Code Editor (I/OCE) Specifications Version 13.2." A related article is available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM7841.pdf> on the Centers for Medicare & Medicaid Services (CMS) website. The key changes in the July 2012 update are as follows:

Changes to Device Edits for July 2012

Claims for OPPS services must pass two types of device edits to be accepted for processing: procedure-to-device edits and device-to-procedure edits. Procedure-to-device edits, which have been in place for many procedures since 2005, continue to be in place. These edits require that when a particular procedural HCPCS code is billed, the claim must also contain an appropriate device code. Procedures for which both a Device A and Device B are specified require that at least one each of a Device A and Device B be present on the claim (i.e., there must be some combination of a Device A with a Device B in order to pass the edit). Device B can be reported with any Device A for the same procedural HCPCS code.

Since January 1, 2007, CMS also has required that a claim that contains one of a specified set of device codes be returned to the provider if it fails to contain an appropriate procedure code. CMS has determined that the devices contained in this list cannot be correctly reported without one of the specified procedure codes also being reported on the same claim. Where these devices were billed without an appropriate procedure code prior to January 1, 2007, the cost of the device was being packaged into the median cost for an incorrect procedure code and therefore inflated the payment for the incorrect procedure code. In addition, hospitals billing devices without the appropriate procedure code were being incorrectly paid. The device-to-procedure edits are designed to ensure that the costs of these devices are assigned to the appropriate APC in OPPS rate setting.

The most current edits for both types of device edits can be found under "Device, Radiolabeled Product, and Procedure Edits" at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/> on the CMS website.. Failure to pass these edits will result in the claim being returned to the provider.

On April 1, 2012, HCPCS code C1882 (Cardioverter defibrillator, other than single or dual chamber (implantable)) was removed from the list of those devices required to be billed with CPT code 33249 (Insertion or replacement of permanent pacing cardioverter-defibrillator system with transvenous lead(s), single or dual chamber) on the procedure-to-device edit list, retroactive to January 1, 2012. Based on clinical input from hospitals and other interested stakeholders, HCPCS code C1882 is being reinstated as a device code that can satisfy the edit for CPT code 33249, retroactive to January 1, 2012.

Category III CPT Codes

The American Medical Association (AMA) releases Category III CPT codes twice per year: in January, for implementation beginning the following July, and in July, for implementation beginning the following January. As discussed in the CY 2006 OPPS final rule with comment period (70 FR 68567), CMS modified its process for implementing the Category III codes that the AMA releases each January for implementation in July to ensure timely collection of data pertinent to the services

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described by the codes; to ensure patient access to the services the codes describe; and to eliminate potential redundancy between Category III CPT codes and some of the C-codes that are payable under the OPSS and were created by CMS in response to applications for new technology services.

For the July 2012 update, CMS is implementing in the OPSS seven (7) Category III CPT codes that the AMA released in January 2012 for implementation on July 1, 2012. All seven (7) Category III CPT codes are separately payable under the hospital OPSS. The Category III CPT codes, status indicators, and APCs are shown in Table 1 below. Payment rates for these services can be found in Addendum B of the July 2012 OPSS Update that is posted at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html> on the CMS website.

Table 1 -- Category III CPT Codes Implemented as of July 1, 2012

CPT Code	Long Descriptor	SI	APC
0302T	Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; complete system (includes device and electrode)	T	0089
0303T	Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; electrode only	T	0106
0304T	Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; device only	T	0090
0305T	Programming device evaluation (in person) of intracardiac ischemia monitoring system with iterative adjustment of programmed values, with analysis, review, and report	S	0690
0306T	Interrogation device evaluation (in person) of intracardiac ischemia monitoring system with analysis, review, and report	S	0690
0307T	Removal of intracardiac ischemia monitoring device	T	0105
0308T*	Insertion of ocular telescope prosthesis including removal of crystalline lens	T	0234

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*HCPCS code C9732 (Insertion of ocular telescope prosthesis including removal of crystalline lens) was deleted June 30, 2012, and replaced with CPT code 0308T effective July 1, 2012.

New Instructions for Device Pass-Through Category C1840

Effective July 1, 2012, device pass-through category C1840 must be billed with CPT code 0308T (Insertion of ocular telescope prosthesis including removal of crystalline lens) to receive pass-through payment, because C9732 is deleted effective June 30, 2012. CPT code 0308T is assigned to APC 0234 (Level IV Anterior Segment Eye Procedures), as was C9732, so no change in the device offset for C1840 is necessary. See the OPSS Web page at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/> for the CY 2012 device offset for APC 0234.

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.

Hospitals are reminded that under the OPSS, 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 descriptor, HCPCS descriptors 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 July 1, 2012

For CY 2012, payment for nonpass-through drugs, biologicals and therapeutic radiopharmaceuticals 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, biological or therapeutic radiopharmaceutical. In CY 2012, 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. Note that for the third quarter of CY 2012, 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 was suspended beginning January 1, 2009. Should the Part B Drug CAP program be reinstated sometime during CY 2012, CMS would again use the Part B

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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 2012 OPSS/ASC final rule with comment period, CMS 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 July 2012 release of the OPSS PRICER. The updated payment rates, effective July 1, 2012 will be included in the July 2012 update of the OPSS Addendum A and Addendum B, which will be posted at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html> the CMS website.

b. Drugs and Biologicals with OPSS Pass-Through Status Effective July 1, 2012
 Two drugs and biologicals have been granted OPSS pass-through status effective July 1, 2012. These items, along with their descriptors and APC assignments, are identified in Table 2 below.

Table 2 -- Drugs and Biologicals with OPSS Pass-Through Status Effective July 1, 2012

HCPCS Code	Long Descriptor	APC	Status Indicator Effective 7/1/12
C9368*	Grafix core, per square centimeter	9368	G
C9369*	Grafix prime, per square centimeter	9369	G

NOTE: The HCPCS codes identified with an "*" indicate that these are new codes effective July 1, 2012.

c. New HCPCS Codes Effective July 1, 2012 for Certain Drugs and Biologicals

Six new HCPCS codes have been created for reporting certain drugs and biologicals (other than new pass-through drugs and biologicals listed above in Table 2) in the hospital outpatient setting for July 1, 2012. These codes are listed in Table 3 below and are effective for services furnished on or after July 1, 2012.

Table 3 -- New HCPCS Codes Effective for Certain Drugs and Biologicals Effective July 1, 2012

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HCPCS Code	Long Descriptor	APC	Status Indicator Effective 7/1/12
Q2045*	Injection, human fibrinogen concentrate, 1 mg	1414	K
Q2046**	Injection, aflibercept, 1 mg	1420	G
Q2047	Injection, Peginesatide, 0.1 MG (for ESRD on Dialysis)	N/A	A
Q2048***	Injection, doxorubicin hydrochloride, liposomal, doxil, 10 mg	7046	K
Q2049	Injection, doxorubicin hydrochloride, liposomal, imported lipodox, 10 mg	1421	K
Q2034	Influenza virus vaccine, split virus, for intramuscular use (Agriflu)	N/A	L

*Level II HCPCS code J1680 (Injection, human fibrinogen concentrate, 100 mg) will be replaced with HCPCS code Q2045 effective July 1, 2012. The status indicator for HCPCS code J1680 will change to E, "Not Payable by Medicare", effective July 1, 2012.

**Level II HCPCS code C9291 (Injection, aflibercept, 2 mg vial) will be deleted June 30, 2012, and replaced with HCPCS code Q2046 effective July 1, 2012.

***Level II HCPCS code J9001 (Injection, doxorubicin hydrochloride, all lipid formulations, 10 mg) will be replaced with HCPCS code Q2048 effective July 1, 2012. The status indicator for HCPCS code J9001 will change to E, "Not Payable by Medicare", effective July 1, 2012.

d. Adjustment to the Status Indicator for Certain HCPCS Codes Effective April 1, 2012

Effective April 1, 2012, the status indicators for several HCPCS codes listed in Table 4 below will change from SI=E (not paid by Medicare when submitted on outpatient claims (any outpatient bill type)) to SI=K (paid under OPPS; separate APC payment). For the remainder of CY 2012, these HCPCS codes will be separately paid and the price will be updated on a quarterly basis.

The payment rates for these HCPCS codes are listed in Table 4 below and have been installed in the July 2012 OPPS Pricer effective for services furnished on April 1, 2012 through the implementation of the July 2012 update.

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Table 4 -- Adjustment to Status Indicators for Certain Drugs and Biologicals Effective April 1, 2012

HCPCS Code	Long Descriptor	APC	Status Indicator Effective 4/1/12	Payment Rate	Minimum Unadjusted Copayment Rate
90581	Anthrax vaccine, for subcutaneous or intramuscular use	1422	K	\$112.86	\$22.57
J2265	Injection, minocycline hydrochloride, 1 mg	1423	K	\$0.57	\$0.11
J8650	Nabilone, oral, 1 mg	1424	K	\$22.99	\$4.60
Q0174	Thiethylperazine maleate, 10 mg, oral, fda approved prescription anti-emetic, for use as a complete therapeutic substitute for an iv anti-emetic at the time of chemotherapy treatment, not to exceed a 48 hour dosage regimen	1425	K	\$0.80	\$0.16
Q4123	Alloskin rt, per square centimeter	1427	K	\$13.77	\$2.75
Q4125	Arthroflex, per square centimeter	1428	K	\$123.61	\$24.72
Q4128	Flexhd or allopatch hd, per square centimeter	1429	K	\$39.93	\$7.99
Q4129	Unite biomatrix, per square centimeter	1430	K	\$35.49	\$7.10

e. Correct Reporting of Biologicals When Used As Implantable Devices

When billing for products that are used as either a surgically implanted or inserted biological or as a skin substitute, hospitals should report the appropriate HCPCS code for the product. Implantable biologicals with pass-through status receive separate payment, but for those that do not have pass-through status, the OPBS payment for the implanted biological is packaged into the payment for the associated procedure. Products that can be used as either a skin substitute or as an implantable biological will only be separately paid when billed with a skin substitute application procedure. Units should be reported in multiples of the units included in the HCPCS descriptor. Providers and hospitals should not bill the units based on the way the implantable biological is packaged, stored, or stocked, if different from the HCPCS descriptor. 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.

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Inpatient Only List

Section 1833(t)(1)(B)(i) of the Social Security Act allows CMS to define the services for which payment under the OPSS is appropriate and the Secretary has determined that the services designated to be "inpatient only" services are not appropriate to be furnished in a hospital outpatient department. Medicare billing instructions in the "Medicare Claims Processing Manual," Chapter 4, Sections 10.12 and 180.7, for inpatient only reporting guidelines are being clarified to state that procedures removed from the "inpatient only" list may be appropriately furnished in both the inpatient and outpatient settings and such procedures continue to be payable when furnished in the inpatient setting.

Drugs Treated as Hospital Outpatient Supplies

Language has also been added to Chapter 15, Section 50.2 of the "Medicare Benefit Policy Manual" to discuss drugs treated as hospital outpatient supplies. The revised chapter is attached to CR7847. That language is as follows:

In certain circumstances, Medicare pays for drugs that may be considered usually self-administered by the patient when such drugs function as supplies. This is the case when the drugs provided are an integral component of a procedure or are directly related to it, i.e., when they facilitate the performance of or recovery from a particular procedure. Except for the applicable copayment, hospitals may not bill beneficiaries for these types of drugs because their costs, as supplies, are packaged into the payment for the procedure with which they are used. Listed below are examples of when drugs are treated as supplies and hospitals should bill Medicare for the drug as a supply and should not separately bill the beneficiary.

- Sedatives administered to a patient while he or she is in the preoperative area being prepared for a procedure.
- Mydriatic drops instilled into the eye to dilate the pupils, anti-inflammatory drops, antibiotic drops/ointments, and ocular hypotensives that are administered to a patient immediately before, during, or immediately following an ophthalmic procedure. This does not refer to the patient's eye drops that the patient uses pre-and postoperatively.
- Barium or low osmolar contrast media provided integral to a diagnostic imaging procedure.
- Topical solution used with photodynamic therapy furnished at the hospital to treat nonhyperkeratotic actinic keratosis lesions of the face or scalp.
- Antibiotic ointments such as bacitracin, placed on a wound or surgical incision at the completion of a procedure.

The following are examples of when a drug is not directly related or integral to a procedure, and does not facilitate the performance of or recovery from a procedure. Therefore the drug is not considered a packaged supply. In many of these cases the drug itself is the treatment instead of being integral or directly related to the procedure, or facilitating the performance of or recovery from a particular procedure.

- Drugs given to a patient for his or her continued use at home after leaving the hospital.

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- Oral pain medication given to an outpatient who develops a headache while receiving chemotherapy administration treatment.
- Daily routine insulin or hypertension medication given preoperatively to a patient.
- A fentanyl patch or oral pain medication such as hydrocodone, given to an outpatient presenting with pain.
- A laxative suppository for constipation while the patient waits to receive an unrelated X-ray.

These two lists of examples may serve to guide hospitals in deciding which drugs are supplies packaged as a part of a procedure, and thus may be billed under Part B. Hospitals should follow CMS' guidance for billing drugs that are packaged and paid as supplies, reporting coded and uncoded drugs with their charges under the revenue code associated with the cost center under which the hospital accumulates the costs for the drugs.

Corrected OPPS Payment Rates for July 2012

CMS made corrections to the CY 2012 OPPS payment rates issued in the CY 2012 OPPS/ASC final rule with comment period (CMS-1525-FC), in a correction notice published in the Federal Register on January 4, 2012 (CMS-1525-CN). CMS made additional corrections to CMS-1525-FC, in a correction notice published in the Federal Register on April 24, 2012. The July 2012 addenda A and B are impacted by these corrections and reflect the corrected rates. These payment rates are retroactive to dates of service beginning with January 1, 2012. To view the revised OPPS payment rates, see the July 2012 addenda posted at <http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html> on the CMS website. Providers who think they may have received an incorrect payment between January 1, 2012 and June 30, 2012, may request contractor adjustment of the previously processed claims.

Hospital Outpatient Therapy Services

Medicare pays for physical therapy, occupational therapy, and speech language pathology services that are furnished to hospital outpatients at the applicable amount under the physician fee schedule. The manual language has been revised to clarify that the site of service and other requirements in chapter 6, section 20 of the "Medicare Benefit Policy Manual" do not apply to these services when they are furnished "as therapy," meaning under a therapy plan of care. The paragraph on End Stage Renal Disease (ESRD) services has been edited to clarify that the requirements in section 20 do not apply to services that are covered and paid under the ESRD prospective payment system. The revised manual section is attached to CR7847.

Supervision Levels for Hospital Outpatient Therapeutic Services

In the Calendar Year (CY) 2012 OPPS /ASC Final Rule, CMS established a process to obtain independent advice from the Hospital Outpatient Payment Panel regarding the appropriate supervision levels for individual hospital outpatient therapeutic services. Based on the Panel's recommendations to CMS at its meeting on February 27-28, 2012, CMS is issuing changes to the required supervision levels for 28 HCPCS codes effective July 1, 2012. These changes are an attachment to one of the transmittals of CR7847, which is at <http://www.cms.hhs.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R157BP.pdf> on the CMS website.

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Coverage Determinations

The fact that a drug, device, procedure or service is assigned a HCPCS code and a payment rate under the OPPS does not imply coverage by the Medicare program, but indicates only how the product, procedure, or service may be paid if covered by the program. 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.

Additional Information

The official instruction, CR 7847, was issued to your Medicare contractor regarding this change in two transmittals. The first updates the " Medicare Benefit Policy Manual" and it may be viewed at <http://www.cms.hhs.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R157BP.pdf> on the CMS website. The second provides claims processing requirements and it is at <http://www.cms.hhs.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2483CP.pdf> on the same site.

If you have any questions, please contact your Medicare contractor at their toll-free number, which may be found at <http://www.cms.hhs.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/CallCenterTollNumDirectory.zip> on the CMS website.

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