



News Flash – Health care providers, health plans, clearinghouses and vendors should be finished with their internal testing of the Version 5010 HIPAA electronic health care transaction standards by the first recommended deadline for internal testing, December 31, 2010, and be ready to start testing with their external partners, beginning in January 2011, just about four months away. Please visit <http://www.cms.gov/Medicare/Coding/ICD10/index.html> for the latest news and sign up NOW for Version 5010 and ICD-10 e-mail updates!

MLN Matters® Number: MM7117 **Revised**

Related Change Request (CR) #: 7117

Related CR Release Date: October 1, 2010

Effective Date: October 1, 2010

Related CR Transmittal #: R2061CP

Implementation Date: October 4, 2010

Note: This article was updated on December 10, 2012, to reflect current Web addresses. This article was previously updated on December 10, 2012, to reflect current Web addresses. This article was previously revised on October 3, 2010, to reflect revisions made to CR 7117 on October 1, 2010. In this article, the CR release date, transmittal number, and the Web address for accessing CR 7117 were revised. All other information remains the same.

October 2010 Update of the Hospital Outpatient Prospective Payment System (OPPS)

Provider Types Affected

Providers submitting claims to Medicare contractors (Fiscal Intermediaries (FIs), A/B Medicare Administrative Contractors (A/B MACs), and/or Regional Home Health Intermediaries (RHHIs)) for services subject to the OPPS that are provided to Medicare beneficiaries are affected.

Provider Action Needed

This article is based on Change Request (CR) 7117 which provides the October 2010 update for the OPPS and describes changes to and billing instructions for various payment policies implemented in the OPPS. The October 2010 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 CR 7117. October 2010 revisions to I/OCE data files, instructions, and specifications are provided in CR 7111 titled "October 2010 Integrated Outpatient Code Editor

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(I/OCE) Specifications Version 11.3." An MLN Matters® article related to CR7111 is available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM7111.pdf> on the Centers for Medicare & Medicaid Services (CMS) website.

Background

Key changes to and billing instructions for various payment policies implemented in the October 2010 OPPS update are as follows:

Procedure and Device Edits for October 2010

Procedure to device edits require that when a particular procedural HCPCS code is billed, the claim must also contain an appropriate device code. Failure to pass these edits will result in the claim being returned to the provider. Procedures for which both a Device A and a Device B are specified require that at least one each of 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.

Device to procedure edits require 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. The updated lists of both types of edits can be found under "Device, Radiolabeled Product, and Procedure Edits" at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html> on the CMS website.

New Device Pass-Through Category

The Social Security Act (Section 1833(t)(6)(B); see http://www.ssa.gov/OP_Home/ssact/title18/1833.htm on the Internet) 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) also requires that the Center for Medicare & Medicaid Services (CMS) create additional categories for transitional pass-through payment of new medical devices not described by existing or previously existing categories of devices.

CMS is establishing one new device category as of October 1, 2010, and the following table provides a listing of new coding and payment information concerning the new device category for transitional pass-through payment.

Table 1: New Device Pass-Through Codes

| HCPCS | Effective Date | SI | APC | Short Descriptor | Long Descriptor | Device Offset from Payment |
|-------|----------------|----|------|----------------------------|---|----------------------------|
| C1749 | 10-01-10 | H | 1749 | Endo, colon, retro imaging | Endoscope, retrograde imaging/illumination colonoscope device (implantable) | \$0 |

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The Social Security Act (Section 1833(t)(6)(D)(ii)) requires that CMS deduct from pass-through payments for devices an amount that reflects the portion of the APC payment amount that CMS determines is associated with the cost of the device (70 FR 68627-8; see 2005 Federal Register, Vol. 70, page 68627 at <http://www.gpoaccess.gov/fr/retrieve.html> on the Internet). CMS has determined that they are not able to identify a portion of the APC payment amount associated with the cost of the device, that is, Endoscope, retrograde imaging/illumination colonoscope device (implantable), in APC 143, Lower GI Endoscopy. The Device Offset from Payment represents this deduction from pass-through payments for category C1749, when it is billed with a service included in APC 143. Therefore, CMS is establishing an offset amount for C1749 of \$0 and will not make any deductions from pass-through payment for category C1749.

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 should note 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 October 1, 2010

For Calendar Year (CY) 2010, payment for nonpass-through drugs, biologicals and therapeutic radiopharmaceuticals is made at a single rate of ASP plus 4 percent, which provides payment for both the acquisition cost and pharmacy overhead costs associated with the drug, biological, or therapeutic radiopharmaceutical. In CY 2010, a single payment of ASP plus 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. We note that for the third quarter of CY 2010, payment for drugs and biologicals with pass-through status is

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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 2010, CMS 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 2010 OPPS/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 October 2010 release of the OPPS Pricer. The updated payment rates, effective October 1, 2010, will be included in the October 2010 update of the OPPS Addendum A and Addendum B, which will be posted on the CMS Web site.

b. Drugs and Biologicals with OPPS Pass-Through Status Effective October 1, 2010

Five drugs and biologicals have been granted OPPS pass-through status effective October 1, 2010. These items, along with their descriptors and APC assignments, are identified in Table 2 below.

Table 2: Drugs and Biologicals with OPPS Pass-Through Status Effective October 1, 2010

| HCPCS Code | Long Descriptor | APC | Status Indicator Effective 10/1/10 |
|------------|---|------|------------------------------------|
| C9269* | Injection, C-1 esterase inhibitor (human), Berinert, 10 units | 9269 | G |
| C9270* | Injection, immune globulin (Gammalex), intravenous, non-lyophilized (e.g. liquid), 500 mg | 9270 | G |
| C9271* | Injection, velaglucerase alfa, 100 units | 9271 | G |
| C9272* | Injection, denosumab, 1 mg | 9272 | G |
| 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 | 9273 | G |

NOTE: The "*" indicate that these are new codes effective October 1, 2010.

c. Supplemental Information on 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-

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GM-CSF in 250 mL 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, the language given in the long descriptor of Provenge that states "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.

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

The payment rate for HCPCS code 90476 was incorrect in the April 2010 OPSS Pricer. The corrected payment rate is listed in Table 3 below and has been installed in the October 2010 OPSS Pricer, effective for services furnished on April 1, 2010, through implementation of the July 2010 update.

Table 3: Updated Payment Rate for HCPCS Code 90476 Effective April 1, 2010, through June 30, 2010

| HCPCS Code | Status Indicator | APC | Short Descriptor | Corrected Payment Rate | Corrected Minimum Unadjusted Copayment |
|------------|------------------|------|----------------------------|------------------------|--|
| 90476 | K | 1254 | Adenovirus vaccine, type 4 | \$72.17 | \$14.43 |

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

The payment rates for several HCPCS codes were incorrect in the July 2010 OPSS Pricer. The corrected payment rates are listed in Table 4 below and have been installed in the October 2010 OPSS Pricer, effective for services furnished on July 1, 2010, through implementation of the October 2010 update.

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Table 4: Updated Payment Rates for Certain HCPCS Codes Effective July 1, 2010, through September 30, 2010

| HCPCS Code | Status Indicator | APC | Short Descriptor | Corrected Payment Rate | Corrected Minimum Unadjusted Copayment |
|------------|------------------|------|--------------------------|------------------------|--|
| J9264 | K | 1712 | Paclitaxel protein bound | \$9.22 | \$1.84 |
| C9268 | G | 9268 | Capsaicin patch | \$25.55 | \$5.01 |

- f. Adjustment to Status Indicator for CPT Code 90670 Effective April 1, 2010**
 CPT code 90670 (Pneumococcal vacc, 13 val im) was erroneously assigned status indicator "K" effective April 1, 2010, in the July 2010 update issued in CR 6996 (see <http://www.cms.gov/Transmittals/downloads/R1980CP.pdf> on the CMS website). Therefore, retroactively effective April 1, 2010, the status indicator for CPT code 90670 will change from status indicator "K" (paid under OPPS; separate APC payment) to status indicator "L" (Not paid under OPPS. Paid at reasonable cost; not subject to deductible or coinsurance). Beginning April 1, 2010, CPT code 90670 will be paid at reasonable cost.
- g. Payment for Vaccine CPT Code 90662**
 CPT code 90662 (Influenza virus vaccine, split virus, preservative free, enhanced immunogenicity via increased antigen content, for intramuscular use) has been assigned status indicator "E". However, 90662 received approval from the FDA on December 23, 2009. Therefore, effective December 23, 2009, CPT code 90662 is assigned status indicator "L" (Not paid under OPPS. Paid at reasonable cost; not subject to deductible or coinsurance). CPT code 90662 will be paid at reasonable cost.
- h. Correct Reporting of 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. 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. 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. In circumstances where the implanted biological has pass-through status, either as a biological or a device, a separate payment for the biological or device is made. In circumstances where the implanted biological does not have pass-through status, the OPPS payment for the biological is packaged into the payment for the associated procedure.

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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 OPPI, 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.

i. 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, 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 the Medicare Claims Processing Manual, Chapter 17, Section 40, CMS encourages hospitals to use drugs efficiently and in a clinically appropriate manner. However, CMS also recognizes that hospitals 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.

j. Reporting of Outpatient Diagnostic Nuclear Medicine Procedures

With the specific exception of HCPCS code C9898 (Radiolabeled product provided during a hospital inpatient stay) to be reported by hospitals on outpatient claims for nuclear medicine procedures to indicate that a radiolabeled product that provides the radioactivity necessary for the reported diagnostic nuclear medicine procedure was provided during a hospital inpatient stay, hospitals should only report HCPCS codes for products they provide in the hospital

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outpatient department and should not report a HCPCS code and charge for a radiolabeled product on the nuclear medicine procedure-to-radiolabeled product edit list solely for the purpose of bypassing those edits present in the I/OCE.

CMS stated in the October 2009 OPSS update that in the rare instance when a diagnostic radiopharmaceutical may be administered to a beneficiary in a given calendar year prior to a hospital furnishing an associated nuclear medicine procedure in the subsequent calendar year, hospitals are instructed to report the date the radiolabeled product is furnished to the beneficiary as the same date that the nuclear medicine procedure is performed. CMS believes that this situation is extremely rare and expects that the majority of hospitals will not encounter this situation.

When a radiolabeled product is administered in one hospital and the nuclear medicine scan is subsequently performed at another hospital, hospitals should comply with the OPSS policy that requires that radiolabeled products be reported and billed with nuclear medicine scans. In these specific cases, the hospital that bills for the nuclear medicine procedure would receive payment for both the nuclear medicine procedure and the radiolabeled product since a hospital cannot bill and be paid for a radiolabeled product solely submitted on a claim. In order for the hospital that administers the radiolabeled product to be paid, hospitals may enter into an arrangement (under section 1861 (w)(1) of the Act and as discussed in 42 CFR 410.28(a)(1) and defined in 42 CFR 409.3) where the hospital that administers the nuclear medicine scan pays the appropriate amount for the radiolabeled product to the hospital that administers the radiolabeled product. CMS considers the radiolabeled product and the nuclear medicine scan to be part of one procedure and expects both services to be performed together.

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 OPSS providers to bill for certain MRA services that were previously non-covered but may now be covered at local Medicare contractor discretion. 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 OPSS 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)). CMS has changed the assignment of CPT codes 72159 and 73225 from status indicator "E" to status indicator "B" to indicate that these codes are not recognized by OPSS when submitted on an outpatient hospital Part B bill type 12x or 13x.

Under the hospital OPSS, these new HCPCS codes are assigned status indicator "Q3" to indicate that these services will be paid with one composite APC payment each time a hospital bills for

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second and subsequent imaging procedures in the same imaging family on a single date of service. The standard (non-composite) APC will be assigned when there are no other imaging procedures in the same imaging family present on the claim for the same date of service. The I/OCE logic will determine the assignment of the composite APCs for payment.

Table 5 – MRA Codes

| HCPCS Code | Long Descriptor | Composite APC | Standard (Non-Composite) APC |
|------------|--|---------------|------------------------------|
| C8931 | Magnetic resonance angiography with contrast, spinal canal and contents | 8008 | 0284 |
| C8932 | Magnetic resonance angiography without contrast, spinal canal and contents | 8007 or 8008 | 0336 |
| C8933 | Magnetic resonance angiography without contrast followed by with contrast, spinal canal and contents | 8008 | 0337 |
| C8934 | Magnetic resonance angiography with contrast, upper extremity | 8008 | 0284 |
| C8935 | Magnetic resonance angiography without contrast, upper extremity | 8007 or 8008 | 0336 |
| C8936 | Magnetic resonance angiography without contrast followed by with contrast, upper extremity | 8008 | 0337 |

Clarification on Billing for Observation Services on Condition Code 44 Claims

CR 7117 includes as an attachment, an update to the Medicare Claims Processing Manual (Chapter 1, Section 50.3) which clarifies billing for observation services on Condition Code 44 claims. The following is an extract from that attachment:

“When Condition Code 44 is appropriately used, the hospital reports on the outpatient bill the services that were ordered and provided to the patient for the entire patient encounter. However, in accordance with the general Medicare requirements for services furnished to beneficiaries and billed to Medicare, even in Condition Code 44 situations, hospitals may not report observation services using HCPCS code G0378 (Hospital observation service, per hour) for observation services furnished during a hospital encounter prior to a physician's order for observation services. Medicare does not permit retroactive orders or the inference of physician orders. Like all hospital outpatient services, observation services must be ordered by a physician. The clock time begins at the time that observation services are initiated in accordance with a physician's order.”

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“While hospitals may not report observation services under HCPCS code G0378 for the time period during the hospital encounter prior to a physician’s order for observation services, in Condition Code 44 situations, as for all other hospital outpatient encounters, hospitals may include charges on the outpatient claim for the costs of all hospital resources utilized in the care of the patient during the entire encounter. For example, a beneficiary is admitted as an inpatient and receives 12 hours of monitoring and nursing care, at which point the hospital changes the status of the beneficiary from inpatient to outpatient and the physician orders observation services, with all criteria for billing under Condition Code 44 being met. On the outpatient claim on an uncoded line with revenue code 0762, the hospital could bill for the 12 hours of monitoring and nursing care that were provided prior to the change in status and the physician order for observation services, in addition to billing HCPCS code G0378 for the observation services that followed the change in status and physician order for observation services. For other rules related to billing and payment of observation services, see Chapter 4 Section 290 of this manual, and Chapter 6 Section 20.6 of the Medicare Benefit Policy Manual (IOM Pub. 100-02).”

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.

Additional Information

The official instruction, CR 7117, issued to your FIs, A/B MACs, and/or RHHs regarding this change may be viewed at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2061CP.pdf> on the CMS website.

If you have any questions, please contact your FIs, A/B MACs, and/or RHHs at their toll-free number, which may be found at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html> on the CMS website.

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