



Medicare will cover immunizations for H1N1 influenza also called the "swine flu." There will be no coinsurance or copayment applied to this benefit, and beneficiaries will not have to meet their deductible. For more information, go to www.cms.gov/About-CMS/Agency-Information/H1N1/index.html on the CMS website.

MLN Matters Number: MM6857

Related Change Request (CR) #: 6857

Related CR Release Date: February 26, 2010

Effective Date: April 1, 2010

Related CR Transmittal #: R1924CP

Implementation Date: April 5, 2010

Note: This article was revised on June 6, 2014, to add a reference to MLN Matters® article MM8636 (<http://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnmattersarticles/downloads/MM8636.pdf>) to alert DMEPOS suppliers to the updated procedures that DME MACs will now follow in pursuing payment under a surety bond. All other information remains the same.

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

Provider Types Affected

Providers submitting claims to Medicare contractors (fiscal intermediaries (FIs), Medicare Administrative Contractors (MACs), and/or Regional Home Health Intermediaries (RHHIs)) for outpatient services provided to Medicare beneficiaries and paid under the OPSS.

Provider Action Needed

This article is based on change request (CR) 6857, which describes changes to the OPSS to be implemented in the April 2010 OPSS update. Be sure billing staffs are aware of these changes.

Background

April 2010 OPSS Update

Change Request (CR) 6857 describes changes to and billing instructions for various payment policies implemented in the April 2010 OPSS update. The April 2010 Integrated

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Outpatient Code Editor (I/OCE) and OPPS Pricer will reflect the HCPCS, Ambulatory Payment Classification (APC), HCPCS Modifier, and Revenue Code additions, changes, and deletions identified in this notification.

April 2010 revisions to I/OCE data files, instructions, and specifications are provided in CR 6857, "April 2010 Integrated Outpatient Code Editor (I/OCE) Specifications Version 11.1."

Key OPPS Updates for April 2010

1. Procedure and Device Edits for April 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. 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 www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html on the CMS website.

2. Editing of Hospital Part B Inpatient Services

Blood and blood products are not included in the list of services that may be covered when furnished to persons who are inpatients, but for whom no Medicare inpatient coverage is available. Therefore, no Part B payment may be made for them.

The Medicare Claims Processing Manual, Chapter 4, Section 240.1 is revised to add revenue codes 038x (Blood and Blood Components) and 039x (Administration, Processing and Storage for Blood and Blood Components) to the table of revenue codes that are not allowed to be reported on a claim for payment of services furnished to hospital inpatients for whom there is no Medicare Part A coverage of their inpatient hospital care (12x type of bill (TOB)).

The instruction is also revised to reflect that these edits are currently locally controlled by the Medicare A/B MAC or FI and are not imbedded in the FI Standard System.

For more information, you may view the *Medicare Benefits Policy Manual*, Chapter 6, Section 2 for the services for which payment may be made under the Part B Medicare hospital outpatient benefit for services to hospital inpatients and the *Medicare Claims Processing Manual*, Chapter 4, Section 240 for claims processing instructions for these claims.

3. Clarification to Coding Requirements for Pulmonary Rehabilitation Services Furnished On or After January 1, 2010

Section 140.4 .1 (Coding Requirements for Pulmonary Rehabilitation Services Furnished On or After January 1, 2010), Chapter 32 in the *Medicare Claims Processing Manual*, is being revised to reflect instructions to hospitals and practitioners' offices for reporting respiratory or pulmonary services furnished to a patient when those services do not meet the diagnosis and coverage criteria for pulmonary rehabilitation services.

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4. Warfarin Testing

Effective August 3, 2009, Medicare covers pharmacogenomic testing to predict warfarin responsiveness only in the context of an approved, clinical study, in addition to the coverage criteria outlined in the *Medicare National Coverage Determinations (NCD) Manual*, Chapter 1, Section 90.1, and in the *Medicare Claims Processing Manual*, Chapter 32, Section 240. New Level II HCPCS code G9143 was developed to enable implementation of this new coverage policy. Pharmacogenomic testing for warfarin response is a once-in-a-lifetime test absent any reason to believe that the patient's personal genetic characteristics would change over time.

Under the hospital OPPS, HCPCS code G9143 will be assigned status indicator "A" effective in the April 2010 update, and payment for this lab test will be made under the clinical lab fee schedule (CLFS). However, because of CLFS payment requirements and the timing of creation of the new code, HCPCS code G9143 does not appear in the CY 2010 CLFS with an assigned rate. Therefore, its CY 2010 payment will be determined by Medicare FIs and/or A/B MACs.

Medicare FIs and/or A/B MACs will determine the hospital outpatient payment rate for HCPCS code G9143 in the same manner that payment rates for unlisted laboratory CPT codes are currently determined. The reporting hospital's FI or A/B MAC will contact the carrier or A/B MAC in the reporting hospital's jurisdiction to obtain an appropriate payment amount for HCPCS code G9143. If that carrier or A/B MAC cannot provide a payment amount for the service, then to establish a payment rate, the hospital's FI or A/B MAC should contact the carrier or A/B MAC in the jurisdiction of the reference laboratory that performed the test. If neither carrier nor A/B MAC has a payment amount for HCPCS code G9143 and the FI or A/B MAC for the reporting hospital determines that the service is covered, that FI or A/B MAC must determine the payment amount.

Further information on billing and coverage for warfarin testing can be found in CR 6715 issued December 18, 2009, (under Transmittals 111 and 1880). These transmittals are available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R111NCD.pdf> and <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1889CP.pdf> on the CMS website.

Table 1—Warfarin Testing

HCPCS	Long Descriptor	APC	SI
G9143	Warfarin responsiveness testing by genetic technique using any method, any number of specimen(s)	NA	A

5. Human Immunodeficiency Virus (HIV) Screening Tests

The Centers for Medicare and Medicaid Services (CMS) has determined that screening for HIV infection, which is recommended with a grade of A by the U.S. Preventive Services Task Force (USPSTF) for certain individuals, is reasonable and necessary for early detection of HIV and is appropriate for individuals entitled to benefits under Part A or enrolled under Part B. Therefore, effective December 8, 2009, Medicare covers HIV screening tests for beneficiaries that are at

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increased risk for HIV infection per the USPSTF guidelines and beneficiaries that are pregnant whose diagnosis of pregnancy is known during the third trimester and at labor.

Three new Level II HCPCS G-codes were created to implement this new coverage decision. The three HCPCS G-codes (G0432, G0433, and G0435) describe both standard and Food and Drug Administration (FDA)-approved rapid HIV screening tests. Under the hospital OPPS, HCPCS G-codes G0432, G0433, and G0435 will be assigned status indicator “A” effective in the April 2010 update. Payment for these tests will be made under the CLFS.

However, because of CLFS payment requirements and the timing of creation of the new codes, HCPCS codes G0432, G0433, and G0435 do not appear in the CY 2010 CLFS with assigned rates. Therefore, payment for them must be determined by Medicare FIs and/or A/B MACs. Medicare FIs and/or A/B MAC will determine the hospital outpatient payment rates for HCPCS codes G0432, G0433, and G0435 in the same manner that the payment rates for unlisted laboratory Current Procedural Terminology (CPT) codes are currently determined.

The reporting hospital’s FI or A/B MAC will contact the carrier or A/B MAC in the reporting hospital’s jurisdiction to obtain an appropriate payment amount for HCPCS codes G0432, G0433, and G0435. If that carrier or A/B MAC cannot provide a payment amount for the service, then to establish a payment rate, the hospital’s FI or A/B MAC should contact the carrier or A/B MAC in the jurisdiction of the reference laboratory that performed the test. If neither carrier nor A/B MAC has a payment amount for the HCPCS G-code and the FI or A/B MAC for the reporting hospital determines that the service is covered, that FI or A/B MAC must determine the payment amount. Further information on coverage for HIV screening tests under this new coverage decision can be found in a separate CR, which will be released shortly.

Table 2—HIV Testing

HCPCS	Long Descriptor	APC	SI
G0432	Infectious agent antigen detection by enzyme immunoassay (EIA) technique, qualitative or semi-quantitative, multiple-step method, HIV-1 or HIV-2, screening	NA	A
G0433	Infectious agent antigen detection by enzyme-linked immunosorbent assay (ELISA) technique, antibody, HIV-1 or HIV-2, screening	NA	A
G0435	Infectious agent antigen detection by rapid antibody test of oral mucosa transudate, HIV-1 or HIV-2, screening	NA	A

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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.

Hospitals are reminded 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 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, 2010

For CY 2010, payment for non-pass-through drugs, biologicals and therapeutic radiopharmaceuticals is made at a single rate of ASP + 4 percent, which provides payment for both the acquisition and pharmacy overhead costs associated with the drug, biological or therapeutic radiopharmaceutical. In CY 2010, a single payment of ASP + 6 percent for pass-through drugs, biologicals and radiopharmaceuticals is made to provide payment for both the acquisition and pharmacy overhead costs of these pass-through items. For the second quarter of CY 2010, 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 2010, Medicare 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, 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, Medicare will incorporate changes to the payment rates in the April 2010 release of the OPPS Pricer. The updated payment rates, effective April 1, 2010, will be included in the April 2010 update of the OPPS Addendum A and Addendum B, which will be posted on the CMS website.

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

Six drugs and biologicals have newly been granted OPPS pass-through status, effective April 1, 2010. These items, along with their descriptors and APC assignments, are identified in Table 3 below.

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Table 3—Drugs and Biologicals with New OPSS Pass-Through Status Effective April 1, 2010

HCPCS Code	Long Descriptor	APC	Status Indicator Effective April 1, 2010
C9258	Injection, telavancin, 10 mg	9258	G
C9259	Injection, pralatrexate, 1 mg	9259	G
C9260	Injection, ofatumumab, 10 mg	9260	G
C9261	Injection, ustekinumab, 1 mg	9261	G
C9262	Fludarabine phosphate, oral, 1 mg	9262	G
C9263	Injection, ecallantide, 1 mg	9263	G

c. Updated Payment Rate for HCPCS Code J9031 Effective January 1, 2009 through March 31, 2009

The payment rate for one HCPCS code was incorrect in the January 2009 OPSS Pricer. The corrected payment rate is listed in Table 4 below and has been installed in the April 2010 OPSS Pricer, effective for services furnished on January 1, 2009, through implementation of the April 2009 update.

Table 4—Updated Payment Rate for HCPCS Code J9031 Effective January 1, 2009 through March 31, 2009

HCPCS Code	Status Indicator	APC	Short Descriptor	Corrected Payment Rate	Corrected Minimum Unadjusted Copayment
J9031	K	0809	Bcg live intravesical vac	\$118.96	\$23.79

Note: Medicare contractors may adjust as appropriate claims previously paid under the OPSS brought to their attention that:

1. Have dates of service that fall on or after January 1, 2009, but prior to April 1, 2009;
2. Contain HCPCS code listed in Table 4 above; and
3. Were originally processed prior to the installation of the April 2010 OPSS Pricer.

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d. Updated Payment Rates for Certain HCPCS Codes Effective October 1, 2009 through December 31, 2009

The payment rates for several HCPCS codes were incorrect in the October 2009 OPSS Pricer. The corrected payment rates are listed in Table 5 below and have been installed in the April 2010 OPSS Pricer effective for services furnished on October 1, 2009, through implementation of the January 2010 update.

Table 5—Updated Payment Rates for Certain HCPCS Codes Effective October 1, 2009 through December 31, 2009

HCPCS Code	Status Indicator	APC	Short Descriptor	Corrected Payment Rate	Corrected Minimum Unadjusted Copayment
90371	K	1630	Hep b ig, im	\$113.78	\$22.76
J1458	K	9224	Galsulfase injection	\$333.49	\$66.70
J2278	K	1694	Ziconotide injection	\$6.38	\$1.28
J2323	K	9126	Natalizumab injection	\$7.97	\$1.59

Note: Providers should also note that Medicare contractors may adjust as appropriate claims previously paid under the OPSS brought to their attention that:

1. Have dates of service that fall on or after October 1, 2009, but prior to January 1, 2010;
2. Contain HCPCS code listed in Table 5 above; and
3. Were originally processed prior to the installation of the April 2010 OPSS Pricer.

e. 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. 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 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

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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.

Examples:

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.

g. 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 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.

As was stated in the October 2009 OPSS update, 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. This situation is extremely rare and it is expected that the majority of hospitals will not encounter this situation.

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7. 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. FIs and/or 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

For complete details regarding this CR please see the official instruction issued to your Medicare FI, RHHI, or A/B MAC, which may be viewed by going to <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1924CP.pdf> on the CMS website.

If you have questions, please contact your Medicare FI, A/B MAC, or RHHI, 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.

Detailed information about OPSS is available at www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html on the CMS website.

A fact sheet entitled, Hospital Outpatient Prospective Payment System (OPSS), may be found in the Medicare Learning Network catalog. This fact sheet provides general information about the Hospital Outpatient Prospective Payment System, ambulatory payment classifications, and how payment rates are set. The document may be viewed at <http://www.cms.gov/MLNProducts/downloads/HospitalOutpaysysfctsh.pdf> on the CMS website.

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