Medlearn Matters
Information for Medicare Providers
CMS CENTERS for MEDICARE & MEDICAID SERVICES

Related Change Request (CR) #: 3322 **Medlearn Matters Number:** MM3322
Related CR Release Date: June 4, 2004
Related CR Transmittal #: 194
Effective Date: July 1, 2004
Implementation Date: July 6, 2004

MMA - July 2004 Update of the Hospital Outpatient Prospective Payment System (OPPS): Payment for Drugs, Biologicals, and Radiopharmaceuticals

Provider Types Affected

Hospitals and other providers paid under the OPPS

Provider Action Needed

This instruction outlines changes in the Outpatient Prospective Payment System (OPPS) for the July 1, 2004 quarterly update. Unless otherwise noted, all changes in this instruction are effective for services furnished on or after July 1, 2004.

Background

This instruction describes changes to the Hospital OPPS, to be implemented in the July 2004 update. The July 2004 Outpatient Code Editor (OCE) and OPPS PRICER will reflect the Healthcare Common Procedure Coding System (HCPCS) codes and ambulatory payment classification (APC) additions, changes, and other revisions identified in this notification. Unless otherwise noted, all changes addressed in this notification are effective for services furnished on or after July 1, 2004.

Certain information provided reflects changes resulting from enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) on December 8, 2003. An Interim Final Rule with comment period describing these changes was published in the Federal Register on January 6, 2004 (69 FR 820). In addition, Change Requests CR3144 and CR3145, issued February 27, 2004, and CR 3154, issued March 30, 2004, also addresses changes resulting from the MMA.

1. Payment for Drugs and Biologicals Recently Approved by the FDA

a. Beginning in 2004, the MMA requires payment at 95 percent of average wholesale price (AWP) for new drugs and biologicals after FDA approval but before it receives a product-specific HCPCS code.
b. For services furnished on or after the designated effective date in Table B1, through June 30, 2004, payment for the drugs and biologicals in Table B1 will be made at 95 percent of AWP.

Disclaimer
Medlearn Matters articles are prepared as a service to the public and are not intended to grant rights or impose obligations. Medlearn Matters articles may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations, and other interpretive materials for a full and accurate statement of their contents.

c. For services furnished on or after the designated effective date in Table B1, through June 30, 2004, beneficiary copayment will equal 20 percent of the designated payment rate.

d. Effective July 1, 2004, the drugs and biologicals in Table B1 are approved for payment as pass-through drugs and biologicals (see section 2, below).

e. Hospitals that used a different HCPCS code to bill for the drugs and biologicals listed in Table B1 that were furnished prior to installation of the July 2004 release may submit adjustment bills.

f. The "Effective Date of Payment Rate" listed in Table B1 reflects the date the drug or biological received FDA approval. Claims submitted with dates of service prior to these effective dates will receive OCE edit code 67, "Service provided prior to FDA approval." OCE edits are also addressed in the July 2004 OCE update (CR3314).

Table B1 - Payment for Drugs and Biologicals Recently Approved by the FDA

HCPCS	SI	APC	Short Descriptor	Long Descriptor	Payment Rate	Minimum Unadjusted Copayment	Effective Date of Payment Rate
C9213	K	9213	Injection, Pemetrexed	Injection, Pemetrexed, per 10 mg	$46.31	$9.26	02/04/04
C9214	K	9214	Injection, Bevacizumab	Injection, Bevacizumab, per 10 mg	$65.31	$13.06	02/26/04
C9215	K	9215	Injection, Cetuximab	Injection, Cetuximab, per 10 mg	$54.72	$10.94	02/12/04
C9216	K	9216	Abarelix, Inject Suspension	Abarelix for Injectable Suspension, per 10 mg	$89.72	$17.94	01/01/04
C9217	K	9300	Injection, Omalizumab	Injection, Omalizumab, per 5 mg	$17.14	$3.43	01/01/04

2. Drugs and Biologicals Newly-Approved for Pass-Through Payment

a. The drugs and biologicals listed in Table B2 have been designated as eligible for pass-through payment under the OPPS effective July 1, 2004. The effective date of pass-through status for C9213, C9214, C9215, C9216 and C9217 coincides with the date of assignment of product-specific HCPCS codes for each of these drugs.

b. Pass-through payment for the drugs and biologicals listed in Table B2 equals 95 percent of AWP.

c. The minimum unadjusted copayment amounts for the drugs and biologicals listed in Table B2 is calculated in accordance with pass-through payment rules and, therefore, is different from the minimum unadjusted copayment amounts listed in Table B1.

Disclaimer
Medlearn Matters articles are prepared as a service to the public and are not intended to grant rights or impose obligations. Medlearn Matters articles may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations, and other interpretive materials for a full and accurate statement of their contents.

Table B2 - Drugs and Biologicals Newly Approved for Pass-Through Payment

HCPCS	SI	APC	Short Descriptor	Long Descriptor	Payment Rate	Minimum Unadjusted Copayment	Effective Date of Pass-Through Status
C9213	G	9213	Injection, Pemetrexed	Injection, Pemetrexed, per 10 mg	$46.31	$6.92	07/01/04
C9214	G	9214	Injection, Bevacizumab	Injection, Bevacizumab, per 10 mg	$65.31	$9.76	07/01/04
C9215	G	9215	Injection, Cetuximab	Injection, Cetuximab, per 10 mg	$54.72	$8.18	07/01/04
C9216	G	9216	Abarelix, Inject Suspension	Abarelix for Injectable Suspension, per 10 mg	$89.72	$13.41	07/01/04
C9217	G	9300	Injection, Omalizumab	Injection, Omalizumab, per 5 mg	$17.14	$2.56	07/01/04

3. Billing and Payment for Fulvestrant, J9395

Effective January 1, 2004, CMS is correcting the payment rate for J9395, Injection, Fulvestrant, per 25 mg. Medicare fiscal intermediaries shall mass adjust payment for claims with J9395 that were incorrectly paid for services furnished January 1, 2004 through June 30, 2004 and which were processed prior to installation of the July 2004 OPPS PRICER by the fiscal intermediaries. Providers need take no action to effect these adjustments.

HCPCS	SI	APC	Short Descriptor	Payment Rate	Minimum Unadjusted Copayment
J9395	G	9120	Injection, Fulvestrant, per 25 mg	$81.57	$13.63

4. Misclassified Radiopharmaceutical: Billing and Payment for Strontium-89, Chloride, Generic versus Brand Name Form

In the January 6, 2004 interim final rule, CMS inadvertently misclassified Strontium-89, Chloride as a sole-source product. Strontium-89, Chloride should have been listed in CR 3144, "April 2004 Changes to the Hospital Outpatient Prospective Payment System (OPPS): Payment for Drugs, Biologicals and Radiopharmaceuticals, Generic Versus Brand Name." In this CR, CMS addressed coding and payment for innovator multiple-source (brand name) drugs and non-innovator multiple-source (generic) drugs, and

Disclaimer
Medlearn Matters articles are prepared as a service to the public and are not intended to grant rights or impose obligations. Medlearn Matters articles may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations, and other interpretive materials for a full and accurate statement of their contents.

implemented HCPCS codes and payment amounts for brand name drugs that CMS was not able to implement in the January 6, 2004 interim final rule.

The new HCPCS codes implemented in the April 2004 OPPS update were required to enable differentiation between the payment amount required under the MMA for a brand name drug and the payment amount required under the MMA for its generic form.

Effective January 1, 2004, Strontium-89, Chloride is classified as a ***multi-source product*** and is implemented with both a generic and brand name HCPCS code and payment amount. Fiscal intermediaries shall mass adjust claims with A9600 that were incorrectly paid for services furnished January 1, 2004 through June 30, 2004 and which were processed prior to installation by the intermediaries of the July 2004 OPPS PRICER. Providers need take no action to effect these adjustments.

HCPCS	SI	APC	Short Descriptor	Long Descriptor	Payment Rate	Minimum Unadjusted Copayment	Effective Date
A9600	K	0701	Strontium-89 Chloride	Supply of Therapeutic Radiopharmaceutical, Strontium-89 Chloride, per mCi	$402.85	$80.57	01/01/04
C9401	K	9401	Strontium-89 Chloride, Brand	Supply of Therapeutic Radiopharmaceutical, Strontium-89 Chloride, Brand Name	$402.85	$80.57	01/01/04

5. Change in Long Descriptor for C9125, Injection, Risperidone, Long Acting, per 12.5 mg

The Long Descriptor for C9125 is changed, effective July 1, 2004, from "Injection, Risperidone, per 12.5 mg" to "Injection, Risperidone, Long Acting, per 12.5 mg."

6. Clarification: Positron Emission Tomography (PET) Scans for Thyroid Cancer and Perfusion of the Heart Using Ammonia N-13

In the October 2003 update of the Hospital OPPS, Transmittal A-03-076, Change Request 2887, CMS provided instructions concerning PET scans for thyroid cancer and perfusion of the heart using Ammonia N-13.

In the October 2003 instruction, CMS incorrectly stated that Q3000 and Q4078 were reportable with G0296. CMS is clarifying this issue and specifying, according to Transmittal AB-03-092, CR 2687, that Q3000 and Q4078 are not reportable with G0296. Rather, Q3000 and Q4078 are only reportable with HCPCS code series G0030-G0047.

Disclaimer
Medlearn Matters articles are prepared as a service to the public and are not intended to grant rights or impose obligations. Medlearn Matters articles may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations, and other interpretive materials for a full and accurate statement of their contents.

7. Reporting Line Item Date of Service for Revenue Code without a HCPCS

In order to accurately determine hospital costs for purposes of updating payment rates for drugs and all other services paid under the hospital OPPS, and in order to package services appropriately, CMS relies on the service line date. Therefore, it is extremely important that the date and charge reported with a revenue code on a line without a HCPCS code represent a single date of service rather than a range of dates.

8. Coverage Determinations

The fact that a drug, device, procedure, or service has 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 shall determine whether a drug, device, procedure, or service meets all program requirements for coverage, for example, that it is reasonable and necessary to treat the beneficiary's condition and whether it is excluded from payment.

Implementation

The implementation date for this instruction is July 6, 2004.

Additional Information

For complete details, please see the official instruction issued to the intermediary which may be viewed by going to:

http://www.cms.hhs.gov/manuals/pm_trans/R194CP.pdf

If you have any questions, please contact your intermediary at their toll-free number, which may be found at:

http://www.cms.hhs.gov/medlearn/tollnums.asp

Disclaimer

Medlearn Matters articles are prepared as a service to the public and are not intended to grant rights or impose obligations. Medlearn Matters articles may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations, and other interpretive materials for a full and accurate statement of their contents.