# CMS Manual System

## Pub. 100-04 Medicare Claims Processing

**Department of Health & Human Services (DHHS)**
**Centers for Medicare & Medicaid Services (CMS)**

**Transmittal 194** **Date: JUNE 4, 2004**

**CHANGE REQUEST 3322**

**I. SUMMARY OF CHANGES:** This transmittal issues a Recurring Update Notification that describes changes to the Hospital Outpatient Prospective Payment System (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. OPPS additions, changes, and other revisions, other than those related to drugs, biologicals and radiopharmaceuticals are addressed in CR 3324, which is being issued separately. This notification includes changes in payment for certain drugs, biologicals, and radiopharmaceuticals that are mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

**NEW/REVISED MATERIAL - EFFECTIVE DATE: July 1, 2004**
***IMPLEMENTATION DATE: July 6, 2004**

***Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. 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:**
**(R = REVISED, N = NEW, D = DELETED)**

| R/N/D | CHAPTER/SECTION/SUBSECTION/TITLE |
|---|---|
| N/A | |

***III. FUNDING:**

**These instructions shall be implemented within your current operating budget.**

**IV. ATTACHMENTS:**

| | |
|---|---|
| | **Business Requirements** |
| | **Manual Instruction** |
| | **Confidential Requirements** |
| | **One-Time Notification** |
| X | **Recurring Update Notification** |

***Medicare contractors only**

# Attachment – Recurring Update Notification

| Pub. 100-04 | Transmittal: 194 | Date: June 4, 2004 | Change Request 3322 |
|---|---|---|---|

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

## I. GENERAL INFORMATION

**A. Background:** This Recurring Update Notification 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. OPPS additions, changes, and other revisions, other than those related to drugs, biologicals and radiopharmaceuticals, are addressed in CR 3324, which is being issued separately.

Certain information provided in this Recurring Update Notification 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). CRs 3144 and 3145, issued February 27, 2004, and CR 3154, issued March 30, 2004, further address these changes.

**B. Policy:**

**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 assignment of product-specific HCPCS codes.

b. For services furnished on or after the designated effective date in Table B1, through June 30, 2004, but prior to the effective date of pass-through status and assignment of a product-specific HCPCS code, payment for the drugs and biologicals in Table B1 will be made at 95 percent of AWP. Pass-through payment for these codes shall continue at 95 percent of AWP.

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 that are submitted with dates of service prior to the specified "Effective Date of Payment Rate" found in Table B1 will receive OCE edit 67, "Service provided prior to FDA approval." OCE edits are addressed in the July 2004 OCE Specifications Recurring Update Notification, CR 3314.

**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. Beginning January 1, 2004, the MMA requires payment at 95 percent of AWP for a drug before it receives a product-specific HCPCS code. Therefore, each of these codes will be paid at 95 percent of AWP for the period prior to assignment of a product-specific HCPCS code, and also for the duration of their pass-through status.

**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, we are correcting the payment rate for J9395, Injection, Fulvestrant, per 25 mg. Fiscal intermediaries shall mass adjust payment for claims with J9395 that were (1) incorrectly paid for services furnished January 1, 2004 through June 30, 2004; and (2) processed prior to installment of the July 2004 OPPS PRICER.

| 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, we 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 which we address coding and payment for innovator multiple-source (brand name) drugs and non-innovator multiple-source (generic) drugs, and in which we implement HCPCS

codes and payment amounts for brand name drugs that we were not able to previously implement in the January 1, 2004 OPPS update. The new HCPCS codes implemented in the April 2004 OPPS update were required to enable us to differentiate 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 (1) incorrectly paid for services furnished January 1, 2004 through June 30, 2004; and (2) processed prior to installment of the July 2004 OPPS PRICER.

| 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, we provided instruction concerning PET scans for thyroid cancer and perfusion of the heart using Ammonia N-13. In the October 2003 instruction, we incorrectly stated that Q3000 and Q4078 were reportable with G0296. We are 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.

**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.

**C. Provider Education:** A provider education article related to this notification will be available at www.cms.hhs.gov/medlearn/matters shortly after the CR is released. You will receive notification of the article release via the established "medlearn 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 1 week of the availability of the provider education article. In addition, the provider education article must be included in your next regularly scheduled bulletin."

## II. BUSINESS REQUIREMENTS

*"Shall" denotes a mandatory requirement*
*"Should" denotes an optional requirement*

| Requirement # | Requirements | Responsibility |
|---|---|---|
| 3322.1 | The shared system maintainer shall install the OPPS PRICER for July 2004. | SSM |
| 3322.2 | FIs 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. | FI |
| 3322.3 | Fiscal intermediaries shall mass adjust payment for claims with J9395 that were (1) incorrectly paid for services furnished January 1, 2004 through June 30, 2004; and (2) processed prior to installment of the July 2004 OPPS PRICER. | FI |

| | | |
|---|---|---|
| 3322.4 | Fiscal intermediaries shall mass adjust claims with A9600 that were (1) incorrectly paid for services furnished January 1, 2004 through June 30, 2004; and (2) processed prior to installment of the July 2004 OPPS PRICER. | FI |

## III. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

### A. Other Instructions: N/A

| X-Ref Requirement # | Instructions |
|---|---|
| | |

### B. Design Considerations: N/A

| X-Ref Requirement # | Recommendation for Medicare System Requirements |
|---|---|
| | |

### C. Interfaces: N/A

### D. Contractor Financial Reporting /Workload Impact: N/A

### E. Dependencies: N/A

### F. Testing Considerations: N/A

## IV. SCHEDULE, CONTACTS, AND FUNDING

| | |
|---|---|
| **Effective Date:** July 1, 2004<br><br>**Implementation Date:** July 6, 2004<br><br>**Pre-Implementation Contact(s):** Melissa Dehn mdehn@cms.hhs.gov<br><br>**Post-Implementation Contact(s):** Regional Office | **These instructions shall be implemented within your current operating budget.** |