

# CMS Manual System

## Pub 100-04 Medicare Claims Processing

Transmittal 691

Department of Health & Human Services (DHHS)

Center for Medicare & Medicaid Services (CMS)

Date: SEPTEMBER 30, 2005

Change Request 4035

*NOTE: Transmittal 662, dated August 26, 2005 is rescinded and replaced with Transmittal 691, dated September 30, 2005. There were changes made in the policy section, the requirement section and in the implementation date. All other information remains the same.*

**SUBJECT: October 2005 Update of the Hospital Outpatient Prospective Payment System (OPPS)**

**I. SUMMARY OF CHANGES:** This Recurring Update Notification describes changes to the OPPS, to be implemented in the October 2005 update. This notification further describes changes to payment policy and billing procedures under the OPPS.

**NEW/REVISED MATERIAL :**

**EFFECTIVE DATE : October 01, 2005**

**IMPLEMENTATION DATE : October 03, 2005**

*The implementation date for the following requirements are dependent on the installment date for the October 2005 OPPS Pricer version released on September 28, 2005:*

- 4035.1
- 4035.1.1
- 4035.1.2

*Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. 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:** (N/A if manual is not updated)

R = REVISED, N = NEW, D = DELETED – *Only One Per Row.*

R/N/D	Chapter / Section / SubSection / Title
-------	--

**III. FUNDING:**

No additional funding will be provided by CMS; Contractor activities are to be carried out within their FY 2005 operating budgets.

**IV. ATTACHMENTS:**

Recurring Update Notification

*\*Unless otherwise specified, the effective date is the date of service.*

# Attachment – Recurring Update Notification

Pub. 100-04	Transmittal: 691	Date: September 30, 2005	Change Request 4035
-------------	------------------	--------------------------	---------------------

*NOTE: Transmittal 662, dated August 26, 2005 is rescinded and replaced with Transmittal 691, dated September 30, 2005. There were changes made in the policy section, the requirement section and in the implementation date. All other information remains the same.*

**SUBJECT: October 2005 Update of the Hospital Outpatient Prospective Payment System (OPPS)**

## I. GENERAL INFORMATION

**A. Background:** This Recurring Update Notification describes changes to the OPSS, to be implemented in the October 2005 update. This notification further describes changes to payment policy and billing procedures under the OPSS. The October 2005 OPSS OCE and OPSS 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 notification. Unless otherwise noted, all changes addressed in this notification are effective for services furnished on or after October 1, 2005. October 2005 revisions to the OPSS OCE data files, instructions, and specifications are provided in Change Request 4007, 'October 2005 Outpatient Prospective Payment System Code Editor (OPSS OCE) Specifications Version 6.3.'

### B. Policy:

#### 1. Expansion of the Device Dependent Edits

Effective April 1, 2005, CMS implemented the first phase of device edits in the OCE. These edits return to providers claims for services in which the provider did not include a code for a major device that is necessary to perform the procedure where there is a HCPCS code for the device.

Effective October 1, 2005, CMS is expanding the device edits to apply to more procedure codes for which the use of a device is essential to the performance of the procedure. Refer to Change Request 4017 'Billing for Devices Under the Hospital Outpatient Prospective Payment System (OPSS)'. These edits can be found at <http://www.cms.hhs.gov/providers/hopps/default.asp>.

These edits have been posted on the CMS website and continuously open to public comment since the issuance of the 2005 OPSS final rule on November 1, 2004. We have incorporated many of the comments we have received into the device edits for implementation on October 1, 2005.

You will note that there are some HCPCS codes for procedures that require a device but for which there are no device edits. This is not an oversight. In some cases, the device codes that exist do not describe all possible devices that could be used in the procedure and, therefore, an edit could return a claim that properly coded the procedure but omitted the device because there is not an appropriate code for the device that was used. In other cases, the procedure is not on the list of procedures that have received

adjusted payment and special scrutiny in the past and, therefore, no device editing is being applied at this time. CMS may, in the future, expand the device edits.

Comments or questions about the content of the edits should be directed to [Outpatientpps@cms.hhs.gov](mailto:Outpatientpps@cms.hhs.gov). The inquirer should identify the writer and the HCPCS code involved and should include rationale for why the commenter believes that the edit of concern should be revised.

Claim specific questions should be directed to the Fiscal Intermediary.

## 2. No Cost Device Billing Clarification

In Change Request 3915, transmittal 585 dated June 17, 2005, we provided direction regarding how to report devices for which the hospital incurs no cost. That instruction stated that hospitals paid under the OPSS that surgically implant a device furnished at no cost to the hospital shall report a charge of zero for the device, or, if the hospital's billing system requires that a charge be entered, the hospital shall submit a token charge (e.g. \$1.00) on the line with the device code.

Since the FISS system will only accept a zero for the line reporting surgical procedure, hospitals should submit a token charge (e.g. \$1.00) on the line with the device code and not report a zero charge as previously stated.

## 3. New Service

The following new service is assigned for payment under the OPSS:

HCPCS	Effective Date	SI	APC	Short Descriptor	Long Descriptor	Payment	Minimum Adjusted Copayment
C9725	10/01/05	S	1507	Place endorectal app	Placement of endorectal intracavity applicator for high intensity brachytherapy	\$550.00	\$110.00

## 4. Payment for New Brachytherapy Sources

Section 621(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) established separate payment for brachytherapy devices consisting of a seed or seeds (or radioactive source), based on the hospital's charges for the source(s), adjusted to cost, effective January 1, 2004 through December 31, 2006. CR 3154, issued March 30, 2004, provided instructions regarding this change to billing and payment for brachytherapy sources and identified the applicable codes that became effective for this payment as of January 1, 2004.

The following table lists one new code that may be reported for payment as a brachytherapy source under the OPSS:

HCPCS	Effective Date	SI	APC	Short Descriptor	Long Descriptor
C2637	10/01/05	H	2637	Brachytx, Ytterbium-169	Brachytherapy source, Ytterbium-169, per source

*The formal release of the October OPSS Pricer did not include APC 2637 in a list of brachytherapy codes subject to coinsurance. The October 2005 OPSS Pricer was re-released on September 28, 2005 to include APC 2637 in the list. Contractors will mass adjust affected claims incorrectly processed before the installation of the OPSS Pricer version released on September 28, 2005.*

## 5. Drugs and Biologicals

### a. Drugs with Payments Based on Average Sales Price (ASP) Effective October 1, 2005

The table below lists the drugs and biologicals whose payments under the OPSS will be established in accordance with the ASP methodology that is used to calculate payment for drugs and biologicals in the physician office setting. In the 2005 OPSS final rule (69 FR 65777), it was stated that payments for drugs and biologicals based on ASP will be updated on a quarterly basis as later quarter ASP submissions become available. In cases where adjustments to payment rates are necessary, we will incorporate changes to the payment rates in an appropriate quarterly release of the OPSS PRICER and we will not be publishing the updated payment rates in the program instructions implementing the associated quarterly update of the OPSS. However, the updated payment rates can be found in the October 2005 update of OPSS Addendum A and Addendum B on the CMS web site.

Single-indication orphan drugs payable under OPSS are also listed below. The methodology used to establish payment rates for these drugs is discussed in the 2005 OPSS final rule (69 FR 65807).

HCPCS	APC	Long Description
C9123	9123	Human fibroblast derived temporary skin substitute, per 247 square centimeters
C9127	9127	Injection, paclitaxel protein-bound particles, per 1 mg
C9128	9128	Injection, pegaptamib sodium, per 0.3 mg
C9129	9129	Injection, Clofarabine, per 1 mg
C9203	9203	Injection, Perflexane lipid microspheres, per single use vial
C9205	9205	Injection, Oxaliplatin, per 5 mg
C9206	9206	Collagen-glycosaminoglycan bilayer matrix, per cm <sup>2</sup>
C9211	9211	Injection, Alefacept, for intravenous use per 7.5 mg
C9212	9212	Injection, Alefacept, for intramuscular use per 7.5 mg
C9218	9218	Injection, azacitidine, 1 mg
C9220	9220	Sodium hyaluronate per 30 mg dose, for intra-articular injection
C9221	9221	Acellular dermal tissue matrix, per 16cm <sup>2</sup>

<b>HCPCS</b>	<b>APC</b>	<b>Long Description</b>
C9222	9222	Decellularized soft tissue scaffold, per 1 cc
C9224	9224	Injection, Galsulfase, per 5 mg
C9225	9225	Injection, Fluocinolone acetonide intravitreal implant, per 0.59 mg
C9226	9226	Injection, Ziconotide for intrathecal infusion, per 5 mcg
J0128	9216	Abarelix for injectable suspension, per 10 mg
J0135	1083	Injection, adalimumab, 20 mg
J0180	9208	Injection, IV, Agalsidase beta, per 1 mg
J0205	900	Injection, Alglucerase, per 10 units
J0256	901	Alpha 1 proteinase inhibitor-human, 10 mg
J0595	703	Injection, Butorphanol tartrate 1 mg
J0878	9124	Injection, daptomycin per 1 mg
J1457	1085	Injection, gallium nitrate, 1 mg
J1785	916	Injection imiglucerase, per unit
J1931	9209	Injection, laronidase, 0.1 mg
J2185	729	Injection, meropenem, 100 mg
J2280	1046	Injection, moxifloxacin 100 mg
J2355	7011	Oprelvekin injection, 5 mg
J2357	9300	Injection, omalizumab, per 5 mg
J2469	9210	Injection, palonosetron HCl, 25 mcg
J2783	738	Injection, rasburicase, 0.5 mg
J2794	9125	Injection, risperidone, long acting, 0.5 mg
J3240	9108	Injection Thyrotropin Alpha , 0.9 mg, provided in 1.1 mg vial
J3411	1049	Injection, Thiamine HCL 100 mg
J3415	1050	Injection, Pyridoxine HCL 100 mg
J3465	1052	Injection, voriconazole, 10 mg
J3486	9204	Injection, Ziprasidone mesylate, per 10 mg
J7308	7308	Aminolevulinic acid HCL for topical administration, 20%, single unit dosage form (354mg)
J7513	1612	Daclizumab, parenteral, 25 mg
J7518	9219	Mycophenolic acid, oral, per 180 mg
J7674	867	Methacholine chloride administered as inhalation solution through a nebulizer, per 1mg
J8501	868	Aprepitant, oral, 5 mg
J9010	9110	Alemtuzumab, 10 mg
J9015	807	Aldesleukin, per single use vial
J9017	9012	Arsenic trioxide, 1 mg
J9035	9214	Injection, Bevacizumab, per 10 mg
J9041	9207	Injection, Bortezomib, 0.1 mg
J9055	9215	Injection, Cetuximab, per 10 mg
J9160	1084	Denileukin diftitox, 300 mcg
J9216	838	Interferon gamma 1-b, 3 million units

<b>HCPCS</b>	<b>APC</b>	<b>Long Description</b>
J9300	9004	Gemtuzumab ozogamicin, 5 mg
J9305	9213	Injection, Pemetrexed, per 10 mg
Q2019	1615	Injection, Basiliximab, 20 mg
Q4075	1062	Injection, Acyclovir, 5 mg
Q4076	1070	Injection, Dopamine HCL, 40 mg
Q4077	1082	Injection, Treprostinil, 1 mg
Q4079	9126	Injection, Natalizumab, per 1 mg

**b. Updated Payment Rates for Certain Drugs and Biologicals Effective July 1, 2005 through September 30, 2005**

The payment rates for the drugs and biologicals listed below were incorrect in the July 2005 OPPS PRICER. The corrected payment rates will be installed in the October 2005 OPPS PRICER, effective for services furnished on July 1, 2005 through implementation of the October 2005 update.

<b>HCPCS</b>	<b>APC</b>	<b>Short Description</b>	<b>Corrected Payment Rate</b>	<b>Corrected Minimum Adjusted Copayment</b>
C9129	9129	Inj clofarabine	\$29.21	\$5.84
C9211	9211	Inj, alefacept, IV	\$593.60	\$118.72
J0595	0703	Butorphanol tartrate 1 mg	\$0.94	\$0.19
Q4075	1062	Acyclovir, 5 mg	\$0.03	\$0.01

**c. Newly-Approved Drugs and Biologicals Eligible for Pass-Through Status**

The following drugs and biologicals have been designated as eligible for pass-through status under the OPPS effective October 1, 2005. Payment rates for these items can be found in the October 2005 update of OPPS Addendum A and Addendum B on the CMS web site.

<b>HCPCS</b>	<b>APC</b>	<b>SI</b>	<b>Long Description</b>
C9225	9225	G	Injection, fluocinolone acetonide intravitreal implant, per 0.59 mg
C9226	9226	G	Injection, ziconotide for intrathecal infusion, per 5 mcg

**d. Payment for Drugs and Biologicals Recently Approved by the FDA**

Transmittal 188 (CR 3287), the Medicare Claims Processing Manual, Pub. 100-04 issued May 28, 2004, explains how hospitals may report new drugs and biologicals after the Food and Drug Administration (FDA) approval but before assignment of product-specific HCPCS codes. The MMA requires, beginning in 2004, that payment for new drugs and biologicals after FDA approval but before assignment of product-specific HCPCS codes be equal to 95 percent of Average Wholesale Price. We are assigning the following product-specific HCPCS code for billing a biological that was approved by the FDA on May 31, 2005. Payment rate for this item can be found in the October 2005 update of OPPS Addendum A and Addendum B on the CMS web site.

<b>HCPCS</b>	<b>SI</b>	<b>APC</b>	<b>Short Descriptor</b>	<b>Long Descriptor</b>	<b>Effective Date</b>
C9224	K	9224	Injection, galsulfase	Injection, galsulfase, per 5 mg	5/31/2005

For claims submitted prior to successful implementation of the October 2005 OPPS OCE, hospitals may bill for this biological using HCPCS code C9399, Unclassified Drug or Biological, in accordance with CR 3287. For claims submitted on or after implementation of the October 2005 OPPS OCE, hospitals should bill for this biological using HCPCS code C9224.

**e. Change in the effective date of HCPCS code J8501 (Aprepitant, oral, 5 mg)**

In the July 2005 update of the OPPS, we stated that HCPCS code J8501 was approved for pass-through status effective April 6, 2005. However, a national coverage decision for oral aprepitant was announced with an effective date of April 4, 2005. Therefore, the effective date of pass-through status for J8501 has been changed to April 4, 2005. On or after the implementation of the October 2005 OPPS OCE, hospitals may submit claims for oral aprepitant furnished on April 4, 2005 and April 5, 2005.

**6. Coverage Determinations**

The fact that a drug, device, procedure, or service is assigned an 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 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.

## II. BUSINESS REQUIREMENTS

"Shall" denotes a mandatory requirement

"Should" denotes an optional requirement

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers				Other
						F I S S	M C S	V M S	C W F	
4035.1	FISS shall install the October 2005 OPSS PRICER <i>released by CMS on September 28, 2005.</i>					X				
<i>4035.1.1</i>	<i>Using the October 2005 OPSS Pricer version described in requirement 4035.1, contractors shall mass adjust payment for lines that 1) have line item dates of service on or after October 1, 2005, 2) were processed before installation of the October 2005 Pricer version described in requirement 4035.1, and 3) have HCPCS code C2637.</i>	X	X							
<i>4035.1.2</i>	Using the October 2005 OPSS Pricer <i>version described in requirement 4035.1, contractors shall mass adjust payment for lines that 1) have one of the following HCPCS codes and 2) were previously processed through the July 2005 OPSS PRICER.</i>  C9129, C9211, J0595, Q4075	X	X							
4035.2	Using the October 2005 OPSS OCE, contractors shall mass adjust payment for lines that 1) have HCPCS code J8501, 2) have line item date of service April 4, 2005 or April 5, 2005, and 3) were processed prior to installment of the October 2005 OPSS OCE.	X	X							
4035.3	FIs shall return to providers claims for Injection, galsulfase, per 5 mg billed using HCPCS code C9399 that are submitted after the installation of the October 2005 OPSS OCE.	X	X							

### III. PROVIDER EDUCATION

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers				Other
						F I S S	M C S	V M S	C W F	
4035.4	A provider education article related to this instruction will be available at <a href="http://www.cms.hhs.gov/medlearn/matters">www.cms.hhs.gov/medlearn/matters</a> 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 shall be included in your next regularly scheduled bulletin and incorporated into any educational events on this topic. Contractors are free to supplement Medlearn Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X	X							

### IV. 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

V. SCHEDULE, CONTACTS, AND FUNDING

<p><b>Effective Date*:</b> October 1, 2005</p> <p><b>Implementation Date:</b> October 3, 2005 <i>The implementation date for the following requirements are dependent on the installment date for the October 2005 OPPS Pricer version released on September 28, 2005:</i></p> <ul style="list-style-type: none"><li>• 4035.1</li><li>• 4035.1.1</li><li>• 4035.1.2</li></ul> <p><b>Pre-Implementation Contact(s):</b> Marina Kushnirova <a href="mailto:marina.kushnirova@cms.hhs.gov">marina.kushnirova@cms.hhs.gov</a> Robert Braver <a href="mailto:robert.braver@cms.hhs.gov">robert.braver@cms.hhs.gov</a></p> <p><b>Post-Implementation Contact(s):</b> Regional Office</p>	<p><b>No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2005 operating budgets.</b></p>
--	--

\*Unless otherwise specified, the effective date is the date of service.