CMS Manual System

Pub. 100-04 Medicare Claims Processing

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

Transmittal 188 **Date: MAY 28, 2004**

CHANGE REQUEST 3287

I. SUMMARY OF CHANGES: Describes billing and payment under the hospital outpatient prospective payment system (OPPS) in calendar year 2004 for new drugs and biologicals after the FDA approval but before assignment of product-specific drug/biological HCPCS codes, implementing §621(a)(15) of the Medicare Modernization Act of 2003 (MMA).

NEW/REVISED MATERIAL - EFFECTIVE DATE: January 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
R	17/ Table of Contents
N	17/90.3/ Hospital Outpatient Payment Under OPPS for New, Unclassified Drugs and Biologicals After FDA Approval But Before Assignment of a Product-Specific Drug/Biological HCPCS Code

***III. FUNDING:**

These instructions shall be implemented within your current operating budget.

IV. ATTACHMENTS:

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

***Medicare contractors only**

Attachment - One-Time Notification

Pub. 100-04	Transmittal: 188	Date: May 28, 2004	Change Request 3287

SUBJECT: Hospital Outpatient Billing and Payment under OPPS for New, Unclassified Drugs or Biologicals Approved by the FDA After January 1, 2004, But Before Assignment of a Product-Specific Drug/Biological HCPCS Code

I. GENERAL INFORMATION

A. Background:

- Section 621(a) of the MMA amends Section 1833(t) of the Social Security Act by adding paragraph (15), Payment for New Drugs and Biologicals Until HCPCS Code Assigned. Under this provision, payment for an outpatient drug or biological that is furnished as part of covered outpatient department services for which a product-specific HCPCS code has not been assigned shall be paid an amount equal to 95 percent of average wholesale price (AWP). This provision applies only to payments under the hospital outpatient prospective payment system (OPPS).

B. Policy:

- Beginning January 1, 2004, hospital outpatient departments may bill for new drugs and biologicals that are approved by FDA on or after January 1, 2004, for which pass-through status has not been approved and a C-code and APC payment have not been assigned, as follows:
  - Beginning on and after the date of FDA approval, hospitals may bill for the drug or biological using a new "unclassified" drug/biological code, C9399, Unclassified drug or biological.
  - Hospitals report in the ANSI ASC X-12 837 I in specific locations, or in the "Remarks" section of the CMS-1450 or its electronic equivalent (UB-92 flat file v.6.0) the National Drug Code (NDC), the quantity of the drug that was administered, expressed in the unit of measure applicable to the drug or biological, and the date the drug was furnished to the beneficiary.
  - Fiscal intermediaries (FIs) shall manually price the drug or biological at 95 percent of AWP.
  - FIs shall pay hospitals 80 percent of the calculated price and shall bill beneficiaries 20 percent of the calculated price, after the deductible is met.
  - Drugs/biologicals manually priced at 95 percent of AWP are not eligible for outlier payment.
- Beginning January 1, 2004, CMS will assign a drug/biological, product-specific HCPCS C-code and APC payment to a drug or biological approved by the FDA <u>after</u> January 1, 2004 that is approved for pass-through status.

- The process to apply for pass-through status for a drug or biological is explained on the CMS Web site at www.cms.hhs.gov/regulations/hopps/d&bfr101002.pdf
- C-codes and APC payments for drugs or biologicals approved for pass-through status are implemented prospectively, beginning in July 2004.
- CMS will issue further instructions in the future regarding billing and payment under the 2005 OPPS for drugs or biologicals approved by the FDA after January 1, 2004 for which a product-specific C code has been assigned.

C. Provider Education: A provider education article related to this instruction 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 one 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
3287.1	The OPPS OCE shall assign edit 66 to suspend for manual pricing any hospital outpatient claim (TOB = 13x) containing revenue code 0636, HCPCS code C9399, and NDC number present in Loop 2400 LIN 03 of the 837 I.	FISS SSM
3287.2.	FIs shall manually price drugs and biologicals newly approved by the FDA billed in revenue code 0636 with the unclassified HCPCS code C9399, "Unclassified drug or biological".	FIs
3287.2.1	FIs shall advise hospitals to report such drugs and biologicals in revenue code 0636 with HCPCS code C9399, and showing the following data elements on the ANSI ASC X-12 837 I: the NDC code (Loop 2400 LIN 03), quantity administered (UNITS) expressed in the unit of measure applicable to the drug or biological (Loop 2400 SV205) and line item date of service (LIDOS) (Loop 2400, DTP Date of Service), the CMS-1450, or its electronic equivalent (UB-92 flat file, v.6.0, Record Type	FIs

	90, Field 18).	
3287.2.1.2	FIs shall edit claims for such drugs and biologicals for the presence of the following data elements: NDC code, Quantity administered, and LIDOS. If any are missing or invalid, FIs shall RTP the claim.	FIs
3287.2.2	FIs shall check Redbook for the price for the NDC.	FIs
3287.2.2.1	FIs shall calculate payment at 95 percent of average wholesale price (AWP) for the NDC as listed in Redbook.	FIs
3287.2.3	FIs shall override OCE edit 66 after manual pricing to allow payment to be made.	FIs
3287.2.3.1	FIs shall make payment to hospital outpatient departments for HCPCS code C9399 at 80 percent of 95 percent of AWP for the particular NDC code, after deductible has been met.	FIs
3287.2.3.2	FIs shall instruct providers that beneficiaries are responsible for 20 percent of 95 percent of AWP for the particular NDC code, after deductible has been met.	FIs

III. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions: N/A

B. Design Considerations: N/A

C. Interfaces: Since the OPPS OCE will not assign an APC to HCPCS code C9399, the OPPS Pricer will have no action on this HCPCS code.

D. Contractor Financial Reporting /Workload Impact: Minimal

E. Dependencies: N/A

F. Testing Considerations: N/A

IV. SCHEDULE, CONTACTS, AND FUNDING

Effective Date: January 1, 2004 **Implementation Date:** July 6, 2004	**These instructions shall be implemented within your current operating budget**

Pre-Implementation Contact(s): Joan Sanow (jsanow@cms.hhs.gov) for policy issues, and Cindy Murphy (cmurphy1@cms.hhs.gov) for claims processing issues. **Post-Implementation Contact(s):** Local ROs	

Medicare Claims Processing Manual

Chapter 17 - Drugs and Biologicals

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(Rev. 188, 05-28-04)

90.3 – Hospital Outpatient Payment Under OPPS for New, Unclassified Drugs and Biologicals After FDA Approval But Before Assignment of a Product-Specific Drug or Biological HCPCS Code

Section 621(a) of the MMA amends Section 1833(t) of the Social Security Act by adding paragraph (15), Payment for New Drugs and Biologicals Until HCPCS Code Assigned. Under this provision, payment for an outpatient drug or biological that is furnished as part of covered outpatient department services for which a product-specific HCPCS code has not been assigned shall be paid an amount equal to 95 percent of average wholesale price (AWP). This provision applies only to payments under the hospital outpatient prospective payment system (OPPS).

Beginning January 1, 2004, hospital outpatient departments may bill for new drugs and biologicals that are approved by FDA on or after January 1, 2004, for which pass-through status has not been approved and a C-code and APC payment have not been assigned.