CMS Manual System

Pub. 100-04 Medicare Claims Processing

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

Transmittal 112 **Date: FEBRUARY 27, 2004**

CHANGE REQUEST 3144

I. SUMMARY OF CHANGES: The attached Recurring Update Notification identifies codes and payment amounts for certain multiple source innovator and non-innovator drugs, biologicals, and radiopharmaceuticals that are payable under the hospital outpatient prospective payment system (OPPS). The codes and payment amounts are being implemented in accordance with requirements set forth in the Medicare Prescription Drug, Improvement, and Modernization Act of 2004 (MMA). The OTN provides billing and coding guidance when these products are furnished on or after January 1, 2004 and submitted for payment under the OPPS prior to and following installation of the April 1, 2004 OCE and PRICER.

NEW/REVISED MATERIAL - EFFECTIVE DATE: January 1, 2004
***IMPLEMENTATION DATE: April 5, 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: N/A

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE

***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: 112	Date: February 27, 2004	Change Request 3144

SUBJECT: April 2004 Changes to the Hospital Outpatient Prospective Payment System (OPPS): Payment for Drugs, Biologicals and Radiopharmaceuticals, Generic Versus Brand Name

I. GENERAL INFORMATION

A. Background: This instruction describes changes to the hospital Outpatient Prospective Payment System (OPPS) to be implemented in the April 2004 update. The April 2004 Outpatient Code Editor (OCE) and OPPS PRICER will reflect the Healthcare Common Procedure Coding System (HCPCS) codes and ambulatory payment classification (APC) additions and changes identified in this instruction. Unless otherwise noted, all changes addressed in this instruction are effective for services furnished on or after January 1, 2004. The information provided in this instruction 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). This instruction addresses coding and payment for innovator multiple-source drugs (brand name drugs) and non-innovator multiple-source drugs (generic drugs) only, and implements codes and payment amounts for brand name drugs that we were not able to implement in the January 1, 2004 OPPS update. The new codes implemented in the April 1, 2004 release are 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.

B. Policy:

1. Section 621(a) of the MMA mandates three categories as the basis for payment of radiopharmaceuticals and drugs and biologicals that had pass-through status on or before December 31, 2002 ("specified covered drugs"):
   a. Single source drugs, i.e., drugs for which there are no generic alternatives available on the market, are to be paid between 88 and 95 percent of the Average Wholesale Price (AWP) published in the Red Book on May 1, 2003;
   b. Innovator multiple-source drugs, i.e., drugs that have FDA New Drug Application approval and for which there exists generic alternatives on the market, are to be paid an amount not to exceed 68 percent of the May 1, 2003 AWP; and
   c. Non-Innovator multiple-source drugs, i.e., drugs that do not have FDA New Drug Application approval and are, in effect, generic drugs, are to be paid an amount not to exceed 46 percent of the May 1, 2003 AWP.

2. This instruction implements new HCPCS alphanumeric C-codes and new APCs to describe and set payment amounts for the brand name form of specified covered drugs affected by the MMA requirements. The descriptors for the new alphanumeric C-codes implemented by this instruction include "brand name" to distinguish the new C-codes from existing HCPCS codes, which generally describe the chemical designation of the product without identifying whether the drug is a brand name or generic.

3. Attachment A identifies the specified covered drugs for which there exists both a generic and a brand name form. We list the HCPCS code, APC, Descriptor, Status Indicator, Payment Rate and Copayment amount for both the generic and the brand name forms of each multiple-source specified covered drug, biological, or radiopharmaceutical whose payment is affected by MMA.

4. Billing for specified covered brand name and generic drugs, biologicals, and radiopharmaceuticals furnished on or after January 1, 2004 through March 31, 2004, **prior to installation of the April 1, 2004 release**:
   a. Hospitals shall report the existing HCPCS code for the drug, biological, or radiopharmaceutical, regardless of whether a brand name or a generic product was administered.
   b. Claims reporting the new C-codes for brand name drugs prior to installation of the April 1, 2004 release cannot be processed for payment and will be returned to the provider.

5. Payment amount for specified covered brand name and generic drugs, biologicals, and radiopharmaceuticals furnished on or after January 1, 2004 through March 31, 2004, for claims processed **prior to installation of the April 1, 2004 release**: Payment is based on the payment amount required by MMA for the generic product, which was installed in the January 1, 2004 PRICER.

6. Billing for specified covered brand name and generic drugs, biologicals, and radiopharmaceuticals furnished on or after April 1, 2004, **following installation of the April 1, 2004 release**:
   a. Hospitals shall report the appropriate existing HCPCS code listed in Attachment A when the generic form of a product is furnished.
   b. Hospitals shall report the appropriate new C-code listed in Attachment A when the brand name form of a product is furnished.

7. Payment amount for specified covered brand name and generic drugs, biologicals, and radiopharmaceuticals furnished on or after April 1, 2004, **following installation of the April 1, 2004 release**:
   a. Innovator multiple-source products, i.e., brand name products, are paid an amount not to exceed 68 percent of the May 1, 2003 AWP.
   b. Non-innovator multiple-source products, i.e., generic products, are paid an amount not to exceed 46 percent of the May 1, 2003 AWP.

8. Billing for specified covered brand name and generic drugs, biologicals, and radiopharmaceuticals furnished on or after January 1, 2004 through March 31, 2004, **following installation of the April 1, 2004 release**:
    a. Hospitals shall report the appropriate existing HCPCS code listed in Attachment A when the generic form of a product is furnished.
    b. Hospitals shall report the appropriate new C-code listed in Attachment A when the brand name form of a product is furnished.

9. Payment amount for specified covered brand name and generic drugs, biologicals, and radiopharmaceuticals furnished on or after January 1, 2004 through March 31, 2004, **following installation of the April 1, 2004 release**:
    a. Innovator multiple-source products, i.e., brand name products, are paid an amount not to exceed 68 percent of the May 1, 2003 AWP.
    b. Non-innovator multiple-source products, i.e., generic products, are paid an amount not to exceed 46 percent of the May 1, 2003 AWP.

10. As soon as the April 1, 2004 release is installed, hospitals may submit an adjustment bill utilizing the new C-code for a brand name drug to receive appropriate payment for specified covered brand name drugs administered on or after January 1, 2004 through March 31, 2004 that were processed to payment **prior to installation of the April 1 release**.

11. The C-codes and payment amounts implemented by this instruction apply ONLY to payments under the OPPS. Hospitals that are not paid under the OPPS should continue to bill and be paid for the drugs and biologicals and radiopharmaceuticals listed in Attachment A under existing billing and payment methods.

12. Coding and payment for sole source drugs under the OPPS is addressed in the January 6, 2004 interim final rule with comment period and in a separate notification issuance, Change Request (CR) 3145.

13. Hospitals should be reminded to use revenue code 636 when billing for items with a status indicator = K.

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
3144.1	FIs shall educate providers regarding the proper billing by posting language on their Web site as soon as possible but no later than one week from the issuance of this instruction.	FI
3144.2	FIs shall publish the information contained in this notification in their next regularly scheduled bulletin or listserv.	FI
3144.3	Standard System Maintainers shall install the new OPPS PRICER as part of the April release.	SSM

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: January 1, 2004 **Implementation Date: April 5, 2004** **Pre-Implementation Contact(s): Melissa Dehn at (410) 786-5721** **Post-Implementation Contact(s): Melissa Dehn at (410) 786-5721**	**These instructions shall be implemented within your current operating budget.**

	A	B	C	D	E	F	G	H	I	J	K	L
1	**Attachment A--April 2004 Changes to Hospital Outpatient Prospective Payment System (OPPS): □□**											
2	**Payment for Specified Covered Multiple Source Drugs and Biologicals and Radiopharmaceuticals**											
3	**Codes and Payment Rates for Generic Products**						**Codes and Payment Rates for Brand Name Products**					
4	**HCPCS (Generic)**	**SI**	**APC (Generic)**	**Description (Generic)**	**Payment Rate (Generic)**	**Copayment (Generic)**	**HCPCS (Brand)**	**SI**	**APC**	**Description (Brand)**	**Payment Rate (Brand)**	**Copayment (Brand)**
5	A9505	K	1603	Thallous chloride TL 201/mci	$18.29	$3.66	C9400	K	9400	Thallous chloride, brand	$19.89	$3.98
6	A9517	K	1064	Th I131 so iodide cap millic	$5.48	$1.10	C9402	K	9402	Th I131 so iodide cap, brand	$5.48	$1.10
7	A9528	K	1064	Dx I131 so iodide cap millic	$5.48	$1.10	C9403	K	9403	Dx I131 so iodide cap, brand	$5.48	$1.10
8	A9529	K	1065	Dx I131 so iodide sol millic	$6.49	$1.30	C9404	K	9404	Dx I131 so iodide sol, brand	$6.49	$1.30
9	A9530	K	1065	Th I131 so iodide sol millic	$6.49	$1.30	C9405	K	9405	Th I131 so iodide sol, brand	$6.49	$1.30
10	C1775	K	1775	FDG, per dose (4-40 mCi/ml)	$324.48	$64.90	C9408	K	9408	FDG, brand, per dose	$324.48	$64.90
11	J1190	K	0726	Dexrazoxane HCl injection	$112.48	$22.50	C9410	K	9410	Dexrazoxane HCl inj, brand	$112.48	$22.50
12	J2430	K	0730	Pamidronate disodium /30 MG	$128.74	$25.75	C9411	K	9411	Pamidronate disodium, brand	$174.32	$34.86
13	J7310	K	0913	Ganciclovir long act implant	$86.54	$17.31	C9412	K	9412	Ganciclovir implant, brand	$86.54	$17.31
14	J7317	K	7316	Sodium hyaluronate injection	$67.16	$13.43	C9413	K	9413	Sodium hyaluronate inj, brand	$99.29	$19.86
15	J8560	K	0802	Etoposide oral 50 MG	$21.91	$4.38	C9414	K	9414	Etoposide oral, brand	$27.37	$5.47
16	J9000	K	0847	Doxorubic hcl 10 MG vl chemo	$4.69	$0.94	C9415	K	9415	Doxorubic hcl chemo, brand	$6.61	$1.32
17	J9031	K	0809	Bcg live intravesical vac	$77.54	$15.51	C9416	K	9416	Bcg live intravesical, brand	$103.75	$20.75
18	J9040	K	0857	Bleomycin sulfate injection	$88.32	$17.66	C9417	K	9417	Bleomycin sulfate inj, brand	$130.56	$26.11
19	J9060	K	0813	Cisplatin 10 MG injection	$7.73	$1.55	C9418	K	9418	Cisplatin inj, brand	$11.42	$2.28
20	J9065	K	0858	Inj cladribine per 1 MG	$24.84	$4.97	C9419	K	9419	Inj cladribine, brand	$36.72	$7.34
21	J9070	K	0815	Cyclophosphamide 100 MG inj	$2.77	$0.55	C9420	K	9420	Cyclophosphamide inj, brand	$4.10	$0.82
22	J9093	K	0816	Cyclophosphamide lyophilized	$2.36	$0.47	C9421	K	9421	Cyclophosphamide lyo, brand	$3.50	$0.70
23	J9100	K	0817	Cytarabine hcl 100 MG inj	$1.55	$0.31	C9422	K	9422	Cytarabine hcl inj, brand	$2.28	$0.46
24	J9130	K	0819	Dacarbazine 100 mg inj	$5.31	$1.06	C9423	K	9423	Dacarbazine inj, brand	$5.31	$1.06
25	J9150	K	0820	Daunorubicin	$35.94	$7.19	C9424	K	9424	Daunorubicin, brand	$53.14	$10.63
26	J9181	K	0824	Etoposide 10 MG inj	$0.83	$0.17	C9425	K	9425	Etoposide inj, brand	$1.22	$0.24
27	J9200	K	0827	Floxuridine injection	$66.24	$13.25	C9426	K	9426	Floxuridine inj, brand	$97.92	$19.58
28	J9208	K	0831	Ifosfomide injection	$72.81	$14.56	C9427	K	9427	Ifosfomide inj, brand	$106.04	$21.21
29	J9209	K	0732	Mesna injection	$17.66	$3.53	C9428	K	9428	Mesna injection, brand	$26.11	$5.22
30	J9211	K	0832	Idarubicin hcl injection	$178.21	$35.64	C9429	K	9429	Idarubicin hcl inj, brand	$178.21	$35.64
31	J9218	K	0861	Leuprolide acetate injeciton	$14.48	$2.90	C9430	K	9430	Leuprolide acetate inj, bran	$21.41	$4.28
32	J9265	K	0863	Paclitaxel injection	$79.04	$15.81	C9431	K	9431	Paclitaxel inj, brand	$112.14	$22.43
33	J9280	K	0862	Mitomycin 5 MG inj	$30.91	$6.18	C9432	K	9432	Mitomycin inj, brand	$45.70	$9.14
34	J9340	K	0851	Thiotepa injection	$45.31	$9.06	C9433	K	9433	Thiotepa inj, brand	$59.93	$11.99
35	Q3002	K	1619	Gallium ga 67	$11.22	$2.24	C9434	K	9434	Gallium ga 67, brand	$11.22	$2.24
36	J7502	K	0888	Cyclosporine oral 100 mg	$2.41	$0.48	C9438	K	9438	Cyclosporine oral, brand	$2.56	$0.51
37												
38	02/19/2004 final											
39												