CMS Manual System

Pub. 100-04 Medicare Claims Processing

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

Transmittal 374 **Date: NOVEMBER 22, 2004**

CHANGE REQUEST 3370

NOTE: This transmittal rescinds, Transmittal 327, CR 3370, issued on October 22, 2004. Section C (Provider Education) of the business requirements is being corrected to state "provider education is not needed". All other information remains the same.

SUBJECT: Clarification to IOM Chapter 17, Section 80.4 regarding claims for Blood Clotting Factors

I. SUMMARY OF CHANGES: Claims submitted by suppliers for blood clotting factors shall be processed by the local Part B carriers.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: NOVEMBER 22, 2004
IMPLEMENTATION DATE: NOVEMBER 22, 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 if manual not updated.*)
(R = REVISED, N = NEW, D = DELETED) – (*Only One Per Row.*)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	17/80.4/ Billing for Blood Clotting Factors

III. FUNDING: Medicare contractors shall implement these instructions within their current operating budgets.

IV. ATTACHMENTS:

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

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

Attachment - Business Requirements

Pub. 100-04	Transmittal: 374	Date: November 22, 2004	Change Request 3370

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SUBJECT: Clarification to IOM Chapter 17, Section 80.4 Regarding claims for Blood Clotting Factors

I. GENERAL INFORMATION

A. Background: The IOM is unclear about claims processing jurisdiction for blood clotting factor claims billed by Part B suppliers.

B. Policy: Claims submitted by suppliers for blood clotting factors shall be processed by the local Part B carriers.

C. Provider Education: None

II. BUSINESS REQUIREMENTS

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

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
3370.1	Local Part B carriers shall process claims submitted by suppliers for blood clotting factors.			X			X	X		

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*: November 22, 2004 Implementation Date: November 22, 2004 **Pre-Implementation Contact(s):** Tracey Hemphill**,** **themphill@cms.hhs.gov** **or** Joanne Spalding**,** **jspalding@cms.hhs.gov** **Post-Implementation Contact(s):** Appropriate Regional Office	**Medicare Contractors shall implement these instructions within their current operating budgets.**

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

10 - Payment Rules for Drugs and Biologicals

(Rev.374, Issued: 11-22-04, Effective: 11-22-04, Implementation: 11-22-04)

Drugs for inpatient hospital and inpatient skilled nursing facility (SNF) beneficiaries are included in the respective prospective payment system (PPS) rates except for hemophilia clotting factors for hospital inpatients under Part A. These drugs and the codes used to bill for them are listed in Addendum B on the Centers for Medicare & Medicaid Services (CMS) Web site: http://cms.hhs.gov/providerupdate/regs/cms1206cn2.pdf. The Web site is updated as the list of drugs or codes change. HCPCS codes are used by hospitals and SNFS to bill for drugs that are separately billable through September 30, 2002, at which time national drug codes (NDC) are required by the Health Insurance Portability and Accountability Act (HIPAA). A separate payment may be made for hospital inpatients, who receive hemophilia clotting factors (but not SNF). See Chapter 3 for instructions on billing inpatient hospital hemophilia clotting factors.

All hospital outpatient drugs are excluded from SDP because the payment allowance for such drugs is determined by a different procedure. Most drugs furnished to hospital outpatients are packaged under the outpatient prospective payment system (OPPS). Their costs are recognized and included but paid as part of the ambulatory payment classification (APC) for the service with which they are billed. Certain drugs, however, are paid separately. These include chemotherapeutic agents and the supportive and adjunctive drugs used with them, immunosuppressive drugs, orphan drugs, radiopharmaceuticals, and certain other drugs such as those given in the emergency room for heart attacks.

The classes of drugs required to have “pass through” payments made under the Balanced Budget Refinement Act of 1999 (BBRA) have coinsurance amounts that can be less than 20 percent of the Average Wholesale Price (AWP). This is because pass-through amounts, by law, are not subject to coinsurance. The CMS considers the amount of the payment rate that exceeds the estimated acquisition cost of the drug to be the pass-through amount. Thus, the coinsurance is based on a portion of the payment rate, not the full payment rate.

Drugs are billed in multiples of the dosage specified in the HCPCS/NDC. If the dosage given is not a multiple of the Health Insurance Common Procedure Coding System (HCPCS) code, the provider rounds to the next highest units in the HCPCS description for the code.

If the full dosage provided is less than the dosage for the code specifying the minimum dosage for the drug, the provider reports the code for the minimum dosage amount.

OPPS PRICER includes a table of drugs and prices and provides the intermediary (FI) with the appropriate prices.

Section 90 relates specifically to billing for hospital outpatients. The remainder of this chapter relates to procedures for pricing and paying DME recipients, and to beneficiaries who receive drugs under special benefits such as pneumococcal, flu and hepatitis vaccines; clotting factors, immunosuppressive therapy, self administered cancer and anti emetic drugs, and drugs incident to physicians services.

Drugs and biologicals not paid on cost or prospective payment basis have been paid based on the lower of the billed charge or 95 percent of the average wholesale price (AWP) as reflected in published sources (e.g., Red Book, Price Alert, etc.). Examples of drugs that have been paid on this basis include but are not limited to drugs furnished incident to a physician's service, immunosuppressive drugs furnished by pharmacies, drugs furnished by pharmacies under the durable medical equipment benefit, covered oral anticancer drugs, and blood clotting factors. The Medicare Prescription Drug, Improvement, and Modernization Act (MPDIMA) of 2003 changed the basis for payment of drugs and biologicals not paid on a cost or prospective payment basis. Beginning January 1, 2004, through December 31, 2004, such drugs or biologicals are paid based on various standards specified in the statute, although the default standard is 85 percent of AWP. See §20, below for a full discussion of the basis for drugs in this category during 2004.

Drugs or biologicals must meet the coverage requirements in Chapter 15 of the Medicare Benefit Policy Manual. Additionally, for end stage renal disease (ESRD) patients, see the Medicare Benefit Policy Manual, Chapter 11 . For ESRD patient billing for drugs and claims processing, see Chapter 8 of this manual.

The following chart describes the payment provisions for drugs.

Table - Drug Payment Methodology

(Rev. 374, Issued: 11-22-04, Effective: 11-22-04, Implementation: 11-22-04)

References:
MIM 3610.18, 3660.7,5202.4, PM A-01-93, A-01-133, A-02-129, AB-02-075, AB-02-174 and Various CMS staff

In the table below, if the item does not have an asterisk ("*") the bill is submitted to the FI. An asterisk ("*") indicates the bill is submitted to the local carrier or DMERC, as applicable.

Key to the following Table:

* Bills carrier; no asterisk means bills FI or RHHI NOTE: DMERCs do not process claims for blood clotting factors.
† - Drugs & biologicals outside the composite rate are paid as described in 2 below. Those inside the composite rate are paid as described in 1.
1 - Included in PPS rate, or other provider-type all inclusive encounter rate
2 – Price taken from CMS drug/biological pricing file effective on the specific date of service.
3 - Reasonable cost
4 - Lower of cost or 95% AWP paid for drug in addition to PPS rate, or in addition to reasonable cost if excluded from PPS
5 - OPPS-APC, whether pass-thru drug or not
6 - Can not furnish as that "provider" type;
7 - $10.00 per 1000 units (Payment rate for EPO set in statute)
8 - May get carrier billing number if qualified and bill carrier
++ Except in the State of Washington, where we permit the RDF to bill immunosuppressives due to the unique State assistance to the beneficiary provided only via the RDF.

Provider/Drug	**Hepatitis B Vaccine**	**Pneumococcal & Flu Vaccines**	**Hemophilia Clotting Factors**	**Immuno - Suppressive**	**Erythro- (EPO)**	**Self Admin Anti-Cancer Anti-Emetic**	**Other**
Hospital Inpatient (IP) A - Prospective Payment System (IPPS)	1	1	4	1	1	1	1
Hospital IP A - not IPPS	3	3	3	3	3	3	3
Hospital IP B Outpatient Prospective Payment System (OPPS)	5	3	5	5	5	5	5
Hospital IP B - not OPPS	3	3	3	3	3	3	3

Provider/Drug	**Hepatitis B Vaccine**	**Pneumococcal & Flu Vaccines**	**Hemophilia Clotting Factors**	**Immuno - Suppressive**	**Erythro- (EPO)**	**Self Admin Anti-Cancer Anti-Emetic**	**Other**
Hospital Outpatient (OP) - OPPS	5	3	5	5 (30 day supply)	5	5	5
Hospital OP - not OPPS hospital	3	3	3	3	3	3	5
Skilled Nursing Facility (SNF)	1	1	1	1	1	1	1
SNF IP B	3	3	3	3	6	6	6
SNF OP	3	3	3	3	6	6	6
Independent Renal Dialysis Facility (RDF)	3	3	6	6++	7	6	1/2†
Hospital based RDF	5	5	5	6	7	6	3
Comprehensive Outpatient Rehabilitation Facility (CORF)/ Outpatient Rehabilitation Facility (ORF)	5	2	6	2 *	2	6	2
Community Mental Health Clinic (CMHC)	6	6	6	6	6	6	6
Rural Health Clinical (RHC)/Federally Qualified Health Clinic (FQHC) -hospital based	1	1	5	5	5	5	5
RHC/FQHC-independent	1	1	8,2*	8,2*	8,2*	8,2*	8,2*
Home Health Agencies (HHA)	5	3	5	5	5	5	5
Hospice	6 1	6 1	6 1	6 1	6 1	6 1	6 1
Physicians	2*	2 *	2 *	2 *	2 *	2 *	2 *
Pharmacy	2*	2 *	2 *	2 *	7 *	2 *	2 *
Durable Medical Equipment, *Prosthetics, Orthotics,and Supplies* (DME*POS*) Supplier	2*	2 *	2 *	2 *	7 *	2	2 *
Critical Access Hospital (CAH) Outpt-Method I	3	3	3	3	3	3	3

Provider/Drug	Hepatitis B Vaccine	Pneumococcal & Flu Vaccines	Hemophilia Clotting Factors	Immuno - Suppressive	Erythro- (EPO)	Self Admin Anti-Cancer Anti-Emetic	Other
CAH Outpt-Method II	3	3	3	3	3	3	3
CAH Inpt	3	3	3	3	3	3	3

NOTE: RHCs do not bill for vaccines. These are paid on the cost report. Vaccine payment to FQHCs is bundled into the encounter rate.
Hepatitis B vaccine is paid on an APC basis in a hospital outpatient department. Deductible and coinsurance apply.
Influenza and pneumococcal vaccines are also paid on an APC basis in a hospital outpatient department. Neither deductible nor coinsurance apply.
HHAs cannot bill for vaccines, except on TOB 34X, since vaccines are not part of the HH benefit and cannot be paid under HH PPS.
Pneumococcal and influenza are paid once for the vaccine and once for the administration of the vaccine. The provider or supplier (including physician) must enter each of the HCPCS on separate lines of the claim."

A Part B blood clotting factor claim from a Part B supplier is processed by the Local Part B Carrier.
A Part A blood clotting factor claim from a Part A provider, including a hospital-based hemophilia center, is processed by the FI.

80.4 - Billing for Blood Clotting Factors

(Rev. 374, Issued: 11-22-04, Effective: 11-22-04, Implementation: 11-22-04)

See the table in §10 for claims jurisdiction and payment method. *Suppliers, including independent pharmacies, Red Cross, DME suppliers, independent blood bank, and independent hemophilia centers, shall submit claims to the Part B Local Carriers. Providers, including hospital-based hemophilia centers, shall submit claims to the FIs.*

Blood clotting factors are priced as a drug/biological under the drug pricing fee schedule effective for the specific date of service. An exception to this pricing methodology is OPPS drugs. (See IOM Chapter 3-Inpatient Part A Hospital, Section 20.7.3.)

The payment amount is based upon the least expensive medically necessary blood clotting factors. Blood clotting factors are available both in virally inactivated forms and a recombinant form. The FDA has determined that both varieties are safe and effective. Therefore, unless the prescription specifically calls for the recombinant form (HCPCS code J7190 for factors 8), payment is based on the less expensive, non-recombinant forms (HCPCS codes J7191 and J7195).

If carriers or FIs determine an unusual billing pattern that demonstrates the provider or supplier is billing much more frequently for the recombinant form than others, they may review the records of the provider/supplier to verify that the records show the blood clotting factors were prescribed by a licensed doctor of medicine or osteopathy and such physician's written, signed prescription specifies the recombinant form is required.

NOTE: *For Part B, covered related supplies, such as syringes, are paid by the DMERC only if the clotting factors given to the beneficiary are to be self-administered. These payments are made based on the DMEPOS fee schedule. For Part A inpatients, related supplies are considered part of the PPS rate. (See IOM, Chapter 3.)*