CMS Manual System

Pub 100-04 Medicare Claims Processing

Transmittal 903

Department of Health & Human Services (DHHS)

Centers for Medicare & Medicaid Services (CMS)

Date: APRIL 14, 2006

Change Request 4229

SUBJECT: Payment for Blood Clotting Factors Administered to Hemophilia Inpatients

I. SUMMARY OF CHANGES: This instruction clarifies the billing practices for the providers to ensure that the units of service for blood clotting factor are reported accurately. The provider determines the dosage furnished to the patient and using the definition of the appropriate HCPCS code, translates the dosage into Units of Services.

NEW/REVISED MATERIAL

EFFECTIVE DATE: July 14, 2006

IMPLEMENTATION DATE: July 14, 2006

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
R	3/Table of Contents
R	3/20.7.3 Payment for Blood Clotting Factor Administered to Hemophilia Inpatients
R	4/230.1.4 Non Pass-Through Drugs

III. FUNDING:

No additional funding will be provided by CMS; Contractor activities are to be carried out within their FY 2006 operating budgets.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

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

Attachment - Business Requirements

Pub. 100-04	Transmittal: 903	Date: April 14, 2006	Change Request 4229

SUBJECT: Payment for Blood Clotting Factor Administered to Hemophilia Inpatients

I. GENERAL INFORMATION

A. Background: Some Medicare providers have been billing units of drugs and biologicals incorrectly on outpatient bills as well as on inpatient claims for hemophilia clotting factors. The erroneous reporting of units of service has resulted in Medicare overpayments.

B. Policy: The provider must determine the actual dosage furnished to the patient, and using the definition of the appropriate HCPCS code, translate the dosage into **UNITS OF SERVICE.**

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	
4229.1	The FIs shall calculate the payment amount and subtract the charges from those submitted to Pricer so that the clotting factor charges are not included in cost outlier computations.	X								
4229.2	The FI shall get the blood-clotting factors HCPCS codes from the Medicare Part B Drug Pricing File.	X								
4229.3	The FI shall use the average sales price (ASP) plus 6 percent to make payment to facilities that are not paid on cost or prospective payment system (PPS). This amount is available in the Medicare Part B Drug Pricing File, which is made available quarterly.	X								

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
4229.4	The FI shall pay for hemophilia clotting factors during a covered part A stay in a PPS hospital at ASP plus 6 percent in addition to the DRG payment.	X								
4229.4.1	FIs are no longer to multiply the payment amount by 100 when loading the fee amounts to the HCPCS file for inpatient hemophilia clotting factors.	X								
4229.5	The FI shall pay the APC to OPPS hospitals for hemophilia clotting factors administered in inpatient Part B and outpatient settings.	X								
4229.6	The FI shall pay for hemophilia clotting factors to beneficiaries based on cost for Part B SNF services, including an inpatient Part B stay, and all such factors administered by a CAH.	X								
4229.7	The FI shall not pay a separate add-on for hemophilia clotting factors under SNF PPS for inpatient SNF stays or swing bed services.	X								
4229.8	The FI shall pay for hemophilia clotting factors based on cost for non-PPS swing bed services.	X								
4229.9	The FIs shall educate their providers that they may no longer divide the number of units by 100 when billing for clotting factors.	X								

III. PROVIDER EDUCATION

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)					
		FI	RHHI	Carrier	DMERC	Shared System Maintainers	Other

						FISS	MCS	VMS	CWF	
4229.10	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 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								

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

Effective Date*: July 14, 2006 **Implementation Date:** July 14, 2006 **Pre-Implementation Contact(s):** Cindy Murphy, 410-786-5733 **Post-Implementation Contact(s):** Appropriate regional office.	**No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2006 operating budgets.**

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

Medicare Claims Processing Manual
Chapter 3 - Inpatient Hospital Billing

Table of Contents
(Rev. 903, 04-14-06)

20.7.3 - Payment for Blood Clotting Factor Administered to Hemophilia Inpatients

(Rev. 903, Issued: 04-14-06; Effective/Implementation Dates: 07-14-06)

Section 6011 of Public Law (P.L.) 101-239 amended §1886(a)(4) of the *Social Security* Act *(the Act)* to provide that prospective payment *system (PPS)* hospitals receive an additional payment for the costs of administering blood clotting factor to Medicare hemophiliacs who are hospital inpatients. Section 6011(b) of P.L. 101.239 specified that the payment be based on a predetermined price per unit of clotting factor multiplied by the number of units provided. This add-on payment originally was effective for blood clotting factors furnished on or after June 19, 1990, and before December 19, 1991. Section 13505 of P. L. 103-66 amended §6011 (d) of P.L. 101-239 to extend the period covered by the add-on payment for blood clotting factors administered to Medicare inpatients with hemophilia through September 30, 1994. Section 4452 of P.L. 105-33 amended §6011(d) of P.L. 101-239 to reinstate the add-on payment for the costs of administering blood-clotting factor to Medicare beneficiaries who have hemophilia and who are hospital inpatients for discharges occurring on or after October 1, 1998.

Local carriers shall process non-institutional blood clotting factor claims.
The FIs shall process institutional blood clotting factor claims payable under either Part A or Part B.

A. Inpatient Bills

Under the Inpatient Prospective Payment System (PPS), hospitals receive a special add-on payment for the costs of furnishing blood clotting factors to Medicare beneficiaries with hemophilia, admitted as inpatients of PPS hospitals. The clotting factor add-on payment is calculated using the number of units(as defined in the HCPCS code long descriptor) billed by the provider under special instructions for units of service.

The PPS Pricer software does not calculate the payment amount. The Fiscal Intermediary Standard System (FISS) calculates the payment amount and subtracts the charges from those submitted to Pricer so that the clotting factor charges are not included in cost outlier computations.

Blood clotting factors not paid on a cost or PPS basis are priced as a drug/biological under the Medicare Part B Drug Pricing File effective for the specific date of service. As of January 1, 2005, the average sales price (ASP) plus 6 percent shall be used.

If a beneficiary is in a covered Part A stay in a PPS hospital, the clotting factors are paid in addition to the DRG/HIPPS payment (For FY 2004, this payment is based on 95 percent of average wholesale price.) For a SNF subject to SNF/PPS, the payment is bundled into the SNF/PPS rate.

For SNF inpatient Part A, there is no add-on payment for blood clotting factors.

The codes for blood-clotting factors are found on the Medicare Part B Drug Pricing File. This file is distributed on a quarterly basis.

For discharges occurring on or after October 1, 2000, *and before December 31, 2005,* report HCPCS Q0187 based on 1 billing unit per 1.2 mg. *Effective January 1, 2006, HCPCS code J7189 replaces Q0187 and is defined as 1 billing unit per 1 microgram (mcg).*

The examples below include the HCPCS code and indicate the dosage amount specified in the descriptor of that code. Facilities use the units field as a multiplier to arrive at the dosage amount.

EXAMPLE 1

HCPCS	*Drug*	*Dosage*
J7189	*Factor VIIa*	*1 mcg*

Actual dosage: 13,365 mcg
On the bill, the facility shows J7189 and 13,365 in the units field (13,365 mcg divided by 1 mcg = 13,365 units).

NOTE: The process for dealing with one international unit (IU) is the same as the process of dealing with one microgram.

EXAMPLE 2

HCPCS	*Drug*	*Dosage*
J9355	*Trastuzumab*	*10 mg*

Actual dosage: 140 mg
On the bill, the facility shows J9355 and 14 in the units field (140 mg divided by 10mg = 14 units).

When the dosage amount is greater than the amount indicated for the HCPCS code, the facility rounds up to determine units. When the dosage amount is less than the amount indicated for the HCPCS code, use 1 as the unit of measure.

EXAMPLE 3

HCPCS	*Drug*	*Dosage*
J3100	*Tenecteplase*	*50 mg*

Actual Dosage: 40 mg
The provider would bill for 1 unit, even though less than 1 full unit was furnished.

At times, the facility provides less than the amount provided in a single use vial and there is waste, i.e.; some drugs may be available only in packaged amounts that exceed the needs of an individual patient. Once the drug is reconstituted in the hospital's pharmacy, it may have a limited shelf life. Since an individual patient may receive less than the fully reconstituted amount, we encourage hospitals to schedule patients in such a way that the hospital can use the drug most efficiently. However, if the hospital must discard the remainder of a vial after administering part of it to a Medicare patient, the provider may bill for the amount of drug discarded plus the amount administered.

> ***Example 1**:*
> *Drug X is available only in a 100-unit size. A hospital schedules three Medicare patients to receive drug X on the same day within the designated shelf life of the product. An appropriate hospital staff member administers 30 units to each patient. The remaining 10 units are billed to Medicare on the account of the last patient. Therefore, 30 units are billed on behalf of the first patient seen and 30 units are billed on behalf of the second patient seen. Forty units are billed on behalf of the last patient seen because the hospital had to discard 10 units at that point.*
>
> ***Example 2**:*
> *An appropriate hospital staff member must administer 30 units of drug X to a Medicare patient, and it is not practical to schedule another patient who requires the same drug. For example, the hospital has only one patient who requires drug X, or the hospital sees the patient for the first time and did not know the patient's condition. The hospital bills for 100 units on behalf of the patient, and Medicare pays for 100 units.*

When the number of units of blood clotting factor administered to hemophiliac inpatients exceeds *99,999*, the hospital reports the excess as a second line for revenue code 0636 and repeats the HCPCS code. One *hundred thousand fifty (100,050)* units are reported on one line as *99,999*, and another line shows *1,051*.

Revenue Code 0636 is used. It requires HCPCS. Some other inpatient drugs continue to be billed without HCPCS codes under pharmacy.

No changes in beneficiary notices are required. Coverage is applicable to hospital Part A claims only. Coverage is also applicable to inpatient Part B services in SNFs and all types of hospitals, including CAHs. Separate payment is not made to SNFs for beneficiaries in an inpatient Part A stay.

B. FI Action

The FI is responsible for the following:

- It accepts HCPCS codes for inpatient services;
- It edits to require HCPCS codes with Revenue Code 0636. Multiple iterations of the revenue code are possible with the same or different HCPCS codes. It does not edit units except to ensure a numeric value;

- It reduces charges forwarded to Pricer by the charges for hemophilia clotting factors in revenue code 0636. It retains the charges and revenue and HCPCS codes for CWF; and
- *It modifies data entry screens to accept HCPCS codes for hospital (including CAH) swing bed, and SNF inpatient claims (bill types 11X, 12X, 18x, 21x and, 22x).*

The September 1, 1993, IPPS final rule (58 FR 46304) states that payment will be made for the blood clotting factor only if an ICD-9-CM diagnosis code for hemophilia is included on the bill.

Since inpatient blood-clotting factors are covered only for beneficiaries with hemophilia, the FI must ensure that one of the following hemophilia diagnosis codes is listed on the bill before payment is made:

286.0	Congenital factor VIII disorder
286.1	Congenital factor IX disorder
286.2	Congenital factor IX disorder
286.3	Congenital deficiency of other clotting factor
286.4	von Willebrands' disease

Effective for discharges on or after August 1,2001, payment may also be made if one of the following diagnosis codes is reported:

286.5	Hemorrhagic disorder due to circulating anticoagulants
286.7	Acquired coagulation factor deficiency

C. Part A Remittance Advice

1. X12.835 Ver. 003030M

For remittance reporting PIP and/or non-PIP payments, the Hemophilia Add on will be reported in a claims level 2-090-CAS segment (CAS is the element identifier) exhibiting an “OA” Group Code and adjustment reason code “97” (payment is included in the allowance for the basic service/ procedure) followed by the associated dollar amount (POSITIVE) and units of service. For this version of the 835, “OA” group coded line level CAS segments are informational and are not included in the balancing routine. The Hemophilia Add On amount will always be included in the 2-010-CLP04 Claim Payment Amount

For remittance reporting PIP payments, the Hemophilia Add On will also be reported in the provider level adjustment (element identifier PLB) segment with the provider level adjustment reason code “CA” (Manual claims adjustment) followed by the associated dollar amount (NEGATIVE).

NOTE: A data maintenance request will be submitted to ANSI ASC X12 for a new PLB adjustment reason code specifically for PIP payment Hemophilia Add On situations for future use. However, continue to use adjustment reason code “CA” until further notice.

The FIs enter MA103 (Hemophilia Add On) in an open MIA (element identifier) remark code data element. This will alert the provider that the reason code 97 and PLB code "CA" adjustments are related to the Hemophilia Add On.

2. X12.835 Ver. 003051

For remittances reporting PIP and/or non-PIP payments, Hemophilia Add On information will be reported in the claim level 2-062-AMT and 2-064-QTY segments. The 2-062-AMTO1 element will carry a "ZK" (Federal Medicare claim MANDATE - Category 1) qualifier code followed by the total claim level Hemophilia Add On amount (POSITIVE). The 2-064QTY01 element will carry a "FL" (Units) qualifier code followed by the number of units approved for the Hemophilia Add On for the claim. The Hemophilia Add On amount will always be included in the 2-010-CLP04 Claim Payment Amount.

NOTE: A data maintenance request will be submitted to ANSI ASC X12 for a new AMT qualifier code specifically for the Hemophilia Add On for future use. However, continue to use adjustment reason code "ZK" until further notice.

For remittances reporting PIP payments, the Hemophilia Add On will be reported in the provider level adjustment PLB segment with the provider level adjustment reason "ZZ" followed by the associated dollar amount (NEGATIVE).

NOTE: A data maintenance request will be submitted to ANSI ASC X12 for a new PLB, adjustment reason code specifically for the Hemophilia Add On for future use. However, continue to use PLB adjustment reason code "ZZ" until further notice.

The FIs enter MA103 (Hemophilia Add On) in an open MIA remark code data element. This will alert the provider that the ZK, FL and ZZ entries are related to the Hemophilia Add On. (Effective with version 4010 of the 835, report ZK in lieu of FL in the QTY segment.)

3. Standard Hard Copy Remittance Advice

For paper remittances reporting non-PIP payments involving Hemophilia Add On, add a "Hemophilia Add On" category to the end of the "Pass Thru Amounts" listings in the "Summary" section of the paper remittance. Enter the total of the Hemophilia Add On amounts due for the claims covered by this remittance next to the Hemophilia Add On heading.

The FIs add the Remark Code "MA103" (Hemophilia Add On) to the remittance advice under the REM column for those claims that qualify for Hemophilia Add On payments. This will be the full extent of Hemophilia Add On reporting on paper remittance notices; providers wishing more detailed information must subscribe to the Medicare Part A specifications for the ANSI ASC X12N 835, where additional information is available. See chapter 22, for detailed instructions and definitions.

Medicare Claims Processing Manual
Chapter 4 - Part B Hospital
(Including Inpatient Hospital Part B and OPPS)

230.1.4 - Non Pass-Through Drugs

(Rev. 903, Issued: 04-14-06; Effective/Implementation Dates: 07-14-06)

Drugs, biologicals (including blood and blood products), and radiopharmaceuticals that do not have pass-through status are either packaged into existing Ambulatory Payment Classification (APC) payments for services or receive separate APC payment. To find a listing of HCPCS codes used to bill for drugs and biologicals, reference Addendum B of the OPPS Final Rule (updated annually) or the CMS Web site, http://www.cms.hhs.gov/.

For hospitals subject to OPPS, the clotting factors, when paid under Part B, are paid the APC. For SNFs and CAHs the blood clotting factors, when paid under Part B, are paid based on cost.