

Local Coverage Determination Coding Guidelines

Contractor Name

Wisconsin Physicians Service (WPS)

Contractor Number

00951, 00952, 00954
05101, 05201, 05301, 05401,
05102, 05202, 05302,
05402, 52280
08101, 08102, 08201, 08202

LCD Title

Hemophilia Clotting Factors

LCD Database ID Number**Contractor's Determination Number**

INJ-003

Primary Geographic Jurisdiction

Carrier B: Wisconsin, Illinois, Minnesota

Fiscal Intermediary A: Alaska, Alabama, Arizona, Arkansas, Connecticut, Florida, Georgia, Iowa, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Massachusetts, Maine, Michigan, Minnesota, Missouri, Mississippi, Montana, North Carolina, North Dakota, Nebraska, New Hampshire, Ohio, Oregon, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Virginia, Vermont, Washington, Wisconsin, West Virginia, Wyoming, U.S. Virgin Islands

MAC A/B: Iowa, Missouri, Nebraska, Kansas

MAC A/B: Indiana, Michigan

Coding Guidelines

A. The following are examples of the appropriate HCPCS code to use for the products administered:

1. Factor VIIa (anti-inhibitor)
Novo7- (Coagulation Factor Recombinant) J7189
For the treatment of bleeding episodes in Hemophilia A or B patients with inhibitors to Factor VIII or Factor IX
2. Factor VIII
Hemofil M - J7190
Koate H.P. - J7190
Monocolate - J7190
Humate P - J7190 or J7186 or J7187
Profilate HP- J7190
AHF M - J7190
Alphanate - J7190
Antihemophilic Factor (Porcine) Hyate:C - J7191

Recombinate (Recombinant) - J7192
Kogenate - J7192
Bioclata - J7192
Helixate - J7192
Xyntha – J7185

3. Factor VIII inhibitors
 - Autoplex T (anti-inhibitor) - J7198
 - Feiba VH (anti-inhibitor) - J7198
4. Factor IX
 - Konyne (Heat Treated) - J7194
 - Profilnine Heat-Treated - J7194
 - Proplex - J7194
 - Hemonyne - J7194
 - Bebulin VH - J7194
 - Benefix (recombinant) - J7195
 - AlphaNine (Human, affinity purified) - J7193
 - Mononine (Human, Monoclonal, purified) - J7193
5. von Willebrand factor complex (human)
 - Wilate, 1 I.U J7183
6. Factor XIII Injection Factor XIII (antihemophilic factor, human) 1 I.U.
 - Corifact J7180

B. Jurisdiction and Reimbursement
Blood Clotting Factors

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. DMERCs do not process claims for blood clotting factors.

Supplies associated with Blood Clotting Factors

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.)

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.

Local carriers shall process non-institutional blood clotting factor claims

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 - OPSS-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

| Provider/Drug | Hemophilia Clotting Factors |
|--|------------------------------------|
| Hospital Inpatient (IP) A -Prospective Payment System (IPPS) | 4 |
| Hospital IP A - not IPPS | 3 |
| Hospital IP B Outpatient Prospective Payment System (OPPS) | 5 |
| Hospital IP B - not OPSS | 3 |
| Hospital Outpatient (OP) - OPSS 1 | 5 |
| Hospital OP - not OPSS hospital | 3 |
| Skilled Nursing Facility (SNF) | 1 |
| SNF IP B | 3 |
| SNFOP | 3 |
| Independent Renal Dialysis Facility (RDF) | 6 |
| Hospital based RDF | 5 |
| Comprehensive Outpatient Rehabilitation Facility (CORF)/ Outpatient Rehabilitation Facility (ORF) | 6 |
| Community Mental Health Clinic (CMHC) | 6 |
| Rural Health Clinical (RHC)/Federally Qualified Health Clinic (FQHC) -hospital based | 5 |
| RHC/FQHC-independent | 8, 2* |
| Home Health Agencies (HHA) | 5 |
| Hospice | 6, 1 |
| Physicians | 2 * |
| Pharmacy | 2 * |
| Durable Medical Equipment, <i>Prosthetics, Orthotics,and Supplies</i> (DMEPOS) Supplier | 2 * |
| Critical Access Hospital (CAH) Outpt-Method I | 3 |

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

B. Reimbursement

1. *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 OPFS 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.

2. **Clotting Factor Furnishing Fee – 80.4.1**

(Rev. 1908; Issued: 02-05-10; Effective Date: 01-01-05; Implementation Date: 03-05-10)

The Medicare Modernization Act section 303(e)(1) added section 1842(o)(5)(C) of the Social Security Act which requires that, beginning January 1, 2005, a furnishing fee will be paid for items and services associated with clotting factor.

Beginning January 1, 2005, a clotting factor furnishing fee is separately payable to entities that furnish clotting factor unless the costs associated with furnishing the clotting factor is paid through another payment system.

The clotting factor furnishing fee is updated each calendar year based on the percentage increase in the consumer price index (CPI) for medical care for the 12-month period ending with June of the previous year.

3. **Non Pass-Through Drugs 230.1.4 -**

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 OPFS Final Rule (updated annually) or the CMS Web site, <http://www.cms.hhs.gov/>.

C. Inpatient Bills

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

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/HPPS 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.

Calculating Payment (CR4229):

- a. Calculate the payment amount and subtract the charge from those submitted to Pricer so that the clotting factor charges are not included in cost outlier computations;
- b. Use the blood-clotting factors HCPCS codes from the Medicare Part B Drug Pricing File, which is made available on a quarterly basis;
- c. Use the Average Sales Price (ASP) plus six percent to make payment to facilities that are not paid on cost or Prospective Payment System (PPS);
- d. Pay for hemophilia clotting factors during a covered part A stay in a PPS hospital at ASP plus six percent in addition to the Diagnosis Related Group (DRG) payment;
- e. Pay the Ambulatory Patient Classification (APC) rate to Outpatient Prospective Payment System (OPPS) hospitals for hemophilia clotting factors administered in inpatient Part B and outpatient settings;
- f. Pay for hemophilia clotting factors to beneficiaries based on cost for Part B skilled nursing facility (SNF) services, including inpatient Part B, and all such factors administered by critical access hospitals (CAHs);
- g. Pay for hemophilia clotting factors based on cost for non-PPS swing bed services; and
- h. **Not** pay a separate add-on under SNF PPS for SNF or swing bed services.

Note: Providers should no longer divide the number of units by 100 when billing for clotting factors.

SNF Inpatient Part A

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.

J7189 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.

Claim Submission

FI Claims

1. 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.
2. Revenue Code 0636 is used. It requires HCPCS. Some other inpatient drugs continue to be billed without HCPCS codes under pharmacy.
3. No changes in beneficiary notices are required.
4. Coverage is applicable to hospital Part A claims only.
5. Coverage is also applicable to inpatient Part B services in SNFs and all types of hospitals, including CAHs.
6. Separate payment is not made to SNFs for beneficiaries in an inpatient Part A stay.
7. 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).*
8. 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.

Carrier Claims

1. Providers must indicate the total dosage per number of Units or in micrograms (not the number of vials used) in item 19 of the Centers for Medicare & Medicaid Services (CMS) 1500 form, or in the narrative record if filing electronically. List the units of service as one in item 24G of the 1500 form.
2. When using the NOC code J7199, Hemophilia clotting factor, not otherwise classified, indicate the name of the drug, the **total** dosage, and the method of administration on item 19 of the CMS 1500 form, and in the narrative record if filing electronically. List the units of service (not vials) as one in item 24G of the 1500 form. If filing electronically, the total units should be placed in the NSF Format, Record FAO-18.0, ANSI 837 format Segment SV1-05 (3032) or Segment SV1-04 (3051).

Original Effective Date

11/15/2010

Start Date of Notice Period

(Published)

01/01/2012; 07/01/2011; 10/01/2010

Revision History

This LCD is effective for J-8 providers in Michigan MAC B 07/16/12, Michigan MAC A 07/23/12, Indiana MAC A 07/23/12 and Indiana MAC B 08/20/12

01/01/2012 Added codes **J7180** and **J7183** and retired code Q2041; 07/01/2011, Q2041, Injection, Von Willebrand factor complex (human), Wilate, 1 I.U. will replace J7184, Injection, von Willebrand factor complex (human), Wilate, per 100 IU effective January 1, 2011 Implementation date July 5, 2011. This is based on CR 7430. Note the dosage change in the dosage.