CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 12380	Date: November 24, 2023
	Change Request 13381

Transmittal 12290 issued October 05, 2023, is being rescinded and replaced by Transmittal 12380, dated November 24, 2023, to Update BR 13381.3 to remove HCPCS J7191 and J7199, and to add HCPCS J7177, J7178, and J7214. All other information remains the same.

SUBJECT: Diagnosis Code Update for Add-on Payments for Blood Clotting Factor Administered to Hemophilia Inpatients

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to provide updates to diagnosis codes required in order to allow add-on payments under the Inpatient Prospective Payment System (IPPS).

EFFECTIVE DATE: October 1, 2022

*Unless otherwise specified, the effective date is the date of service. IMPLEMENTATION DATE: April 1, 2024

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	3/20.7.3/ Payment for Blood Clotting Factor Administered to Hemophilia Inpatients	

III. FUNDING:

For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements Manual Instruction

Attachment - Business Requirements

Pub. 100-04	Transmittal: 12380	Date: November 24, 2023	Change Request: 13381
1 40. 100 01	11 ansinitual. 12000		Change Request. 19901

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SUBJECT: Diagnosis Code Update for Add-on Payments for Blood Clotting Factor Administered to Hemophilia Inpatients

EFFECTIVE DATE: October 1, 2022 *Unless otherwise specified, the effective date is the date of service. **IMPLEMENTATION DATE: April 1, 2024**

I. GENERAL INFORMATION

A. Background: Section 20.7.3, Payment for Blood Clotting Factor Administered to Hemophilia Inpatients, of Chapter 3, Inpatient Hospital Billing, is updated with the following diagnosis codes required in order to allow add-on payments under the Inpatient Prospective Payment System (IPPS):

ADD:

Effective 10/1/2022,

ICD-10-CM Code

Description

D68.00

Von Willebrand disease, unspecified

D68.01

Von Willebrand disease, type 1

D68.020

Von Willebrand disease, type 2A

D68.021

Von Willebrand disease, type 2B

D68.022

Von Willebrand disease, type 2M

D68.023

Von Willebrand disease, type 2N

D68.029

Von Willebrand disease, type 2, unspecified

D68.03

Von Willebrand disease, type 3

D68.04

Acquired von Willebrand disease

D68.09

Other von Willebrand disease

TERMINATE:

Effective 9/30/2022,

ICD-10-CM Code

Description

D68.0

Von Willebrand's disease

B. Policy: 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-CM diagnosis code for hemophilia is included on the bill.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Re	Responsibility							
		A/B MAC		MAC DME Shared-System Maintainers			tainers	Other		
		Α	В	HHH	MAC	FISS	MCS	VMS	CWF	
13381.1	Effective for discharges on or after October 1, 2022, FISS and Medicare contractors shall add diagnosis codes D68.00, D68.01, D68.020, D68.021, D68.022, D68.023, D68.029, D68.03, D68.04, D68.09 to the conditions required to receive the hemophilia clotting factor add-on payment.	X				X				
13381.2	FISS and Medicare contractors shall add a termination date of September 30, 2022, for ICD-10- CM Code D68.0 in the hemophilia clotting factor add-on payment criteria.	X				X				
13381.3	Within 60 days of the	Х								

Number	Requirement	Re	spoi	nsibility	7					
		A	/B I	MAC	DME	Share	d-Syster	m Maint	tainers	Other
		Α	В	HHH		FISS	MCS	VMS	CWF	
					MAC					
	implementation date of this									
	Change Request, Medicare									
	contractors shall adjust inpatient									
	claims (bill type 11X) with									
	discharge dates on or after									
	10/01/2022 that contain the									
	following:									
	• HCPCS codes for									
	furnishing blood clotting									
	factors: J7170, J7175,									
	J7177, J7178, J7179,									
	J7180, J7181, J7182,									
	J7183, J7185, J7186,									
	J7187, J7188, J7189,									
	J7190, J7192, J7193,									
	J7194, J7195, J7198,									
	J7200, J7201, J7202,									
	J7203, J7204, J7205,									
	J7207, J7208, J7209,									
	J7210, J7211, J7212,									
	J7213, or J7214 and									
	• ICD-10 diagnosis codes:									
	D68.00, D68.01, D68.020,									
	D68.021, D68.022,									
	D68.023, D68.029,									
	D68.03, D68.04 or									
	D68.09.									

III. PROVIDER EDUCATION TABLE

Number	Requirement	Re	spo	nsibility	7	
			A/ M/		DME MAC	CEDI
		А	В	HHH		
10001						
13381.4	Medicare Learning Network® (MLN): CMS will market provider education content through the MLN Connects® newsletter shortly after CMS releases the CR. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 instructions for distributing the MLN Connects newsletter information to providers and link to relevant information on your website. You may supplement MLN content with your local information after we release the MLN Connects newsletter.	X				

Number	Requirement	Re	spoi	nsibility	7	
		A	A/ M/		DME MAC	CEDI
	Subscribe to the "MLN Connects" listserv to get MLN content notifications. You don't need to separately track and report MLN content releases when you distribute MLN Connects newsletter content per the manual section referenced above.					

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref	Recommendations or other supporting information:
Requirement	
Number	

Section B: All other recommendations and supporting information: $N\!/\!A$

V. CONTACTS

Pre-Implementation Contact(s): Chava Sheffield, 410-786-2298 or chava.sheffield@cms.hhs.gov, Yvette Rivas, 410-786-1160 or yvette.rivas@cms.hhs.gov

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0

20.7.3 - Payment for Blood Clotting Factor Administered to Hemophilia Inpatients (*Rev. 12380; Issued:11-24-23; Effective:10-01-22; Implementation:04-01-24*)

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.

A/B MACs (B) shall process non-institutional blood clotting factor claims.

The A/B MACs (A) shall process institutional blood clotting factor claims payable under either Part A or Part B.

A. - Inpatient Bills

Under the Inpatient Prospective Payment System (IPPS), 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 Shared 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. - A/B MAC (A) Action

The contractor 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 diagnosis code for hemophilia is included on the bill.

Inpatient blood-clotting factors are covered only for beneficiaries with hemophilia. One of the following hemophilia diagnosis codes must be reported on the claim for payment to be made for blood clotting factors.

Table 1 - Effective for discharges September 1 1993 through the implementation of ICD-10

ICD-9- CM code	Description
286.0	Congenital factor VIII disorder
286.1	Congenital factor IX disorder
286.2	Congenital factor XI deficiency
286.3	Congenital deficiency of other clotting factors
286.4	von Willebrands' disease

Table 2 - Effective for discharges August 1, 2001 through the implementation of ICD-10, payment may be made if a diagnosis codes from either Table 1 or Table 2 is reported is reported:

CM code	ICD-9- CM code	Description
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286.5	Hemorrhagic disorder due to intrinsic circulating anticoagulants (terminate effective September 30, 2011)
286.7	Acquired coagulation factor deficiency

Table 3 - Effective for discharges on October 1, 2011, through the implementation of ICD-10 payment may be made if a diagnosis code from any of Table 1, Table 2 or Table 3 is reported:

ICD-9- CM code	Description
286.52	Acquired hemophilia
286.53	Antiphospholipid antibody with hemorrhagic disorder
286.59	Other hemorrhagic disorder due to intrinsic circulating anticoagulants, antibodies, or inhibitors

Effective for discharges on or after the implementation of ICD-10-CM and prior to October 1, 2022, the following codes are applicable, and payment may be made for blood clotting factors only if one of the following hemophilia diagnosis codes from the range D66 - D68.4 is reported.

ICD-9-Description **ICD-10-**Description CM Code CM Code 286.0 Congenital factor VIII D66 Hereditary factor VIII disorder deficiency 286.1 Congenital factor IX disorder D67 Hereditary factor IX deficiency Congenital factor XI 286.2 D68.1 Hereditary factor XI deficiency deficiency Congenital deficiency of D68.2 286.3 Hereditary deficiency of other other clotting factors clotting factors 286.4 D68.0 Von Willebrand's disease von Willebrands' disease 286.5 Hemorrhagic disorder due to N/A intrinsic circulating anticoagulants (terminate effective September 30, 2011) 286.52 Acquired hemophilia D68.311 Acquired hemophilia 286.53 Antiphospholipid antibody D68.312 Antiphospholipid antibody with hemorrhagic disorder with hemorrhagic disorder 286.59 Other hemorrhagic disorder D68.318 Other hemorrhagic disorder due to intrinsic circulating due to intrinsic circulating anticoagulants, antibodies, or anticoagulants, antibodies, or inhibitors inhibitors 286.7 Acquired coagulation factor D68.32 Antiphospholipid antibody deficiency with hemorrhagic disorder

A crosswalk of ICD 9 to ICD10 hemophilia diagnosis codes follows:

ICD-9- CM Code	Description	ICD-10- CM Code	Description
286.7	Acquired coagulation factor deficiency	D68.4	Acquired coagulation factor deficiency

(Note, ICD-10-CM Code D68.32 (Hemorrhagic disorder due to extrinsic circulating anticoagulants) is no longer eligible for payment for blood clotting factors effective July 1, 2018; however, payment may be made for blood clotting factors when ICD-10-CM Code D68.32 is reported on discharges on or after the implementation of ICD-10-CM and on or before July 1, 2018.)

Effective for discharges on or after October 1, 2022, D68.0 (Von Willebrand's disease) is no longer eligible for payment for blood clotting factors; however, payment may be made for blood clotting factors when ICD-10-CM Code D68.0 is reported on discharges on or after the implementation of ICD-10-CM and on or before September 30, 2022.

Effective for discharges on or after October 1, 2022, the following codes are applicable, and payment may be made for blood clotting factors only if one of the following hemophilia diagnosis codes from the range D66 - D68.4 is reported.

ICD-10- CM Code	Description
D66	Hereditary factor VIII deficiency
D67	Hereditary factor IX deficiency
D68.00	Von Willebrand disease, unspecified
D68.01	Von Willebrand disease, type 1
D68.020	Von Willebrand disease, type 2A
D68.021	Von Willebrand disease, type 2B
D68.022	Von Willebrand disease, type 2M
D68.023	Von Willebrand disease, type 2N
D68.029	Von Willebrand disease, type 2, unspecified
D68.03	Von Willebrand disease, type 3
D68.04	Acquired von Willebrand disease
D68.09	Other von Willebrand disease
D68.1	Hereditary factor XI deficiency
D68.2	Hereditary deficiency of other clotting factors
D68.311	Acquired hemophilia
D68.312	Antiphospholipid antibody with hemorrhagic disorder
D68.318	Other hemorrhagic disorder due to intrinsic circulating anticoagulants, antibodies, or inhibitors
D68.4	Acquired coagulation factor deficiency

C. - Part A Remittance Advice

For remittance reporting PIP and/or non-PIP payments, the Hemophilia Add On is included in the overall claim payment (Provider Reimbursement, CLP04).

If an inpatient claim has a Hemophilia Add On payment, the payment to the provider is increased in the PLB segment with a PLB adjustment HM. The Hemophilia Add On amount will always be included in the 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 HM. For remittances reporting PIP payments, the sum of inpatient claims, CLP04, is backed out at PLB with PI/PA. If an inpatient claim has a Hemophilia Add On payment, the payment to the provider is increased in the PLB segment with a PLB adjustment HM.

D. - 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 following reflects the remittance advice messages and associated codes that will appear when processing claims under this policy. The CARC below is not included in the CAQH CORE Business Scenarios.

Group Code: OA CARC: 94 RARC: MA103 MSN: N/A

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 ASC X12 835 remittance advice, where additional information is available.

See chapter 22, for detailed instructions and definitions.