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Medicare Coding and Payment Guide
Hospital Inpatient and Outpatient Settings

Effective: October 1, 2021

Pathogen Reduced Cryoprecipitated Fibrinogen Complex

(INTERCEPT® Fibrinogen Complex)

(Pooled Fibrinogen Complex, Cryoprecipitated, Psoralen Treated)

Billing *Inpatient*

Medicare Reimbursement for INTERCEPT® Fibrinogen Complex in the Hospital Inpatient Setting

New Technology Add-On PAYMENT

Under the Medicare hospital inpatient prospective payment system (IPPS), each inpatient stay is assigned to a single Medicare severity diagnosis-related group (MS-DRG).

INTERCEPT Fibrinogen Complex has been granted a New Technology Add-on Payment (NTAP).

In some cases for extraordinary new technologies, Medicare will provide a product-specific NTAP payment on top of the MS-DRG payment. Medicare sets the maximum NTAP payment at 65% of the average cost of treatment with the technology.

The maximum NTAP payment amount for the INTERCEPT Fibrinogen Complex is $2,535 for eligible cases and will vary on a case-by-case basis.

- The NTAP payment amount is determined by the total cost for the case and is not based on the dosage of INTERCEPT Fibrinogen Complex administered.
- The NTAP payment for INTERCEPT Fibrinogen Complex is capped at $2,535 per inpatient stay but could be lower if the cost of the case is less than the MS-DRG payment. It could also be $0 if the cost of the case does not exceed the DRG payment amount.

Inpatient CODING

In order for an inpatient stay to be eligible for an NTAP, hospitals must bill for the administration of INTERCEPT Fibrinogen Complex using one of the following ICD-10-PCS codes:

30233D1	OR	30243D1
Transfusion of Pathogen Reduced Cryoprecipitated Fibrinogen Complex Into **Peripheral Vein**, Percutaneous Approach		Transfusion of Pathogen Reduced Cryoprecipitated Fibrinogen Complex Into **Central Vein**, Percutaneous Approach

These codes signal to the Medicare Administrative Contractor (MAC) that an NTAP payment for INTERCEPT Fibrinogen Complex needs to be calculated; **without these codes no NTAP payment evaluation will be made.**

CMS has also indicated that the NTAP only applies to cases in which INTERCEPT Fibrinogen Complex is used to treat massive bleeding associated with fibrinogen deficiency, the indication for which FDA Breakthrough Device designation was awarded.

CMS is limiting the NTAP to cases with the following diagnosis codes:[1,2]

D62
Acute posthemorrhagic anemia
OR
D65
Disseminated intravascular coagulation
OR
D68.2
Hereditary deficiency of other clotting factors
OR
D68.4
Acquired coagulation factor deficiency
OR
D68.9
Coagulation defect, unspecified

Hospitals are responsible for determining the appropriate and accurate diagnosis code(s) for each patient.

Hospitals should report their charges for INTERCEPT Fibrinogen Complex on inpatient claims using an appropriate revenue code. One possible code is 0390 (Blood and Blood Component Administration, Processing, and Storage; General Classification).[3]

It is important to set an appropriate charge for INTERCEPT Fibrinogen Complex considering the hospital's overall cost-to-charge ratio so the charge will accurately reflect the cost of INTERCEPT Fibrinogen Complex. The actual charges for INTERCEPT Fibrinogen Complex will help CMS set an MS-DRG relative weight that reflects the resources required to treat patients requiring the therapy.

Inpatient Coding Summary

Item	Code	
ICD-10-PCS Procedure Codes	30233D1	Transfusion of Pathogen Reduced Cryoprecipitated Fibrinogen Complex Into Peripheral Vein, Percutaneous Approach
	OR	
	30243D1	Transfusion of Pathogen Reduced Cryoprecipitated Fibrinogen Complex Into Central Vein, Percutaneous Approach
ICD-10-CM Diagnosis Codes	D62	Acute posthemorrhagic anemia
	OR	
	D65	Disseminated intravascular coagulation
	OR	
	D68.2	Hereditary deficiency of other clotting factors
	OR	
	D68.4	Acquired coagulation factor deficiency
	OR	
	D68.9	Coagulation defect, unspecified
Revenue code	0390	Blood and Blood Component Administration, Processing, and Storage; General Classification.

1. CMS Manual System, Pub 100-04 Medicare Claims Processing, Transmittal 10995, Change Request 12373, September 16, 2021, accessed October 29, 2021 at: https://www.cms.gov/files/document/r10995cp.pdf
2. CMS FY 2022 IPPS Final Rule, MAC Implementation File 8 – FY 2022 New Technology Add-on Payment, accessed October 29, 2021 at: https://www.cms.gov/medicare/acute-inpatient-pps/fy-2022-ipps-final-rule-home-page
3. Cerus Corporation charges only processing and storage fees for INTERCEPT Fibrinogen Complex product. There is no charge for the blood component itself. Revenue Code 0390 is the best match for blood products for which only processing and storage fees are charged. For CMS guidance on blood product revenue codes see: Centers for Medicare and Medicaid Services. Medicare claims processing manual. Chapter 4, Section 231.3. Baltimore, MD: CMS. Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c04.pdf

Billing *Outpatient*

Medicare Reimbursement for INTERCEPT® Fibrinogen Complex in the Hospital Outpatient Setting

HCPCS CODING

Healthcare Common Procedure Coding System (HCPCS) Code for INTERCEPT Fibrinogen Complex provided in the hospital outpatient setting:

HCPCS	Long Descriptor	Short Descriptor
P9026	Cryoprecipitated fibrinogen complex, pathogen reduced, each unit	Cryo fib comp path redu each

INTERCEPT Fibrinogen Complex is available in multiple configurations (doses).
Billing with HCPCS P9026 should occur for each unit of INTERCEPT Fibrinogen Complex within the administered container.

Number of INTERCEPT Fibrinogen Complex Units In 1 Container	Blood Product Codes Representing this Product*						
1	EA484V00	OR	EA489V00	OR	EA494V00	OR	EA495V00
2	EA485V00	OR	EA490V00	OR	EA496V00	OR	EA500V00
3	EA486V00	OR	EA491V00	OR	EA497V00	OR	EA501V00
4	EA487V00	OR	EA492V00	OR	EA498V00	OR	EA502V00
5	EA488V00	OR	EA493V00	OR	EA499V00	OR	EA503V00

*Last 3 characters of product code may vary.

Facility-based pooling of INTERCEPT Fibrinogen Complex

If multiple units of INTERCEPT Fibrinogen Complex are pooled at your facility prior to transfusion, bill the number of product units, and additionally bill one unit of pooling with **CPT 86965 (Pooling of platelets or other blood products).**

Standard billing practices apply to transfusion procedures used to administer INTERCEPT Fibrinogen Complex in the outpatient treatment setting.

Frequently Asked Questions

Why was INTERCEPT Fibrinogen Complex granted NTAP status in the Medicare hospital setting?

INTERCEPT Fibrinogen Complex was granted NTAP status because it meets the criteria established by the Centers for Medicare & Medicaid Services (CMS) for FDA Breakthrough Device designated products.

What codes do hospitals need to include on inpatient claims involving INTERCEPT Fibrinogen Complex?

Claims for inpatient stays involving INTERCEPT Fibrinogen Complex must include one of the following ICD-10-PCS procedure codes:

30233D1 Transfusion of Pathogen Reduced Cryoprecipitated Fibrinogen Complex Into Peripheral Vein, Percutaneous Approach

OR

30243D1 Transfusion of Pathogen Reduced Cryoprecipitated Fibrinogen Complex Into Central Vein, Percutaneous Approach

Medicare will evaluate a claim using one of the above administration codes for NTAP payment if it also includes one of the following ICD-10-CM diagnosis codes:

D62 Acute posthemorrhagic anemia

OR

D65 Disseminated intravascular coagulation

OR

D68.2 Hereditary deficiency of other clotting factors

OR

D68.4 Acquired coagulation factor deficiency

OR

D68.9 Coagulation defect, unspecified

Hospitals are responsible for determining the accurate and appropriate diagnosis codes to report for each particular patient.

How much additional payment will hospitals receive for INTERCEPT Fibrinogen Complex in the inpatient setting?

The amount of the NTAP will vary based on the hospital's costs for the inpatient stay and will be capped at $2,535 if the costs of the case exceed the DRG payment. The NTAP payment is not based on the actual dose of INTERCEPT Fibrinogen Complex administered.

How will private payers and Medicaid plans reimburse for INTERCEPT Fibrinogen Complex?

Unless otherwise noted, the information in this guide applies specifically to Medicare. The coding and payment policies of other payers may vary.

Notes

About INTERCEPT® Fibrinogen Complex

Pathogen Reduced Cryoprecipitated Fibrinogen Complex (INTERCEPT Fibrinogen Complex) is indicated for:

- Treatment and control of bleeding, including massive hemorrhage, associated with fibrinogen deficiency.
- Control of bleeding when recombinant and/or specific virally inactivated preparations of factor XIII or von Willebrand factor (vWF) are not available.
- Second-line therapy for von Willebrand disease (vWD).
- Control of uremic bleeding after other treatment modalities have failed.

Limitations of Use: Pathogen Reduced Cryoprecipitated Fibrinogen Complex should not be used for replacement of factor VIII.

Contraindications

- Contraindicated for preparation of blood components intended for patients with a history of hypersensitivity reaction to amotosalen or other psoralens.
- Contraindicated for preparation of blood components intended for neonatal patients treated with phototherapy devices that emit a peak energy wavelength less than 425 nm, or have a lower bound of the emission bandwidth <375 nm, due to the potential for erythema resulting from interactions between ultraviolet light and amotosalen.

Warnings and Precautions

- Only the INTERCEPT Blood System for Cryoprecipitation is approved for use to produce Pathogen Reduced Cryoprecipitated Fibrinogen Complex.
- For management of patients with vWD or factor XIII deficiency, Pathogen Reduced Cryoprecipitated Fibrinogen Complex should not be used if recombinant or specific virally-inactivated factor preparations are available. In emergent situations, if recombinant or specific virally-inactivated factor preparations are not available, Pathogen Reduced Cryoprecipitated Fibrinogen Complex may be administered.

Rx only. See package insert for full prescribing information.

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