

## Clinical Policy: Protein C Concentrate, Human (Ceprotin)

Reference Number: LA.PHAR.330

Effective Date: 11.04.23

Last Review Date: 03.05.25

Line of Business: Medicaid

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

**\*\*Please note: This policy is for medical benefit\*\***

### Description

Protein C concentrate, human (Ceprotin®) is an enzyme manufactured from human plasma.

### FDA Approved Indication(s)

Ceprotin is indicated in neonate, pediatric, and adult patients with severe congenital Protein C deficiency for the prevention and treatment of venous thrombosis and purpura fulminans.

### Policy/Criteria

*Provider must submit documentation (including such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of Louisiana Healthcare Connections that Ceprotin is **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

##### A. Congenital Protein C Deficiency (must meet all):

1. Diagnosis of congenital protein C deficiency;
2. Prescribed by or in consultation with a hematologist or physician with expertise in inherited thrombophilias;
3. One of the following (a or b):
  - a. Prescribed for use in an acute setting;
  - b. Lab result confirms low protein C activity (due to low protein C levels or function or both).

**Approval duration: 6 months**

##### B. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy LA.PMN.53.

#### II. Continued Therapy

**A. Congenital Protein C Deficiency (must meet all):**

1. Currently receiving medication via Louisiana Healthcare Connections benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If not previously determined, lab result confirms baseline low protein C activity (due to low protein C levels or function or both).

**Approval duration: 12 months**

**B. Other diagnoses/indications (must meet 1 or 2):**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy LA.PMN.53.

**III. Diagnoses/Indications for which coverage is NOT authorized:**

- A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – LA.PMN.53.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

FDA: Food and Drug Administration

*Appendix B: Therapeutic Alternatives*

Not applicable

*Appendix C: Contraindications/Boxed Warnings*

None reported

**V. Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose
Acute episode/short-term prophylaxis	Initial dose: 100-120 IU/kg IV Subsequent 3 doses: 60-80 IU/kg IV Q6 hours Maintenance dose: 45-60 IU/kg IV Q6 or 12 hours	Individualized
Long-term prophylaxis	Maintenance dose: 45-60 IU/kg IV Q12 hours	Individualized

**VI. Product Availability**

Lyophilized powder for IV injection: 500 IU per vial; 1,000 IU per vial

## VII. References

1. Ceprotin Prescribing Information. Westlake Village, CA: Baxalta US, Inc.; March 2023. Available at: [https://www.shirecontent.com/PI/PDFs/CEPROTINHCP\\_USA\\_ENG.pdf](https://www.shirecontent.com/PI/PDFs/CEPROTINHCP_USA_ENG.pdf). Accessed October 29, 2024.
2. Stevens SM, Woller SC, Bauer KA, et al. Guidance for the evaluation and treatment of hereditary and acquired thrombophilia. *J Thromb Thrombolysis*. 2016; 41(1): 154-164.
3. Minford A, Brandão LR, Othman M, et al. Diagnosis and management of severe congenital protein C deficiency (SCPCD): Communication from the SSC of the ISTH [published correction appears in *J Thromb Haemost*. 2022 Oct;20(10):2449] [published correction appears in *J Thromb Haemost*. 2023 Apr;21(4):1069]. *J Thromb Haemost*. 2022;20(7):1735-1743.
4. Medical and Scientific Advisory Council (MASAC) of the National Bleeding Disorders Foundation (formerly National Hemophilia Foundation): Database of treatment guidelines. Available at <https://www.hemophilia.org/healthcare-professionals/guidelines-on-care/masac-documents>. Accessed November 18, 2024.

## Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J2724	Injection, protein C concentrate, intravenous, human, 10 IU

Reviews, Revisions, and Approvals	Date	LDH Approval Date
Converted corporate to local policy.	06.19.23	10.05.23
Annual review: no significant changes; references reviewed and updated	05.01.24	07.29.24
Annual review: no significant changes; references reviewed and updated.	03.05.25	

## Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

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