Clinical Policy: Protein C Concentrate, Human (Ceprotin)

Reference Number: LA.PHAR.330
Effective Date: 11.04.23
Last Review Date: 03.05.25~~05.01.24~~ Coding Implications
Line of Business: Medicaid 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 ~~for the relevant line of business:~~ LA.PMN.53 ~~for Medicaid~~.

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 ~~for the relevant line of business:~~ LA.PMN.53 ~~for Medicaid~~.

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 ~~for Medicaid, or evidence of coverage documents~~.

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. Accessed October ~~26, 2023~~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.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom LHCC has no control or right of control. Providers are not agents or employees of LHCC.

This clinical policy is the property of LHCC. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.