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

Reference Number: ERX.SPA.300
Effective Date: 03.01.19
Last Review Date: 02.22
Line of Business: Commercial, Medicaid

Revision Log

**See Important Reminder at the end of this policy for important regulatory and legal information.**

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

*Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.*

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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**
1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

**II. Continued Therapy**

**A. Congenital Protein C Deficiency** (must meet all):
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions 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. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   **Approval duration: Duration of request or 6 months (whichever is less)**; or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

**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 – ERX.PA.01 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<br>Subsequent 3 doses: 60-80 IU/kg IV Q6 hours<br>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.; August 2021. Available at: http://ww.shirecontent.com/PI/PDFs/CEPROTINPATIENT_USA_ENG.pdf. Accessed November 23, 2021.
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.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| Policy created | 11.13.18 | 02.19 |
| 1Q 2020 annual review: no significant changes; references reviewed and updated. | 11.08.19 | 02.20 |
| 1Q 2021 annual review: no significant changes; references reviewed and updated. | 11.06.20 | 02.21 |
| 1Q 2022 annual review: no significant changes; references reviewed and updated. | 11.23.21 | 02.22 |

**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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.