Clinical Policy: Protein C Concentrate, Human (Ceprotin)

Reference Number: PA.CP.PHAR.330
Effective Date: 01/2018
Last Review Date: 01/2026

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 PA Health & Wellness® 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 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: 12 months

B. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

A. Congenital Protein C Deficiency (must meet all):
1. Previously received this medication via PA Health & Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.PHARM.01) applies;
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 PA Health & Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.PHARM.01) applies;
   Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to PA. CP.PMN.53

III. 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

IV. 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

V. Product Availability

Lyophilized powder for IV injection: 500 IU per vial; 1000 IU per vial

References

1. Ceprotin Prescribing Information. Westlake Village, CA: Baxalta US, Inc.; September 2024. Available at: http://www.shirecontent.com/PI/PDFs/CEPROTINPATIENT_USA_ENG.pdf. Accessed October 21, 2025.
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. P 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 24, 2025.

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
Diagnosis specified. References reviewed and updated.	02/2018
1Q 2019 annual review: no significant changes; references reviewed and updated.	01/2019
1Q 2020 annual review: no significant changes; references reviewed and updated.	01/2020
1Q 2021 annual review: no significant changes; references reviewed and updated.	01/2021
1Q 2022 annual review: no significant changes; references reviewed and updated.	01/2022
1Q 2023 annual review: no significant changes; references reviewed and updated.	01/2023
1Q 2024 annual review: no significant changes; references reviewed and updated.	01/2024
1Q 2025 annual review: no significant changes; references reviewed and updated.	01/2025
1Q 2026 annual review: no significant changes; revised initial approval duration from 6 months to 12 months; references reviewed and updated.	01/2026