Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review. Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 02/01/2021**
Policy Number: PA.CP.PHAR.330	**Effective Date: 01/01/2018** **Revision Date: 01//2021**
Policy Name: Protein C Concentrate, Human (Ceprotin)	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ☐ **Revised Policy***
- ✓ **Annual Review - No Revisions**
- ☐ **Statewide PDL** - *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

1Q 2021 annual review: references reviewed and updated.

Name of Authorized Individual (Please type or print): **Auren Weinberg, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Protein C Concentrate, Human (Ceprotin)

Reference Number: PA.CP.PHAR.330
Effective Date: 01/2018
Last Review Date: 01/2021

Coding Implications
Revision Log

Description
Protein C Concentrate, Human (Ceprotin®) is an enzyme manufactured from human plasma.

FDA Approved Indication(s)
Ceprotin is indicated in 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 health plans affiliated with Pennsylvania Health and 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 confirming low protein C activity (due to low protein C levels or function or both).

Approval duration: 6 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 Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.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 Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;

Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to PA. CP.PMN.53

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**Common causes of inherited thrombophilias include Factor V Leiden, prothrombin gene mutation, and deficiencies in protein S, protein C, and antithrombin.*
***Treatment should not be delayed by testing requirements in the acute setting nor should testing be performed in the presence of acute thrombosis or initial anticoagulation therapy (at least three months) as these factors will influence the results.*

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 Subsequent 3 doses: 60-80 IU/kg Q6 hours Maintenance dose: 45-60 IU/kg Q6 or 12 hours	Individualized
Long-term prophylaxis	Maintenance dose: 45-60 IU/kg 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.; December 2018. Available at http://www.shirecontent.com/PI/PDFs/CEPROTINPATIENT_USA_ENG.pdf. Accessed November 6, 2020.
2. Stevens SM, Woller SC, Bauer KA, et al. Guidance for the evaluation and treatment of hereditary and acquired thrombophilia. J Thromb Thrombolysis. January 2016; 41(1): 154-164.

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	Approval Date
Diagnosis specified. References reviewed and updated.	02/18	
1Q 2019 annual review: references reviewed and updated.	01/19	
1Q 2020 annual review: references reviewed and updated.	01/2020	
1Q 2021 annual review: references reviewed and updated.	01/2021	