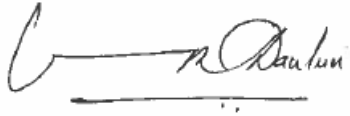


## Prior Authorization Review Panel

### 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.

<b>Plan: PA Health &amp; Wellness</b>	<b>Submission Date: 02/01/2022</b>
<b>Policy Number: PA.CP.PHAR.330</b>	<b>Effective Date: 01/01/2018</b> <b>Revision Date: 01//2022</b>
<b>Policy Name: Protein C Concentrate, Human (Ceprotin)</b>	
<p><b>Type of Submission – <u>Check all that apply</u>:</b></p> <p> <input type="checkbox"/> New Policy  <input checked="" type="checkbox"/> Revised Policy*  <input type="checkbox"/> Annual Review - No Revisions  <input type="checkbox"/> Statewide PDL - <i>Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.</i> </p>	
<p><b>*All revisions to the policy <u>must</u> be highlighted using track changes throughout the document.</b></p> <p><b>Please provide any changes or clarifying information for the policy below:</b></p> <p>1Q 2022 annual review: no significant changes; references reviewed and updated.</p>	
<b>Name of Authorized Individual (Please type or print):</b>  <b>Venkateswara R. Davuluri, MD</b>	<b>Signature of Authorized Individual:</b> 

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

Reference Number: PA.CP.PHAR.330

Effective Date: 01/2018

Last Review Date: 01/2022

[Coding Implications](#)

[Revision Log](#)

### Description

Protein C Concentrate, Human (Ceprotin<sup>®</sup>) 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 health plans affiliated with Pennsylvania Health and Wellness<sup>®</sup> 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: 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

### 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

- Ceprotin Prescribing Information. Westlake Village, CA: Baxalta US, Inc.; August 2021. Available at: [http://www.shirecontent.com/PI/PDFs/CEPROTINPATIENT\\_USA\\_ENG.pdf](http://www.shirecontent.com/PI/PDFs/CEPROTINPATIENT_USA_ENG.pdf). Accessed November 23, 2021.
- 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.

### 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.

HCPSC 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	

Reviews, Revisions, and Approvals	Date	Approval Date
1Q 2020 annual review: references reviewed and updated.	01/2020	
1Q 2021 annual review: references reviewed and updated.	01/2021	
1Q 2022 annual review: references reviewed and updated.	01/2022	