Clinical Policy Title:	protein C concentrate, human
Policy Number:	RxA.61
Drug(s) Applied:	Ceprotin®
Original Policy Date:	02/07/2020
Last Review Date:	03/09/2021
Line of Business Policy Applies to:	All lines of business

Background

Protein C concentrate, Human (Ceprotin®) is an enzyme manufactured from human plasma.
It is indicated in pediatric and adult patients with severe congenital Protein C deficiency for the prevention and treatment of venous thrombosis and purpura fulminans.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Protein C Concentrate, Human (Ceprotin®)	Acute episode/short-term prophylaxis	Initial dose: 100-120 IU/kg IV Subsequent 3 doses: 60-80 IU/kg IV every 6 hours Maintenance dose: 45-60 IU/kg IV every 6 or 12 hours	Individualized
	Long-term prophylaxis	Maintenance dose: 45-60 IU/kg IV every 12 hours	Individualized

Dosage Forms

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

Clinical Policy

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

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 confirming low protein C activity (due to low protein C levels or function or both).

Approval duration

Commercial: 6 months

Medicaid: 6 months

II. Continued Therapy Approval

A. Congenital Protein C Deficiency (must meet all):

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
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
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
IU: international units
IV: intravenous

APPENDIX B: Therapeutic Alternatives
Not applicable.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None reported.

- Boxed Warning(s):
  - None reported.

APPENDIX D: General Information
None.

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 February 18, 2021.
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. Accessed February 18, 2021.
3. Kang, Steven. Protein C Deficiency. NORD (National Organization for Rare Disorders); 2016. Available at: https://rarediseases.org/rare-diseases/protein-c-deficiency/. Accessed February 18, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy was established	01/2020	02/07/2020
Updated references	04/29/2020	05/20/2020
Policy was reviewed: Updated Criteria II.A.i to: “Currently receiving medication that has been authorized by Rxadvance…".	05/08/2020	05/20/2020

Policy was reviewed: 1. Policy title table was updated: Clinical Policy Title was updated to “All lines of business”. 2. Added route of administration to dosing regimen. 3. Continued therapy approval criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by RxAdvance…”. 4. Approval duration was updated to include Medicaid plans in initial and continued therapy. 5. Appendix A updated for accuracy. 6. References were updated.	02/18/2021	03/09/2021