Mass General Brigham
Health Plan

Ceprotin (protein C concentrate)
Effective 04/01/2023

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit (NLX)		
Specialty Limitations			
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions			

Overview

Ceprotin® (protein C concentrate) is an anticoagulant indicated for neonates, pediatric and adult patients with severe congenital Protein C deficiency for the prevention and treatment of venous thrombosis and purpura fulminans.

No PA	Drugs that require PA
Arixtra® # (fondaparinux)	Ceprotin® (protein C concentrate)^
Coumadin® # (warfarin)	Savaysa® (edoxaban) *
Eliquis® (apixaban)	
Fragmin® (dalteparin)	
Lovenox® # (enoxaparin)	
Pradaxa® (dabigatran)	
Xarelto® (rivaroxaban 10 mg, 15 mg, 20 mg, starter pack)	

^ This agent is available through the medical benefit.

This is a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.

* Please refer to the Anticoagulants guideline.

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization will be granted when all the following criteria has been met and documentation has been submitted:

1. **ONE** of the following:
    a. Diagnosis of inherited protein C deficiency
        i. Prescriber is a hematologist or consult notes from a hematologist are provided
        ii. Physician attestation of inadequate response (i.e. recurrent thromboembolic episodes), adverse reaction to **ONE** or contraindication to **ALL** of the following:
            1. Eliquis® (apixaban)
            2. Pradaxa® (dabigatran)
            3. Savaysa® (edoxaban
            4. warfarin
            5. Xarelto® (rivaroxaban)
        iii. Physician attestation of inadequate response (i.e. recurrent thromboembolic episodes), adverse reaction to **ONE** or contraindication to **ALL** of the following:
            1. enoxaparin
            2. fondaparinux
            3. Fragmin® (dalteparin)
    b. Diagnosis of prophylaxis for upcoming procedure

Continuation of therapy

Reauthorization by physician will infer a positive response to therapy.

Limitations

1. Initial approvals and reauthorizations will be granted for 6 months.

References

1. Ceprotin® [package insert]. Westlake Village (CA): Baxter Healthcare Corporation; 2018 Dec.
2. Micromedex® Healthcare Series [database on the Internet]. Greenwood Village (CO): Truven Health Analytics, Inc.; Updated periodically [cited 2020 Oct 22]. Available from: http://www.micromedex.com/.
3. National Organization for Rare Disorders (NORD). Protein C Deficiency. [webpage on the internet]. Danbury (CT): National Organization for Rare Disorders; 2016 Jul 9 [cited 2020 Oct 22]. Available from: https://rarediseases.org/rare-diseases/protein-c-deficiency/
4. Baxter Announces FDA Approval for Ceprotin for Severe Congenital Protein C Deficiency [press release on the Internet]. Deerfield (IL): Baxter Healthcare Corporation.: 2007 Mar 30 [cited 2020 Oct 22]. Available from: http://finance.bnet.com/bnet/news/read?GUID=1607742
5. Bauer KA. Protein C deficiency. In: Basow DS (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2020 [cited 2020 Oct 22]. Available from: http://www.utdol.com/utd/index.do.
6. Kroiss S, Albisetti M. Use of human protein C concentrates in the treatment of patients with severe congenital protein C deficiency. Biologics: Targets and Therapy. 2010:4:51-60.
7. Lip GY, Hull RD. Rationale and indications for indefinite anticoagulations in patients with venous thromboembolism. In: Basow DS (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2020 [cited 2020 Oct 22]. Available from: http://www.utdol.com/utd/index.do.
8. Allaart CF, Rosendaal FR, Noteboom WM, Vandenbroucke JP, Briet E. Survival in families with hereditary protein C deficiency, 1820 to 1993. BMJ. 1995 Oct;311(7010):910-3.

9. Bauer KA. The thrombophilias: Well-defined risk factors with uncertain therapeutic implications. Ann Intern Med. 2001 Sep;135(5):367-73.
10. Chan A, Bhatt MD. Management of thrombosis in the newborn. In: Basow DS (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2020 [cited 2020 Oct 22]. Available from: http://www.utdol.com/utd/index.do.
11. Goldenberg NA, Manco-Johnson MJ. Protein C deficiency. Haemophilia. 2008; 14:1214-21.
12. Knoebl PN. Severe congenital protein C deficiency: the use of protein C concentrates (human) as replacement therapy for life-threatening blood-clotting complications. Biologics: Targets and Therapy. 2008:2(2):285-96.
13. Blood formation and coagulation 20:00, Antithrombotic drugs 20:12, Anticoagulants 20:12.04, Anticoagulants-miscellaneous 20:12.04.92. In: McEvoy GK, editor; American Hospital Formulary Service. AHFS drug information 2014 [monograph on the Internet]. Bethesda (MD): American Society of Health-System Pharmacists; 2014 [cited 2014 Jul 8]. Available from: http://online.statref.com.

Review History

01/11/23 - Reviewed and created for Jan P&T; matched MH UPPL. Created criteria to be in compliance with MassHealth unified formulary requirements. Effective 4/1/23.