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5.85.003

Section:	Prescription Drugs	**Effective Date:**	April 1, 2023
Subsection:	Hematological Agents	**Original Policy Date:**	September 9, 2008
Subject:	Ceprotin	**Page:**	1 of 3

Last Review Date: March 10, 2023

Ceprotin

Description

Ceprotin (protein C)

Background
Ceprotin is an anticoagulant used to treat Protein C deficiency, a severe congenital condition. Protein C plays an important part in blood clotting. Protein C is the precursor of a vitamin K-dependent anticoagulant glycoprotein that is synthesized in the liver. It is converted to activated Protein C (APC) which exerts its effects by the inactivation of the activated forms of factors V and VIII, which leads to a decrease in thrombin formation. A severe deficiency of this anticoagulant protein causes a defect in the control mechanism and leads to unchecked coagulation activation, resulting in thrombin generation and intravascular clot formation with thrombosis (1).

Regulatory Status
FDA-approved indication: Ceprotin is indicated for pediatric and adult patients with severe congenital Protein C deficiency for the prevention and treatment of venous thrombosis and purpura fulminans (1).

Simultaneous administration with tPA and/or anticoagulants may increase risk of bleeding (1).

Ceprotin is made from pooled human plasma, therefore the possibility of transmitting infectious agents cannot be ruled out (1).

Related policies

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Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Ceprotin may be considered **medically necessary** for the prevention and treatment of congenital protein C deficiency for the prevention and treatment of venous thrombosis and purpura fulminans.

Ceprotin may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnosis

Patient must have the following:

1. Congenital protein C deficiency
    a. Prevention and treatment of venous thrombosis and purpura fulminans

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 2 years

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

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Ceprotin is an anticoagulant used to prevent and treat protein purpura fulminans and venous thrombosis in patients with protein C deficiency. Lifetime treatment will be required (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of the Ceprotin while maintaining optimal therapeutic outcomes.

References

1. Ceprotin [package insert]. Westlake Village, CA: Baxalta US Inc.; August 2021.

Policy History

Date	Action
December 2011	Annual review
December 2012	Annual review
June 2014	Annual editorial review and reference update
September 2015	Annual review
December 2016	Annual review and reference update Addition of prevention and treatment of venous thrombosis and purpura fulminans Policy code changed from 5.10.03 to 5.85.03
September 2017	Annual review and reference update
September 2018	Annual editorial review
September 2019	Annual review and reference update. Changed approval duration from lifetime to 2 years
September 2020	Annual review
March 2021	Annual review
March 2022	Annual review and reference update
March 2023	Annual review. Changed policy number to 5.85.003

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 10, 2023 and is effective on April 1, 2023.