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
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

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration Lifetime

Rationale

Summary

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.
5.85.03

Section: Prescription Drugs  Effective Date: October 1, 2019
Subsection: Hematological Agents  Original Policy Date: September 9, 2008
Subject: Ceprotin  Page: 3 of 3

References

Policy History

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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 13, 2019 and is effective on October 1, 2019.