Recombinant Antihemophilic factor (Obizur®) – Acquired Hemophilia A
EOCCO POLICY

Policy Type: PA/SP Pharmacy Coverage Policy: EOCCO055

Description
Obizur is an antihemophilic factor indicated for the treatment of bleeding episodes in adults with acquired hemophilia. Obizur is not indicated for the treatment of congenital hemophilia A or von Willebrand disease.

Length of Authorization
- Initial: 6 months
- Renewal: 6 months

Quantity limits

Product Name	Dosage Form	Indication/ FDA Labeled Dosing	Quantity Limit
Obizur, antihemophilic factor (recombinant), porcine sequence	500 units	**Treatment of bleeding episodes in adults with acquired hemophilia A:** • Minor and moderate: Loading dose of 200 IU/kg, followed by maintenance dose titrated to maintain recommended factor VIII trough levels at 50-100 IU/dL every four to 12 hours • Major: Minor and moderate: Loading dose of 200 IU/kg, followed by maintenance dose titrated to maintain recommended factor VIII trough levels at 100-200 IU/dL (to treat acute bleed) every four to 12 hours, then 50-100 IU/dL (after acute bleed is controlled) every four to 12 hours	**Treatment of bleeding episodes in adults with acquired hemophilia A:** Up to the number of doses requested every 28 days

Initial Evaluation

I. Obizur may be considered medically necessary when the following criteria below are met:
   A. Member has a confirmed diagnosis of **<u>acquired</u> hemophilia A (acquired factor VIII deficiency)** when the following are met:
      1. Treatment is prescribed by or in consultation with a hematologist; **AND**

2. Diagnosis of acquired factor VIII deficiency has been confirmed by blood coagulation testing; **AND**
3. Used as treatment of bleeding episodes; **AND**
4. Obizur is not being used for congenital hemophilia A or von Willebrand disease

II. Obizur is considered investigational when used for congenital hemophilia or von Willebrand disease, or any other condition.

Renewal Evaluation

I. Documentation of clinical benefit, including decreased incidence of bleeding episodes or stability of bleeding episodes relative to baseline

Supporting Evidence

I. Acquired inhibitors of coagulation are antibodies that either inhibit the activity or increase the clearance of a clotting factor. The most common autoantibodies that affect clotting factor activity and lead to a bleeding disorder are directed against, and interfere with, the activity of factor VIII. This condition is also called acquired hemophilia.

II. Obizur is a recombinant, B domain-deleted porcine (pig) factor VIII indicated for the treatment of patients with autoantibodies to factor VII (i.e. patients with an acquired factor VIII inhibitor). It is not approved for use in patients with congenital (i.e. inherited) hemophilia A.

III. The safety and efficacy of Obizur was established in a small prospective study in patients with an acquired factor VIII inhibitor and severe bleeding. Obizur controlled bleeding in 86% of patients.

Investigational or Not Medically Necessary Uses

There is no evidence to support the use of Obizur in any other condition.

References

1. Obizur® [Prescribing Information]. Lexington, MA: Baxalta; September 2017
2. National Hemophilia Foundation. MASAC Recommendations Concerning products Licensed for the Treatment of Hemophilia and Other Bleeding Disorders. Available from: https://www.hemophilia.org/Researchers-Healthcare-Providers/Medical-and-Scientific-Advisory-Council-MASAC/MASAC-Recommendations/MASAC-Recommendations-Concerning-Products-Licensed-for-the-Treatment-of-Hemophilia-and-Other-Bleeding-Disorders. Accessed July 5, 2019.
3. UpToDate, Inc. Aquired inhibitors of coagulation. UpToDate [database online]. Last updated June 19, 2019.

Policy Implementation/Update:

Date Created	August 2019
Date Effective	August 2019
Last Updated	August 2019

Last Reviewed	08/2019

Action and Summary of Changes	Date
New policy created for Obizur	08/2019