

Specialty Guideline Management

Obizur

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Obizur	antihemophilic factor [recombinant], porcine sequence

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications¹

Obizur is indicated for the on-demand treatment and control of bleeding episodes in adults with acquired hemophilia A.

Limitations of Use

- Safety and efficacy of Obizur has not been established in patients with a baseline anti-porcine factor VIII inhibitor titer of greater than 20 Bethesda units (BU).
- Obizur is not indicated for the treatment of von Willebrand disease.

All other indications are considered experimental/investigational and not medically necessary.

Reference number(s)
1948-A

Prescriber Specialties

Must be prescribed by or in consultation with a hematologist.

Coverage Criteria

Acquired hemophilia A¹⁻³

Authorization of 1 month may be granted for treatment of acquired hemophilia A.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria.

References

1. Obizur [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; March 2023.
2. National Hemophilia Foundation. MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Selected Disorders of the Coagulation System. Revised October 2024. MASAC Document #290. <https://www.hemophilia.org/sites/default/files/document/files/MASAC-Products-Licensed.pdf>. Accessed December 10, 2024.
3. Gomperts E. Recombinant B domain deleted porcine factor VIII for the treatment of bleeding episodes in adults with acquired hemophilia A. *Expert Review of Hematology*. 2015 Aug;8(4):427-32.