CVS Caremark®

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| Reference number(s) |
| 1948-A |

# 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.

## 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 Pharmaceucticals 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.