| Reference number(s) |
| --- |
| 4850-A |

# Standard Medicare Part B 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 Indications[1]

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 will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.


© 2026 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

| Reference number(s) |
| --- |
| 4850-A |

# Coverage Criteria

## Acquired hemophilia A[1-3]

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.

# Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Obizur.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Selected Disorders of the Coagulation System.

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Obizur are covered.

# Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.


© 2026 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

| Reference number(s) |
| --- |
| 4850-A |

# References


1. Obizur [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; December 2024.
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 3, 2025.
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.



© 2026 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.