

## SPECIALTY GUIDELINE MANAGEMENT

### OBIZUR (antihemophilic factor [recombinant], porcine sequence)

#### POLICY

##### I. 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 Indication

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

###### *Limitations of Use:*

- A. Safety and efficacy of Obizur has not been established in patients with a baseline anti-porcine factor VIII inhibitor titer of greater than 20 BU.
- B. Obizur is not indicated for the treatment of congenital hemophilia A or von Willebrand disease.

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

##### II. PRESCRIBER SPECIALTIES

Must be prescribed by or in consultation with a hematologist.

##### III. CRITERIA FOR INITIAL APPROVAL

###### **Acquired hemophilia A**

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

##### IV. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

##### V. REFERENCES

1. Obizur [package insert]. Lexington, MA: Baxalta US Inc.; September 2021.
2. National Hemophilia Foundation. MASAC recommendations concerning products licensed for the treatment of hemophilia and other bleeding disorders. Revised March 2022. MASAC Document #272. [https://www.hemophilia.org/sites/default/files/document/files/272\\_Treatment.pdf](https://www.hemophilia.org/sites/default/files/document/files/272_Treatment.pdf). Accessed December 2, 2022.

Reference number(s)
1948-A

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.