

<b>Reference number(s)</b>
1948-A

## 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. CRITERIA FOR INITIAL APPROVAL

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

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

##### III. CONTINUATION OF THERAPY

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

##### IV. REFERENCES

1. Obizur [package insert]. Lexington, MA: Baxalta US Inc.; July 2020.
2. National Hemophilia Foundation. MASAC recommendations concerning products licensed for the treatment of hemophilia and other bleeding disorders. Revised August 2020. MASAC Document #263. [https://www.hemophilia.org/sites/default/files/document/files/263\\_treatment.pdf](https://www.hemophilia.org/sites/default/files/document/files/263_treatment.pdf). Accessed November 20, 2020.
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.