	♥aetna				
	TTER HEALTH®				
Coverage Policy/Guideline					
Name:	Obizur		Page:	1 of 2	
Effective Date: 4/7/2024			Last Review Date:	4/2024	
A	⊠Illinois	□Florida	⊠Florida Kids		
Applies to:	⊠New Jersey	⊠Maryland	□Michigan		
	⊠Pennsylvania Kids	□Virginia	□Texas		

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Obizur under the patient's prescription drug benefit.

Description:

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 antiporcine 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.

Applicable Drug List:

Obizur

Policy/Guideline:

Prescriber Specialty:

Must be prescribed by or in consultation with a hematologist.

Criteria for Initial Approval:

Acquired hemophilia A

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 initial authorization criteria.

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Approval Duration and Quantity Restrictions:

Approval: 1 month

References:

- 1. Obizur [package insert]. Lexington, MA: Takeda Pharmaceucticals U.S.A., Inc.; March 2023.
- National Hemophilia Foundation. MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Selected Disorders of the Coagulation System. Revised August 2023. MASAC Document #280.
 - https://www.hemophilia.org/sites/default/files/document/files/MASAC-Products-Licensed.pdf. Accessed December 8, 2023.
- 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.