

**Obizur®**  
(recombinant antihemophilic factor)

Date of Origin: 01/22/2020

Last Review Date: 01/22/2020

Effective Date: 02/01/2020

Dates Reviewed: 01/22/2020

Developed By: Medical Criteria Committee

**I. Length of Authorization**

- Initial: 6 months
- Renewal: 12 months

**II. Dosing Limits**

Product Name	Dosage Form	Indication/ FDA Labeled Dosing	Quantity Limit
Obizur, antihemophilic factor (recombinant), porcine sequence	500 units	<p><b>Treatment of bleeding episodes in adults with acquired hemophilia A:</b></p> <ul style="list-style-type: none"> <li>• Minor and moderate: Loading dose of 200 IU/kg, followed by maintenance dose titrated to maintain recommended factor VIII trough levels at 50-100 IU/dL every four to 12 hours</li> <li>• Major: Minor and moderate: Loading dose of 200 IU/kg, followed by maintenance dose titrated to maintain recommended factor VIII trough levels at 100-200 IU/dL (to treat acute bleed) every four to 12 hours, then 50-100 IU/dL (after acute bleed is controlled) every four to 12 hours</li> </ul>	<p><b>Treatment of bleeding episodes in adults with acquired hemophilia A:</b> Up to the number of doses requested every 28 days</p>

**III. Initial Approval Criteria**

- I. Obizur may be considered medically necessary when the following criteria below are met:
  - A. Member has a confirmed diagnosis of **acquired hemophilia A (acquired factor VIII deficiency)** when the following are met:
    1. Treatment is prescribed by or in consultation with a hematologist; **AND**

2. Diagnosis of acquired factor VIII deficiency has been confirmed by blood coagulation testing; **AND**
3. Used as treatment of bleeding episodes; **AND**
4. Obizur is not being used for congenital hemophilia A or von Willebrand disease

II. Obizur is considered investigational when used for congenital hemophilia or von Willebrand disease, or any other condition.

### III. Renewal Criteria

- I. Documentation of clinical benefit, including decreased incidence of bleeding episodes or stability of bleeding episodes relative to baseline

### VI. Billing Code/Availability Information

Drug	Manufacturer	J-Code	1 Billable Unit Equiv.	Vial Size	NDC
Obizur	Baxter Healthcare	J7188	1 IU	500 units	00944-5001-01

### VII. References

1. Obizur® [Prescribing Information]. Lexington, MA: Baxalta; September 2017
2. National Hemophilia Foundation. MASAC Recommendations Concerning products Licensed for the Treatment of Hemophilia and Other Bleeding Disorders. Available from: <https://www.hemophilia.org/Researchers-Healthcare-Providers/Medical-and-Scientific-Advisory-Council-MASAC/MASAC-Recommendations/MASAC-Recommendations-Concerning-Products-Licensed-for-the-Treatment-of-Hemophilia-and-Other-Bleeding-Disorders>. Accessed July 5, 2019.
3. UpToDate, Inc. Hemophilia A and B: Routine management including prophylaxis Acquired inhibitors of coagulation. UpToDate [database online]. Last updated June 19, 2019.

### Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
D68.311	Acquired hemophilia

### Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be

found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

<b>Medicare Part B Administrative Contractor (MAC) Jurisdictions</b>		
<b>Jurisdiction</b>	<b>Applicable State/US Territory</b>	<b>Contractor</b>
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corporation (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corporation (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Cahaba Government Benefit Administrators, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC