Reference number(s)
4026-A

JURISDICTION SPECIFIC MEDICARE PART B

ALPHANATE (antihemophilic factor/von Willebrand factor complex [human])

POLICY

I. COVERED USES

The indications below are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

The list of covered ICD-10 codes is prohibitively long to include within this policy. A complete list can be found at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. The FDA-labeled indications uses are listed below:

A. Control and prevention of bleeding episodes and perioperative management in adult and pediatric patients with factor VIII deficiency due to hemophilia A
B. Surgical and/or invasive procedures in adult and pediatric patients with von Willebrand disease (VWD) in whom desmopressin (DDAVP) is either ineffective or contraindicated. It is not indicated for patients with severe VWD (type 3) undergoing major surgery.

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

II. DOCUMENTATION

The following documentation must be available in a legible format with patient identification information (e.g., complete name and dates of service) and signature of physician or non-physician practitioner responsible for and providing care to the member, upon request, for all submissions:

A. The submitted medical record must support the use of the selected ICD-10-CM codes. The submitted CPT/HCPCS code must describe the service performed.
B. The medical record documentation must support the medical necessity of the services as stated in this policy.

III. CRITERIA FOR APPROVAL

A. Hemophilia A

Authorization of 12 months may be granted for treatment of hemophilia A when the requested drug will be used for any of the following:

1. Primary prophylactic therapy when the member has less than 1 percent of normal factor with the aim of keeping the factor VIII level above 1 percent between doses.

2. Continuous prophylactic therapy when the member does not have severe disease (greater than 1 percent of normal factor levels) and the member experiences repeated episodes of spontaneous bleeding.
3. The requested drug will be used as on-demand treatment to control bleeding episodes.
4. The requested drug will be used for immune tolerance therapy.

B. Von Willebrand Disease
Authorization of 12 months may be granted for von Willebrand disease.

IV. REFERENCES

1. Hemophilia Factor Products LCD (L35111) Version R16. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed December 6, 2021.
2. Billing and Coding: Hemophilia Factor Products (A56433) Version R7. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed December 6, 2021.
3. Alphanate [package insert]. Los Angeles, CA: Grifols Biologicals, LLC; June 2018.

