| | |
|---|---|
| **Clinical Policy Title:** | Factor VIII/von Willebrand Factor Complex (Human – Alphanate, Humate-P, Wilate); von Willebrand Factor (Recombinant – Vonvendi) |
| **Policy Number:** | RxA.801 |
| **Drug(s) Applied:** | Factor VIII/von Willebrand Factor Complex (Human – Alphanate, Humate-P, Wilate); von Willebrand Factor (Recombinant – Vonvendi) |
| **Original Policy Date:** | 10/19/2023 |
| **Last Review Date:** | 10/19/2023 |
| **Line of Business Policy Applies to:** | All lines of business (except Medicare) |

## Criteria

**I. Initial Approval Criteria**

**A. Congenital Hemophilia A** (must meet all):

1. Diagnosis of congenital hemophilia A (factor VIII deficiency);
2. Request is for Alphanate, Humate-P, or Wilate;
3. Prescribed by or in consultation with a hematologist;
4. Request is for one of the following uses (a, b, or c):
   a. Control or prevention of bleeding episodes;
   b. Perioperative management (Alphanate only);
   c. Routine prophylaxis to reduce the frequency of bleeding episodes (Wilate only);
5. For routine prophylaxis requests (Wilate only), for members who have not previously used Wilate for routine prophylaxis, member meets one of the following (a or b):
   a. Member has severe hemophilia (defined as factor VIII level of < 1%);
   b. Member has experienced at least one serious spontaneous bleed ;
6. Documentation of member's current body weight (in kg);
7. Dose does not exceed FDA-approved maximum recommended dose refer to doing information table.

**Approval Duration**

**All Lines of Business (except Medicare):** 3 months

**B. Von Willebrand Disease** (must meet all):

1. Diagnosis of von Wsillebrand disease must meet (a and b):
   a. VWD type 1 or 2 (except type 2B), and member has had a failure of desmopressin acetate, unless contraindicated, clinically significant adverse effects are experienced, or an appropriate formulation of desmopressin acetate is unavailable;
   b. VWD type 2B or 3;
2. Prescribed by or in consultation with a hematologist;
3. Request is for one of the following uses (a, b, or c):
   a. Treatment of bleeding episodes (Humate-P, Vonvendi, and Wilate only);
   b. Perioperative management;

c. Routine prophylaxis to reduce the frequency of bleeding episodes in patients with severe VWD type 3 receiving on-demand therapy (Vonvendi only);

4. Documentation of member's current body weight (in kg);
5. Dose does not exceed the FDA approved maximum recommended dose refer to doing information table.

**Approval Duration**

**All Lines of Business (except Medicare):** 3 months

**II. Continued Therapy Approval**

**A. All Indications in Section I** (must meet all):

1. Member is currently receiving medication, excluding manufacturer samples;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed the FDA approved maximum recommended dose refer to doing information table.

**Approval Duration**

**All Lines of Business (except Medicare):** 3 months

**References**

1. Medical and Scientific Advisory Council (MASAC) of the National Hemophilia Foundation (NHF): Database of treatment guidelines. Available at: https://www.hemophilia.org/healthcare-professionals/guidelines-on-care/masac-documents. Accessed August 31, 2023.
2. MASAC Document 266 - MASAC Recommendations Regarding the Treatment of von Willebrand Disease (Revised March 2021). Available at: https://www.hemophilia.org/healthcare-professionals/guidelines-on-care/masacdocuments/masac-document-266-masac-recommendations-regarding-the-treatment-of-vonwillebrand-disease. Accessed August 31, 2023.

| Review/Revision History | Review/Revision Date | P&T Approval Date |
|---|---|---|
| Policy established. | 10/19/2023 | 10/19/2023 |