Reference number(s)
1950-A

SPECIALTY GUIDELINE MANAGEMENT

STIMATE (desmopressin acetate nasal spray)

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.

A. FDA-Approved Indications
1. Hemophilia A with factor VIII activity level >5%
2. Mild to moderate type 1 von Willebrand disease (VWD) with Factor VIII activity level >5%

B. Compendial Uses
1. Type 2A, 2M, 2N VWD
2. Qualitative platelet disorders
3. Acquired hemophilia A
4. Acquired von Willebrand syndrome

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

A. Von Willebrand Disease
1. Type 1 VWD
   Authorization of 12 months may be granted for treatment of mild or moderate type 1 VWD.
2. Type 2A, 2M, or 2N VWD
   a. Authorization of one month may be granted for treatment of type 2A, 2M, or 2N VWD in members who are initiating therapy.
   b. Authorization of 12 months may be granted for treatment of type 2A, 2M, or 2N VWD in members who are continuing therapy and have demonstrated a response to an initial trial of Stimate.

B. Hemophilia A
Authorization of 12 months may be granted for treatment of hemophilia A with factor VIII activity level greater than 5% (see Appendix).

C. Qualitative Platelet Disorders
Authorization of 12 months may be granted for treatment of a qualitative platelet disorder.

D. Acquired Hemophilia A
Authorization of 12 months may be granted for treatment of acquired hemophilia A.

E. Acquired von Willebrand Syndrome

Authorization of 12 months may be granted for treatment of acquired von Willebrand syndrome.

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when the member is experiencing benefit from therapy (e.g., reduced frequency or severity of bleeds).

IV. APPENDIX

Appendix: Classification of Hemophilia by Clotting Factor Level (% Activity) and Bleeding Episodes

Severity	Clotting Factor Level % activity^	Bleeding Episodes
Severe	<1%	Spontaneous bleeding episodes, predominantly into joints and muscles Severe bleeding with trauma, injury or surgery
Moderate	1% to 5%	Occasional spontaneous bleeding episodes Severe bleeding with trauma, injury or surgery
Mild	6% to 40%	Severe bleeding with serious injury, trauma or surgery

^Factor assay levels are required to determine the diagnosis and are of value in monitoring treatment response.

*Note: **This program addresses the appropriate use of Stimate Nasal Spray only**. Stimate Nasal Spray and DDAVP (desmopressin) Nasal Spray are two distinct products and are not interchangeable. DDAVP Nasal Spray is not indicated for hemophilia or VWD.

V. REFERENCES

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