

SPECIALTY GUIDELINE MANAGEMENT

WILATE (von Willebrand factor/coagulation factor VIII complex [human])

POLICY

A. 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.

FDA-Approved Indication

- Wilate is indicated in children and adults with von Willebrand Disease (vWD) for:
 - The treatment and control of bleeding episodes
 - Perioperative management of bleeding

Compendial Use

- Acquired von Willebrand Syndrome

All other indications are considered experimental/investigational and are not a covered benefit.

B. CRITERIA FOR APPROVAL

1. von Willebrand Disease

1.1 Type 1 vWD

Authorization for 12 months may be granted to members prescribed Wilate for type 1 vWD who have had an insufficient response to desmopressin or have a documented clinical reason for not using desmopressin (see Appendix).

1.2 Type 2A, 2M, or 2N vWD

Authorization for 12 months may be granted to members prescribed Wilate for type 2A, 2M, or 2N vWD who have had an insufficient response to desmopressin or have a documented clinical reason for not using desmopressin (see Appendix).

1.3 Type 2B or Type 3 vWD

Authorization for 12 months may be granted to members who are prescribed Wilate for type 2B or type 3 vWD.

2. Acquired von Willebrand Syndrome

Authorization for 12 months may be granted to members who are prescribed Wilate for acquired von Willebrand syndrome.

C. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

D. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

E. APPENDIX

Appendix: Clinical Reasons Commonly Stated For Not Utilizing Desmopressin in Patients with Type 1, 2A, 2N and 2M vWD

- a. Age < 2 years
- b. Pregnancy
- c. Fluid/electrolyte imbalance
- d. High risk for cardiovascular or cerebrovascular disease (especially the elderly)
- e. Predisposition to thrombus formation
- f. Trauma requiring surgery
- g. Life-threatening bleed
- h. Contraindication or intolerance to desmopressin
- i. Severe type 1 von Willebrand disease

REFERENCES

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