

**Clinical Policy: Betrixaban (Bevyxxa)**

Reference Number: CP.PMN.114

Effective Date: 08.08.17

Last Review Date: 11.17

Line of Business: Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

**Description**

Betrixaban (Bevyxxa<sup>®</sup>) is a factor Xa inhibitor.

**FDA Approved Indication(s)**

Bevyxxa is indicated for:

- The prophylaxis of venous thromboembolism (VTE) in adult patients hospitalized for an acute medical illness who are at risk for thromboembolic complications due to moderate or severe restricted mobility and other risk factors for VTE.

Limitation(s) of use: Safety and efficacy of Bevyxxa have not been established in patients with prosthetic heart valves because this population has not been studied.

**Policy/Criteria**

Provider *must* submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Centene Corporation<sup>®</sup> that Bevyxxa is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria****A. Prophylaxis of Venous Thromboembolism** (must meet all):

1. Request is for prophylaxis of VTE;
2. Age  $\geq$  18 years;
3. Member has received Bevyxxa during hospitalization and will be continuing therapy following discharge from the hospital;
4. Member is at risk for VTE (*See Appendix B for examples of risk factors for VTE*);
5. Member has not received up to 42 days of Bevyxxa therapy;
6. Dose does not exceed 80 mg per day (1 capsule per day).

**Approval duration: Up to a total treatment duration of 42 days**

**II. Continued Therapy****A. Prophylaxis of Venous Thromboembolism** (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy (e.g., no VTE);
3. Member has not received up to 42 days of Bevyxxa therapy;

4. If request is for a dose increase, new dose does not exceed 80 mg per day (1 tablet per day)

**Approval duration: Up to a total treatment duration of 42 days**

**III. Diagnoses/Indications for which coverage is NOT authorized:**

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.PMN.53 or evidence of coverage documents.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

VTE: venous thromboembolism

*Appendix B: Risk Factors for Venous Thromboembolism*

The APEX pivotal trial evaluated patients hospitalized for an acute medical illness (heart failure, respiratory failure, infectious disease, rheumatic disease, or ischemic stroke) at risk for VTE due to moderate or severe immobility, and had additional risk factors for VTE. Additional risk factors for VTE included age  $\geq$  75 years, age 60 through 74 years with D-dimer  $\geq$  2 times the upper limit of normal (ULN) or age 40 through 59 years with D-dimer  $\geq$  2 ULN and a history of either VTE or cancer.

**V. Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose
VTE prophylaxis in acute medical illness	160 mg one time oral loading dose, followed by 80 mg orally once daily	80 mg/day

**VI. Product Availability**

Capsule: 40 mg and 80 mg

**VII. References**

1. Bevyxxa [Prescribing Information]. San Francisco, CA: Portola Pharmaceuticals, Inc.; June 2017.
2. Cohen AT, Harrington RA, Goldhaber SZ, et al. Extended thromboprophylaxis with betrixaban in acutely ill medical patients. *N Eng J Med* 2016;375:543-44.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	08.08.17	11.17

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical

policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

**Note: For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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