# Clinical Policy: Betrixaban (Bevyxxa)

Reference Number: CP.PMN.114
Effective Date: 08.08.17
Last Review Date: 11.19 Revision Log
Line of Business: Medicaid

**See Important Reminder at the end of this policy for important regulatory and legal information.**

**Description**
Betrixaban (Bevyxxa®) 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 (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation® 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 VTE prophylaxis;
2. Age ≥ 18 years;
3. Member has received Bevyxxa during hospitalization and will be continuing therapy upon discharge;
4. Member has not received 42 or more days of Bevyxxa therapy;
5. Dose does not exceed 80 mg (1 capsule) per day.

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

**B. Other diagnoses/indications**

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

**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;
3. Member has not received 42 or more days of Bevyxxa therapy;
4. If request is for a dose increase, new dose does not exceed 80 mg (1 tablet) per day.

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

**B. Other diagnoses/indications** (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   **Approval duration: Duration of request or 42 days (whichever is less)**; or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

## 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 policies – CP.PMN.53 for Medicaid or evidence of coverage documents.

## IV. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*
FDA: Food and Drug Administration
VTE: venous thromboembolism

*Appendix B: Therapeutic Alternatives*
Not applicable

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s):
  - Active pathological bleeding
  - Severe hypersensitivity reaction to betrixaban
- Boxed warning(s):
  - Spinal/epidural hematoma

## V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| VTE prophylaxis in acute medical illness | 160 mg one time PO loading dose, followed by 80 mg PO QD | 80 mg/day |

## VI. Product Availability

Capsule: 40 mg, 80 mg

## VII. References

1. Bevyxxa Prescribing Information. San Francisco, CA: Portola Pharmaceuticals, Inc.; June 2017. Available at https://www.bevyxxa.com/ . Accessed August 5, 2019.
2. Prevention of VTE in nonsurgical patients: Antithrombotic therapy and prevention of thrombosis, 9th ed: American College of Chest Physicians evidence-based clinical practice guidelines. CHEST 2012; 141(2)(Suppl):e195S–e226S.
3. 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 |
| 4Q 2018 annual review: criteria removed requiring VTE risk reevaluation on discharge and VTE as positive response (VTE risk was established in hospital, continuing risk/response involves clinical judgment, the total treatment course is limited to 42 days, premature discontinuation may pose risk); continuation of care added; references reviewed and updated. | 08.07.18 | 11.18 |
| 4Q 2019 annual review: no significant changes; references reviewed and updated. | 08.05.19 | 11.19 |

**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.