RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title: **betrixaban (Bevyxxa®)**
Policy Number: **RxA.29**
Drug(s) Applied: **betrixaban (Bevyxxa®)**
Last Review Date: **04/2020**
Line of Business: **Commercial, HIM, Medicaid**

Background

Betrixaban (Bevyxxa®) is a factor Xa inhibitor. It 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.

Indication	Dosing Regimen	Maximum Dose
VTE prophylaxis in acute medical illness	160 mg PO as a single loading dose, then followed by 80 mg PO daily for 35 to 42 days	80 mg/day

Capsule: 40 mg, 80 mg

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that the member has met all approval criteria.

I. Initial Approval Criteria

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

1. Member has an increased risk of VTE supporting the need for VTE prophylaxis;
2. Age 18 years of age or older;
3. Member has received betrixaban during hospitalization and will be continuing therapy upon discharge;
4. Member has not received more than 42 days of betrixaban therapy; and
5. Dose does not exceed 80 mg (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 that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member is responding positively to therapy (e.g. no incidence of VTE);
3. Member has not received more than 42 days of betrixaban therapy; and
4. If request is for a dose increase, new dose does not exceed 80 mg (1 capsule) per day.

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

III. Appendices

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
PO: by mouth
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 may occur in patients treated with betrixaban who are receiving neuraxial anesthesia or undergoing spinal puncture.

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.
4. Betrixaban. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI; 2020, March 1. Accessed with subscription at: http://www.micromedexsolutions.com. Accessed April 29, 2020.
5. Bevyxxa Prescribing Information. South San Francisco, CA: Portola Pharmaceuticals, Inc: July 2019. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208383s006lbl.pdf. Accessed April 29, 2020.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy was established	01/2020	02/07/2020
Policy reviewed & updated.	04/29/2020	05/20/2020