

### Policy Type: PA Pharmacy Coverage Policy: EOCCO114

#### Description

Betrixaban (Bevyxxa) is an oral factor XA (FXa) inhibitor that inhibits free FXa and prothrombinase activity thereby decreasing thrombin generation without any effect on platelet aggregation.

#### Length of Authorization

- Initial: Duration of request or up to 42 days (whichever is less)
- Renewal: not eligible

#### Quantity Limits

Product Name	Dosage Form	Indication	Quantity Limit
betrixaban (Bevyxxa)	40 mg capsules	Prophylaxis of venous thromboembolism (VTE) in adult patients hospitalized for acute medical illness who are at risk for thromboembolic complications due to moderate or severe restricted mobility and other risk factors for VTE	44 capsules/365 days
	80 mg capsules		44 capsules/365 days

#### Initial Evaluation

- I. Betrixaban (Bevyxxa) may be considered medically necessary when the following criteria below are met:
  - A. Member is 18 years of age or older; **AND**
  - B. Member has **not** already taken a 42-day course of betrixaban (Bevyxxa) due to hospitalization for an acute medical illness; **AND**
  - C. Member has been recently hospitalized for an acute medical illness; **AND**
  - D. Member requires venous thromboembolism (VTE) prophylaxis due to moderate or severe restricted mobility, and other risk factors for VTE [e.g. heart failure, stroke, infection, pulmonary disease, age ≥ 75 years, history of VTE, or active cancer]; **AND**
  - E. Member does **not** have active bleeding or is at risk for bleeding; **AND**
  - F. Dosage does **not** exceed 80 mg per day; **AND**
  - G. Betrixaban (Bevyxxa) has been initiated during member’s hospitalization and will be continuing therapy upon discharge; **OR**

- H. Provider states in documentation that member has medical necessity for using betrixaban (Bevyxxa) over enoxaparin or fondaparinux

### Renewal Evaluation

- I. Duration of treatment beyond 42 days is not eligible for renewal; **AND**
- II. If continuing therapy of current treatment course or requesting a new course, please see initial criteria

### Supporting Evidence

- I. Betrixaban (Bevyxxa) is FDA-approved only 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.
- II. There is currently no evidence to demonstrate the use of betrixaban (Bevyxxa) beyond 42 days. Total duration of use listed by the provider should be evaluated to ensure this limit is not exceeded. However, if a member is re-hospitalized, clinician should review as a new course of therapy.
- III. The recommended duration of treatment is 35 to 42 days.
- IV. Though extended duration (42 days) of betrixaban (Bevyxxa) is associated with significantly less VTEs compared to standard duration (14 days) enoxaparin, it has higher non-major bleeding risk in comparison to enoxaparin for VTE prophylaxis. Therefore, if betrixaban (Bevyxxa) was not initiated in the hospital, it may be more beneficial to utilize enoxaparin over betrixaban (Bevyxxa) unless patient has a very low bleeding potential.
- V. Patients who are actively bleeding or are at risk for bleeding should not start betrixaban (Bevyxxa); there is currently no reversal (antidote) for betrixaban (Bevyxxa).

### Investigational or Not Medically Necessary Uses

- I. All condition(s) listed as investigational use
  - A. Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE)
  - B. Prevent the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation

### References

1. Bevyxxa [package insert]. South San Francisco, CA: Portola Pharmaceuticals, Inc; 2017.
2. Cohen AT, Harrington RA, Goldhaber SZ, et al. Extended thromboprophylaxis with betrixaban in acutely ill medical patients. The New England Journal of Medicine. May 2016; 375:534-544. doi: 10.1056/NEJMoa1601747.
3. American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. "Prevention of VTE in nonsurgical patients: Antithrombotic Therapy and Prevention of Thrombosis". Chest. 2012 Feb; 141(2 Suppl): e195S–e226S. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278052/>. Accessed September 20, 2017.

### Policy Implementation/Update:

Date Created	September 2017
Date Effective	November 2017
Last Updated	November 2019
Last Reviewed	11/2019

Action and Summary of Changes	Date
Criteria updated to new policy format. Specific changes include: member is 18 years of age or older was added.	11/2019
Criteria created	09/2017