Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 11/1/2018**
Policy Number: PA.CP.PMN.114	**Effective Date: 10/17/2018** **Revision Date: 10/17/2018**
Policy Name: Betrixaban (Bevyxxa)	**HC Approval Date:**

Type of Submission – Check all that apply:

- ✓ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review – No Revisions**
- ☐ **Attestation of HC PARP Policy –** *This option should only be used during Readiness Review for Community HealthChoices. The policy must be identical to the PARP approved policy for the HealthChoices Program, with the exception of revisions/clarifications adding the term "Community HealthChoices" to the policy.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

New Policy created.

Name of Authorized Individual (Please type or print): **Francis G. Grillo, MD**	**Signature of Authorized Individual:**

Clinical Policy: Betrixaban (Bevyxxa)

Reference Number: PA.CP.PMN.114
Effective Date: 10.17.18
Last Review Date: 10.17.18 Revision Log

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

Commented [ZL1]: Bevyxxa is not eligible for coverage by MA. The manufacturer does not participate in the CMS rebate program.

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 PA Health & Wellness® 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. Member has received Bevyxxa during hospitalization and will be continuing therapy upon discharge;
3. Member has not received 42 or more days of Bevyxxa therapy;
4. Dose does not exceed 80 mg per day (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 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

II. Continued Therapy

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
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 per day (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 Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 42 days (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

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 – PA.CP.PMN.53 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 oral loading dose, followed by 80 mg orally once daily	80 mg per 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/wp-content/uploads/2017/11/bevyxxa-betrixaban-capsules-prescribing-information-pdf.pdf. Accessed July 2018.
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	10/18	