BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 11/16/17
LAST REVIEW DATE: 11/16/17
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

BEVYXXA® (betrixaban maleate) oral capsule

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

BEVYXXA® (betrixaban maleate) oral capsule (cont.)

Description:

- Bevyxxa is an oral factor Xa inhibitor that inhibits free factor Xa and prothrombinase activity, ultimately decreasing thrombin generation.
- The safety and effectiveness of Bevyxxa have not been established in patients with prosthetic heart valves because this population has not been studied.
- The safety and efficacy of Bevyxxa were based on data from the APEX study of 7,513 patients hospitalized for an acute medical illness with VTE risk factors randomized to treatment with Bevyxxa for 35 to 42 days or treatment with enoxaparin for 6 to 14 days for VTE prophylaxis.
    - Efficacy was measured in 7,441 patients by a composite of either the occurrence of asymptomatic or symptomatic proximal deep vein thrombosis (DVT), non-fatal pulmonary embolism (PE), or VTE-related death.
    - The primary outcome occurred in fewer patients receiving Bevyxxa (4.4%) vs. those taking enoxaparin (6%) [Relative risk (RR) = 0.75, 95% CI: 0.61, 0.91].
    - Fewer symptomatic events, defined as symptomatic DVT, non-fatal PE or VTE-related death, were observed with Bevyxxa vs. enoxaparin (0.9% vs. 1.5%, respectively; RR = 0.64, 95% CI: 0.42, 0.98).
- Bevyxxa carries a boxed warning for spinal/epidural hematoma.
- Bevyxxa is contraindicated in patients with active pathological bleeding and in patients with severe hypersensitivity reaction to betrixaban.
- Warnings and precautions of Bevyxxa include risk of bleeding, spinal/epidural anesthesia or puncture, use in patients with severe renal impairment, and use in patients on concomitant P-gp inhibitors.
- The most common adverse reaction (> 5%) with Bevyxxa use was bleeding.
- The recommended dose of Bevyxxa is an initial single dose of 160 mg, followed by 80 mg once daily, taken at the same time each day with food. The recommended duration of treatment is 35 to 42 days.

Bevyxxa (betrixaban maleate)

Medication class:
Anticoagulants, Direct Factor XA Inhibitors

FDA-approved indication(s):

- 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.

BEVYXXA® (betrixaban maleate) oral capsule (cont.)

Recommended Dose:
- The recommended dose of Bevyxxa is an initial single dose of 160 mg, followed by 80 mg once daily, taken at the same time each day with food. The recommended duration of treatment is 35 to 42 days.
- Reduce dose for patients with severe renal impairment
- Reduce dose for patients on P-glycoprotein (P-gp) inhibitors.

Available Dosage Forms:
- Capsules: 40 mg and 80 mg

Limitations of use:
- Safety and efficacy of Bevyxxa have not been established in patients with prosthetic heart valves because this population has not been studied.

Warnings and Precautions:
- Risk of Bleeding: Can cause serious, potentially fatal bleeding. Promptly evaluate signs and symptoms of blood loss.
- Severe Renal Impairment: Increased risk of bleeding events; reduce Bevyxxa dose
- Concomitant P-gp Inhibitors: Increased risk of bleeding events; reduce Bevyxxa dose

Criteria:

- **Criteria for initial therapy:** Bevyxxa is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Individual is 18 years of age or older
2. A confirmed diagnosis of 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.
3. Member has received Bevyxxa during hospitalization and will be continuing therapy following discharge from the hospital
4. Member has not received up to 42 days of Bevyxxa therapy
5. Dose does not exceed 80 mg per day (1 capsule per day)
6. There are **NO** contraindications.
    - Contraindications include:
        - Active pathological bleeding
        - Severe hypersensitivity reaction to betrixaban

Initial approval duration: 30 capsules per month for 42 days only

BEVYXXA® (betrixaban maleate) oral capsule (cont.)

Resources:

Bevyxxa. Package Insert. Revised by manufacturer 6/2017. Accessed 10/18/17.

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Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.
REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information

Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information

Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information

Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information

Medication Name:	Strength:	Dosage Form:
Directions for Use:	Quantity: / Refills:	Duration of Therapy/Use:

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

Clinical Information

1. **What is the diagnosis? Please specify below.**

   ICD-10 Code: _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. **Are there any supporting labs or test results? Please specify below.**

Date	Test	Value

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Pharmacy Prior Authorization Request Form

6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: Date:

Please note: Some medications may require completion of a drug-specific request form.

Incomplete forms or forms without the chart notes will be returned.

Office notes, labs, and medical testing relevant to the request that show medical justification are required.