



An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 11/16/2017
LAST REVIEW DATE: 11/18/2021
LAST CRITERIA REVISION DATE: 11/19/2020
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.

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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.**



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Criteria:

- **Criteria for therapy:** Bevyxxa (betrixaban) 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 (betrixaban) during hospitalization and will be continuing therapy following discharge from the hospital
 4. Dose does not exceed 80 mg per day (1 capsule per day)
 5. Creatinine clearance greater than 15 mL/min
 6. Individual does not have moderate or severe hepatic impairment
 7. There are **NO** FDA-label contraindications, such as:
 - a. Active pathological bleeding

Approval duration: 30 capsules per month for 42 days only

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:
 1. **Off-Label Use of a Non-cancer Medications**
 2. **Off-Label Use of a Cancer Medication for the Treatment of Cancer without a Specific Coverage Guideline**

Description:

Bevyxxa (betrixaban) is an oral factor Xa inhibitor that inhibits free factor Xa and prothrombinase activity, ultimately decreasing thrombin generation. The safety and effectiveness of Bevyxxa (betrixaban) have not been established in patients with prosthetic heart valves because this population has not been studied.

There is no established way to reverse the anticoagulant effect of Bevyxxa (betrixaban), which can be expected to persist for at least 72 hours after the last dose. A specific reversal agent for Bevyxxa (betrixaban) is not available. It is unknown whether hemodialysis removes Bevyxxa (betrixaban). There is no experience with hemodialysis in individuals receiving betrixaban. Protamine sulfate, vitamin K, and tranexamic acid are not expected to reverse the anticoagulant activity of betrixaban.



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Definitions:

Factors that increase risk of developing DVT include:

- A personal or family history of DVT or PE
- Age. Being older than 60 increases your risk of DVT, though it can occur at any age
- Being overweight or obese
- Birth control pills (oral contraceptives) or hormone replacement therapy. Both can increase blood's ability to clot
- Cancer. Some forms of cancer increase substances in your blood that cause blood to clot. Some forms of cancer treatment also increase the risk of blood clots
- Heart failure
- Inheriting a blood-clotting disorder
- Injury or surgery. Injury to veins or surgery can increase the risk of blood clots
- Inflammatory bowel disease. Bowel diseases, such as Crohn's disease or ulcerative colitis
- Pregnancy. The risk of blood clots from pregnancy can continue for up to six weeks after delivery.
- Prolonged bed rest, such as during a long hospital stay, or paralysis
- Sitting for long periods of time, such as when driving or flying
- Smoking

Resources:

Bevyxxa (betrixaban) product information, revised by Portola Pharmaceuticals Inc. 08-2020. Available at [Drugs@FDA: FDA-Approved Drugs](#). Accessed September 14, 2021.

Pai M, Douketis JD. Prevention of venous thromboembolic disease in acutely ill hospitalized medical adults. In: UpToDate, Leung LK, Mandel J, Finlay G (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at <http://uptodate.com>. Accessed September 14, 2021.
