BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES	
SECTION: DRUGS	
ORIGINAL EFFECTIVE DATE:	**11/16/2017**
LAST REVIEW DATE:	**8/19/2021**
LAST CRITERIA REVISION DATE:	**8/19/2021**
ARCHIVE DATE:	

SAVAYSA™ (edoxaban tosylate) oral

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.**

SAVAYSA™ (edoxaban tosylate) oral

Criteria:

- **Criteria for initial therapy:** Savaysa (edoxaban tosylate) 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 **ONE** of the following:
     a. Non-valvular atrial fibrillation (NVAF)
     b. Deep vein thrombosis (DVT) and pulmonary embolism (PE) following 5-10 days of initial therapy with a parenteral anticoagulant

  3. Individual has failure, contraindication per FDA label, or intolerance to **at least 2** of the following:
     a. Eliquis (apixaban)
     b. Pradaxa (dabigatran)
     c. Xarelto (rivaroxaban)

  4. Creatinine clearance (CrCl) between 15-95 mL/minute

  5. Individual does not have **any** of the following:
     a. Mechanical heart valve
     b. Moderate to severe mitral stenosis
     c. Triple positive antiphospholipid syndrome (positive for lupus anticoagulant, anticardiolipin antibodies, and anti-beta 2-glycoprotein I antibodies)
     d. Moderate to severe hepatic impairment (Child-Pugh Class B and C)

  6. There are **NO** FDA-label contraindications, such as:
     a. Active pathological bleeding

  7. There are no significant interacting drugs

  Initial approval duration:
  For NVAF: 12 months
  For DVT and PE: 6 months

- **Criteria for continuation of coverage (renewal request):** Savaysa (edoxaban tosylate) is considered ***medically necessary*** for **NVAF** and will be approved when **ALL** of the following criteria are met:

  1. Individual's condition responded while on therapy
     a. Response is defined as:
        i. No embolic events in last 12 months for NVAF
        ii. No embolic events in last 6 months for DVT/PE

  2. Creatinine clearance (CrCl) between 15-95 mL/minute

SAVAYSA™ (edoxaban tosylate) oral

3. Individual does not have **any** of the following:
    a. Mechanical heart valve
    b. Severe mitral stenosis
    c. Triple positive antiphospholipid syndrome (positive for lupus anticoagulant, anticardiolipin antibodies, and anti-beta 2-glycoprotein I antibodies)
    d. Moderate to severe hepatic impairment (Child-Pugh Class B and C)

4. Individual has been adherent with the medication

5. Individual has not developed any contraindications or other significant adverse drug effects that may exclude continued use
    a. Contraindications as listed in the criteria for initial therapy section
    b. Significant adverse effect such as:
        i. Severe bleeding

6. There are no significant interacting drugs

Renewal duration:
For NVAF: 12 months
For DVT and PE: 6 months

- 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**

Resources:

Savaysa (edoxaban tosylate) product information, revised by Daiichi Sankyo, Inc. 03-2021. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed on August 03, 2021.