PHARMACY COVERAGE GUIDELINE

SAVAYSA™ (edoxaban tosylate) oral

This Pharmacy Coverage Guideline (PCG):
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope
- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require precertification is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Criteria:

- **Criteria for initial therapy:** Savaysa (edoxaban tosylate) is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met:

  1. Individual is 18 years of age or older.

  2. Individual has 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

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3. Documented failure, contraindication per FDA label, intolerance, or not a candidate to **at least TWO** 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 Active pathological bleeding.

7. There are no significant interacting drugs such as:
    a. Anticoagulants (e.g., heparin, enoxaparin, others)
    b. Antiplatelets (e.g., aspirin, ibuprofen, naproxen, others),
    c. Thrombolytics (e.g., alteplase, reteplase, others)
    d. Selective serotonin reuptake inhibitors (e.g., citalopram, fluoxetine, sertraline, others)
    e. Serotonin norepinephrine reuptake inhibitors (e.g., duloxetine, venlafaxine, others)
    f. Rifampin

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*** and will be approved when **ALL** the following criteria are met **(samples are not considered for continuation of therapy**):

1. Individual's condition has responded while on therapy with response defined as **ALL** of the following:
    a. No embolic events in last 12 months for NVAF
    b. No embolic events in last 6 months for DVT/PE

2. Individual has been adherent with the medication.

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

4. There are no significant interacting drugs such as:
    a. Anticoagulants (e.g., heparin, enoxaparin, others)
    b. Antiplatelets (e.g., aspirin, ibuprofen, naproxen, others),
    c. Thrombolytics (e.g., alteplase, reteplase, others)

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d. Selective serotonin reuptake inhibitors (e.g., citalopram, fluoxetine, sertraline, others)
e. Serotonin norepinephrine reuptake inhibitors (e.g., duloxetine, venlafaxine, others)
f. Rifampin

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 Non-Cancer Medications**

2. **Off-Label Use of Cancer Medications**

Resources:

Savaysa (edoxaban tosylate) product information, revised by Daiichi Sankyo, Inc. 04-2020. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed July 29, 2022.

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