MEDICAL MUTUAL®

Drug Policy

Policy: SD	Savaysa (edoxaban tablets)	Annual Review Date: 03/16/2023 Last Revised Date: 03/16/2023

OVERVIEW

Savaysa, a factor Xa inhibitor, is indicated to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation. A limitation of use in nonvalvular atrial fibrillation is that Savaysa should not be used in patients with a creatinine clearance (CrCl) > 95 mL/min due to an increased risk of ischemic stroke compared with warfarin at the highest dose studied (60 mg). Savaysa is also indicated for the treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) following 5 to 10 days of initial therapy with a parenteral anticoagulant. The recommended dose of Savaysa in both indications is 60 mg once daily (QD). Dose reduction is recommended in certain circumstances (e.g., decreased CrCl, low body weight and if receiving certain P-glycoprotein [P-gp] inhibitors). The use of Savaysa is not recommended in patients with mechanical heart valves or moderate to severe mitral stenosis as the safety and efficacy have not been evaluated.

POLICY STATEMENT

This policy involves the use of Sayvasa. Prior authorization is recommended for pharmacy benefit coverage of Savaysa. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Savaysa is recommended in those who meet the following criteria:

1. **Atrial Fibrillation (or Atrial Flutter).** Approve for 1 year if the patient meets one of the following (A and B):
   - **A)** The patient has an estimated creatinine clearance (CrCl) ≤ 95 mL/min; AND
   - **B)** The patient is ≥ 18 years of age

2. **Deep Vein Thrombosis or Pulmonary Embolism, Treatment.** Approve for 1 year if the patient is 18 years of age or older

Other Uses with Supportive Evidence

3. **Deep Vein Thrombosis in Patients Undergoing Hip Replacement Surgery, Prophylaxis.** Approve for 60 days if the patient is 18 years of age or older

4. **Treatment or Prevention of Other Thromboembolic-Related Conditions (e.g., superficial vein thrombosis, splanchnic vein thrombosis, hepatic vein thrombosis, prophylaxis of venous thromboembolism in high-risk patients).** Approve for 6 months if the patient meets ONE of the following criteria (A or B):
   A) The patient meets one of the following for the condition (i or ii or iii):
      i. The patient has tried warfarin, fondaparinux, or a low molecular weight heparin product (e.g., enoxaparin, Fragmin® [dalteparin injection]); OR
      ii. The patient has tried Xarelto or Eliquis; OR
      iii. The patient has been started on Savaysa for the treatment of an acute thromembolic condition.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Savaysa has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. **Venous Thromboembolism in an Acutely Ill Medical Patient, Prophylaxis.** (Note: This includes post-discharge thromboprophylaxis for a patient hospitalized with coronavirus disease 19 [COVID-19]). Xarelto and Bevyxxa are labeled for prophylaxis of venous thromboembolism in acutely ill medical patients and are supported in clinical practice guidelines, including guidelines which address prophylaxis of venous thromboembolism in COVID-19 patients.[7-9]

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

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4. The NCCN Cancer-Associated Venous Thromboembolic Disease Clinical Practice Guidelines in Oncology (Version 1.2020—April 16, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on November 10, 2020.
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9. Barnes GD, Burnett A, Allen A, et al. Thromboembolism and anticoagulant therapy during the COVID-19 pandemic: interim clinical guidance from the anticoagulation forum. *J Thromb Thrombolysis*. 2020 Jul;50(1):72-81.
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