

UnitedHealthcare Pharmacy Clinical Pharmacy Programs

Program Number	2024 P 3166-3
Program	Step Therapy
Medication	Savaysa® (edoxaban)
P&T Approval Date	7/2022, 10/2023, 10/2024
Effective Date	1/1/2025

1. Background:

Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. Savaysa is FDA approved to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation (NVAF) and for the treatment of deep vein thrombosis and pulmonary embolism following 5 to 10 days of initial therapy with a parenteral anticoagulant. Savaysa should not be used in patients with creatine clearance greater than 95 mL/min for NVAF because of increased risk of ischemic stroke compared to warfarin at the highest dose studied.

This program requires a member to try an alternative oral anticoagulant prior to providing coverage for Savaysa.

2. Coverage Criteria^a:

A. Initial Authorization

- 1. Savaysa will be approved based <u>one</u> of the following criteria:
 - a. History of failure, contraindication, or intolerance to <u>one</u> of the following:
 - (1) Eliquis
 - (2) Xarelto

-OR-

b. Member is currently established on Savaysa

Authorization will be issued for 12 months.

B. Reauthorization

- 1. Savaysa will be approved based on the following criterion:
 - a. Documentation of positive clinical response to therapy

Reauthorization will be issued for 12 months.



State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and reauthorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may also be in place.

4. References:

- 1. Savaysa [package insert]. Basking Ridge, NJ: Daiichi Sankyo Inc; October 2023.
- 2. Antithrombotic Therapy for Atrial Fibrillation. CHEST Guideline and Expert Panel Report. CHEST 2018; 154(5):1121-1201.
- 3. Antithrombotic Therapy for VTE Disease: Second Update of the CHEST Guildeine and Expert Panel Report. CHEST 2021; 160(6):2247-2259.
- 4. American Society of Hematology 2020 guidelines for management of venous thromboembolism: treatment of deep vein thrombosis and pulmonary embolism. Blood Advances 2020; 4(19): 4693-4738.

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Change Control	
7/2022	New program.
10/2023	Annual review with no changes.
10/2024	Annual review with updated references.