# PRIOR AUTHORIZATION POLICY

**POLICY:** Anticoagulants – Xarelto Prior Authorization with Step Therapy Policy
- Xarelto® (rivaroxaban tablets [generic for the 2.5 mg tablet strength only] and oral suspension [generic] – Janssen)

**REVIEW DATE:** 05/21/2025; selected revision 07/30/2025

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***INSTRUCTIONS FOR USE***

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## CIGNA NATIONAL FORMULARY COVERAGE:

## OVERVIEW

Xarelto, a Factor Xa inhibitor, is indicated for the following uses:[1]
- **Non-valvular atrial fibrillation,** to reduce the risk of stroke and systemic embolism in adults.
- **Coronary artery disease**, in combination with aspirin, to reduce the risk of major adverse cardiovascular events in adults.
- **Prophylaxis of deep vein thrombosis (DVT)**, which may lead to pulmonary embolism (PE), in adults undergoing knee or hip replacement surgery.
- **Prophylaxis of venous thromboembolism in acutely ill medical patients**, in adults at risk for thromboembolic complications and not at high risk of bleeding.
- **Peripheral artery disease**, including patients after recent lower extremity revascularization due to symptomatic peripheral artery disease, in combination with aspirin, to reduce the risk of major thrombotic vascular events in adults.

- **Treatment of DVT and/or PE**, as well as **reduction in the risk of recurrence of DVT and/or PE** in patients at continued risk for recurrent DVT and/or PE after completion of initial treatment. Xarelto is approved for these indications in pediatric patients from birth to < 18 years of age as well as adults.
- **Thromboprophylaxis in a patient with congenital heart disease after the Fontan procedure**, in pediatric patients ≥ 2 years of age.

## Dosing and Administration

It is noted in the prescribing information for Xarelto that different dosage forms can be utilized to achieve the necessary dose and route of administration for adult and pediatric patients.[1] Adult patients can be given tablets or oral suspension.

For pediatric patients, tablets must not be split in an attempt to provide a fraction of a tablet dose.[1] For treatment of venous thromboembolism (VTE) and reduction in risk of VTE recurrence in pediatric patients, it is noted that the oral suspension or tablets may be used for a patient weighing ≥ 30 kg; for patients weighing < 30 kg, only the oral suspension should be used. For thromboprophylaxis in pediatric patients with congenital heart disease after the Fontan procedure, the oral suspension or tablets may be used for a patient weighing ≥ 50 kg; only the oral suspension should be used for a patient weighing < 50 kg. It is noted that there are no safety, efficacy, pharmacokinetic, and pharmacodynamic data to support the use of Xarelto 2.5 mg tablets in pediatric patients; therefore, Xarelto 2.5 mg tablets are not recommended in pediatric patients.

## Guidelines

Guidelines are available which support the use of direct oral anticoagulants (DOACs) in their commonly used clinical settings, such as DVT/PE[2-5] and atrial fibrillation.[6,7] In patients who are eligible for a DOAC, these are generally preferred over vitamin K antagonists (e.g., warfarin). It is noted that in the randomized trials in atrial fibrillation, DOACs were consistently at least non-inferior to warfarin regarding the composite of stroke or systemic embolism and were associated with lower risk of serious bleeding.[7] Guidelines from the Canadian Cardiovascular Society for peripheral arterial disease (2022) recommend Xarelto in combination with aspirin in selected patients with peripheral arterial disease (high risk of ischemic events).[8]

## Other Uses with Supportive Evidence

Although data are not robust regarding use of DOACs in other off-label thromboembolic-related conditions, American College of Chest Physicians (CHEST) guidelines (2021) suggest anticoagulation for certain patients (e.g., superficial vein thrombosis).[2] The choice of anticoagulant is often individualized based on patient-specific factors; therefore, for certain patients, DOAC use may be considered in practice. Evidence for DOACs is limited for off-label scenarios; in general, there is more clinical experience with agents such as vitamin K antagonists (e.g., warfarin) and low molecular weight heparin in these settings.

**POLICY STATEMENT**

Prior Authorization is recommended for prescription benefit coverage of Xarelto. All approvals are provided for the approval duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days.

- **Xarelto® (rivaroxaban tablets [generic for the 2.5 mg tablet strength only] and oral suspension [generic] – Janssen)**

**is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):**

**FDA-Approved Indications**

1. **Atrial Fibrillation (or Atrial Flutter).** Approve for 1 year if the patient meets BOTH of the following (A and B):
   **A)** Patient is ≥ 18 years of age; AND
   **B)** If rivaroxaban oral suspension (brand or generic product) is being requested, approve if the patient is unable to have Xarelto tablets appropriately administered.

2. **Coronary Artery Disease.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   **A)** Patient is ≥ 18 years of age; AND
   **B)** Patient is taking concomitant aspirin, at least 75 mg daily; AND
   **C)** If rivaroxaban oral suspension (brand or generic product) is being requested, approve if the patient is unable to have Xarelto tablets appropriately administered.

3. **Deep Vein Thrombosis in a Patient Undergoing Knee or Hip Replacement Surgery, Prophylaxis.** Approve for 60 days if the patient meets BOTH of the following (A and B):
   **A)** Patient is ≥ 18 years of age; AND
   **B)** If rivaroxaban oral suspension (brand or generic product) is being requested, approve if the patient is unable to have Xarelto tablets appropriately administered.

4. **Deep Vein Thrombosis or Pulmonary Embolism, Treatment.** Approve for 1 year if the patient meets ONE of the following (A or B):
   **A)** Xarelto tablets: Approve.
   **B)** Rivaroxaban oral suspension (brand or generic product): Approve if the patient meets ONE of the following (i or ii):
      **i.** Patient is unable to have Xarelto tablets appropriately administered; OR
      **ii.** The prescribed dose cannot be achieved by Xarelto 10 mg, 15 mg, or 20 mg tablets.

5. **Deep Vein Thrombosis or Pulmonary Embolism, to Reduce the Risk of Recurrence.** Approve for 1 year if the patient meets ONE of the following (A or B):
   **A)** Xarelto tablets: Approve.
   **B)** Rivaroxaban oral suspension (brand or generic product): Approve if the patient meets ONE of the following (i or ii):
      **i.** Patient is unable to have Xarelto tablets appropriately administered; OR
      **ii.** The prescribed dose cannot be achieved by Xarelto 10 mg, 15 mg, or 20 mg tablets.

6. **Peripheral Artery Disease.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   **A)** Patient is ≥ 18 years of age; AND
   **B)** Patient is taking concomitant aspirin, at least 75 mg daily; AND
   **C)** If rivaroxaban oral suspension (brand or generic product) is being requested, patient is unable to have Xarelto tablets appropriately administered.

7. **Thromboprophylaxis in a Patient with Congenital Heart Disease.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   **A)** Patient is ≥ 2 years of age and < 18 years of age; AND
   **B)** Patient has undergone the Fontan procedure; AND
   **C)** If rivaroxaban oral suspension (brand or generic product) is being requested, patient meets ONE of the following (i or ii):
      **i.** Patient is unable to have Xarelto tablets appropriately administered; OR
      **ii.** The prescribed dose cannot be achieved by Xarelto 10 mg, 15 mg, or 20 mg tablets.

8. **Venous Thromboembolism in an Acutely Ill Medical Patient, Prophylaxis.** Approve for 60 days if the patient meets BOTH of the following (A and B):
   **A)** Patient is ≥ 18 years of age; AND
   **B)** If rivaroxaban oral suspension (brand or generic product) is being requested, patient is unable to have Xarelto tablets appropriately administered.

**Other Uses with Supportive Evidence**

9. **Treatment or Prevention of Other Thromboembolic-Related Conditions.** Approve for 6 months if the patient meets BOTH of the following (A and B):
   Note: Examples of other thromboembolic-related conditions include superficial vein thrombosis, splanchnic vein thrombosis, hepatic vein thrombosis, or prophylaxis of venous thromboembolism in a high-risk patient.
   **A)** Patient meets ONE of the following (i or ii):
      **i.** Patient has tried warfarin, fondaparinux or a low molecular weight heparin product (e.g., enoxaparin, Fragmin [dalteparin injection]); OR
      Note: A patient who has tried Eliquis (apixaban tablets or tablets for oral suspension), Eliquis Sprinkle (apixaban capsules for oral suspension), Pradaxa (dabigatran capsules and oral pellets), or Savaysa (edoxaban tablets) is not required to try warfarin, fondaparinux, or a low molecular weight heparin.

**ii.** Patient has been started on Xarelto for the treatment of an acute thromboembolic condition; AND

**B)** If rivaroxaban oral suspension (brand or generic product) is being requested, approve if the patient meets ONE of the following (i or ii):

**i.** Patient is unable to have Xarelto tablets appropriately administered; OR

**ii.** The prescribed dose cannot be achieved by Xarelto 10 mg, 15 mg, or 20 mg tablets.

## CONDITIONS NOT COVERED

- **Xarelto® (rivaroxaban tablets [generic for the 2.5 mg tablet strength only] and oral suspension [generic] – Janssen)**

**is(are) considered not medically necessary for ANY other use(s); criteria will be updated as new published data are available.**

## REFERENCES


1. Xarelto® tablets and oral suspension [prescribing information]. Titusville, NJ: Janssen; June 2025.
2. Stevens SM, Woller SC, Kreuziger LB, et al. Antithrombotic therapy for VTE disease. Second update of the CHEST guideline and Expert Panel Report. *Chest*. 2024; 166(2): 388-404.
3. Key NS, Khorana AA, Kuderer NM, et al. Venous thromboembolism prophylaxis and treatment in patients with cancer: ASCO guideline update. *J Clin Oncol*. 2023;41:3063-3071.
4. The NCCN Cancer-Associated Venous Thromboembolic Disease Clinical Practice Guidelines in Oncology (version 1.2025 – February 27, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 15, 2025.
5. Ortel TL, Neumann I, Ageno W, Beyth R, et al. American Society of Hematology 2020 guidelines for management of venous thromboembolism: treatment of deep vein thrombosis and pulmonary embolism. *Blood Adv*. 2020;4(19):4693-4738.
6. Lip G, Banerjee A, Boriani G, et al. Antithrombotic therapy for atrial fibrillation: CHEST guideline and expert panel report. *Chest*. 2018;154(5):1121-1201.
7. Joglar JA, Chung MK, Armbruster AL, et al. 2023 ACC/AHA/ACCP/HRS guidelines for the diagnosis and management of atrial fibrillation. A report of the American College of Cardiology/American Heart Association Joint Committee on Practice guidelines. Developed in collaboration and endorsed by the American College of Clinical Pharmacy and the Heart Rhythm Society. *J Am Coll Cardiol*. 2024;83(1):109-279.
8. Abramson BL, Al-Omran M, Anand SS, et al. Canadian Cardiovascular Society 2022 guidelines for peripheral arterial disease. *Can J Cardiol*. 2022;38:560-587.
9. COVID-19 Treatment Guidelines Panel. Coronavirus Disease 2019 (COVID-19) Treatment Guidelines. Antithrombotic therapy in patients with COVID-19. National Institutes of Health. Updated February 29, 2024.


## HISTORY

| Type of Revision | Summary of Changes | Review Date |
|---|---|---|
| Early Annual Revision | No criteria changes. | 01/11/2023 |
| Annual Revision | No criteria changes. | 01/24/2024 |
| Annual Revision | No criteria changes. | 02/12/2025 |

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| Selected Revision | Generic rivaroxaban 2.5 mg tablets were added to the policy. | 04/23/2025 |
| Early Annual Revision | **Treatment or Prevention of Other Thromboembolic-Related Conditions:** For the criterion that requires a patient to try warfarin, fondaparinux, or a low molecular weight heparin product, Eliquis tablets for oral suspension and Eliquis Sprinkle were added to the Note of medications that a patient could alternatively try.<br><br>**Venous Thromboembolism in an Acutely Ill Medical Patient, Prophylaxis:** The note that this condition includes "post-discharge thromboprophylaxis for a patient hospitalized with coronavirus disease 2019 was removed. | 05/21/2025 |
| Selected Revision | The policy name was changed to as listed. Previously, it was **Anticoagulants – Xarelto PA Policy**.<br><br>Generic rivaroxaban oral suspension was added to the policy. Exceptions were updated to reflect approval of rivaroxaban oral suspension (brand or generic product) if tablets could not be appropriately administered or if the dose could not be achieved with Xarelto 10 mg, 15 mg, or 20 mg tablets. | 07/30/2025 |