

PRIOR AUTHORIZATION POLICY

POLICY: Anticoagulants – Eliquis Prior Authorization Policy

- Eliquis® (apixaban tablets – Bristol-Myers Squibb/Pfizer)

REVIEW DATE: 01/24/2024

OVERVIEW

Eliquis, a Factor Xa inhibitor, is indicated for the following uses:¹

- **Non-valvular atrial fibrillation**, to reduce the risk of stroke and systemic embolism.
- **Prophylaxis of deep vein thrombosis (DVT)**, which may lead to pulmonary embolism (PE), in patients who have undergone hip or knee replacement surgery.
- **Treatment of DVT and PE**, as well as **reduction in the risk of recurrence of DVT and PE** following initial therapy.

Safety and effectiveness of Eliquis in pediatric patients have not been established.¹

Guidelines

Guidelines are available which support the use of direct oral anticoagulants (DOACs) in their commonly used clinical settings, such as DVT/PE²⁻⁵ 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

Anticoagulants and Coronavirus Disease 2019 (COVID-19)

Several clinical practice guidelines have been published with regard to use of anticoagulant therapy in the management of COVID-19. Per National Institutes of Health treatment guidelines regarding antithrombotic therapy in patients with COVID-19 (updated October 10, 2023), hospitalized patients with COVID-19 should not be routinely discharged from the hospital while on venous thromboembolism (VTE) prophylaxis.⁸ For hospitalized patients, anticoagulant or antiplatelet therapy should not be used to prevent arterial thrombosis outside of the usual standard of care for patients without COVID-19. In nonhospitalized patients with COVID-19, it is not recommended to use anticoagulant and antiplatelet therapy for the prevention of VTE or arterial thrombosis, except in a clinical trial. Of note, Xarelto® (rivaroxaban tablets and oral suspension) is FDA-approved for prophylaxis of VTE in acutely ill medical patients; Eliquis is not indicated in this setting. Other guidelines have similar recommendations.⁹⁻¹¹

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, antiphospholipid syndrome).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.

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POLICY STATEMENT

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

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

- 1. Atrial Fibrillation (or Atrial Flutter).** Approve for 1 year if the patient is ≥ 18 years of age.
- 2. Deep Vein Thrombosis in a Patient Undergoing Hip or Knee Replacement Surgery, Prophylaxis.** Approve for 60 days if the patient is ≥ 18 years of age.
- 3. Deep Vein Thrombosis or Pulmonary Embolism, Treatment.** Approve for 1 year if the patient is ≥ 18 years of age.
- 4. Deep Vein Thrombosis or Pulmonary Embolism to Reduce the Risk of Recurrence.** Approve for 1 year if the patient is ≥ 18 years of age.

Other Uses with Supportive Evidence

- 5. 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 is ≥ 18 years of age; AND
B) Patient meets one of the following (i or ii):
 - Patient has tried warfarin, fondaparinux injection, or a low molecular weight heparin product (e.g., enoxaparin injection, Fragmin [dalteparin injection]); OR
Note: A patient who has tried Xarelto (rivaroxaban tablets and oral suspension), Pradaxa (dabigatran capsules), or Savaysa (edoxaban tablets) is not required to try warfarin, fondaparinux, or a low molecular weight heparin product.
 - Patient has been started on Eliquis for the treatment of an acute thromboembolic condition.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Eliquis is not recommended in the following situations:

- 1. Venous Thromboembolism in an Acutely Ill Medical Patient, Prophylaxis.** (Note: This includes post-discharge thromboprophylaxis for a patient hospitalized with coronavirus disease 2019 [COVID-19]). Eliquis has been compared with enoxaparin for post-discharge prophylaxis in acutely ill medical patients; however, superiority vs. enoxaparin was not achieved, and bleeding was increased with Eliquis.¹² Xarelto is labeled for prophylaxis of venous thromboembolism in acutely ill medical patients

and is supported in clinical practice guidelines, including guidelines which address prophylaxis of venous thromboembolism in COVID-19 patients.⁸⁻¹¹

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

REFERENCES

1. Eliquis® tablets [prescribing information]. Princeton, NJ and New York, NY: Bristol-Myers Squibb and Pfizer; April 2021.
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*. 2021;160(6):e545-e608.
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 2.2023 – June 1, 2023). © 2023 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on January 14, 2024.
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. COVID-19 Treatment Guidelines Panel. Coronavirus Disease 2019 (COVID-19) Treatment Guidelines. Antithrombotic therapy in patients with COVID-19. National Institutes of Health. Updated October 23, 2023. Available at: <https://www.covid19treatmentguidelines.nih.gov/>. Accessed on January 14, 2024.
9. Moores LK, Tritschler T, Brosnahan S, et al. Prevention, diagnosis, and treatment of VTE in patients with Coronavirus Disease 2019: CHEST Guideline and Expert Panel Report. *Chest*. 2020;158(3):1143-1163.
10. Spyropoulos AC, Levy JH, Ageno W, et al. Scientific and Standardization Committee communication: Clinical guidance on the diagnosis, prevention, and treatment of venous thromboembolism in hospitalized patients with COVID-19. *J Thromb Haemost*. 2020;18:1859-1865.
11. Barnes GD, Burnett A, Allen A, et al. Thromboembolic prevention and anticoagulant therapy during the COVID-19 pandemic: updated clinical guidance from the anticoagulation forum. *J Thromb Thrombolysis*. 2022;54:197-210.
12. Goldhaber SZ, Leizorovicz A, Kakkar AK, et al. Apixaban versus enoxaparin for thromboprophylaxis in medically ill patients. *N Engl J Med*. 2011;365(23):2167-2177.