MEDICAL MUTUAL®

Drug Policy

Policy:	Xarelto (rivaroxaban)	Annual Review Date: 10/17/2024 Last Revised Date: 10/17/2024

OVERVIEW

Xarelto is an oral factor Xa inhibitor anticoagulant indicated for reduction in the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, for prophylaxis of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE), in patients who have undergone hip or knee replacement surgery, for treatment of DVT and PE, for the reduction in the risk of recurrent DVT and PE following initial therapy, peripheral/coronary artery disease and for prophylaxis of venous thromboembolism in acutely ill medical patients. Additionally, Xarelto is indicated in combination with aspirin to reduce the risk of major cardiovascular (CV) events (CV death, myocardial infarction [MI], and stroke) in patients with chronic coronary artery disease (CAD) or peripheral artery disease (PAD).

Anticoagulants and Coronavirus Disease 19 (COVID-19)

Several clinical practice guidelines have been published with regard to use of anticoagulant therapy in the management of COVID-19. In a guideline from the American College of Chest Physicians (CHEST) [June 2, 2020], anticoagulant thromboprophylaxis is suggested over no prophylaxis for acutely ill hospitalized patients with COVID-19.[7] Extended thromboprophylaxis after hospital discharge is not routinely recommended but may be considered for a patient with low bleeding risk, if emerging data on the post-discharge risk of venous thromboembolism (VTE) and bleeding indicate a net benefit of such prophylaxis. Randomized, controlled trials have not been conducted to evaluate the efficacy of various anticoagulants or placebo in COVID-19 patients; however, the guideline notes that most patients with COVID-19 would have been eligible to participate in landmark trials of anticoagulant thromboprophylaxis in acutely ill medical inpatients. According to guidance from the International Society of Thrombosis and Hemostasis (May 27, 2020), extended post-discharge thromboprophylaxis should be considered for all hospitalized patients with COVID-19 who meet high VTE risk criteria.[8] Xarelto and Bevyxxa (betrixaban capsules) are cited as treatment options for extended-duration thromboprophylaxis. Likewise, guidance from the Anticoagulation Forum (May 21, 2020) states that for a COVID-19 patient in whom post-discharge prophylaxis is deemed reasonable, an adequately studied and/or approved agent such as Bevyxxa or Xarelto is recommended.

POLICY STATEMENT

This policy involves the use of Xarelto. Prior authorization is recommended for pharmacy benefit coverage of Xarelto. 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.

Automation: When available, the following ICD-10 codes and corresponding approval durations will be used for automation to allow approval of the requested medication:

1. I48.*; I82*; I27.82; 2 years
2. Z96.6*; 60 days

RECOMMENDED AUTHORIZATION CRITERIA

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

1. **Atrial Fibrillation, Nonvalvular (or Atrial Flutter)**
   Criteria. *Approve for 2 years.*

2. **Deep Vein Thrombosis (DVT) in Patients Undergoing Hip or Knee Replacement Surgery, Prophylaxis**
   Criteria. *Approve for 60 days.*

3. **Deep Vein Thrombosis (DVT) or Pulmonary Embolism (PE), Treatment**
   Criteria. *Approve for 2 years.*

4. **Coronary Artery Disease**
   Criteria. *Approve for 2 years if patient will be taking concomitant aspirin at least 75mg daily*

5. **Peripheral Artery Disease**
   Criteria. *Approve for 2 years if patient will be taking concomitant aspirin at least 75mg daily*

6. **Deep Vein Thrombosis (DVT) or Pulmonary Embolism (PE) to Reduce the Risk of Recurrence**
   Criteria. *Approve for 2 years.*

7. **Reduction in Risk of Major Cardiovascular Events** Approve for 2 years if the patient has coronary artery disease or peripheral artery disease;

8. **Venous Thromboembolism in Acutely Ill Medical Patients, Prophylaxis**
   Criteria. *Approve for 60 days.*
   Note: This includes post-discharge thromboprophylaxis for a patient hospitalized with coronavirus disease 19 (COVID-19).

Initial Approval/ Extended Approval.

indication specific, see above.

OTHER USES WITH SUPPORTIVE EVIDENCE

9. <u>Treatment or Prevention of Other Thromboembolic-Related Conditions (e.g., superficial vein thrombosis, splanchnic vein thrombosis, hepatic vein thrombosis, prophylaxis of venous thromboembolism [VTE] in high-risk patients)</u>

Criteria. *Approve for 6 months if the patient meets ONE of the following criteria (A, B, <u>or</u> C):*

A. The patient has tried warfarin, fondaparinux injection, or a low molecular weight heparin (LMWH) product (e.g., enoxaparin injection, Fragmin [dalteparin injection]); OR
B. The patient has tried another direct oral anticoagulant (e.g. Pradaxa, Savaysa, etc.); OR
C. The patient has been started on Xarelto for the treatment of an acute thromboembolic condition.

Initial Approval/ Extended Approval.
indication specific, see above.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Xarelto have 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. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. 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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