Clinical Policy: Rivaroxaban (Xarelto)

Reference Number: MDN.CP.PMN.247
Effective Date: 04.01.22
Last Review Date: 04.22
Line of Business: Illinois Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Rivaroxaban (Xarelto®) is a factor Xa inhibitor.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Xarelto is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Meet one of the following indications (a, b, c, d, e, f, g, or h):

a. Reduction of the risk of stroke and systemic embolism in member with NVAF;
b. Treatment and risk reduction of DVT or PE;
c. Prophylaxis of DVT or PE in those who have undergone knee or hip replacement surgery;
d. Continuation of VTE prophylaxis following hospital discharge and member was admitted for an acute medical illness at risk for thromboembolic complications;
e. To reduce the risk of major cardiovascular events (cardiovascular death, myocardial infarction and stroke) in patients with chronic coronary artery disease and prescribed in combination with aspirin;
f. To reduce the risk of major thrombotic vascular events in patients with PAD, including patients after recent lower extremity revascularization due to symptomatic PAD;
g. Treatment of VTE and risk reduction of recurrent VTE in pediatric patients < 18 years after at least 5 days of initial parenteral anticoagulant treatment;
h. Thromboprophylaxis in pediatric patients aged ≥ 2 years with congenital heart disease who have undergone the Fontan procedure;

2. Dose does not exceed maximum dose indicated in Section V.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All FDA-approved Indications (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed maximum dose indicated in Section V.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information *Appendix A: Abbreviation/Acronym Key*

CrCl: creatinine clearance
DVT: deep venous thrombosis
FDA: Food and Drug Administration
NVAF: non-valvular atrial fibrillation
PAD: peripheral artery disease
PE: pulmonary embolism
VTE: venous thromboembolism

Appendix B: Contraindications/Boxed Warnings •
Contraindication(s):

- ○ Active pathological bleeding ○ Severe hypersensitivity reaction to Xarelto

• Boxed warning(s):

- ○ Premature discontinuation of Xarelto increases the risk of thrombotic events ○ Spinal/epidural hematoma may occur in patients treated with Xarelto who are receiving neuraxial anesthesia or undergoing spinal puncture

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
NVAF	15 mg or 20 mg PO QD	20 mg/day

Indication	Dosing Regimen	Maximum Dose

Treatment of DVT and PE	15 mg PO BID for the first 21 days, followed by 20 mg PO QD for the remaining treatment	See dosing regimen
Reduction in the risk of recurrence of DVT and PE	10 mg PO QD	10 mg/day
Prophylaxis of DVT and PE following hip replacement surgery	10 mg PO QD	10 mg/day
Prophylaxis of VTE in acutely ill medical patients at risk for thromboembolic complications not at high risk of bleeding	10 mg PO QD in hospital and after discharge for a total recommended duration of 31 to 39 days	10 mg/day
Coronary artery disease	2.5 mg PO BID in combination with aspirin 75-100 mg PO QD	5 mg/day
Reduction in the risk of major thrombotic vascular events in PAD, including patients after lower extremity revascularization due to symptomatic PAD	2.5 mg PO BID in combination with aspirin 75-100 mg once daily	5 mg/day
Treatment of VTE and risk reduction of recurrent VTE in pediatric patients	*Oral suspension only* 2.6 kg to 2.9 kg: 0.8 mg TID 3 kg to 3.9 kg: 0.9 mg TID 4 kg to 4.9 kg: 1.4 mg TID 5 kg to 6.9 kg: 1.6 mg TID 7 kg to 7.9 kg: 1.8 mg TID 8 kg to 8.9 kg: 2.4 mg TID 9 kg to 9.9 kg: 2.8 mg TID 10 kg to 11.9 kg: 3 mg TID 12 kg to 22.9 kg: 5 mg BID *Oral suspension or tablets* 30 kg to 49.9 kg: 15 mg QD ≥ 50 kg: 20 mg QD	20 mg/day
Thromboprophylaxis in pediatric patients with congenital heart disease	*Oral suspension only* 7 kg to 7.9 kg: 1.1 mg BID 8 kg to 9.9 kg: 1.6 mg BID 10 kg to 11.9 kg: 1.7 mg BID 12 kg to 19.9 kg: 2 mg BID 20 kg to 29.9 kg: 2.5 mg BID 30 kg to 49.9 kg: 7.5 mg QD	10 mg/day

Indication	Dosing Regimen	Maximum Dose
	Oral suspension or tablets ≥ 50 kg: 10 mg QD	

VI. Product Availability

Tablet: 2.5 mg, 10 mg, 15 mg, 20 mg
Oral suspension: 1 mg/mL

VII. References

1. Xarelto Prescribing Information. Titusville, NJ: Janssen Pharmaceuticals, Inc.; December 2021. Available at: www.xareltohcp.com. Accessed January 10, 2022.
2. Ortel TL, Neumann I, Ageno W, 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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created, adapted from CP.PMN.247 to align with HFS PDL	03.15.22	04.22

requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.