UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Xarelto

Program	Prior Authorization
Medication	Xarelto (rivaroxaban)
Markets in Scope	California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York CHIP, New York EPP, Pennsylvania-CHIP, Rhode Island, South Carolina
Issue Date	7/2018
Pharmacy and Therapeutics Approval Date	2/2021
Effective Date	4/2021

1. Background:

Xarelto is a factor Xa inhibitor indicated to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation; for the treatment of deep vein thrombosis (DVT); for the treatment of pulmonary embolism (PE); for the 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 lasting at least 6 months; for the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery; in combination with aspirin, to reduce the risk of major cardiovascular events [cardiovascular (CV) death, myocardial infarction (MI) and stroke] in patients with chronic coronary artery disease (CAD) or peripheral artery disease (PAD); and for the prophylaxis of venous thromboembolism (VTE) and VTE related death during hospitalization and post hospital discharge in adult patients admitted for an acute medical illness who are at risk for thromboembolic complications due to moderate or severe restricted mobility and other risk factors for VTE and not at high risk of bleeding.

Xarelto contains a black boxed warning for spinal/epidural hematoma and premature discontinuation of Xarelto increasing the risk of thrombotic events. Please see full prescribing information for additional details.

2. Coverage Criteria:

A. <u>Continuation of Therapy Upon Hospital Discharge</u>

1. <u>Authorization</u>

a. Xarelto will be approved as continuation of therapy upon hospital discharge

Authorization will be issued for 35 days.

B. Stroke and Systemic Embolism Prevention in Patients with Non-Valvular Atrial Fibrillation (AF)

1. Authorization

a. Diagnosis of atrial fibrillation (AF)

-AND-

b. Patient does not have an artificial heart valve

-AND-

c. **One** of the following:

(1) History of failure, contraindication, or intolerance to **both** of the following:

- Eliquis
- Savaysa

-OR-

(2) Continuation of prior Xarelto therapy

Authorization will be issued for 12 months.

C. Prophylaxis of venous thromboembolism (VTE) after orthopedic surgery (hip replacement or knee replacement)

1. Authorization

a. **One** of the following:

- Patient has or is scheduled to have total knee replacement surgery
- Patient has or is scheduled to have total hip replacement surgery

Authorization will be issued for 35 days.

D. Treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE)

1. Authorization

a. Diagnosis of **one** of the following:

- Deep vein thrombosis (DVT)
- Pulmonary embolism (PE)

-AND-

b. **One** of the following:

(1) History of failure, contraindication, or intolerance to **both** of the following:

- Eliquis
- Savaysa

-OR-

(2) Continuation of prior Xarelto therapy

Authorization will be issued for 12 months.

E. Reduction in the risk of recurrence of deep vein thrombosis (DVT) and pulmonary embolism (PE)

1. Authorization

a. Previous diagnosis of **one** of the following:

- Deep vein thrombosis (DVT)
- Pulmonary embolism (PE)

-AND-

b. Patient must have been treated with an anticoagulant [e.g., warfarin, Eliquis (apixiban)] for at least 6 months prior to request

-AND-

c. **One** of the following:

(1) History of failure, contraindication, or intolerance to Eliquis

-OR-

(2) Continuation of prior Xarelto therapy

Authorization will be issued for 12 months.

F. Reduction in the risk of major cardiovascular events [cardiovascular (CV) death, myocardial infarction (MI) and stroke] in patients with chronic coronary artery disease (CAD) or peripheral artery disease (PAD)

1. Authorization

a. Diagnosis of **one** of the following:

- Chronic coronary artery disease (CAD)
- Peripheral artery disease (PAD)

-AND-

b. Patient is on concurrent aspirin therapy.

Authorization will be issued for 12 months.

G. Prophylaxis of venous thromboembolism (VTE) in acutely ill medical patients at risk for thromboembolic complications not at high risk of bleeding

1. Authorization

a. **All** of the following:
(1) Patient was admitted to the hospital for an acute medical illness

-AND-

(2) Patient is at risk of thromboembolic complications due to moderate or severe restricted mobility

-AND-

(3) Patient is not at high risk of bleeding

Authorization will be issued for 2 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization 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 be in place.

4. References

1. Xarelto [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; March 2020.
2. Eliquis [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; November 2019.
3. Savaysa [package insert]. Tokyo, Japan: Daiichi Sankyo, Inc.; April 2020.

Program	Prior Authorization – Xarelto (rivaroxaban)
Change Control	
Date	Change
7/2018	New Program.
4/2019	Added new indication for use in combination with aspirin, to reduce the risk of major cardiovascular events (cardiovascular (CV) death, myocardial infarction (MI) and stroke) in patients with chronic coronary artery disease (CAD) or peripheral artery disease (PAD).
2/2020	Added new indication for prophylaxis of VTE in acutely ill medical patients at risk for thromboembolic complications.
2/2021	Annual review, updated background and references. Updated authorization duration for treatment of DVT/PE.