



## Prior Authorization Approval Criteria

### *Xarelto (rivaroxaban)*

<b>Generic name:</b>	rivaroxaban
<b>Brand name:</b>	Xarelto
<b>Medication class:</b>	Anticoagulant
<b>FDA-approved uses:</b>	-Reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation. -DVT prophylaxis in patients undergoing knee or hip replacement surgery.
<b>Available dosage forms:</b>	10 mg, 15 mg, and 20 mg tablets
<b>Usual dose:</b>	Non-valvular atrial fibrillation: 20 mg once daily with evening meal if CrCl > 50mL/min 15 mg once daily with evening meal if CrCl 15-50mL/min Avoid if CrCl < 15 mL/min  DVT prophylaxis: 10 mg once daily with or without food, 6-10 hours after surgery
<b>Approximate monthly cost:</b> (based on AWP 2011)	\$263.00 per month
<b>Duration of therapy:</b>	Non-valvular atrial fibrillation: To be determined by physician DVT prophylaxis: Hip replacement surgery: 35 days recommended Knee replacement surgery: 12 days recommended

**Criteria for use for stroke prevention in A-fib** (*bullet points below are all inclusive unless otherwise noted*):

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.
- Must have non-valvular atrial fibrillation.
- Must have moderate to high risk for stroke as determined by the following: either history of stroke, TIA, or systemic embolism or two of the following: heart failure or LVEF  $\leq$ 35%, HTN,  $\geq$ 75 years old, or diabetes mellitus (i.e. CHADS<sub>2</sub> score of 2 or more).
- Must have tried and failed or intolerant to warfarin therapy.
- Must provide recent CrCl or SCr, weight, and height.

**Criteria for use for DVT prophylaxis after knee or hip replacement surgery** (*bullet points below are all inclusive unless otherwise noted*):

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.
- Must have undergone elective total hip arthroplasty or total knee arthroplasty.
- Must be at least 18 years of age.

**Caution:**

- Black Box Warning:
  - Discontinuing Xarelto can lead to higher risk of stroke. If discontinuation is warranted for reasons other than pathological bleeding, consider use of another anticoagulation agent.
  - Administration of Xarelto while also receiving neuraxial anesthesia or undergoing spinal puncture can lead to epidural or spinal hematomas, which can result in long term or permanent paralysis.
- If discontinuation is warranted due to risk of bleeding with surgery or other procedures, temporarily stop Xarelto at least 24 hours before procedure. Restart after the procedure once adequate hemostasis has been established.
- Avoid if CrCl < 15mL/min.
- Avoid use with P-gp and strong CYP3A4 inhibitors/inducers.

**Monitoring:**

- SCr/CrCl
- Signs and symptoms of bleeding

**Contraindication:**

- Active pathological bleeding.
- Severe hypersensitivity reaction to Xarelto.

**Not approved if:**

- Patient has contraindications to the use of Xarelto.
- Patient does not meet the above stated criteria.

**Special considerations:**

- Risk of fatal and critical bleeding and intracranial hemorrhage was lower with rivaroxaban than with warfarin for A-fib; however, risk of GI bleed was higher with rivaroxaban than warfarin.
- No specific antidote is available.

FCHP Pharmacy and Therapeutics Committee approval: \_\_\_\_\_

Date: \_\_\_\_\_

Adopted: 12/14/11