Xarelto® (rivaroxaban) – Expanded indication

- On August 24, 2021, Janssen announced the FDA approval of Xarelto (rivaroxaban), in combination with aspirin, to reduce the risk of major thrombotic vascular events (myocardial infarction, ischemic stroke, acute limb ischemia, and major amputation of a vascular etiology) in patients with peripheral artery disease (PAD), including patients who have recently undergone a lower extremity revascularization procedure due to symptomatic PAD.
    - Xarelto was previously approved in combination with aspirin to reduce the risk of major cardiovascular events (cardiovascular death, myocardial infarction, and stroke) in patients with PAD.
- Xarelto is also approved for:
    - Reduction of risk of stroke and systemic embolism in nonvalvular atrial fibrillation
    - Treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE)
    - Reduction in the risk of recurrence of DVT and/or PE
    - Prophylaxis of DVT following hip or knee replacement surgery
    - Prophylaxis of venous thromboembolism in acutely ill medical patients at risk for thromboembolic complications not at high risk of bleeding
    - Reduction of risk of major cardiovascular events in patients with coronary artery disease (CAD).
- The approval of Xarelto for the expanded indication was based on VOYAGER PAD, a randomized, double-blinded, placebo-controlled study in 6,564 patients undergoing a lower extremity infrainguinal revascularization procedure due to symptomatic PAD. Patients received Xarelto or placebo, with background therapy of aspirin. The primary endpoint was the composite rate of myocardial infarction, ischemic stroke, cardiovascular death, acute limb ischemia (ALI), and major amputation of a vascular etiology.
    - The event rate (%/year) was 6.8 with Xarelto vs. 8.0 with placebo (hazard ratio 0.85, 95% CI: 0.76, 0.96; p = 0.0085).
- The results from VOYAGER PAD complement findings from the previous COMPASS study, which also examined the dual pathway approach of Xarelto with aspirin in CAD and/or PAD patients.
- Xarelto carries a boxed warning for (1) premature discontinuation of Xarelto increasing the risk of thrombotic events and (2) spinal/epidural hematoma.
- The recommended dose of Xarelto for reduction of risk of major thrombotic vascular events in PAD is 2.5 mg orally twice daily, plus aspirin (75 to 100 mg) once daily. When starting therapy after a successful lower extremity revascularization procedure, treatment should be initiated once hemostasis has been established.
    - Refer to the Xarelto drug label for dosing for all its other indications.