Xarelto® (rivaroxaban) – New indication

- On October 14, 2019, Janssen announced the FDA approval of Xarelto (rivaroxaban), 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 is also approved for:

    - Reduction of risk of stroke and systemic embolism in nonvalvular atrial fibrillation
    - Treatment of deep vein thrombosis (DVT)
    - Treatment of pulmonary embolism (PE)
    - Reduction in the risk of recurrence of DVT and/or PE
    - Prophylaxis of DVT following hip or knee replacement surgery
    - Reduction of risk of major cardiovascular events in patients with chronic coronary artery disease or peripheral artery disease

- More than 7 million Americans are hospitalized each year with an acute medical illness, which is a broad term used to describe serious, yet common, medical conditions. These patients are at increased risk of blood clots for up to 3 months after hospital discharge, with 80% of events happening within the first 6 weeks.

- The approval of Xarelto for the new indication was based on MAGELLAN, a randomized, double-blind study comparing Xarelto to enoxaparin, in the prevention of VTE in hospitalized acutely ill medical patients during the in-hospital and post-hospital discharge period. A total of 6,024 patients were evaluable for the major efficacy outcome analysis. The major efficacy outcome was a composite endpoint that included asymptomatic proximal DVT in lower extremity, symptomatic proximal or distal DVT in the lower extremity, symptomatic non-fatal PE, and death related to VTE.

    - In the overall modified intent-to-treat population, 4.4% and 5.7% of patients in the Xarelto and enoxaparin group had a composite endpoint event (relative risk [RR] 0.77; 95% CI: 0.62, 0.96).
    - In the subgroup of patients not at a high risk of bleeding, 3.9% and 5.7% of patients in the Xarelto and enoxaparin group had a composite endpoint event (RR 0.68; 95% CI: 0.53, 0.88).

- Xarelto carries a boxed warning for premature discontinuation of Xarelto increases the risk of thrombotic events and spinal/epidural hematoma.

- The recommended dose of Xarelto for this new indication is 10 mg orally once daily in hospital and after hospital discharge, for a total recommended duration of 31 to 39 days.

- Refer to the Xarelto drug label for dosing for all its other indications.

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