



## Preferred Drug List

### NEW DRUG REVIEW

**Proprietary Name:** Xarelto®

**Common Name:** Rivaroxaban

**PDL Category:** Anticoagulants

<u>Comparable Products</u>	<u>Preferred Drug List Status</u>
Lovenox®	Preferred

#### Summary

**Indications and Usage:** Indicated for the prophylaxis of deep vein thrombosis (DVT) which may lead to pulmonary embolism (PE) in patients undergoing knee or hip replacement surgery.<sup>1</sup>

**Mechanism of Action:** Inhibits platelet activation and aggregation through the irreversible binding to platelet receptors.<sup>1</sup>

**Dosage Forms:** Tablets: 10mg

**Recommended Dosage:** 10mg orally, once daily with or without food.<sup>1</sup>

**Common Adverse Drug Reactions:** Bleeding.<sup>1</sup>

**Contraindications:** Active major bleeding.<sup>1</sup>

**Manufacturer:** Janssen Pharmaceuticals, Inc.

**Analysis:** Xarelto® is an oral direct factor Xa inhibitor indicated for the prevention of DVT in patients undergoing knee or hip replacement surgery. In the trials used to gain FDA approval for DVT prophylaxis post knee or hip replacement surgery, Xarelto® was compared to enoxaparin 40mg once daily. There was a lower incidence of the primary endpoint venous thromboembolism (VTE) with Xarelto® versus enoxaparin. For hip replacement, the occurrence of total VTE was 1.1% vs. 3.9% and 2.0% vs. 8.4% for the two trials respectively. For knee replacement patients, total VTE occurred 9.7% vs. 18.8% of patients respectively. The trials also indicate a similar rate of bleeding events with Xarelto® and enoxaparin. Major bleeding events occurred in 0.3% vs. 0.2% and any bleeding event occurred 5.8% vs. 5.6% respectively. These differences are not considered statistically significant. Xarelto® offers an advantage for oral therapy which does not require coagulation monitoring and is a cost effective alternative for DVT prophylaxis post knee or hip replacement surgery. It is not known if Xarelto® will be cost effective for other indications which are being or have been studied. Therefore, it is recommended that Xarelto® be added to the Preferred Drug List as a preferred drug for the indications of DVT prophylaxis post knee or hip replacement surgery only. Xarelto® will require prior authorization to confirm the diagnosis of use and duration of therapy.

**IME Recommendation:**  Preferred Drug  Recommended Drug  
 Non-Preferred Drug  Non-Recommended Drug  
 Preferred Drug with Conditions

1. Xarelto® [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; 2011.