

Xarelto (rivaroxaban) 1mg/mL Granules for Suspension

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Xarelto (Rivaroxaban) is a medication utilized to treat or prevent blood clots. It has been designed to lower the risk of heart attack, stroke, and death in certain individuals. Additionally, Xarelto has been shown to decrease the likelihood of decreased blood flow to the legs, amputation, and serious heart problems in some patients.

Xarelto is available in two forms: tablets and granules for suspension. The tablets are taken orally, usually once daily with food, while the granules for suspension are mixed with a liquid and taken orally. The recommended dose of Xarelto may vary based on the indication and the patient's individual characteristics, such as weight, renal function, and concomitant medications.

Xarelto (Rivaroxaban) is indicated:

- to reduce the risk of stroke and systemic embolism in adult patients with nonvalvular atrial fibrillation (AF).

There are limited data on the relative effectiveness of Xarelto (Rivaroxaban) and warfarin in reducing the risk of stroke and systemic embolism when warfarin therapy is well controlled.

- 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 adult 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 adult patients undergoing knee or hip replacement surgery.
- 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.
- in combination with aspirin, to reduce the risk of major cardiovascular events (cardiovascular death, myocardial infarction, and stroke) in adult patients with coronary artery disease (CAD).
- 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 adult patients with peripheral artery disease (PAD), including patients who have recently undergone a lower extremity revascularization procedure due to symptomatic PAD.
- for the treatment of VTE and reduction in the risk of recurrent VTE in pediatric patients from birth to less than 18 years after at least 5 days of initial parenteral anticoagulant treatment.
- for thromboprophylaxis in pediatric patients aged 2 years and older with congenital heart disease who have undergone the Fontan procedure.

Definitions

“Congenital heart disease” refers to a range of conditions that are present at birth and affect the structure and function of the heart. Congenital heart disease can range from minor abnormalities to serious conditions that require ongoing medical care.

“Coronary artery disease (CAD)” is a condition in which the blood vessels that supply blood to the heart become narrow or blocked, reducing the flow of oxygen and nutrients to the heart. CAD can lead to chest pain (angina), heart attack, and other serious health problems.

“Deep vein thrombosis (DVT)” is a condition in which a blood clot forms in one of the deep veins, usually in the legs. DVT can cause swelling, pain, and redness in the affected leg, and can lead to serious complications if the clot travels to the lungs (pulmonary embolism).

"Fontan procedure" is a surgical treatment for certain types of congenital heart disease. It is used to redirect the flow of blood from the right side of the heart to the lungs, bypassing the heart's right ventricle and reducing the workload on the heart.

"Nonvalvular atrial fibrillation (AF)" is a type of irregular heartbeat in which the two upper chambers of the heart (the atria) beat in a fast and irregular manner. This can increase the risk of blood clots and stroke.

"Parenteral" refers to the administration of a medication or other substance into the body through a route other than the digestive tract, such as injection or infusion.

"Prophylaxis" refers to the use of measures to prevent the development of a disease or condition. In the context of medication, prophylaxis refers to the use of a drug to prevent the occurrence of a disease or condition.

"Pulmonary embolism (PE)" is a condition in which a blood clot travels to the lungs and blocks one or more blood vessels, causing chest pain, shortness of breath, and other symptoms. PE can be life-threatening if left untreated.

"Recurrent" refers to the occurrence of a disease, condition, or event more than once.

A **"Stroke"** is a medical condition in which the blood supply to the brain is interrupted, causing brain cells to die. Strokes can have a range of effects, including weakness or paralysis on one side of the body, difficulty speaking or understanding speech, and vision loss.

"Systemic embolism" refers to the obstruction of a blood vessel by an embolus, a clot or other material that has broken off from another part of the body and traveled through the bloodstream. Systemic emboli can cause serious health problems, including heart attack, stroke, and organ damage.

"Venous thromboembolism (VTE)" is a term used to describe a condition in which a blood clot forms in a vein and causes a blockage. VTE includes deep vein thrombosis (DVT) and pulmonary embolism (PE).

Medical Necessity Criteria for Authorization

The Plan considers **Xarelto (Rivaroxaban) granules for suspension** medically necessary when **ONE** of the following criteria are met:

1. The member is 18 years of age or older and there is documented evidence that the member cannot take or have Xarelto tablets appropriately administered; **OR**
2. The member is a pediatric patient <18 years of age and Xarelto (Rivaroxaban) is being prescribed for **ANY** of the following:
 - a. thromboprophylaxis in members with congenital heart disease following the Fontan procedure; **or**
 - b. reduce risk of recurrent venous thromboembolism (VTE) after ≥5 days of initial treatment with a parenteral anticoagulant; **or**
 - c. treatment of venous thromboembolism (VTE) after ≥5 days of initial treatment with a parenteral anticoagulant.

If the above prior authorization criteria are met, Xarelto (Rivaroxaban) will be authorized for the following time frame based on its intended use:

- **60-days** for:
 - superficial vein thrombosis (acute symptomatic); **or**
 - venous thromboembolism prophylaxis in acutely ill medical patients, nonmajor orthopedic surgery of the lower limb, or total hip or knee arthroplasty; **or**
- **6-months** for heparin-induced thrombocytopenia (treatment); **or**
- **12-months** for all other indications.

Experimental or Investigational / Not Medically Necessary

Xarelto (Rivaroxaban) for any other indication or use is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

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