Manitoba Exception Drug Status Request Form

FAX: (204) 942-2030 or 1-877-208-3588

Xarelto® (rivaroxaban) 2.5 mg will be considered for coverage under the Exception Drug Status (EDS) program in combination with acetylsalicylic acid (ASA; 75 mg to 100 mg) for the prevention of stroke, myocardial infarction, and cardiovascular death, and for the prevention of acute limb ischemia and mortality in patients with concomitant coronary artery disease (CAD) and peripheral artery disease (PAD). Patients must meet the criteria described on this form.

1. PRESCRIBER INFORMATION

Name (Including First Initial):	
Address:	
Postal Code:	
Phone Number:	Fax Number:
Prescriber License Number (NOT Billing Number):	

2. PATIENT INFORMATION

Patient First Name:
Patient Last Name:
Manitoba Health Registration Number (MHRN):
Personal Health Information Number (PHIN):
Date of Birth:

3. MEDICATION INFORMATION

Xarelto® (rivaroxaban) 2.5 mg

DIN: 02480808

Dosage Form: Tablet

Expected Dosing: Twice daily, in combination with acetylsalicylic acid (ASA; 75 mg to 100 mg) once daily

Expected Therapy Duration:

4. MEDICATION JUSTIFICATION

Xarelto® 2.5 mg is requested for the prevention of stroke, myocardial infarction, and cardiovascular death, and for the prevention of acute limb ischemia and mortality in this patient with concomitant coronary artery disease (CAD) and peripheral artery disease (PAD), in whom the following conditions are met:

Patient's CAD is defined by one or more of the following:

- ☐ myocardial infarction within the last 20 years
- ☐ multi-vessel coronary disease (i.e., stenosis of ≥50% in two or more coronary arteries, or in one coronary territory if at least one other territory has been revascularized) with symptoms or history of stable or unstable angina
- ☐ multi-vessel percutaneous coronary intervention
- ☐ multi-vessel coronary artery bypass graft surgery

AND patient meets at least one of the following criteria:

- ☐ aged 65 years or older, or
- ☐ aged younger than 65 years with documented atherosclerosis or revascularization involving at least two vascular beds (coronary and other vascular) or at least two additional risk factors (current smoker, diabetes mellitus, estimated glomerular filtration rate <60 mL/min, heart failure, non-lacunar ischemic stroke 1 month or more ago).

Patient's PAD is defined by one or more of the following:

- ☐ previous aorto-femoral bypass surgery, limb bypass surgery, or percutaneous transluminal angioplasty revascularization of the iliac or infrainguinal arteries
- ☐ previous limb or foot amputation for arterial vascular disease
- ☐ history of intermittent claudication and one or more of the following:
  - ☐ an anklebrachial index less than 0.90, or
  - ☐ significant peripheral artery stenosis (≥50%) documented by angiography or by duplex ultrasound
- ☐ previous carotid revascularization or asymptomatic carotid artery stenosis greater than or equal to 50%, as diagnosed by duplex ultrasound or angiography.

5. ADDITIONAL CRITERIA OR CLINICAL INFORMATION

Xarelto® 2.5 mg should not be reimbursed for patients who have CAD or PAD alone or in patients with any one of the following characteristics:

- ☐ at high risk of bleeding
- ☐ a history of stroke within one month of treatment initiation or any history of hemorrhagic or lacunar stroke
- ☐ severe heart failure with a known ejection fraction less than 30% or New York Heart Association class III or IV symptoms
- ☐ an estimated glomerular filtration rate less than 15 mL/min
- ☐ require dual antiplatelet therapy, other non-ASA antiplatelet therapy, or oral anticoagulant therapy.

Prescriber Signature:	Date (mm/dd/year):	For EDS Office:

Fax the completed form to (204) 942-2030 or 1-877-208-3588

PrXarelto® (rivaroxaban) film-coated tablet (2.5 mg), in combination with 75 mg–100 mg acetylsalicylic acid (ASA), is indicated for the prevention of stroke, myocardial infarction and cardiovascular death, and for the prevention of acute limb ischemia and mortality in patients with coronary artery disease (CAD) with or without peripheral artery disease (PAD).

Consult the Xarelto® Product Monograph at https://www.bayer.ca/omr/online/xarelto-pm-en.pdf for contraindications, warnings, precautions, adverse reactions, interactions, dosing, and conditions of clinical use. The Product Monograph is also available by calling 1-800-265-7382.

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