BC PharmaCare Drug Information

The drug below is being considered for possible coverage under the B.C. PharmaCare program. PharmaCare is a government-funded drug plan that helps British Columbians with the cost of eligible prescription drugs and specific medical supplies. For more information on PharmaCare, visit Ministry of Health - PharmaCare.

PharmaCare reviews each drug for treating a specific illness or medical condition (known as an "indication"). If a decision is made to cover the drug, it will be only for that illness or condition.

In some cases, PharmaCare may cover a drug only for people who have the illness or condition and have not responded to other drugs used to treat that illness or condition.

For more information on PharmaCare's drug coverage review process, see the last page of this information sheet.

Information about the drug	
Generic name (scientific name)	**Rivaroxaban**
Brand name	**Xarelto®**
Manufacturer	Bayer Inc.
Indication	For the treatment of venous thromboembolic events (VTE) and prevention of VTE recurrence in term neonates, infants and toddlers, and children and adolescents aged less than 18 years after at least 5 days of initial parenteral[a] anticoagulation treatment.
Has the drug been reviewed by Canada's Drug and Health Technology Agency (CADTH)? (see the note below this table.)	Yes For more information about the CADTH Reimbursement Review (CRR) of rivaroxaban, please see the CADTH Report.
Public input start date	Wednesday, March 27, 2024

[a] Parenteral means giving medication through a needle or catheter directly into the body, rather than through the digestive system, i.e. via a subcutaneous (under the skin) injection or intravenous (through a vein) (IV) infusion.

Information about the drug	
Public input closing date	**Tuesday, April 23, 2024, AT 11:59 PM**
How is the drug taken?	Rivaroxaban is taken orally (by the mouth). The formulation being reviewed consists of granules which are mixed with water and given with an oral dosing syringe.
How often is the drug taken?	For pediatric patients with a body weight of at least 30 kg, rivaroxaban tablet or oral suspension is taken once daily. The dose is determined based on body weight. For pediatric patients with a body weight of at least 2.6 kg to less than 30 kg, only the oral suspension should be used. The dose and frequency of administration is based on body weight.
General drug and/or drug study information	Rivaroxaban is being reviewed by the Ministry of Health for the treatment of venous thromboembolic events (VTE) and prevention of VTE recurrence in term newborns[b], infants and toddlers, and children and adolescents aged less than 18 years. It is taken after at least 5 days of initial parenteral[c] anticoagulation treatment. VTEs occur when a blood clot forms in one of the deep veins of the leg, groin, or arm. The clot may break free from the vein wall and travel to the lungs, blocking some or all of the blood supply. This is called a pulmonary embolism (PE) and it can often be fatal. Rivaroxaban is an anticoagulant. It helps prevent blood clots from forming by directly blocking the activity of a specific protein in the blood called clotting Factor-Xa. Studies looked at the following: • VTE recurrence (with or without symptoms) • Complete resolution of thrombus (blood clot) on repeat imaging without recurrent VTE • Composite (combined) outcome of recurrent VTE and asymptomatic (without symptoms) deterioration • Net clinical benefit (Composite outcome of symptomatic recurrent VTE or major bleeding events.) • Nonfatal pulmonary embolism

[b] Newborns who at birth had at least 37 weeks of gestation, weigh at least 2.6 kg, and have had at least 10 days of oral feeding.
[c] Parenteral means giving medication through a needle or catheter directly into the body, rather than through the digestive system, i.e. via a subcutaneous (under the skin) injection or intravenous (through a vein) (IV) infusion.

Information about the drug	
	• Bad reactions • Serious bad reactions • Patients leaving the trial due to bad reactions • Bad reactions of special interest, such as any confirmed bleeding, major bleeding, and clinically relevant nonmajor bleeding
Other considerations	None

Note:
Canada's Drug and Health Technology Agency (CADTH) is a national organization that reviews drugs on behalf of Canadian public sector plans when manufacturers want to have the jurisdictions provide coverage for the drugs. For detailed information on B.C. PharmaCare's drug review process, including the role of the CADTH Reimbursement Review (CRR) in that process, see The Drug Review Process in B.C. - Overview.

Cost of the drug under review compared to other drugs used to treat the same indication				
generic name (Brand Name) of Drug Comparator	**PharmaCare Status (if and how the drug is already covered)**	**Dosage Form**	**Usual Dose**	**Daily Cost of Therapy[d]**
Rivaroxaban (Xarelto)	Under review for the treatment and prevention of VTE in pediatric patients under 18 years of age	Granules for oral suspension	1 to 3 times daily, (dosage and frequency is weight-dependent)	$1.22 to $3.65[e]
Direct oral anticoagulants (DOACs)[f]				
Dabigatran etexilate (Pradaxa, generics)	Non-Benefit for the treatment and/or prevention of VTE	Oral tablets and capsules	Twice daily	$2.94 to $3.61

[d] All prices as per PharmaCare Formulary, unless otherwise stated. Weight-based dosing assumes a range of 5 kg to 50 kg. Prices also took into consideration drug wastage.
[e] Price as per CADTH Reimbursement Review for rivaroxaban for pediatric patients plus 8% markup.
[f] Pediatric use not authorized by Health Canada.

Cost of the drug under review compared to other drugs used to treat the same indication				
generic name (Brand Name) of Drug Comparator	**PharmaCare Status (if and how the drug is already covered)**	**Dosage Form**	**Usual Dose**	**Daily Cost of Therapy[d]**
Edoxaban (Lixiana)	Non-benefit	Oral tablets	Once daily	$2.94[g]
Low molecular weight heparins (LMWHs)[h]				
Dalteparin sodium (Fragmin)	Limited Coverage	Multiuse vial	Twice daily, dosed by weight in kg	$3.50 to $29.00
Enoxaparin (Redesca)	Limited Coverage	Multiuse vial	Once or twice daily, dosed by weight in kg	$1.91 to $18.00
Nadroparin calcium (Fraxiparine, 9,500 IU/mL)	Limited Coverage	Prefilled syringes for subcutaneous (SC) or intravenous (IV) injection	Once daily, dosed by weight in kg	$2.93 to $9.78
Tinzaparin sodium (Innohep)	Limited Coverage	Prefilled syringes for SC or IV injection	Once daily, dosed by weight in kg	$6.92 to $28.00
Unfractionated heparin[i]				
Unfractionated heparin (Heparin Sodium Injection)	Regular benefit, Subject to LCA	Prefilled syringes for SC or IV injection	6 times per day, dosed by weight in kg or by m^2 of body surface area	$5.67 to $17.00
Vitamin K antagonists[j]				

[g] Price as per CADTH Reimbursement Review for rivaroxaban for pediatric patients.
[h] Pediatric use not authorized by Health Canada
[i] No adequate and well controlled studies in pediatric patients.
[j] No adequate and well controlled studies pediatric patients.

Cost of the drug under review compared to other drugs used to treat the same indication				
generic name (Brand Name) of Drug Comparator	**PharmaCare Status (if and how the drug is already covered)**	**Dosage Form**	**Usual Dose**	**Daily Cost of Therapy[d]**
Warfarin (Generics)	Regular benefit, Subject to LCA	Oral tablets	Dosage adjusted individually so patients can maintain an INR[k] in the range of 2.0 to 3.0 with a target INR of 2.5	$0.21 to $0.32
Fondaparinux[l]				
Fondaprinux	Non-benefit	SC injection	Once daily	$11.13 to $29.27[m]

[k] The international normalised ratio (INR) blood test tells you how long it takes for your blood to clot. It is used to test clotting times in people taking warfarin. Your doctor will use your INR result to work out what dose of warfarin you should take.
[l] Pediatric use not authorized by Health Canada.
[m] Price as per CADTH Reimbursement Review for rivaroxaban for pediatric patients.

The Drug Review Process in B.C.

A manufacturer submits a request to the Ministry of Health (Ministry).

An independent group called the Drug Benefit Council (DBC) gives advice to the Ministry. The DBC looks at:

- whether the drug is safe and effective
- advice from a national group called Canada's Drug and Health Technology Agency (CADTH)
- what the drug costs and whether it is a good value for the people of B.C.
- ethical considerations involved with covering or not covering the drug
- input from physicians, patients, caregivers, patient groups and drug submission sponsors

The Ministry makes PharmaCare coverage decisions by taking into account:

- the existing PharmaCare policies, programs and resources
- the evidence-informed advice of the DBC
- the drugs already covered by PharmaCare that are used to treat similar medical conditions
- the overall cost of covering the drug

For more information about the B.C. Drug Review Process, visit: The Drug Review Process in B.C. - Overview.

This document is intended for information only.
It does not take the place of advice from a physician or other qualified health care provider.