

BC PharmaCare Drug Information

The drug below is being considered for coverage under the BC PharmaCare program. PharmaCare is a government-funded drug plan that helps B.C. residents with the cost of eligible prescription drugs and medical supplies. For more information about PharmaCare, visit the [PharmaCare website](#).

PharmaCare reviews each drug for treating a specific illness or medical condition (also called an “indication”). If PharmaCare decides to cover a drug, that coverage applies only to the indication(s) specified. In some cases, PharmaCare covers a drug only for people who have not responded to other drugs that treat the same indication.

More information about the PharmaCare drug review process is provided on the last page of this document.

Drug information	
Generic name (scientific name)	rozanolixizumab
Brand name	TBC
Manufacturer	UCB Canada Inc.
Indication	Rozanolixizumab is indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients.
Has the drug been reviewed by CDA-AMC, or will CDA-AMC be reviewing it? (See note below.)	Yes For more information about the CDA-AMC Reimbursement Review (CRR) of rozanolixizumab (TBC), Search the CDA-AMC Reports .
Public input start date	Monday , December 23, 2024
Public input closing date	Wednesday, February 5, 2025, at 11:59 pm
How is the drug taken?	Rozanolixizumab is given by subcutaneous (under the skin) infusion. It is intended to be infused in the lower right or lower left part of the abdomen below the navel.
How often is the drug taken?	Rozanolixizumab is administered once weekly in six-week cycles. Subsequent treatment cycles are based on clinical evaluation and may vary by patient.

Drug information	
General drug and/or drug study information	<p>Rozanolixizumab is used to treat generalized myasthenia gravis (gMG). gMG is a rare, chronic, autoimmune condition where the body's immune system turns on itself and attacks the receptors on the body's muscles, which are needed to receive nerve signals that tell the muscles to move. gMG is characterized by weakness and fatigue of skeletal muscles (muscles involved with moving parts of the body and breathing). Patients with gMG may experience impaired mobility, speaking, swallowing, and vision, shortness of breath, pulmonary failure, and fatigue. Their muscle weakness fluctuates through the day, worsening over periods of activity, and improving with rest.</p> <p>Rozanolixizumab is a monoclonal antibody that inhibits neonatal fragment crystallizable receptor (FcRN) from recycling immunoglobulin G (IgG) antibodies, resulting in reduced IgG levels in the bloodstream. Reducing IgG can improve muscle strength and function in people with gMG.</p> <p>Studies looked at the following to determine if rozanolixizumab was safe and effective:</p> <ul style="list-style-type: none"> • Disease severity, measured by Myasthenia Gravis Activities of Daily Living (MG-ADL), Quantitative Myasthenia Gravis (QMG) and Myasthenia Gravis Composite (MGC) Total Scores • Health-Related Quality of Life (HRQoL) and fatigue, measured by Revised 15-Component Myasthenia Gravis Quality of Life (MG-QoL 15r) Total Score • Bad reactions • Serious bad reactions • Patients leaving the trial due to bad reactions • Bad reactions of special interest such as infections and infestations
Other considerations	None

Note:

CDA-AMC ([Canada's Drug Agency-L'Agence des Médicaments du Canada](#)) is a national organization that reviews drugs on behalf of Canadian public sector plans when drug manufacturers want those plans to provide coverage for the drug. For detailed information about the PharmaCare drug review process, including the role of the CDA-AMC Reimbursement Review (CRR) in that process, visit [How PharmaCare Decides Which Drugs to Cover](#).

Cost of the drug compared to other drugs used to treat the same indication^a				
Generic Name (Brand Name) of Drug Comparator	PharmaCare Status (if and how the drug is already covered)	Dosage Form	Usual Dose	Annual Cost of Therapy
rozanolixizumab (TBC)	Under Review	Pre-filled syringe for subcutaneous (SC) injection	Once weekly, in milligrams (mg) per kilogram (kg) of body weight, for 6 weeks. Subsequent treatment cycles are based on clinical evaluation.	TBC (to be confirmed)
Complement Inhibitors Indicated for the Treatment of gMG				
eculizumab (Soliris)	Non-Benefit for gMG Exceptional, case-by-case coverage provided through the BC PharmaCare EDRD process for atypical hemolytic uremic syndrome and paroxysmal nocturnal hemoglobinuria	Single-use vial for intravenous (IV) infusion	Once weekly for 5 weeks, then once every 2 weeks thereafter	First year: \$728,136 Subsequent years: \$701,168
ravulizumab (Ultomiris)	Under Review for gMG	Single-use vial for IV infusion	Loading dose, with maintenance doses given starting 2 weeks after, then administered every 8 weeks thereafter, based on body weight	First year: \$515,017 ^b to \$620,933 ^b Subsequent years: \$474,965 ^b to \$569,958 ^b

^a All prices as per PharmaCare formulary, unless otherwise specified. Weight-based dosing assumes a weight of 65 kg; dosing based on body surface area assumes an area of 1.8 m².

Cost of the drug compared to other drugs used to treat the same indication ^a				
Generic Name (Brand Name) of Drug Comparator	PharmaCare Status (if and how the drug is already covered)	Dosage Form	Usual Dose	Annual Cost of Therapy
efgartigimod alfa (Vyvgart)	Under Review	Single-use vial for IV infusion	Once weekly for 4 weeks. Subsequent treatment cycles are based on clinical evaluation.	\$298,304 ^b to \$447,456 ^b
zilucoplan (Zilbrysq)	Under Review	Pre-filled syringe for SC injection	One daily, in mg per kg of body weight	\$237,512 ^b to \$463,577 ^b
Off-Label Treatments				
Other Biologics				
rituximab (biosimilars)	Non-Benefit for gMG <u>Limited Coverage</u> for rheumatoid arthritis (RA), granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA), and relapsing- remitting multiple sclerosis (RRMS)	Vial for IV infusion	Once weekly for four doses, by body surface area in mg/m ² Alternate dosing: One dose, followed by another dose two weeks later, and then every 6 months	Cost per course: \$8,981 Alternate dosing in year 1: \$12,563

^b Price as per CDA Pharmacoeconomic Review Report for rozanolixizumab (TBC) gMG.

Cost of the drug compared to other drugs used to treat the same indication ^a				
Generic Name (Brand Name) of Drug Comparator	PharmaCare Status (if and how the drug is already covered)	Dosage Form	Usual Dose	Annual Cost of Therapy
Glucocorticoids				
prednisone (Winpred, generics)	Regular Benefit, subject to LCA	Tablet	Once per day, dosed in mg/kg of body weight. Alternate dosing: Once per day in flat-fixed dose, then taper after improvement	\$32 to \$116 Alternate dosing: \$100 to \$163
Immunosuppressive agents				
azathioprine (generics)	Regular Benefit, subject to LCA	Tablet	Once per day, first for five days of flat-fixed dosing, then dosed in mg/kg thereafter	\$379
cyclophosphamide (Procytox, generics)	Regular Benefit	Tablet	Once per month for 6 months, dosed in mg/m ²	Cost per course: \$52 to \$103 ^b
	Non-Benefit	IV Vial, powder for injection		Cost per course: \$1,106 to \$2,035 ^b
cyclosporine (generics)	Non-Benefit for gMG Limited Coverage for rheumatoid arthritis (RA), ocular inflammatory disease, psoriasis, and nephrotic syndrome	Capsule	Starting dose: flat-fixed dose, twice daily Target dose: in mg/kg/day in 2 divided doses, daily thereafter	\$3,942 to \$5,306

Cost of the drug compared to other drugs used to treat the same indication ^a				
Generic Name (Brand Name) of Drug Comparator	PharmaCare Status (if and how the drug is already covered)	Dosage Form	Usual Dose	Annual Cost of Therapy
methotrexate (generic, Metoject SC)	Regular Benefit, subject to LCA	Tablet	Once weekly	\$152 to \$304
	Non-Benefit for gMG Limited Coverage for rheumatoid arthritis (RA)	Pre-filled syringe for subcutaneous (SC) use		\$393 to \$629
mycophenolate mofetil (generics)	Regular Benefit, subject to LCA	Capsule, Tablet	Twice daily	\$1,170
mycophenolate Sodium (generics)	Non-Benefit	Enteric Tablet	Twice daily	\$2,917 ^b
tacrolimus (generics)	Non-Benefit	Capsule	Once per day	\$1,421 to \$2,372 ^b
Cholinesterase inhibitors				
pyridostigmine (Mestinon, generics)	Regular Benefit, subject to LCA	Tablet	Once every 3-8 hours, while awake	\$474 to \$1,580
	Regular Benefit	Sustained Release (SR) Tablet		\$1,438 to \$2,397
Blood products				
Intravenous immunoglobulin				Price Confidential
Plasma Exchange				Price Confidential

^a All prices as per PharmaCare formulary, unless otherwise specified. Weight-based dosing assumes a weight of 65 kg; dosing based on body surface area assumes an area of 1.8 m².

^b Price as per CDA Pharmacoeconomic Review Report for rozanolixizumab (TBC) gMG.

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 Agency-L'Agence des médicaments du Canada \(CDA-AMC\)](#)
- what the drug costs and whether it is a good value to the citizens of B.C.
- ethical considerations related to 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:

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

For more information about the drug review process in B.C., visit: the [How PharmaCare decides which drugs to cover](#).

This document provides information only.

It does not take the place of advice from a physician or other qualified health care provider.