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. 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)	**ravulizumab**
Brand name	**Ultomiris®**
Manufacturer	Alexion Pharma GmBH
Indication	Ultomiris® is indicated for the treatment of adult patients with anti-acetylcholine receptor (AChR) antibody-positive generalized Myasthenia Gravis (gMG) whose symptoms persist despite adequate treatment with acetylcholinesterase inhibitors, corticosteroids, and/or non-steroidal immunosuppressants.
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 ravulizumab (Ultomiris®), Search the CDA-AMC Reports.
Public input start date	**Wednesday,** September 25, 2024
Public input closing date	**Tuesday,** October 22, 2024, **at 11:59 pm**
How is the drug taken?	Ravulizumab is administered by intravenous (IV) infusion (directly into the bloodstream through the vein).
How often is the drug taken?	Ravulizumab is administered once, then once again after two weeks, and then again, every eight weeks thereafter.

Drug information	
General drug and/or drug study information	Ravulizumab is used to treat anti-acetylcholine receptor (AChR) antibody-positive generalized myasthenia gravis (gMG). Myasthenia Gravis (MG) is a rare chronic autoimmune condition characterized by weakness and fatigue of skeletal muscles (muscles involved with moving parts of the body and breathing). In patients with anti-AChR antibody-positive gMG, the body's own immune system turns on itself and attacks its AChRs, which are receptors used by nerve cells to control the muscles. 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. Ravulizumab belongs to a class of medicines called monoclonal antibodies (MABs). Ravulizumab works by attaching to and blocking the actions of a specific protein in the body, stopping your immune system from attacking and destroying its own cells. Studies looked at the following to determine if ravulizumab was safe and effective: • Disease severity, measured by Myasthenia Gravis Activities of Daily Living (MG-ADL) and Quantitative Myasthenia Gravis (QMG) Total Scores • Improvement in activities of daily living, measured by greater than or equal to 5 point and greater than or equal to 3 point increases in QMG and MG-ADL, respectively • Health-Related Quality of Life (HRQoL) and fatigue, measured by Revised 15-Component Myasthenia Gravis Quality of Life (MG-QoL 15r) Total Score and Neurological Quality of Life (Neuro-QoL) Fatigue Score • Bad reactions, like diarrhea, headache, and nausea • Serious bad reactions, including back pain and infections, such as serious meningococcal infections • Patients leaving the trial due to bad reactions or death
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 under review 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**
ravulizumab (Ultomiris)	Under Review	Single dose vial of concentrate for solution for intravenous (IV) infusion	Loading dose, with maintenance doses given starting 2 weeks after, then administered every 8 weeks thereafter, based on weight	≥40 kg to < 60 kg:[b] Year 1: $569,140 Subsequent years: $474,284 ≥60 kg to < 100 kg: Year 1: $627,514 Subsequent years: $521,712 ≥100 kg: Year 1: $685,887 Subsequent years: $569,140
Drugs Indicated for the Treatment of Generalized Myasthenia Gravis				
eculizumab (Soliris)	Non-Benefit for gMG Exceptional, case-by-case coverage provided through the BC PharmaCare EDRD program for atypical hemolytic uremic syndrome and paroxysmal nocturnal hemoglobinuria	Single-use vial for IV infusion	Once weekly for 5 weeks, then once every two weeks thereafter	First year: $728,136 Subsequent years: $701,168
Efgartigimod alfa (Vyvgart)	Under Review	Single-use vial for IV infusion	Once weekly for 4 weeks then every 4 or 8 weeks thereafter based on clinical evaluation	≥40 kg to 80 kg: $298,304[b] >80 kg: $447,456[b]
Off-Label Treatments				
Other Biologics				

[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 m^2.
[b] Manufacturer's submitted price.

Cost of the drug under review 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**
rituximab (biosimilars)	Non-Benefit for gMG Limited Coverage for rheumatoid arthritis (RA), granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA), and relapsing-remitting multiple sclerosis (RRMS)	Vial for intravenous 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
Glucocorticoids				
prednisone (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	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)	Regular Benefit	Tablet	Once per month for 6 months, dosed in mg/m^2	Cost per course: $154 to $309
	Non-Benefit	IV Vial, powder for injection		Cost per course: $1,064 to $1,956[c]

[c] Price as per CADTH Pharmacoeconomic Review Report for ravulizumab (Ultomiris) gMG.

Cost of the drug under review 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**
cyclosporine (generic)	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
methotrexate (generic)	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 (Myfortic, generics)	Non-Benefit	Enteric Tablet	Twice daily	$2,917[d]
tacrolimus (generics)	Non-Benefit	Capsule	Once per day	2,075 to 3,459[d]
Cholinesterase inhibitors				
pyridostigmine (Mestinon)	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 $2397
Blood products				
Intravenous immunoglobulin				Price Confidential
Plasma Exchange				Price Confidential

[d] Price as per CADTH Pharmacoeconomic Review Report for ravulizumab (Ultomiris) 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.