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)	**teprotumumab**
Brand name	**TBC**
Manufacturer	**Amgen Canada Inc.**
Indication	For the treatment of moderate to severe active thyroid eye disease (TED) in adults
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 teprotumumab, Search the CDA-AMC Reports.
Public input start date	**Wednesday, February 26, 2025**
Public input closing date	**Tuesday, March 25, 2025 at 11:59 PM**
How is the drug taken?	Teprotumumab is given by intravenous (IV) infusion. It is administered directly into the bloodstream, through a vein.
How often is the drug taken?	Teprotumumab is given once, as an initial dose, and then every three weeks for seven additional infusions.

General drug and/or drug study information	Teprotumumab is being reviewed by PharmaCare for the treatment of chronic and active (also known as "acute") thyroid eye disease (TED). While active TED typically lasts for weeks to a few months, chronic TED can last for months or even years. This document and survey are for active TED. Another survey for chronic TED is also available for input on the Your Voice webpage. TED, which is also known as Graves' ophthalmopathy/orbitopathy (GO), or dysthyroid eye disease, or thyroid-associated orbitopathy, is a serious, autoimmune disease that is associated with Graves'/Basedow's autoimmune thyroid disease. TED is caused by an autoimmune reaction, in which the body's immune system mistakenly attacks the tissues around the eyes. TED is linked to an overactive thyroid (hyperthyroidism). In TED, the tissues around the eyes become inflamed, leading to symptoms such as bulging eyes, redness and swelling, blurred or double vision, pain or discomfort in the eyes, and even blindness, in severe cases. Teprotumumab is designed to bind to a protein called type 1 insulin-like growth factor receptor (IGF-1R). When teprotumumab binds to IGF-1R, it blocks its activation and signaling. This reduces inflammation and prevents tissue buildup. Teprotumumb helps to improve the symptoms of TED by calming the immune system and reducing swelling. Studies looked at the following: • Proptosis (protrusion of the eyeball from the orbit) responder rate at week 24[a] • Overall responder rate at week 24[b] • Diplopia (double vision) responder rate at week 24[c] • Complete binocular diplopia responder rate at week 24 (a diplopia score of 0 among patients with binocular diplopia score of greater than 0 at baseline) • Health-related quality of life (HRQoL) as measured by changes from baseline to week 24 in the Graves' Ophthalmopathy Quality of Life questionnaire (GO-QoL) visual functioning subscale • HRQoL as measured by changes from baseline to week 24 in the GO-QoL appearance questionnaire subscale • Bad reactions • Serious bad reactions • Patients leaving the trial due to bad reactions

Drug information	
	• Bad reactions of special interest: infusion-related reactions, hyperglycemia (high blood sugar) events, and hearing impairment
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				
Generic Name (Brand Name) of Drug Comparator	**PharmaCare Status (if and how the drug is already covered)**	**Dosage Form**	**Usual Dose**	**Cost per Course of Therapy[d]**
teprotumumab (TBC)	Under Review	Vial for IV infusion	Initial dose followed by doses every 3 weeks for 7 additional infusions	TBC
Off-label treatments				
intravenous methylprednisolone	Regular Benefit, Subject to LCA	Sterile powder and diluent for injection	Once weekly, by IV infusion, for 12 weeks	$295
mycophenolate mofetil	Non-benefit for TED	Oral capsule and tablet	Once daily for 24 weeks	$269

[a] Responder defined as greater than or equal to 2 millimetre (mm) reduction from baseline in protopsis in the study eye without deterioration [greater than or equal to 2 mm increase] in the fellow eye.
[b] Overall responder rate defined as greater than or equal to 2 mm reduction in proptosis AND greater than or equal to 2 point reduction in clinical activity score (CAS) from baseline in the study eye, provided there was no corresponding deterioration [greater than or equal to 2 mm/point increase] in proptosis or CAS in the fellow eye.
[c] Dislopia responder defined as a greater than or equal to 1 grade reduction among patients with diplopia scores of greater than 0 at baseline. Diplopia, or double-vision, is graded using a scale that classifies severity based on the angle of eye misalignment or the patient's experience of double vision. Grade 0: No diplopia; Grade 1: Slight diplopia; Grade 2: Moderate diplopia, noticeable during certain activities; Grade 3: Severe diplopia, persistent double vision affecting daily activities.
[d]All prices as per PharmaCare Formulary, unless otherwise specified. Weight-based dosing assumes a weight of 75 kilograms.

Cost of the drug 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**	**Cost per Course of Therapy[d]**
rituximab	Non-benefit for TED	Sterile liquid concentrate for injection	Once weekly, by IV infusion, for two weeks	$6,415
tocilizumab	Non-benefit for TED	Sterile concentrate solution for injection	Every 4 weeks for 16 weeks, by IV infusion, dosed in mg/kg in body weight	$6,046

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.