

# 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	ТВС			
Manufacturer	Amgen Canada Inc.			
Indication	For the treatment of moderate to severe chronic 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, <u>Search the CDA-AMC Reports</u> .			
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 given?	Teprotumumab is given once, as an initial dose, and then every three weeks thereafter for seven additional infusions.			

# General drug and/or drug study information

Teprotumumab is being reviewed by PharmaCare for the treatment of both chronic and active 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 chronic TED. Another survey for active 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:

- Changes from baseline to week 24 in proptosis (protrusion of the eyeball from the orbit) in the study eye, in millimetres
- Changes from baseline to week 24 in binocular diplopia (double vision) responder rate (A greater than or equal to 1 grade reduction among patients with a diplopia rating of greater than 0 at baseline)<sup>a</sup>
- Complete binocular diplopia responder rate at week 24 (A diplopia score of 0 among patients with binocular diplopia of greater than 0 at baseline)
- Health-related quality of life (HRQoL) as measured by changes from baseline to week 24 in Graves' Ophtalmopathy Quality of Life Questionnaire (GO-QoL) visual function scores
- Health-related quality of life (HRQoL) as measured by changes from baseline to week 24 in GO-QoL appearance scores
- Bad reactions
- Serious bad reactions

# BC PharmaCare Drug Information — teprotumumab (TBC) continued...

Drug information				
	Patients leaving the trial due to bad reactions			
	Bad reactions of special interest: infusion-related reactions, hyperglycemia (high blood sugar) events, and hearing impairment			
Other considerations	None			

### Note:

CDA-AMC (<u>Canada's Drug Agency-L'Agence des Médicaments du Canada</u>) 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 <u>How PharmaCare Decides Which Drugs to Cover</u>.

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		
teprotumumab (TBC)	Under Review	Vial for intravenous (IV) infusion	Initial dose followed by doses every 3 weeks for 7 additional infusions	ТВС		

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<sup>&</sup>lt;sup>a</sup> 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.

# The Drug Review Process in B.C.

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

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

- whether the drug is safe and effective
- advice from a national group called <u>Canada's Drug Agency-L'Agence des médicaments</u> <u>du Canada (CDA-AMC)</u>
- 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 <u>How PharmaCare decides which</u> 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.