

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 <u>PharmaCare website</u>.

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)	guselkumab		
Brand name	Tremfya®		
Manufacturer	Janssen Inc.		
Indication	Moderately to severely active ulcerative colitis 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 guselkumab (Tremfya), <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?	Guselkumab is given by both intravenous (IV) infusion and subcutaneous (SC) injection. An IV infusion is put directly into a person's vein using a tube or syringe, whereas a SC injection is injected into the layer of tissue between the skin and muscle, using a short needle.		
How often is the drug given?	Induction: Guselkumab is given by IV infusion at weeks 0, 4, and 8. Maintenance: Guselkumab is then given by SC injection at week 16, and every 8 weeks thereafter, after completion of induction dosing. Gusulkumab may also be given by SC injection at week 12 and every 4 weeks thereafter, after completion of induction dosing.		

BC PharmaCare Drug Information — guselkumab (Tremfya®) continued...

Drug information				
General drug and/or drug study information	 Guselkumab is being reviewed by PharmaCare for the treatment of moderately to severely active ulcerative colitis (UC) in adults. UC is a chronic inflammatory bowel disease (IBD) that involves the inflammation of the intestinal mucosa (the membrane lining the intestir and the colon. People with UC may experience bloody diarrhea, fever, abdominal pain, weight loss, fatigue, and loss of appetite. Guselkumab is a monoclonal antibody. Monoclonal antibodies are protect that recognize and bind specifically to certain proteins in the body. This medicine works by neutralizing the activity of a protein called IL-23, which is present at increased levels in diseases such as UC. By blocking IL-23 signaling, guselkumab may reduce inflammation and help to heal the intestinal lining. 			
	 Studies looked at the following: Proportion of patients with clinical remission at 12 weeks and 44 weeks Proportion of patients with endoscopic healing at 12 weeks and 44 weeks Proportion of patients with clinical response and maintenance of clinical response at 12 weeks and 44 weeks Proportion of patients with corticosteroid-free clinical remission at 44 weeks Health-related quality of life (HRQoL) as measured by the proportion of patients with Inflammatory Bowel Disease Questionnaire (IBDQ) remission at 12 weeks and 44 weeks Bad reactions Serious bad reactions Bad reactions of special interest: infections and serious infections 			
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</u> <u>Decides Which Drugs to Cover</u>.

BC PharmaCare Drug Information — guselkumab (Tremfya[®]) continued...

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	Annual Cost of Therapyª
guselkumab (Tremfya)	Under review for UC, non-benefit for plaque psoriasis and psoriatic arthritis	Pre-filled syringe, pen, or auto- injector for SC injection; Vial for IV infusion	Induction: By IV infusion in weeks 0, 4, and 8 Maintenance: By SC injection at week 16 and every 8 weeks thereafter, or at week 12 and every 4 weeks thereafter	Year 1: \$24,1667 to \$41,909 ^b Year 2+: \$20,955 to \$41,909
S1P receptor agonist	S			
etrasimod (Velsipity)	Under review for UC	Tablet	Once daily	\$16,518°
ozanimod (Zeposia)	Limited Coverage	Capsule	Once daily	\$26,250
Biologics	L	L	L	
adalimumab biosimilars	Limited Coverage	Pre-filled syringe or auto-injector for SC injection	Once every two weeks	Year 1: \$14,845 Year 2+: \$12,866
golimumab (Simponi)	Non-Benefit for UC	Prefilled syringe or auto-injector for SC injection	Induction: Week 0 and week 2 Maintenance: Every 4 weeks	Year 1: \$29,176 Year 2+: \$21,673

^a All prices as per PharmaCare Formulary, unless otherwise stated. Weight-based dosing assumes a weight of 75 kg.

^b Price as per CDA Pharmacoeconomic Review Report for guselkumab (Tremfya) UC, plus 5% markup.

^c Manufacturer's submitted price plus 5% markup.

BC PharmaCare Drug Information — guselkumab (Tremfya[®]) continued...

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	Annual Cost of Therapyª
infliximab biosimilar (Inflectra)	<u>Limited Coverage</u>	Vial Powder for IV infusion	Induction: At weeks 0, 2, and 6 in mg/kg Maintenance: Every 8 weeks in	Year 1: \$17,089 Year 2+: \$14,333
infliximab biosimilar (Avsola, Renflexis)	Limited Coverage	Vial Powder for IV infusion	mg/kg Induction: At weeks 0, 2, and 6 in mg/kg Maintenance: Every 8 weeks in mg/kg	Year 1: \$16,047 Year 2+: \$13,459
mirikizumab (Omvoh)	Limited Coverage	Vial for IV infusion, Autoinjector pen for SC injection or pre-filled syringe for SC injection	Induction: By IV infusion at weeks 0, 4, and 8 Maintenance: By SC injection every 4 weeks	Year 1: \$37,281 Year 2+: \$34,618
ustekinumab biosimilar (Wezlana)	Limited Coverage	Pre-filled syringe or vial for SC injection, Vial for IV infusion	Induction: By IV infusion at week 0 Maintenance: By SC injection every 8 weeks thereafter	Year 1: \$22,604 Year 2+: \$18,809

BC PharmaCare Drug Information — guselkumab (Tremfya[®]) continued...

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	Annual Cost of Therapyª
vedolizumab (Entyvio)	<u>Limited Coverage</u>	Vial for IV infusion	Induction: By IV infusion at weeks 0, 2, and 6 Maintenance: By IV infusion every 8 weeks thereafter	Year 1: \$27,754 Year 2+: \$24,379
vedolizumab SC (Entyvio)	<u>Limited Coverage</u>	Pre-filled syringe or pen for SC injection	Induction: By IV infusion at weeks 0 and 2 (using vial for IV infusion) Maintenance: By SC injection every 2 weeks thereafter (using pre-filled syringe or pen for SC injection)	Year 1: \$29,683 Year 2+: \$25,075
JAK inhibitors	-		-	
tofacitinib (generics)	Limited Coverage	Tablet	Twice daily	Year 1: \$5,242 to \$8,114 Year 2+: \$4,722 to \$8,114
upadacitinib (Rinvoq)	Non-Benefit for UC	Extended-release tablet	Once daily	Year 1: \$22,700 to \$30,875 Year 2+: \$19,807 to \$29,495

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> <u>drugs to cover</u>.

This document provides information only.

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