

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)	Tofacitinib			
Brand name	Xeljanz® and generics			
Manufacturer	Pfizer Canada Inc and generics			
Indication	For the treatment of adult patients with active psoriatic arthritis (PsA) with a previous inadequate response to a disease-modifying antirheumatic drug (DMARD).			
Has the drug been reviewed by CDA-AMC, or will CDA-AMC be reviewing it? (See note below.)	No, CDA-AMC did not review tofacitinib for the treatment of PsA.			
Public input start date	Wednesday, June 12, 2024			
Public input closing date	Tuesday, July 9, 2024, at 11:59 pm			
How is the drug taken?	Tofacitinib is taken orally (by the mouth).			
How often is the drug taken?	Tofacitinib is taken twice daily.			

General drug and/or drug study information

PharmaCare is reviewing to facitinib for the treatment of adult patients with active psoriatic arthritis (PsA) who had a previous inadequate response to a disease-modifying antirheumatic drug (DMARD). The most common conventional synthetic DMARDs are methotrexate, sulfasalazine, hydroxychloroquine, and leflunomide. The biologic disease-modifying antirheumatic drugs (bDMARDs) are tumour necrosis factor α inhibitors and interleukin (IL) inhibitors.

PsA is a type of arthritis that affects some people who have psoriasis, a condition that causes red, scaly patches of skin. Symptoms of PsA include mild to severe joint pain, stiffness, and swelling. It can occur in any part of the body. PsA is a chronic condition that can get worse over time. If left untreated, PsA can lead to permanent joint damage and long-term disability. This disease usually has both flare-ups and periods of remission. Tofacitinib is a type of anti-inflammatory drug called a Janus kinase (JAK) inhibitor. It works by blocking the activity of enzymes called Janus kinases (JAKs). These enzymes play a key role in the body's inflammatory response. By targeting these enzymes, tofacitinib can reduce the signs and symptoms of PsA.

Studies looked at the following:

- All-cause mortality including PsA-related deaths and deaths secondary to short or long-term effects of treatment with tofacitinib
- Non-fatal serious adverse events (SAEs) and illnesses
- Changes to the body's immune system, such as tumor development, opportunistic infections, and autoimmune diseases
- Long-term outcomes, such as induction/maintenance of remission or complete clinical response, frequency of joint replacement surgery and soft tissue release surgery for contractures, functional disability, radiographic (X-ray) progression, diseases not affecting the joints, such as inflammation inside the eye (uveitis) and cardiovascular complications, and quality of life.
- Short-term outcomes such as pain, morning stiffness, tender joint count, functional disability, patient and physician global assessments^a, C-reactive protein (CRP)^b or erythrocyte sedimentation rate (ESR)^c, swollen joint count, and drug tolerability
- Bad reactions
- Serious bad reactions

BC PharmaCare Drug Information — tofacitinib (Xeljanz® and generics) continued...

Drug information			
	Patients leaving the trial due to bad reactions		
	Bad reactions of special interest: None		
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 CADTH Reimbursement Review (CRR) in that process, visit <u>How PharmaCare Decides Which Drugs to Cover</u>.

Cost of the drug under review 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 of Therapy ^d	
tofacitinib (Xeljanz and generics)	Under Review for the treatment of PsA Subject to <u>LCA</u>	Tablet	Twice daily	\$4,722	
Tumor Necrosis Factor (TNF) Inhibitors					
adalimumab (biosimilars)	Limited Coverage	Pre-filled syringe or pen	Every 2 weeks	\$12,866	
certolizumab pegol (Cimzia)	Limited Coverage	Single-use pre- filled syringe	Once at weeks 0, 2, and 4, then every 2 weeks or every 4 weeks thereafter	First year: \$21,874 Subsequent: \$18,957	

Ministry of Health

^a The Patient Global Assessment (PGA) asks a patient to rate on a scale how they feel overall. The Physician Global Assessment (MDGA) is a similar item completed by the assessing physician.

^b C-reactive protein (CRP) is a protein made by the liver. The level of CRP increases when there is inflammation in the body.

^c An erythrocyte sedimentation rate (ESR) test measures how quickly red blood cells settle to the bottom of a test tube. This test measures inflammation in the body.

^d All prices as per PharmaCare Formulary, unless otherwise specified. Weight-based dosing assumes a weight of 70 kg and wastage of excess medication in vials.

Cost of the drug under review 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 of Therapy ^d
etanercept (biosimilars)	Limited Coverage	Vial Pre-filled syringe or auto-injector	Once weekly	\$13,535
golimumab SC (Simponi)	Limited Coverage	Pre-filled syringe or auto-injector	Once monthly	\$20,007
infliximab (Inflectra)	Limited Coverage	Vial	Initial dose in mg/kg, followed with additional similar doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter	First year: \$19,294 Subsequent: \$14,333
infliximab (Renflexis, Avsola)	Limited Coverage	Vial		First year: \$18,118 Subsequent: \$13,459
Interleukin-17 (IL-17) Inhibitors				
secukinumab (Cosentyx)	Limited Coverage	Pre-filled syringe or vial	Once at weeks 0, 1, 2, 3, and 4 followed by monthly dosing	First year: \$14,711 Subsequent: \$11,769

Cost of the drug under review 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 of Therapy ^d
ixekizumab (Taltz)	Limited Coverage	Pre-filled syringe or pen	Once at week 0, followed by every 4 weeks or Once at week 0, followed by once at at weeks 2, 4, 6, 8, 10, and 12, then every 4 weeks thereafter	First year: \$27,418 to \$33,293 Subsequent: \$25,459
bimekizumab (Bimzelx)	Under Review for PsA	Pre-filled syringe or autoinjector	Once every 4 weeks or Every 4 weeks for the first 16 weeks, and every 8 weeks thereafter	First Year: \$22,181 to \$27,300 Subsequent: \$22,181
Interleukin-23 (IL-23) Inhibitors				
guselkumab (Tremfya)	Non-Benefit	Pre-filled syringe or patient- controlled injector	Once at weeks 0 and 4, then every 8 weeks thereafter	First year: ^e \$20,722 Subsequent: \$19,957
Interleukin-12/23 (IL-12/23) Inhibitors				
ustekinumab (biosimilars)	Limited Coverage	Pre-filled syringe or vial	Once at weeks 0 and 4, then every 12 weeks thereafter	First year: \$18,602 ^f Subsequent: \$13,435
Janus Kinase (JAK) Ini	hibitors			

^e Price as per CDA-AMC Pharmacoeconomic Review Report for bimekizumab (Bimzelx) PsA.

^f Manufacturer's submitted price, plus 8% markup.

Cost of the drug under review 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 of Therapy ^d
upadacitinib (Rinvoq)	Non-Benefit for PsA	Tablet	Once daily	\$19,807
Phosphodiesterase ty	pe 4 inhibitors	,		,
apremilast (Otezla)	Non-Benefit	Tablet	Twice daily, after titration	\$13,809 ⁹
Conventional synthet	tic disease-modifying	antirheumatic drugs	(csDMARDs)	
methotrexate (generics)	Regular Benefit, Subject to <u>LCA</u>	Tablet	Once per week until adequate response is achieved.	\$157 to \$343
	Regular Benefit, Subject to <u>LCA</u>	Vial		\$197
leflunomide (generics)	Regular Benefit, subject to <u>LCA</u>	Tablet	Once daily	First year: \$1,076 Subsequent: \$1,042
sulfasalazine (generics)	Regular Benefit, subject to <u>LCA</u>	Tablet	Once daily	First year: \$410 Subsequent: \$422
	Regular Benefit, subject to <u>LCA</u>	Enteric-coated (EC) Tablet		First year: \$624 Subsequent: \$642
hydroxychloroquine (generics)	Regular Benefit, subject to <u>LCA</u>	Tablet	Once daily	First year: \$67 to \$139 Subsequent: \$62 to \$124

g Price as per CDA-AMC Pharmacoeconomic Review Report for bimekizumab (Bimzelx) for PsA.

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.