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.
Indication	For the treatment of adult patients with active ankylosing spondylitis (AS) who responded inadequately to biologic disease modifying anti-rheumatic drugs (DMARDs) or when those drugs are not advised.
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 AS.
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	Tofacitinib is being reviewed by PharmaCare for the treatment of active ankylosing spondylitis (AS) in adults who responded inadequately to biologic disease modifying anti-rheumatic drugs (DMARDs) or when those drugs are not advised. AS is a chronic inflammatory disease that primarily affects the spine and the joints that link the pelvis and the lower spine (the sacroiliac joints). The primary symptoms of AS are back pain and spinal stiffness that gets worse over time. AS may also result in compression fractures of the spine, which can injure the spinal cord and the nerves that pass through the spine. Other parts of the body can also be affected by AS, resulting in conditions such as skin psoriasis, inflammatory bowel disease (IBD), and inflammation inside the eye (uveitis). 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 AS. Studies looked at the following: • All-cause mortality and serious adverse events (SAEs): e.g., surgery (hip replacement, spinal stabilization procedures, etc.) • Disease progression: structural damage (spine, hip X-rays); clinical evidence of progression (spinal mobility, function, and disability) • Symptom modification: pain, swelling, tenderness, muscle spasm and stiffness, spinal mobility, peripheral joint entheses[a] • Physical function • Health-related quality of life (HRQoL) • Patient and physician global assessments[b] • Diseases not affecting the joints, such as uveitis, cardiac inflammation, and IBD • Markers of inflammation such as C-reactive protein (CRP)[c], erythrocyte sedimentation rate (ESR)[d], acute changes on magnetic resonance imaging (MRI), and conventional radiographic (X-ray) changes • Bad reactions • Serious bad reactions • Patients leaving the trial due to bad reactions

Drug information	
	• Bad reactions of special interest: None
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 CADTH 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[e]				
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**
tofacitinib (Xeljanz, generics)	Under Review for active AS Subject to LCA	Tablet	Twice daily	$4,722
Tumor Necrosis Factor-alpha (TNF-alpha) 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 or every 4 weeks thereafter	First year: $21,874 Subsequent: $18,957
etanercept (biosimilars)	Limited Coverage	Vial, Pre-filled syringe or auto-injector	Once per week	$13,535

[a] An enthesis is the place where a tendon or ligament meets the bone.
[b] 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.
[c] C-reactive protein (CRP) is a protein made by the liver. The level of CRP increases when there is inflammation in the body.
[d] 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.
[e] All prices as per PharmaCare Formulary, unless otherwise specified. Any weight-based dosing assumes an average patient 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[e]				
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**
golimumab SC (Simponi)	Limited Coverage	Pre-filled syringe or auto-injector	Once monthly	$20,007
infliximab (Renflexis, Avsola)	Limited Coverage	Vial	Initial dose in mg/kg, followed with additional similar doses at 2 and 6 weeks after the first infusion, then every 6-8 weeks thereafte	First year: $18,118 to $21,741 Subsequent: $13,459 to $17,945
infliximab (Inflectra)	Limited Coverage	Vial		First year: $19,294 to $23,153 Subsequent: $14,333 to $19,110
Interleukin-17A (IL-17A) Inhibitors				
secukinumab (Cosentyx)	Limited Coverage	Pre-filled syringe or vial	Once at weeks 0, 1, 2, 3, and 4, then once monthly	First year: $14,711 to $23,168 Subsequent: $11,769 to $24,519
bimekizumab (Bimzelx)	Under Review for AS	Pre-filled syringe or autoinjector	Every 4 weeks	$22,181
ixekizumab (Taltz)	Non-Benefit for AS	Pre-filled syringe or pen	Every 4 weeks	$25,459
Janus Kinase (JAK) Inhibitors				
upadacitinib (Rinvoq)	Under Review for AS	Tablet	Once daily	$19,807
Conventional synthetic disease-modifying antirheumatic drugs (csDMARDS)				

Cost of the drug under review compared to other drugs used to treat the same indication[e]				
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**
methotrexate (generics)	Regular Benefit, Subject to LCA	Tablet	Once per week until adequate response is achieved.	$157 to $343
	Regular Benefit, Subject to LCA	Vial		$197
leflunomide (generics)	Regular Benefit, subject to LCA	Tablet	Once daily	First year: $1,076 Subsequent: $1,042
sulfasalazine (generics)	Regular Benefit, subject to LCA	Tablet	Once daily	First year: $410 Subsequent: $422
	Regular Benefit, subject to LCA	Enteric-coated (EC) Tablet		First year: $624 Subsequent year: $642
hydroxychloroquine (generics)	Regular Benefit, subject to LCA	Tablet	Once daily	First year: $67 to $139 Subsequent: $62 to $124

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.