BC PharmaCare Drug Information

The drug below is being considered for possible coverage under the B.C. PharmaCare program. PharmaCare is a government-funded drug plan that helps British Columbians with the cost of eligible prescription drugs and specific medical supplies. For more information on PharmaCare, visit Ministry of Health - PharmaCare.

PharmaCare reviews each drug for treating a specific illness or medical condition (known as an "indication"). If a decision is made to cover the drug, it will be only for that illness or condition.

In some cases, PharmaCare may cover a drug only for people who have the illness or condition and have not responded to other drugs used to treat that illness or condition.

For more information on PharmaCare's drug coverage review process, see the last page of this information sheet.

Information about the drug	
Generic name (scientific name)	**bimekizumab**
Brand name	**Bimzelx®**
Manufacturer	UCB Canada Inc.
Indication	For the treatment of adult patients with active psoriatic arthritis (PsA).
Has the drug been reviewed by Canada's Drug and Health Technology Agency (CADTH)? (see the note below this table.)	Yes For more information about the CADTH Reimbursement Review (CRR) of bimekizumab (Bimzelx), you can Search the CADTH Reports.
Public input start date	Wednesday, February 28, 2024
Public input closing date	**Tuesday, March 26, 2024, AT 11:59 PM**
How is the drug taken?	Bimekizumab is given by subcutaneous (under the skin) injection.
How often is the drug injected?	Bimekizumab is injected once every four weeks.

General drug and/or drug study information	Bimekizumab is being reviewed by PharmaCare for the treatment of adult patients with active PsA. Bimekizumab can be used alone or in combination with a conventional non-biologic disease-modifying antirheumatic drug (cDMARD) such as methotrexate. PsA is a type of arthritis that affects some people who have psoriasis, a condition that causes red, scaly patches of skin. Symptoms of psoriatic arthritis 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. Bimekizumab is a type of drug called a monoclonal antibody or mAb. Monoclonal antibodies are laboratory-made proteins that recognize and bind to certain proteins in the body. Bimekizumab works by blocking three proteins in the body called interleukin-17A (IL-17A), interleukin-17F (IL-17F), and IL-17AF which are involved in causing inflammation. This can help to improve the symptoms of AS. Studies looked at the following: • Proportion of patients achieving at least a 50% American College of Rheumatology (ACR50)[a] response at 16 weeks, with or without prior exposure to biologics • Proportion of patients achieving an ACR20 response at 16 weeks, with or without prior exposure to biologics • Proportion of patients achieving an ACR70 response at 16 weeks, with or without prior exposure to biologics • Proportion of patients achieving Minimal Disease Activity[b] response at 16 weeks, with or without prior exposure to biologics • Resolution of enthesitis[c] as per the Leeds Enthesitis Index (LEI) at 16 weeks, in pooled population of patients with and without prior exposure to biologics • Resolution of dactylitis[d] as per the Leeds Dactylitis Index (LDI) at 16 weeks, in pooled population of patients with and without prior exposure to biologics • Changes from baseline to 16 weeks in swollen joint count (SJC), in patients with or without prior exposure to biologics

Information about the drug	
	• 90% or greater improvement in the Psoriasis Area and Severity Index (PASI90) in patients with baseline psoriasis affecting 3% or more body surface area (BSA) at 16 weeks, with or without prior exposure to biologics • Investigator's Global Assessment (IGA) Score of 0 or 1 and at least 2-grade Reduction from Baseline in patients with baseline psoriasis affecting 3% or more body surface area (BSA) at 16 weeks, with or without prior exposure to biologics • Changes from baseline in Health Assessment Questionnaire-Disability Index (HAQ-DI) total scores at 16 weeks, in patients with or without prior exposure to biologics • Change from baseline in Short Form 36-item Health Survey Physical Component Summary (SF-36 PCS) score at 16 weeks, in patients with or without prior exposure to biologics • Change from baseline in Patient's Assessment of Arthritis Pain (PtAAP) at week 16, in patients with or without prior exposure to biologics • Bad reactions • Serious bad reactions • Patients leaving the trial due to bad reactions • Bad reactions of special interest, such as liver problems, opportunistic infections, fungal infections, reactivation of tuberculosis infection, major cardiovascular event, cancer, anaphylaxis, serious injection-related adverse event, and inflammatory bowel disease (IBD).
Other considerations	None

[a] ACR50 response is defined as an improvement of at least 50% in both swollen and tender joint counts and at least 3 of 5 additional disease criteria.

[b] Minimal disease activity (MDA) is a combined end point and is considered to be achieved if at least 5 of the 7 following criteria are met: tender joint count (TJC) of 0 or 1, swollen joint count (SJC) of 0 or 1, Psoriasis Area and Severity Index (PASI) of 1 or lower or affected body surface area (BSA) of 3% or less, pain visual analogue scale score of 15 or lower, Patient's Global Assessment of Psoriatic Arthritis visual analogue scale score of 20 or lower, Health Assessment Questionnaire – Disability Index (HAQ-DI) of 0.5 or lower, and tender entheseal points of 0 or 1 (The place where a tendon or ligament meets your bone is called an enthesis. These points are entheseal points).

[c] Enthesitis is the medical term for inflammation of one or more entheses, which are sites where tendons and ligaments attach to bones.

[d] Dactylitis is the medical term for severe swelling that affects your fingers or toes.

Note:
Canada's Drug and Health Technology Agency (CADTH) is a national organization that reviews drugs on behalf of Canadian public sector plans when manufacturers want to have the jurisdictions provide coverage for the drugs. For detailed information on B.C. PharmaCare's drug review process, including the role of the CADTH Reimbursement Review (CRR) in that process, see The Drug Review Process in B.C. - Overview.

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[e]**
bimekizumab (Bimzelx)	Under Review for PsA	Pre-filled syringe or autoinjector	Every 4 weeks; **or** Every 4 weeks for the first 16 weeks, and every 8 weeks thereafter	TBC
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: $20,234 Subsequent: $18,141
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

[e] 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[e]**
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: $17,640 Subsequent: $15,435
infliximab (Renflexis, Avsola)	Limited Coverage	Vial		First year: $16,565 Subsequent: $14,494
Interleukin-17A (IL-17A) 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: $13,901 Subsequent: $11,121
ixekizumab (Taltz)	Limited Coverage	Pre-filled syringe or pen	Once at week 0, followed every 4 weeks, thereafter; **or** Once at week 0, followed by once at weeks 2, 4, 6, 8, 10, and 12, then every 4 weeks, thereafter	First year: $25,341 to $30,771 Subsequent: $23,531
Interleukin-23 (IL-23) Inhibitors				

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[e]**
guselkumab (Tremfya)	Non-Benefit	Pre-filled syringe or patient-controlled injector	Once at weeks 0 and 4 then every 8 weeks thereafter	First year:[f] $20,722 Subsequent: $19,957
Interleukin-12/23 (IL-12/23) Inhibitors				
ustekinumab (biosimilars)	Under Review for PsA	Pre-filled syringe or vial	Once at weeks 0 and 4, then every 12 weeks thereafter	First year: $15,071[g] Subsequent: $11,575
Janus Kinase (JAK) Inhibitors				
tofacitinib (Xeljanz)	Non-Benefit for PsA	Tablet	Twice daily	$4,591
upadacitinib (Rinvoq)	Non-Benefit for PsA	Tablet	Once daily	$19,734
Phosphodiesterase type 4 inhibitors				
apremilast (Otezla)	Non-Benefit	Tablet	Twice daily, after titration	$13,809[f]
Conventional synthetic disease-modifying antirheumatic drugs (cDMARDs)				
methotrexate (generics)	Regular Benefit, Subject to LCA	Tablet	Once per week until adequate response is achieved.	$56 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

[f] Price as per CADTH Pharmacoeconomic Review Report for bimekizumab (Bimzelx) PsA.
[g] Manufacturer's submitted price, plus 5% 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[e]**
sulfasalazine (generics)	Regular Benefit, subject to LCA	Tablet	Once daily	First year: $410 Subsequent: $422
	Regular Benefit, subject to LCA	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 and Health Technology Agency (CADTH)
- what the drug costs and whether it is a good value for the people of B.C.
- ethical considerations involved with 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:

- the existing PharmaCare policies, programs and resources
- the evidence-informed advice of the DBC
- the drugs already covered by PharmaCare that are used to treat similar medical conditions
- the overall cost of covering the drug

For more information about the B.C. Drug Review Process, visit: The Drug Review Process in B.C. - Overview.

This document is intended for information only.
It does not take the place of advice from a physician or other qualified health care provider.