BRITISH COLUMBIA | Ministry of Health

Drug Coverage Decision for B.C. PharmaCare

About PharmaCare B.C. PharmaCare is a government-funded drug plan. It helps British Columbians with the cost of eligible prescription drugs and specific medical supplies.

Details of Drug Reviewed

Drug	**Adalimumab biosimilars**				
Brand Name	Amgevita®	Hadlima®	Hulio®	Hyrimoz®	Idacio®
Dosage Forms: pre-filled syringe (PFS); pre-filled auto injector (AI); pre-filled pen (PEN)	20 mg/0.4 mL PFS 40 mg/0.8 mL PFS 40 mg/0.8 mL AI	40 mg/0.8 mL PFS 40 mg/0.8 mL AI	20 mg/0.4 mL PFS 40 mg/0.8 mL PFS 40 mg/0.8 mL PEN	20 mg/0.4 mL PFS 40 mg/0.8 mL PFS 40 mg/0.8 mL AI	40 mg/0.8 mL PEN
Manufacturer	Amgen Canada Inc.	Samsung Bioepis Co Ltd.(Merck Canada Inc.)	BGP Pharma ULC. (Viatris)	Sandoz Canada Inc.	Fresenius Kabi Canada Ltd.
Brand Name	Abrilada® (**NEW**)	Simlandi™ (**NEW**)	Yuflyma™ (**NEW**)		
Dosage Forms: pre-filled syringe (PFS); pre-filled auto injector (AI); pre-filled pen (PEN)	20 mg/0.4 mL PFS 40 mg/0.8 mL PFS 40 mg/0.8 mL PEN	**100 mg/mL:** 40 mg/0.4 mL PFS 80 mg/0.8 mL PFS 40 mg/0.4 mL AI	**100 mg/mL:** 40 mg/0.4 mL PFS 40 mg/0.4 mL PEN		
Manufacturer	Pfizer Canada ULC	JAMP Pharma Corporation	Celltrion Healthcare Canada Ltd.		
Submission Type	**New Submission**				
Use Reviewed	Rheumatoid arthritis, polyarticular juvenile idiopathic arthrits, ankylosing spondylitis, psoriatic arthritis, Crohn's disease, ulcerative colitis, hidradenitis suppurativa for adults and plaque psoriasis.				

Common Drug Review (CDR)	No, CDR did not review.
Provincial Review	In June 2019, the Canadian Agency for Drugs and Technologies in Health (CADTH) provided confirmation that a CDR submission for adalimumab biosimilars for the same indications as the biologic reference, Humira®; as such, a full Drug Benefit Council (DBC) review is not required and the Ministry's drug coverage decision will be based on an internal review only.
Drug Coverage Decision	**Limited Coverage Benefit. Access the adalimumab criteria from www.gov.bc.ca/pharmacarespecialauthority**
Date	**August 18, 2022.** This Drug Coverage Decision supersedes the Drug Coverage Decision for the drugs and indications dated April 7, 2021.
Reason(s)	• Health Canada's review concluded that the adalimumab biosimilars were similar to and had no clinically meaningful differences from the biologic reference drug, Humira®, with respect to efficacy, safety, pharmacokinetics and immunogenicity. • Results from a CADTH Rapid Response evaluating switching from the biologic reference to biosimilars suggested that switching from Humira to adalimumab biosimilars can be performed safely with no impact on drug efficacy and clinical response. • Based on the submitted product price, the adalimumab biosimilars cost significantly less than the biologic reference, Humira. • BC participated in the pan-Canadian Pharmaceutical Alliance (pCPA) negotiations that concluded agreements with the five drug manufacturers for the biosimilars.

Other Information	• On **April 7, 2021,** all new Special Authority (SA) requests including renewals for adalimumab will only be approved for Amgevita, Hadlima, Hulio, Hyrimoz or Idacio.
	• On **April 7, 2021**, the six-month transition period starts, which means patients with existing PharmaCare coverage for Humira, and that wish to maintain their coverage must, in consultation with their prescriber, switch to Amgevita, Hadlima, Hulio, Hyrimoz or Idacio by **October 6, 2021.**
	• During the transition period, both Humira and its biosimilar products will be covered for patients with existing adalimumab SA approval , with no new request required for coverage of the biosimilar until the next SA renewal date. To maintain patients' coverage, prescribers must write a new prescription for their patients on Humira, indicating the transition to a specific biosimilar.
	• On **October 7, 2021** coverage for Humira comes to an end and only the approved biosimilar products will be authorized for continued coverage.
	• Additional information is available online at www.gov.bc.ca/biosimilars/
	• On **August 18, 2022**, PharmaCare is adding coverage for additional biosimilar products and dosages to the existing biosimilars.
	  ○ New dosage for an existing covered biosimilar:
	  ▪ Hulio 20 mg/0.4 mL PFS
	  ○ New biosimilar products:
	  ▪ Abrilada® 40 mg/0.8 mL PFS and 40 mg/0.8 mL PEN
	  ○ New biosimilar products with **HIGH dose formulations (100 mg/mL):**
	  ▪ Simlandi™ 40 mg/0.4 mL PFS, 80 mg/0.8 mL PFS and 40 mg/0.4 mL Autoinjector
	  ▪ Yuflyma™ 40 mg/0.4 mL PFS and 40 mg/0.4 mL PEN

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 the Common Drug Review (CDR)
- 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

Visit The Drug Review Process in B.C. - Overview and Ministry of Health - PharmaCare for more information.

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