

Drug Coverage Decision for BC PharmaCare

About PharmaCare BC PharmaCare is a publicly funded drug plan that helps B.C. residents pay for most prescription drugs and pharmacy services, and some medical devices and supplies.

Details of Drug Reviewed

Drug	Ustekinumab biosimilars	
Brand name	Wezlana™	Steqeyma™
Dosage forms	 45 mg/0.5 mL solution in a prefilled syringe (PFS) for subcutaneous (SC) injection. 90 mg/1.0 mL solution in a PFS for SC injection. 45 mg/0.5 mL in a single use vial for SC injection. 136 mg/26 mL (5 mg/mL) solution in a vial for intravenous (IV) infusion. 	 45 mg/ 0.5 mL solution in a PFS for SC injection. 90 mg/1.0 mL solution in a PFS for SC injection. 130 mg/26 mL (5 mg/mL) solution in a vial for IV infusion.
Manufacturer	Amgen Canada	Celltrion Healthcare Canada
Submission type	Biosimilars	
Indication reviewed	Plaque psoriasis	Plaque psoriasis
	Psoriatic arthritis	Psoriatic arthritis
	Crohn's disease	Crohn's disease
	Ulcerative colitis	
Canada's Drug	As of June 1, 2019, the Canada's Drug Agency (CDA-AMC) no longer conducts	
Agency (CDA-AMC)	reviews of biosimilars as it became apparent that the CRR process may delay	
Clinical	access to new biosimilar treatments, and because it allows CDA-AMC to deploy its	
Reimbursement	limited resources to other drug reviews.	
Reviews (CRR)		
Provincial Review	PharmaCare no longer requires the Drug Benefit Council (DBC) to review biosimilars	
	as we believe Health Canada's review of biosimilars is thorough and without	
	compromise to efficacy and patient safety. Therefore, Wezlana and Steqeyma were reviewed internally by the Ministry of Health.	

Drug Coverage Decision	Limited Coverage Benefit	
Date	September 17, 2024	
Reasons	 Based on Health Canada's reviews on comparative chemistry and manufacturing studies, comparative non-clinical studies, comparative pharmacokinetic (PK) / pharmacodynamics (PD) and clinical trials in patients that established the similarity between Wezlana and Steqeyma and the reference biologic ustekinumab, Stelara® in efficacy, safety, PK and immunogenicity. Based on the submitted product price, the ustekinumab biosimilars cost significantly less than the originator biologic ustekinumab (Stelara). BC participated in the pan-Canadian Pharmaceutical Alliance (pCPA) negotiations with the manufacturer of Wezlana and Steqeyma that concluded with an agreement. 	

The drug review process in B.C.

A manufacturer submits a request to the Ministry of Health (the Ministry).

An independent group called the <u>Drug Benefit Council (DBC)</u> gives advice to the Ministry by considering:

- whether the drug is safe and effective
- advice from a national group called <u>Canada's Drug and Health Technology Agency</u> (CADTH)
- what the drug costs and whether funding it provides good value to the province
- ethical considerations of covering and not covering the drug
- input from physicians, patients, caregivers, patient groups and drug submission sponsors

The Ministry makes a BC PharmaCare coverage decision by taking into account:

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

Visit <u>BC PharmaCare</u> and <u>Drug reviews</u> for more information.

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