

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 biosimilar
Brand name	Jamteki [™]
Dosage form(s)	45 mg/0.5 mL prefilled syringe for injection 90 mg/1.0 mL prefilled syringe for injection
Manufacturer	JAMP Pharma Corporation
Submission type	Biosimilars
Indication reviewed	For the treatment of adult patients with active psoriatic arthritis and for the treatment of chronic moderate to severe plaque psoriasis in adult patients.
Canada's Drug Agency (CDA-AMC) reimbursement reviews (CRR)	As of June 1, 2019, the Canada's Drug Agency (CDA-AMC) no longer conducts reviews of biosimilars as it became apparent that the CRR process may delay access to new biosimilar treatments, and because it allows CDA-AMC to deploy its limited resources to other drug reviews.
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 Jamteki was reviewed internally by the Ministry of Health.
Drug Coverage	Limited Coverage Benefit
Decision	Access the ustekinumab criteria from www.gov.bc.ca/pharmacarespecialauthority
Date	May 30, 2024
Reason(s)	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 Jamteki and the reference biologic ustekinumab, Stelara® in efficacy, safety, PK and immunogenicity.

- Based on the submitted product price, the ustekinumab biosimilar cost significantly less than the originator biologic, Stelara.
- BC participated in the pan-Canadian Pharmaceutical Alliance (pCPA) negotiations with the manufacturer of Jamteki that concluded with an agreement.

Other Information

PharmaCare is changing coverage of ustekinumab for plaque psoriasis (PsO). To maintain PharmaCare coverage, patients currently covered for the originator biologic Stelara® must, in consultation with their prescriber, switch to an approved biosimilar product: Jamteki™.

May 30, 2024 - All new Special Authority (SA) requests, including renewals, for ustekinumab will only be approved for Jamteki.

May 30, 2024, to December 2, 2024 – During the six-month transition period, patients with PharmaCare coverage for the originator ustekinumab (Stelara) and who wish to maintain their coverage must transition to an approved biosimilar ustekinumab product; a new SA request is not required for coverage of the biosimilar until the next scheduled renewal date. To maintain patients' coverage of ustekinumab, prescribers must write a new prescription for their patients on the originator ustekinumab (Stelara), indicating the transition to a specific biosimilar ustekinumab.

December 3, 2024 – The originator ustekinumab (Stelara) is no longer an eligible PharmaCare benefit and only the approved biosimilar ustekinumab products are authorized for continued coverage.

Special Authority requests for patients who are unable to transition to a ustekinumab biosimilar will be considered on an exceptional case-by-case basis.

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 CDA-AMC)
- 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.

This document is intended for information only.

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