



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	Etanercept biosimilar
Brand name	Rymti™
Dosage form(s)	50 mg/mL solution for Injection in prefilled syringe 50 mg/mL solution for Injection in prefilled auto-injector pen
Manufacturer	Lupin Pharma Canada Ltd.
Submission type	Biosimilars
Use Reviewed	For the treatment of moderately to severely active rheumatoid arthritis (RA), reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (JIA) in patients aged 4 to 17 years, reducing signs and symptoms of active ankylosing spondylitis (AS), inhibiting the progression of structural damage of active arthritis, and improving physical function in adult patients with psoriatic arthritis (PsA), and treatment of chronic moderate to severe plaque psoriasis (PsO) in adults.
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 Rymti was reviewed internally by the Ministry of Health.
Drug Coverage Decision	Limited Coverage Benefit Access the etanercept criteria from www.gov.bc.ca/pharmacarespecialauthority
Date	June 25, 2024
Reason(s)	<ul style="list-style-type: none"> Based on Health Canada's review 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 Rymti and the reference biologic etanercept, Enbrel® in efficacy, safety, pharmacokinetics and immunogenicity.

- Based on Health Canada’s reviews on Study YLB113-002 and Study ETA.50/334 there were no clinically meaningful safety or immunological differences observed with Rymti and Enbrel, further supporting the biosimilarity of Rymti to Enbrel.
- BC participated in the pan-Canadian Pharmaceutical Alliance (pCPA) negotiations with the manufacturer of Rymti that concluded with an agreement.
- Effective **June 25, 2024** Rymti will be listed as a Limited Coverage benefit with the same criteria as the other etanercept biosimilars, Brenzys® and Erelzi®.

The drug review process in B.C.

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

An independent group called the [Drug Benefit Council \(DBC\)](#) gives advice to the Ministry by considering:

- 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 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 [BC PharmaCare](#) and [Drug reviews](#) 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.