

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	Rituximab
Originator	Rituxan®
Dosage Form(s)	Riximyo®
Manufacturer	Sandoz Canada
Submission Type	Biosimilars Initiative
Use Reviewed	Granulomatosis Polyangiitis (GPA) and Microscopic Polyangiitis (MPA)
Common Drug Review (CDR)	As of June 1, 2019, the Canadian Agency for Drugs and Technologies in Health (CADTH) no longer conducts reviews of biosimilars as it became apparent that their existing Common Drug Review (CDR) process may delay access to new biosimilar treatments, and because it allows CADTH to deploy its limited resources to other drug reviews. For similar reasons, 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 Riximyo was reviewed internally by PharmaCare.
Provincial Review	PharmaCare covers rituximab biosimilar products for rheumatoid arthritis (RA), relapsing-remitting multiple sclerosis (RRMS), and MPA or GPA. As of August 19, 2021 patients with MPA or GPA will be eligible for reimbursement of Riximyo in addition to two other rituximab biosimilars - Truxima™ and Ruxience™.
Drug Coverage Decision	Limited Coverage Benefit. Access the rituximab criteria from www.gov.bc.ca/pharmacarespecialauthority

Date	August 19, 2021 (This supersedes the listing decision for the drug and indications dated August 20, 2020)
Reason(s)	 To enable expansion of the PharmaCare formulary and B.C. health services, PharmaCare develops evidence-informed strategies to better optimize how our public resources are used. Biologic drugs represent a huge portion of the annual PharmaCare budget, and biosimilars represent a correspondingly large, but unrealized, opportunity to find value that can be applied to new treatments and services. PharmaCare is always reviewing new drugs, new indications, and existing coverage and criteria; the provincial formulary must evolve and adapt to the current market, clinical requirements, best practices, and the needs of B.C. residents and practitioners. The safety, efficacy, immunogenicity, and therapeutic similarity of biosimilars is evidenced by a large body of clinical evidence, extensive post-market pharmacovigilance, as well as the results of biosimilar programs in other jurisdictions. Additional reading and study summaries are available online at www.gov.bc.ca/biosimilars/ The Ministry will be carefully monitoring drug utilization, patient outcomes, and the response from patients and healthcare practitioners during and after the biosimilar initiative in B.C. On June 30, 2021, Riximyo received a noticed of compliance (NOC) from Health Canada for the new indication of GPA and MPA.
Other Information	None

The Drug Review Process in B.C.

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

An independent group called the <u>Drug Benefit Council (DBC)</u> 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.