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

<table>
<thead>
<tr>
<th>Generic</th>
<th>infliximab</th>
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<tbody>
<tr>
<td>Originator</td>
<td>Remicade®</td>
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<tr>
<td>Biosimilar</td>
<td>Inflectra®</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>Pfizer Canada</td>
</tr>
<tr>
<td>Submission Type</td>
<td>Biosimilars Initiative</td>
</tr>
<tr>
<td>Indications Affected</td>
<td>Ankylosing Spondylitis</td>
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<td></td>
<td>Plaque Psoriasis</td>
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<td></td>
<td>Psoriatic Arthritis</td>
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<td>Rheumatoid Arthritis</td>
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<tr>
<td>Common Drug Review (CDR)</td>
<td>CDR reviewed Inflectra and Reflexis. For more information please see <a href="https://www.cadth.ca/about-cadth/what-we-do/products-services/cdr/reports">https://www.cadth.ca/about-cadth/what-we-do/products-services/cdr/reports</a></td>
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Provincial Review

PharmaCare is introducing a Biosimilars Initiative. In Phase 1, this will change coverage for PharmaCare-covered patients who use infliximab (Remicade) to treat rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, or plaque psoriasis. Patients who use Remicade for rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, or plaque psoriasis, and who depend on PharmaCare coverage, must switch to using either the Inflectra® or Renflexis™ brand of infliximab. During the switch period between May 27, 2019 and November 25, 2019, coverage will be provided for all biologic and biosimilar brands, in order to provide time for patient identification, communication, discussion with prescribers, and switching. Coverage of Remicade will end on November 26, 2019 for affected patients. In Phase 2 of the biosimilars switch, coverage will change for patients taking Remicade for Crohn’s disease or ulcerative colitis. More information and additional patient materials will be provided when Phase 2 begins later in the summer of 2019.

Drug Coverage Decision

Limited Coverage Benefit. Access the infliximab criteria from www.gov.bc.ca/pharmacarespecialauthority

Date

May 27, 2019

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.
Biosimilars Initiative Continued...

- 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.

Other Information

| Affected patients must make an appointment with their prescriber to discuss switching to a biosimilar version of their medication and get a new prescription by November 20, 2019 in order to maintain their PharmaCare coverage |

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 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.