Alberta Biosimilar Initiative

Guide for health professionals

Information on Alberta's Biosimilar Initiative, the special authorization process, and resources for health professionals.

Alberta Health

Table of Contents

Overview

Biologics are drugs manufactured in, extracted from or semi-synthesized from living cells through a highly complex manufacturing process. The biologic drugs that are part of this initiative are often used to treat chronic health conditions such as rheumatoid arthritis and inflammatory bowel disease, diabetes, and neutropenia.

Biologic drugs that are the first of their kind are commonly referred to as reference, innovator or originator biologic drugs. Biosimilar drugs (biosimilars) are similar, but not identical, to the originator biologics, but are a cost-saving alternative and clinically effective treatment option.

Due to the complexity of biologic drugs and the natural variability that results from using living cells, it is not possible for a biosimilar to be identical to its originator biologic drug. Nor is it possible for different lots or batches of an originator biologic drug to be identical. These variations are not clinically meaningful.

In Alberta, biologic drug expenditures were more than $262 million in the 2019-2020 fiscal year, and had been increasing at an average of 13.9% per year over the previous five years. The originator biologic drugs Remicade, Humira and Enbrel were 3 of the top 4 drivers of drug spending in Alberta's government-sponsored drug plans.

Costs per patient for originator biologics can exceed $25,000 per patient per year, with biosimilar versions costing up to 50% less than originator biologics. Health Canada has indicated that no differences are expected in efficacy and safety following switching from an originator biologic to its biosimilar for an authorized indication.

Biosimilars have been used in Canada for over 15 years and in many other countries, including the United States, Australia, the United Kingdom and the European Union, for more than 17 years for some products. Regulators have not identified any relevant differences in the type, severity or frequency of side effects between biosimilars and their respective originator biologics.

Alberta's Biosimilar Initiative builds on this growing evidence and will reduce costs while continuing to provide safe and effective treatments. This will help to keep Alberta's health system sustainable and provide opportunities to expand treatment options and improve access for patients.

Alberta's Biosimilar Initiative

Under the Biosimilar Initiative, the use of biosimilar drugs is expanding in Alberta. The changes will impact originator biologic and biosimilar medications.

These changes only apply to Albertans on the following Alberta government sponsored drug plans:

- Non-Group Coverage (Group 1)
- Coverage for Seniors (Group 66)
- Palliative Coverage (Group 20514. Note: Client may have Group 1 or Group 66 coverage)
- Child and Family Services (Group 20403)
- Alberta Child Health Benefit (Group 20400)
- Children and Youth Services (Group 19824)
- Income Support (Group 19823)
- Learners Program (Group 22128)
- Assured Income for the Severely Handicapped (Group 19823)
- Alberta Adult Health Benefit (Group 23609)

Changes to coverage – Switching
Patients currently on an originator drug, for which there is a biosimilar version for their medical condition, must switch to the biosimilar before the switch date to maintain coverage through their Alberta government-sponsored drug plan.

Switching to biosimilars

Patients currently on an originator biologic drug, for which there is a biosimilar version for their specific indication, must switch to the biosimilar before the designated switch date to maintain coverage through their Alberta government-sponsored drug plan. Biosimilar switching applies to all patients 18 years of age and older. Patients under the age of 18 are not required to switch to a biosimilar at this time.

During the switching period, both the originator biologic drug and biosimilar versions of the affected drugs will be covered to allow health professionals and patients time to discuss the biosimilar and develop a plan for switching.

All special authorization approvals in place for the originator biologic will be automatically applied to its biosimilar.

Once the switching period has ended, Alberta government-sponsored drug plans will no longer provide coverage for the originator biologic drug(s).

Process for health professionals

As part of the Biosimilar Initiative, health professionals need to identify affected patients and discuss switching their medication therapy.

1. Identify affected patients who may be required to switch from an originator biologic to its biosimilar.

   Physicians can identify their affected patients by:

   a. completing and submitting a Patient List Request form, which is available on the Alberta Blue Cross website. Alberta Blue Cross will send a list of patients on the Alberta government sponsored drug plans who have an active special authorization approval or have filled a prescription in the last 6 months for the originator biologic requested by you, or
   b. running a patient query in your local electronic medical record (EMR). The search will need to include drug plan information in order to identify the affected patients. For information on running a patient query, contact your system vendor.
      - For physicians using an EMR system, resources can be found on the Alberta Medical Association website
      - Vendor specific information and contacts for EMR systems can be found on the Canadian EMR website under the EMR Vendors tab.

   Pharmacists can identify affected patients by running a patient query in your pharmacy management system. The search will need to include drug name and drug plan information to identify the affected patients. For additional information on running a patient query, contact your system vendor.

2. Discuss switching to a biosimilar and other options with the patient. Download the biosimilar patient information sheet, which is available on the Alberta Blue Cross website.

3. Initiate enrollment in the patient support program for the biosimilar (if applicable). Write the patient a new prescription (as per professional standards of practice) clearly indicating the change to the biosimilar.

4. For any patients unable to switch due to a medical reason, submit the Special Authorization request form for exceptional coverage of the originator biologic to Alberta Blue Cross.

Special authorization

During the switching period, both the originator biologic drug and biosimilar versions of the affected drugs will be covered to allow prescribers and patients time to discuss treatment options and to develop a plan for switching.

All special authorization approvals in place for the originator biologic drug will be automatically applied to its biosimilar version(s). Following the deadline for switching to the biosimilar, all subsequent submissions for renewal of the special authorization will be renewed only for the biosimilar.

Patients who want to continue on the same molecule are expected to initiate treatment with a biosimilar unless they have a medical reason that prevents switching. If there is a medical reason why a patient cannot switch to the biosimilar, the prescriber can submit a request for exceptional coverage to Alberta Blue Cross. Requests will be reviewed on a case-by-case basis. The exception request form can be found on the Alberta Blue Cross website under resources for providers.

Discussion with patients – avoiding the “nocebo effect”

Health care professionals play a vital role in switching to a biosimilar by serving as a trusted source for information, coordinating care, and managing patient expectations. Health care professionals are encouraged to visit the links provided in the Resources section to feel more confident in biosimilars and engage in positive framing of biosimilars with patients when discussing switching and treatment options.

Patients who have not previously received an originator biologic may be more accepting of biosimilars, while more support and additional information may be needed for patients currently stable on an originator biologic. Some patients may be impacted by the nocebo effect, where their beliefs, previous experiences, and attitude can result in a negative expectation for treatment that adversely affects the outcomes of their treatment.

Providing information regarding the need for the Biosimilar Initiative and explaining how switching will affect an individual’s therapy in a positive and supportive environment will

allow patients to express any concerns and ask questions, resulting in more positive outcomes.

Essential information to help you talk to your patients:

- Biosimilars are safe and effective and have the same treatment benefits and same potential side effects as their originator biologic.
- Biosimilars undergo a rigorous approval process to receive Health Canada approval.
- The drugs included in this initiative are already approved by Health Canada and currently in use in Alberta, across Canada and around the world.
- Policies that require switching from an originator biologic to its biosimilar have been implemented successfully in many other jurisdictions, including Norway, Scotland, and recently in British Columbia.
- Patient support programs are available for the biosimilars to provide assistance with benefit coordination and access to infusion clinics.
- Research studies and systemic reviews of switching from an originator biologic to its biosimilar have found no meaningful differences in safety and effectiveness.
- The savings achieved by switching to the lower priced biosimilar will provide opportunities to expand treatment options and improve access for patients.

Exceptions

If a prescriber determines there is a medical reason that prevents a patient from switching to the biosimilar drug, they have the ability to request exceptional coverage of the originator drug by clearly identifying why their patient is unable to switch.

All requests for an exception are reviewed on a case-by-case basis by an exceptions team and peer-reviewed by a group of independent clinical specialists, as needed. If there are multiple brands of a biosimilar available for an originator drug, patients may be asked to try alternate brands of the biosimilar prior to gaining access to the originator drug.

At this time, three groups of patients are exempt from the requirement to switch from their originator biologic to the biosimilar version:

- Patients under 18 years of age,
- Pregnant patients - in order to obtain the exemption, an exception request form must be submitted by the prescriber, and
- Patients using their originator biologic for polyarticular juvenile idiopathic arthritis (pJIA).

Patient supports

Patient support programs are available to minimize the impact of switching on patients and health care professionals. For specific information, contact the program specific to your patient's drug. A list of support programs can be found on the Alberta Blue Cross website.

Biosimilar basics

Biologics and biosimilars

Biologics are drugs manufactured in, extracted from or semi-synthesized from living cells through a highly complex manufacturing process. A biosimilar drug is a highly similar version of biologic drug currently in use, known as the originator biologic. Biosimilars become available after the patent for the originator biologic has expired.

Health Canada's rigorous approval process ensures that patients and health professionals can have the same confidence in the quality, efficacy and safety of a biosimilar as in any other biologic drug. As with all approved drugs, Health Canada continues to monitor the safety of biosimilars following their addition to the market.

Due to the complexity of biologic drugs and the natural variability that results from using living cells, it is not possible for a biosimilar to be identical to its originator biologic drug, nor is it possible for different lots or "batches" of an originator biologic drug to be identical. These variations are not clinically meaningful.

As biosimilars cannot be proven to be identical to their biologic originator, they are not classified as interchangeable. Biosimilars and their originator biologics are proven to be functionally and effectively equivalent. Health Canada has indicated that no differences

are expected in efficacy and safety following switching from a biologic originator to a biosimilar in an authorized indication.

Safety and efficacy

Biosimilars have been used in Canada for more than 15 years and many other countries, including the United States, Australia, the United Kingdom and the European Union, for more than 17 years. Recently, the governments of British Columbia and Manitoba implemented changes to increase the use of biosimilars in their provinces. Regulators have not identified any relevant differences in the type, severity or frequency of side effects between biosimilars and their respective biological originators.

Health Canada reviews and approves all drug products, including biosimilars, before they can be sold in Canada. To receive Health Canada approval, biosimilars undergo a rigorous review process and must demonstrate they are highly similar to their originator biologic, including their effectiveness and safety.

The biosimilars included in Alberta's Biosimilar Initiative are already approved by Health Canada and currently in use in Alberta, in Canada and around the world.

Statements from regulators and expert advisory boards

Health Canada

“Patients and health care professionals can have confidence that biosimilars are effective and safe for each of their authorized indications. No differences are expected in efficacy and safety following a change in routine use between a biosimilar and its reference biologic drug in an authorized indication.” – Biosimilar biologic drugs in Canada: Fact Sheet, 2019

Advisory Council on the Implementation of National Pharmacare

Recommendation 31: “The council recommends formulary management policies, including requiring biosimilar substitution that support the use of biosimilars and encourage patients and prescribers to choose the most cost-effective therapies to ensure the sustainability of national pharmacare. Prescribers and patients should be better supported with information reinforcing the safety, efficacy and benefits of biosimilars.” – A Prescription for Canada: Achieving Pharmacare for All, Final Report of the Advisory Council on the Implementation of National Pharmacare, June 2019

U.S. Food and Drug Administration

“By increasing treatment options, biosimilars can enhance competition in the market for biological products without reducing incentives to innovate.” – Biosimilars Action Plan: Balancing Innovation and Competition, July 2018

“Biosimilar medications offer additional safe and effective treatment options that have the potential to increase access for people requiring treatment for inflammatory diseases,” said Nikolay Nikolov, M.D., Director of the Office of Immunology and Inflammation in the FDA’s Center for Drug Evaluation and Research - FDA Approves Interchangeable Biosimilar for Multiple Inflammatory Diseases, October 2023

Canadian Agency for Drugs and Technology in Health

“In Europe, the availability of lower priced biosimilars has been reported to reduce the average list prices of reference products as well as prices of products within the whole

therapeutic class." – Biosimilars – Regulatory, Health Technology Assessment, Reimbursement Trends, and Market Outlook January 2018

European Medicines Agency

"Over the past 10 years, the EU has approved the highest number of biosimilars worldwide, amassing considerable experience in their use and safety. The evidence acquired over 10 years of clinical experience shows that biosimilars approved through EMA can be used safely and effectively in all their approved indications as other biological medicines. Over the last 10 years, the EU monitoring system for safety concerns has not identified any relevant difference in the nature, severity or frequency of adverse effects between biosimilars and their reference medicines." – Biosimilars in the EU: Information Guide for Healthcare Professionals

European Crohn's and Colitis Organization

"Switching from the originator to a biosimilar in patients with IBD is acceptable. Studies of switching can provide valuable evidence for safety and efficacy." European Crohn's and Colitis Organization (ECCO) Position Statement on the Use of Biosimilars for Inflammatory Bowel Disease

Resources

For patients

Alberta Rheumatology – Biosimiliars

Arthritis Consumer Experts Biosimilars in Canada

Arthritis Consumer Experts – Biosim•Exchange

Biosimilars in the EU: Information Guide for Patients

Biosimilars Patient Information Sheet

British Columbia Ministry of Health – Biosimilars Initiative for Patients

CADTH Biosimilar Drugs: Your Questions Answered – patient hand-out (PDF 162 KB)

CADTH Common Drug Review Report Glatiramer Acetate

Canadian Arthritis Patient Alliance – What is a biosimilar

Canadian Digestive Health Foundation- BC Biosimilars Initiative: Phase Two – Information

Canadian Digestive Health Foundation: What's Health Canada Saying about Biosimilars? (YouTube)

Canadian Digestive Health Foundation: IBD: Crohn's Disease: IBD: Switching from a Biologic to a Biosimilar (video)

Cancer Care Ontario: Biosimilars – What you need to know – patient fact sheet

FDA Biosimilar Basics (infographic)

Health Canada – Biosimilar biologic drugs in Canada: Fact Sheet

International Coalition of Medicines Regulatory Authorities - Statements on Biosimilars for Patients and the General Public

The Arthritis Society: Biologics/Biosimilars for the Treatment of Inflammatory Arthritis

For health care professionals

Biosimilars in the EU: Information Guide for Healthcare Professionals (PDF, 1.9 MB)

CADTH Biosimilar Drugs: Health care provider hand-out (PDF, 153 KB)

FDA Biosimilars: Health care provider materials

Health Canada – Biosimilar biologic drugs in Canada: Fact Sheet

International Coalition of Medicines Regulatory Authorities – Biosimilars Statement (PDF, 626 KB)

Pan-Canadian Oncology Biosimilars Initiative

- Biosimilars – What You Need to Know – for Providers
- Discussing Biosimilars with Patients: A Resource for Healthcare Providers (PDF, 521 KB)
- Biologics and Biosimilars: Information for Healthcare Providers (Youtube)

Patients Experience Evidence Research (PEER) – Tools for Practice #236 (PDF, 145 KB)

Supporting evidence

CADTH International Policies on the Appropriate Use of Biosimilar Drugs

Cohen HP, et al. Switching reference medicines to biosimilars: A systematic literature review of clinical outcomes. Drugs; 2018:463-478.

Drug Discontinuation in Studies Including a Switch from an Originator to a Biosimilar Monoclonal Antibody: A Systematic Literature Review

ECCO: Position Statement on the Use of Biosimilars for Inflammatory Bowel Disease

Efficacious transition from reference infliximab to biosimilar infliximab in clinical practice

Non-medical Switch from originator infliximab to biosimilar (rheumatology)

Non-medical switch from originator etanercept to biosimilar (rheumatology)

NOR-SWITCH study: non-medical switching for all indications, originator infliximab to biosimilar (PDF, 499 KB)

NOR-SWITCH study: long-term follow-up after switching from originator infliximab to its biosimilar

Switching to Insulin Glargine Biosimilar (PDF, 726 KB)

Similar efficacy and safety between insulin glargine biosimilar and biologic (Lantus)

Alberta College of Family Physicians Tools for Practice #236CADTH Biosimilar Drugs: Health care provider hand-out

CADTH Biosimilar Drugs: Your Questions Answered (PDF, 162 KB)

Canadian Family Physician – Biosimilars versus biologics for inflammatory conditions

ECCO Position Statement on the Use of Biosimilars for Inflammatory Bowel Disease—An Update

Switching Reference Medicines to Biosimilars: A Systematic Literature Review of Clinical Outcomes

Therapeutics Initiative. Biosimilars or Biologics. What's the difference? Therapeutic Letter, Sept-Oct 2019

British Columbia Biosimilars Initiative

Biosimilars Initiative for Prescribers

Biosimilars Initiative FAQ for Pharmacists

Contact

Alberta Blue Cross

- General Alberta Biosimilar Initiatives: 1-800-661-6995

  Hours of operation

  Monday to Friday: 6 a.m. – 6 p.m. (MT)

- Provider Relations Contact Centre

  Phone 1-800-361-9632 (toll free)

  Edmonton and area 780-498-8370

  Calgary and area 403-294-4041

  Hours of operation

  Monday to Friday: 8 a.m. – 8 p.m. (MT)

  Weekends and holidays: 9 a.m. – 5 p.m. (MT)

Online: Alberta Blue Cross