New Nouveau Brunswick

New Brunswick Drug Plans Biosimilars Initiative

Guide for Prescribers and Health Professionals

Updated April 21, 2021

Overview

The New Brunswick Department of Health is launching a Biosimilars Initiative which involves switching patients from originator biologic drugs to their biosimilar versions. It follows the successful implementations of similar initiatives by British Columbia and Alberta where tens of thousands of patients have been transitioned without compromise to patient safety, effectiveness or quality of care. In addition, switching to biosimilars has been conducted extensively in Europe, where countries have had over 15 years of experience with biosimilars.

The Biosimilars Initiative is a result of the New Brunswick Drug Plans' evidence-informed strategy to better optimize our public resources, get the best value for new treatments and improve access to drugs for patients.

Originator biologic drugs make up some of the New Brunswick Drug Plans' largest drug expenditures and their costs are growing at an unsustainable rate. In 2019-20, New Brunswick Drug Plans' spending on biologic drugs grew by 19% to $63.8 million. In the same year, biologic drugs accounted for 29.4% of drug costs but only represented 1.5% of the total number of claims. Even though they are up to 50% less expensive and proven to be as safe and effective as originator versions, the uptake of biosimilars in Canada continues to be very low, lagging significantly behind Europe.

Between April 21, 2021 and November 30, 2021, patients who use certain originator biologics (listed in the table below) must switch to a biosimilar brand to maintain their coverage under the New Brunswick Drug Plans. During this period, both the originator biologic and its biosimilar versions will be covered to allow prescribers and patients time to discuss treatment options and to switch patients to a biosimilar. Coverage of the originator biologics will end on November 30, 2021 or on the last day of the current special authorization approval (SA), whichever is sooner.

- SA requests do not need to be submitted for patients switching to the biosimilars.
  - Insulin lispro (Admelog®), insulin glargine Basaglar™) and glatiramer (Glatect™) are regular benefits so SA is not required.
  - SA approvals for Humira®, Enbrel®, Remicade®, and Rituxan® already include the respective biosimilar brands.
- Annual SA renewal requests will not be required for continued coverage of these biosimilars for patients who are switching.

Switching patients to biosimilars has been proven to be cost-effective, yet Health Canada approved biosimilar versions with no clinically meaningful differences, remain underused. The originator biologics listed in the table below represent some of the largest drug expenditures for the New Brunswick Drug Plans. The Biosimilars Initiative works to improve the use of biosimilars, allows for a competitive drug market and helps to reinvest significant savings back into our public drug plans.

Biologic Drugs Included in the Biosimilars Initiative

Drug	Originator (Switch from)	Biosimilar (Switch to)	Indications
Adalimumab	Humira®	Idacio® Amgevita™ Hadlima® Hyrimoz® Hulio®	Ankylosing Spondylitis Plaque Psoriasis Psoriatic Arthritis Rheumatoid Arthritis Crohn's Disease Ulcerative Colitis Polyarticular Juvenile Idiopathic Arthritis Hidradenitis Suppurativa Non-Infectious Uveitis
Etanercept	Enbrel®	Brenzys® Erelzi®	Ankylosing Spondylitis Plaque Psoriasis Psoriatic Arthritis Polyarticular Juvenile Idiopathic Arthritis Rheumatoid Arthritis
Infliximab	Remicade®	Inflectra® Renflexis™ Avsola™	Ankylosing Spondylitis Plaque Psoriasis Psoriatic Arthritis Rheumatoid Arthritis Crohn's Disease Ulcerative Colitis
Insulin glargine	Lantus®	Basaglar™	Diabetes
Insulin lispro	Humalog®	Admelog®	Diabetes
Rituximab	Rituxan®	Ruxience™ Truxima™ Riximyo®	Rheumatoid Arthritis Vasculitis Autoimmune Diseases
Glatiramer[1]	Copaxone®	Glatect™	Multiple Sclerosis

[1]Non-biologic complex drug

Evidence for Biosimilar Switching

Leading regulators in the world – including the European Medicines Agency, the Food & Drug Administration in the United States and Health Canada – support well-controlled transitions to biosimilars. Patients need to know that transition policies have been safely and effectively implemented in many countries in Europe.

Health Canada is responsible for ensuring the safety and efficacy of all new drugs on the market including biosimilars. For a biosimilar to be approved for use in Canada, Health Canada evaluates functional, structural, and clinical studies comparing biosimilars to their originators. Authorized biosimilars are shown to be highly similar to their originators and Health Canada expects no meaningful differences in switching from routine use of an originator biologic to a biosimilar for an approved indication.

There are now more than 100 research studies on biosimilars in rheumatology, gastroenterology, dermatology and other diseases, which collectively show little to no clinical differences between biosimilars and their originators, either when used with treatment-naïve patients, or for patients switching to a biosimilar. The majority of switching studies also found that efficacy loss associated with switching to biosimilars was the same as is expected for patients who remain on the originator drug. There is no scientific reason to expect a different clinical outcome, but patient perspectives should be considered.

Process for Switching Patients

Prescribers play an important role in the switching process. As a trusted source of information, a prescriber can set the tone of the discussion, facilitate continuity of care, and empower the patient to understand and realize the best outcomes. The following steps may help patients with their switch to a biosimilar. Additional information is contained in the Biosimilars Initiative Frequently Asked Questions (FAQs) for Prescribers.

- Identify a patient using a biologic included in the Biosimilars Initiative.
- Discuss switching to a biosimilar with the patient.
- Initiate enrolment in the patient support program for the biosimilar (if applicable). Write your patient a new prescription, indicating the chosen biosimilar. Information on patient support programs (and infusion clinics) is available online at www.gnb.ca/biosimilars.
- For patients who are unable to switch due to a medical reason, submit an SA request for exceptional coverage of the originator biologic.

How do I identify patients using a biologic included in the Biosimilars Initiative?
To assist in identifying patients, prescribers may request a list of their patients who are using a biologic that is included in the initiative by submitting the Patient List Request Form. The list will include patients who are covered by the New Brunswick Drug Plans who have had an SA approval for the biologic in the last twelve months.

What about patients who cannot switch?
For patients who are unable to switch for medical reasons, you may submit an SA request for exceptional coverage of the originator biologic. Clearly identify in the request the medical reason why the patient cannot switch.

Exceptional requests are reviewed on a case-by-case basis. To avoid uninterrupted coverage, exceptional requests should be submitted as soon as possible.

Resources for Prescribers and Health Professionals

The Biosimilars Initiative Guide for Prescribers and Health Professionals is available online at http://www.gnb.ca/biosimilars

If you would like printed copies of the Biosimilars Initiative Guide for Prescribers and Health Professionals or the Guide for Patients, please contact the NB Drug Plans at 1-800-332-3691 or info@nbdrugs-medicamentsnb.ca.

Resources for Patients

Patient resources are available at www.gnb.ca/biosimilars, where patients can find information about biosimilar switching, how it affects them, the difference between originator and biosimilar versions, answers to frequently asked questions and more.

The Biosimilars Initiative Guide for Patients is available online. If you would like printed copies of the Guide for Patients, please contact the NB Drug Plans at 1-800-332-3691 or info@nbdrugs-medicamentsnb.ca.

Frequently Asked Questions

1. **Why is coverage changing?**
   Biologic drugs have become Canada's largest drug expense, with costs increasing at an unsustainable rate. As the patents for biologics expire, other manufacturers can produce biosimilar versions at a much lower cost. Biologic drugs account for some of the New Brunswick public drug plans' largest expenditures.

2. **Has a Biosimilars Initiative that switches patients been done before?**
   Yes. British Columbia and Alberta both successfully implemented Biosimilar Initiatives. Tens of thousands of patients were safely switched, including those living with inflammatory arthritis, diabetes, psoriasis and inflammatory bowel disease. In addition, biosimilars switching has been performed extensively in Europe, where countries have had over 15 years of experience with biosimilars.

3. **How does switching to a biosimilar impact patient outcomes? How much does it differ from a treatment-naïve patient?**
   Based on growing evidence in support of biosimilars, the Biosimilar Initiative aims to switch the existing treatment-experienced patients. Health Canada's approval process requires that studies demonstrate no clinically meaningful differences in immunogenicity between the biosimilar and the originator biologic. Health Canada indicates that patients and health care providers can be confident that biosimilars are effective and safe for each of their authorized indications, and that no differences in efficacy and safety are expected following a change in routine use between an originator biologic and its biosimilar in an authorized indication.

Treatment-experienced patients sometimes require more information about biosimilars to help them understand the change. Health Canada recommends that the patient should be well-informed and discuss the switch to a biosimilar with their prescriber. For more information on biosimilars and studies around switching to them, see the section entitled "Additional Information and Studies".

4. Do I need to write a new prescription for a biosimilar?

Yes. After discussing the biosimilar switch with your patient, initiate enrolment in the patient support program (if applicable). Write a new prescription for your patient, indicating the change to the chosen biosimilar.

For more details about the switching process, see "Process for Switching Patients".

5. Do I need to request a new SA approval for the patient to have coverage for the corresponding biosimilar?

No, SA requests do not need to be submitted for patients who are switching. Insulin lispro (Admelog®), insulin glargine (Basaglar™) and glatiramer (Glatect™) are regular benefits so SA is not required. SA approvals for Humira®, Enbrel®, Remicade® and Rituxan® already include the respective biosimilar brands. Also, annual SA renewal requests will not be required for continued coverage of these biosimilars for patients who are switching.

6. What is the process for switching patients?

Prescribers play an important role in the switching process. As a trusted and experienced information source, a prescriber may set the tone of the discussion, facilitate continuity of care, and empower the patient to understand and realize the best outcomes. The following steps may help patients with their switch to a biosimilar.

- Identify a patient using a biologic included in the Biosimilars Initiative.
- Discuss switching to a biosimilar with the patient.
- Initiate enrolment in the patient support program for the biosimilar (if applicable). Write your patient a new prescription, indicating the chosen biosimilar.
- For any patients unable to switch due to a medical reason, submit an SA request for exceptional coverage of the originator biologic.

To assist in identifying patients, prescribers may request a list of their patients who are using a biologic that is included in the initiative by submitting the "Patient List Request Form".

The list will include patients who are covered by the New Brunswick Drug Plans who have had a prescription claim paid for the biologic in the last twelve months.

7. How should I explain the biosimilar switch to patients?

As a trusted source of information, prescribers play an important role in the switching process, especially in setting the tone of the discussion. The Guide for Patients can be a helpful primer for patient discussions. A copy of the Guide for Patients was enclosed with the Prescriber Letter sent to you by the NB Drug Plans. If you would like additional copies of the Guide for Patients, please contact the NB Drug Plans at 1-800-332-3691 or info@nbdrugs-medicamentsnb.ca. They are also available online at www.gnb.ca/biosimilars.

8. What if I can't see patients before the end of the switch period?

The switch period ends on November 30, 2021. If you cannot prescribe a biosimilar for your patients by then, their originator biologic drug will no longer be covered by the New Brunswick Drug Plans as of November 30, 2021, unless exceptional coverage is requested and approved.

9. What if a patient can't switch? What is the process for requesting exceptional coverage of an originator biologic?

If you determine a clinical requirement that prevents a patient from switching, you may submit an SA request for exceptional coverage of the originator biologic, clearly identifying the medical reason why the patient cannot switch.

Exceptional requests are reviewed on a case-by-case basis. To avoid uninterrupted coverage, exceptional requests should be submitted as soon as possible.

10. Which biosimilar should I prescribe?

The originator biologics included in the initiative and the respective biosimilars are listed in the table below. You do not need to submit a new SA request for the biosimilars.

Drug	Originator (Switch from)	Biosimilar (Switch to)	Indications
Adalimumab	Humira®	Idacio® Amgevita™ Hadlima® Hyrimoz® Hulio®	Ankylosing Spondylitis Plaque Psoriasis Psoriatic Arthritis Rheumatoid Arthritis Crohn's Disease Ulcerative Colitis Polyarticular Juvenile Idiopathic Arthritis Hidradenitis Suppurativa Non-Infectious Uveitis
Etanercept	Enbrel®	Brenzys® Erelzi®	Ankylosing Spondylitis Plaque Psoriasis Psoriatic Arthritis Polyarticular Juvenile Idiopathic Arthritis Rheumatoid Arthritis
Infliximab	Remicade®	Inflectra® Renflexis™ Avsola™	Ankylosing Spondylitis Plaque Psoriasis Psoriatic Arthritis Rheumatoid Arthritis Crohn's Disease Ulcerative Colitis
Insulin glargine	Lantus®	Basaglar™	Diabetes

Insulin lispro	Humalog®	Admelog®	Diabetes
Rituximab	Rituxan®	Ruxience™ Truxima™ Riximyo®	Rheumatoid Arthritis Vasculitis Autoimmune Diseases
Glatiramer[1]	Copaxone®	Glatect™	Multiple Sclerosis

[1]Non-biologic complex drug

11. Where can I find more information on biosimilars and switching?

More information for prescribers is available online at www.gnb.ca/biosimilars.

12. Can switching be done even in the context of COVID-19?

Yes, the Department of Health has introduced temporary virtual care service codes using telephone or secure digital media to physicians. Both British Columbia and Alberta successfully and safely implemented their Biosimilar Initiatives during COVID-19. In fact, British Columbia launched additional phases of its policy in recent months, leveraging an increased use of virtual care options.

Additional Information and Studies

Links to additional information and studies are listed below.

- Health Canada Fact Sheet: Biosimilars
- CADTH: Biosimilar Drugs – Your Questions Answered
- International Coalition of Medicines Regulatory Authorities Biosimilars Statement (PDF)
- Biosimilars in the EU: Information Guide for Healthcare Professionals
- Arthritis Consumer Experts "Biosim•Exchange" Research
- Arthritis Consumer Experts: Facts About Biosimilars
- Arthritis Consumer Experts: Biosimilars in Canada – What inflammatory arthritis patients need to know
- Arthritis Research Canada: Biosimilars – What you need to know
- The Arthritis Society: Biologics/Biosimilars for the Treatment of Inflammatory Arthritis
- Canadian Digestive Health Foundation: Video on Biosimilar Transitioning
- Canadian Digestive Health Foundation: Infographic on What's Health Canada Saying about Biosimilars
- Canadian Digestive Health Foundation: Video on What's Health Canada Saying about Biosimilars

Adalimumab

- CADTH: Summary of findings from literature search of trials and studies regarding switching from Humira to biosimilar adalimumab

Etanercept

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

- CADTH: Switching from Reference to Biosimilar Etanercept for Patients with Plaque Psoriasis

Infliximab

- Clinical study: Non-medical Switch from originator infliximab to biosimilar (rheumatology)
- ECCO: Position Statement on the Use of Biosimilars for Inflammatory Bowel Disease
- Efficacious transition from reference infliximab to biosimilar infliximab in clinical practice
- NOR-SWITCH study: non-medical switching for all indications, originator infliximab to biosimilar
- Study on Effectiveness of Switching from originator Infliximab to an Infliximab biosimilar in Patients with Inflammatory Bowel Disease in the United States

Insulin Glargine

- Clinical study for: Switching to Insulin Glargine Biosimilar
- Clinical study: Similar efficacy and safety between insulin glargine biosimilar and biologic (Lantus)

Rituximab

- Efficacy and safety of switching from rituximab to biosimilar CT-P10 in rheumatoid arthritis
- Long-term efficacy and safety of biosimilar CT-P10 versus innovator rituximab in rheumatoid arthritis
- Comparison of biosimilar CT-P10 and innovator rituximab in patients with rheumatoid arthritis

Glatiramer

- Switching from branded to generic glatiramer acetate: 15-month GATE trial extension results

General

- Cohen HP, Drugs, 2018: Switching Reference Medicines to Biosimilars: A Systemic Literature Review of Clinical Outcomes
- Edwards CJ et al. Switching to biosimilars: current perspectives in immune-mediated inflammatory diseases. Expert Opinion on Biological Therapy (2019)
- Moots et al. Switching between reference biologics and biosimilars for the treatment of rheumatology, gastroenterology, and dermatology inflammatory conditions: Considerations for the clinician.

Contact Information

If you have any questions about the Biosimilars Initiative, contact the NB Drug Plans.

Phone: 1-800-332-3691, Monday to Friday, 8am to 5pm

Email: info@nbdrugs-medicamentsnb.ca.