Number 826 • December 2019

Alberta Health announces an important change to coverage for biologic products under Alberta government sponsored programs

Effective December 12, 2019, the Alberta government, under the Alberta Biosimilars Initiative, is changing the funding of select biologic medications for adult patients on Alberta government sponsored drug plans.

The changes will impact originator biologic medications and their biosimilar versions and a medication known as a Non-Biologic Complex Drug (NBCD) and its subsequent entry version, termed subsequent entry NBCD. The Alberta Biosimilar Initiative aims to expand the use of lower cost biosimilar medications and savings from this Initiative will help ensure Alberta has a patient-centered health system focused on providing the high-quality care Albertans deserve.

Although the NBCD and its subsequent entry version is not a biologic drug, they are included in this Initiative and the changes outlined to the biologic/biosimilars in this Benefact will also apply to the NBCD and its subsequent entry version.

Switching to a biosimilar

Patients currently on an originator drug for which there is a biosimilar version for their health condition must switch to its biosimilar version before July 1, 2020, in order to maintain coverage for the molecule through their Alberta government sponsored drug plan. Effective July 1, 2020, Alberta Health will no longer provide coverage for the originator brand drugs listed in the second column of the table below. Any patient using the originator drug for one of the listed health conditions will be required to switch to its corresponding biosimilar in the third column¹.

Drug name	Originator brand name	Biosimilar brand name	Health conditions
etanercept	Enbrel	Brenzys	Ankylosing Spondylitis
			Rheumatoid Arthritis
		Erelzi	Ankylosing Spondylitis
			Psoriatic Arthritis
			Rheumatoid Arthritis
infliximab	Remicade	Inflectra	Ankylosing Spondylitis
		Renflexis	Plaque Psoriasis
			Psoriatic Arthritis
			Rheumatoid Arthritis
			Crohn's Disease
			Ulcerative Colitis
insulin glargine	Lantus	Basaglar	Diabetes (Type 1 and 2)
filgrastim	Neupogen	Grastofil	Neutropenia
pegfilgrastim	Neulasta	Lapelga	Neutropenia
glatiramer ²	Copaxone	Glatect	Multiple Sclerosis

¹ Patients under the age of 18 do not have to switch to a biosimilar at this time.

² Glatiramer is a non-biologic complex drug.

During the switching period from December 12, 2019 to June 30, 2020, both the originator biologic drug and biosimilar versions of the affected drugs will be covered in order to allow prescribers and patients time to discuss treatment options and to develop a plan for switching.

All special authorization approvals that are in place for the originator biologic drug will be automatically be applied to its biosimilar version(s). All special authorization approvals that expire between December 12, 2019 and September 30, 2020 will be automatically extended by 12 months for the biosimilar. All subsequent submissions for renewal of the special authorization will be renewed only for the biosimilar.

Patients that 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.

As a reminder, pharmacists may be eligible for claims under the Compensation Plan for Pharmacy Services for the Assessment for Prescribing when supporting patients who are switching Schedule 1 drugs.

In addition, pharmacists may also be eligible for claims under the Compensation Plan for Pharmacy Services for the Assessment for an Adaptation, which can include both Schedule 1 drugs and insulin. Formal changes to the Ministerial Order will be coming in the near future to reflect this understanding.

Special Authorization criteria changes for selected biologic drugs—Tiering

Special Authorization criteria will change for a number of biologic drugs. These changes will not apply to patients currently using these medications for the indications noted but will apply to new patients or patients seeking to change their current treatment. The special authorization criteria changes will require patients to try a number of first-line therapeutic options prior to gaining access to the following tier 2 drugs:

- · Enbrel (etanercept) for the treatment of plaque psoriasis,
- Stelara (ustekinumab) for the treatment of plaque psoriasis,
- Humira (adalimumab) for the treatment of plaque psoriasis, Crohn's disease, ankylosing spondylitis, psoriatic arthritis and rheumatoid arthritis, and
- Rituxan (rituximab) for the treatment of rheumatoid arthritis.

Additional information

The Alberta Drug Benefit List will be updated with the changes for the drugs affected by the Alberta Biosimilar Initiative. Additional information can be accessed online on the Alberta Blue Cross website. Furthermore, Alberta Health will also be notifying physicians of this Initiative and patients who are on an originator drug that will no longer be covered after July 1, 2020.

To assist with communicating these changes to your patients, please find attached a Patient Information Sheet which is also available on the Alberta Blue Cross website.

When you have questions:

For assistance with benefit or claim inquiries, please contact an Alberta Blue Cross Pharmacy Services Provider Relations contact centre representative at:

780-498-8370 (Edmonton and area) • **403-294-4041** (Calgary and area) • **1-800-361-9632** (toll free) **FAX 780-498-8406** (Edmonton and area) • **FAX 1-877-305-9911** (toll free)

Alberta Blue Cross offers online access to current Pharmacy Benefacts and supplemental claiming information to assist with the submission of your direct bill drug claims. **Visit** ab.bluecross.ca/providers/pharmacy-home.php





Patient information Switching to a biosimilar drug

BIOLOGICS VS BIOSIMILARS

Biologics are drugs made in, taken from or partly-made from living cells through a complex manufacturing process. The first version of a biologic drug is called an originator biologic drug but may also be called an innovator or reference biologic.

A biosimilar drug, or biosimilar, is a biologic drug that is very similar to but less expensive than its originator biologic drug. Biosimilars become available after the patent on the originator biologic drug expires. There are no expected differences in efficacy and safety between a biosimilar and the originator biologic drug.

WHY IS THIS CHANGE HAPPENING?

Alberta spent more than \$238 million in the 2018 to 2019 fiscal year on biologic drugs, and these costs are increasing every year. Costs per patient for originator biologics can be more than \$25,000 per patient per year, with biosimilar versions costing up to 50 per cent less than originator biologics.

Alberta is implementing the Biosimilar Initiative which will save approximately \$30 million annually that can be invested into other health care services for Albertans.

WHAT IS CHANGING?

Albertans using certain originator biologic drugs that are covered by an Alberta government sponsored drug plans will need to switch to the biosimilar version by June 30, 2020 to continue coverage of that drug. Effective July 1, 2020, the Alberta government sponsored drug plans will no longer reimburse the originator biologic.

For individuals starting a biologic or changing their biologic drug, a tiered framework will apply requiring cost-effective biologic agents to be used first. However, there are several medication options available to continue to provide choice to patients and physicians.

IMPORTANT:

Call your health care professional before July 1 to discuss switching.

Your health care professional can

- answer questions about switching from an originator biologic drug to a biosimilar,
- explain the process for switching,
- discuss biosimilar options,
- · write a new prescription, and
- enroll you in a new patient support program, if appropriate.

You are affected by these changes if you are an adult member enrolled in one of these government sponsored drug plans provided through Alberta Blue Cross:

- Non-Group Coverage (Group 1)
- Coverage for Seniors (Group 66)
- Palliative Coverage (Group 20514)
- 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)



SAFETY AND EFFECTIVENESS

Health Canada must review and approve all drugs before they can be sold in Canada. Both originator biologics and biosimilar drugs are authorized for sale by Health Canada. Health Canada approves biosimilars for sale based on a thorough comparison to the originator biologic drug.

Health Canada says that patients and health care professionals can have confidence that biosimilars are effective and safe for each of their authorized health conditions. Tests are done to help ensure there are no expected differences in how the drug works and the safety of a biosimilar compared to the originator biologic drug.

SWITCHING

In Europe, where biosimilars have been used since 2006, more than 40 biosimilar products have been approved and are on the market, accounting for nearly a billion patient days of experience spanning 12 years. There are also numerous research studies showing that patients who have switched to a biosimilar experience little to no difference between the biosimilar and its biologic originator.

If you are using an originator biologic drug listed in the second column of the table below for one of the listed health conditions, you will need to speak to your health care professionals¹.

Drug name	Originator brand name	Biosimilar brand name	Health conditions
		Brenzys	Ankylosing Spondylitis Rheumatoid Arthritis
etanercept	Enbrel		Ankylosing Spondylitis Psoriatic Arthritis Rheumatoid Arthritis
infliximab	Remicade		Ankylosing Spondylitis Plaque Psoriasis Psoriatic Arthritis Rheumatoid Arthritis Crohn's Disease Ulcerative Colitis
insulin glargine	Lantus	Basaglar	Diabetes (Type 1 and 2)
filgrastim	Neupogen	Grastofil	Neutropenia
pegfilgrastim	Neulasta	Lapelga	Neutropenia
glatiramer ²	Copaxone	Glatect	Multiple Sclerosis

¹ Patients under the age of 18 years of age are not required to switch to the biosimilar at this time.

MORE INFORMATION

If you have any questions about these changes, you should speak to your health care professional. You may also contact Alberta Blue Cross at 1-800-661-6995.



² Glatiramer is a non-biologic complex drug.