Alberta Biosimilar Initiative

Guide for health professionals

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

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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 $238 million in the 2018 to 2019 fiscal year, and have been increasing at an average of 16.2% per year over the last five years. The originator biologic drugs Remicade, Humira and Enbrel are 3 of the top 4 drivers of drug spending in Alberta's government sponsored drug plans. The changes being implemented through the Biosimilar Initiative will save approximately $30 million annually that can be invested into other health care services for Albertans.

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 10 years and many other countries including the United States, Australia, the United Kingdom and in the European Union for more than 13 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 and a medication known as non-biologic complex drug (NBCD) and its subsequent entry version, called subsequent entry NBCD. Although the NBCD and its subsequent entry version are not biologic drugs, they are included in this initiative and the same changes described for originator biologics and biosimilars will apply.

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 to the switch date in order to maintain coverage for the molecule through their Alberta government sponsored drug plan.

See Table 1 for a list of affected drugs and their designated switching periods (page 6).

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 (see table 1) in order to maintain coverage for the molecule 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 from, both the originator biologic drug and biosimilar versions of the affected drugs listed below will be covered to allow health professionals and patients time to discuss the biosimilar and develop a plan for switching.

All special authorization approvals that are in place for the originator biologic will be automatically applied to its biosimilar. In addition, special authorization approvals, except Rituxan, that term between December 12, 2019 and December 12, 2020 will be automatically extended by 12 months.

Once the respective switching period has ended, the Alberta government sponsored drug plans will no longer provide coverage for the following originator biologic drugs: Remicade (for all indications), Enbrel (all indications except Pediatric Juvenile Idiopathic Arthritis), Lantus, Neupogen, Neulasta, Rituxan (for Rheumatoid Arthritis, Granulomatosis with Polyangiitis or Microscopic Polyangiitis) and the NBCD, Copaxone as outlined in column 2 of Table 1. Only the biosimilars and subsequent entry drug, in column 3 of Table 1 will be reimbursed.

Table 1: List of drugs and biosimilar replacements[1]

Drug name	Originator biologic brand name	Biosimilar drug brand name	Indication/ Health Condition	Switch Date Patients must switch to the biosimilar version by **the following date**
etanercept	Enbrel	Brenzys	Ankylosing Spondylitis Rheumatoid Arthritis	**January 15, 2021**
		Erelzi	Ankylosing Spondylitis Psoriatic Arthritis Rheumatoid Arthritis	**January 15, 2021**
		Erelzi	Plaque Psoriasis	**May 1, 2021**
infliximab	Remicade	Inflectra Renflexis	Ankylosing Spondylitis Plaque Psoriasis Psoriatic Arthritis Rheumatoid Arthritis Crohn's Disease Ulcerative Colitis	**January 15, 2021**
insulin glargine	Lantus	Basaglar	Diabetes (Type 1 and 2)	**January 15, 2021**
filgrastim	Neupogen	Grastofil	Neutropenia	**January 15, 2021**
pegfilgrastim	Neulasta	Lapelga Fulphila Ziextenzo	Neutropenia	**January 15, 2021**
rituximab	Rituxan	Truxima Riximyo Ruxience	Rheumatoid Arthritis	**January 15, 2021**
rituximab	Rituxan	Ruxience	Granulomatosis with Polyangiitis Microscopic Polyangiitis	**March 1, 2021**

Drug name	Originator NBCD brand name	Subsequent entry drug NBCD brand name	Indication/ Health conditions	Switch Date Patients must switch to the biosimilar version by **the following date**
glatiramer[2]	Copaxone	Glatect	Multiple Sclerosis	**January 15, 2021**

[1]Patients under the age of 18 are not affected by biosimilar switching at this time.

[2]Glatiramer is a non-biologic complex drug

Process for health professionals

As part of the Biosimilar Initiative, health professionals will need to identify the 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 either:

   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 an originator biologic (Remicade, Enbrel, Lantus, Neupogen, Neulasta, Rituxan Copaxone) requested by you.
   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 listed below 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 applied to its biosimilar version(s). All patients with special authorization approvals for drugs affected by the January 15, 2021 switch date, except Rituxan, that expire between December 12, 2019 and December 12, 2020 will be automatically extended by 12 months. All subsequent submissions for renewal of the special authorization will be renewed only for the biosimilar. Patients currently using Rituxan for all indications and who require retreatment courses will be able to access Rituxan until the end of the switching period.

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.

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 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.

Patient supports and infusion clinics

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.

Inflectra

Pfizer's Patient Support Program for Inflectra is called PfizerFlex.

Hours: Monday to Friday, 6 am to 6 pm MST

Phone: 1-855-935-3539 or 1 855 935 FLEX

Fax: 1-833-958-3539 or 1 833 958 FLEX

Email: inflectra@innomar-strategies.com

Website: https://www.pfizerflex.ca/

Alberta Inflectra Navigators:

Sarah Horne, LPN: Nurse Patient Coordinator - Calgary

Email: shorne@pfizerflex.com

Phone: 403-461-2879

Stephanie Stoness, RN, BN: Nurse Patient Coordinator - Calgary

Email: sstoness@pfizerflex.com

Phone: 587-340-6678

Sasha Farand, RN, BN: Nurse Patient Coordinator – Calgary and Red Deer

Email: sfarand@pfizerflex.com

Phone: 403-352-2088

Stephanie Selcuk, RN, BScN: Patient Coordinator – Edmonton, St. Albert, Fort McMurray, Grande Prairie

Email: sselcuk@pfizerflex.com

Phone: 587-337-9294

Audree-Anne Rousselle, RN: Patient Coordinator - Edmonton

Email: arousselle@pfizerflex.com

Phone: 587-338-3741

Alex Zimmer, RN: Patient Coordinator – Calgary and Lethbridge

Email: azimmer@pfizerflex.com

Phone: 403-702-047

Myrna Mahon, LPN: Patient Coordinator – Edmonton

Email: mmahon@pfizerflex.com

Phone: 587-337-2370

Table 2: Inflectra infusion clinic locations

City	Clinic	Address
Calgary	Specialty Rx	Suite 2314 – 8561 8A Avenue SW
Calgary	Innomar Calgary North	8555 Sculfield Dr. NW, Suite 209
Calgary	Innomar Calgary South	1011 Glenmore Trail SW, Suite 311
Calgary	Innomar Calgary NE	2675-36 Street NE, Suite 306
Calgary	Inviva Access To Care	4411 – 16th Avenue NW, Suite 160

City	Clinic	Address
Calgary	Inviva Access To Care	4307 – 130 Avenue SE
Calgary	Shoppers Drug Mart Specialty Health	1645 – 32nd Ave NE
Calgary	Specialty RX	Holy Cross Centre 2204 – 2nd Street SW
Canmore	Innomar Canmore	1001 – 6th Avenue, Suite 105
Edmonton	Specialty Rx	205B – 11010 101 St. NW
Edmonton	Inviva Access To Care	6203 – 28 Avenue, Suite 208
Edmonton	Rheumatology Research Associates	10839 – 124th Street
Edmonton	Innomar Edmonton Downtown	10665 Jasper Avenue, Suite 1370
Edmonton	Innomar Edmonton South	8215 – 112th Street, Suite 409
Edmonton	Innomar Edmonton West	8708 – 155th Street NW, Suite 001
Fort McMurray	Innomar Fort McMurray	8600 Franklin Avenue, Suite 511
Grande Prairie	Innomar Grande Prairie	9625-97th Street Suite 104
Grande Prairie	Inviva Access To Care	11745 – 105th Street
Lethbridge	Innomar Lethbridge Clinic	740 – 4th Avenue South, Suite 201
Lethbridge	Inviva Access To Care	740 – 4th Avenue S
Medicine Hat	Innomar Medicine Hat	770 – 6th Street SW, Suite 107
Red Deer	Innomar Red Deer (Assoc. Medical Group)	4320-50th Avenue Suite 204

City	Clinic	Address
Red Deer	Inviva Access To Care Red Deer	6900 Taylor Avenue
St Albert	Innomar St Albert	24 Inglewood Dr., Suite 201

Innomar Clinic Hours:

- Monday to Friday: 8 AM to 5 PM MST
- Weekend and evening hours by Appointment

Inviva Access To Care Clinic Hours:

- Monday to Friday: 8 AM to 8 PM MST
- Saturday by Appointment

Renflexis and Brenzys

The MERCK HARMONY Patient Support Program provides support services, including assistance from a dedicated coordinator to confirm coverage options and assist with co-pay and deductibles (for patients taking Renflexis or Brenzys), and to coordinate with infusion centres (for patients taking Renflexis) and assist with self-injection training (for patients taking Brenzys).

To enroll a patient, contact the MERCK HARMONY program central number and you will be directed to your assigned MERCK HARMONY Coordinator:

Hours: Monday to Friday, 9 am to 9 pm MST, Saturday and Sunday 1 pm to 6 pm MST

Phone: 1-866-556-5663

Fax: 1-866-240-4076

Email: info@merckharmony.ca

Alberta MERCK HARMONY Coordinators:

Beth-Anne Holbrook, LPN

Email: bethanne.holbrook@merckharmony.ca

Phone: 289-295-0711

Neveya Hoiness, BSc RN

Email: neveya.hoiness@merckharmony.ca

Phone 289-295-1075

For additional information on the MERCK HARMONY program, contact the Merck Patient Support Services Manager in Alberta:

Daina Kelm, BSc RN

Email: dkelm@naviego.ca

Phone: 780-222-0048

Table 3: Renflexis infusion clinic locations

City	Clinic	Address
Calgary	Bayshore – Calgary (North) ICN	1212 – 31 Avenue NE, Suite 105
Calgary	Bayshore – Calgary (South) ICN	1011 Glenmore Trail SW, Suite 404
Calgary	McKesson Calgary Bow River	4411 – 16th Avenue NW, Suite 160
Calgary	Inviva Calgary South Trail	4307 130th Avenue SE, Suite 82
Calgary	Shoppers Drug Mart Calgary NE	1645 – 32nd Avenue NE
Edmonton	Bayshore – Edmonton ICN	10230 – 142 Street NW, Suite 205
Edmonton	McKesson Millwoods	6203 – 28 Ave NW, Suite 208
Edmonton	The Bailey Health Centre – Also known as Gastroenterology Health Center	11010 – 101 Street, Suite 205B

City	Clinic	Address
Edmonton	McKesson Campus Tower	8625 - 112th Street
Edmonton	Coverdale Clinics Edmonton Hys	11010-101 Street N.W., Suite 206B
Edmonton	Coverdale Clinics West Edmonton	8944 - 182 Street, Suite 222
Grande Prairie	Bayshore – Grande Prairie ICN	10309 – 98th Street, Suite 101
Grande Prairie	McKesson Grande Prairie Oak Ridge Business Centre	11745 – 105th Street, Suite 205
Lethbridge	McKesson	740 – 4th Avenue S
Red Deer	Bayshore – Red Deer Infusion Clinic	4309 52 Avenue
Red Deer	McKesson Red Deer	6900 Taylor Drive

Non-exclusive infusion centres

Access to Care by INVIVA Coordinators:

Crystal Coffey, RN

Nurse Navigator for Access to Care by Inviva

Email: a2c@supportprogram.com

Phone: 1.833.262.1640 Ext. 10

Fax: 1.833.262.1642

Liza Ursini, RN

Nurse Navigator for Access to Care by Inviva

Email: a2c@supportprogram.com

Phone: 1.833.262.1640 Ext. 1011

Fax: 1.833.262.1642

Table 4: Access to Care by INVIVA Alberta Clinics

City	Clinic	Address
Calgary	Inviva Access To Care	4411 16th Ave NW
Calgary	Inviva Access To Care	4307 130th Ave SE
Lethbridge	Inviva Access To Care	740 4th Ave S
Edmonton	Inviva Access To Care	6203 28 Ave NW
Grand Prairie	Inviva Access To Care	11745 – 105th Street

Erelzi

The XPOSE® Patient Support Program provides support services to physicians / nurses and their patients through a single point of contact. Services include; assisting and securing coverage, financial assistance and educational materials for patients.

To enroll a patient or have any of your questions answered, please contact the XPOSE® program to speak to your personal case worker or nurse:

Hours: Monday to Friday, 6 am to 6 pm MST

Email: erelzi@xposeprogram.ca

Phone: 1-844-279-7673

Fax: 1-844-872-5771

You can also contact the XPOSE® your program field case manager nurse in Alberta:

Freda Kwaning, RN BN

Email: freda.kwaning@xposeprogram.ca

Phone: 1-844-279-7673 x 7468

Cell: 403-585-7182

Carolyn Gillis, RN

Email: carolyn.gillis@xposeprogram.ca

Phone: 1-844-279-7673 x 7411

Cell: 403-542-0748

Amy Fossey, RN

Email: amy.fossey@xposeprogram.ca

Phone: 1-844-279-7673 x 7254

Cell: 587-334-1537

Grastofil and Lapelga

ANSWERS Patient Support Program

Website: www.apoanswers.ca for an online version of the enrolment form

Hours: Monday to Friday, 6 am to 6 pm MST

Email: ANSWERS@innomar-strategies.com

Phone: 1-866-276-1664

Fax: 1-866-772-1458

Fulphila

Patient Support Program

Website: www.BiosimilarsCanadaPSP.com for an online version of the enrolment form

Hours: Monday to Friday, 6 am to 6 pm MST

Email: BiosimilarsCanada@innomar-strategies.com

Phone: 1-833-847-4323

Fax: 1-833-794-2382

Ziextenzo

Sandoz Canada Inc.'s Patient Support Program for Ziextenzo® is called the Bio Care Patient Support Program. The program provides support services to physicians / nurses and their patients through one point of contact; including assisting and securing coverage, financial assistance and educational materials for patients. The program offers injection services through a broad network of locations for greater patient accessibility. We also have an online portal that facilitates patient registration and tracking patient status.

The program operates Monday to Friday from 6 am to 6 pm MST

Bio Care Patient Support Program

Email: biocare@programsupport.ca

Phone: 1-833-726-3690

Fax: 1-833-726-3698

Truxima

Teva Canada Innovation's Patient Support Program for TRUXIMA is called the Truxima Teva Support Solutions – Patient Support Program. The program offers a range of services that include: educational materials for patients, reimbursement services, financial assistance and medical updates to prescribers.

The program operates from 6 am to 6 pm MST

Phone: 1 877 714 2469

Fax: 1 833 981-2254

Email: tss.info@truximacanada.com

Table 5: Truxima infusion clinic locations

City	Clinic	Address
Red Deer	Bayshore - Red Deer	4309 52nd Ave, suite 103,
Calgary (North)	Bayshore - Calgary North	A121 31 Ave NE, Suite 105
Calgary (South)	Bayshore - Calgary South	1011 Glenmore Trail SW, Suite 404
Edmonton	Bayshore - Edmonton	10230 142 St NW, Suite 2015
Grande Prairie	Bayshore - Grande Prairie	10309 98 St, Suite 1010
Fort McMurray	Bayshore - Fort McMurray	Suite 103, 9816 Hardin Street
Medicine Hat	Bayshore – Medicine Hat	770-6 Street SW. Suite #107 Opening in September 2020
Lethbridge	Coming soon	Opening in September 2020

Riximyo

Sandoz Canada Inc.'s Patient Support Program for Riximyo® is called the XPOSE® by Sandoz Patient Support Program. The program provides support services to physicians / nurses and their patients through a single point of contact. Services include; assisting and securing coverage, financial assistance and educational materials for patients. The program also offers infusion services and has secured a broad network of infusions centers for greater patient accessibility.

The program operates Monday to Friday from 6 am to 6 pm MST

Phone: 1-888-449-7673

Fax: 1-844-449-7673

Email: xpose@sandozprogramsupport.ca

Table 6: Riximyo infusion clinic locations

City	Clinic	Address
Airdrie	Coverdale - Airdrie	401 Cooper's Boulevard SW, Suite 1109 Building 1000
Barrhead	Coverdale - Barrhead	5607 47th St
Calgary	Coverdale - Calgary ANC	1608 17 Avenue SW, Suite 300
Calgary	Coverdale - Calgary Harvest Hills	178 96 Avenue NE, Suite 213
Calgary	Coverdale - Calgary Mission	2303 4th St SW, suite 604
Calgary	Coverdale - Calgary SE	220-8500 Blackfoot trail SE
Calgary	INVIVA - Bow River	4411 16th Ave NW Suite 160
Calgary	INVIVA - Seton	3815 Front Street SE # 233
Calgary	INVIVA - Midpark	290 Midpark Way SE Suite 110
Calgary	INVIVA - McKnight	3131 27th Street Unit 65
Calgary	SDM - Northeast Clinic	1645 32 AVE NE
Canmore	Coverdale - Canmore	50 Lincoln Park Avenue, suite 201
Edmonton	Coverdale - Edmonton Hys Centre	11010 101 Street NW, suite 206B
Edmonton	Coverdale - Edmonton South	4207 98th St NW, suite 102, Greystone Building 4
Edmonton	Coverdale - Edmonton West	8944-182 St, suite 222
Edmonton	INVIVA - Campus Tower	312 - 8625 112th St.
Edmonton	INVIVA - 124th Street A	10839 124th Street #110

City	Clinic	Address
Edmonton	INVIVA - Gateway Clinic	Building #110 (second floor), 6925 Gateway Boulevard NW
Edmonton	INVIVA - Millwoods	6203 28 Ave NW #208
Fort McMurray	Coverdale - Fort McMurray	8600 Franklin Ave, suite 604B, 2nd floor NOTE TEMP LOCATION - East Village Suite, 355 Loutit Road, suite 215
Grande Prairie	INVIVA - Grande Prairie	Oak Ridge Business Centre, 11745 105th St Suite 205
Lethbridge	INVIVA - Lethbridge	740 4th Ave S Suite 215
Lloydminster	Coverdale - Lloydminster	3602 51st Ave, suite 102
Medicine Hat	Coverdale - Medicine Hat	770 6th St SW, suite 202
Red Deer	Coverdale - Red Deer	4808 50th (Ross) St, unit 404
Red Deer	INVIVA - Red Deer	2827-30th Avenue, Suite1213
St. Albert	INVIVA - St. Albert	7 St. Anne Street #234

Ruxience

Pfizer's Patient Support Program for Ruxience is called PfizerFlex.

Hours: Monday to Friday, 6 am to 6 pm MST

Phone: 1 855 935 3539 or 1 855 935 FLEX

Fax: 1 833 958 3539 or 1 833 958 FLEX

Email: ruxience@pfizerflex.com

Website : https://www.pfizerflex.ca/

Table 7: Ruxience infusion clinic locations

City	Clinic	Address
Calgary	Innomar Calgary North	8555 Sculfield Dr. NW, Suite 209
Calgary	Innomar Calgary South	1011 Glenmore Trail SW, Suite 311
Calgary	Innomar Calgary NE	2675 36th street NE Suite 306
Calgary	Shoppers Drug Mart Specialty Health	1645 – 32nd Ave NE
Calgary	Specialty RX	Holy Cross Centre 2204 – 2nd Street SW
Canmore	Innomar Canmore	1001 – 6th Avenue, Suite 105
Edmonton	Rheumatology Research Associates	10839 – 124th Street
Edmonton	Innomar Edmonton Downtown	10665 Jasper Avenue, Suite 1370
Edmonton	Innomar Edmonton South	8215 – 112th Street, Suite 409
Edmonton	Innomar Edmonton West	8708 – 155th Street NW, Suite 001
Fort McMurray	Innomar Fort McMurray	8600 Franklin Avenue, Suite 511
Grande Prairie	Innomar Grande Prairie	9625-97th Street Suite 104
Lethbridge	Innomar Lethbridge Clinic	740 – 4th Avenue South, Suite 201
Medicine Hat	Innomar Medicine Hat	770 – 6 Street SW, Suite 107
Red Deer	Innomar Red Deer (Assoc. Medical Grp)	4320 50th Avenue Suite 204
St Albert	Innomar St Albert	24 Inglewood Dr., Suite 201

Innomar Clinic hours:
Monday to Friday: 8 AM to 5 PM MST
Weekend and evening hours by Appointment

Glatect

The Ally Patient Support Program has been designed to provide Canadian Multiple Sclerosis (MS) patients and their healthcare professionals, a highly efficient and value-added service aimed at insuring rapid treatment onset and sustained medication compliance on Glatect.

The program operates from 6 am to 6 pm MST

Phone: 1-833-ALLY100 (1-833-255-9100)

Email: ally@patientassistance.ca

Website: https://glatect.com/en/all-about-the-ally-program/

For questions regarding Glatect please contact the *Pendopharm* Medical Information Department

Toll free: 1-888-550-6060

Email: medinfo@pendopharm.com

Special authorization changes - Tiering

Effective immediately, patients seeking to change their current treatment to a biologic drug will be required to try a number of first-line therapeutic options prior to being able to access a second-line agent. This change will provide value for Alberta's government sponsored drug programs while maintaining prescriber and patient choice.

Change process

There are a number of biologics that will have changes to their special authorization criteria. These changes will not apply to patients currently using these biologics for the indications noted but will apply to patients seeking to change their current treatment. The special authorization criteria changes apply to the following drugs and will require patients to try a number of first-line therapeutic options prior to gaining access to these Tier 2 drugs:

- Stelara for the treatment of plaque psoriasis,

For a new patient seeking biologic therapy or for an existing patient seeking to change their current treatment, the patient must trial the number of drugs in Tier 1 equal to the number of different mechanisms of action of the Tier 1 drug products prior to accessing a Tier 2 drug. Please refer to Table 4 below. For example: there are 3 unique mechanisms of action for the drugs in Tier 1 for plaque psoriasis. Patients must trial at least 3 drugs in Tier 1 before accessing the Tier 2 drugs. The 3 drugs to be trialed in Tier 1 can be the same mechanism of action or different mechanisms of action.

For existing patients that are currently on a Tier 2 drug and fail therapy, they must trial the number of drugs in Tier 1 equal to the number of different mechanisms of action of the Tier 1 drug products prior to accessing another Tier 2 drug.

Prescribers may request an exception to Tiering by submitting the Special Authorization request form for the preferred Tier 2 drug to Alberta Blue Cross:

- If the patient unable to trial a Tier 1 drug due to a medical reason, or
- If the patient is new to a government-sponsored drug plan and is currently stable on a Tier 2 drug.

For the most current Special Authorization criteria, consult the Interactive Drug Benefit List and search the drug name.

Special Authorization Criteria Changes – Flowchart

For a new patient seeking biologic therapy, the patient must trial the number of drugs in Tier 1 equal to the number of different mechanisms of action of the Tier 1 drug products prior to accessing a Tier 2 drug.

For example: there are two unique mechanisms of action for the drugs in Tier 1 for plaque psoriasis. Patients must trial at least 2 drugs in Tier 1 before accessing Tier 2 drugs.

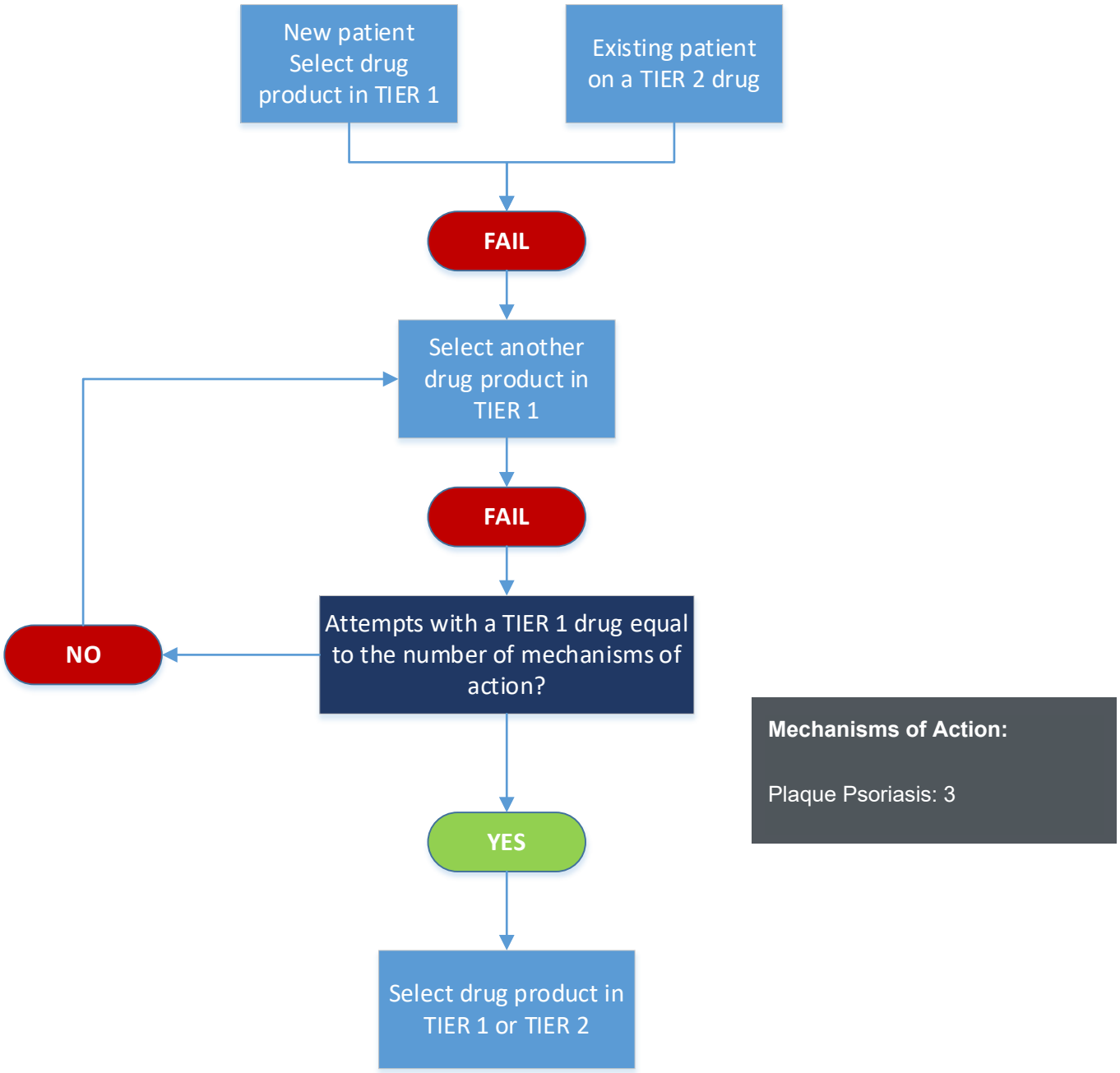

Table 4: Tier 1 and Tier 2 drugs by indication

Indication/ Health Condition	Drugs in Tier 1 Brand Name (generic name) [mechanism of action target]	Drugs in Tier 2 Brand Name (generic name) [mechanism of action target]
Dermatology (Plaque Psoriasis)	• Cosentyx (secukinumab) [IL-17A] • Erelzi (etanercept) [TNF] • Humira (adalimumab) [TNF] • Inflectra (infliximab) [TNF] • Renflexis (infliximab) [TNF] • Skyrizi (risankizumab) [IL-23] • Taltz (ixekizumab) [IL-17] Number of Tier 1 drugs that must be trialed: 3	• Stelara (ustekinumab) (IL12&23)

Abbreviations: Tumor Necrosis Factor- alpha (TNF), Interleukin-12 (IL12), Interleukin-17 (IL-17 & IL-17A), Interleukin-23 (IL-23

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 professional 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.

Subsequent entry non-biologic complex drugs

Non-biologic complex drugs (NBCD) are synthetic compounds that contain different closely related molecular structures often with nanoparticular properties. They cannot be fully characterized by physiochemical analytical means. Like biosimilar drugs, subsequent entry NBCD enter the market following an approved originator brand version, and must demonstrate similarity in safety and efficacy to their originators.

Safety and efficacy

Biosimilars have been used in Canada for 10 years and many other countries including the United States, Australia, the United Kingdom and in the European Union for more than 13 years. Recently, the government 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

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