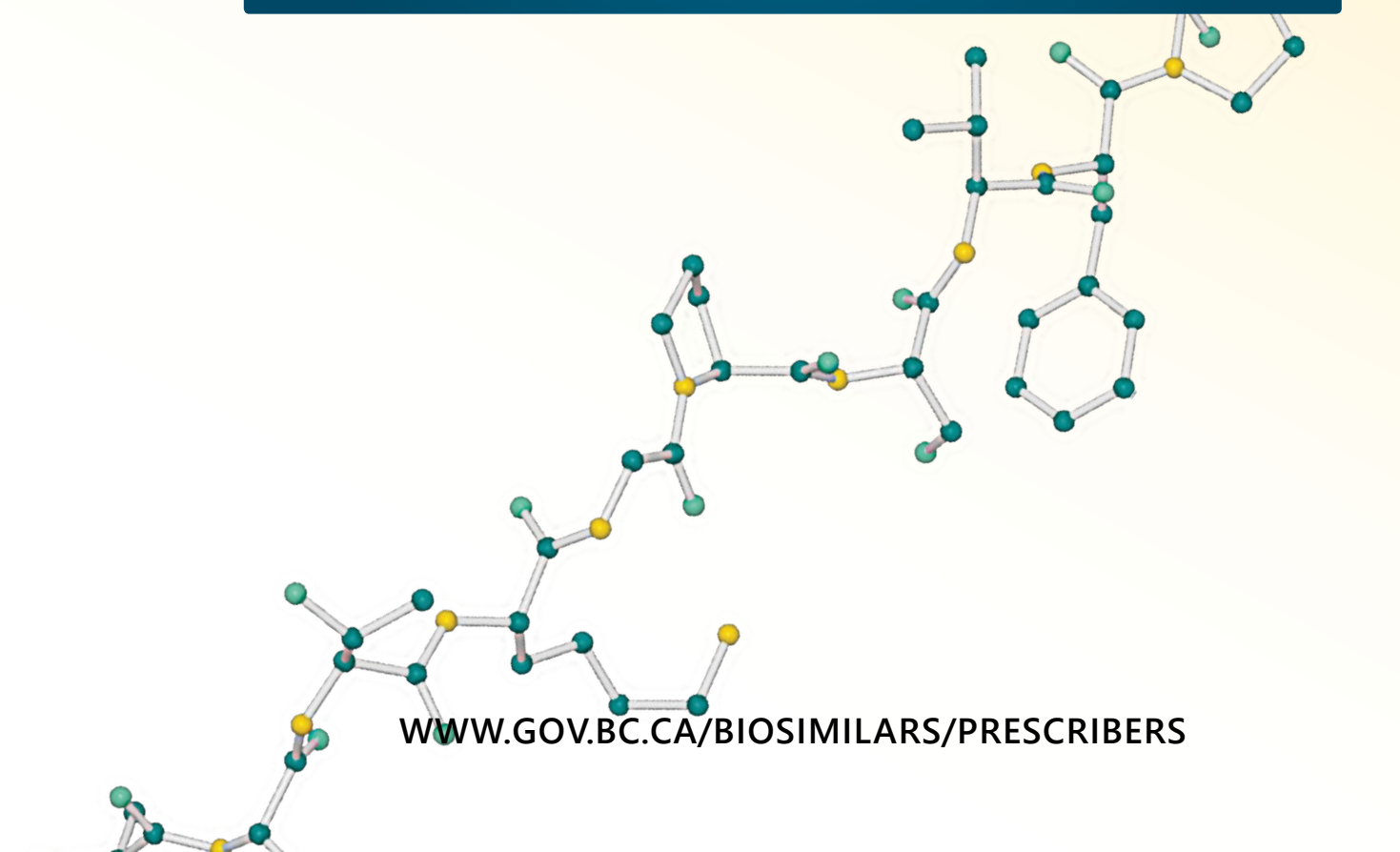
BIOSIMILARS INITIATIVE

PRESCRIBER GUIDE

Gastroenterologists & Internal Medicine Specialists



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BC PHARMACARE BIOSIMILARS INITIATIVE

PRESCRIBER GUIDE: GASTROENTEROLOGISTS & INTERNAL MEDICINE SPECIALISTS

In This Guide

Across Canada, biologic drugs are a major contributor to healthcare costs increasing at an unsustainable rate. In 2017, Canada spent over $1.1 billion on Remicade® alone—more than on any other drug. With new drugs frequently entering the market (including new biologics and innovative therapies), the cost pressures for Canada's drug plans will only continue to increase.

One solution to this challenge is already available: biosimilar versions of originator biologic drugs offer significant cost savings. In B.C., infliximab biosimilars are priced 50% lower than Remicade.

Despite these price differences, biosimilars have not yet captured much market share in Canada. At the end of 2018, infliximab biosimilars (approved in Canada since January 2014) accounted for only 8.1% of infliximab use.

Biosimilar uptake has been limited by many factors, including misconceptions about the safety and efficacy of biosimilars and reluctance to change the status quo.

B.C.'s previous strategy to encourage biosimilar uptake by listing those brands preferentially for treatment-naïve patients has been well-received; however, the impact of this strategy is limited by the small proportion of new starts.

With an ever-growing body of evidence and the support of many stakeholders, PharmaCare is now positioned to enable the expansion of treatment options and the improvement of patient access by introducing the Biosimilars Initiative.

The Biosimilars Initiative changes coverage for specific biologic drugs. Patients and their prescribers have a period of 6 months to discuss switching from an originator brand to a biosimilar brand. Coverage and Special Authority (SA) approval is provided for both originator and biosimilar brands during the switch. Patients unable to switch or who have an adverse response to the biosimilar(s) can seek exceptional SA coverage for the originator.

PharmaCare's strategy to ensure a successful switch includes:

- Involving various practitioners in patient identification, education and support
- Providing time to identify affected patients and guide them through the switch process
- Ensuring patient supports are in place for continuous care
- Having options for those unable to switch or experience challenges with switching
- Identifying areas of concern and providing information for both patients and practitioners
- Providing call-in information sessions and responsive contacts for healthcare practitioners
- Monitoring drug utilization, patient outcomes, and stakeholder feedback

The role of the prescriber in the switch process is paramount. A prescriber sets the tone of the switch discussion, serving as the primary and most trusted information source, facilitates continuity of care, and empowers the patient to expect and realize the best outcomes.

Health Canada encourages patients to discuss any questions about switching from one biologic drug to another with their healthcare professional. PharmaCare has created this guide to provide information to support your discussions with affected patients.

(National statistics referenced in the section above are found in the Patented Medicine Prices Review Board *Meds Entry Watch 2017* report.)

What is changing?

PharmaCare is changing coverage of certain biological drugs, including infliximab.

Coverage for the original biologic (originator) drugs will be discontinued for affected patients, and coverage will instead be provided for their biosimilars:

PHASE 1: May 27 to November 25, 2019			
Drug	**Originator**	**Biosimilars**	**Indications Affected**
etanercept	Enbrel®	Brenzys®	Ankylosing Spondylitis Rheumatoid Arthritis
		Erelzi™	Ankylosing Spondylitis Psoriatic Arthritis* Rheumatoid Arthritis
infliximab	Remicade®	Inflectra® Renflexis®	Ankylosing Spondylitis Plaque Psoriasis Psoriatic Arthritis Rheumatoid Arthritis
insulin glargine	Lantus®	Basaglar™	Diabetes (Type 1 and 2)

*At this time, Erelzi is the only etancercept biosimilar with an approved indication for psoriatic arthritis.

For affected patients with existing SA approval for etanercept or infliximab to maintain their coverage, prescribers must write a new prescription, indicating the switch to a biosimilar option. The patient's existing SA remains in effect until the next renewal date (if applicable).

New SA requests and renewals for etanercept and infliximab will be granted for biosimilar brands only.

At this time, coverage of insulin glargine is also changing to biosimilar Basaglar™, and coverage of Lantus® will be discontinued. If your patients may be affected by this change in addition to their infliximab or etanercept, please encourage them to speak with their endocrinologist, general practitioner, nurse practitioner, or Diabetes Education Centre.

In Phase 2 of the Biosimilars Initiative, PharmaCare is changing coverage for patients taking Remicade for Crohn's disease or ulcerative colitis. The switching of Remicade patients has been designed in two phases to allow for stakeholder engagement and ensure that switch support resources have capacity to address patient and prescriber needs. Additionally, the Ministry of Health has added coverage of Fecal Calprotectin (FC) testing and nursing support fees to improve patient care for Inflammatory Bowel Disease (IBD) patients.

PHASE 2: September 5, 2019 to March 5, 2020			
Drug	**Originator**	**Biosimilars**	**Indications Affected**
infliximab	Remicade®**	Inflectra® Renflexis®	Crohn's Disease Ulcerative Colitis

**Pediatric patients on Remicade will be switched to an infliximab biosimilar. PharmaCare is working closely with B.C. Children's Hospital to accomplish this, and pediatric patients may not be switched on the same timeline as adult patients.

When do these changes take effect?

Crohn's disease and ulcerative colitis patients using Remicade who wish to maintain PharmaCare coverage must switch to either Inflectra or Renflexis before March 6, 2020.

All three brands of infliximab, originator and biosimilar, will be covered during the phase two switch period (September 5, 2019 to March 5, 2020) to provide time for patients to discuss the switch with their prescriber and get a new prescription. Remicade will no longer be covered for affected patients as of March 6, 2020.

If you are unable to discuss the switch with a specific patient before the end of the switch period, please submit an SA request explaining the need for an extension.

Who will be affected?

Your patients will be affected by the biosimilars switch beginning September 5, 2019, if they:

- have Crohn's disease or ulcerative colitis, and
- use Remicade, and
- receive PharmaCare coverage (i.e., have existing SA for infliximab)

Why is coverage changing?

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.

In B.C., the biologic drugs being switched (Lantus, Enbrel, and Remicade) represent some of the largest provincial drug expenditures. In 2018, PharmaCare spent $125 million on just these three originator drugs.

Despite being listed preferentially for new starts, the biosimilars for these drugs have captured only a fraction of the market: Basaglar represented only 1.7% of 2018 insulin glargine PharmaCare expenditures, Brenzys and Erelzi only 6.8%, and Inflectra and Renflexis only 5.9%.

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.

How do patients access Fecal Calprotectin testing?

As of August 15, 2019, all biologic patients are eligible for fully covered FC laboratory testing. This test is intended to improve gastrointestinal patient care. LifeLabs will be the first B.C. provider offering FC testing, which must be ordered for each patient by the prescriber. For more details on FC testing, see www.bcaplm.ca

How can I identify which of my patients will be affected?

To assist in identifying which of your patients you may need to speak with about biosimilar switching, we can send you a list of PharmaCare-covered patients who have filled a prescription for Remicade, written by you, in the past 6 months.

Please complete and submit the enclosed *HLTH 5841 Patient List Request* form. Within two weeks, we will send you a list of the names of patients who may be affected by biosimilar switching.

Will patients need new Special Authority approval?

Patients with existing SA for infliximab do not require a new SA for the biosimilar version of their medication. The existing SA remains in effect until the next scheduled renewal date (if applicable).

If a patient's SA expires during the switch period, it will be renewed for biosimilars only.

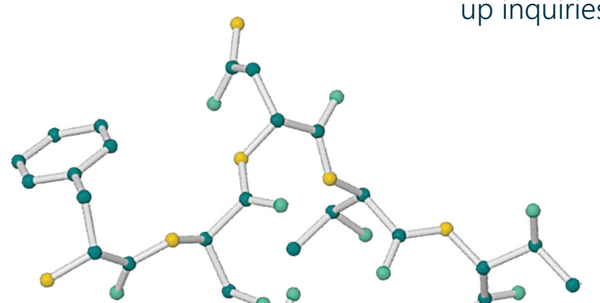
Note that patients are expected to trial a biosimilar. If a trial has been attempted and halted, the rationale for halting the trial must be well documented in the request for exceptional coverage, and be unlikely to recur or intensify if the patient resumes taking the originator.

Patients with a clinical requirement that prevents switching can have their prescriber submit a new SA request for exceptional coverage of the originator biologic. Exceptional requests will be reviewed by Special Authority on a case-by-case basis.

What is the Biosimilars Patient Support Fee?

The Biosimilar Patient Support Fee is a $50 fee billable to MSP in addition to other services billed on the same date of service, using the Teleplan claims system. They are being offered in recognition of the additional effort involved in contacting patients and supporting their switch to a biosimilar. This fee can be claimed once per affected patient during the transition period, regardless of whether that patient switches to a biosimilar.

- Biosimilar Patient Support Fee: Remicade to Biosimilar Infliximab
  Fee code: **97009**
  Effective: September 5, 2019–March 5, 2020
  Limited to: Gastroenterologists, Internal Medicine Specialists



What is the Nursing Support Fee?

Gastroenterologists are also able to bill MSP for nursing staff to support care of GI patients. This is a $60.00 fee payable once every six months for patients with a confirmed diagnosis of Crohn's disease or ulcerative colitis. The fee (**fee code 97012**) must be billed in addition to a consultation or visit on the same date of service and is only payable when a Registered Nurse or Licensed Practical Nurse is present. Claims must include the ICD-9 code for IBD (555 or 556).

What do I need to do to switch patients?

To switch your patients to a biosimilar:

1. Identify an affected patient.
2. Discuss switching to a biosimilar with the patient.
3. Write your patient a new prescription, clearly indicating the discontinuation of the originator and start of the biosimilar brand chosen.
4. Initiate enrolment in the patient support program for the biosimilar (if applicable).
5. Submit the Biosimilar Patient Support Fee with your MSP billing.
6. For any patients unable to switch, submit a new SA request for exceptional coverage of Remicade.

What about patients who cannot switch to a biosimilar?

For patients with a clinical requirement that prevents switching, you can request exceptional coverage of Remicade by submitting a new SA request (*HLTH 5368* for Crohn's disease, *HLTH 5388* for ulcerative colitis) and clearly identifying why the patient is unable to switch.

Exceptional requests will be reviewed by Special Authority on a case-by-case basis. After an initial review by SA pharmacists, any requests requiring additional input will be submitted to the Drug Benefit and Adjudication Advisory Committee for review by a panel of three gastroenterologists.

Exceptional requests should be submitted as soon as possible to allow for review, follow-up inquiries, and to ensure uninterrupted coverage.

What patient support programs are available for biosimilars?

Biosimilar manufacturers are committed to minimizing the impact of this initiative for both patients and prescribers, especially regarding patient support program processes and services, as well as access to infusion centres. For more information, support, and enrollment forms and assistance, contact the patient support programs below.

INFLECTRA
The Inflectra Patient Assistance Program provides support services, including coordination with private payers and infusion centres, for patients taking Inflectra. After you submit the enrolment form on behalf of your patient, they will be contacted by an Inflectra Navigator.

Phone: 1-844-466-6627 | Fax: 1-844-295-0219 | Email: inflectrasupport@innomar-strategies.com
Hours: Monday to Friday, 5:00 a.m. to 5:00 p.m. PST

B.C. Inflectra Navigators

- Marlena Giordano: District Manager, B.C. and Ontario
  mgiordano@innomar-strategies.com, 1-416-452-3464
- Zunobia Shafiqe: District Manager/Inflectra Navigator, Vancouver and Lower Mainland
  zshafiqe@innomar-strategies.com, 1-604-347-8815
- Kelly Blumeschein: Inflectra Navigator, Kelowna and Kamloops
  kblumenschein@innomar-strategies.com, 1-250-300-1313
- Jennifer Bayntun: Inflectra Navigator, Vancouver
  jbayntun@innomar-strategies.com, 1-604-340-3795
- Jennifer Paronen: Inflectra Navigator, Vancouver Island
  jparonen@innomar-strategies.com, 1-250-418-5549

RENFLEXIS
The Merck Harmony® Patient Support Program provides support services, including coordination with private payers (for patients taking Renflexis or Brenzys), infusion centres (for patients taking Renflexis), and self-injection training (for patients taking Brenzys). To enroll a patient, contact the Merck Harmony® central number, and you will be directed to your assigned coordinator.

Phone: 1-866-556-5663 | Fax: 1-866-240-4076 | Email: info@merckharmony.ca
Hours: Monday to Friday, 8:00 a.m. to 8:00 p.m. PST
Saturday and Sunday 12:00 p.m. to 5:00 p.m. PST

B.C. Merck Harmony Coordinators

- Bobbie Uppal: bobbie.uppal@merckharmony.ca, 1-289-295-0709
- Kristina Leckie: kristina.leckie@merckharmony.ca, 1-289-295-0696
- Beth-Anne Holbrook: bethanne.holbrook@merckharmony.ca, 1-289-295-0711
- Meghan Keenan: meghan.keenan@merckharmony.ca, 1-289-295-0702
- Sara Boychuk: sara.boychuk@merckharmony.ca, 1-289-295-0707

For additional information, contact the B.C. Patient Support Program Managers:

- Rose Wilbee: rose.wilbee@merck.com, 1-604-999-1164
- Baloo Dosanjh: baloo.dosanjh@merck.com, 1-604-999-1173

Will patient access to infusion centres change?

Patients receiving their Remicade infusions at a BioAdvance clinic will move to a new infusion centre as part of their biosimilar switch. The patient support program will coordinate this change. Infusion centres are available across the province:

INFLECTRA		
City	**Clinic**	**Address**
Abbotsford	InnomarClinics™ Abbotsford	2168 McCallum Road, Unit 2
Burnaby	InnomarClinics™ Burnaby	7885-6 Street, Suite 208
Chilliwack	InnomarClinics™ Chilliwack	45800 Promontory Road, Suite 203
Courtenay	InnomarClinics™ Courtenay	1350 England Avenue, Suite 101
Courtenay	PerCuro Clinical	104-1350 England Avenue
Cranbrook	InnomarClinics™ Cranbrook	44-12 Avenue S
Delta	InnomarClinics™ Delta-Surrey	6345-120 Street, Suite 115
Kamloops	InnomarClinics™ Kamloops	546 St. Paul Street, Suite 160
Kelowna	InnomarClinics™ Kelowna	3001 Tutt Street, Suite 303
Nanaimo	InnomarClinics™ Nanaimo	1450 Waddington Road, Suite 202
North Vancouver	InnomarClinics™ North Vancouver	145-15 Street W, Suite 101
Penticton	InnomarClinics™ Penticton	1496 Balfour Street
Penticton	Penticton Infusion Clinic	577 Carni Avenue
Prince George	InnomarClinics™ Prince George	1811 Victoria Street, Suite 306
Richmond	InnomarClinics™ Richmond	6091 Gilbert Road, Suite 440
Vancouver	Artus Health Centre	839 West Broadway
Vancouver	InnomarClinics™ Vancouver-Fairmont	750 West Broadway Avenue, Suite 1406
Vancouver	Pacific Gastroenterology Associates	1190 Hornby St., Suite 770
Vancouver	Mary Pack Arthritis Clinic	895 West 10 Avenue
Vernon	InnomarClinics™ Vernon	3210-25 Avenue, Suite 304
Victoria	InnomarClinics™ Victoria	1590 Cedar Hill Cross Road, Suite 330
Victoria	PerCuro Clinical	305-1120 Yates Street
Victoria	PerCuro Clinical	2349 Millstream Road
West Vancouver	InnomarClinics™ West Vancouver	520-17 Street, Suite 202

RENFLEXIS		
City	**Clinic**	**Address**
Abbotsford	Bayshore Abbotsford ICN	2151 McCallum Road, Suite 401
Burnaby	Bayshore Burnaby ICN	3825 Sunset Street, Suite 206
Chilliwack	Bayshore Chilliwack ICN	9181 Main Street, Suite 101
Courtenay	Bayshore partner Courtenay (ICN)	1350 England Avenue, Suite 104
Kamloops	WeCare Clinic	1315 Summit Drive, Suite 103
Kelowna	Bayshore Kelowna ICN	3001 Tutt Street, Suite 210
Nanaimo	Bayshore Nanaimo ICN	1650 Terminal Ave N, Suite 204
New Westminster	Bayshore New Westminster ICN	301 Columbia Street E, Suite 104
North Vancouver	Bayshore North Vancouver ICN	168 13th Street East, Suite 210
Penticton	Penticton Infusion Clinic	577 Carmi Ave
Richmond	Bayshore Richmond ICN	6051 Gilbert Road, Suite 301
Sidney	Bayshore Sidney ICN	9840 Fifth Street, Suite 102

(clinics continued on next page...)

RENFLEXIS		
City	**Clinic**	**Address**
Surrey	Bayshore Surrey ICN	13710 94A Avenue, Suite 307
Vancouver	Artus Health Centre	839 West Broadway
Vancouver	Bayshore Vancouver ICN	555 West 12 Avenue, Suite 410
Vancouver	Mary Pack Arthritis Clinic	895 West 10 Avenue
Vancouver	Pacific Gastroenterology Associates	1190 Hornby Street, Suite 770
Vernon	Bayshore Vernon ICN	2306 Hwy 6, Suite 225
Victoria	Bayshore Victoria ICN	1900 Richmond Road, Suite 380
Victoria	Bayshore partner Langford (ICN)	2349 Millstream Road, Suite 105
Victoria	Bayshore partner Victoria (ICN)	1120 Yates Street, Suite 305

What evidence supports biosimilar adoption and switching?

The safety, efficacy, immunogenicity, and therapeutic similarity of biosimilars is supported by a large body of clinical evidence, extensive post-market pharmacovigilance, as well as the results of switch programs in other jurisdictions.

Additional reading and study summaries are available online at www.gov.bc.ca/biosimilars/prescribers.

The Ministry will be carefully monitoring drug utilization, patient outcomes, and the response from patients and healthcare practitioners during and after biosimilar switching in B.C.

Will this be the only biosimilar switch?

In Phase 1 of the Biosimilars Initiative, the focus is on switching all Lantus users, patients using Remicade for rheumatological or dermatological indications, and those using Enbrel for rheumatological indications.

In Phase 2 of the Biosimilars Initiative, the focus is on switching patients using Remicade for GI indications.

It is likely that further switches to biosimilars will occur for other indications and drugs. All switches will be planned in consultation with the affected prescribers and stakeholders.

> "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."
>
> European Medicines Agency
> *Biosimilars in the EU: Information Guide for Healthcare Professionals*, 2017

What is the nocebo effect and how can I help prevent it?

The greatest hurdle for successful switch to a biosimilar is the potential for the nocebo effect, where a patient's negative expectations both psychologically and physiologically affect the outcomes of and adherence to their treatment.

Patients' pre-existing beliefs, previous healthcare experiences, and mindset can have a very real effect on symptoms and their sense of wellbeing.

Many factors contribute to a patient's likelihood of experiencing the nocebo effect:

- Patient factors, such as other mental health comorbidities (especially anxiety, depression, or cognitive impairment), language barriers, a history of negative interactions with the healthcare system, or the use of online media as a source of medical information (where negative responses are highly over-represented, and bias or misrepresentation go unchecked).
- Practitioner factors, such as language choices, manner, non-verbal communication, or unbalanced focus on potential adverse reactions.
- Health care setting factors, such as the physical environment, comfort, ease of access, and interactions with other staff and patients.
- Drug factors, such as an appearance or smell, administration route or routine, change in delivery device, labelling, and price.

A variety of strategies can be effective in preventing the nocebo effect:

- Empower people with information and an active role in the switch process.
- Be attentive and empathetic, so patients feel safe asking questions or expressing concerns.
- Balance the presentation of desired effects and adverse effects.
- Promote a neutral or positive outlook instead of reiterating fears.
- Acknowledge the nocebo effect itself.
- Speak face-to-face, when possible.
- Discuss a plan for follow-up, acknowledging that there are options, no matter the outcome.

In international studies, the nocebo effect was of particular note in the treatment of rheumatoid arthritis, where patient-reported outcomes were central to assessing response to a drug and fewer objective clinical measures exist.

How can I support patients with questions and concerns?

Patient acceptance of biosimilars is, understandably, easier to achieve among treatment-naïve patients started on a biosimilar. Treatment-experienced, stable patients using an originator biologic may require more support.

The best response to any concern your patient may have is your expertise and experience as a healthcare practitioner, as well as the provision of additional information. Patients who feel they understand the change and why it's necessary, who trust their practitioners, and who understand that there is a support plan in place are more positive and achieve better outcomes.

PharmaCare has created a brief patient information sheet for you to provide to patients to summarize the change and direct them to more detailed resources available at www.gov.bc.ca/biosimilars. Included later in this guide is a biosimilars primer that may be useful in explaining biosimilars to your patients.

The most critical information usually required by patients is that biosimilars:

- are safe and effective
- will work like their current medication
- have no additional risk of adverse reactions or immunological response
- do not require significant changes to their routines or dosing
- are accompanied by patient support programs that will help them with benefits coordination, scheduling, access, etc.
- are available at infusion centres near them (though it may be a different infusion centre than they currently attend)
- are well-understood, that switching from an originator has been extensively studied, and that switch programs have been successful around the world

Other resources for you and your patients are available at **www.gov.bc.ca/biosimilars/prescribers**.

It is important to recognize this is a switch process (not a substitution policy), where patient and practitioner education, collaborative decision making, and exception options for those who need them are key. Practitioners are essential in empowering patients with information, demonstrating that there is a support system in place, and setting people up for success.

> "Health Canada has not observed unexpected post-authorization safety signals for biosimilars marketed in Canada. The efficacy and safety profiles of biosimilars authorized in Canada remain in line with those of their reference biologic drugs."
>
> *Health Canada Fact Sheet: Biosimilars 2019*

Where can I find more resources for my patients?

A library of patient resources is available online at **www.gov.bc.ca/biosimilars**. Here they can find detailed information about:

- the Biosimilars Initiative
- how they may be affected
- biologic and biosimilar drugs
- answers to frequently asked questions
- other resources and reading (including materials developed by patient groups)

If you require additional printed patient information sheets, please contact us at **Biosimilars.Initiative@gov.bc.ca** or **1 844 915-5005** Monday to Friday, 8:30AM-4:30PM.

What if I have questions or need more information?

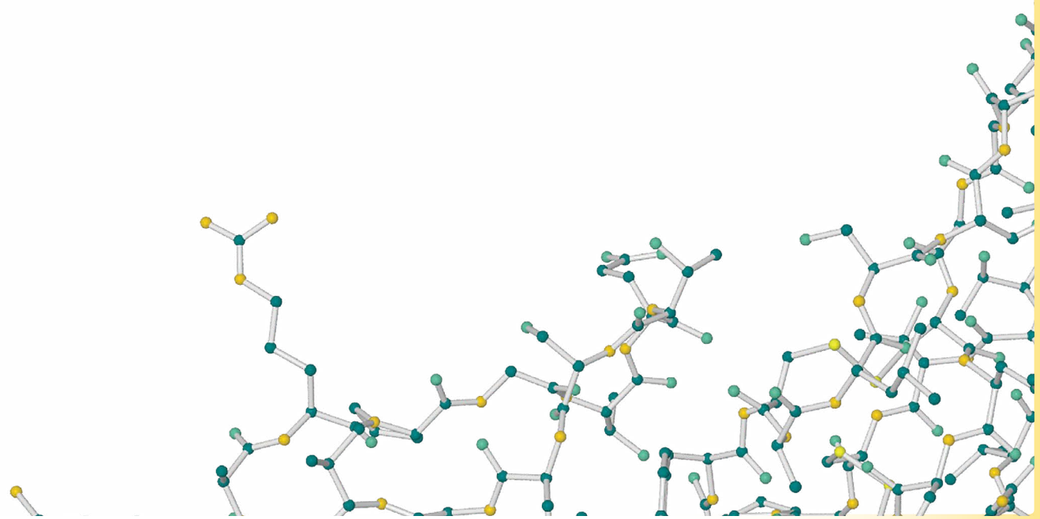
PharmaCare is committed to supporting and working with healthcare practitioners throughout the Biosimilars Initiative.

Additional information is available at **www.gov.bc.ca/biosimilars/prescribers.**

Call-in information sessions, hosted by members of the PharmaCare team and specialist physicians, will be scheduled throughout the transition period. An up-to-date schedule of information sessions will be available at the link above. If you wish to be notified when dates are posted, please click the subscribe button on the right-hand side of the page for alerts.

Call-in numbers can be found in the prescriber guide sent to you and will not be posted online to ensure that prescribers receiving the guide have priority access to information sessions.

For more questions and feedback, contact the PharmaCare team at **Biosimilars.Initiative@gov.bc.ca** or **1 844 915-5005** Monday to Friday, 8:30AM—4:30PM.



BIOSIMILAR BASICS

A PRIMER FOR PATIENT DISCUSSIONS

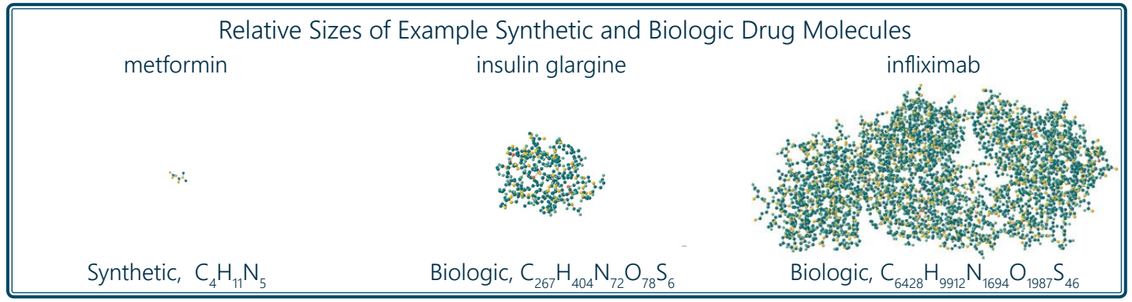
What is a biologic drug?

Most drugs (like aspirin, metformin, antibiotics, etc.) are considered synthetic drugs, where certain chemicals can be combined in a lab using a set recipe. The result is a consistent drug product composed of relatively small molecules that can be easily tested to ensure everything is identical in composition and potency across different batches and different manufacturers.

Biologic drugs were first introduced in the 1980s, as advancements allowed scientists to manipulate other organisms' cells and better identify complex compounds and feedback systems involved in human metabolism and disease processes.

Biologic drugs are produced by engineering a living cell line (like bacteria, yeast, or mammal cells, etc.) to produce a specific protein compound that is then collected and purified for human use. These protein compounds are very large and complex compared to synthetic drugs.

Biologic drugs have created new fields of research and disease treatment, providing more and better options for cancer treatment and the management of chronic diseases like rheumatoid arthritis, Crohn's disease, and diabetes.



What is a biosimilar drug?

Like with synthetic drugs, when a unique biologic drug is no longer protected by patents, other manufacturers can begin to produce the protein compound under a different brand name. These new versions of a biologic drug are called biosimilars.

Biosimilars are designed to be highly similar to the biologic originator and have no difference in effect. Because biologics are so complex, both to manufacture and in structure, it is not possible to demonstrate that a biologic originator and its biosimilar are perfectly identical. (Nor is it possible to demonstrate that a batch of any biologic—originator or biosimilar—is identical to its previous batches).

Producing biosimilars builds on the work already done for the biologic originator, and therefore requires less investment into research and development. This means the biosimilar product can be offered at a lower cost, providing patients and the healthcare system better value for the same benefit.

> "Patients and health care providers 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."
>
> Health Canada
> *Fact Sheet: Biosimilars*
> 2019

How is a biosimilar drug proven to be as safe and effective as the originator?

Health Canada's rigorous requirements demand that a biosimilar demonstrate that there are no clinically meaningful differences in terms of physiochemical structure, quality, potency, pharmacokinetics, and immunogenicity. Clinical efficacy studies must demonstrate that the therapeutic effects of the biosimilar (both risk and benefit) are consistent.

After a drug is approved for sale, post-market analyses and studies can further demonstrate no meaningful differences in clinical efficacy between a biosimilar and the originator. These studies are common in the European Union, where biosimilars have been in use longer and have a higher adoption rate.

Are biosimilars interchangeable with their biologic originator?

As biosimilars cannot be proven to be identical to their biologic originator, they are not classified as interchangeable; that is, a pharmacist could not substitute one for the other at the pharmacy level without involvement of the prescribing physician.

Biosimilars and their originator biologics are proven to have no clinically meaningful differences in function or effect, meaning that switching from one to another is appropriate at the direction of the prescribing physician, in collaboration with the patient.

> "Health Canada considers a well-controlled switch from a reference biologic drug to a biosimilar in an approved indication to be acceptable, and recommends that a decision to switch a patient being treated with a reference biologic drug to a biosimilar, or between any biologics, be made by the treating physician in consultation with the patient and take into account any policies of the relevant jurisdiction."
>
> *Health Canada's 2017 Biosimilars Workshop: Summary Report*

What are the benefits of biosimilars?

Biosimilars offer major cost savings to the healthcare system, which allows for improved access to drug therapies for more people who need them. Biosimilars also contribute to a healthy and competitive drug market in Canada, supporting diversification of drug products and manufacturers, as well as driving both demand and capacity for newer, better drugs.

WHAT OFFICIALS ARE SAYING ABOUT BIOSIMILARS

"Policies and position statements on biosimilars are evolving to reflect increasing experience with and confidence in biosimilars as a treatment option."

Health Canada's 2017 Biosimilars Workshop: Summary Report

"By increasing treatment options, biosimilars can enhance competition in the market for biological products without reducing incentives to innovate."

U.S. Food and Drug Administration
Biosimilars Action Plan: Balancing Innovation and Competition
July 2018

"Biosimilars have been used safely for many years. Regulators monitor the safety of all medicines on the market, including biosimilars, to protect the health and safety of patients."

International Coalition of Medicines Regulatory Authorities: Biosimilars Statement 2019

"Patients and their physicians can expect that there will be no clinically meaningful differences between taking a reference product and a biosimilar when these products are used as intended."

U.S. Food and Drug Administration
Prescribing Biosimilar Products
2019

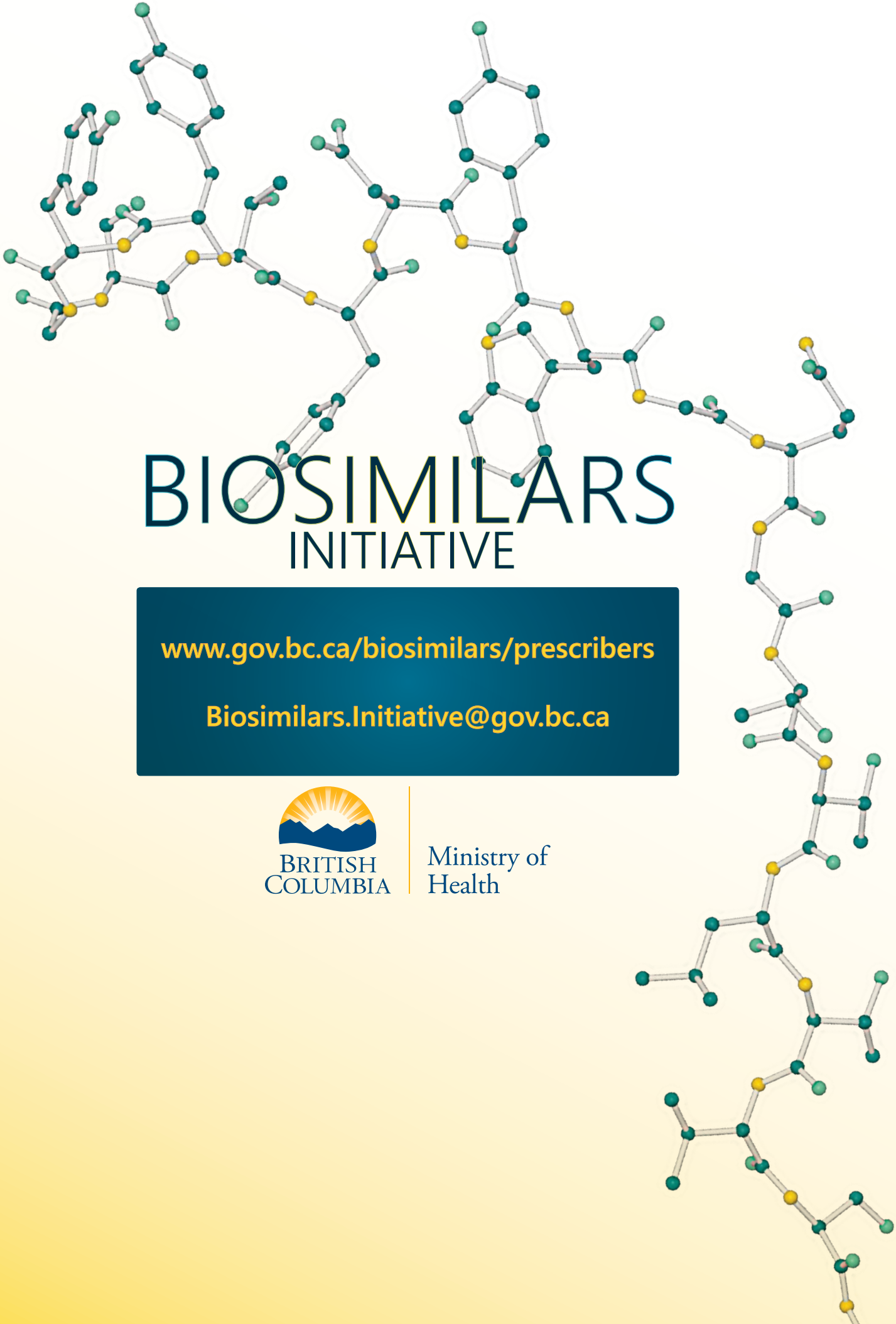
"In Europe, the availability of lower priced biosimilars has been reported to reduce the average list prices of reference products as well as prices of products within the whole therapeutic class."

Canadian Agency for Drugs and Technology in Health
Biosimilars—Regulatory, Health Technology Assessment, Reimbursement Trends, and Market Outlook
January 2018

"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."

European Medicines Agency
Biosimilars in the EU: Information Guide for Healthcare Professionals
2017

complete infliximab protein structure and assembly



BIOSIMILARS INITIATIVE

www.gov.bc.ca/biosimilars/prescribers

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