Our Perspectives

The Canadian Psoriasis Network's (CPN) recognizes that many people with psoriatic disease (psoriasis and psoriatic arthritis) in Canada continue to struggle with accessing medicines that are right for them.

- **People with psoriasis and psoriatic arthritis often cannot afford medications that are available in Canada,** particularly new treatments. Access to innovative medicines in particular, which can put people into full remission in many cases, are out of reach for many people who do not have (or have inadequate) drug insurance or financial support through a Patient Support Program. For those who do have public or private drug insurance, the copayments and deductibles can be significant.

- Moreover, **therapeutic options matter to people with psoriasis and psoriatic arthritis.** Treating psoriatic disease in Canada can be an onerous process and for many, it involves failing on several different medications before finding one that is effective for the individual. Many factors may contribute to this, including the individual's unique response to treatments, as well as the nature of psoriatic disease and the tendency for people to build a tolerance to treatments over time. This is compounded by drug plan policies that often take a step-therapy approach that requires patients to fail on certain treatments in order to possibly access others that may be more appropriate for them. Many people worry that options may run out and that symptoms may return and/or worsen.

CPN contends that people with psoriasis and psoriatic arthritis should be able to access the treatment that is right for them throughout the course of their lives.

As such, CPN supports efforts to save costs for health systems, individuals and families. At the same time, the primary goal of any drug policy must be **to enhance health outcomes and quality of life, as defined by patients.** Biosimilar policies that are not focused on this primary goal risk any savings made potentially being lost to poorer health outcomes, increased physician or hospital visits, and lost productivity.

Our Recommendations

In light of these perspectives, CPN makes the following recommendations to drug plans in Canada that have adopted, or that are considering adopting, biosimilar policies:

- **Shared decision-making between patients and their physicians must underlie any changes to treatment.** A meaningful exception policy framework must be built into any biosimilar policy to help preserve patient-physician decision-making, patient autonomy and equity and to help minimize any potential hardships to people who rely on public or private drug plans to afford their treatment.

    - This framework should include time-sensitive, case-by-case reviews for patients whose treatment success could be compromised as a result of the policy, whether as a result of clinical or psychosocial reasons. People should be allowed to remain on their treatment during this review process.
- **Clear and accessible information about treatment options and policies**, including exception policies, should be made available to physicians, patients and other relevant stakeholders (e.g., pharmacists, patient groups) in advance of policy implementation.
- **Governments should invest in robust post-implementation surveillance** to understand the outcomes of any biosimilar policy change to the system, but most importantly to patients in order to make any necessary adjustments. This becomes increasingly important as more biosimilars enter the Canadian market. To ensure transparency, these plans should be made public for consultation, including who will be overseeing this process, how it will be funded, and how information will be reported back publicly.
- **Savings from any new biosimilar policy should be directed to support reimbursement of additional treatments and improved patient care.**

If drug plans have adopted or are considering **policies that require a person to switch from a reference product to its biosimilar:**

- Ample time should be provided prior to policy implementation to enable physicians to consider reaching out proactively to patients who may be affected to consult with them prior to the implementation date. Patients and physicians should be given the time and opportunity to have a meaningful discussion so that they can consider the individual's medical, social and psychological needs when determining treatment options and suitability for pursuing an exception to the policy. Research from the United Kingdom and Norway[1] finds that the process of switching from biologic to biosimilar medication is best achieved when a patient feels supported and in control of the situation.
- Each situation, like each patient, is different. As such, there should be leeway for people, depending on their circumstances, to have more time to meaningfully discuss any potential changes to their care as a result of biosimilar policy changes.
- Patients should continue to have access to their current treatment until all necessary supports for a new treatment are in place (e.g., immunizations, dosing and scheduling, patient support program, etc.)
- There should be a seamless way for people to transition from the biosimilar back to the biologic treatment in the event that a switch results – or is likely to result in – worse health outcomes.

If drug plans have adopted or are considering **policies that impose tiering:**

- Options available in each tier must be based on best clinical evidence to ensure that people have access to appropriate options in every tier (e.g., each tier, including the first, should include multiple options that work on different parts of the inflammation process such as TNF inhibitors, and all available interleukin inhibitors, including newer treatments).

[1] *Småstuen, Brandvold & Andenaes. (2018). Is patients' satisfaction with being switched to a biosimilar medication associated with their level of health literacy? Results from a Norwegian user survey. [Abstract]. BMJ Journals, Annals of Rheumatic Diseases, 77, Issue Suppl 2, 86*

- Patients with specific comorbidities or personal experiences (e.g., planning to start a family) should be able to access biologic therapies that have been demonstrated to be safe for this specific population.
- Any tiering that would be implemented for pediatric populations should be the subject of a specific consultation with patients and physicians.

Background

Many payers in Canada (i.e., governments and private insurance companies) have implemented, or may be considering adopting, new biosimilar policies as part of their drug plans.

According to Health Canada, "a biosimilar is a biologic drug that is highly similar to a biologic drug that was already authorized for sale. Health Canada authorizes biosimilars for sale using the same rigorous regulatory standards for quality, efficacy and safety as for all other biologic drugs." Biosimilars may come to market once the patent protection of an originator drug is expired.

Biosimilars may create cost savings and treatment options for health systems and for individuals. At the same time, any policy changes that impact on one's treatment may present undue challenges for some individuals.

Some of the common policy options that have been adopted, or that are under consideration by drug plans include:

Non-Medical Switching
In this option, payers develop and implement a policy framework that switches patients currently being treated with an originator biologic to its biosimilar. Typically, this switch is made by the prescriber through a new prescription for the biosimilar based on the expectation that the two products provide the same therapeutic effect. Before a change in therapy is made, the prescriber would typically discuss the drug therapy with the patient.

Tiering
In this option, payers develop and implement a policy framework consisting of drug product options across multiple tiers. The patient must first 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. The same requirement is applicable for Tier 2 drug products before possibly accessing Tier 3 drugs and so forth. Typically, tiering policies would apply to a new patient seeking biologic therapy or to existing patient seeking to change their current biologic treatment.

Generally, exceptions to these policies could be requested by the prescriber where the application of the policy may not be appropriate for the individual based on medical reasons. For these circumstances, prescribers may request exceptional coverage of the originator biologic.