Biosimilars Position Statement

The Canadian Association of Psoriasis Patients (CAPP) supports efforts to help health systems across Canada save money and improve patients' access to new therapies for psoriasis and psoriatic arthritis. Biosimilars can reduce costs to patients and the health system but policies designed to increase their use risk reducing treatment options for our patients. The goal of any biosimilar policy must be to improve health outcomes and quality of life, as defined by patients. CAPP urges drug plans to respect shared decision-making between a patient and their physician as they explore these policy options.

To reduce health system costs, drug plans are considering different approaches that increase the use of biosimilars. In particular, **non-medical switching** from a biologic to one of its biosimilars and **tiering** (where a patient has to fail on certain treatments before being eligible to access other treatment options) are being considered, and in some places, implemented.

Psoriasis treatment is often stepwise in nature: patients are typically only prescribed stronger treatments, such as biologics, after failing on several other medications, including topicals and oral medications. Biologics and biosimilars are important treatment options for patients who have not been able to successfully manage their disease with other medications.

Because of the role of the immune system in psoriasis and psoriatic arthritis, people can sometimes experience major differences in how they respond to a particular treatment and can build a tolerance to a specific medication and experience medication fatigue, leaving the patient in need of different treatment options. It is imperative that biosimilar policies provide multiple treatment options to patients.

Nearly 40% of psoriasis patients have lived with uncontrolled psoriasis for more than 10 years before finding a treatment that worked for them.[1] Approximately 40% of people living with psoriatic arthritis and receiving biologic treatments continue to have persistent disease activity.[2] Treatment decisions can be emotional and onerous for people with psoriatic disease and patients trust their physician to understand their specific history and circumstances when considering options.

To improve health outcomes and quality of life for people living with psoriasis and psoriatic arthritis, CAPP urges drug plans to:

1. **Enshrine shared decision-making between the patient and physician** at the heart of any policy to impose non-medical switching and **include exceptions** for patients whose treatment success could be compromised if required to switch.
2. **Empower patients to start with the best option** for them. if considering requiring patients to fail on one tier of medications in order to access other treatments (i.e., tiering), not just the least expensive for the drug plan.
3. **Conduct robust post-implementation surveillance** to monitor for any unintended consequences, and address them publicly, with input from patients.

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[1] Canadian Association of Psoriasis Patients and Canadian Psoriasis Network, *Psoriasis: Journey to Stability – National Report: Canadians' Journey Living with Psoriasis*, Winter 2018, https://www.canadianpsoriasis.ca/images/pdfs/Psoriasis_Journey_to_Stability_Report_FINAL.pdf

[2] Filip Van den Bosch & Laura Coates, "Clinical management of psoriatic arthritis", *Lancet* (2018) 391:2285-94.

Recommendations

1. **If a drug plan is considering non-medical switching, it should:**
    - Place shared decision-making between the patient and physician at the centre. Research from the United Kingdom and Norway show that switching from a biologic to biosimilar medication is more successful when a patient feels supported and in control of the situation.[3,4]
    - Ensure that the policy makes multiple treatment options available for people living with psoriasis and psoriatic arthritis particularly considering different cytokine targets.
    - Include exceptions, including case-by-case reviews, for patients whose treatment success could be compromised by switching to a biosimilar.
    - Provide clear criteria for a patient to return to a previously used biologic treatment in the event that a switch results – or is likely to result in – worse health outcomes.
    - Support a seamless transition between treatments by continuing to provide access to a patient's current treatment until all necessary supports for a new treatment are in place (e.g., immunizations, dosing and scheduling, patient support program, etc.).
    - Proactively make information available and reach out to patients to educate and inform them about their options, including any exceptions.
    - Engage patients and their representatives to help develop resources for impacted patients.

2. **If a drug plan is considering tiering, it should:**
    - Support best clinical care by including options that reflect the best clinical evidence in each tier (e.g., newer medications that have better and faster disease control) so that patients have access to appropriate options in every tier. Asking patients to fail on older or less effective therapies is fundamentally inconsistent with best clinical care. Evidence shows that the first biologic prescribed gives the best chance of disease control. *In psoriasis, "lead with your best" is an evidence-supported strategy.*
    - Include multiple treatment options in each tier that work on different parts of the inflammatory cascade, such as TNF-α, IL-17 and IL-23.
    - Provide access to biologic therapies that have been demonstrated to be safe for patients with specific comorbidities or personal circumstances (e.g., planning to start a family)

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[3] The Patient Association. (2018). Understanding patient needs in switching from biologic to biosimilar medicines. Final report of survey and focus group findings. Retrieved from https://www.patients-association.org.uk/Handlers/Download.ashx?IDMF=b17810ee-8470-4173-8efc-e7c13d117fbe

[4] 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.

- Conduct a full and focused consultation with patients, caregivers and physicians if contemplating any tiering policy that impacts pediatric populations.

3. **All drug plans implementing biosimilar policies should conduct robust post-implementation surveillance that:**
    - Monitors for any problems so that governments can take action to address them. *Policies designed to maximize cost-savings or expand the biosimilars market run the risk that any realized savings could be lost to potential non-adherence, increased physician or hospital visits and lost productivity.*
    - Is designed, implemented and publicly reported with input from patients and that includes details about who will be overseeing this process, how it will be funded, and how information will be made public.

Glossary

What is a biosimilar?
Biosimilars are medications that are similar to, but not identical versions of, an existing biologic drug. Biologic drugs, including biosimilars, are produced by living organisms, which makes it impossible for different manufacturers to make exact copies.

What is a biologic?
A biologic is a protein-based drug that is produced from living cells. They are often used in the treatment of severe psoriasis and psoriatic arthritis and are administered by injection or intravenous (IV) infusion. Biologics target the cytokines responsible for inflammation in the body (such as TNF-α, IL-17 and IL-23.) These cells and proteins all play a major role in developing psoriasis and psoriatic arthritis.