

CADTH

Feedback on Scoping Document

[Formulary Management of Biologics in Plaque Psoriasis](#)

1. Do you think that the project as proposed in the project scope document will be useful to those making policy or clinical practice decisions? Why or why not?

The Canadian Association of Psoriasis Patients (CAPP) and the Canadian Psoriasis Network (CPN) appreciate the opportunity to provide feedback on CADTH's Proposed Project Scope regarding Formulary Management of Biologics in Plaque Psoriasis.

People living with plaque psoriasis are fortunate in that there are several biologic treatments that have market authorization from Health Canada. However, not all these treatments are available to all patients in Canada. If publicly released, this document should help us make sense of the biologics and biosimilars treatment landscape for plaque psoriasis. In addition, this document would be most useful if it takes into account the needs, priorities and experiences of plaque psoriasis patients to help inform those making policy or clinical practice decisions.

Currently, people in Canada face inconsistent access to biologic drugs for plaque psoriasis. For instance, CPN and CAPP have heard from patients with severe psoriasis who make life decisions, like moving from one province to another or changing jobs, based on concerns that their drug may not be covered through a different drug benefit plan. Typically, these are patients with moderate to severe forms of psoriasis who struggled with managing their symptoms over the course of their lives and who are relieved to find a treatment that works for them.

Moreover, treatment decisions are often difficult and emotional. It can take years – sometimes longer than 10 years – for a person to feel that their psoriasis has stabilized. This can be due to many reasons including barriers to accessing care and treatments that are appropriate for the individual.

Based on what we hear from our community, beyond access to a cure for plaque psoriasis, patients would like to see timely, affordable and consistent access to safe and efficacious treatments for plaque psoriasis to help address unmet need and to ensure that medicines (including new treatments) reach the people who need them. Moreover, the rise of biosimilar policies has also been confusing for patients and we look forward to the inclusion of these policies in CADTH's review.

2. Are there policy, practice or research questions not considered in the project scope that are required to change or influence practice? If so, what would these be?

One gap in this proposed project scope document is that the perspectives of patients and the healthcare providers who treat them are not explicitly included. Psoriasis is a complex disease which increases one's risks of other serious health conditions. To understand if there is "optimal utilization" of biologics in the treatment of plaque psoriasis across Federal, Provincial and Territorial (FPT) plans, patient experiences with biologics used to treat plaque psoriasis – including experiences with living with psoriasis and comorbidities, experiences with treatment trial and error, and experiences with accessing these drugs – should be considered. Moreover, the experiences and perspectives of clinicians who treat psoriatic disease with biologics should also be included.

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Plaque psoriasis is an immune disorder. Patients experience a time-limited usefulness of a given biologic before their immune system essentially begins to “outsmart” the drug. It is essential that patients have access to a variety of biologics for plaque psoriasis and that new treatments be adopted into the health systems across Canada. CAPP and CPN often hear from patients that they are afraid they will run out of options, only to have their moderate to severe plaque psoriasis return, and with it the itchiness, pain, fatigue, stress, stigma and discrimination that they have experienced in the past. Some patients have been unable to work without an effective biologic drug; some have been unable to get out of bed.

Patients may also require a different biologic for a short period of time – such as to address a flare. Some patients who experience a flare may be transitioned to a different biologic to address the flare, and then transitioned back to the biologic they were using before the flare as part of their treatment plan.

Phototherapy is a useful treatment option for many but is not widely available across Canada. In order to be covered for patients via medicare, phototherapy is most often delivered in hospitals and clinics. Those who use this as a treatment must go to the hospital or clinic multiple times per week or month for therapy. Conventional private plans do not usually cover home-based phototherapy equipment, but they may be covered by health spending accounts.

Given challenges with accessing treatments including biologics, one policy question that we have is how well are FPT plans meeting the needs of patients with plaque psoriasis with regard to accessing biologic drugs?

We also encourage you to consider identifying which of the biologics included in your review are also indicated for psoriatic arthritis. Approximately one-third (30%) of people living with psoriasis will develop psoriatic arthritis. There are some biologics that are indicated in Canada to treat both psoriasis and psoriatic arthritis and others that are only indicated for one of the two. Some patients will privilege the use of a biologic to treat their psoriatic arthritis to manage the constant pain of that disease at the expense of managing their plaque psoriasis.

Because of the inflammation underlying plaque psoriasis, people living with this disease also live with a host of comorbidities, including atherosclerotic diseases, metabolic diseases, mental health conditions, and joint diseases. In fact, cardiovascular diseases are the leading cause of death of psoriasis patients in Canada. There are important new research questions about whether the inflammation driving psoriasis also drives depression. We know, however, that anxiety and depression are often experienced by people living with plaque psoriasis. We also know that certain biologics should be avoided in patients who have, or are at higher risk of developing, particular comorbidities. We offer this to you for context as it is important to consider the full picture when tackling a formulary management question specific to the underlying disease.

Sex and gender also play a role in terms of management of plaque psoriasis. Women who may be planning to get pregnant – or who are pregnant – have important questions about the use of

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methotrexate and other treatments for their plaque psoriasis – in particular, questions about which treatments are safe to use when conceiving, during pregnancy, when delivering, and when breastfeeding. Following delivery, it is not uncommon for women to experience a flare of their psoriasis, or a change of their plaque psoriasis to another type (e.g., pustular psoriasis). Last year, a consensus statement was published by leading Canadian dermatologists about managing psoriasis in women of child-bearing potential and we urge you to consider the gendered impacts of living with plaque psoriasis in your review. (See list of studies and resources below for details.)

Few biologic treatments are available for children and youth with psoriasis. We encourage you to also provide specific information about the treatments options available to them and include a special section in your report that focuses on children and youth. It is particularly concerning that we ask children to take powerful drugs like cyclosporine and methotrexate for long periods of time during their development in order to be eligible for biologics and having a better sense of the requirements specific to this population will be helpful to guide patients, parents and their healthcare providers.

We do not have good safety data on the use of biologics in people over 65 years. Dr Aaron Drucker has just (July 2021) received funding from CIHR to study the safety of biologics in people over 65. The findings of this real-world evidence research may impact formulary management by public drug plans, and we encourage you to monitor over time for the release of his findings. We have provided three relevant journal articles for your review below.

In addition, the limited research that exists regarding how socioeconomic factors may affect psoriasis and health outcomes suggests that lower socioeconomic status may be associated with decreased clinical response to biologics, presumably due to issues affecting a patient's ability to adhere to treatment (e.g., cost, barriers accessing healthcare). Given that individuals who do not have private insurance, and/or who cannot afford paying for medications out-of-pocket, would benefit the most from public drug plans, it is particularly important that these plans include a range of treatment options should a given treatment fail to work for an individual. In addition, this research highlights the importance of having access to different modalities for treatments (such as subcutaneous injections and oral options) to help decrease barriers related to a person's ability to adhere to treatment.

Another question that arises is how biosimilars have impacted the utilization of biologics in the treatment of plaque psoriasis across FPTs. For instance, British Columbia has stated that the province's Biosimilar Initiative enables the government to add new drugs to its PharmaCare formulary. As the expansion of biosimilars in this treatment space has evolved since CADTH's 2012 Rapid Response with Critical Appraisal, we wonder how the adoption of biosimilars has improved access to biologics overall and specifically to new biologic options to treat plaque psoriasis in jurisdictions that have expanded their biosimilar policies.

3. Do you have any suggestions for improving the project as proposed in the project scope document?

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We encourage you to consider the following points.

- The perspectives of patients and the healthcare providers who treat them are not explicitly included in the scoping document draft
- Psoriasis is a disorder of the immune system that is driven by inflammation
- People living with moderate to severe plaque psoriasis also live with other diseases that are driven by (or suspected to be linked to) the underlying inflammation of the disease
- It is essential to the management of plaque psoriasis that treatment options be available to patients throughout their lives – this is not a disease that can be cured nor managed long-term by a single treatment option
- Phototherapy is an important treatment option but is not widely available in Canada
- There are critical sex and gender impacts of living with – and treating – plaque psoriasis that should be reflected in how formularies manage biologics to treat the disease
- Few treatments are currently available for children and youth, and they are still required to fail on drugs like methotrexate or cyclosporine to access biologic therapies via a public drug plan
- There are valid questions about the safety of biologics in older adults that are being investigated and those findings should also inform formulary management of biologics to treat plaque psoriasis
- Lower socioeconomic status may be associated with decreased clinical response to biologics, presumably due to issues affecting a patient’s ability to adhere to treatment

4. Please provide any additional comments you may have about this document or the project itself, including any studies you think should be included in our review.

CAPP and CPN are collaborating with the Canadian Arthritis Patient Alliance and the Canadian Spondylitis Association on a forthcoming report on sexual and reproductive health of people who identify as female (women+), which is currently being finalized. Approximately one-third of the more than 400 respondents live with plaque psoriasis. This report contains recommendations on behalf of all four organizations specific to sex and gender. We would be delighted to share a copy with you when it is available in September 2021.

Additional studies for consideration

- Yeung et al., Management of Plaque Psoriasis With Biologic Therapies in Women of Child-Bearing Potential Consensus Paper, J Cutan Med Surg. Jul/Aug 2020;24(1_suppl):3S-14S. doi: 10.1177/1203475420928376. Epub 2020 Jun 5.
- Canadian Association of Psoriasis Patients and Canadian Psoriasis Network, Impact of COVID-19 on the Psoriasis and Psoriatic Arthritis Community in Canada, October 29, 2020: <https://www.canadianpsoriasis.ca/en/resources/awareness-campaigns/world-psoriasis-day/wpd-2020>
- Canadian Association of Psoriasis Patients, Pso Serious (2018): <https://www.canadianpsoriasis.ca/en/resources/reports/pso-serious-2018>

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- Canadian Association of Psoriasis Patients and Canadian Psoriasis Network, Journey to Stability (2018), <https://www.canadianpsoriasis.ca/en/resources/reports/journey-to-stability>
 - CADTH Fact Sheet:
https://www.canadianpsoriasis.ca/images/2021/Reports/fact_sheet_cadth_psoriasis_journey_to_stability_8-5x11_en_x1a_trim.pdf
- Canadian Psoriasis Network, Fact Sheet: Health Care Providers, Women and Psoriasis: Findings from a Survey of Women with Psoriatic Disease: https://www.canadianpsoriasisnetwork.com/wp-content/uploads/2020/02/vx190303_03-04_CPN_Fact_Sheet_HCP-Women_8-5x11_EN_web.pdf
- Schaap MJ, van Winden MEC, Seyger MMB, de Jong EMGJ, Lubeek SFK. Representation of older adults in randomized controlled trials on systemic treatment in plaque psoriasis: a systematic review. *J Am Acad Dermatol.* 2019;S0190-9622(19) 32472-32477. doi:10.1016/j.jaad.2019.07.079
- Tang, E et al., Safety of Systemic Medications Among Older Adults With Psoriasis and Atopic Dermatitis: A Systematic Review of Observational Studies, *Journal of Cutaneous Medicine and Surgery*, 2021, Vol. 25(4) 397–408.
- van Winden et al., Effectiveness and Safety of Systemic Therapy for Psoriasis in Older Adults: A Systematic Review, *JAMA Dermatology*, 2020;156(11):1229-1239. doi:10.1001/jamadermatol.2020.2311.

Please do not hesitate to contact us with questions about this submission.

Sincerely,

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