CADTH

**CADTH Proposed Project Scope**

# Formulary Management of Biologics in Plaque Psoriasis

Date: July 20, 2021
For Stakeholder Feedback

## Background and Rationale

Plaque psoriasis (PSO) is an inflammatory condition in which inflamed scaly patches of skin develop all over the body resulting in itching, redness, pain, discomfort, and lowered quality of life.[1,2] PSO is also recognized as a multi-systemic disease because it is associated with serious comorbidities including psoriatic arthritis, cardiovascular disease, metabolic syndrome, obesity, inflammatory bowel disease, and depression.[3] PSO is common in Canada, with 2.5% of adults in Ontario diagnosed.[4]

First-line treatments include phototherapy, topical creams, and oral systemic anti-inflammatory medications such as methotrexate, acitretin, and cyclosporine.[1] Severe disease that does not respond to first-line treatment is treated with biologic medications. Older generation biologics for PSO included anti–tumour necrosis factor (anti-TNF) biologics such as etanercept, adalimumab, and infliximab, followed by an interleukin (IL)12/23 inhibitor (ustekinumab).[2] Some of these anti-TNF biologics have had biosimilar versions approved in recent years, although the reimbursement of the originator versions would likely have pre-dated any pan-Canadian Pharmaceutical Alliance (pCPA) agreements.

New biologics with different mechanisms of action (anti-IL17 and anti-IL23 inhibitors) have been reimbursed across Canada in the past few years and have undergone negotiations through the pCPA (e.g., ixekizumab, risankizumab). Unlike other inflammatory diseases treated with biologics, registry clinical trials in PSO for these new biologics included head-to-head active comparator designs compared with older generation biologics (such as etanercept, adalimumab, and ustekinumab).[5] CADTH has not conducted class-level health technology assessment projects of PSO since a Rapid Response With Critical Appraisal in 2012,[6] and many new drugs have been approved since then. Given these dynamics, there is rationale to conduct an Environmental Scan to aid in discussions to support harmonization and modernization of formularies for Federal, Provincial, and Territorial drug plans (FPTs). This Environmental Scan will focus on the following policy questions and products (Table 1).

**Policy questions:**

1. What is the current reimbursement status for biologics in the treatment of plaque psoriasis?
2. Is there optimal utilization of biologics in the treatment of plaque psoriasis across FPTs?

### Table 1: Products Available in Canada

| Product | Manufacturer |
|---|---|
| Adalimumab | AbbVie Corporation, Amgen Canada Inc., BGP Pharma ULC, Fresenius Kabi Canada Ltd., Pfizer Canada ULC, Samsung Bioepis Co., Ltd., and Sandoz Canada Inc. |
| Brodalumab | Bausch Health, Canada Inc. |
| Certolizumab pegol | UCB Canada Inc. |
| Etanercept | Immunex Corporation |
| Guselkumab | Janssen Inc. |
| Infliximab | Amgen Canada Inc., Celltrion Healthcare Co., Ltd., Janssen Inc., and Samsung Bioepis Co., Ltd. |
| Ixekizumab | Eli Lilly Canada Inc. |
| Risankizumab | AbbVie Corporation |
| Secukinumab | Novartis Pharmaceuticals Canada Inc. |

| Product | Manufacturer |
|---|---|
| Tildrakizumab | Sun Pharma Global FZE |
| Ustekinumab | Janssen Inc. |

## Project Description

This project will be an Environmental Scan of the reimbursement status, data exclusivity status, summary of CDEC recommendations, and expenditure and/or market share data for biologics for the treatment of PSO, as outlined in Table 2.

### Table 2: Project Scope

| Criteria | Description |
|---|---|
| **Population** | Adults with moderate to severe plaque psoriasis |
| **Interventions** | Biologics approved for the treatment of plaque psoriasis (i.e., adalimumab, brodalumab, certolizumab pegol, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab) |
| **Outcomes** | • Reimbursement status and coverage criteria for FPTs<br>• Status and expiration dates of data protection and patents<br>• CDEC recommendation summaries<br>• Expenditures (total accepted cost for 2020) and market share of new and existing users (claimants for ODB for 2020) |

The research questions will aim to answer the policy questions and will be based on the outcomes collected within the project scope (Table 2).

**Research questions:**

1. What is the reimbursement status of approved biologics used to treat plaque psoriasis for public drug plans?
2. What is the data exclusivity status (i.e., data protection and patent expiration dates) for biologics used to treat plaque psoriasis?
3. What are the CDEC recommendations for biologics used to treat plaque psoriasis?
4. What are the expenditures and market shares of biologics used to treat plaque psoriasis for public drug plans?
5. The output of the project will be a published report that will provide FPTs with context for formulary management discussions and guidance on potential supplementary analyses.

## Key Project and Protocol Components

To address the research questions, this Environmental Scan project will include the following key components:

- A systematic review of the grey literature related to reimbursement status, data exclusivity status, and previous CDEC recommendations
  - Key features:
    - publicly available websites will contain all information
    - reimbursement status to include listing type and reimbursement criteria
    - data exclusivity to include data protection timelines and patent registry timelines
    - CDEC recommendations to include a summary of recommendations and key discussion points
- A preliminary utilization scan
  - Key features:
    - IQVIA data on expenditure of biologics nationally
    - Market share to be based on claimants (new and existing) from previous years using Ontario Drug Benefit data, as provided by the Reformulary Group
- Depending on the outcomes of the Environmental Scan, other CADTH work may be considered to assist with policy and implementation.

## Status of the Document

This proposed project scope will be posted for 10 business days as of the date of this posting (July 19, 2021) for stakeholder feedback. The feedback will be considered as the project plan is finalized.

## References

1. Kim WB, Jerome D, Yeung J. Diagnosis and management of psoriasis. *Can Fam Physician.* 2017;63(4):278-285.
2. Armstrong AW, Read C. Pathophysiology, Clinical Presentation, and Treatment of Psoriasis: A Review. *Jama.* 2020;323(19):1945-1960.
3. Oliveira MdFSPd, Rocha BdO, Duarte GV. Psoriasis: classical and emerging comorbidities. *An Bras Dermatol.* 2015;90(1):9-20.
4. Eder L, Widdifield J, Rosen C, et al. Trends in the Prevalence and Incidence of Psoriasis and Psoriatic Arthritis in Ontario, Canada: A Population-Based Study. *Arthritis Care & Research.* 2018;71.
5. CADTH. CADTH Reference List: newer biologics for the treatment of plaque psoriasis. 2021.
6. CADTH. Infliximab versus Methotrexate, Etanercept, Adalimumab, and Ustekinumab for Plaque Psoriasis: A Review of the Comparative Clinical Efficacy, Safety and Cost Effectiveness. 2012.