Biologics in Plaque Psoriasis: A Summary

Implications for Policy-Makers

New-generation biologics have been shown to be more effective for treating plaque psoriasis; however, old-generation biologics continue to be used. To optimize value in this class of drugs, formulary management strategies could be employed. Examples of those are the pursuing of negotiations with the pan-Canadian Pharmaceutical Alliance to lower costs for old-generation biologics that do not have biosimilar versions or establishing tiered formularies to prioritize the reimbursement of old-generation biosimilars and new-generation biologics for the treatment of plaque psoriasis.

Definitions

Biologics: a class of drugs derived through complex manufacturing procedures that use human or animal tissue or micro-organisms as the starting material, rather than being synthesized by chemical reactions.

Biosimilars: a new, highly similar but not exact copy of a biologic drug that comes to the Canadian market after the patent for the original biologic has expired. Biosimilars are less expensive than biologics.

Exclusivity Status: a function of patent and data protection.

Patent Protection: a 20-year period offered to innovative drugs from the date of filing their Notice of Compliance with Health Canada. Patent protection can be applied in different ways such as chemically or for changes in the use of the drug.

Data Protection Regulations: provide data protection for an 8-year term after receiving their notice of compliance from Health Canada. These regulations started in 2006 and are governed by the *Food and Drug Regulations* in Canada.

Background

Plaque psoriasis is a chronic inflammatory condition whereby inflamed, scaly patches of skin develop on the body. These patches are associated with itching, redness, pain, discomfort, and lowered quality of life. It is estimated that 1% to 3% of people in Canada are affected by psoriasis. There are many first-line treatments for the management of plaque psoriasis, including phototherapy, topical steroids, topical vitamin D, and oral systemic anti-inflammatory medications (e.g., methotrexate). Adults who have moderate to severe plaque psoriasis and do not respond to first-line treatment can be treated with biologic medications.

Biologics for plaque psoriasis can be divided into 2 groups based on their mechanisms of action (how they work to produce an effect on the body) and when they received market authorization. Older-generation biologics for plaque psoriasis include anti–tumour necrosis factor (TNF) agents (etanercept, adalimumab, infliximab, and certolizumab pegol) and an anti-interleukin (IL)-12/IL-23 inhibitor (ustekinumab). More recently, a new generation of biologics have been approved for plaque psoriasis use. These include anti–IL-17 inhibitors (secukinumab, ixekizumab, brodalumab) and anti–IL-23 inhibitors (guselkumab, tildrakizumab, and risankizumab)

Policy Issue

Given the significant cost of biologics to public drug plans, the loss of exclusivity for the old-generation biologics, and the new-generation biologics becoming available, there is a need to assess how biologics used to treat adults with moderate to severe plaque psoriasis are reimbursed.

Objectives

CADTH undertook an Environmental Scan to summarize the regulatory status, exclusivity status, CADTH review status, reimbursement status, and utilization patterns for biologic and biosimilar use in plaque psoriasis.

Methods

A grey literature search was conducted to inform this Environmental Scan.

Findings

- Health Canada has approved 11 biologics for plaque psoriasis. Biologics for plaque psoriasis can be divided into 2 groups based on mechanisms of action and market authorization dates:
  - *Old-generation biologics (5)*: include anti–TNF drugs (etanercept, adalimumab, infliximab, and certolizumab pegol) and an anti–IL-12/IL-23 inhibitor (ustekinumab), which were approved in Canada before 2010
  - *New-generation biologics (6)*: include anti–IL-17 inhibitors (secukinumab, ixekizumab, and brodalumab) and anti–IL-23 inhibitors (guselkumab, tildrakizumab, and risankizumab), which were approved in Canada in 2015 or later.
- Patent protection has expired for infliximab, certolizumab, and ustekinumab, and there is no valid data protection status for all 5 old-generation biologics because they predated the data protection regulations. Three of the old-generation biologics have biosimilar versions (adalimumab, etanercept, and infliximab) that are available in Canada. Despite the expiry of data and patent protection for both ustekinumab and certolizumab, no biosimilar versions are available in Canada.
- Nine biologics were reviewed by CADTH, and all received comparable CADTH Canadian Drug Expert Committee reimbursement recommendations. In research studies, most of the new-generation biologics have been shown to be superior to or result in a statistically significant improvement in efficacy outcomes compared with old-generation biologics.
- With the exception of certolizumab, old-generation biologics predated the pan-Canadian Pharmaceutical Alliance process. This may have resulted in varying product listing agreements across public drug plans. Biologics are reimbursed diversely and some public drug plans have active forms of restricted benefit status (e.g., review through special authorization forms), while others have passive forms of restricted benefit status (e.g.,

Limited Use codes in Ontario). Three public drug plans have employed 2-tiered formularies (i.e., Alberta, Manitoba, and Correctional Service Canada) that require a trial of new-generation biologics or old-generation biosimilars before the reimbursement of old-generation biologics.

- The proportion of patients reimbursed for old-generation biologics through the Ontario Public Drug Programs decreased from 54.4% in 2019 to 36.8% in 2020. A significant proportion of new patients are still being treated with old-generation biologics.

Full Report
cadth.ca/biologics-plaque-psoriasis

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