

CADTH Reference List

# Switching From Reference to Biosimilar Etanercept for Patients with Plaque Psoriasis

February 2021

**Authors:** Thyna Vu, Charlene Argáez

**Cite As:** *Switching from Reference to Biosimilar Etanercept for Patients with Plaque Psoriasis*. Ottawa: CADTH; 2021 Feb. (CADTH reference list: summary of abstracts).

**Disclaimer:** The information in this document is intended to help Canadian health care decision-makers, health care professionals, health systems leaders, and policy-makers make well-informed decisions and thereby improve the quality of health care services. While patients and others may access this document, the document is made available for informational purposes only and no representations or warranties are made with respect to its fitness for any particular purpose. The information in this document should not be used as a substitute for professional medical advice or as a substitute for the application of clinical judgment in respect of the care of a particular patient or other professional judgment in any decision-making process. The Canadian Agency for Drugs and Technologies in Health (CADTH) does not endorse any information, drugs, therapies, treatments, products, processes, or services.

While care has been taken to ensure that the information prepared by CADTH in this document is accurate, complete, and up-to-date as at the applicable date the material was first published by CADTH, CADTH does not make any guarantees to that effect. CADTH does not guarantee and is not responsible for the quality, currency, propriety, accuracy, or reasonableness of any statements, information, or conclusions contained in any third-party materials used in preparing this document. The views and opinions of third parties published in this document do not necessarily state or reflect those of CADTH.

CADTH is not responsible for any errors, omissions, injury, loss, or damage arising from or relating to the use (or misuse) of any information, statements, or conclusions contained in or implied by the contents of this document or any of the source materials.

This document may contain links to third-party websites. CADTH does not have control over the content of such sites. Use of third-party sites is governed by the third-party website owners' own terms and conditions set out for such sites. CADTH does not make any guarantee with respect to any information contained on such third-party sites and CADTH is not responsible for any injury, loss, or damage suffered as a result of using such third-party sites. CADTH has no responsibility for the collection, use, and disclosure of personal information by third-party sites.

Subject to the aforementioned limitations, the views expressed herein do not necessarily reflect the views of Health Canada, Canada's provincial or territorial governments, other CADTH funders, or any third-party supplier of information.

This document is prepared and intended for use in the context of the Canadian health care system. The use of this document outside of Canada is done so at the user's own risk.

This disclaimer and any questions or matters of any nature arising from or relating to the content or use (or misuse) of this document will be governed by and interpreted in accordance with the laws of the Province of Ontario and the laws of Canada applicable therein, and all proceedings shall be subject to the exclusive jurisdiction of the courts of the Province of Ontario, Canada.

The copyright and other intellectual property rights in this document are owned by CADTH and its licensors. These rights are protected by the Canadian *Copyright Act* and other national and international laws and agreements. Users are permitted to make copies of this document for non-commercial purposes only, provided it is not modified when reproduced and appropriate credit is given to CADTH and its licensors.

**About CADTH:** CADTH is an independent, not-for-profit organization responsible for providing Canada's health care decision-makers with objective evidence to help make informed decisions about the optimal use of drugs, medical devices, diagnostics, and procedures in our health care system.

**Funding:** CADTH receives funding from Canada's federal, provincial, and territorial governments, with the exception of Quebec.

Questions or requests for information about this report can be directed to [requests@cadth.ca](mailto:requests@cadth.ca)

## Key Message

- Two randomized controlled trials were identified regarding the clinical effectiveness of switching from reference etanercept to biosimilar etanercept in adult or pediatric patients with plaque psoriasis.

## Research Question

What is the clinical effectiveness of switching from reference to biosimilar etanercept in adult or pediatric patients with plaque psoriasis?

## Methods

### Literature Search Methods

A limited literature search was conducted by an information specialist on key resources including MEDLINE, Embase, the Cochrane Database of Systematic Reviews, the international HTA database, the websites of Canadian and major international health technology agencies, as well as a focused internet search. The search strategy comprised both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The main search concepts were etanercept and plaque psoriasis. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2016 and February 2, 2021. Internet links were provided, where available.

### Selection Criteria and Summary Methods

One reviewer screened literature search results (titles and abstracts) and selected publications according to the inclusion criteria presented in Table 1. Full texts of study publications were not reviewed. The Overall Summary of Findings was based on information available in the abstracts of selected publications.

## Results

Two randomized controlled trials were identified regarding the clinical effectiveness of switching from reference to biosimilar etanercept in adult or pediatric patients with plaque psoriasis.<sup>1,2</sup> No relevant health technology assessments, systematic reviews, or non-randomized studies were identified.

Additional references of potential interest that did not meet the inclusion criteria are provided in Appendix 1.

**Table 1: Selection Criteria**

Criteria	Description
Population	Patients (any age) with plaque psoriasis
Intervention	Switching from reference etanercept (i.e., Enbrel) to biosimilar etanercept (i.e., Erelzi, Brenzys)
Comparator	Continuous use of reference etanercept; pre/post switch comparisons
Outcomes	Effectiveness (e.g., change in disease severity or clinical response, disease activity, clinical remission, health-related quality of life) and safety (e.g., adverse events, withdrawal due to adverse event)
Study designs	Health technology assessments, systematic reviews, randomized controlled trials, non-randomized studies

## Overall Summary of Findings

Two randomized controlled trials<sup>1,2</sup> analyzed data from the EGALITY study. Patients were randomly assigned to self-administer reference etanercept or biosimilar etanercept, and those that had at least a 50% improvement based on the Psoriasis Area and Severity Index (PASI 50) at week 12 were re-randomized to either continue using their initially assigned treatment, or to undergo 3 consecutive treatment switches until week 30. Following this, all patients remained on the last assigned treatment until week 52. Patients initially assigned to reference etanercept and patients assigned to biosimilar etanercept did not differ significantly in response rate at week 12.<sup>2</sup> Patients who switched treatments and patients who continued with the same treatment had similar treatment responses up to week 30 as measured by PASI 50, PASI 75, and PASI 90 response rates and percent change from baseline in PASI scores.<sup>1</sup> Incidence of treatment-emergent adverse events was also comparable across groups up to week 30<sup>1</sup> and week 52.<sup>2</sup> No patients tested positive for binding anti-drug antibodies.<sup>1</sup>

## References

### Health Technology Assessments

No literature identified.

### Systematic Reviews and Meta-analyses

No literature identified.

### Randomized Controlled Trials

- Gerdes S, Thaci D, Griffiths CEM, et al. Multiple switches between GP2015, an etanercept biosimilar, with originator product do not impact efficacy, safety and immunogenicity in patients with chronic plaque-type psoriasis: 30-week results from the phase 3, confirmatory EGALITY study. *J Eur Acad Dermatol Venereol*. 2018 Mar;32(3):420-427. [Medline](#)
- Griffiths CEM, Thaci D, Gerdes S, et al. The EGALITY study: a confirmatory, randomized, double-blind study comparing the efficacy, safety and immunogenicity of GP2015, a proposed etanercept biosimilar, vs. the originator product in patients with moderate-to-severe chronic plaque-type psoriasis. *Br J Dermatol*. 2017 Apr;176(4):928-938. [Medline](#)

## Non-Randomized Studies

No literature identified.

## Appendix 1: References of Potential Interest

### Systematic Reviews and Meta-analyses

#### *Alternative Comparator – Biosimilar Trials Compared to Pivotal Trials*

- Moots RJ, Curiale C, Petersel D, Rolland C, Jones H, Mysler E. Efficacy and safety outcomes for originator TNF inhibitors and biosimilars in rheumatoid arthritis and psoriasis trials: a systematic literature review. *Biodrugs*. 2018 Jun;32(3):193-199. [Medline](#)

#### *Unclear Intervention and Unclear Population – Not Specific to Etanercept or Plaque Psoriasis*

- Jacobs I, Petersel D, Isakov L, Lula S, Lea Sewell K. Biosimilars for the treatment of chronic inflammatory diseases: a systematic review of published evidence. *Biodrugs*. 2016 01 Dec;30(6):525-570. [Medline](#)

### Non-Randomized Studies

#### *Alternative Intervention – Non-Switching*

- Egeberg A, Ottosen MB, Gniadecki R, et al. Safety, efficacy and drug survival of biologics and biosimilars for moderate-to-severe plaque psoriasis. *Br J Dermatol*. 2018 02;178(2):509-519. [Medline](#)

#### *Unclear Population and Alternative Intervention – Not Specific to Plaque Psoriasis and Non-Switching*

- Pescitelli L, Lazzeri L, Di Cesare A, Tripo L, Ricceri F, Prignano F. Clinical experience with the etanercept biosimilar SB4 in psoriatic patients. *Int J Clin Pharm*. 2019 Feb;41(1):9-12. [Medline](#)

#### *Alternative Population – Inflammatory or Rheumatoid Arthritis*

- Jaworski J, Matucci-Cerinic M, Schulze-Koops H, et al. Switch from reference etanercept to SDZ ETN, an etanercept biosimilar, does not impact efficacy, safety, and immunogenicity of etanercept in patients with moderate-to-severe rheumatoid arthritis: 48-week results from the phase III, randomized, double-blind EQUIRA study. *Arthritis Res Ther*. 2019 05 28;21(1):130. [Medline](#)
- Madenidou AV, Jeffries A, Varughese S, et al. Switching patients with inflammatory arthritis from etanercept (Enbrel) to the biosimilar drug, SB4 (Benepali): a single-centre retrospective observational study in the UK and a review of the literature. *Mediterr J Rheumatol*. 2019;30(Supplement1):69-75. [Medline](#)

#### *Alternative Population and Alternative Intervention – Arthritis and Non-Switching*

- Codreanu C, Popescu CC, Mogosan C, et al. Efficacy and safety of original and biosimilar etanercept (SB4) in active rheumatoid arthritis - a comparison in a real-world national cohort: original and biosimilar etanercept in RA. *Biologicals*. 2019 November;62:27-32. [Medline](#)

### Review Articles

#### *Unclear Population – Not Specific to Plaque Psoriasis*

- Deeks ED. GP2015: An etanercept biosimilar. *Biodrugs*. 2017 Dec;31(6):555-558. [Medline](#)
- Moots R, Azevedo V, Coindreau JL, et al. Switching between reference biologics and biosimilars for the treatment of rheumatology, gastroenterology, and dermatology inflammatory conditions: considerations for the clinician. *Curr Rheumatol Rep*. 2017 01 Jun;19 (6):37. [Medline](#)

#### *Alternative Population – Arthritis*

- Lyseng-Williamson KA, McKeage K. SB4 (Benepali; an etanercept biosimilar): a profile of its use. *Drugs Ther Perspect*. 2018 01 Feb;34(2):50-61.
- Cantini F, Benucci M. Focus on biosimilar etanercept - bioequivalence and interchangeability. *Biologicals*. 2018;12:87-95. [Medline](#)
- Burness CB, Duggan ST. Etanercept (SB4): a review in autoimmune inflammatory diseases. *Biodrugs*. 2016 Aug;30(4):371-378. [Medline](#)

### Additional References

- Fisher A, Kim JD, Dormuth CR. Rapid monitoring of health services utilization following a shift in coverage from brand name to biosimilar drugs in British Columbia-an interim report. *Pharmacoepidemiol Drug Saf*. 2020 Jul;29(7):803-810. [Medline](#)