TITLE: Switching from Innovator to Biosimilar (Subsequent Entry) Infliximab: Clinical Effectiveness, Cost-Effectiveness, and Guidelines

DATE: 26 November 2015

RESEARCH QUESTIONS

1. What is the clinical effectiveness and safety of switching from innovator infliximab to subsequent entry infliximab for patients with rheumatoid arthritis?

2. What is the clinical effectiveness and safety of switching from innovator infliximab to subsequent entry infliximab for patients with ankylosing spondylitis?

3. What is the clinical effectiveness and safety of switching from innovator infliximab to subsequent entry infliximab for patients with plaque psoriasis?

4. What is the clinical effectiveness and safety of switching from innovator infliximab to subsequent entry infliximab for patients with Crohn’s disease?

5. What is the clinical effectiveness and safety of switching from innovator infliximab to subsequent entry infliximab for patients with ulcerative colitis?

6. What is the clinical effectiveness and safety of switching from innovator infliximab to subsequent entry infliximab for patients with psoriatic arthritis?

7. What is the cost-effectiveness of switching from innovator infliximab to subsequent entry infliximab?

8. What are the evidence-based guidelines regarding switching from innovator infliximab to subsequent entry infliximab?
KEY FINDINGS

Three non-randomized studies and two economic evaluations were identified regarding switching from innovator infliximab to subsequent entry infliximab. No evidence-based guidelines were identified.

METHODS

This report makes use of a literature search conducted for a previous CADTH report. The original literature search was conducted in January 2015 on key resources including PubMed, The Cochrane Library, University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. No filters were applied to limit retrieval by study type. Where possible, retrieval was limited to the human population. The initial search was also limited to English-language documents published between January 1, 2010 and January 28, 2015. For the current report, database searches were rerun on November 17 to capture any articles published since the initial search date. The search of major health technology agencies was also updated to include documents published since February 1, 2015.

The summary of findings was prepared from the abstracts of the relevant information. Please note that data contained in abstracts may not always be an accurate reflection of the data contained within the full article.

SELECTION CRITERIA

One reviewer screened citations and selected studies based on the inclusion criteria presented in Table 1.

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<th>Table 1: Selection Criteria</th>
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<td><strong>Population</strong></td>
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<td><strong>Intervention</strong></td>
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<td><strong>Comparator</strong></td>
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<td><strong>Outcomes</strong></td>
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RESULTS

Rapid Response reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment reports, systematic reviews, and meta-analyses are presented first. These are followed by randomized controlled trials, non-randomized studies, economic evaluations, and evidence-based guidelines.
Three non-randomized studies (two of which were conference abstracts) and two economic evaluations (one of which was a conference abstract) were identified regarding switching from innovator infliximab to subsequent entry infliximab. No relevant health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, or evidence-based guidelines were identified.

Additional references of potential interest are provided in the appendix.

OVERALL SUMMARY OF FINDINGS

Three non-randomized studies\(^1\)\(^-\)\(^3\) (two of which were conference abstracts\(^2\)\(^-\)\(^3\)) and two economic evaluations\(^5\)\(^-\)\(^6\) (one of which was a conference abstract\(^6\)) were identified regarding switching from innovator infliximab to subsequent entry infliximab.

In a patient cohort with various rheumatic diseases, no differences were observed in patient reported outcomes or disease-activity measures during the first year in patients who were switched to infliximab-biosimilar CT-P13 (INB) from Remicade (infliximab [INX]).\(^1\) In addition, there were no immediate safety issues apparent.\(^1\) A cohort of pediatric patients with Crohn's disease were switched from either INX or adalimumab (ADA) to INB in a different study.\(^2\) No significant differences in the occurrence of mild adverse reactions were observed when comparing INX and INB treatment and no infusion reactions occurred with INB-switch treatment.\(^2\) In addition, no disease flare ups were evident for up to 32 weeks post-INB infusion.\(^2\) The authors from a study consisting of Korean patients with inflammatory bowel disease (IBD) who switched to Remsima (biologics to INX) from either INX or ADA, observed improved short-term clinical response (86% with Crohn’s and 67% with ulcerative colitis) and a good safety profile in patients with moderate to severe IBD.\(^3\)

In one direct drug cost analysis, patients with inflammatory autoimmune diseases received Remsima after either being switched from INX or who were INX-naïve.\(^4\) The authors determined that Remsima could lead to substantial cost-related savings across the five European countries examined assuming the cost of INB was 10% to 30% less than INX.\(^4\) The conference abstract,\(^5\) which was part of the aforementioned study,\(^4\) stated that the projected savings of using Remsima ranged from 0.7 million in Italy to 17.9 million in Germany for patients with Crohn's disease and ranged from 0.3 million in the United Kingdom to 5.3 million in Germany for patients with ulcerative colitis.\(^5\) The currency of cost savings were not overtly specified in either abstract.\(^4\)\(^-\)\(^5\)
REFERENCES SUMMARIZED

Health Technology Assessments
No literature identified.

Systematic Reviews and Meta-analyses
No literature identified.

Randomized Controlled Trials
No literature identified.

Non-Randomized Studies


Conference Abstracts


Economic Evaluations


Conference Abstract

Switching from Innovator to Biosimilar Infliximab

Guidelines and Recommendations

No literature identified.

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APPENDIX – FURTHER INFORMATION:

Previous CADTH Reports


Systematic Reviews and Meta-analyses

Comparison of Innovator and Biosimilar – No Switching


Randomized Controlled Trials

Comparison of Innovator and Biosimilar – No Switching


Non-Randomized Studies

Comparison of Innovator and Biosimilar – No Switching


Conference Abstracts

Comparison of Innovator and Biosimilar – No Switching


**Economic Evaluation**

**Switching Not Specifically Mentioned**


**Conference Abstracts**


**Review Articles**


**Additional References**