Early Biologic Treatment versus Conventional Treatment for the Management of Luminal Crohn’s Disease: Comparative Clinical Effectiveness and Cost-Effectiveness
References:


Acknowledgments:

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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.

Authors: Dave K. Marchand, Charlene Argáez

Research Questions
1. What is the clinical effectiveness of early biologic treatment compared with conventional treatment for the management of Crohn’s disease?
2. What is the cost-effectiveness of early biologic treatment compared with conventional step-up treatment for the management of Crohn’s disease?

Key Findings
Seven relevant non-randomized studies and one economic evaluation were identified regarding early biologic treatment compared with conventional treatment for the management of Crohn’s disease.

Methods
A limited literature search was conducted 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 methodological filters were applied to limit by study type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2008 and November 21, 2018. Internet links were provided, where available.

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

<table>
<thead>
<tr>
<th>Population</th>
<th>Q1 and Q2: Adults and pediatric patients with active moderate to severe Crohn’s disease</th>
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<tr>
<td>Intervention</td>
<td>Q1, 2, 3: Biologics: adalimumab, infliximab, vedolizumab, ustekinumab given in the context of an early initiation algorithm. May be given in combination with immunosuppressants (azathioprine, 6-mercaptopurine, methotrexate, cyclosporine)</td>
</tr>
<tr>
<td>Comparator</td>
<td>Q1, 2: Conventional management sequence (“step-up”) typically consisting of giving steroids, then switching to immunosuppressants when remitting or not responding, and then switching to biologics if not responding to previous drugs.</td>
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| Outcomes | Q1. Clinical effectiveness based on: 
- Commonly accepted disease activity scales such as the Crohn’s Disease Activity Index (CDIA) or the Harvey-Bradshaw Index, 
- clinical response rate, 
- clinical remission, 
- steroid-free remission, 
- endoscopic remission (mucosal healing), 
- corticosteroid use, 
- need for surgery, 
- hospitalization, 
- mortality, 
- quality of life, 
- safety outcomes (harms including infections and malignancies, discontinuation) 
Q2. Cost-effectiveness |
| Study Designs | Health technology assessment, systematic review, meta-analysis, randomized controlled trials, non-randomized studies, and economic evaluations. |

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, and economic evaluations.

Seven relevant non-randomized studies and one economic evaluation were identified regarding early biologic treatment compared with conventional treatment for the management of Crohn’s disease. No relevant health technology assessments, systematic reviews, meta-analyses, or randomized controlled trials were identified.

Additional references of potential interest are provided in the appendix.

Health Technology Assessments

No literature identified.

Systematic Reviews and Meta-analyses

No literature identified.
Randomized Controlled Trials

No literature identified.

Non-Randomized Studies

Pediatric Population


Adult Population


Population Age not Defined


Economic Evaluation

Appendix — Further Information

Systematic Reviews and Meta-analyses - Alternative comparator


Randomized Controlled Trials

Population Insufficiently Defined – Disease Severity Unknown


Non-Randomized Studies

Pediatric Population – Disease Severity Unknown


**Adult Population – Disease Severity Unknown**


**Population Insufficiently Defined – Disease Severity Unknown**


Mixed Disease Population


Economic Evaluations

Mixed Disease Population


Population Insufficiently Defined – Disease Severity Unknown


Alternate comparator


Review Articles


Additional References - Clinical Trial Currently Enrolling