Early Biologic Treatment versus Conventional Step-Up Treatment for the Management of Fistulising Crohn’s Disease: Comparative Clinical Effectiveness and Cost-Effectiveness
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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.
Research Questions

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

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

Key Findings

No relevant literature was identified regarding early biologic treatment compared with conventional step-up treatment for the management of fistulising 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 8, 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>
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<th>Population</th>
<th>Adults and pediatric patients with fistulising Crohn’s disease not previously treated with immunosuppressants, antibiotics, or biologics</th>
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| Intervention | Biologics: adalimumab, infliximab or vedolizumab prescribed in the context of an early initiation algorithm  
- May be given in combination with immunosuppressants (azathioprine, 6-mercaptopurine) |
| Comparator | Conventional management sequence (“step-up”) typically consisting of giving antibiotics with or without immunosuppressants, and then giving biologics if not responding to previous drugs |
| Outcomes | Q1: Clinical effectiveness based on:  
- Commonly accepted disease activity scales such as Crohn’s Disease Activity Index (CDIA) or the Harvey-Bradshaw Index,  
- Clinical response rate,  
- Fistula improvement/resolution/closure,  
- Need for surgery,  
- Hospitalization,  
- Mortality,  
- Quality of life,  
- Safety outcomes (harms including infections and malignancies, discontinuation)  
Q2: Cost-effectiveness |
| Study Designs | Health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies, 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.

No relevant health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies, or economic evaluations were identified regarding the clinical effectiveness or cost-effectiveness of early biologic treatment compared with conventional step-up treatment for the management of fistulising Crohn’s disease.

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
No literature identified.

Economic Evaluations
No literature identified.
Appendix — Further Information

Systematic Reviews and Meta-Analyses

**Population Insufficiently Defined — Naïveté to Biologic Use Unknown**

   PubMed: PM29374617

Non-Randomized Studies

**Population Insufficiently Defined — Naïveté to Biologic Use Unknown or Type of Crohn’s Not Defined**

**Pediatric Population**

   PubMed: PM29298460

   PubMed: PM25564801

   PubMed: PM22728632

   PubMed: PM20626362

   PubMed: PM20380012

**Population Age Undefined**

   PubMed: PM29401297


**Adult Population**


**No comparator**


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Review Articles
