

Proposed Project Scope

Fidaxomicin for Clostridium difficile Infection

Date: November 2024

Background and Rationale

CDA-AMC received a request from public drug programs for a Non-Sponsored Reimbursement Review of fidaxomicin for the treatment of adults with Clostridium difficile infection.

Table I: Policy Questions

Item	Policy Question
1	Should fidaxomicin be publicly reimbursed for the treatment of adults with Clostridium difficile infection?

Table II: Products Available in Canada

Product	Manufacturer
Fidaxomicin	Merck
Vancomycin	Generics
Metronidazole	Generics

Project Description

Table III: Project Scope

Criteria	Description
Population	Adults (≥ 18 years old) for the initial treatment of severe and severe-complicated Clostridium difficile infection. Subgroups of interest: <ul style="list-style-type: none"> • Age > 65 years old • Severe immunosuppression • A recurrence of infection • An allergy to vancomycin
Intervention(s)	Fidaxomicin
Comparators	<ul style="list-style-type: none"> • Vancomycin • Metronidazole
Outcomes	<p>Efficacy</p> <ul style="list-style-type: none"> • Clinical cure rate of C difficile at 10 days • Sustained clinical cure rate at 30 days after treatment end • Global cure rate • Rate of relapse at 90 days • Time to recurrence of diarrhea • Disease-free survival after day 10 • Microbiological efficacy • All-cause mortality • Quality of life end points <p>Safety</p> <ul style="list-style-type: none"> • Any grade adverse events • Serious adverse events • Withdrawal due to adverse events • Mortality • Adverse events of special interest

Table IV: Research Questions

Item	Policy Question
1	What is the effectiveness of fidaxomicin for the treatment of Clostridium difficile infection in adults?
2	What are the harms associated with fidaxomicin for the treatment of Clostridium difficile infection in adults?
3	What is the expected cost of fidaxomicin for the treatment of Clostridium difficile infection in adults vs. other reimbursed regimens?

Key Project and Protocol Components

This project will follow the [Procedures for Non-Sponsored Reimbursement Reviews](#).

Status of the Document

This proposed project scope is being posted for information.