

Proposed Project Scope

Naloxegol for the treatment of opioid-induced constipation (OIC) in adult patients with cancer and non-cancer pain who have had an inadequate response to laxative(s).

Background and Rationale

CADTH received a request from public drug programs for a Non-Sponsored Reimbursement Review of Naloxegol for Opioid-Induced Constipation (OIC)

Table I: Policy Questions

Item	Policy Question
1	Should naloxegol be publicly reimbursed for the treatment of opioid-induced constipation (OIC) in patients with cancer and non-cancer pain who have had an inadequate response to laxative(s)?

Table II: Products Available in Canada

Product	Manufacturer
naloxegol (Movantik™)	Knight Therapeutics Inc.

Project Description

Table III: Project Scope

Criteria	Description
Population	<ul style="list-style-type: none"> Adults (≥ 18 years of age) with opioid induced constipation who have been taking an opioid analgesic for management of pain (cancer and non-cancer related pain) and had an inadequate response or intolerance to laxative(s).
Intervention(s)	naloxegol administered orally, 25 mg once daily
Comparators	Placebo; Laxatives (Stimulants (e.g., senna, bisacodyl), osmotic laxatives, bulk-forming laxatives, lubricants, and Stool softeners (e.g., docusate, lactulose, polyethylene glycol)).
Outcomes	<p>Efficacy</p> <ul style="list-style-type: none"> Increase in spontaneous bowel movements (SBMs) Increase in SBMs response rate over 12 weeks Time to first SBM Mean number of days per week with ≥ 1 SBM Decrease in straining Severity Decrease in stool hardness Stool consistency (Bristol stool scale). Reduction in rescue laxative use. <p>Safety:</p> <ul style="list-style-type: none"> Rates of discontinuation due to AEs Diarrhea, abdominal pain, GI symptoms. Serious cardiovascular adverse events and QT prolongation Serious gastrointestinal adverse events Vital signs Risk of withdrawal symptoms or withdrawal signs Changes in opioid dose and pain scores.

Table IV: Research Questions

Item	Research Question
1	What is the clinical effectiveness of naloxegol for opioid-induced constipation (OIC)?
2	What are the harms associated with naloxegol for OIC?
3	What is the expected cost of naloxegol for use in OIC vs. other reimbursed regimes?

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.