

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Health Technology Appraisal

**Methylnaltrexone for the treatment of opioid-induced bowel dysfunction
in advanced illness or palliative care**

Draft scope (Pre-referral)

Draft remit/appraisal objective

To appraise the clinical and cost effectiveness methylnaltrexone within its licensed indication for the treatment of opioid-induced bowel dysfunction in advanced illness or palliative care.

Background

Opioid analgesics, such as morphine, are widely used for the treatment of pain. Opioid analgesics produce pain relief by blocking pain signals through interaction with opioid receptors distributed through the central and peripheral nervous systems. Opioid receptors are present in the gastrointestinal tract. When opioids bind to these receptors, they can disrupt normal gastrointestinal function, resulting in bowel dysfunction. Adverse gastrointestinal effects, may include constipation, abdominal cramping, bloating and gastro-oesophageal reflux.

Studies report constipation occurring in half of people with advanced cancer rising to 87% in people with advanced cancer receiving hospice care.

Laxatives are commonly prescribed prophylactically during opioid therapy in order to maintain bowel moment.

The technology

Methylnaltrexone bromide (Wyeth Pharmaceuticals) is a selective antagonist at opioid receptors. Methylnaltrexone does not cross the blood brain and, therefore, the action of methylnaltrexone on opioid receptors is restricted to the periphery, thereby preserving the analgesic effect of opioid drugs within the central nervous system.

Methylnaltrexone does not currently have a UK marketing authorisation for opioid-induced bowel dysfunction. Unpublished clinical trials examine the use of subcutaneously administered methylnaltrexone in people with advanced illness receiving palliative care and with opioid-induced constipation.

Methylnaltrexone is used in addition to standard therapy (which may include laxatives and stool softeners).

Intervention(s)	Methylnaltrexone in additional to standard therapy
Population(s)	Adults with advanced illness receiving palliative care and with opioid-induced bowel dysfunction
Current standard comparators	Standard therapy such as laxatives and stool softeners
Outcomes	Outcomes to be considered include: <ul style="list-style-type: none"> • frequency of bowel movement • pain • adverse effects of treatment • health related quality of life
Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared. Costs will be considered from a NHS and Personal Social Services Perspective.
Other considerations	Guidance will be issued in accordance with the marketing authorisation.
Related NICE recommendations	None.

Questions for consultation

How should advanced illness or palliative care be defined? Given that the definition of the patient population is not clear, are there any other organisations that should be included on the matrix of consultees and commentators?

What is used in current UK practice for the treatment of people with opioid-induced constipation/ opioid-induced bowel dysfunction?

Are there any subgroups of patients in whom the technology is expected to be more clinically effective and cost effective or other groups that should be examined separately?

Are there any issues that require special attention in light of the duty to have due regard to the need to eliminate unlawful discrimination and promote equality?

Which process would be the most suitable for appraising this technology, the single technology or multiple technology process? (Information on these processes is available at http://www.nice.org.uk/aboutnice/howwework/devnicetech/technologyappraisalprocessguides/technology_appraisal_process_guides.jsp)