

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Health Technology Appraisal

Lubiprostone for treating opioid-induced constipation in people with chronic, non-cancer pain

Final scope

Remit/appraisal objective

To appraise the clinical and cost effectiveness of lubiprostone within its licensed indication for treating opioid-induced constipation in people with chronic, non-cancer pain.

Background

Opioid analgesics, such as morphine, are widely used for the treatment of pain. Opioid receptors are present in the gastrointestinal tract and when opioids bind to these receptors, they can disrupt normal gastrointestinal function, resulting in bowel dysfunction. Constipation is one of the most common and debilitating symptoms of opioid-induced bowel dysfunction.

Opioid-induced constipation is a side effect that affects nearly all patients taking opioid treatment and will persist unless treated. The prevalence of opioid-induced constipation is not known. However, in England in 2010 there were over 17 million prescriptions for opioid items. In 2010-11 there were 57,506 hospital admissions due to constipation in England, and in 2011, there were 57 deaths registered in England and Wales due to constipation.

NICE clinical guideline 140 'Opioids in palliative care' recommends laxative treatment to be taken regularly at an effective dose for all patients initiating strong opioids in palliative care. Long-term laxative use should be avoided where possible. When oral laxative therapy is ineffective at producing a bowel movement, a suppository or enema may be appropriate.

The technology

Lubiprostone (Amitiza, Sucampo Pharma Europe) is a prostone that specifically activates a chloride ion channel located in the apical intestinal membrane enhancing the intestinal fluid secretion. It is administered orally.

Lubiprostone does not have a UK marketing authorisation for treating opioid-induced constipation. It has been studied in clinical trials, compared with placebo, in adults with opioid bowel dysfunction who have been treated with opioids for chronic non-cancer pain.

Intervention	Lubiprostone
Populations	Adults receiving treatment for chronic non-cancer pain who have opioid-induced constipation
Comparators	<ul style="list-style-type: none"> oral laxative treatment without lubiprostone <p>For people in whom oral laxatives have provided inadequate relief:</p> <ul style="list-style-type: none"> peripheral mu-opioid antagonists (methylnaltrexone and naloxone-oxycodone) rectal interventions (e.g. suppositories and enemas)
Outcomes	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> frequency of spontaneous bowel movements sense of complete evacuation symptoms of constipation severity of constipation use of rescue medication or interventions adverse effects of treatment health-related quality of life.
Economic analysis	<p>The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.</p> <p>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.</p> <p>Costs will be considered from an NHS and Personal Social Services perspective.</p>
Other considerations	Guidance will only be issued in accordance with the marketing authorisation.

Related NICE recommendations	<p>Related Technology Appraisals:</p> <p>Technology Appraisal in Preparation 'Lubiprostone for treating chronic idiopathic constipation'. Earliest anticipated date of publication October 2014</p> <p>Related Guidelines:</p> <p>Clinical Guideline No. 140, May 2012, 'Opioids in palliative care: safe and effective prescribing of strong opioids for pain in palliative care of adults'. Review proposal date TBC</p> <p>Related Pathways:</p> <p>NICE Pathway: 'Opioids in palliative care', Pathway created: Jun 2012.</p> <p>http://pathways.nice.org.uk/pathways/opioids-in-palliative-care#content=view-node%3Anodes-communication-and-review</p>
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