

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal

Naloxegol for treating opioid-induced constipation

Final scope

Remit/appraisal objective

To appraise the clinical and cost effectiveness of naloxegol within its licensed indication for treating opioid-induced constipation.

Background

Opioid analgesics 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 opioid-induced bowel dysfunction. Constipation is one of the most common and debilitating symptoms of opioid-induced bowel dysfunction.

Opioid-induced constipation is considered to be a side effect that will affect nearly all people taking strong opioid treatment and that 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 No. 140 recommends laxative treatment to be taken regularly at an effective dose for all people initiating strong opioids. When oral laxative therapy is ineffective at producing a bowel movement, a suppository or enema may be appropriate.

The technology

Naloxegol (Brand name unknown, AstraZeneca) is a pegylated form of naloxol, an analogue of the opioid receptor antagonist naloxone that selectively antagonises peripheral opioid receptors to relieve constipation. It is administered orally.

Naloxegol does not currently have a UK marketing authorisation for treating opioid-induced constipation. It has been studied in clinical trials compared with placebo and usual care in adults with non-cancer pain and cancer pain and opioid-induced constipation, including people for whom laxatives have been ineffective in providing adequate relief.

Intervention(s)	Naloxegol
Population(s)	Adults with opioid-induced constipation
Comparators	<ul style="list-style-type: none"> • oral laxative treatment without naloxegol <p>For adults in whom oral laxatives have provided inadequate relief:</p> <ul style="list-style-type: none"> • peripheral mu-opioid receptor antagonists (methylnaltrexone) • opioid analgesic and opioid receptor antagonist combinations (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 • symptoms of constipation • use of rescue medication or interventions • response rate • upper gastrointestinal symptoms including nausea • effects on analgesic efficacy • 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	<p>If the evidence allows the following subgroup will be considered:</p> <ul style="list-style-type: none"> adults for whom previous treatment with laxatives has been unsuccessful in providing adequate relief. <p>Guidance will only be issued in accordance with the marketing authorisation.</p>
Related NICE recommendations and NICE pathways	<p>Related Technology Appraisals:</p> <p>Technology Appraisal in Preparation, 'Lubiprostone for treating opioid-induced constipation in people with chronic, non-cancer pain'. 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 June 2016.</p> <p>Related Pathways:</p> <p>NICE Pathway: 'Opioids in palliative care', Pathway created June 2012 (last updated November 2013): http://pathways.nice.org.uk/pathways/opioids-in-palliative-care#content=view-node%3Anodes-communication-and-review.</p>
Related National Policy	<p>None</p>