

**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****Final scope****Remit/appraisal objective**

To appraise the clinical and cost effectiveness of methylnaltrexone within its licensed indication for the treatment of opioid-induced constipation in patients with advanced illness who are receiving palliative care when response to usual laxative therapy has not been sufficient.

**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 and the analgesic effect of opioids is predominately through central opioid receptors. Peripheral mu-opioid receptors are partially responsible for bowel motility.

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 movement but are not t always effective. When patients do not respond to laxatives, it is usual to move on to rectal interventions such as suppositories and enemas.

**The technology**

Methylnaltrexone bromide (Relistor, 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 is indicated for the treatment of opioid - induced constipation in patients with advanced illness who are receiving palliative care when response to usual laxative therapy has not been sufficient.

National Institute for Health and Clinical Excellence  
Final scope for the proposed appraisal of methylnaltrexone for the treatment of opioid-induced bowel dysfunction in advanced illness or palliative care

<b>Intervention</b>	Methylnaltrexone
<b>Population(s)</b>	Patients with advanced illness who are receiving palliative care when response to usual laxative therapy has not been sufficient.
<b>Standard comparators</b>	<ul style="list-style-type: none"> <li>• Usual therapy alone</li> <li>• Rectal interventions e.g. suppositories and enemas</li> </ul>
<b>Outcomes</b>	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> <li>• time to bowel movement</li> <li>• inpatient care</li> <li>• pain</li> <li>• adverse effects of treatment</li> <li>• health related quality of life</li> </ul>
<b>Economic analysis</b>	<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>Consideration will be given to alternative approaches to economic analysis over and above the reference case</p> <p>The time horizon for the economic evaluation should reflect the period over which relevant costs and benefits can reasonably be expected.</p> <p>Costs will be considered from an NHS and Personal Social Services perspective.</p>
<b>Other considerations</b>	Guidance will only be issued in accordance with the marketing authorisation.
<b>Related NICE recommendations</b>	<p>Related NICE clinical guideline:</p> <p>None</p>