NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Health Technology Appraisal

Prucalopride for the treatment of chronic constipation in women

Final scope

Appraisal objective

To appraise the clinical and cost effectiveness of prucalopride within its licensed indication for the treatment of chronic constipation in women in whom laxatives fail to provide adequate relief.

Background

Constipation is the subjective complaint of passing abnormally delayed or infrequent dry, hardened faeces (stools) often accompanied by straining and/or pain. Chronic constipation has been defined as two or more of the following symptoms at least a quarter of the time for at least six months: straining, lumpy or hard stools, a sensation of incomplete evacuation, a sensation of anorectal obstruction or blockage, and/or less than 3 defecations per week.

Reported prevalence rates of constipation in the UK vary widely between studies, with figures ranging from 3% in young adults to 20% or more in the elderly. Constipation affects twice as many women as men, with prevalence rates in women varying from 8.2% to 52% in the UK.

Mild cases of constipation are often intermittent and may result from dietary changes, stress or immobility. However, constipation may also be the consequence of an underlying condition. In the UK, approximately half of all patients admitted to specialist palliative care units have constipation, and almost 80% of these patients require laxatives, mainly due to the use of opioid analgesics.

The first step in the management of constipation should be appropriate dietary and lifestyle changes. If this is ineffective or impractical, a short course of laxatives may relieve symptoms and restore normal bowel function. There are several laxatives available including bulk-forming laxatives, stimulant laxatives, faecal softeners and osmotic laxatives. Choice of treatment depends on the presenting symptoms, patient acceptability, side-effect profile and cost. 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.

If persistent and inadequately managed, complications of constipation can include haemorrhoids, faecal impaction, intestinal obstruction or perforation,

faecal and urinary incontinence, urinary tract infection, rectal bleeding, general weakness and psychological disorders.

The technology

Prucalopride (Resolor, Movetis) is a selective, high-affinity, enterokinetic 5-HT4 receptor agonist, which increases colon motility and transit. It has been studied in adults with chronic constipation who are refractory to standard laxatives.

Prucalopride has a UK marketing authorisation for the symptomatic treatment of chronic constipation in women in whom laxatives fail to provide adequate relief.

Intervention(s)	Prucalopride
Population(s)	Women with chronic constipation in whom standard laxative regimens have failed to provide adequate relief, and for whom more invasive procedures, such as direct rectal intervention, are being considered
Comparators	• standard therapy without prucalopride • invasive procedures such as rectal interventions (including enemas, suppositories and manual evacuation) • bowel surgery
Outcomes	The outcome measures to be considered include: • proportion of patients with ≥3 SCBM per week • number of spontaneous complete bowel movements per week • improvement in symptoms of constipation • 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 an NHS and Personal Social Services perspective.
Other considerations	Guidance will only be issued in accordance with the marketing authorisation.
Related NICE recommendations	Related Technology Appraisals: Technology Appraisal in Development. 'Methylnaltrexone for the treatment of opioid-induced bowel dysfunction in advanced illness or palliative care'. Earliest date of publication to be confirmed. Related Guidelines: Clinical Guideline No. 61, February 2008. 'Irritable bowel syndrome in adults: diagnosis and management of irritable bowel syndrome in primary care'. Clinical Guideline in Development. 'Constipation: the diagnosis and management of idiopathic childhood constipation in primary and secondary care'. Earliest date of publication May 2010.