National Institute for Health and Clinical Excellence

This is not NICE's final guidance on this technology, and the recommendations may change after consultation.

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Press release

NICE appraisal of prucalopride for chronic constipation in women

In draft guidance published today (3 August 2010), NICE recommends prucalopride (Resolor, Movetis) as an option for the treatment of chronic constipation in women, in whom laxatives have failed to provide adequate relief.

Prucalopride[1] should only be considered for women who have tried at least two different types of laxative and lifestyle changes for at least 6 months, but have not had relief from constipation.

Constipation is defined as the subjective complaint of passing abnormally delayed or infrequent dry, hardened faeces (stools), often accompanied by straining and/or pain. People with chronic constipation have two or more of the following symptoms, at least a quarter of the time, for at least three months: (and such symptoms for at least six months before presenting these problems to their GP)

- straining, lumpy or hard stools
- a sensation of incomplete evacuation
- a sensation of anorectal obstruction or blockage,
- manual manoeuvres to facilitate defecation (for example, digital evacuation[2] or support of the pelvic floor[3]), and/or

[1] Prucalopride stimulates colonic activity and transit.
[2] Digital evacuation (removal) of faeces involves using a gloved lubricated finger to remove stool from the back passage.
[3] Support of the pelvic floor refers to aiding the muscles that underpin the rectum, in order to help bowel movements. It may involve physio activities and other various techniques.

- less than three defecations a week.

It affects on average two to three times as many women as men, with prevalence rates of around 10% in women under 65 years of age in the UK. Rates are often higher (around 20%) in women over 65 years of age.

Current treatments are limited for people in whom laxatives fail to provide adequate relief from constipation, and may include intrusive interventions such as suppositories, enemas, rectal irrigation, and manual disimpaction or in severe cases, bowel surgery. These treatments, however, only provide temporary relief.

Professor Peter Littlejohns - Clinical and Public Health Director at NICE said: “Prucalopride has been preliminarily recommended as a clinically and cost effective treatment for women with chronic constipation who have failed to achieve adequate relief from at least two prior laxative treatments. There have not been any new treatments available for this distressing condition in the UK for over 25 years, and current treatment for this condition is very limited, and has some very unpleasant side-effects. We are pleased therefore, that the evidence considered by the Appraisal Committee shows this drug would be a useful treatment for people who have been unable to manage their constipation with standard laxatives.”

This draft guidance has been issued for consultation; NICE has not yet issued final guidance to the NHS.

Final guidance is likely to be published in December 2010.

Ends

Notes to Editors

About the appraisal

- The appraisal consultation document (ACD) is available for comment until 5.00pm, Tuesday 24 August 2010 at http://guidance.nice.org.uk/TA/Wave22/6/Consultation/Latest
- After consultation the Appraisal Committee will meet again on Wednesday 8 September to consider the evidence, this appraisal consultation document and any comments from the consultees.
- Through the data presented, prucalopride was shown to be clinically effective in providing relief to some patients with chronic constipation. It was also shown that prucalopride was more cost effective than placebo. Other costs of managing chronic constipation such as consultation time could also be reduced by the use of prucalopride.
- Prucalopride is administered orally. The summary of product characteristics (SPC) states that the recommended dose of prucalopride is 2 mg once daily for adult women (up to 65 years old) and 1 mg once daily for older women (over 65 years old). The dose for older women can be increased to 2 mg once daily if needed. If the intake of once daily prucalopride is not effective after four weeks, the patient should be re-examined and the benefit of continuing treatment reconsidered.
- The SPC reports that the most common undesirable effects that may be associated with prucalopride treatment include headache and gastrointestinal symptoms (abdominal pain, nausea or diarrhoea).
- Prucalopride is available in 1mg and 2mg tablets. The acquisition cost of prucalopride 1 mg is £38.69 for a pack of 28 tablets. The acquisition cost of prucalopride 2mg is £59.52 for a pack of 28 tablets (excluding VAT; MIMS, June 2010 edition). The manufacturer estimated that the annual cost of treatment with prucalopride is £622 for adult women and £403 for older women, excluding any monitoring costs, assuming that each patient receives treatment for an average of 220 days each year. Costs may vary in different settings because of negotiated procurement discounts.

About NICE

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- NICE produces guidance in three areas of health:
    1. **public health** – guidance on the promotion of good health and the prevention of ill health for those working in the NHS, local authorities and the wider public and voluntary sector.
    2. **health technologies** – guidance on the use of new and existing medicines, treatments and procedures within the NHS.
    3. **clinical practice** – guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS.