

Enc 6 Appx 3

Clinical Expert Summary Linaclotide (Constella[®]▼) 290 microgram hard capsules

Linaclotide (Constella[®]▼) for the symptomatic treatment of moderate to severe irritable bowel syndrome (IBS) with constipation in adults.

1. Existing guidelines

National Institute for Health and Care Excellence and British Society of Gastroenterology guidance (2007) were identified.

2. Disease prevalence/incidence

The proportion of the population having IBS with constipation (IBS-C) was estimated as 5% with 0.25% requiring treatment. The majority of people with IBS-C have mild IBS, which can be controlled by laxatives. One expert reported that between two and four patients, for whom laxatives, antispasmodics and diet modification had failed, were referred to hospital in their catchment area per week.

3. Current treatment options

Current treatments mentioned were lifestyle advice, diet modification (principally reduction in fibre containing foods), antispasmodics, laxatives, prucalopride (Resolor[®]), anti-depressants, hypnotherapy and acupuncture.

4. Unmet needs

There was an opinion that there is no effective medicine for IBS and the need for new medicines for this indication was highlighted. The following unmet needs were pointed out: incorporation of faecal calprotectin screening in the primary care treatment pathway, awareness of when to use the emerging classes of prokinetic medicines, availability of psychological and hypnotherapy services and rational use of dietetic services for community and hospital care.

5. Knowledge of product in given indication

The product might be used in patients intolerant or unresponsive to laxatives. Currently a proportion of patients with severe IBS utilise significant health resources due to extensive investigation in secondary care. Use of linaclotide in patients with IBS-C in primary care could prevent this need for referral to extensive investigation in some patients with consequent cost savings. Referral to secondary care would then be considered in patients not responding to linaclotide.

It should be noted that one expert involved in compiling this response declared a personal specific interest in relation to linaclotide for the indication under consideration.