Linaclotide (Constella®) for the treatment of irritable bowel syndrome with constipation (IBS-C) in adults

NHS Devon

Commissioning policy

The routine commissioning of linaclotide (Constella®) is not accepted in Devon for the treatment of irritable bowel syndrome with constipation (IBS-C) in adults. The Formulary Interface Group should not include this in locally defined treatment recommendations.

Rationale for the decision

There are no studies which compare linaclotide to other treatment options in IBS-C; the data available are limited to comparisons with placebo over short durations only. Patients could take additional laxative during the trials and it is unclear how this influenced study outcomes. The short duration of study is considered a limitation in a condition which is characterised by fluctuating severity over a long period of time. Although statistically significant, the difference in the proportion who reported benefit was small compared to those who benefited from placebo. Furthermore a high placebo response rate in general was noted across a range of outcomes. The difference compared to placebo suggests that only 13-25% of patients obtained a benefit that could be attributed to the drug.

In a review of evidence conducted in 2015, the National Institute for Health and Care Excellence (NICE) guideline committee concluded that very low to moderate quality evidence suggests linaclotide may improve quality of life, stool frequency, combination of pain and stool frequency, degree of relief, constipation and bloating in people with IBS-C; weaknesses in the studies make it unclear whether it was linaclotide, other medication taken, or a combination of these that had a positive effect. NICE CG61 includes a weak recommendation that linaclotide may be

considered for people with IBS only if optimal or maximum tolerated doses of previous laxatives from different classes have not helped; and they have had constipation for at least 12 months.

The direct acquisition cost of linaclotide is higher than other established treatment options; given the limitations in the research trial evidence it is considered that the effectiveness of the drug does not justify the potential impact upon the budget of the local health community.

Guidance notes on exceptionality

This general policy does not replace clinical judgement on the appropriate treatment of an individual patient. Where a specialist believes this treatment is the only option and other commissioned treatments are not appropriate, an application may be made to their acute trust's DTC for approval to use this treatment in line with NICE CG61 on an individual patient basis. If approved, the specialist shall retain responsibility for prescribing the treatment for that patient for a minimum of six months. If, after this time, the treatment has been shown to be successful, the specialist may ask the GP to take on prescribing.

Date of publication:	Version:
29.11.2016	Policy agreed by Northern, Eastern and Western Devon CCG and South Devon and Torbay CCG Policy adopted by NHS Devon CCG on 01.04.2019 Policy adopted by NHS Devon ICB on 01.07.2022