



Berkshire West Area Prescribing Committee Policy Statement

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| Drug Name | Linaclootide (Constella®) |
| Indication under review | Symptomatic treatment of moderate-to-severe irritable bowel syndrome with constipation (IBS-C) in adults. |
| Policy No: | APC 008 |
| Date of Issue: | September 2013, reissued November 2015 |
| Review Date: | November 2018 |
| Policy Statement: Linaclootide should be a treatment option for a subgroup of patients with moderate to severe IBS-C not responding to other treatments. | |
| Traffic Light Status | Amber |
| Key Points considered: <ul style="list-style-type: none">• In 2 double-blind, randomised, placebo-controlled trials of patients with IBS-C, a statistically greater proportion of linaclootide-treated patients, compared with placebo treated patients, met the 2 primary efficacy end points which were '12-week abdominal pain/discomfort responders' (trial 1: 54.8% compared with 41.8%; trial 2: 54.1% compared with 38.5%; $p < 0.001$) and 'IBS degree-of-relief responders' (trial 1: 37.0% compared with 18.5%; trial 2: 39.4% compared with 16.6%; $p < 0.0001$).• Treatment should only be initiated in refractory patients on the advice of a specialist | |
| References: NICE ESNM16: Irritable bowel syndrome with constipation in adults: linaclootide | |
| Date 1st taken to APC: | 3 rd July 2013 |
| Date re-ratified by MOC on Behalf of the Board: | 18th November 2015 |