

Northern (NHS) Treatment Advisory Group

Treatment Appraisal: Decision Summary

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| Date | 6 th September 2016 |
| Appraisal & Details | The Northern (NHS) Treatment Advisory Group considered an appraisal of Eluxadoline (Truberizi®, Allergan) for the treatment of diarrhoea dominant irritable bowel syndrome (IBS-D). |
| Recommendation | <p>The Northern (NHS) Treatment Advisory Group does not recommend the use of eluxadoline for the treatment of diarrhoea dominant IBS.</p> <p>The group noted that there are no available data comparing eluxadoline with other treatments for IBS-D and efficacy data against placebo is limited to 26 weeks. In addition patients were only eligible for the clinical trials if they were not taking any other anti-diarrhoeal medicines meaning that the trial populations may not be representative of the target population in the UK.</p> |
| Clinical evidence summary | <p>In two phase III clinical trials, eluxadoline 75 mg or 100 mg twice daily was compared to placebo for the outcome of treatment response, which was defined as improvement in abdominal pain by $\geq 30\%$ plus Bristol Stool Form < 5 on at least 50% of study days.</p> <p>Treatment response after 26 weeks was more common with eluxadoline 75 mg (27%) and eluxadoline 100 mg (31%) than placebo (20%, both comparisons $p \leq 0.001$). When examined separately, stool consistency was significantly improved over baseline but abdominal pain was not.</p> |
| Safety | The most common adverse effects were gastrointestinal (e.g. constipation, nausea, abdominal pain). Several cases of pancreatitis and sphincter of Oddi dysfunction were reported in the eluxadoline groups. History of these conditions is a contraindication to use in the USA, where eluxadoline has been marketed for some time. |
| Patient Perspective | Symptoms of IBS tend to follow a relapsing-remitting course and disease is often life-long. People with a longer history of disease are less likely to ever recover, as are those experiencing chronic stress. IBS therefore has a potentially large impact on quality of life, productivity and psychological wellbeing. Patients will be interested in a potential new treatment option however it is unclear whether eluxadoline will improve patient outcomes any more than current treatment options available. |
| Cost analysis summary | The cost of eluxadoline is not yet known however US costs indicate that it will be more expensive than loperamide. Loperamide costs £26 to £71 per year, depending on dose used. |
| Financial impact PbR: In-tariff | The financial impact of this recommendation is expected to be nil. |