Northern Treatment Advisory Group

Northern (NHS) Treatment Advisory Group

Treatment Appraisal: Decision Summary

Date	6th September 2016
Appraisal & Details	The Northern (NHS) Treatment Advisory Group considered an appraisal of **Ferric Maltol (Feracrru®,Sheild TX,UK) for the treatment of iron deficiency anaemia (IDA) in adults with inflammatory bowel disease (IBD).**
Recommendation	**The Northern (NHS) Treatment Advisory Group recommends the use of oral Ferric Maltol as an alternative option in patients with mild to moderate IDA with IBD who have tried at least two oral ferrous salts and have a reported intolerance to oral ferrous salts due to adverse effects after an adequate trial. Initiation and prescribing of Ferric Maltol should be carried out by an IBD specialist.** In these patients, it should be considered as an alternative to IV iron if there is no urgent need to raise Hb levels (e.g. prior to surgery).The group noted that the clinical trial data suggested that Feraccru® may be well tolerated in many patients with previous intolerance of oral ferrous salts. Whilst it is substantially more expensive than oral ferrous salts, it is cheaper than IV iron.
Clinical evidence summary	The pivotal phase III trial programme of Feraccru® consisted of two identical prospective randomised, double blind, placebo-controlled, multicentre trials; AEGIS-1 and AEGIS-2 which involved 128 patients with mild to moderate IDA associated with (stable) IBD. After 12 weeks, Feraccru® led to a statistically significant improvement in Hb of 2.25g/dL from baseline to week 12 compared to placebo ($p<0.0001$) with the median time to normalisation of Hb levels being 57 days. Ferritin and transferrin saturation also improved over 12 weeks compared to placebo. Hb levels continued to increase to an average maximum of 14g/dL at 48 weeks in the open label extension study with continued use of Feraccru®. However the AEGIS studies were relatively small, of short duration and only compared Feraccru® with placebo. They included only patients with mild to moderate IDA at baseline so it is not clear how these results would apply to patients with more severe IDA.
Safety	Data from the AEGIS studies suggest that Feraccru® may be well tolerated in many patients with previous intolerance of oral ferrous salts. The most commonly reported adverse effects were arthralgia and mild to moderate gastrointestinal effects - abdominal pain, reflux, flatulence, rectal haemorrhage, abdominal distension and constipation. The EMA notes in the EPAR for Feraccru® that it did not exacerbate IBD during the AEGIS studies or during the open label extension study.
Patient Perspective	There is an unmet need for effective and well tolerated treatments for IDA in IBD that are easy and safe to administer and patients will be pleased with the availability of a new treatment option. Compliance with oral ferrous salts due to adverse effects is difficult to achieve and reduces the likelihood of desired treatment outcomes (raised serum iron levels) being achieved. It is thought

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	that oral Ferric Maltol will be better tolerated than other iron salts such as ferrous sulphate and unlike IV iron; it can be safely self-administered by the patient at home.
Cost analysis summary	Ferric Maltol costs £47.60 for a pack of 56 for a 28 day supply compared to £2.75 - £8.34 for 28 days of oral ferrous salts and £185.08 for IV Ferinject® (drug cost only and based on a 70kg patient) A 6 month treatment course of Ferric Maltol costs £285.60.
Financial impact PbR: In-tariff	It is assumed that mild to moderate IDA patients get oral iron salts first but if they fail they would then be given Ferric Maltol. Severe IDA patients would get IV iron straight away. The estimated budget impact per 100,000 population is a *cost saving* of £12,740. For the North East and Cumbria population this would be a cost saving £412,763. Predicted savings are based on patients requiring fewer attendances in secondary care for IV iron.