

**South East London Area Prescribing Committee
Formulary recommendation**

Reference	076
Intervention	Ferric maltol capsules for the treatment of iron deficiency anaemia in adults with inflammatory bowel disease (IBD) (Ferric maltol is an iron supplement licensed specifically for use in people with IBD)
Date of Decision	August 2017
Date of Issue	September 2017
Recommendation	Amber 2 – initiation and first prescription supplied by the specialist gastroenterology team
Further Information	<ul style="list-style-type: none"> • Ferric maltol (Feraccru[®]) is accepted for use within its licence for the treatment of iron deficiency anaemia (IDA) in adult patients with IBD. • Ferric maltol is restricted for use as a 3rd line oral iron preparation where: <ul style="list-style-type: none"> - The patient has a diagnosis of IBD and a haemoglobin >95g/L but less than normal range (120g/L in women, 130g/L in men) AND - Two different oral iron salts have been tried for an adequate period of time but are not tolerated AND - The next treatment step would otherwise be intravenous iron. • The previous oral iron salts tried must include either the gluconate or fumarate salt. • Initiation of ferric maltol is restricted to gastroenterology specialists only. • Adverse effects of oral iron supplements are a common cause of non-compliance with treatment. At each initiation of an oral iron salt, patients should be counselled to persevere with treatment. In line with NICE CKS guidance for treating IDA, patients should be counselled on the following: <ul style="list-style-type: none"> - The importance of compliance with treatment and reassurance about the adverse effects associated with iron supplements. - Adverse effects usually settle down with time. - Although iron preparations are best absorbed on an empty stomach they can be taken after food to reduce gastro-intestinal side-effects. - In the case of the sulphate, gluconate or fumarate salts, consideration may be given to reducing the dose frequency to help manage the adverse effects (for example one or two tablets daily). • The recommended dose of ferric maltol is one capsule twice daily on an empty stomach. Treatment duration will depend on the severity of iron deficiency but generally at least 12-weeks treatment is required. Treatment would be discontinued when there is an improvement in haemoglobin to within normal range • A treatment pathway for iron deficiency in people with IBD will be developed through the SEL IBD pathway group. • A report summarising outcomes in relation to the use of ferric maltol will be presented back to the Committee in 1 year. This report will be co-ordinated across all trusts in SEL by the original formulary applicant and will include: <ul style="list-style-type: none"> - The total number of patients treated with ferric maltol across SEL - Whether use is in line with this recommendation - The baseline number of intravenous iron infusions being carried out per year prior to the formulary introduction of ferric maltol - The proportion of patients going onto require intravenous iron infusions in 1 year despite treatment with ferric maltol and the reasons for this (e.g. adverse effects, non-response) - The number of intravenous iron infusions avoided in 1 year through use of ferric maltol - Impact on patient related outcomes, such as (i) adverse effects (ii) compliance (iii) normalisation of Hb/resolution of anaemia - The number of patients discontinuing treatment with ferric maltol and reasons for stopping • This formulary recommendation will be reviewed, if necessary, on receipt of the report.

Shared Care/ Transfer of care required:	N/A – iron supplements are routinely prescribed in primary care without shared care arrangements.
Cost Impact for agreed patient group	<ul style="list-style-type: none"> Ferric maltol is intended as an alternative to IV iron in patients who do not require urgent treatment. It may be cost saving compared to intravenous iron if costs for a twelve week course are considered, however there are no head to head trials comparing ferric maltol with either oral or parenteral iron treatments and comparative tolerability with oral iron, and comparative efficacy with parenteral iron is uncertain. Due to uncertainty on equivalent efficacy with intravenous iron a budget impact estimate is difficult to perform, and it is unclear if introduction of ferric maltol would be cost saving, or result in increased costs. The cost of a 12 week course of Feraccru is £142.80 (excluding VAT). It is estimated that within 12 months 130 patients in SE London would be treated with ferric maltol as a 12 week course, with approximately 25 patients remaining on continued treatment. This would equate to £15,000 costs for patients requiring a 12 week course, and £15,500 costs in patients on ongoing treatment; £30,500 per annum in total. Anticipating treatment costs from prevalence rates however might be higher. In view of the uncertainties around the budget impact, the applicants are required to present back outcomes from the use of ferric maltol in a year's time to the Committee.
Usage Monitoring & Impact Assessment	<p>Acute Trusts:</p> <ul style="list-style-type: none"> Monitor use and submit usage data and audit reports (against this recommendation and the pathway) upon request to the APC. Collate data at a SEL level as outlined in "Further Information" section and present report to APC after August 2018 and by December 2018 at the latest. <p>CCGs:</p> <ul style="list-style-type: none"> Monitor ePACT data. Exception reports from GPs if inappropriate prescribing requests are made to primary care.
Evidence reviewed	<p>References (from evidence evaluation)</p> <p>The evidence evaluation used to review this formulary application was prepared by the London Medicines Evaluation Network in May 2016. References are noted at the end of the evaluation, which can be accessed via the Specialist Pharmacy Services (SPS) website at: https://www.sps.nhs.uk/wp-content/uploads/2016/06/LMEN_Ferric_Maltol_IDA_IBD_FINAL_May16_v2.pdf</p> <p>Additional references referred to in a supplementary local review:</p> <ol style="list-style-type: none"> Ferric maltol (Feraccru). All Wales Medicines Strategy Group (ref 2631) Jan 2017. Available online at: http://www.awmsg.org/awmsgonline/app/appraisalinfo/2631 (accessed 02/08/2017) Ferric maltol (Feraccru). Scottish Medicines Consortium (ref 1202/16) December 2016. Available online at: https://www.scottishmedicines.org.uk/SMC_Advice/Advice/1202_16_ferric_maltol_Feraccru/ferric_maltol_Feraccru (accessed 02/08/2017) Safety and Efficacy of oral ferric maltol compared to intravenous iron to treat iron deficiency anaemia. NCT02680756. Available online at: https://clinicaltrials.gov/ct2/show/NCT02680756 (accessed 02/08/2017)

NOTES:

- Area Prescribing Committee recommendations and minutes are available publicly on the APC website.
- This Area Prescribing Committee recommendation has been made on the cost effectiveness, patient outcome and safety data available at the time. The recommendation will be subject to review if new data becomes available, costs are higher than expected or new NICE guidelines or technology appraisals are issued.
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