

**South East London Integrated Medicines Optimisation 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)
Date of Decision:	August 2017, updated February 2019. December 2022 to update criteria for use in patients requiring repeat iron supplementation and have previously not tolerated standard oral iron supplements
Date of Issue:	September 2017, re-issued February 2019 and February 2023
Recommendation:	Amber 2 – initiation and first prescription supplied by the specialist gastroenterology team
Further Information	<ul style="list-style-type: none"> • Ferric maltol (Feracru®) is accepted for restricted use for the treatment of iron deficiency anaemia (IDA). Use is restricted to adult patients with inflammatory bowel disease (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. • Patients who become iron deficient after previous intravenous (IV) iron treatment, requiring repeat iron supplementation and who have previously not tolerated standard oral iron supplements can start ferric maltol directly for treatment of their IDA. • 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 can be accessed via this link • February 2023: An audit summarising the outcomes in relation to the use of ferric maltol was presented and discussed at the SEL IBD pathway group in April 2022. The findings demonstrated that it may not be appropriate for patients previously treated with IV iron who did not tolerate standard iron supplements to be initiated on standard oral iron supplements when they require iron supplementation again. In line with this, SEL IBD group members agreed by consensus that where it is known a patient does not tolerate standard oral iron supplements; it may be appropriate for such patients to be treated with ferric maltol instead of cycling through different preparations.
Shared Care/ Transfer of care required:	N/A
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.

	<ul style="list-style-type: none"> • 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 SEL IMOC <p>SEL Borough Medicines Teams</p> <ul style="list-style-type: none"> • Monitor ePACT2 prescribing 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 (LMEN) in May 2016.</p> <p>References from LMEN review:</p> <ol style="list-style-type: none"> (1) Tidy, C. PatientPlus (Professional) Article: Crohn's Disease. Document ID: 2020 (v26) available here <Accessed 26/03/2016> (2) Tidy, C. PatientPlus (Professional) Article: Ulcerative Colitis. Document ID: 2898 (v26) available here <Accessed 26/03/2016> (3) Goddard, AF, James, MW, McIntyre, AS. Management of iron deficiency anaemia. Gut 2011; 60:1309-1316. (4) Stallmach A, Buning C. Ferric maltol (ST10): A novel oral iron supplement for the treatment of iron deficiency anaemia in inflammatory bowel disease. Expert Opinion on Pharmacotherapy 2015; 16(18):1-9. (5) Van-Assche G, Dignass A, Bokemeyer B. Second European evidence-based consensus on the diagnosis and management of ulcerative colitis Part 3: Special situations. Journal of Crohn's and Colitis 2013; 7:1-33. (6) Dignass AU, Gasche C, Bettenworth D. ECCO Guideline/Consensus Paper: European consensus on the diagnosis and management of iron deficiency and anaemia in inflammatory bowel diseases. Journal of Crohn's and Colitis 2015; 9(3):211-222. (7) Summary of Product Characteristics (Ferrous gluconate 300mg tablets), revised 20/4/2016 by Kent Pharmaceuticals via www.medicines.org.uk <Accessed 16/04/2016> (8) Summary of Product Characteristics (Galfer Capsules), revised 11/02/2015 by Thornton & Ross Ltd via www.medicines.org.uk <Accessed 16/04/2016> (9) Summary of Product Characteristics (Ferrous Sulfate 200mg coated tablets), revised 8/2/2016 by Wockhardt UK Ltd via www.medicines.org.uk <Accessed 16/04/2016> (10) Joint Formulary Committee. British National Formulary (online) London: BMJ Group and Pharmaceutical Press available here <Accessed 16/04/2016> (11) Harvey RSJ, Reffitt DM, Doig LA. Ferric trimaltol corrects iron deficiency anaemia in patients intolerant of iron. Aliment Pharmacol Ther 1998; 1998(12):845-848. (12) Schmidt, C., Ahmad, T., and Tulassay, Z (Iron Therapeutics Ltd). Poster presentation at the 23rd United European Gastroenterology (UEG) week, Barcelona (Spain) in October 2015: Long-Term Treatment with Ferric Maltol is Effective and Well Tolerated in Treating Iron Deficiency Anaemia in Patients with Inflammatory Bowel Disease: Results from a Phase-3 Open-Label Study. Available on request from Shield Therapeutics. (13) Kelsey, S. M., Hider, R. C., and Bloor, J. R. Absorption of low and therapeutic doses of ferric maltol, a novel ferric iron compound, in iron deficient subjects using a single dose iron absorption test. Journal of Clinical Pharmacy and Therapeutics 1991; 16 (2): 117-122 (Abstract). (14) Gasche C, Ahmad T, Tulassay Z. Ferric maltol is effective in correcting iron deficiency anemia in patients with inflammatory bowel disease: results from a phase-3 clinical trial program. Inflammatory Bowel Disease 2015; 21(3):579-587. (15) Healthwise Inc A-Z Guides: Ferritin available here <Accessed 20/04/2016> (16) Paruthi, S. and Staros, EB. Transferrin Saturation available here <Accessed 20/04/2016> (17) Personal Communication, Dr Mark Sampson, VP medical Affairs, Shield Therapeutics. (18) Shield Therapeutics. Trial protocol: Safety and efficacy study of oral ferric maltol compared to intravenous iron to treat iron deficiency anaemia in IBD (NCT02680756) available here <Accessed 16/04/2016> (19) Summary of the risk management plan (RMP) for Feraccru (ferric maltol) European Medicines Agency (EMA 14796/2016) 2016 available here <Accessed 26/03/2016> (20) European Medicines Agency (EMA). New recommendations to manage risk of allergic reactions with intravenous iron-containing medicines [EMA/377372/2013] 2013 via here <Accessed 18/04/2016> (21) Walmsley RS, Ayres RCS, Pounder RE et al. A simple clinical colitis activity index. Gut 1998; 43:29-32. (22) Best WR, et al. Development of a Crohn's disease activity index. Gastroenterology 70:439-444, 1976. (23) Participation and Quality of Life (PAR-QoL) project: Quality of Life Concepts University Health Network (Toronto, ON and the Centre for Interdisciplinary Research in Rehabilitation and Social Integration Canada via here <Accessed 20/04/2016> <p>Additional references referred to in a supplementary local review:</p> <ol style="list-style-type: none"> 1. Ferric maltol (Feraccru). All Wales Medicines Strategy Group (ref 2631) Jan 2017. Available here: (accessed 02/08/2017) 2. Ferric maltol (Feraccru). Scottish Medicines Consortium (ref 1202/16) December 2016. Available here (accessed 02/08/2017) 3. Safety and Efficacy of oral ferric maltol compared to intravenous iron to treat iron deficiency anaemia. NCT02680756. Available here (accessed 02/08/2017)

NOTES:

- a) SEL IMOC recommendations and minutes are available via the [website](#)
- b) This SEL IMOC 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.
- c) **Not to be used for commercial or marketing purposes. Strictly for use within the NHS.**