Wrightington, Wigan and Leigh Teaching Hospitals
NHS Foundation Trust

Title of Guideline	Iron Deficiency Anaemia (IDA) Treatment with Intravenous Ferinject (Ferric Carboxymaltose)
Contact Name and Job Title (Author)	Dr Chris Gregory - Consultant Haematologist, Clinical Director Scheduled Care & Chair of Thrombosis Committee
Division & Specialty	Medicine - Haematology
Guideline Number	CG17-021
Version Number	3
Date of Review	November 2024
Approving Committee(s)	Medicine Division Quality & Effectiveness Group
Date of Approval	November 2021
Explicit definition of patient group to which it applies	Adult patients who have Iron Deficiency Anaemia (IDA) and oral iron therapy is ineffective, or they are unable to tolerate it.
Abstract	
Statement of evidence base of the guideline Evidence Base (1-5)	

1a	Meta analysis of RCT
1b	At least 1 RCT
2a	At least 1 well designed controlled study without randomisation
2b	At least 1 other well designed quasi experimental study
3	Well –designed non-experimental descriptive studies (ie comparative / correlation and case studies)
4	Expert committee reports or opinions and / or clinical experiences of respected authorities
5	Recommended best practise based on the clinical experience of the guideline developer

Consultation Process	
Target Audience	
This guideline has been registered with the trust. However, clinical guidelines are guidelines only. The interpretation and application of clinical guidelines will remain the responsibility of the individual clinician. If in doubt contact a senior colleague or expert. Caution is advised when using guidelines after the review date.	

Definition

The purpose of this guideline is to give information and advice regarding the indications, referral, prescribing, administration and monitoring of intravenous iron within a Department or Ward setting.

Introduction

The first line treatment for most patients with Iron Deficiency Anaemia (IDA) should be an oral iron preparation such as Ferrous Sulphate 200mg one to be taken three times a day. However some patients may not be able to tolerate oral iron due to its side-effects and some patients may not adequately respond to it due to their underlying conditions.

This guideline is aimed at highlighting which patients can be considered for intravenous iron replacement and how that medicine should be safely administered. Treating IDA, including pre and post-operatively, can reduce the need for blood transfusion. This avoids serious risks associated with blood transfusions, for example infection, fluid overload or the incorrect blood group being administered.

Intravenous iron is considered a safer and more cost-effective treatment than blood transfusions, as recommended by NICE, and will be employed in this Trust as the preferred option, where appropriate, for all divisions.

This Trust currently uses Ferinject (ferric carboxymaltose) as the first choice of intravenous iron therapy. Other preparations may be available but the indications for them should be approved by a Consultant Haematologist and Pharmacy.

Definition of Iron Deficiency

Iron deficiency is diagnosed by a low serum ferritin (<15µg/l) with or without anaemia. However, ferritin is a protein that rises with inflammation and so patients with acute or chronic medical conditions may be iron deficient despite having a normal or even elevated ferritin. Therefore, ferritin levels of up to 100µg/l may still be consistent with iron deficiency in the presence of inflammation.

Patients who are anaemic and who have ferritin levels above 100µg/l should be investigated for other pathologies and can be discussed with the Haematology team if needed.

Eligibility Criteria

1) Malabsorption where oral iron supplements have been ineffective.

2) Inability to tolerate oral iron therapy despite trying at least two different preparations and taking only one tablet three times a week.

3) Cases where oral iron supplements have not improved the haemoglobin (Hb) (these cases need to be discussed with on-call consultant haematologist as it may not be straight forward IDA).

4) Severe symptomatic IDA (usually Hb < 80g/L); then intravenous iron can be used initially to raise the Hb and subsequently oral iron supplements can be initiated.

5) In cases of severe symptomatic IDA (usually Hb 60- 70g/L) requiring blood transfusion, 1 unit of RBC (Red Blood Cell) can be transfused to alleviate symptoms followed by intravenous iron to minimise RBC transfusion. The patient can still be considered for oral iron therapy in the future.

6) In pre-operative patients with IDA (which require surgery sooner) intravenous iron should be used to optimise the Hb at least 4-6 weeks before the operation.

Please note that if the operation is in 1-2 weeks, then intravenous iron may not be of significant benefit as it usually takes 3-4 weeks for Hb to show improvement.

7) Post op patients – refer to previous points 4 or 5 depending on patients Hb and symptoms.

8) Iron deficiency anaemia during the second or third trimester of pregnancy where oral iron is unlikely to adequately correct the Hb before delivery. Intravenous iron is not recommended during the first trimester as it may cross the placenta and influence skeletal development in the foetus. NB. Dose should always be based on the booking weight.

If you have any issues with interpreting lab results please discuss it with the on call haematologist or pharmacist.

Other indications (e.g. Jehovah's Witness, cardiac failure, renal failure) may be considered on an individual basis after discussion with a relevant consultant physician or pharmacist.

Exclusion Criteria

- Known allergy to Ferinject or any of its excipients
- Known serious hypersensitivity to other parenteral iron products
- Ongoing bacteraemia. Use with caution in patients who have acute or chronic infections.
- Anaemia that is not due to iron deficiency
- Evidence of iron overload or disturbances in utilisation of iron
- First trimester of pregnancy

Prescribing Ferinject on Wards

- Ferinject should be prescribed on HIS – if 2 doses are needed prescribe both doses one of which should be a pending order for 1 weeks' time. This must be verified on HIS by the ward pharmacist in the usual manner.

- Doses(s) of Ferinject to be given on the ward will be ordered by the pharmacy team on a "Pharmacy Verified Medications" order sheet from HIS. The paper prescription should stay on the ward in the patient's paper notes.

- A separate prescription sheet (see Appendix 2) must also be completed and clinically checked by the Ward Pharmacist - this prescription must be sent to PIU once the 1st dose has been administered (if a second dose is needed).

- The following medicines should be prescribed before the Ferinject is administered so hypersensitivity or anaphylactic reactions can be treated without delay:

    - Paracetamol 1 gram PO QDS PRN
    - Hydrocortisone 100mg IV single stat dose PRN
    - Chlorphenamine 10mg IV single stat dose PRN

- If the patient is discharged before the second dose is given (if required) then add the pending order for the second dose to the patient's discharge medication so that pharmacy can dispense and send to PIU in advance of the patient's appointment.

Referring the patient to PIU (for 2nd dose if necessary)

- Complete the attached form (Appendix 1)
- Fax the form to PIU
- Phone PIU to arrange the follow up appointment date
- Ensure the original paper prescription is sent to PIU if a second dose is required.
- If the patient is discharged from the ward before the second dose if given, the second dose will be dispensed by pharmacy on the discharge letter and sent to PIU directly so that it is available in time for the appointment.

Administration of Ferinject

- Ferinject should only be administered by staff who have been trained to recognise and manage anaphylactic reactions
- Administration of Ferinject must be recorded on HIS **and** on the paper prescription form by the nurses giving it
- Full facilities for cardio-respiratory resuscitation with equipment for handling acute anaphylactic reactions must be available
- Patients should have their blood pressure, heart rate, oxygen saturations and temperature checked before the Ferinject is administered and repeated 30 minutes after the infusion has finished.
- Patients should only receive Ferinject in an area where they can be directly observed by the staff managing the infusion
- The maximum single dose of Ferinject is 1000mg or 20mg/kg whichever is less.

- Caution should be exercised to avoid paravenous leakage (tissuing) when administering Ferinject. Paravenous leakage may cause irritation of the skin and a long lasting brown discolouration at the site of the injection. In case of paravenous leakage the infusion must be stopped immediately and the Trust Extravasation policy followed

- During the infusion and for 30minutes after it has finished the patient should be observed for signs of an allergic reaction. This may include but is not limited to (see Summary of Product Characteristics (SPC) for full details):

    - Headaches
    - Dizziness
    - Flushing
    - Hypertension or hypotension
    - Nausea and vomiting
    - Infusion site reaction or pain
    - Numbness
    - Abnormal taste
    - Tachycardia
    - Breathlessness
    - Itching
    - Skin rash
    - Muscle aches or spasms
    - Back pain
    - Pyrexia
    - Chest pain
    - Lip or throat swelling

- If hypersensitivity is suspected and the infusion is still running it should be discontinued and the patient given the prescribed medicines as required.

- If anaphylaxis is suspected it should be managed according to the Trust guideline and adrenaline, salbutamol, intravenous fluids and oxygen administered as required.

Please note that the risk of hypersensitivity reactions is enhanced for the following patient groups:

Patients with known allergies including drug allergies, patients with a history of severe asthma, eczema or other atopic allergy, patients with immune or inflammatory conditions (e.g. systemic lupus erythematosus, rheumatoid arthritis).

Administration guidance

Please refer to Medusa - Injectable Medicines Guide search for ferric carboxymaltose (not Ferinject).

References:

- Ferinject - Summary of Product Characteristics (SPC) (last updated 23/05/2017) - https://www.medicines.org.uk/emc/medicine/24167
- Ferric Carboxymaltose (Ferinject) Injectable Medicines Guide http://medusa.wales.nhs.uk

Iron Therapy referral form (Day case)

(To be used in conjunction with telephone referral)

PIU Nurse contact: 01942 822941 **PIU Fax No: 01942 822384**

Form to be completed in black ink, block capitals, authorized abbreviations only.

Referral date	
Referring Consultant/Dr	
Unit number	
Patient Name	
DOB	
Allergies	
Address Post code	
Tel No	
Other contact	

Informed verbal consent obtained?	Yes		No		Date	

Ferinject®- first line IV treatment of iron deficiency

Booking requirements

Patients current: Hb _____ Ferritin_____ Weight: ___kg / Pre pregnancy____kg

- Advise patient to stop taking oral iron, they must be omitted for 5 days prior to PIU admission. Where clinically indicated oral iron can be recommenced 5 days post IV treatment.
- Pregnant patient – please provide the patients **pre** pregnancy weight. Parenteral iron can only be given in the second and third trimesters.
- Infection - Parenteral iron therapy is contraindicated in patients with infection. Referrals will be accepted and therapy begins once the infection has resolved.
- Please have the patient's current medical/drugs history available when telephoning the unit.
- Case notes tracked and forwarded to PIU
- If referring a patient from a ward for a second dose, ensure you send the original prescription to PIU once the patient has received the 1st dose on the ward.

Form faxed on:_____ By: _____ sign

Appendix 2

FERINJECT IV (Ferric carboxymaltose)

ADULT Prescription chart, dosing and instructions for IV infusion.

Wrightington, Wigan and Leigh NHS
NHS Foundation Trust

Name				Ward/Dept	
Date of birth		Unit/NHS number		Weight (Kg)	
Hb (g/L) (within 4 weeks)				Date	

Determination of the dose indicated **NB – For patients weighing <50kg DO NOT exceed 20mg/kg in one infusion. For patients weighing above 50kg do not exceed 1000mg in one infusion, (2 visits may be necessary)**

g/L	below 35 kg	35 kg to <70 kg	70 kg and above
<100	500 mg	1,500 mg	2,000 mg
100 to <140	500 mg	1,000 mg	1,500 mg
≥140	500 mg	500 mg	500 mg

Total dose Ferinject IV		1st dose	(Max dose 1000mg or 20mg/kg)	Date	
		2nd dose (1 week after 1st dose)	(Max dose 1000mg or 20mg/kg)	Date	
Prescribers name & signature		Consultant:		Directorate:	

	Date	Time	Total dose Ferinject to be given (mg)	BN(Batch Number) EXP (Expiry)	IV Fluid NaCl 0.9% 250ml	Flush NaCl 0.9% 30ml	Time to run over	Time commenced	Put up by	Checked by	Discontinuation time
1st dose				BN:	BN:	BN:	15 minutes				
				EXP:	EXP:	EXP:					
2nd dose				BN:	BN:	BN:	15 minutes				
				EXP:	EXP:	EXP:					

Monitoring (for at least 30minutes after infusion)
BP, HR, Pulse & temperature observe for signs of allergic reaction

Adverse reactions
Headache, dizziness, flushing, hypertension, nausea, infusion site reactions, paraethesia, disgeusia, tachycardia, hypotension, dyspnoea, pruritis, rash, myalgia, back pain muscle spasms, pyrexia, chest pain and rarely anaphylaxis

Prescribe the following in case of reaction
*Paracetamol 1gram PO QDS prn * hydrocortisone 100mg IV PRN QDS * chlorphenamine 10mg IV PRN QDS

In case of severe adverse reaction the infusion should be stopped

Pharmacy use only

Clinical check	
Dispensed by	
Accuracy check	