Intravenous Iron Infusion (ferric carboxymaltose (Ferinject®)) Guidance for clinicians working in Powys Community Hospitals

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Bwrdd Iechyd Addysgu Powys yw enw gweithredol Bwrdd Iechyd Lleol Addysgu Powys

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Important information:

- Treatment or prophylaxis of iron deficiency anaemia during pregnancy, post-partum, in children or patients with haemodialysis-dependent chronic kidney disease fall outside the scope of this guidance. The use of IV iron for pre-dialysis and dialysis patients based in Powys must follow the advice and guideline from the referring specialist team.
- No clinician should feel compelled to offer or support the prescribing and administration of Ferinject®, if they believe this treatment is not clinically appropriate, or if they do not have the required competencies.
- Out-of-hours services must not be asked to support any aspect of IV iron administration (including post-administration observations).

1. Introduction

The purpose of this guideline is to support safe prescribing and administration of intravenous (IV) Ferinject® - iron (as ferric carboxymaltose) 50mg/ml solution for infusion.

Hypersensitivity reactions are recognised to occur rarely with IV iron products but, when they do occur, they can be life-threatening or fatal. Ferric carboxymaltose (Ferinject®) must only be administered when staff trained to evaluate and manage anaphylactic reactions are immediately available, in an environment where full resuscitation facilities can be accessed.

Iron deficiency anaemia is usually treated with oral iron supplements because of their cost-effectiveness and safety profiles. However, the use of intravenous (IV) iron can be considered when: (1) oral iron is ineffective, (2) oral iron preparations cannot be used, or (3) when there is a clinical need to deliver iron rapidly.

The risk of hypersensitivity is enhanced in patients with known allergies including drug allergies, patients with a history of severe asthma, eczema or other atopic allergy and patients with immune or inflammatory conditions (e.g. systemic lupus erythematosus, rheumatoid arthritis). The MHRA/CHM has provided advice on risk of serious hypersensitivity reactions with intravenous iron (MHRA link).

All staff working to this guidance should have a good understanding of Chapter 15 of The Royal Marsden Manual of Clinical and Cancer Nursing Procedures: Medicines optimization: ensuring quality and safety - Intravenous Injections and Infusions and of the PTHB Medicines Policy. Prescribers are expected to follow normal prescribing guideline requirements together with specific guidance described in these documents.

2. Indication

Ferric carboxymaltose (Ferinject®) is indicated for the treatment of iron deficiency anaemia (based on laboratory tests) when:

- Oral iron preparations are ineffective;
- Oral iron preparations cannot be used*;
- There is a clinical need to deliver iron rapidly.

*oral iron treatment regimens should be optimised before the decision to use IV iron is taken.

Optimising oral iron treatment:

- reducing the dose frequency of the oral iron supplement;
- recommending oral iron is taken with or after meals;
- giving a different iron formulation/salt with a lower content of elemental iron (see BNF);
- offering reassurance to patients who have black stools (this alone is not an indication for iron infusion);
- offering a laxative to patients with constipation.

In the absence of other clear causes of anaemia, iron deficiency is suggested by:

- Hb < 130 g/L (men) and Hb < 120 g/L (women);
- MCV < 80 femtolitres;
- Serum ferritin < 30 µg/L.

3. Contraindications, cautions and side effects to ferric carboxymaltose

Contraindications	• Previous history of allergy to parenteral iron preparations or true iron allergy • Iron overload or disturbances of iron utilisation (eg haemochromatosis) • Hypersensitivity to the active substance, to Ferinject® or any of its excipients (see SPC) • Anaemia not attributed to iron deficiency, e.g. other microcytic anaemia (see SPC)

Cautions	• If the following conditions are present, the patient is at greater risk of hypersensitivity reactions:
	  ○ Patients with known allergies including drug allergies, symptomatic asthma, eczema, atopy
	  ○ Rheumatoid arthritis/SLE (systemic lupus erythematosus)
	• Active infection
	• Decompensated liver disease
	• Risk of symptomatic hypophosphataemia leading to osteomalacia and fractures (MHRA link)

Side effects	**Immediate** • Hypersensitivity • Anaphylaxis/anaphylactoid reactions. Follow the Guideline available via the intranet to identify and manage anaphylaxis • Extravasation

	Other side effects • Common (>1:100 to <1:10): dizziness; flushing; headache; hypertension; hypophosphataemia; hypotension; nausea; skin reactions; taste altered • Uncommon (>1:1000 to <1:100): arrhythmias, arthralgia, chest pain, chills, fatigue, fever, rash, cramps, GI symptoms (nausea, vomiting, abdominal pain, constipation, diarrhoea), blurred vision, numbness, difficulty breathing, myalgia, arthralgia, peripheral oedema • Rare (>1:10000 to <1:1000): anxiety, influenza like illness, malaise, pallor, palpitations, seizure, tremor, permanent skin discolouration/staining

Any suspected adverse drug reactions should be reported to the Yellow Card Scheme

4. Preparation and referral for treatment

Prescriber Responsibilities

- Ensure that you have the competencies required to prescribe, administer and monitor the administration of IV iron.
- Ensure that the indication for IV iron is clearly documented in the patient's clinical records, along with details of where/who the recommendation to use IV iron came from. Record details of treatment options tried/considered prior to IV iron and why they were discontinued/not suitable. Confirm that there are no contraindications to IV iron.
- Confirm capacity to accommodate patient with hospital ward manager.
- Inform the ward if a Do Not Attempt Cardiopulmonary Resuscitation (DNACPR) is in place and ensure the necessary DNACPR documentation is in place.
- Undertake required blood tests within four months of planned infusion (including, as a minimum, Hb, iron studies and ferritin).
- Ensure that there is an up-to-date weight available for the patient.
- Due to the risk of symptomatic hypophosphataemia leading to osteomalacia and fractures, monitor serum phosphate levels in patients treated with multiple high-dose administrations, or those on long-term treatment, and in those with pre-existing risk factors for hypophosphataemia. Re-evaluate ferric carboxymaltose (Ferinject®) treatment in patients with persistent hypophosphataemia.
- Discuss potential adverse reactions with the patient, including the possibility of skin staining, and safety measures that are put in place in case of a severe adverse reaction.
- Prescribe on an inpatient drug infusion chart or digital records (see Dosage guidance below).

- To allow the Pharmacy Team to order the required dose, email completed Appendix A to Powys.PharmacyTeam@wales.nhs.uk, along with copy of inpatient infusion chart or digital records.
- Once information is provided by the Pharmacy Team about when the IV iron will be available on the ward, inform the patient of the appointment date, time and location.
- Ensure that the patient understands that oral iron must be stopped for at least 24 hours before the iron infusion.
- Arrive on ward at least 1 hour before intended infusion time, remain on the ward during the infusion period and for at least 30 minutes after the dose has been administered. This is to allow for preparation, administration and monitoring.
- Before administration confirm that that maximum daily dose and cumulative dose are not exceeded.
- Inform the patient of when it will be appropriate to restart oral iron – this will usually be at least 5 days after the last infusion.

Pharmacy Responsibilities

- Pharmacist to check prescription and 'Ferinject® Infusion - Pharmacy Request Form' (Appendix A).
- Send request to Nevill Hall or Bronglais Hospital as appropriate to the ward.
- Inform the prescriber when the Ferinject® will be available on the ward.

Nursing Team Responsibilities

- Confirm date, time and location for administration with prescriber.
- Ensure registered nursing staff with the required competencies are available to administer Ferinject®.
- Ensure immediate access to full resuscitation equipment is available, including adrenaline 1 in 1000, and access to a working telephone.
- Before administration confirm that that maximum daily dose and cumulative dose are not exceeded.

5. Dosage and prescribing

A single Ferinject ® infusion should not exceed 20mg iron/kg body weight and must not exceed 1000mg iron in total. Doses greater than 1000mg or greater than 20mg iron/kg body weight must be divided with the second dose given no sooner than 1 week after the first dose.

Hb	**Patient body weight**		
g/L	**below 35 kg**	**35 kg to <70 kg**	**70 kg and above**
<100	30 mg/kg body weight*	1,500 mg*	2,000 mg*
100 to <140	15 mg/kg body weight	1,000 mg	1,500 mg*
≥140	15 mg/kg body weight	500 mg	500 mg

*Divided dose required, second dose to be given no sooner than 1 week after the first dose.

6. Storage, Compatibility and Administration

See also Medusa NHS Injectable Medicines Guide

- Store ferric carboxymaltose (Ferinject®) in the original package to protect from light. Do not store above 30°C. Do not freeze.
- Inspect vials visually for sediment and damage before use. Use only those containing sediment-free, homogeneous solution.
- For IV infusion, firstly dilute, then give via an infusion pump. For infusion, Ferinject® must only be diluted in sterile 0.9% sodium chloride solution as shown in the table below. Do not dilute or infuse with any other medicines or infusions.
- For stability reasons, Ferinject® should not be diluted to concentrations less than 2 mg iron/mL (not including the volume of the ferric carboxymaltose (Ferinject®) solution).
- Each vial of Ferinject® is intended for single use only. Any unused product or waste material should be disposed of in accordance with local requirements.
- For flushing at the end of the infusion, flush the line with sodium chloride 0.9% at the same rate of the infusion as the Ferinject® previously administered. For more information please consult NIVAS Guidance on line flushing.

Dilution plan of Ferinject® for intravenous infusion

Volume of Ferinject® required			Equivalent iron dose			Maximum amount of sterile 0.9% sodium chloride solution	Minimum administration time
2	to	4 mL	100	to	200 mg	50 mL	No minimal prescribed time
>4	to	10 mL	>200	to	500 mg	100 mL	6 minutes
>10	to	20 mL	>500	to	1,000 mg	250 mL	15 minutes

7. Patient monitoring before, during and after infusion:

Caution is needed with every dose, even if previous administrations have been well tolerated.

Prior to infusion:

- Check that anaphylaxis equipment (including adrenaline 1 in 1000) and access to a working telephone is available, **do not proceed if unavailable, incomplete or outdated.**
- A full set of observations and NEWS score must be recorded.
- Ask the patient whether they have any new health concerns**.** If concerns will need discussion with the prescriber **prior to infusion**.

- If the patient has any signs or symptoms of infection inform the prescriber. They will decide whether it is appropriate to delay the infusion until the infection has resolved.
- Relevant past medical history and allergies should have been reviewed by the prescriber at time of dose calculation/prescription and should be confirmed by nurse administering the infusion and any changes checked with the prescriber.

During infusion:

- Observations must be monitored **at 15 minutes** after starting the infusion (blood pressure, heart rate, respiratory rate, temperature, oxygen saturations, National Early Warning Score (NEWS)).
- Monitor for signs of extravasation. If this occurs, stop the Ferinject® infusion immediately. See Royal Marsden Manual for Management.
- If patient feels unwell, observations become unstable or if a hypersensitivity reaction is suspected, the infusion should be stopped and, where appropriate, the PTHB Management of Anaphylaxis Procedure should be followed. Most reactions are self-limiting, and infusion can be restarted and delivered more slowly. **Alert prescriber prior to restarting the infusion.** In case of anaphylactic reaction, **infusion must be stopped and disconnected immediately and anaphylaxis procedure followed.**

After infusion:

- **Immediately following infusion,** observations (blood pressure, heart rate, respiratory rate, temperature, oxygen saturations, National Early Warning Score (NEWS)) should be monitored **30 minutes** post infusion finish.
- Haemoglobin level should be re-assessed at least 4 weeks post final Ferinject® administration.
- Healthcare professionals are advised to monitor serum phosphate levels in patients requiring multiple high-dose administrations, on long-term treatment, or with pre-existing risk factors for hypophosphataemia (MHRA link).

Further information

Refer to the summary of product characteristics via Ferinject SPC.

Appendix A – Ferric Carboxymaltose (Ferinject®) Infusion - Pharmacy Request Form

NB: This form should **NOT** be used when requesting ferric carboxymaltose for the treatment or prophylaxis of iron deficiency anaemia during pregnancy, post-partum, in children or patients with haemodialysis-dependent chronic kidney disease, as these areas fall outside the scope of this guidance.

Apply Addressograph Label or complete:
Forename:
Surname:
Address:
Postcode:
Date of Birth: / /
NHS number:

Ferric carboxymaltose (Ferinject®) 50mg/1mL solution for injection/infusion is available as: • 100mg/2mL • 500mg/10mL • 1000mg/20mL. It is indicated for the treatment of iron deficiency as confirmed by laboratory testing. Due to the risk of hypersensitivity reactions, intravenous iron **should only** be used where oral iron cannot be used or when oral iron is ineffective or not tolerated (and adjustments have not resolved) and/or there is a clinical need to deliver iron rapidly. In the absence of other clear causes of anaemia, iron deficiency is suggested by: • Hb < 130 g/L (men) and Hb < 120 g/L (women); • MCV < 80 femtolitres; • Serum Ferritin < 30µg/l;	***Contraindications to iron infusion*** • Previous history of allergy to iron preparations or true iron allergy • Iron overload or disturbances of iron utilisation (eg. haemochromatosis) • Hypersensitivity to the active substance or to any of the excipients of Ferinject® • Anaemia not attributed to iron deficiency ***Cautions*** • Active infection • Symptomatic asthma, eczema, atopy • Decompensated liver disease • Rheumatoid arthritis/SLE • Risk of symptomatic hypophosphataemia

Indication:
Causes for iron deficiency:
Any contraindications or cautions (see above)? Yes ☐ No ☐

Reason why other treatment options are not suitable?

Allergies:

Determination of the iron need			
	Body weight		
Haemoglobin (g/L)	< 35 Kg	35 to <70 Kg	> 70 Kg
< 100	30 mg/kg body weight*	1,500 mg*	2,000 mg*
100 to <140	15 mg/kg body weight	1,000 mg	1,500 mg*
≥140	15 mg/kg body weight	500 mg	500 mg
NB a single ferric carboxymaltose (Ferinject®) infusion should not exceed 20mg iron/kg body weight and must not exceed 1000mg iron. *An **amount greater than 1000mg or greater than 20mg iron/kg body weight must be given in divided doses at least a week apart**			

Date last blood test: / /
Haemoglobin: g/L
Patient weight: Kg

Date of first ferric carboxymaltose infusion planned: / /
Date of second ferric carboxymaltose infusion planned (if needed):
/ /
Hospital ward name:

Appointment(s) booked with ward? Yes ☐ No ☐
Ward informed if DNACPR is in place/arrange documentation? Yes☐ No☐ NA☐
Patient informed? Yes ☐ No ☐
Infusion chart/prescription record completed and attached? Yes ☐ No ☐

Prescriber signature: Printed:

Date: / /

Pharmacist signature: Printed:

Date: / /