Iron Infusion (Ferric Carboxymaltose) PHC Remote Clinical Guideline

<table>
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<tr>
<th>Target Audience</th>
<th>All Clinical Employees</th>
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<tr>
<td>Jurisdiction</td>
<td>Primary Health Care Remote CAHS; Primary Health Care Remote TEHS</td>
</tr>
<tr>
<td>Jurisdiction Exclusions</td>
<td>N/A</td>
</tr>
<tr>
<td>Document Owner</td>
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<td>Atlas Development Officer Primary Health Care Remote CAHS</td>
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<td>Chair</td>
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<td></td>
<td>Primary Health Care NT Wide Leaders Committee</td>
</tr>
<tr>
<td>Author</td>
<td>PHC Quality and Safety Team</td>
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The attributes in the above table will be auto-filled from the PGC System. Do not update in this document.

Purpose

To provide Primary Health Care remote staff with a clinical protocol on the criteria and management required for administering an iron infusion (Ferric Carboxymaltose) to a client in a remote health centre.

Guideline

**WARNING:**

THIS PROTOCOL IS FOR THE PRESCRIBING AND ADMINISTRATION OF FERRIC CARBOXYMALTOSE (FERINJECT) ONLY.

ENSURE CORRECT PRODUCT SELECTION BEFORE PROCEEDING.

1. Preface

Primary Health Care (PHC) recognises that providing selected clients the opportunity to receive iron infusions in remote health centres can be a beneficial service. The logistics and cost associated with arranging travel to hospital or urban renal unit, social disruption, client preference, and workload in renal units, may each be factors in making local administration of iron a preferred option.

Providing iron infusions at remote health centres has previously also had its own impact in time and resources. Ferric Carboxymaltose infusions have a significantly shorter infusion time and an improved safety profile when compared to other iron products. This allows Ferric Carboxymaltose to be infused with reduced client risk and impact on health centre staff and resources. Ferric Carboxymaltose is therefore the only iron product that should be administered as an infusion in DoH remote health centres.

Iron infusions are not described in the CARPA STM or the CRANA Clinical Procedures Manual. This protocol is provided so that where a decision is made to give iron intravenously at a remote health centre, guidelines are available.

Ferric Carboxymaltose infusions may only be administered in DoH remote health centres when:

- prescribed by a Medical Officer
either a Medical Officer, Nurse, Midwife or Aboriginal and Torres Strait Islander Health Practitioner (ATSIHP) with Immediate Life Support (ILS) or Advanced Life Support (ALS) competency remains with the client throughout the duration of the infusion

- the client is above the age of 14 years
- the procedure is carried out in a room with emergency equipment
- an infusion pump is used

2. When to give a Ferric Carboxymaltose Infusion:

A Ferric Carboxymaltose infusion may be prescribed by a Medical Officer to:

- correct iron deficiency anaemia when oral/IM preparations are ineffective or inappropriate
- replenish/maintain iron stores for clients receiving erythropoietin therapy
- reduce the need for repeated blood transfusions and the inherent problems of increased antibody formation.

3. Contraindications - Do not give Ferric Carboxymaltose if the client:

- has known hypersensitivity to Ferric Carboxymaltose or any listed excipients*
- is under 14 years of age
- is pregnant in the first trimester
- has anaemia not attributed to iron deficiency
- has evidence of iron overload or disturbances in utilisation of iron
- is septic

* Excipients are the pharmacologically inactive substances included in a medicinal product.

4. Ferric Carboxymaltose use in pregnancy

Ferric Carboxymaltose may be used to correct iron deficiency anaemia in pregnancy only where oral or IM preparations are ineffective or inappropriate. A dating scan is mandatory prior to use of ferric carboxymaltose in pregnancy.

Ferric Carboxymaltose:

- is contraindicated in the first trimester of pregnancy
- may be used in the second trimester of pregnancy only after consultation with an obstetrician, and risk/benefit evaluation taking into account both the client and foetus
- may be used in the third trimester of pregnancy following risk/benefit evaluation taking into account both the client and foetus
- must not be used if there is any acute intercurrent maternal illness, including evidence of sepsis or infection
- must not be used if birth is expected in the next few days

5. Prescribing

5.1 Prescription

Ferric Carboxymaltose must be prescribed by a Medical Officer. The decision to prescribe a Ferric Carboxymaltose infusion must only be made after review of the client's haemoglobin and iron studies, and in pregnant women as described above. Oral iron supplements should be withheld for at least five days following Ferric Carboxymaltose administration.
5.2 Determining the Iron Dose

Calculate the cumulative iron dose to determine the client’s total iron requirement.

<table>
<thead>
<tr>
<th>Cumulative Iron Dose Calculation – Simplified Method</th>
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<tbody>
<tr>
<td>(for clients of body weight ≥35kg)</td>
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</table>

<table>
<thead>
<tr>
<th>Haemoglobin (g/L)</th>
<th>Body Weight 35kg to &lt;70kg</th>
<th>Body Weight ≥70kg</th>
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<tbody>
<tr>
<td>&lt;100g/L</td>
<td>1500mg elemental iron</td>
<td>2000mg elemental iron</td>
</tr>
<tr>
<td>≥100g/L</td>
<td>1000mg elemental iron</td>
<td>1500mg elemental iron</td>
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Important Notes:
- The cumulative dose calculations for clients in the second or third trimester of pregnancy should be based on the client's pre-pregnancy weight
- Cumulative iron doses greater than 1000mg must be split into TWO DOSES given AT LEAST ONE WEEK APART
  - up to 20mg iron/kg body weight (to a maximum of 1000mg iron) may be given as a single dose
  - a maximum of 1000mg of iron may be administered per week

5.3 Dilution and Rate of Infusion

Ferric Carboxymaltose must be diluted in sterile sodium chloride 0.9% solution and infused as per below.

<table>
<thead>
<tr>
<th>Iron Dose</th>
<th>Ferric Carboxymaltose (Ferinject) Volume</th>
<th>Sodium Chloride 0.9% Volume</th>
<th>Minimum Infusion Time</th>
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</thead>
<tbody>
<tr>
<td>&gt;200 mg to 500 mg</td>
<td>&gt;4 mL to 10 mL</td>
<td>100 mL</td>
<td>6 minutes</td>
</tr>
<tr>
<td>&gt;500 mg to 1000 mg</td>
<td>&gt;10 mL to 20 mL</td>
<td>100 mL</td>
<td>15 minutes</td>
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Note: For stability reasons Ferric Carboxymaltose must not be diluted to concentrations less than 2mg/ml. The dilutions stated in the Australian Injectables Drugs Handbook 6th ed (AIDH) differ to those in this protocol and are reflective of the minimum allowable Ferric Carboxymaltose concentration.

6. Administration

6.1 Equipment Required

- Medication / IV Fluid order
- Ferric Carboxymaltose complex (Ferinject)
- 100ml 0.9% Sodium Chloride infusion bag
- 10ml 0.9% Sodium Chloride ampoule
- Drawing up equipment
  (10ml syringe, 18g needles x 2)
- Cannulation equipment
- Intravenous Giving Set
- Intravenous Infusion Pump
- Additive Labels
- Alcohol Swabs
- Gloves
- Sharps Container
- Resuscitation Equipment
  - Anaphylaxis kit
  - Resuscitation Trolley - ensure medicines are present and in date:
    - IV Hydrocortisone 100mg vial
    - IM Adrenaline 1:1000 ampoule
    - IM Promethazine 50mg/2mL
## 6.2 Infusion Preparation

Prior to commencing infusion:

- Ensure there is a current valid prescription
- Ensure a Medical Officer has obtained client consent
- Review the dose and fluid calculations with a second practitioner
- Check that the emergency trolley and anaphylaxis kit are at hand and correctly set up
- Review the anaphylaxis protocol in the CARPA Standard Treatment Manual
- Record the pre-infusion observations as listed below
- Check with a second practitioner that the correct product is prescribed and selected for administration. *Do not confuse Ferinject (Ferric Carboxymaltose) with Ferrum-H (iron polymaltose)*
- Visually inspect the vials for sediment or damage. Only use intact vials containing homogenous solution that is sediment free
- Put in an 18G intravenous cannula, ensuring sound integrity of the cannulation
- Using aseptic technique, add the required volume of ferric carboxymaltose to the 100ml 0.9% sodium chloride infusion bag (one minute hand wash, wear gloves, change drawing up needle to new needle for introduction of iron, alcohol swab port and allow to dry)
- Ensure the contents of the bag are adequately mixed by performing a series of bag inversions
- Complete the additive label and attach to the infusion bag
- Assemble and prime the intravenous giving set and attach the intravenous infusion pump
- Flush the IV cannula with 10ml 0.9% sodium chloride to ensure sound integrity of the cannula before connecting the ferric carboxymaltose infusion

## 6.3 Observations

- Check blood pressure, respirations, pulse and temperature prior to the infusion. Do not commence the infusion and contact the Medical Officer if the client has signs of sepsis or infection.
- Check foetal heart rate prior to the infusion if administering in pregnancy
- A Nurse, Midwife or ATSIHP must remain with the client throughout the infusion to observe for adverse reactions. In the event of any adverse reaction, cease the infusion immediately and contact the Medical Officer
- Check blood pressure, respirations, pulse and temperature 5 minutes after commencement, at the end of the infusion, and 30 minutes after the infusion
- Check foetal heart rate post infusion if administering in pregnancy
- Check for signs of cannula displacement following commencement of the infusion and periodically through the duration of the infusion. Cannula displacement will cause tissue infiltration resulting in pain, local irritation and brown discoloration of the skin.

*Note: some adverse reactions such as hypotension or infusion site local irritation may be related to the dose or infusion rate. A decision may be made by the Medical Officer to restart the infusion at a slower rate.*

- The client must remain at the health centre for at least 30 minutes after the end of the infusion

Administration and all observations must be documented in the client's electronic health record using the Administer Medicines service item and Frequent Observations service/clinical item.

## 6.4 Should adverse reactions be noted at any time throughout the infusion:

1. *Stop the infusion immediately*
2. *Contact the Medical Officer*
3. *Refer to CARPA STM – Anaphylaxis*
Document Quality Assurance

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Key Associated Documents

| Forms | Nil |
| References | As above |

Evidence Table

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