CLINICAL PRACTICE GUIDELINE

Iron therapy: Intravenous

This document should be read in conjunction with this Disclaimer

Contents

Background

Intravenous iron is associated with improvements in haematological parameters and may be used to augment haemoglobin levels in women with identified iron deficiency anaemia (see Table 1) who have not responded sufficiently to oral iron or in patients whom a rapid repletion of iron stores is required as a result of a large blood loss or impending blood loss[1, 2, 3]

Whilst IV iron is deemed safe in experienced hands, significant reactions and complications[1,4] can occur. IV iron is not licenced for use as an acute treatment in the management of major haemorrhage. Management of these patients is complicated by red cell loss, acute dilutional anaemia and the inflammatory process which suppresses red cell production.[1]

The iron therapy used at KEMH is either Iron Polymaltose (IP) or Ferric Carboxymaltose (FC). With both components there are some medications whose efficacy is reduced and some medications where toxicity and risk of adverse reaction is increased. Contact pharmacy for further information and see contraindication /precautions below.

Table 1: Classification of anaemia in adult women	
Haemoglobin (g/L)	
<110	1st and 3rd trimester of pregnancy
<105	2nd trimester of pregnancy
<100	Postpartum period
<120	Non-pregnant adult women
A serum ferritin level of < 30ug/L for an adult is diagnostic of iron deficiency [2]	

Please also review O&G Clinical Guideline on 'Anaemia and iron deficiency: Management in pregnancy and postpartum'

Indications for IV iron therapy

- In iron deficiency anaemia (IDA) where oral iron therapy may be impractical or insufficient due to GI intolerance, non-compliance, malabsorption or gastric surgery.
- In situations where a rapid repletion of ferritin is required i.e. planned surgery and significant blood loss anticipated.
- High-risk women (i.e. major placenta praevia, placenta percreta/accreta, recurrent antepartum haemorrhage, and patients refusing blood products) with a haemoglobin level above 110g/L will be considered for haemoglobin optimisation on an individual basis. **In these instances each case will be discussed and approved between the Medical Team, CNC PBM and Haematologist.**
- In iron deficiency when stored iron cannot be released for erythropoiesis. This may be seen in patients with renal disease, inflammatory disease or cancer.

Ferritin can be raised in these conditions as it is an acute phase protein and some women with a 'normal' range ferritin may still benefit from IV iron. Interpretation of the results in patients with co-existing inflammatory disease or cancer is complicated and advice should be sought from a Consultant Haematologist if there are any doubts concerning the indications for IV iron.

- For women with haemoglobinopathy disease who frequently present with moderate to severe anaemia which may be related to iron deficiency. They may benefit from treatment, however IV iron is contraindicated in women presenting with hyperferritinaemia and interpretation of laboratory tests and management is complex. These women should be discussed with a Haematologist if there are concerns.

Contraindications / precautions [1,4, 6, 7]

Contraindications

- Hypersensitivity or allergy to IP or FC
- First trimester of pregnancy (Safety not tested in early pregnancy, animal studies have demonstrated increased fetal skeletal abnormalities and spontaneous abortions at maternally toxic doses during organogenesis. The level of drug crossing the placenta is unknown)
- Iron overload (i.e. haemochromatosis)
- Anaemia not due to iron deficiency (i.e. B12 deficiency, haemolytic anaemia, bone marrow disease or disturbances in erythropoiesis)
- Acute renal infection
- Uncontrolled hyperparathyroidism (FC only)
- Infectious hepatitis

Precautions

- May be more likely in women with a history of asthma and /or other allergic conditions.
- Previous adverse reaction to other forms of parenteral iron
- Liver dysfunction (elevated liver enzymes including lactate dehydrogenase occurs following administration)
- Do not administer to woman currently receiving IV antibiotics for treatment of acute bacterial infection. IV iron may be considered following cessation of IV antibiotics and is dependent upon the woman's condition.
- Concomitant administration of angiotensin converting enzymes (ACE) inhibitors may increase the incidence of adverse effects of intravenous iron including erythema, abdominal cramps, nausea, vomiting and hypotension
- Women with rheumatoid arthritis and other inflammatory diseases may be at particular risk of delayed reaction including fever and reactivation of joint pain

Requesting an iron infusion

See Appendix 1 – Quick Reference Guide for which Iron to prescribe

1. The team requesting the iron infusion are responsible for:
    - Ensuring there are no contraindications for use, discussing the risks and benefits of iron infusion, explaining the procedure, providing the woman with written information and answering any questions. See KEMH Patient brochure: Intravenous Iron Infusions
    - Ensuring recent (within 1 month) FBP and ferritin results are available.
    - Prescribing the IV iron on the intravenous additive order sheet (MR740).
    - In obstetric women use the pre-pregnancy weight. If this is not known then the dose should be based on current weight less 10%.1, 2.
    - In non-obstetric women use current weight.
    - Completing a PBS prescription for outpatients and women receiving IV iron on the day of discharge.
2. Complete all sections of the IV Iron Request Form (MR037.01 - obstetric women and MR037.02 non-obstetric women). Midwives and Nurses can make requests for an iron infusion providing its use has been discussed, approved and prescribed by a Medical Officer. The completed form after scanning and emailing should be placed in the medical record.
    - E-mail to: KEMHIronInfusionBookings@health.wa.gov.au
    - KEMH photocopiers have been programmed with the address under the ‘hot key’ Iron infusion req.).
    - **Incomplete requests will not be accepted and may cause delays to the provision of treatment.**
3. IV iron requests are reviewed, approved and prioritised (Mon – Fri) by the CNC PBM and/or the Consultant Haematologist/medical team against the current guidelines for treatment. Women who are clinically stable will be allocated an appointment for the Infusion Unit (usually Tuesday and Thursday’s).
    - **Urgent cases may be accommodated on other days in ASCU by consultation directly with ASCU.**
4. See appendix 1 - IV Iron quick reference algorithm for further information.

Iron infusion referrals for women deemed high risk (non KEMH patients)

Occasionally requests are received from non-tertiary centres to administer IV iron to women at high risk of a reaction to the drug due to their medical history. Formal requests will only be received through the Central Referral Service (CRS) for gynaecology patients or through the central fax (6458 1031) for obstetric patients. If the patient is within KEMH catchment the request will be reviewed as per criteria above to ensure the hospital receives the appropriate funding for the procedure.

- CNC PBM/Haematology will triage all referrals received by the KEMH Referral Co-ordinator. Triage includes a review of previous reaction and risk factors, blood results, previous iron therapy and assessment against current Clinical Guidelines.
- O&G HOD will assess suitability for IV iron therapy and allocate to a medical team to prescribe iron and concomitant therapy, some women may also need to be seen prior to the iron infusion procedure. If the patient is considered not suitable for IV iron at KEMH, then the PBM CNC will contact the referring centre provide a reason and advise them on other alternative strategies to manage patient.

Dosing

Ferric carboxymaltose (Ferinject®) [8, 9]

- Pregnant and non-pregnant women regardless of body weight receive a single infusion of 1000mg elemental iron as ferric carboxymaltose.
- Maximum daily dose of FC should not be more than 200mg elemental iron in haemodialysis dependent chronic renal disease
- The infusion is to be ordered as '**Elemental Iron as Ferric Carboxymaltose'**.

Iron polymaltose (IP) [6]

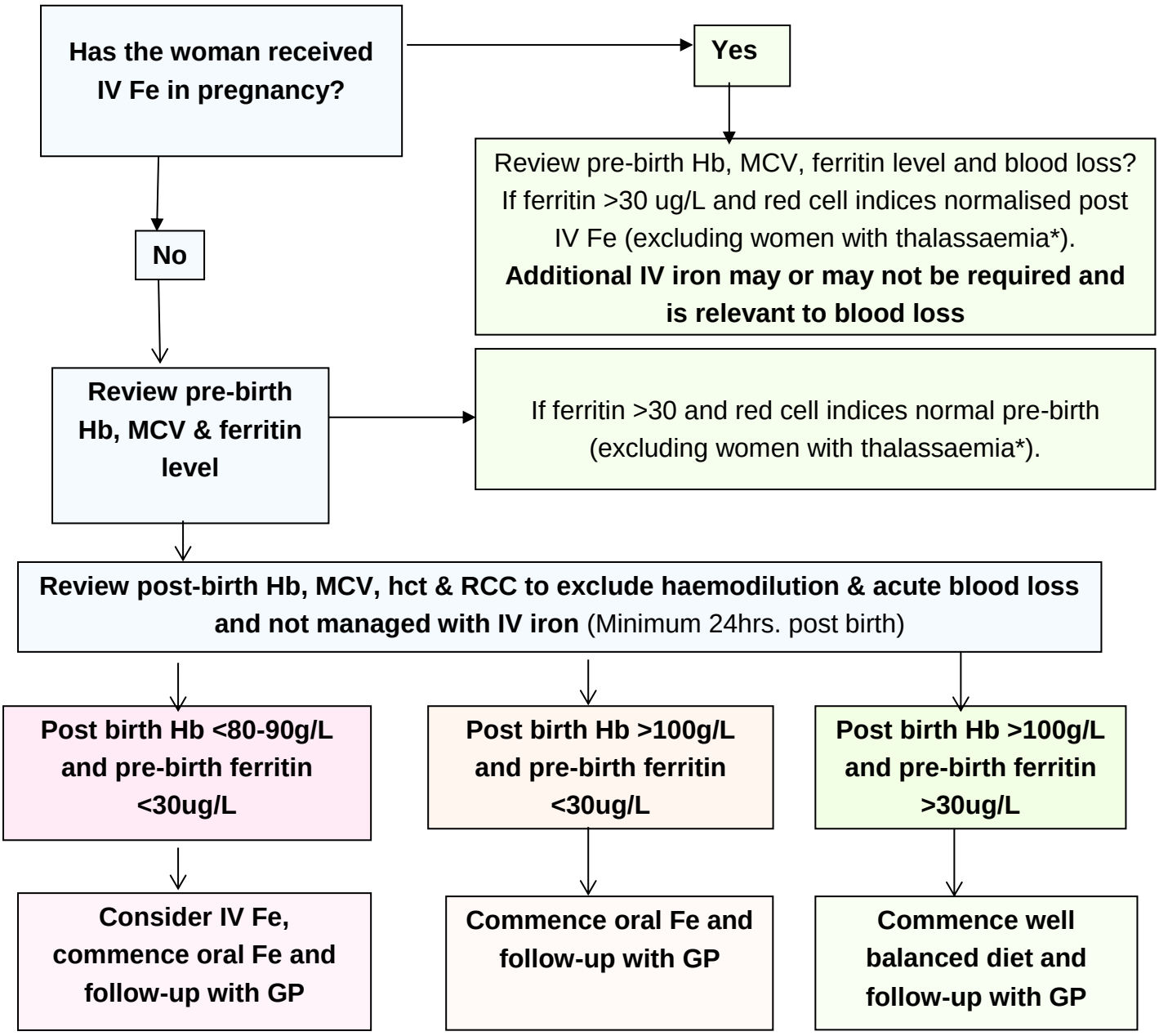
- Use if the elemental iron dose required is >1000mg for a postnatal, gynaecological or oncology patient (can be administered as a large single dose).
- During pregnancy the maximum dose is 1000mg elemental iron.
- The infusion is to be ordered as '**Iron Polymaltose'**.
- Each ampoule contains elemental iron 100mg in 2mLs (318mg/2mL)

Iron Polymaltose (IP) dosage

Body Weight	Hb 60g/L			Hb 75g/L			Hb 90g/L			Hb 105g/L		
kg	*mg	mL	amps	*mg	mL	amps	*mg	mL	amps	*mg	mL	amps
40	1100	22	11	1000	20	10	800	16	8	700	14	7
45	1200	24	12	1000	20	10	800	16	8	700	14	7
50	1200	24	12	1100	22	11	900	18	9	700	14	7
55	1300	26	13	1100	22	11	900	18	9	700	14	7
60	1400	28	14	1200	24	12	1000	20	10	700	14	7
65	1500	30	15	1200	24	12	1000	20	10	800	16	8
70	1500	30	15	1300	26	13	1000	20	10	800	16	8
75	1600	32	16	1300	26	13	1100	22	11	800	16	8
80	1700	34	17	1400	28	14	1100	22	11	800	16	8
85	1700	34	17	1400	28	14	1100	22	11	800	16	8
90+	1800	36	18	1500	30	15	1200	24	12	800	16	8

mg indicates elemental iron, not iron polymaltose. amps = number of ampoules

IV iron in postpartum period



* Women with thalassaemia are prone to iron loading and IV iron must only be used in the treatment of **confirmed iron deficiency i.e. ferritin <30ug/L**. In these women it may be useful to compare blood results against non-pregnant norms and aim for this in treatment plans.

Administration, observations and management post infusion

Infusion Unit /ASCU staff

Prior to the commencement of the IV iron infusion commence MR739 - IV Iron Infusion Care Pathway, and inform the patients about possible adverse reactions:

- Headache, nausea, vomiting, dysgeusia (metallic taste), arthralgia (joint pain), myalgia (muscle pain), dizziness, hypertension, hypotension
- Wheezing, dyspnoea, bronchospasm, hypersensitivity, anaphylaxis
- Localised pain, redness or discolouration at the IV insertion site

Ferric carboxymaltose (Ferinject®) administration[9]

- As injection site reactions and paravenous leakage is common (associated skin staining risk), FC is only administered as an infusion (as opposed to an IV bolus injection of the undiluted solution).
- Confirm the patency of the IV cannula before commencing the infusion to reduce the risk of staining.
- Connect 50mL 0.9% sodium chloride flush and infuse by gravity. If the saline does not infuse freely, or there is swelling, redness or discomfort the cannula **must not be used** for IV iron. See Management of Infiltration / Extravasation of IV Iron Therapy).
- If there is a history of a previous reaction, the Medical Officer must be informed and be present prior to the commencement of the infusion. Consider prophylaxis with loratadine 10mg orally and hydrocortisone 100mg IV.
- Do not mix with any other drugs or with solutions other than 0.9% sodium chloride.
- Do not inject FC into the tubing of the IV administration set.
- FC does not require a test dose.

FC Dosage	**FC volume**	**FC infusion rate and administration time**. Add FC dose to 250mL 0.9% sodium chloride
500 - 1000mg	10 or 20 mL	Commence at 500mL/hour rate for 30 minutes
Total infusion time approx 45 mins		

Iron polymaltose (IP) administration[8]

- All IP infusions require a test dose as anaphylactoid reactions are most likely to occur in the first few minutes of the infusion.
- Confirm the patency of the IV cannula before commencing the infusion to reduce the risk of staining.
- Connect 50mL 0.9% sodium chloride flush and infuse by gravity. If the saline does not infuse freely, or there is swelling, redness or discomfort the cannula

must not be used for IV iron. See Management of Infiltration / Extravasation of IV Iron Therapy).

- If there is a history of a previous reaction, the Medical Officer must be informed and be present prior to the commencement of the infusion. Consider prophylaxis with loratadine 10mg orally and hydrocortisone 100mg IV.
- Do not mix with any other drugs
- Do not inject IP into the tubing of the IV administration set.

<table>
<tr><th colspan="2">IP Test dose and infusion rate
(Add IP to 500mL 0.9% normal saline)</th><td rowspan="3">If the patient experiences an adverse reaction, cease the infusion and see adverse reaction management below.</td></tr>
<tr><td>Infusion rate (pregnant women)</td><td>• Commence at 50mL/hour for first 5 minutes - IF NO REACTION OCCURS
• Increase rate to 250mL/hour for the remainder of the infusion
Total infusion time approx 150 min (2.5 hours)</td></tr>
<tr><td>Infusion rate (non-pregnant women)</td><td>• Commence at 50mL/hour for first 5 minutes - IF NO REACTION OCCURS
• Increase rate to 375mL/hour for the remainder of the infusion
Total infusion time approx 100 min (1.5 hour)</td></tr>
</table>

Observations

Perform and document respiratory rate, oxygen saturation, heart rate, blood pressure, temperature and conscious state on the observation response charts MR285.01 (M-ORC) or MR285.02 (A-ORC) at the following times:

- Prior to commencement and on cessation of all iron infusions
- FC - 5 minutes after commencement of the infusion
- IP - 15 minutes after commencement of the infusion then every 60 minutes
- Pregnant women should have a foetal heart rate (FHR) recorded prior to the infusion and if an adverse event occurs should be considered for a CTG. The FHR should also be recorded at the end of the infusion, prior to discharge.

Post infusion management

- Flush the line with 50mL of 0.9% sodium chloride, administered at the same rate on completion of the iron infusion.
- Document the administration of IV iron. Self-adhesive brown coloured stickers designed to identify the dose and date of iron infusion should be annotated and placed in the patient's current integrated progress notes (MR250), in addition to placement on the special instructions sheet (MR004 and MR005) at the front of the medical records.

- Inpatients are returned to their ward and a clinical handover is given from INFU staff to ward staff as per MR739 pathway. If any delayed adverse reactions occur women are to be advised to report symptoms to ward staff.
- Outpatients remain on the INFU for 30 minutes and are then discharged if no adverse symptoms are present. If symptoms do occur, notify the Medical Officer immediately to review.
- On discharge give the woman the Post IV Iron Infusion Discharge Advice information sheet and discuss possible iron infusion side effects.
- A follow-up full blood picture and iron studies are needed 4-6 weeks post-IV iron infusion to ensure the results have normalised. Give a completed pathology request form with clear instructions to have this taken at a PathWest Collection Centre. A copy of the results is forwarded to the Clinical Nurse Consultant, Haematology, KEMH.
- If birth is imminent in the 2 weeks following infusion, the post IV iron bloods will be collected 4 weeks post birth.
- Women should be instructed not to take any oral iron for 7 days post IP or 5 days post FC infusion.
- Pregnant and post-natal women should be encouraged to continue with oral iron supplements until breastfeeding is complete.

Adverse reaction management

Adverse reactions may be more likely in women with a history of asthma and /or other allergic conditions. The woman must always be able to reach her call bell and must be instructed to use it if she becomes aware of any adverse reactions. In the event of changes to vital signs or an adverse reaction, cease the infusion and notify the Medical Officer.

<table>
<tr><th colspan="2">Possible adverse reactions to discuss with the women pre infusion:</th></tr>
<tr><td colspan="2">• Immediate hypersensitivity adverse reaction events are frequently self-limiting and usually respond to simple measures. Symptoms include headache, nausea, rash, myalgias and cannula site discomfort.</td></tr>
<tr><td>More serious anaphylactoid events include:
• Wheezing, dyspnoea, bronchospasm, hypersensitivity, anaphylaxis. STOP INFUSION</td><td rowspan="2">If the patient experiences a more serious adverse reaction, cease the infusion and see adverse reaction management below.</td></tr>
<tr><td>Infusion site reactions include:
• Localised pain, redness, discolouration of the skin STOP INFUSION</td></tr>
<tr><td colspan="2">Delayed adverse events include pyrexia, fatigue and malaise, headache, arthralgia, myalgia. See Post infusion management below.</td></tr>
</table>

Mild reactions

- Manage hypersensitivity reactions by ceasing the infusion for 10-15 minutes, giving oral Loratidine 10mg (for itch, rash), IV hydrocortisone 100mg or paracetamol 1g orally (headache or discomfort).
- Usually the infusion can be recommenced once the symptoms have resolved but it may be appropriate to reduce the rate and/or remaining dose.

Severe reactions

STOP the infusion immediately and seek urgent medical review

Call a 'code blue medical' if any of the following occur:

- Airway – stridor, facial or neck swelling
- Breathing – respiratory rate >30 or oxygen saturation < 90%
- Circulation – heart rate >130bpm or <40 bpm, or systolic blood pressure < 90mmHg Hypotension in the pregnant woman - place in the full left lateral position to relieve any aortocaval compression and commence foetal heart rate monitoring.
- Altered conscious state
- Any serious concerns

Record observations as indicated by the woman's condition including:

- Heart rate, blood pressure, temperature
- Respiratory rate, oxygen saturation
- Consciousness state
- Consider ECG and cardiac monitoring
- Antenatal women - consider a CTG to assess fetal wellbeing

If a true anaphylactoid reaction occurs, treat accordingly, abandon the infusion and consider transfer the women to ASCU for observation and management. Complete a clinical incident when appropriate and inform the CNC (Haematology) on page # 3257.

Infiltration/extravasation

Paravenous leakage of all forms of IV iron therapy results in permanent skin pigmentation and may cause skin irritation thus it is imperative that the infusion is stopped immediately if infiltration/extravasation is suspected 10. Volumetric pumps will initially continue to flow until fluid accumulates in the subcutaneous tissues, thus careful observation and monitoring of the cannula insertion site is imperative.

Recognition of infiltration/extravasation

Infiltration signs and symptoms	Extravasation signs and symptoms
• Tenderness/discomfort at insertion site • Swelling above or below insertion site • Taut skin above or below insertion site • Fluid leak at insertion site • Coolness/blanching around insertion site • Numbness or tingling above or below insertion site	In addition to signs and symptoms of infiltration: • Burning stinging pain • Redness may occur followed by blistering, tissue necrosis and ulceration

Infiltration management [10]

1. Stop infusion immediately and remove the cannula. The remainder of the IV iron infusion is abandoned.
2. If iron staining is immediately visible, measure the site and arrange for hospital photographs to be taken. This will aid ongoing monitoring of staining. Document the volume of the infused fluid which may aid in assessing the volume of iron infiltrated.
3. Apply a cold pack to the infiltrated site and elevate the affected limb
4. Reassure and provide a full explanation to the patient.
5. Inform the Medical Officer so an assessment can be made of sensory deficit which could indicate nerve damage or compartment syndrome.
6. Document the management in the medical records and complete a clinical incident form
7. Follow-up as an outpatient where long term management will be discussed if needed.
8. Further advice may be required from other specialities including Dermatology (skin staining), Plastic Surgery (sensory deficit) or Haematology (anaemia management). Laser therapy has been successful in reducing the skin staining long term.

Extravasation management [10]

If redness or blistering is apparent, then tissue necrosis can occur, and management is aimed at limiting further tissue damage.

Follow all the steps as above and in addition Hydrocortisone cream may relieve the irritation.

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Related legislation and policies

- Specialist Outpatient Services Access Policy. Operational Directive OD 0530/14
- Central Referral Allocation – Outpatient Services. Operational Directive OD 0503/14
- National Standard for User Applied Labelling of Injectable Medicines Fluids and Lines OD0647/16

Related WNHS policies, procedures and guidelines

KEMH O&G guidelines:

- Anaemia in Pregnancy

Useful resources (including related forms)

Patient information:

- Post IV Iron Infusion Discharge Advice

Forms:

- MR 037.01- Iron Infusion Request Form- Obstetric
- MR 037.02- Iron Infusion Request Form Non-Obstetric
- MR 739- IV Iron Infusion Care Pathway

Keywords:	Booking iron infusion at KEMH, iron infusion for obstetric, gynaecology or oncology patients, Iron infusion, high risk iron infusion, referrals for high risk iron infusion, iron therapy, iron infusions Obs and Gynae, intravenous iron, ward 4 infusion unit, iron therapy, infusion reaction, allergy, polymaltose, ferrosig, carboxymaltose therapy, Ferinject, extravasation, infiltration		
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Endorsed by:	Hospital Transfusion Committee Obstetrics & Gynaecology Directorate Management Committee (approved OOS by Obstetric Medical and Nurse Midwife Co-directors)	Date: Date:	07/08/2019 09/09/2019
NSQHS Standards (v2) applicable:	1 Governance, 4 Medication Safety, 7 Blood Management, 8 Recognising & Responding to Acute Deterioration		
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Appendix I

Suggested Algorithm for iron infusion

Please refer to the Iron Infusion Unit and Hospital Guidelines for complete guide.

Inpatient

Iron Polymaltose
Order on MR740 Intravenous Fluid and Additive Order Form

PBS script is not required as inpatient does not meet the PBS criteria. (PBS only subsidise outpatient or Day of discharge for inpatient.)

Day of discharge (in-patient) OR Outpatient

Clinical Assessment
Assess patient and decide iron polymaltose / ferric carboxymaltose based on the criteria set by the Iron Infusion Unit and Hospital Guidelines.

Cost (PBS)
Advise patients that they will receive an invoice in the mail at a later date
2019 Pricing: *(prices subject to change as per PBS)*
General price: $40.30
Concession price: $6.50

If iron polymaltose is treatment of choice

Iron Polymaltose

Prescribe iron polymaltose 100 mg/2 mL injection on a PBS script.

Strength: 100mg/2mL

Quantity: maximum of 3 boxes (15 ampoules)

Ring PBS authority (1PBS or 1800 888 333).

- Reason for authority: INCREASE QUANTITY
- Document authority approval code on the script.

Attach script with the referral form to the iron infusion unit.

If ferric carboxymaltose is treatment of choice

Ferric carboxymaltose
Prescribe ferric carboxymaltose 1000 mg/20 mL injection on a PBS script

Strength: 1000mg/20mL
Quantity: 1

Attach script with the referral form to the iron infusion clinic.

Last updated July 2019 by Pharmacy Department KEMH