



BLOOD MANAGEMENT CLINICAL PRACTICE GUIDELINE

Iron therapy: Intravenous

Scope (Staff): WNHS Obstetrics and Gynaecology Directorate staff

Scope (Area): Obstetrics and Gynaecology Directorate clinical areas at KEMH

This document should be read in conjunction with this **Disclaimer**

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Background

Iron deficiency is a common problem in women's health and frequently impacts quality of life and may result in anaemia if left untreated. ^{1, 2}

Intravenous iron offers rapid treatment of iron deficiency. It may be used to augment haemoglobin (Hb) levels in women with iron deficiency anaemia (IDA) (defined as per Table 1) who have not responded sufficiently to oral iron¹ or in patients whom a rapid repletion of iron stores is required³ (e.g. impending blood loss, or surgery recent large-volume blood loss or functional iron deficiency anaemia).

Whilst IV iron is deemed safe in experienced hands, significant reactions and complications can occur.⁴ The iron formulations in use at KEMH are <u>Iron polymaltose</u> (IP) for inpatients or <u>Ferric Carboxymaltose</u> (FC) for outpatients.

Contact Pharmacy for further information.

See also the **Contraindications and precautions** section below.

Please also review <u>Obstetrics and Gynaecology Clinical Guideline on 'Anaemia and</u> Iron Deficiency: Management in Pregnancy and Postpartum'

Table 1: Classification of anaemia in adult women				
Hb (g/L)				
<110	1 st and 3 rd trimester of pregnancy			
<105	2 nd trimester of pregnancy			
<100	Postpartum period			
<115	Non-pregnant adult women			

A serum ferritin level of < 30mcg/L for an adult is diagnostic of absolute iron deficiency A serum ferritin of <100mcg/L and transferrin saturations <20% is suggestive of functional iron deficiency

Indications for IV iron therapy

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

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- disease or cancer. Some women with these conditions and ferritin within the reference range but will have low transferrin saturations (TSats <20%). These women may benefit from IV iron.
- Note Ferritin is an acute phase protein which will increase in the above situations, therefore full iron studies (ferritin, transferrin and transferrin saturations) assist in the interpretation of iron status. Interpretation of test results in patients with coexisting inflammatory/malignant disease can be complicated. Seek advice from a Consultant Haematologist if there are doubts concerning the role of IV iron.

Contraindications and precautions

Contraindications

- Anaphylaxis or Hypersensitivity⁵ to IP or FC
- First trimester of pregnancy.⁵ Safety is not demonstrated in early pregnancy and animal studies have demonstrated fetal skeletal abnormalities and spontaneous abortion at maternally toxic doses during organogenesis. The level of drug crossing the placenta is unknown
- Iron overload (i.e. due to haemochromatosis)⁵
- Anaemia not due to iron deficiency (e.g. B12 deficiency, haemolytic anaemia, bone marrow disease)
- Severe acute infection or sepsis⁵
- Uncontrolled hyperparathyroidism⁵
- Infectious hepatitis 5
- Decompensated hepatic cirrhosis ⁵
- Chronic polyarthritis ⁵;

Precautions

- Asthma and/or other allergic conditions may increase the risk of adverse reactions⁵
- Previous adverse reaction to alternative forms of parenteral iron
- Liver dysfunction elevated liver enzymes including lactate dehydrogenase may develop following administration
- Severe acute bacterial infection currently treated with IV antibiotics. IV iron may be considered following cessation of IV antibiotics depending on patient condition.
- Concomitant administration of angiotensin converting enzyme (ACE) inhibitors.
 This may increase the incidence of adverse effects of IV iron including erythema, abdominal cramps, nausea, vomiting and hypotension.
- Rheumatoid arthritis and other inflammatory diseases. These may increase the risk of delayed reaction including fever and joint pain.
- Haemoglobinopathy / thalassaemia.⁵ Some women with these conditions are prone to iron overload discuss with Consultant Haematologist if indication is uncertain.

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Requesting an iron infusion

See <u>Appendix 1 – Quick reference algorithm for iron infusion</u> for which iron formulation 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, providing the patients weight to the PBM CNC, explaining the procedure and answering questions.
 - See KEMH patient fact sheet Intravenous Iron infusion
 - Ensuring recent (within 1 month) Full blood count and iron studies (ferritin acceptable, but iron studies preferred) results are available.

Once the e-referral has been triaged and the patient booked, the Team RMO will be contacted to attend the INFU to complete the

- IV iron on the intravenous additive order sheet (MR740).
- PBS prescription for outpatients and women receiving IV iron on the day of discharge.
- 2. All requests for intravenous iron are now made through the eReferral system:
 - Site: King Edward Memorial Hospital
 - Unit: Haematology
 - Select >> CNC PBM Iron Infusion [HAIF]
 - **Complete all mandatory data.** Failure to complete these accurately may delay treatment.
- 3. IV iron requests are reviewed, triaged and approved Monday to Friday by CNC PBM against the current guidelines for treatment. Women will then be booked an appointment in the Infusion Unit (open Tuesday, Thursday and Friday).
 - Some IV iron infusions may need to be given in ASCU by consultation with CNC PBM and ASCU co-ordinator.
- 4. See <u>Appendix 1 Quick reference algorithm for iron infusion</u> for further information.
- 5. Overseas visitors (OSV) may or may not have adequate insurance cover for IV iron as an outpatient. Once the e-referral is received the CNC PBM will liaise with the patient and also involve private patient liaison office (PPLO) if needed.Some women may choose to explore IV iron infusions in the primary care setting
 - or with pathology service providers. This decision will be documented in the DMR

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

Non-tertiary centres may request IV iron administration for women who are considered at high risk of reaction (e.g. on the basis of medical history) through the <u>Central Referral Service</u>. If the patient is within KEMH catchment the request will be reviewed as per criteria above. KEMH is unable to provide iron infusion services to women outside the catchment area. Following receipt of the referral, the:

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- CNC PBM/Haematology will triage the referral, including a review of previous reaction and risk factors, blood results, previous iron therapy and assessment against current Clinical Guidelines.
- Haematology 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 (e.g. in outpatient clinic) prior to iron infusion if there is
 uncertainty about the history or concern regarding potential for adverse
 reaction.

If the patient is considered not suitable for IV iron at KEMH, the CNC PBM will contact the referring centre to discuss and advise alternative management strategies.

Dosing

Ferric carboxymaltose (Ferinject®)

- Pregnant and non-pregnant women receive a single infusion of 1000mg elemental iron as ferric carboxymaltose.
- If under 45kg discussion with the CNC PBM and Haematologist occurs and the dose may be 500mg.
- Each ampoule contains 1000mg elemental iron in 20mL.⁶

Iron polymaltose (Ferrosig)

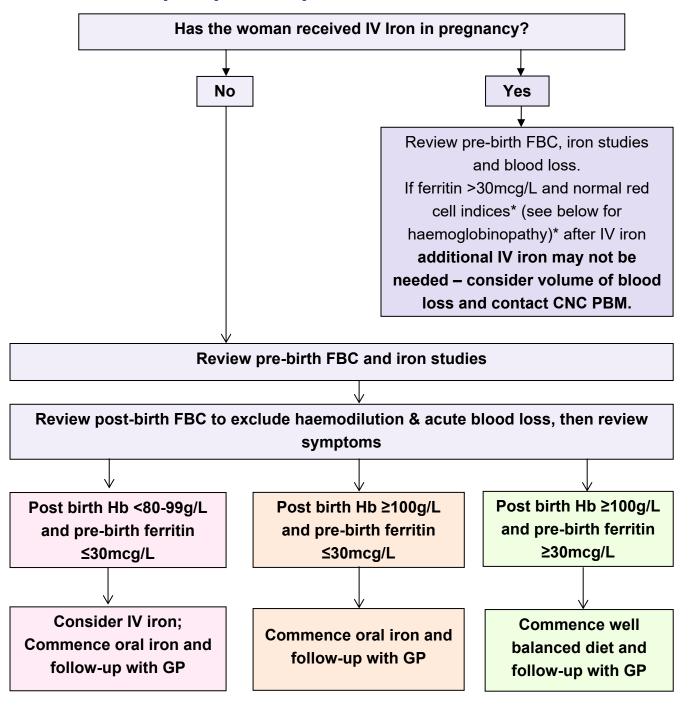
- The dose is calculated according to the table below. Pregnant women receive a maximum dose of 1000mg elemental iron.
- Each ampoule contains 100mg elemental iron in 2mL (318mg iron polymaltose in 2mL)

Iron polymaltose 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

*this refers to dose of elemental iron (in milligrams); amps = number of ampoules

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IV iron in postpartum period



^{*} Women with thalassaemia are prone to iron loading and IV iron should only be used in the treatment of documented iron deficiency (i.e. ferritin <30mcg/L). Compare blood results against non-pregnant baseline and aim for this in treatment plans.

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Administration, observations, and management post infusion

Infusion Unit / ASCU /Theatre

IV iron infusions can only be administered in the Infusion unit, ASCU and theatre by trained staff.

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

- Headache, nausea, vomiting, dysgeusia (metallic taste), arthralgia (joint pain), myalgia (muscle pain), dizziness, hypertension, hypotension
- Anaphylaxis, wheezing, dyspnoea, bronchospasm, hypersensitivity,
- Skin staining at the insertion site
- Consent is obtained prior to proceeding (MR739)

Ferric carboxymaltose (FC) Ferinject® administration

- As injection site reactions and paravenous leakage is common (associated skin staining risk), FC is only administered at KEMH as an infusion (as opposed to an IV bolus injection of the undiluted solution).
- Complete IV cannulation as per hospital guidelines
- Confirm the patency of the IV cannula with 10mL normal saline flush 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 Extravasation).
- If there is a history of a previous reaction, the Medical Officer must be informed prior to the commencement of the infusion and readily available to review the patient should a reaction occur. Consider prophylaxis with loratedine 10mg orally and hydrocortisone 100mg IV 20 mins prior to the infusion for patients with high risk of severe allergic reaction.
- Do not mix with any other drugs or with solutions other than 0.9% sodium chloride.
- Do not inject FC into the tubing of an 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 ⁶			
500 - 1000mg	10 or 20 mL	Commence at 500mL/hour rate for 30 minutes			
Total infusion time approx. 40 mins					

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Iron polymaltose (IP) Ferrosig administration

- All IP infusions require a test dose as anaphylactoid reactions are most likely to occur in the first few minutes of the infusion.⁵
- 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 Extravasation).
- If there is a history of a previous reaction, the Medical Officer must be informed prior to the commencement of the infusion and readily available to review the patient should a reaction occur. Consider prophylaxis with loratedine 10mg orally and hydrocortisone 100mg IV 20 mins prior to the infusion for patients at risk of severe allergic reactions
- Do not mix with any other drugs
- Do not inject IP into the tubing of the IV administration set.

(A		
Infusion rate (pregnant	If the patient experiences an adverse reaction,	
women)	Total infusion time approx. 150 min (2.5 hours)	cease the infusion and see adverse
Infusion rate (non- pregnant women)	 Commence at 50mL/hour for 5 minutes. IF NO REACTION OCCURS then Increase rate to 375mL/hour for the remainder of the infusion Total infusion time approx. 100 min (1.5 hour) 	reaction management below.

Observations

Perform and document respiratory rate, oxygen saturation, heart rate, blood pressure, temperature and conscious state on the observation response chart (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 fetal heart rate (FHR) recorded prior to infusion and following infusion, prior to discharge, as well as obstetric observations as per chart.

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Post-infusion management

- Flush the line with 50mL of 0.9% sodium chloride, administered at the same rate on completion of the iron infusion.
- Remove the IV cannula 10 minutes prior to discharge, or if an inpatient leave in situ if required by Medical team
- Document in the DMR
- Inpatients are returned to their ward. Give clinical handover to ward staff as per MR739 pathway. Advise women to report delayed adverse reactions to ward staff.
- Outpatients remain on the INFU for 30 minutes. If no adverse symptoms are present they are then discharged. If symptoms do occur, notify the Medical Officer immediately to review.
- On discharge discuss the post iron advice as per the patient fact sheet
- Provide a completed FBC and iron studies request form for 4 weeks following infusion to ensure the results have normalized. These results can be forwarded to the GP and CNC PBM
- For pregnant women due to deliver within 2 weeks of infusion, these blood tests should be collected 4 weeks post-partum.
- Women should be instructed not to take any oral iron for 7 days post 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 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.

Possible adverse reactions to discuss with the women pre infusion:

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.

More serious anaphylactoid events include:

 Wheezing, dyspnoea, bronchospasm, hypersensitivity, hypotension, anaphylaxis.

Infusion site reactions include:

Localised pain, redness, discolouration of the skin

If the patient experiences these more serious adverse reactions, STOP THE INFUSION and see adverse reaction management below.

Delayed adverse events include pyrexia, fatigue and malaise, headache, arthralgia, myalgia. See Post infusion management above.

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Mild reactions

- Manage hypersensitivity reactions by ceasing the infusion for 10-15 minutes
- Facilitate medical team review
- The infusion can usually be recommenced once the symptoms have resolved but it may be appropriate to reduce the rate and/or remaining dose.

Severe reactions

- 1. STOP THE INFUSION immediately and seek urgent medical review.
- 2. 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 <40bpm, or onset of hypotension (systolic blood pressure <90mmHg).
 - Altered conscious state
 - Any serious concerns
- 3. If hypotensive, place in full left lateral position to relieve aortocaval compression
- 4. Commence foetal heart rate monitoring.
- 5. Record observations as indicated by the woman's condition including:
 - Heart rate, blood pressure, temperature
 - Respiratory rate, oxygen saturation
 - Level of consciousness
 - Consider ECG and cardiac monitoring
 - Consider CTG to assess fetal wellbeing in pregnant women

If a true anaphylactoid/anaphylactic reaction occurs, the infusion should be abandoned. Treat according to clinical features and consider transfer of the woman to ASCU for observation and management. Complete a clinical incident when appropriate and inform the CNC PBM (Haematology) on page #3257/0439 980 504.

Management of known or suspected previous reaction to IV iron

- 1. If previous mild reaction
 - discuss with Consultant Haematologist
 - pre-medicate (e.g. loratidine 10mg orally)
 - commence infusion at a slower rate (e.g. ferric carboxymaltose at 300mL/hour)
- 2. If previous severe / anaphylactoid reaction
 - discuss with Consultant Haematologist
 - utilise alternative iron formulation
 - pre-medicate (e.g. hydrocortisone 100mg IV, loratadine 10mg orally, paracetamol 1g orally) before commencing infusion
 - commence infusion at a slower rate than usually prescribed

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Extravasation

Paravenous leakage of all forms of IV iron can result in permanent skin pigmentation. It is imperative that the infusion is ceased immediately if extravasation occurs⁷ – infusion of greater volumes may worsen the extent of skin pigmentation. Following extravasation volumetric pumps continue to infuse until fluid accumulates in the subcutaneous tissues – careful observation and monitoring of the cannula insertion site is imperative.

Recognition of extravasation

Signs and symptoms that may indicate extravasation:

- Tenderness/discomfort at insertion site
- · Swelling above/below insertion site
- Taut skin above/below insertion site
- Fluid leak at insertion site
- Coolness/blanching around insertion site
- Numbness or tingling above/below insertion site
- · Burning or stinging pain
- Skin discolouration/pigmentation
- Blistering, ulceration and tissue necrosis are highly unlikely to occur

Note, however, that extravasation can be asymptomatic and that skin pigmentation may not be apparent until hours/days following the extravasation.

Management

- 1. Stop infusion immediately and disconnect the giving set. Aspirate any residual fluid and remove the cannula.⁷ Abandon the infusion further iron should not be given on the same day.
- If skin pigmentation 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 – this may aid in assessing the volume of iron infiltrated.
- 3. Apply a cold pack to the infiltrated site and elevate the affected limb.⁷
- 4. Reassure and provide a full explanation to the patient.
- Inform the Registrar, Senior Registrar or Consultant 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 DMR and complete a clinical incident form.
- 7. Follow-up as an outpatient where long term management will be discussed if needed.

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- 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.
- 9. If there is significant pain/redness hydrocortisone cream may be of use in relieving irritation. There are no specific antidotes for iron extravasation.

Abbreviations

ACE Angiotensin converting enzyme

ASCU Adult Special Care Unit

CNC PBM Clinical Nurse Consultant Patient Blood Management

CTG Cardiotocography
ECG Electrocardiogram

FC Ferric carboxymaltose
GP General Practitioner

Hct Haematocrit
Hb Haemoglobin

IDA Iron deficiency anaemia

IP Iron polymaltose

IV Intravenous mcg microgram

MCV Mean cell volume

O&G Obstetrics and Gynaecology

ORC Observation and response chart
PBS Pharmaceutical Benefits Scheme

RCC Red cell count

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Related legislation and policies

Department of Health WA:

- Central Referral Service Policy: Allocation Outpatient Services
- Specialist Outpatient Services Access Policy

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• National Standard for User Applied Labelling of Injectable Medicines, Fluids and Lines

Related WNHS policies, procedures and guidelines

WNHS Obstetrics and Gynaecology guidelines:

• Anaemia in Pregnancy

Adult Medication Guideline:

• Iron Polymaltose

Useful resources (including related forms)

Patient information:

- Post IV Iron Infusion Discharge Advice
- Iron Supplements

Forms:

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- MR 284 / 285 / 285.02: Observation and Response Charts- MR 284 (Antenatal); MR 285 (Postnatal) or MR285.02 (Adult)
- 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, carboxymaltose therapy, Ferinject, extravasation, infiltration				
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Version history

Version number	Date	Summary
1	April 2019	First version. For a list of changes- see OGD <u>Guideline Updates</u> by month/year of review date
		History : In Sept 2019 amalgamated six individual guidelines on intravenous iron therapy (from O&G dating from May 2009).
		Supersedes:
		Requesting an Iron Infusion for Obstetric, Gynaecology or Oncology Patients (date last amended Jan 2016)
		2. Iron Infusions: Referrals for Obstetrics and Gynaecology patients deemed high risk for iron infusions within non-tertiary care (dated Sept 2017)
		3. IV Iron Polymaltose Therapy (Ferrosig) (date last amended July 2016)
		4. IV Ferric Carboxymaltose Therapy (Ferrinject) (dated Dec 2015)
		5. Midwifery Nursing Management of a Reaction to an Iron Infusion (dated July 2014)
		6. Management of Infiltration / Extravasation of IV Iron Therapy (dated Aug 2014)
2	Sept 2021	Updated with eReferral information, management of known or suspected previous reaction to IV iron, contraindications, postpartum flowchart, extravasation, and updated appendix due to increased patient co-contribution costs (now links to PBS for fee information) and streamlined authority so medical staff do not have to ring PBS for each script.
		For a full list of changes- see OGD <u>Guideline Updates</u> by month/year of review date (available to WA Health employees through HealthPoint).
3	Oct 2024	Review of process for team prescribing an Iron Infusion, including e- referrals; Updated hyperlinks.

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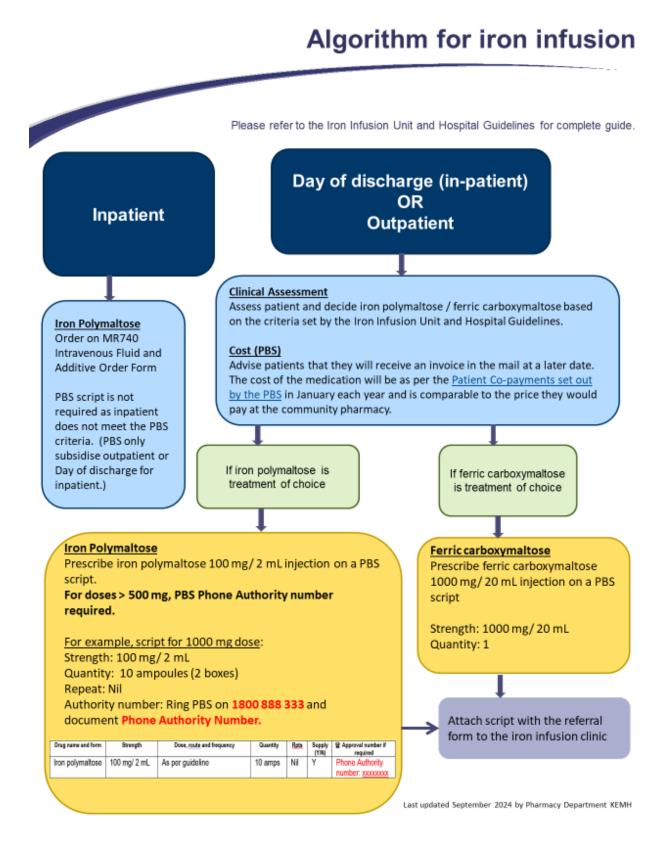
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Appendix 1- Quick reference algorithm for iron infusion



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