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Procedure for the use of Intravenous Iron Dextran (CosmoFer ®)

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VERSION CONTROL SCHEDULE

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1	May 2009	Original document	April 2009
2	February 2013	Title changed to procedure. Reference to other parenteral iron preparations.	QGOC February 2013

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Key Points

- Therapy for iron deficiency anaemia includes treatment of its underlying cause and restoration of normal haemoglobin concentrations and iron stores. This can be accomplished by the oral or parenteral route. Although the oral route is usually preferred, clinical situations exist where the parenteral route is indicated
- Iron can be administered parenterally as iron dextran, iron sucrose, ferric carboxymaltose or iron isomaltoside 1000. Choice of preparation is dependent on patient and physician choice.
- This document refers to IV low molecular weight iron dextran (CosmoFer®)

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Contents Page

Section		Page Number
1	Introduction	5
2	Purpose	5
3	Scope	5
4	Definitions of terms	5
5	Investigations required	5
6	Clinical indications	6
7	Contraindications	6
8	Response	6
9	Flowchart for the use of iron in confirmed iron deficiency anaemia	7
10	Administration of intravenous iron dextran - CosmoFer®	8
11	Adverse events	10
12	Treatment of obstetric patients with CosmoFer ®	10
13	Follow-up	10
14	Endorsement	10
15	Distribution	11
16	References	11

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Procedure for the use of intravenous Iron Dextran (CosmoFer ®)

1. Introduction

- 1.1 Therapy for iron deficiency anaemia includes treatment of its underlying cause and restoration of normal haemoglobin concentrations and iron stores. This can be accomplished by the oral or parenteral route. Although the oral route is usually preferred, clinical situations exist where the parenteral route is indicated.
- 1.2 Iron can be administered parenterally as iron dextran, iron sucrose, ferric carboxymaltose or iron isomaltoside 1000.
- 1.3 Choice of preparation is dependent on patient and physician choice and how immediate the requirement to complete the dose e.g.: iron dextran (CosmoFer ®) can be given as a total dose infusion, iron sucrose (Venofer ®) is given as divided doses.

THIS DOCUMENT REFERS TO LOW MOLECULAR WEIGHT IRON DEXTRAN (COSMOFER ®)

2. Purpose

The purpose of this document is to give guidance on the prescription and use of intravenous Iron Dextran (CosmoFer®).

3. Scope

This document is to be used by all members of staff involved in the prescription and administration of intravenous Iron Dextran (CosmoFer®).

4. Definition of Terms

CosmoFer® -Intravenous low molecular weight Iron Dextran

5. Investigations required

Patients with anaemia should be fully investigated as appropriate.

The following blood investigations are required prior to starting treatment with IV iron:

- Full blood count + film, reticulocyte count
- Iron profile
- CRP

In addition B12 and folate levels may be indicated

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6. Clinical indications

Intravenous iron is indicated for the treatment of iron deficiency in the following situations

- Demonstrated intolerance to oral iron preparations
 - A clinical need to deliver iron rapidly to replenish iron stores
 - Active inflammatory bowel disease where oral iron preparations are not tolerated or contraindicated
 - Patient non-compliance with oral iron therapy
 - Patients over 14 years of age
- Oral iron must not be administered concomitantly with a course of IV iron or until 5 days after the last dose.

7. Contraindications

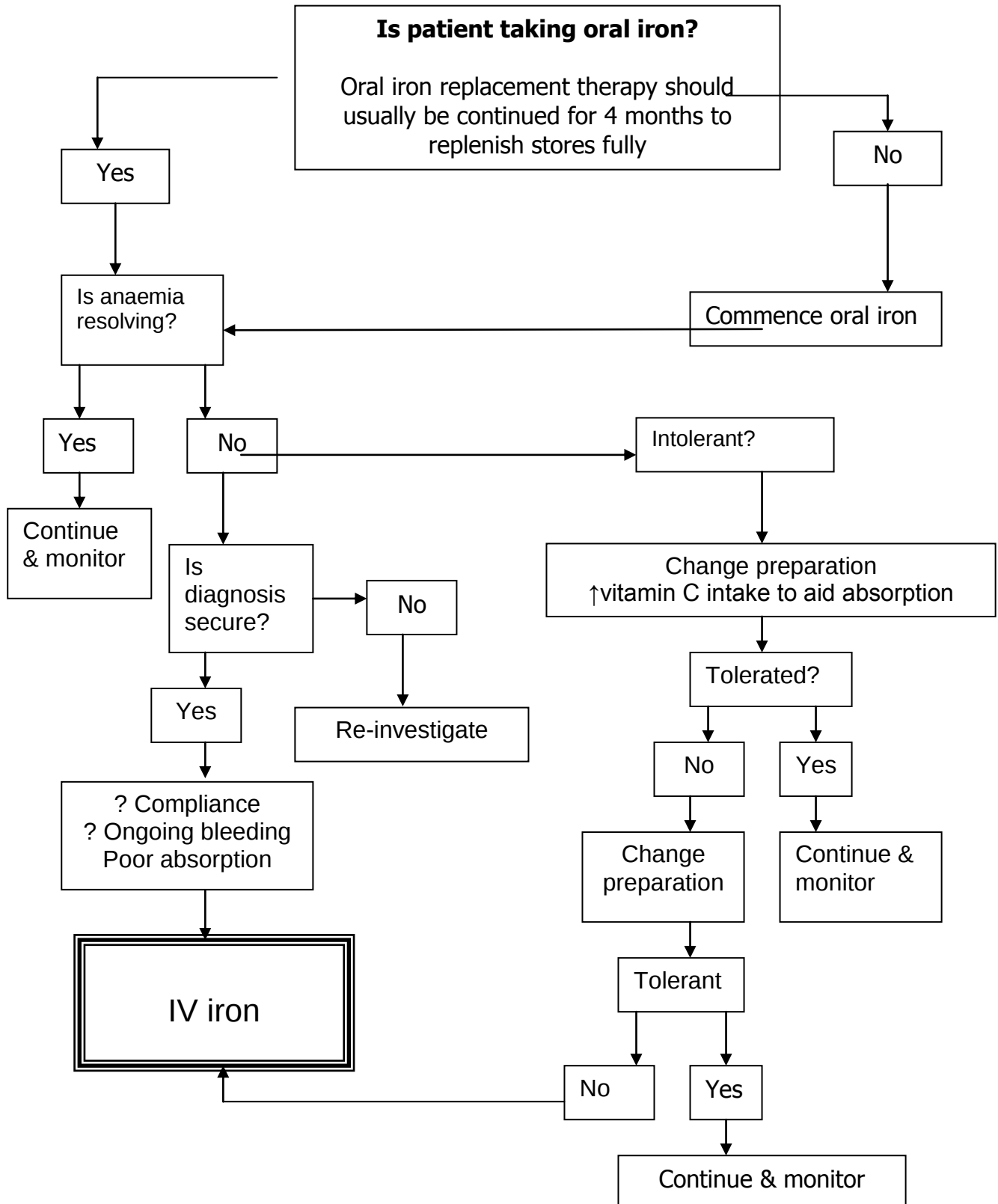
- Anaemia not attributable to iron deficiency
- Iron overload
- A history of hypersensitivity to parenteral iron preparations
- History of cirrhosis of the liver
- Acute or chronic infection
- Active rheumatoid arthritis
- First trimester of pregnancy
- Acute renal failure
- Patients with a history of severe asthma, eczema or other atopic allergy
- Drug hypersensitivity including mono- or di-saccharide complexes and dextran

8. Response

Due to iron metabolic pathways, a rise in reticulocyte count will occur during the second week and thereafter, provided bleeding is not excessive, one can expect a rise in haemoglobin of approximately 1.5g/dL/week.

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9. Flowchart for the use of iron in confirmed iron deficiency anaemia



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10. Administration of intravenous iron dextran - CosmoFer®

10.1 Dosage - Total dose infusion

The dose calculation for CosmoFer® is based on patient's body weight according to the table below and is diluted in 500 mls of 0.9% sodium chloride. If calculating the dose for an obstetric patient, use the pre-pregnancy weight. For obese patients (BMI > 30) use ideal body weight.

10.2 How to select the correct dose of CosmoFer®

- In the left hand column, find the body weight closest to the patient's body weight, read across this row to the column headed by the patients current haemoglobin value, **values for body weight and haemoglobin must be rounded up or down to the nearest stated value**. The number at this point is the dose required (in milligrams of iron). The target Hb using the table shown is 13g/dL.
Note:- If the dose is shaded in grey, it exceeds the total upper limit for total dose infusion (20mg/kg body weight) and must be administered as a divided dose. (See section 11.3)
- CosmoFer® must be added to 500mLs of Sodium Chloride 0.9% IV infusion and infused over 4 to 6 hours. There is no upper concentration limit for the infusion to maintain product stability. Once made up, the infusion should be used immediately but is stable for 24 hours. The patient should be observed for 1 hour after completion of the infusion.
- CosmoFer® must be administered via an IV infusion pump

Body weight (kg)	Actual Haemoglobin (g/dL)					
	7.0	8.0	9.0	10.0	11.0	12.0
40	1075	975	875	775	675	575
45	1125	1025	925	800	700	600
50	1200	1100	975	850	725	600
55	1275	1150	1025	875	750	625
60	1350	1200	1075	925	775	625
65	1425	1275	1100	950	800	650
70	1500	1325	1150	1000	825	650
75	1575	1400	1200	1025	850	675
80	1650	1450	1250	1075	875	675
85	1700	1500	1300	1100	900	700
90	1775	1575	1350	1125	925	700

Example 74kg, current Hb 8.2g/dL – **use body weight 75kg and Hb 8.0g/dL**
dose is 1400mg iron (28mLs Cosmofer® injection) in 500mLs Sodium Chloride 0.9%

- A test dose must be given prior to the infusion.**

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- **Facilities for cardiopulmonary resuscitation/treatment of anaphylaxis, should be available. (See section 12)**

10.3 Dosage – Total dose infusion exceeding 20mg/Kg

If the required dosage exceeds 20mg/kg, then it should be given on two separate days. This can be done by:

- Giving half the dose on each day
- Giving up to 20mg/kg in the first infusion, then the reminder in the second infusion.

An interval of one week for every 600mg of iron given in the first infusion should be allowed between the first and second doses. For example if 1200mg of iron was given in the first dose, then the second infusion containing the remaining iron should be given 2 weeks later.

10.4 Test dose

- The first infusion of CosmoFer® must include a test dose; facilities for cardiopulmonary resuscitation/treatment of anaphylaxis, should be available. (Refer also to section 12 – Adverse events)
- 25mg of CosmoFer® should be infused over a period of 15 minutes. The patient should then be observed for 45 minutes. If no adverse reactions are seen, give the remaining dose. For subsequent doses the 25mg test dose must still be given, however there is no requirement for the 45 minute observation period.
- The test dose should be given by adding CosmoFer® 25mg to Sodium Chloride 0.9% 100mls and infusing over 15 minutes. If no reaction is noted after a further 45 minutes, proceed with the remainder of the infusion (i.e. the total calculated dose minus the 25mg test dose).

10.5 Continuing the infusion

The remainder of the infusion should be given at the following rate:-

- 50mLs/hr for the first hour
- 100mL/hr for the next hour
- 150mL/hr until infusion complete

10.6 Patient monitoring

Blood pressure and pulse should be monitored prior to the infusion and every 15 minutes during the test dose and observation period.

For the remainder of the infusion, BP and pulse should be monitored every 30-60 minutes or as clinically indicated, and recorded on a trust observation chart.

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11. Adverse events

Adverse reactions are rare. However, facilities for dealing with anaphylaxis and cardiopulmonary resuscitation should be available.

It is recommended that the anaphylaxis box be kept in the close vicinity of the patient receiving IV iron. Administration should be carried out by nurses or midwives who are IV certified and who have received training in the management of anaphylaxis.

- Acute, severe anaphylactoid reactions are uncommon. They usually happen within the first few minutes of administration and are generally characterised by the sudden onset of respiratory difficulty and/or cardiovascular collapse.
- Less severe manifestations of immediate hypersensitivity are also uncommon and include urticaria, rashes, itching, nausea and shivering.
- Delayed reactions are characterised by arthralgia, myalgia and sometimes fever. Symptoms may last 2-4 days and settle spontaneously or following the use of simple analgesics such as paracetamol.
- Exacerbation of joint pain in rheumatoid arthritis can occur
- Local reactions such as phlebitis around the administration site may occur.

11.1 Management of adverse events

In the event of a serious anaphylactic or allergic reaction stop the infusion, IM adrenaline should be administered and appropriate resuscitation measures initiated. Mild allergic reactions should be managed by stopping the infusion and administering antihistamines.

Hypotensive episodes may occur if administration is too fast, so decrease infusion rate as clinically indicated.

If an adverse reaction occurs, a DATIX adverse event record must be completed.

12. Treatment of obstetric patients with CosmoFer ®

CosmoFer® should not be used during the first trimester but can be used during the second and third trimester and during lactation if oral iron therapy is ineffective or impracticable. Dosing for antenatal patients should be based on pre-pregnancy weight (or ideal body weight if obese prior to pregnancy).

13. Follow-up

Full blood count, reticulocyte and iron profile should be checked 3-4 weeks after the CosmoFer® infusion.

14. Endorsement

This procedure will be approved by the Hospital Transfusion Committee
Final endorsement will be by the Quality Governance Operational Committee.

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15. Distribution

The procedure will be available on SharePoint, on the Trust intranet.

16. References

CosmoFer® Summary of Product characteristics
http://www.cosmofer.com/media/248844/CosmoFer_SPC.pdf