CLINICAL PROTOCOL FOR THE USE OF ERYTHROPOIETIN IN PATIENTS WITH CHRONIC RENAL DISEASE (CKD) OR ACUTE RENAL FAILURE

Is the patient anaemic caused by CKD?

No

Medical team to refer to Anaemia CNS, RCHT

Yes

Investigation: Anaemia CNS to review:
- Hb level
- Iron status
- RCF & vitamin level
- B/P
- Previous/current malignancy

RCF & vitamin level low

Ferritin < 100 mcg

Previous malignancy?

Yes

B/P elevated

Patient safe to start EPO?

No

Yes

Anaemia CNS to notify referring medic

Monitoring: Anaemia CNS to review:
- Hb monthly
- Iron studies 3

Hb rising?

Yes

No

If Hb does not achieve 100-120 g/l Anaemia CNS and/or referring medic to refer for further OPD investigation

Anaemia CNS to continue to monitor and review patient

1

2

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4
Aim/Purpose of this Guideline

1.1 This protocol is appropriate for staff who work within renal services and/or staff involved with the care of renal patients receiving haemodialysis treatments. It is also applicable to all staff who administer Erythropoietin and those who intend to administer Erythropoietin. All healthcare professionals have a duty of care which cannot be delegated at any time. The practitioners administering erythropoietin are responsible and accountable for their own clinical practice; including clinical competency. The Anaemia Management Nurse employed within renal services is responsible for policy review and update.

1. The Guidance

2.1 This guideline applies to patients with anaemia caused by chronic kidney disease or acute renal failure. Renal function will be determined by creatinine level and estimated glomerular filtration ratio (eGFR). Erythropoietin in drug form (such as Epoetin alfa – Eprex® manufactured by Janssen-Cilag and Epoetin beta – NeoRecormin® and Micrera® manufactured by Roche and Darbepoietin Alfa- Aranesp® manufactured by Amgen) is a genetically engineered hormone which is immunologically identical to the endogenous hormone. Other biosimilar erythropoietin drugs have been licensed.

2.1.1 The main licensed indication for the prescribing of erythropoietin (EPO) is for the correction of anaemia associated with chronic renal failure. The aim of the policy is to maintain the haemoglobin level (Hb) between 100 and 120g/l in the majority of patients. Selection criteria vary a little. Royal Cornwall Hospitals offer...
such treatment to patients who have a haemoglobin (Hb) level persistently below 110 g/l. It is recommended not to wait until the Hb level is outside of the aspirational range before adjusting treatment (NICE 2015).

2.2 The guideline will be implemented following a referral from a member of the medical team by nursing staff employed within RCHT renal services.

2.3 Management of the patient will be divided into two phases:

1. Investigation of anaemia
2. The titrated dosage of EPO given in relation to weight and haemoglobin.

2.4 Investigation of Anaemia

2.4.1 Before prescribing EPO it is important to ensure that there is no other reason for a patient to be anaemic and that the patient is suitable for treatment. In addition to taking a full history and performing a full examination, the following investigations are the minimum required before the drug is prescribed:

1. Haemoglobin
2. Reticulocyte count if medically requested.
3. Iron status – The serum ferritin needs to be >100mcg before commencing treatment. If the ferritin is <100mcg then refer to the iron protocol for treatment guidelines. Serum ferritin may be raised in an acute infection state and other indicators of iron status may be required including iron studies and % hypochromic count. Serum ferritin level must be measured once treatment with iron supplementation is completed to determine if patient is iron replete.
4. Red cell folate and Vitamin B12 levels. (If deficient, treat deficiencies before treatment with EPO is started.)
5. Blood pressure. There must be reasonable control of blood pressure before beginning treatment with EPO.

2.5 If the haemoglobin does not rise into the target range (100 – 120 g/l) or if the haemoglobin falls below the target range without an obvious cause (bleeding, concurrent illness/infection) then the patient should be seen and examined and the following investigations should be checked:

1. Serum CRP
2. Faecal occult blood (now replaced with endoscopy as –ve FOB is not indicative of no gastro-intestinal event)
3. Parathyroid hormone
4. Aluminium levels
5. Thyroid function
6. Urea reduction ratio / Peritoneum equilibrium test

2.6 If the response on starting EPO is too rapid (> 15 g/l/month) then the dose should be decreased by 50%.

2.7 Monitoring

2.7.1. During the initial treatment with EPO therapy the haemoglobin should be checked on a monthly basis until a target haemoglobin of >110 g/l is achieved. The
haemoglobin check remains monthly/2 monthly thereafter. If the patient is commencing EPO with a haemoglobin equal to or greater than 110 g/dl then the haemoglobin is also monitored monthly. Blood pressure and plasma potassium levels should be monitored regularly.

2.7.2. Iron status must be monitored as per renal IV iron protocols.

2.8. Contra-Indications and Cautions:

2.8.1 EPO is contra-indicated in uncontrolled hypertension. Caution should be used in the presence of untreated, inadequately treated or poorly controlled hypertension. A rise in blood pressure from baseline of over 20 mmHg should be reported to medical staff.

2.8.2. EPO can be given when hypertension is present THOUGH medical staff must be informed of the patient’s blood pressure as soon as possible after the EPO is given.

2.8.3 EPO should be used with caution in the presence of epilepsy, thrombocytosis, chronic liver failure, malignant conditions, hyperkalaemia and known hypersensitivity to the medication.

2.8.4. EPO should be used with caution in the presence of malignant conditions. If the patient has a solid tumour and is not undergoing active therapy it would be wise to consider treatment of severe anaemia with blood transfusions to minimize risk of tumour stimulation by avoiding EPO. If the patient has a solid tumour and is receiving palliative chemotherapy and/or radiotherapy, the patient should be informed of the potential benefits of EPO to prevent transfusion dependency. For CKD patients who have curable malignancies and are receiving chemotherapy and/or radiotherapy, EPO should be avoided (Bennett et al, 2008. Seminars in Dialysis, vol:22 Issue 1).

2.8.5 If a CKD patient has a haematological malignancy such as chronic lymphocytic leukaemia; EPO should not have any adverse promoting effect on lymphoid lineage cells and therefore there is no contraindication to its use.

Patients with previous or current malignancies should be advised as per section 2.8.4 and be supported in order to make an independent informed decision.

2. Monitoring compliance and effectiveness

<table>
<thead>
<tr>
<th>Element to be monitored</th>
<th>2.4 Investigation of anaemia before prescribing treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead</td>
<td>Anaemia Management Nurse employed within Renal Services, RCHT.</td>
</tr>
<tr>
<td>Tool</td>
<td>Erythropoietin is to be electronically prescribed on Renal+. Renal + is a clinical computing system and does not allow prescribing of the drug unless there is a weight, haemoglobin level and iron status on the system.</td>
</tr>
<tr>
<td>Frequency</td>
<td>The erythropoietin dose, frequency and haemoglobin level will be monitored by the Anaemia Management Nurse each month. This data will be shown on excel documents stored on Oesdata13-server\Data13. This is a shared drive accessible by</td>
</tr>
</tbody>
</table>
The Anaemia Management Nurse will present this data annually at renal audit meeting.

Any erythropoietin prescribing undertaken by the Anaemia Nurse Manager will be subject to clinical supervision by all four consultant nephrologists annually. If discrepancies are identified at these reviews they will be reported to the medical divisional lead for governance and safety, RCHT and the Anaemia Nurse Manager will be subject to further training and education.

The Anaemia Management Nurse will act on recommendations within 1 month of the annual prescribing review.

If discrepancies are identified following clinical supervision of prescribing undertaken by the Anaemia Nurse Manager the clinical supervision sessions will take place more frequently; every 3 months. Lessons learned will be shared with all the relevant stakeholders.

3. Equality and Diversity

3.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the ‘Equality, Diversity & Human Rights Policy’ or the Equality and Diversity website.

3.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

<table>
<thead>
<tr>
<th>Document Title</th>
<th>Clinical Protocol for the Use of Erythropoietin in Patients with Chronic Renal Disease or Failure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Issued/Approved:</td>
<td>22/01/2016</td>
</tr>
<tr>
<td>Date Valid From:</td>
<td>22/01/2016</td>
</tr>
<tr>
<td>Date Valid To:</td>
<td>22/01/2019</td>
</tr>
<tr>
<td>Directorate / Department responsible (author/owner):</td>
<td>Sharon Benton, Anaemia CNS</td>
</tr>
<tr>
<td>Contact details:</td>
<td>01872 253499</td>
</tr>
<tr>
<td>Brief summary of contents</td>
<td>The policy details the process for the use of Erythropoietin in renal patients. The policy includes guidance to support effective and safe prescribing of the drug.</td>
</tr>
<tr>
<td>Suggested Keywords:</td>
<td>Anaemia, Kidney, Renal, Haemoglobin, Erythropoietin, Haemotynics, EPO, ESA</td>
</tr>
<tr>
<td><strong>Target Audience</strong></td>
<td><strong>RCHT</strong></td>
</tr>
<tr>
<td>---------------------</td>
<td>----------</td>
</tr>
<tr>
<td><strong>Executive Director responsible for Policy:</strong></td>
<td>Medical Director</td>
</tr>
<tr>
<td><strong>Date revised:</strong></td>
<td>09/12/2015</td>
</tr>
<tr>
<td><strong>This document replaces (exact title of previous version):</strong></td>
<td>Clinical Protocol for the Use of Erythropoietin in Patients with Chronic Renal Disease or Failure</td>
</tr>
<tr>
<td><strong>Approval route (names of committees)/consultation:</strong></td>
<td>Dr J Stratton, Medical Division Lead for Governance and Safety, RCHT</td>
</tr>
<tr>
<td><strong>Divisional Manager confirming approval processes</strong></td>
<td>Sheena Wallace</td>
</tr>
<tr>
<td><strong>Name and Post Title of additional signatories</strong></td>
<td>Not Required</td>
</tr>
<tr>
<td><strong>Name and Signature of Divisional/Directorate Governance Lead confirming approval by specialty and divisional management meetings</strong></td>
<td>Name:</td>
</tr>
<tr>
<td><strong>Publication Location (refer to Policy on Policies – Approvals and Ratification):</strong></td>
<td>Internet &amp; Intranet</td>
</tr>
<tr>
<td><strong>Document Library Folder/Sub Folder</strong></td>
<td>Clinical and Renal</td>
</tr>
<tr>
<td><strong>Links to key external standards</strong></td>
<td>Nice Clinical Guideline 39: Anaemia Management in People with Chronic Kidney Disease. NICE, London <a href="http://guidance.nice.org.uk.CG114">http://guidance.nice.org.uk.CG114</a></td>
</tr>
<tr>
<td><strong>Training Need Identified?</strong></td>
<td>No</td>
</tr>
</tbody>
</table>
**Version Control Table**

<table>
<thead>
<tr>
<th>Date</th>
<th>Version No</th>
<th>Summary of Changes</th>
<th>Changes Made by (Name and Job Title)</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 Jun 10</td>
<td>V1.0</td>
<td>Initial Issue</td>
<td>Andrew Rogers Corporate Records Manager</td>
</tr>
<tr>
<td>1 Feb 11</td>
<td>V2.0</td>
<td>Addition of Monitoring Compliance table.</td>
<td>Andrew Rogers Corporate Records Manager</td>
</tr>
<tr>
<td>15 Jan 12</td>
<td>V2.1</td>
<td>Governance information moved to an appendix. EIA updated. Governance information amended to align with format of</td>
<td>Andrew Rogers Corporate Records Manager</td>
</tr>
<tr>
<td>5 Aug 13</td>
<td>V2.2</td>
<td>Updated governance information table to include KCCG.</td>
<td>Andrew Rogers Corporate Records Manager</td>
</tr>
<tr>
<td>9 Dec 15</td>
<td>V2.3</td>
<td>Policy moved to new Trust template. Blood result parameters updated in line with Pathology Harmonisation Guidance 2007</td>
<td>Sharon Benton, Anaemia CNS</td>
</tr>
</tbody>
</table>

All or part of this document can be released under the Freedom of Information Act 2000

*This document is to be retained for 10 years from the date of expiry.*

*This document is only valid on the day of printing*

**Controlled Document**

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Appendix 2. Initial Equality Impact Assessment Form

| Name of the strategy / policy / proposal / service function to be assessed (hereafter referred to as policy) (Provide brief description): | Is this a new or existing Policy? Existing |
| Renal Services, Medical Directorate, RCHT | Existing |
| Name of individual completing assessment: Sharon Benton | Telephone: 01872 253499 |

1. Policy Aim*
Who is the strategy / policy / proposal / service function aimed at?
The aim of the policy is to maintain the haemoglobin level between 100 and 120g/l in the majority of patients

2. Policy Objectives*
To ensure the patient is correctly assessed before Erythropoietin is prescribed

3. Policy – intended Outcomes*
To achieve the above safely

4. *How will you measure the outcome?
As per section 2 of this guideline, ‘Monitoring and Compliance Effectiveness’

5. Who is intended to benefit from the policy?
Patients with chronic kidney disease or failure referred for initiation of Erythropoietin treatment. All staff administering Erythropoietin therapy.

6a) Is consultation required with the workforce, equality groups, local interest groups etc. around this policy?
No

6b) If yes, have these *groups been consulted?

6c) Please list any groups who have been consulted about this procedure.

7. The Impact
Please complete the following table.

Are there concerns that the policy could have differential impact on:

| Equality Strands: | Yes | No | Rationale for Assessment / Existing Evidence |
| Age | No |
| Sex (male, female, trans-gender / gender reassignment) | No |
| Race / Ethnic communities / groups | No |
| Disability - Learning disability, physical disability, sensory impairment and mental health problems | No |
| Religion / other beliefs | No |
| Marriage and civil partnership | No |
| Pregnancy and maternity | No |
| Sexual Orientation, Bisexual, Gay, heterosexual, Lesbian | No |

You will need to continue to a full Equality Impact Assessment if the following have been highlighted:
- You have ticked “Yes” in any column above and
- No consultation or evidence of there being consultation- this excludes any policies which have been identified as not requiring consultation. or
- Major service redesign or development

8. Please indicate if a full equality analysis is recommended. No

9. If you are not recommending a Full Impact assessment please explain why.

Signature of policy developer / lead manager / director
Date of completion and submission

Names and signatures of members carrying out the Screening Assessment
1.
2.

Keep one copy and send a copy to the Human Rights, Equality and Inclusion Lead, c/o Royal Cornwall Hospitals NHS Trust, Human Resources Department, Knowledge Spa, Truro, Cornwall, TR1 3HD

A summary of the results will be published on the Trust’s web site.

Signed ________________
Date ________________