Bro Taf Localities Drugs and Therapeutics Committee

SHARED CARE

Drug: ERYTHROPOIETIN (EPOETIN ALFA and BETA)

Protocol number: CV 08

Indication: ANAEMIA ASSOCIATED WITH CHRONIC RENAL FAILURE IN CHILDREN

General guidance

This protocol sets out details for the shared care of patients requiring **subcutaneous erythropoetin** (epoetin alfa and epoetin beta) and should be read in conjunction with the General Guidelines for Shared Care. Sharing of care requires communication between the specialist, GP and patient. The intention to share care should be explained to the patient by the doctor initiating treatment. **The doctor who prescribes the medication legally assumes responsibility for the drug and the consequences of its use.** The prescriber has a duty to keep themselves informed about the medicines they prescribe, their appropriateness, effectiveness and cost. They should also keep up to date with the relevant guidance on the use of the medicines and on the management of the patient's condition.

Background

This protocol covers the correction of erythropoietin deficiency in dialysis and non-dialysis patients with chronic renal failure associated anaemia in both adults and children. Endogenous erythropoetin is a hormone almost entirely produced by the kidney. This stimulates the production of red blood cells within bone marrow. Chronic kidney disease results in a deficiency of erythropoetin production. Renal patients will become symptomatic with persistent chronic anaemia and this can lead to the development of irreversible left ventricular hypertrophy. Anaemia is an independent risk factor for cardiovascular morbidity and mortality. Correction of anaemia with recombinant erythropoetins has been shown in numerous studies to improve patient wellbeing, appetite, sexual and mental health, as well as physical parameters such as exercise capacity, stamina and angina/PVD symptoms.

The aim for most adult patients is to maintain the haemoglobin between 11.5 g/dl and 13.5 g/dl. The target haemoglobin is 9.5 g/dl for children under 6 months, >10 g/dl for children aged 6months-2 years, and 10.5 g/dl in children over 2 years.

To maximise effectiveness of treatment, iron supplies (assessed by serum ferritin and occasionally transferrin saturation) must first be optimised, and other factors affecting response to treatment be investigated and treated. These include correcting serum folate and B_{12} levels; control of active inflammatory and infective conditions; treatment of any source of excess blood loss, and uncontrolled parathyroid hormone levels. This will be undertaken within the Renal unit/ Children Kidney Centre.

Responsibilities

A. Consultant responsibilities

1. When treatment is **initiated** send Shared Care request form with Shared Care Protocol to GP.
2. Baseline and continued monitoring of biochemical, haematological and clinical parameters. (see below)
3. Initiate therapy following full discussion with the patient of benefits and risks
4. Titrate erythropoetin dose adjusting dose as appropriate and undertake monitoring of clinical response and side effects and check any alteration in patient's medication.
5. When a GP positive response to SC has been received and patient has been stabilised send a letter to GP "handing over" the Shared Care of the patient to the GP.
6. Respond to any request from a GP to review the patient due to adverse effects of therapy.
7. Provide the GP with acceptable ranges and actions to be taken if readings fall outside these ranges.
8. Advise the GP on continuing or stopping erythropoetin therapy following medical review of the patient and associated drug therapy.
9. Notify GP if patient is failing to attend for appropriate monitoring and advise GP on appropriate action.

B. General practitioner responsibilities

1. Within one week of receipt return the completed Shared Care request form to indicate whether or not willing to undertake Shared Care.
2. Prescribe erythropoetin as part of the shared care agreement.
3. Monitor the general health of the patient.
4. Seek advice from the consultant on any aspect of patient care which is of concern.
5. Report adverse effects of therapy to the consultant and the Medicines and Health Care products Regulatory Agency (MHRA).
6. To act on advice provided by the Consultant if patient does not attend for appropriate monitoring.

C. Patient responsibilities

1. Consent to treatment with erythropoietin.
2. Attend regular appointments with specialist centre and GP.
3. Report any side effects to the specialist or GP whilst receiving erythropoietin

Dosage Regimen

Epoetin alfa and beta are administered subcutaneously between one and three times per week depending on the individual patient. The recommended adult starting dose is 60 – 80 IU/kg/week. The initial aim is to increase a patient's Hb by 1-2 g/dl/month until in the target range of 11.5 – 13.5 g/dl. A typical adult maintenance dose is 6000

– 9000 IU in total per week. The specialist will notify the GP in writing of any dosage adjustments required. The recommended starting dose for children is 100 units /kg/ week and the recommended maintenance dose is 100-700 units/kg/week.

Monitoring

Before initiation of EPO treatment

Patients will be monitored and their blood pressure, iron, B_{12} and Folate stores optimised by the Renal unit team prior to treatment.

Ferritin should be kept >100µg/l. [*nb Patients with chronic kidney disease generally require higher levels of ferritin (iron stores) than normal to respond to EPO*]. B_{12} and folate levels should be within the normal reference range.

GPs will be kept informed in writing about the treatments and ongoing issues and asked if they wish to undertake shared care prescribing of EPO beta. If they agree GP prescribing will only be started once Hb is stable and within targets.

During treatment

The Renal Unit will monitor the following until the haemoglobin is stable (in target range): Children will be monitored by the Children's Kidney Centre, UHW.

- Full Blood Count every 4 weeks
- Blood Pressure every 4 weeks
- Ferritin monthly in early stages

Once the patient is stable these will be undertaken every 4 – 8 weeks as determined by response and investigations within the renal unit.

GP Responsibility

If abnormalities that might be relevant to EPO use (e.g. blood tests, BP, adverse effects) are noted in everyday practice, please inform relevant renal unit contact.

Adverse effects

Hypertension is a recognised side effect of EPO therapy. Hypertension should normally be treated with conventional therapy.

Severe refractory hypertension may require suspension of treatment until blood pressure control is managed.

Patients receiving dialysis will be monitored at each dialysis session or in CAPD clinic.

On initiation of treatment patients may occasionally experience flu-like symptoms. Mild discomfort or stinging at the injection site is sometimes noticed. This is rarely a major issue.

Contacts

Each patient will have a clearly named contact within the Renal unit in correspondence. For patients not yet requiring dialysis this will usually be their Clinical Nurse Specialist. For patients on peritoneal dialysis it will be the CAPD Anaemia Link Nurse/Sister. For patients on haemodialysis it will be the relevant dialysis unit Anaemia Link nurse. In addition all patients will have a clearly named Consultant who should be available to discuss queries or concerns. Failing any of these the Senior Renal Pharmacist or nominated shared care protocol Consultants can be contacted. All contacts and their numbers are listed overleaf (Appendix A)

Interactions

There are no known drug interactions of clinical importance.

Special recommendations

None.

Date of review January 2014

Appendix A

List of contacts within the Renal Unit to deal with issues about the Shared Care protocol for epoetin beta.

Pre dialysis patients		
Margaret Lewis	Children's Kidney Centre	UHW Ext 4844
CAPD patients		
Rhian Hughes	Children's Kidney Centre	UHW 4844
HD patients		
Apollo Barcelon	Children's Kidney Centre	UHW 4844
Transplant patients		
Sister Eiddwen Glynn	Transplant Clinical Nurse Specialist	UHW Ext 4817
Senior Renal Pharmacist		
Robert Bradley		UNW Ext 6324
Anjana Bhudia (Paediatrics)		UWH Ext 6795
Shared Care Protocol Lead Consultants		
Dr Kieron Donovan		UHW Ext 6648
Dr Richard Moore		UHW Ext 6638
Dr Judith Van der Voort (Padiatrics)		UHW Ext 4919