SHARED CARE AGREEMENT

Name of medicine **Roxadustat (Evrenzo®)**

Indication Management of symptomatic anaemia in patients with chronic renal failure

Version: **1.0** Approval date: **March 2024** Review date: **March 2027**

The Shared Care Agreement (SCA) is intended to facilitate the accessibility and safe prescribing of complex treatments across the secondary/primary care interface. It does not contain all of the relevant product information, which should be sought using the current British National Formulary and manufacturer's Summary of Product Characteristics. The SCA must be used in conjunction with the NHS Lothian Procedure for the Shared Care of Medicines, available here.

Roles and responsibilities

Listed below are specific responsibilities that are additional to those included in the NHS Lothian Policy and Procedures for Shared Care. Please refer to the policy for core roles and responsibilities that apply to all Shared Care Agreements.

Consultant / Anaemia Co-ordinator

- Ensuring patient is medically stable and iron replete with no contraindications to treatment
- Counselling patients on all appropriate cautions, contraindications, side effects and drug interactions at initiation of treatment
- Counselling patients on the risk of roxadustat in pregnancy and the need for contraception for male and female patients as appropriate.
- Counsel patients on thrombotic risk
- Giving appropriate iron therapy if not replete prior to commencing treatment with Roxadustat
- Initiating therapy during appointment with the Anaemia Co-ordinator
- Supplying the first 4 weeks of roxadustat (as per Erythropoiesis Stimulating Agents SCA)
- Correction phase (around 8 -12 weeks) – fortnightly blood tests taken in primary care monitored by renal team.
- Advise GP of any dose adjustments (see 'Monitoring' section)
- Maintenance phase - adjust dose as necessary and carry out monitoring (see 'Monitoring' section).
- Advise GP of any dose changes based on the results of monitoring

General Practitioner and primary care non-medical prescribers

- Prescribing roxadustat after the initial 4 week period (as per Erythropoiesis Stimulating Agents SCA)
- Contacting the Anaemia Co-ordinator or the patient's named consultant if concerned about side effects
- During the first 12 weeks of treatment - arrange for FBC to be taken every 2 weeks. These results will be remotely monitored by the Anaemia Co-ordinator, who will take any necessary action as appropriate
- After the first 12 weeks of treatment - monitor FBC monthly (longer periods may be advised if clinically indicated). If results are abnormal, contact Anaemia Co-ordinator or patient's renal consultant as indicated in 'Monitoring' on following page
- Iron studies, Vitamin B12 and folate levels will usually be taken at renal clinic visits and should only be taken in primary care if requested by the renal team. These test results and trends will be reviewed by the Anaemia Co-ordinator and the patient's renal consultant

Note: a significant number of patients who require treatment with roxadustat do not necessarily need renal clinic follow-up. Appropriate liaison regards anaemia management can still be obtained through the anaemia coordinators, and further advice regards renal function etc can be obtained from consultants.

Patient, relatives, carers

- As listed in NHS Lothian Policy and Procedures for the Shared Care of Medicines
- Patients are advised to notify their GP practice to make them aware of the reason for their bloods tests

Support and Advice for the GP and primary care non-medical prescribers

Anaemia Co-ordinator: Available 9.00am - 5.00pm, Monday to Friday. Contact: 0131 242 1204 / 1258 / 1293
Email: renalanaemiamanagement@nhslothian.scot.nhs.uk
Renal Advice email line: rie.renaladvice@nhslothian.scot.nhs.uk
Renal Pharmacists: Available 8.30am - 5.00pm, Monday to Friday. Contact via RIE switchboard on 0131 242 1000, bleep 8006 / 5745

Key Information on the Medicine

Refer to the current edition of the British National Formulary (BNF), available at www.bnf.org, and Summary of Product Characteristics (SPC), available at www.medicines.org.uk for detailed product and prescribing information and specific guidance available at Prescribing A-Z – edren.org.

Background to disease and use of drug for the given indication

Anaemia in chronic kidney disease (CKD) is primarily due to erythropoietin deficiency. It is characterised by haemoglobin (Hb) level below 100g/L on 2 or more consecutive readings in a patient with known CKD.
Erythropoietin is a hormone that is produced by the kidney. In chronic renal failure there may be lower levels of erythropoietin which can lead to anaemia. Roxadustat (a Hypoxia Inducible Factor Prolyl Hydroxylase Inhibitor (HIF-i)) acts on the enzyme Hypoxia Inducible Factor Prolyl Hydroxylase, stimulating the natural response to low levels of oxygen, including the production of erythropoietin and haemoglobin. It is the only drug for this indication not given by injection.

Other causes of anaemia should be investigated and addressed prior to commencing roxadustat. Adequate iron stores should be ensured prior to initiating treatment.

Correction of anaemia in chronic renal failure reduces the risk of cardiovascular disease, improves patient well-being, exercise tolerance, quality of life and reduces the need for blood transfusions.

Indication
Roxadustat (Evrenzo®) is indicated for the treatment of adult patients with symptomatic anaemia associated with chronic kidney disease. For further information, see East Region Formulary | East Region Formulary (nhs.scot)

SMC restriction: For use in patients who are non-dialysis dependent at the time of treatment initiation. It may be continued if dialysis is then started.

Dosage and administration
Dose and any changes to dose to be advised by Consultant/ Anaemia Co-ordinator

Recommended starting dose:
70 mg three times per week in patients weighing less than 100kg.
100 mg three times per week in patients weighing 100kg and over.
Dose adjustments and monitoring see SPC/EdRen.

Dosing should be on non-consecutive days.
Maximum dose - 3mg/kg body weight or 300mg three times a week (whichever is lower) in non-dialysis patients.

Roxadustat should be taken at least 1 hour after administration of sevelamer or calcium acetate or other medicinal products or supplements containing calcium, iron or magnesium.

Missed dose advice:
If it is more than 24hours until next dose, take the dose and then the next scheduled dose.
If it is less than 24hours until next dose, do not take dose, take the next scheduled dose.

Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

Monitoring
The aim of roxadustat therapy is to increase Hb by 10 to 20g/L per month to a target range of 105 to 125g/L. This usually takes approximately 8 - 12 weeks.

First 12 weeks of treatment

In the first 12 weeks, blood tests are to be taken in primary care for review by the Anaemia Co-ordinator

During the first 12 weeks of treatment, arrange for FBC to be taken every 2 weeks.
The results will be remotely monitored by the Anaemia Co-ordinator via our laboratory system (regional SCI store), who will take any necessary action as appropriate.

• If using electronic ordering, the Anaemia Co-ordinator will look up these results directly.

• If using paper based method for ordering, please enter "Anaemia Coordinator RIE" in the "Report to Section" of the blood form; this will be sent directly to the Anaemia Services.

Note: There is no need for the GP to monitor the FBC result in the first 12 weeks

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After first 12 weeks of treatment

Monitoring to be done in primary care

After the first 12 weeks of treatment, FBC as detailed below.

Test	Frequency	Abnormal result	Action if abnormal result
FBC	Every month (longer periods may be advised if clinically indicated)	Hb < 105g/L or > 125g/L	Contact Anaemia Co-ordinator or patient's renal consultant

Cautions, contraindications - Refer to current Summary of Product Characteristics: www.medicines.org.uk

Fertility, Pregnancy and Lactation – Roxadustat is contraindicated during pregnancy and breast feeding. Females of childbearing potential should use highly effective contraception during treatment and for at least 1 week after last treatment. Any patients planning pregnancy or wishing to breastfeed should discuss this with their consultant/anaemia co-ordinator.
Refer to current Summary of Product Characteristics: www.medicines.org.uk for full detail.

Adverse effects - Refer to current Summary of Product Characteristics: www.medicines.org.uk for full detail.

This medicinal product is subject to additional monitoring (black triangle). This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions to:
Yellow Card | Making medicines and medical devices safer (mhra.gov.uk)

Drug interactions – For a full list of drug interactions please refer to current Summary of Product Characteristics: www.medicines.org.uk.

- Sevelamer carbonate or calcium acetate or products containing calcium, iron or magnesium.
- Statins (increased AUC of statins, monitor for side effects and consider dose reduction).
- When initiating or discontinuing treatment with strong inhibitors (gemfibrozil) or inducers (rifampicin) of CYP2C8 or inhibitors (probenecid) of UGT129, Hb should be monitored closely.

The presence of this SCA does not compel a primary care prescriber to prescribe if they feel that it is out with the scope of their competencies (as per GMC guidance on safe prescribing) or resources, as ultimate responsibility lies with the prescribing, not the recommending, clinician.

For office use only
Approved by the General Practice Prescribing Committee (GPPC) on 12th March 2024