Shared Care Guideline
For Prescribing
Riluzole

Issue No: 1.3
Review Date (If Applicable):
Accountable Officer: **Heather Lucas, Head of Medicines Management, SKC CCG**
Contact Details:

Document history:

Version	Created by	Date	Main Changes/Comments
1	Chrissie Batts	2/13	
2	Chrissie Batts	4/16	Changes to contact details. Clarification of GP role in monitoring
3	Heather Lucas	5/16	Change of format to include patient details and GP request to share care. . Addition of specific information re. action in renal impairment
4	Heather Lucas	5/16	Change of renal threshold from 90ml/min to 60ml/min

Approved by: East Kent Prescribing Group *(Representing Ashford CCG, Canterbury and Coastal CCG, South Kent Coast CCG and Thanet CCG)*
Date: May 2016 (Version 2)
Address:
Contact:

Shared Care Guideline for Prescribing Riluzole

Please sign and return your agreement (appendix 1) to shared care, to the initiating specialist, within 14 days of receiving this request.

Section A: To be completed by the Specialist Clinician initiating the treatment:

GP Practice Details:	**Patient Details:**
Name: …… Address: …… Tel no: …… Email: ……	Name: …… Address: …… DOB: ……/……/……..… NHS number (10 digits): ……..

Specialist Clinician Details:

Name of specialist: …….

Clinic name: ……..

Address:
.....

Tel no: …….

Email……..

Shared Care Guideline

Shared Care Guideline for prescribing Riluzole (Rilutek®)

INDICATION

Riluzole is licensed to extend life in patients with amylotropic lateral sclerosis, indicated by specialists experienced in the management of motor neurone disease.

The East Kent CCGs have adopted the NICE TA regarding Riluzole which states that Riluzole is recommended for the treatment of individuals with the amyotrophic lateral sclerosis (ALS) form of Motor Neurone Disease (MND). Riluzole therapy should be initiated by a neurological specialist with expertise in the management of MND. Routine supervision of therapy should be managed by locally agreed shared care protocols undertaken by general practitioners.

AREAS OF RESPONSIBILITY FOR SHARED CARE

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of Riluzole can be shared between the specialist and general practitioner (GP). GPs are invited to participate. If the GP is not confident to undertake these roles, then he or she is under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. If a specialist asks the GP to prescribe this drug, the GP should reply to this request as soon as practicable.

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care is usually explained to the patient by the doctor initiating treatment. It is important that patients are consulted about treatment and are in agreement with it.

The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.

PRINCIPLES OF SHARED CARE

- Shared Care is only appropriate if it provides the optimum solution for the patient.
- Patient will only be referred to the GP when the patient is considered to be stable by the specialist.
- Patient will only be referred to the GP once the GP has agreed in each individual case.
- Specialist will continue to review the patient on a regular basis.
- Specialist will provide advice to the GP as required in a timely manner.
- Significant changes in the patient's condition or medication will be communicated between the specialist and the GP in a timely manner.

DOSAGE AND ADMINISTRATION

Riluzole is prescribed orally as 50mg twice a day.

SPECIALIST RESPONSIBILITIES

1. Initiate treatment after discussion and agreement with the patient.

2. Check baseline renal function, liver function tests and full blood count. Riluzole should be avoided in patients with renal or hepatic dysfunction.

3. Prescribe medication: Riluzole 50mg every 12 hours

4. Ensure that follow-up blood tests are performed as per NICE guidelines through provision of the required blood forms for Renal function, full blood count and Liver function tests to enable patient to arrange for tests to be completed at months 1,2 ,3 and 6 with copy of results to Consultant and G.P

5. Monitor patient for side effects as defined in section below (required monitoring) until care is handed over to GP.

6. Discuss the possibility of shared care with the patient when / if the specialist considers the patient to be stable and suitable, this would usually be 3 – 12 months after starting Riluzole but will vary per patient. If the patient is in agreement the specialist should forward a copy of this shared care guideline with a letter detailing the patient and any specific requirements for safe continued prescribing. If the GP does not accept shared care the total clinical responsibility for the patient for the diagnosed condition remains with the specialist.

7. Once Shared care is agreed the Specialist will continue to review the patient but primary responsibility for blood tests and review of the results will be with the GP

8. The patient will be reviewed by Consultant or Specialist Nurse to monitor clinical response approximately every 3 months. The responsibility for stopping treatment due to lack of effect or advancing disease remains with the specialist. The GP will refer back to the specialist if there are concerns.

9. To be available for advice if the patient's condition changes.

10. To ensure that procedures are in place for the rapid re-referral of the patient by the GP.

11. To liaise with the GP on any suggested changes in prescribed therapy.

12. To communicate significant changes in the condition of the patient or the patient's condition to the GP in a timely manner.

GENERAL PRACTITIONER RESPONSIBILITIES

1. Respond to the specialist's request for shared care.

2. If agreed, continue to prescribe Riluzole and perform and review blood tests. Monitor for side effects and stop treatment or refer back to the specialist as defined below (required monitoring).

3. Monitor concordance with therapy.

4. To manage general health issues of the patient.

5. To communicate with the specialist on any aspect of patient care that is of concern to the GP and may affect treatment.

6. To communicate significant changes in the condition of the patient or the patient's condition to the specialist in a timely manner.

MND NURSE RESPONSIBILITIES

1. Provide GP with appropriate information and training as requested.

2. Maintain contact with the patient and support Specialist and GP in providing the best care for the patient.

3. Facilitate communication between patient, specialist and GP.

PATIENT'S ROLE (OR THAT OF CARER)

4. Before shared care is put in place the patient must be fully informed of the plan and must be in agreement with it.

5. The patient should report to the specialist or GP if he or she does not have a clear understanding of the treatment or has any concerns relating to treatment.

6. Attend appropriate specialist, GP and other follow up appointments and co-operate with assessments and blood tests.

7. Inform the specialist or the GP of any other medication being taken, including herbal or over the counter products

8. Seek help urgently if side effects are suspected, or are otherwise unwell.

REQUIRED MONITORING

Renal function, FBC and LFT should be measured:
Prior to initiating therapy
Monthly for the first, second and third months
Three monthly for the remainder of the first year i.e. 6, 9 and 12 months
Annually thereafter.

Neutropenia

- Patients or their carers should be told how to recognise signs of neutropenia and advised to seek immediate medical attention if symptoms such as fever occur.
- If from annual blood monitoring the white blood cell count is <2 riluzole should be discontinued and the specialist contacted for advice.
- For patients with febrile illness a white blood cell count must be determined. If the patient is neutropenic (wbc <2) the riluzole should be discontinued and the specialist contacted for advice.

Anaemia
If from annual blood monitoring haemoglobin is found to less than 130 g/L, Riluzole should be discontinued and the specialist contacted for advice.

Raised ALT levels
Riluzole should be discontinued if the ALT levels increase to 5 times the ULN. There is no experience with dose reduction or rechallenge in patients who have developed an increase of ALT to 5 times ULN. Readministration of riluzole to patients in this situation cannot be recommended.

Interstitial Lung Disease
Cases of interstitial lung disease have been reported in patients treated with riluzole, some of them were severe. If respiratory symptoms develop such as dry cough and/or dyspnea, chest radiography should be performed, and in case of findings suggestive of interstitial lung disease (e.g. bilateral diffuse lung opacities), riluzole should be discontinued immediately.

Renal impairment
Riluzole should not be prescribed for patients with renal impairment as there is insufficient data to support its safe use. If the e GFR falls below 60ml/min the drug should be discontinued and the specialist team contacted.

CONTACT DETAILS OF SPECIALIST TEAM

On call Consultant Neurologist, Treble Ward, Kent and Canterbury Hospital	Tel No: 01227 783110
Mrs Christine Batts, MND Specialist Nurse	E-mail: Christine.batts@nhs.net Tel No: 07771841690
Specialist Neurology Registrar on call via switchboard	Tel No: 01227 766811

SUPPORTING INFORMATION

See Summary of Product Characteristics (SPC) for full prescribing information and updates. www.medicines.org.uk

Contraindications listed in SPC
Hypersensitivity to the active substance or to any of the excipients.
Hepatic disease or baseline transaminases greater than 3 times the upper limit of normal.
Patients who are pregnant or breast-feeding.

Special Warnings and Precautions listed in SPC

Liver impairment:
Riluzole should be prescribed with care in patients with a history of abnormal liver function, or in patients with slightly elevated serum transaminases (ALT/SGPT; AST/SGOT up to 3 times the upper limit of the normal range (ULN)), bilirubin and/or gamma-glutamyl transferase (GGT) levels. Baseline elevations of several liver function tests (especially elevated bilirubin) should preclude the use of riluzole.

Because of the risk of hepatitis, serum transaminases, including ALT, should be measured before and during therapy with riluzole. ALT should be measured every month during the first 3 months of treatment, every 3 months during the remainder of the first year, and periodically thereafter. ALT levels should be measured more frequently in patients who develop elevated ALT levels.

Riluzole should be discontinued if the ALT levels increase to 5 times the ULN. There is no experience with dose reduction or rechallenge in patients who have developed an increase of ALT to 5 times ULN. Readministration of riluzole to patients in this situation cannot be recommended.

Neutropenia:
Patients should be warned to report any febrile illness to their physicians. The report of a febrile illness should prompt physicians to check white blood cell counts and to discontinue riluzole in case of neutropenia.

Interstitial lung disease
Cases of interstitial lung disease have been reported in patients treated with riluzole, some of them were severe. If respiratory symptoms develop such as dry cough and/or dyspnea, chest radiography should be performed, and in case of findings suggestive of interstitial lung disease (e.g. bilateral diffuse lung opacities), riluzole should be discontinued immediately. In the majority of the reported cases, symptoms resolved after drug discontinuation and symptomatic treatment.

Renal impairment:
Studies at repeated doses have not been conducted in patients with impaired renal function.

Side Effects
Common side effects include headache, dizziness, oral paraesthesia, somnolence, tachycardia, nausea, diarrhoea, abdominal pain, vomiting, weakness, vertigo, pain, abnormal liver function tests and asthenia. Side effects of dizziness or vertigo may affect the performance of skilled tasks such as driving.

See manufacturer's SPC for complete list of side effects.

Drug Interactions
There are no interactions listed in BNF 70 (March 2016).

The manufacturer's SPC (last updated December 2013) states that there have been no clinical studies to evaluate the interactions of riluzole with other medicinal products.

In vitro studies using human liver microsomal preparations suggest that CYP 1A2 is the principal isozyme involved in the initial oxidative metabolism of riluzole. Inhibitors of CYP 1A2 (e.g. caffeine, diclofenac, diazepam, nicergoline, clomipramine, imipramine, fluvoxamine, phenacetin, theophylline, amitriptyline and quinolones) could potentially decrease the rate of riluzole elimination, while inducers of CYP 1A2 (e.g. cigarette smoke, charcoal-broiled food, rifampicin and omeprazole) could increase the rate of riluzole elimination.

References
Rilutek® tablets. Summary of Product Characteristics, Sanofi-Aventis. Last updated December 2013. https://www.medicines.org.uk/emc/medicine/1672

NICE TA 20. Guidance on the Use of Riluzole (Rilutek) for the Treatment of Motor Neurone Disease. Published January 2001.

Appendix 1

Shared Care Agreement for Prescribing Riluzole

To be completed by the GP and returned to the Specialist Clinician requesting shared care

To:(insert name of initiating specialist) ……..

GP Practice Details:	**Patient Details:**
Name: …… Address: …… Tel no: …… Email address: ……	Name: …… Address: …… DOB: ……/……../……..… NHS number (10 digits): ……..

Please sign and return your agreement to shared care within 14 days of receiving this request. Tick which applies:

□ I agree to shared care prescribing for this patient, as per the shared care prescribing guideline

□ I would like further information. Please contact me on:…….

□ I am not willing to undertake shared care for this patient for the following reason(s) :……
……
…….
……
…….

GP Signature:……Date: …/…/…