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RILUZOLE

for **Amyotrophic Lateral Sclerosis (a form of Motor Neurone Disease)**

DOCUMENT TO BE SCANNED INTO ELECTRONIC RECORDS AS AND FILED IN NOTES

Patient Name : **Date of Birth:** **NHS No:**

Name of Referring Consultant: **Contact number:**

INTRODUCTION – Indication and Licensing

Riluzole is lindicated to extend life or the time to mechanical ventilation for patients with Amyotrophic Lateral Sclerosis (a form of Motor Neurone Disease)

PATIENT PATHWAY- *brief explanation of why planned arrangements for prescribing and monitoring between primary and secondary care are appropriate*

Clinical Speciality / Indication	Prescribing Initiated by	Prescribing Continued by *(detail when suitable for transfer to occur)*	Monitored by *(detail when suitable for transfer to occur IF APPROPRIATE)*	Duration of treatment
Neurology / Motor Neurone Disease	Dr A Radunovic Consultant Neurologist for first 3 months	GP after 3 months	Consultant Neurologist for first 3 months, then GP. Hospital continue to see patient every three months, or less or more depending on the disease progression	Indefinite

ORAL DOSE AND ADMINISTRATION

- 50mg twice a day by mouth (doses spaced 12 hours apart). Doses should be taken at least one hour before, or two hours after food.
- Supplied as 50mg tablets
  If patient is unable to swallow tablets, they may be crushed for administration via an enteral tube, or may be crushed and mixed with a soft food product to aid swallowing. Care should be taken when using crushed tablets, as they may produce a local anaesthetic effect in the mouth. High fat meals reduce the extent and rate of absorption and should be avoided. *Note: crushing tablets for administration is an off-licence use of riluzole.*

MONITORING STANDARDS FOR MEDICATION AT BARTS AND THE LONDON NHS TRUST

Note: be clear about what needs monitoring, normal parameters, how often and by whom. What results warrant referral back to the hospital team

Parameter	LFTs (bilirubin, ALT gamma-GT) and FBC with differential WBC
Target level	Normal ranges, but see below
Frequency of monitoring	Monthly for 3 months, 3 monthly for 9 months and then annually thereafter. Increase frequency if liver disturbances develop.
Action	**Stop treatment** if ALT rises to five times the normal upper limit (0 -

	56iu/L) or if neutropenic (neutrophils <1x10^9/L).

- The hospital team will undertake baseline U&Es, LFTs and FBC and carry out monitoring for the first 3 months
- Above monitoring to be carried out by GP after 3 months.
- Referral back to the hospital team to be made if clinically significant abnormal results occur as outlined above

KEY ADVERSE EFFECTS & ACTIONS

Adverse effects	**Symptoms/signs** *(specify what would prompt action)*	**Actions (***what action should the GP take if identified in primary care)*
Most commonly: • Asthenia • Nausea • ALT elevation [especially in first 3 months] Other adverse effects include: • Headache • Abdominal pain • Pain • Vomiting • Dizziness • Metallic taste • Tachycardia • Somnolence • Neutropenia (small number of reports)	Loss of strength and energy Patient advised to report febrile illness to GP promptly as this may indicate neutropenia	Refer to hospital team if severe Refer to hospital team if severe Stop riluzole and refer to hospital team if ALT rises to five times the normal upper limit (0 - 56iu/L) Refer to hospital team if severe Stop riluzole if patient is neutropenic (neutrophils <1x10^9/L)

For comprehensive information on cautions, contra-indications and interactions, please refer to the current British National Formulary and Summary of Product Characteristics.

Drugs that significant induce or inhibit the liver enzymes can affect riluzole levels- see SPC for details

PREGNANCY AND BREAST FEEDING

This drug is contra-indicated in pregnancy and if breast feeding. The hospital team will advise on contraception where appropriate and what to do if pregnancy occurs whilst taking the drug. If the GP identifies pregnancy the neurologist should be contacted for advice .

SHARED CARE

Shared care guideline*:* is a document which provides information allowing patients to be managed safely by primary care, secondary care and across the interface. It assumes a partnership and an agreement between a hospital specialist, GP and the patient and also sets out responsibilities for each party. The intention to shared care should be explained to the patient and accepted by them. Patients are under regular follow-up and this provides an opportunity to discuss drug therapy. Intrinsic in the shared care agreement is that the prescribing doctor should be appropriately supported by a system of communication and cooperation in the management of patients. The doctor who prescribes the medicine has the clinical responsibility for the drug and the consequence of its use**.**

Approved by: NHS ONEL Area Prescribing Committee, November 2011; Guideline written by: Mr C. Tugwell and Dr A. Radunovic.
Guidelines adapted for BHRuT use by: Elsy Gomez Campos Review date: November 2013

Consultant

1. Ensure that the patient/carer is an informed recipient in therapy.
2. Ensure that patients understand their treatment regimen and any monitoring or follow up that is required (using advocacy if appropriate). Issue any local patient information leaflets where appropriate.
3. Ensure baseline investigations are normal before commencing treatment. Give the patient a patient held booklet for result monitoring if appropriate.
4. Initiate treatment and prescribe until the GP formally agrees to share care (as a minimum, supply the first month of treatment or until patient is stabilised).
5. Send a letter to the GP requesting shared care for this patient.
6. Clinical and laboratory supervision of the patient by blood monitoring and routine clinic follow-up on a regular basis.
7. Send a letter/results notification to the GP after each clinic attendance ensuring current dose, most recent blood results and frequency of monitoring are stated (unless otherwise covered by letter eg from Rheumatology Clinical Nurse Specialist or Pharmacy Drug Monitoring Service).
8. Where the GP is not performing the phlebotomy, the blood test form MUST be annotated to request that blood results are also copied to the GP
9. Evaluation of any reported adverse effects by GP or patient.
10. Advise GP on review, duration or discontinuation of treatment where necessary. Where urgent action is required following tests the hospital team will telephone the patient and inform GP.
11. Inform GP of patients who do not attend clinic appointments.
12. Counsel the patient on contraception and what to do if pregnancy occurs. Document in the notes.
13. Ensure that backup advice is available at all times.
14. Ensure, where timing is appropriate, that the patient has received a flu vaccine prior to commencing treatment that is likely to cause immunosuppression. Document this in the patient notes and inform the GP it has been given

General Practitioner

1. Reinforce the patient's understanding of the nature, effect and potential side effects of the drug before prescribing it as part of the shared care programme and contact the specialist for clarification where appropriate.
2. Monitor patient's overall health and well-being.
3. Report any adverse events to the consultant, where appropriate.
4. Report any adverse events to the CSM, where appropriate.
5. Help in monitoring the progression of disease
6. Maintain a patient held monitoring booklet where used
7. Prescribe the drug treatment as described.

PCT

1. To provide feedback to trusts via Trust Medicines Committee.
2. To support GPs to make the decision whether or not to accept clinical responsibility for prescribing.
3. To support trusts in resolving issues that may arise as a result of shared care.

Patient/ Carer

1. Report any adverse effects to their GP and/or specialist
2. Ensure they have a clear understanding of their treatment.
3. Report any changes in disease symptoms to GP and/or specialist
4. Alert GP and/or specialist of any changes of circumstance which could affect management of disease e.g. plans for pregnancy
5. Take/ administer the medication as prescribed
6. Undertake any monitoring as requested by the GP and/or specialist

Costs

Drug Product	Cost in primary care
Riluzole (Rilutek)	Basic NHS price: £320.33 for 1 month (56 x 50mg tablets)

Based on BNF edition 62 (September 2011)

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RESOURCES AVAILABLE

Barking, Havering and Redbridge University Hospitals NHS Trust	
Consultant Neurologist (Dr A. Radunovic) SpR in Neurology on-call out of hours	01708 435 000, extension: 7241 Aircall via switchboard
Clinical Nurse Specialist (Esther Larsson)	020-73777000, extension 2523
Drug Monitoring Clinic Pharmacist (where appropriate)	Khalid Khan, DECT 6880
NHS ONELPrescribing Team	To confirm new number

References

- NICE Guidance on the Use of Riluzole (Rilutek) for the Treatment of Motor Neurone Disease (TA20), 2001.
- British National Formulary (September 2011) page 312.
- Summary of Product Characteristics – Rilutek (Sanofi-Aventis); last updated on the eMC: 07/07/2009.

Refer to the NHS ONEL website to obtain the latest version of this guideline

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Appendix 1

Name of Trust

RILUZOLE SHARED CARE AGREEMENT LETTER

Name of GP ……..… Address …….
……..……....
……..……
..……..…

Dear GP

Re: Patient's Name……..……

Date of Birth……..……

Hospital Number……..…….

Indication for ……..……

Route……(Oral/Intramuscular/Subcutaneous)- DELETE AS APPROPRIATE

Dose……..mg per week.

Enclosed is a copy of the shared care guidelines for [Drug Name] to be retained in the patient's notes.

Should you agree to shared care, we will send a letter containing the details of the patient's treatment plan, the dose to be prescribed and all relevant blood results.

Please sign below and return this letter to the Hospital Specialist if you agree to the shared care arrangements for this patient.

Many thanks

Hospital Specialist	GP
Signature……...	Signature……...
Name ……..……...	Name ……...
Date……...	Date……..…..……...

If you are not taking on shared care for this patient please state the reason why and return this letter to the Hospital Specialist.

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