Shared Care Agreement

RILUZOLE FOR THE TREATMENT OF THE AMYOTROPHIC LATERAL SCLEROSIS (ALS) FORM OF MOTOR NEURONE DISEASE (MND)

Referral Criteria

- These guidelines are for patients over 18 years of age.
- Shared Care is only appropriate if it provides the optimum solution for the patient.
- Prescribing responsibility will only be transferred when it is agreed by the consultant and the patients' GP
- Safe prescribing must be accompanied by effective monitoring.
- When transfer is agreed, the patient will be given a supply of Riluzole sufficient for 4 week maintenance therapy.
- **The doctor who prescribes the medication has the clinical responsibility for the drug and the consequences of its use.**

SHARED CARE RESPONSIBILITIES

Consultant

1. Confirm diagnosis of ALS after appropriate investigations.
2. Complete appropriate funding application and receive funding approval from CCG.
3. Ensure that patient is aware of risks and benefits of medication and has read the appropriate information leaflet.
4. Ensure the patient understands the shared care agreement and has signed the Patient Agreement Letter.
5. Perform baseline tests (see Monitoring section) and provide results to GP.
6. Ensure Riluzole is compatible with other concomitant medication at time of initiation.
7. Initiate treatment and monitor/prescribe until the GP formally agrees to share care (as a minimum, supply the first month treatment and until patient is stabilised).
8. Promptly send a letter to the GP requesting shared care for this patient.
9. Review the patient in outpatients as clinically appropriate and inform GP, by letter, of each clinic attendance and action taken for the management of the patient ensuring current dose, most recent blood results and frequency of monitoring are stated.
10. Evaluate any reported adverse effects by GP or patient.
11. Notify GP of patients who do not attend clinic appointments.
12. Ensure that backup advice is available at all times. (see Contacts section).
13. Report any adverse effects to the GP and MHRA yellow card scheme. http://www.mhra.gov.uk/Safetyinformation/Howwemonitorthesafetyofproducts/Medicines/TheYellowCardScheme/Informationforhealthcareprofessionals/index.htm

General Practitioner

1. Respond to the request for Shared Care as soon as practicable. If concerns regarding shared care, urgently contact the Consultant and complete attached letter with clinical reasons and return to Consultant and Pharmacy department.
2. Monitor patient's overall health and well-being.
3. Ensure compatibility with other concomitant medication prescribed by GP since initiation.
4. Prescribe at the dose recommended by specialist.
5. Monitor side effects, FBC and LFTs at recommended frequencies (see monitoring section) and refer back to specialist as necessary.
6. Stop treatment on advice of specialist or immediately if any urgent need to stop treatment arises (see Monitoring section).
7. Report any adverse events to the specialist and MHRA yellow card scheme. http://www.mhra.gov.uk/Safetyinformation/Howwemonitorthesafetyofproducts/Medicines/TheYellowCardScheme/Informationforhealthcareprofessionals/index.htm
8. Inform specialist of any change in the medical condition of patient which may have effect on disease/ medications.

Patient

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1. Report to specialist or GP if there is not a clear understanding of their treatment and discuss any concerns in relation to treatment
2. Report any adverse effects to their GP and/or specialist whilst taking Riluzole. A febrile illness should be reported on the same day it starts.
3. Report any changes in disease symptoms to GP and/or specialist whilst taking Riluzole.
4. Alert GP and/or specialist of any changes of circumstance which could affect management of disease
5. Inform GP or specialist of any other medicines being taken including over-the-counter products.
6. Ensure regular attendance for review and blood monitoring tests.

CONTACT NUMBERS FOR ADVICE AND SUPPORT

Princess Alexandra Hospital NHS Trust - Neurology	
Consultant via switchboard:	01279 444455 ext 7422

Princess Alexandra Hospital NHS Trust - Pharmacy	
Medicines Information (for medicines related queries)	01279 827054

CLINICAL INFORMATION

Prescribed Indications

Riluzole is licensed to extend life or the time to mechanical ventilation for individuals with the amyotrophic lateral sclerosis (ALS) form of motor neurone disease (MND).

Therapeutic Summary

Motor neurone disease is the term used to describe progressive muscular atrophy (PMA) and amyotrophic lateral sclerosis (ALS) which includes Progressive Bulbar Palsy. ALS, which is characterised by both upper and lower motor neurone signs, is the most common form of MND, accounting for 65% to 85% of all cases. Adult-onset MND is characterised by progressive degeneration of the motor neurones of the brain, brain stem or spinal cord, starting insidiously with symptoms and signs including stumbling, foot drop, weakened grip, slurred speech, cramp, muscle wasting, twitching and tiredness. Other symptoms of MND include muscle stiffness, paralysis, incoordination and impaired speech, swallowing and breathing. Most individuals die from ventilatory failure, resulting from progressive weakness and wasting of limb, respiratory and bulbarmuscles within approximately 3 years of the onset of symptoms.

NICE TA 20 Guidance on the use of Riluzole (Rilutek) for the treatment of Motor Neurone Disease January 2001
https://www.nice.org.uk/Guidance/TA20

Dose and Route of Administration

Riluzole 50mg every 12 hours for adults and elderly. There is no significant benefit in increasing dose further.

Administration - swallowing difficulties:
The tablets can be crushed and mixed with soft food e.g. yoghurt or puree to aid swallowing. Tablets crushed onto food should be eaten within 15 minutes as there is no stability data available for this method of administration. Use crushed tablets with care as they may have a local anaesthetic effect in the mouth.

Administration – enteral tubes:

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The tablets can be crushed and dispersed in water for enteral tube administration. Give immediately. Riluzole may block enteral feeding tubes, so ensure that the tube is flushed well after each dose.

Duration of Treatment

- Indefinite

Adverse Effects and Management

Undesirable effects include:

- Nausea, vomiting, weakness, tachycardia, somnolence, headache, dizziness, vertigo, pain, parasthesia, neutropenia and alterations in liver function tests. Transient increases in ALT can occur in the first 3 months of treatment, with levels returning to below twice the upper limit of normal after 2 to 6 months while treatment continues.

See BNF for comprehensive list.

Cautions

- Patients should be warned about the potential for dizziness or vertigo, and advised not to drive or operate machinery if these symptoms occur.
- 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 (see advice and action)

Contraindications

- Hepatic disease or baseline transaminases greater than 3 times the Upper Limit of Normal (ULN).
- Renal impairment
- Pregnancy
- Lactation

MONITORING STANDARDS FOR RILUZOLE AT PRINCESS ALEXANDRA HOSPITAL NHS TRUST

The following standards have been agreed for the monitoring of Riluzole in all patients at Princess Alexandra Hospital NHS Trust.

Pre-treatment responsibility of the Specialist	FBC, U&Es, LFTs, creatinine	
Ongoing monitoring responsibility of the GP	FBC	Monthly for three months then every 3 months for a further 9 months, and annually thereafter. Patients should be warned to report any febrile illness to their physicians.
	LFTs	Monthly for three months then every 3 months for a further 9 months, and annually thereafter. ALT levels should be measured more frequently in patients who develop elevated ALT levels.
	U&Es	Every 6 months (more frequently if there is any reason to suspect deteriorating renal function)

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Action and Advice

If a GP has taken blood tests for the general medical management of a patient and blood test results fall into the categories below or the patient reports one of the adverse events below, these are recommendations for considering the withdrawal of Riluzole therapy:

Blood Test Results	
• FBC	Check white cell count and discontinue Riluzole if WBC <3.5 or neutrophils <2.0 and contact Specialist for advice
• U&Es	Contact Specialist if renal function deteriorates
• ALT > 5 times ULN	Discontinue and discuss with specialist team. There is limited experience with dose reduction or re-challenge in these patients.
Symptoms	
• Febrile illness	Check white cell count and discontinue Riluzole if WBC <3.5 or neutrophils <2.0 and contact Specialist
• Dry cough/dyspnoea	Chest radiography should be performed to exclude interstitial lung disease. Discontinue Riluzole if bilateral diffuse lung capacities observed suggestive of interstitial lung disease. Refer back to specialist.

Clinically relevant Drug interactions

No clinical data available but since Riluzole is extensively metabolised by the enzyme cytochrome P450 1A2, inhibitors (e.g. theophylline, quinolones) and inducers (e.g. rifampicin, omeprazole) of this enzyme could potentially affect the rate of elimination.
Consult product literature for more details.

Further Information

This document does not replace the SPC and BNF and should be read in conjunction with it.

Riluzole Rilutek® SPC
http://www.medicines.org.uk/emc/medicine/1672

MHRA Yellow card scheme for reporting adverse effects
http://www.mhra.gov.uk/Safetyinformation/Howwemonitorthesafetyofproducts/Medicines/TheYellowCardScheme/Informationforhealthcareprofessionals/index.htm

NICE TA 20 Guidance on the use of Riluzole (Rilutek) for the treatment of Motor Neurone Disease January 2001
https://www.nice.org.uk/Guidance/TA20

West Essex CCG webpage for Shared Cared Agreements –
https://westessexccg.nhs.uk/your-health/medicines-optimisation-and-pharmacy/shared-care-medicines

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GP response to Shared Care Agreement

(only complete & send if NOT participating in shared care)

This shared care agreement has been approved by the Medicines Management Optimisation Programme Board February 2016

Patient Name:	NHS No:
Consultant:	Medicine requested for shared care: **Riluzole**

I will **NOT** be undertaking the GP responsibilities as described in the agreed shared care agreement. My clinical reasons for declining shared care for this patient are listed in the box below:

Yours sincerely

{GP name}

{Surgery}

Please send a copy of this response to:
1. The specialist/consultant requesting shared care
2. **AN ANONYMISED COPY OF THIS FORM ONLY** to the E-MAIL: **tpa-tr.ClinicalPharmacy@nhs.net**

(sending a copy of this form to the PAH pharmacy will help to identify any inappropriate requests for shared care e.g. indication not covered, hospital monitoring requirements not fulfilled. It will also help to inform the CCG Medicines Optimisation Team of the reasons shared care is not being undertaken by GPs allowing for changes to be made in future updates to improve patient safety)

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P14064

The Princess Alexandra Hospital NHS
NHS Trust

Hamstel Road
Harlow, Essex
CM20 1QX

Tel: 01279 444455

Information for patients:

SHARED CARE:
Agreement information and confirmation

Patient name:

.....

Medicine:

.....

We would be grateful if you would take time to read this information as it will help us work with you to manage your condition and ensure safe prescribing of the specific medicine listed above.

What is a Shared Care Agreement (SCA)?

A Shared Care Agreement (SCA) enables the care you have for a specific condition to be shared between the hospital and your GP.

The agreement means that the medicine the hospital has started, can be continued by your GP, so you won't have to visit the hospital to collect your medicine.

The SCA gives information on your medicine, guidance on the prescribing and monitoring responsibilities for your consultant (in the hospital), your GP and you. For an SCA, to work everyone involved must understand it and communicate effectively.

Your consultant and your GP will need to sign the agreement and if you agree to this approach, we would ask you to sign this letter, to indicate your agreement to have your care managed in this way.

How does shared care work?

Your consultant and GP share responsibility for your care.

The consultant is a specialist in your condition and will start prescribing your medicine, making sure it is suitable for you. There will come a point in your treatment when you may not need to be monitored by the consultant as often and this monitoring can be done by your GP.

Once your GP has agreed to the SCA, they will be able to prescribe the same medicine for you at the dose recommended by the consultant.

The organisation which regulates GPs, the General Medical Council, says that 'when a GP prescribes a medicine, the GP needs to satisfy themselves that the prescription is needed, appropriate for the patient and within the limits of their competence'.

So, your GP can only issue a prescription if the consultant and you keep to the responsibilities you have agreed (see below). If responsibilities are not kept or if the GP no longer feels it is safe to prescribe the medicine, he/she will explain the reasons to you and your consultant, then prescribing responsibilities will be transferred back to the hospital.

What do I need to do to ensure the SCA can continue?

- **Attend hospital outpatients**
  You must still attend the hospital for regular reviews as directed by your consultant (these may be less frequent than before). If you do not attend your hospital appointments, your GP will not be able to continue issuing prescriptions for this medication.
- **Attend GP appointments**
  You must attend any appointments you have with your GP in relation to this medicine, so they can look after you effectively.
- **Have blood tests as you have been advised to**
  Your consultant should have informed you

continued overleaf

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if and how often you need to have blood monitoring tests. You can usually have your blood taken at an appropriate clinic and not need to go to the hospital.

- If you do not have the blood monitoring tests as advised by your consultant, your GP will no longer be able to issue you with prescriptions as it would not be safe to do so.

What do I do if I am having side-effects to the medicine?

Your consultant should have informed you of the common side-effects to expect and what to do if you experience them. If you think you may be having side-effects from a medicine report these directly to your consultant. Your GP may need to seek advice from your consultant before issuing you with another prescription; this is to ensure it is safe for you to continue on the medication.

What if my disease symptoms change or get worse?

Report any changes in disease symptoms or circumstances that could affect management of your disease to your consultant.

What about the other medicines I take?

Inform your GP and the consultant of all other medicines you are taking, including those you may have bought yourself. Do not take new medicines (including those you could buy) until you have discussed this with your pharmacist, GP or consultant.

If you would like to go ahead with a shared care agreement for the specific medication identified on page 1, please sign below to confirm that you:

- Understand the shared care agreement.
- Are happy to have your care for this aspect of your health managed by a shared care agreement.
- You agree to attend regular review appointments as requested.
- You agree to have blood tests as required.

Patient's signature .....

Date .....

Print name .....

If at any point in time you would like this shared care agreement to stop, please talk to your GP.