DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE
SHARED CARE AGREEMENT

Riluzole for the treatment of the Amyotrophic Lateral Sclerosis (ALS) form of Motor Neurone Disease (MND)

1. REFERRAL CRITERIA

- 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 patient's GP that the patient's condition is stable or predictable.
- Patients will only be referred to the GP once the GP has agreed in each individual case.
- The patient will be given a supply of riluzole 50mg tablets sufficient for 12 weeks maintenance therapy.

2. AREAS OF RESPONSIBILITY

GP responsibilities	Consultant responsibilities
1. If NOT participating in shared care reply to the request from the consultant/specialist as soon as practicable (see appendix 1) **2.** Prescribing riluzole after the first 3 months of therapy **3.** Monitoring the patient with regard to side- effects, FBC & LFT three monthly for 9 months then annually thereafter as per monitoring guidelines once GP has taken over prescribing of riluzole **4.** ALT should be measured more frequently in patients who develop elevated ALT levels and treatment discontinued if levels increase to five times the ULN **5.** White blood cell counts should be checked and riluzole discontinued if WBC <3.5 or neutrophils < 2.0. **6.** Referral back to the specialist physician if side-effects become troublesome, or in the presence of raised LFTs **7.** Refer back to specialist if patients develop respiratory symptoms such as dry cough and/or dyspnoea **8.** Report any adverse effects to the referring specialist and the MHRA yellow card scheme **9.** Stop treatment on advice of a specialist	**1.** Diagnosis of ALS after appropriate investigations **2.** Baseline U&E, LFT, FBC **3.** To review suitability of patient for treatment and discuss benefits and side effects of treatment with patient. **4.** Advise patients to seek medical advice if they develop infective symptoms such as dry cough and/or dyspnoea **5.** Initiation of riluzole and prescribing for the first 3 months of therapy **6.** Monitoring side-effects, FBC and LFT in the first 3 months of treatment **7.** If patients develop respiratory symptoms such as dry cough and/or dyspnoea, chest radiography should be performed **8.** Assessment of the continuing need for treatment **9.** Send copy of the shared care agreement to GP and ask whether they are willing to participate in shared care, handover treatment to GP at 3 months if agreement reached **10.** Communicate promptly with GP any changes in treatment or if any dosage adjustments required **11.** Report any adverse effects to the MHRA yellow card scheme and GP

Patient responsibilities

1. Report any adverse effects to the specialist or GP whilst taking riluzole
2. A febrile illness should be reported on the same day that it starts
3. Report to the specialist or GP if they do not have a clear understanding of their treatment
4. Ensure regular attendance for review and blood monitoring tests
5. Patients should be warned to report respiratory symptoms to their physician

3. COMMUNICATION AND SUPPORT

i. Hospital contacts:	ii. Out of hours contacts and procedures:
University Hospitals of Derby and Burton NHS Foundation Trust Dr M Phillips 01332 258238 Dr Michael Knopp, Consultant Neurologist: 01332 783548 Sarah Cole, MND Nurse Specialist: 01332 788865	**University Hospitals of Derby and Burton NHS Foundation Trust** On-call Pharmacist via switchboard 01332 340131

iii. Specialist support/resources available to GP including patient information

The manufacturers patient information leaflet will be provided with all riluzole dispensed. For newly diagnosed patients, a booklet from the Motor Neurone Disease Association on practical management of the disease will be provided to each patient. The MNDA website has further supportive information for GPs.

4. CLINICAL INFORMATION

i. Prescribed indications	Riluzole is licensed to extend life for individuals with the amyotrophic lateral sclerosis (ALS) form of motor neurone disease (MND)
ii. 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.
iii. Dose & Route of administration	**50mg every 12 hours; Use tablets 1st line** **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:** 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. A licensed oral suspension is available however this is significantly more expensive. The MND specialists may recommend suspension in exceptional circumstances in patients with severe dysphagia causing coughing and aspiration, or in patients using enteral feeding where there is a risk of crushed riluzole tablets blocking feeding tubes.
iv. Duration of treatment	Indefinite
v. Adverse effects	Nausea, vomiting, weakness, tachycardia, somnolence, headache, dizziness, vertigo, pain, parasthesia, neutropaenia 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.
vi. Monitoring Requirements	LFT and FBC before and during therapy, every month for 3 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. Riluzole should be discontinued if ALT levels increase to five times the ULN. There is limited experience with dose reduction or re-challenge in these patients. Patients should be warned to report any febrile illness to their physicians. White blood cell counts should be checked and riluzole discontinued if WBC <3.5 or neutrophils < 2.0. Patients should be warned to report respiratory symptoms to their physician. Chest radiography should be performed and in case of findings suggestive of interstitial lung disease, riluzole should be discontinued immediately.
vii. 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.
viii. Contraindication	Hepatic disease or baseline transaminases greater than 3 times the Upper Limit of Normal (ULN). Renal impairment, pregnancy, breast feeding
ix. Supply, storage and reconstitution instructions	Not applicable
x. Prepared by **Reviewed by (2019)**	Dr M Phillips, Consultant in Rehabilitation Medicine University Hospitals of Derby and Burton NHS Foundation Trust The Derbyshire Medicines Management Shared Care & Guideline Group

This does not replace the SPC, which should be read in conjunction with it.
First prepared: May 2010 Updated: September 2019 Review date: August 2022

Sample transfer letter

{Insert Hospital Logo here}

Hospital No: «HOSPITAL_NUMBER»
NHS No: «NHS_NUMBER»

{Insert date}

PRIVATE & CONFIDENTIAL
«GP_TITLE» «GP_INITIALS» «GP_SURNAME»
«GP_ADDRESS_1»
«GP_ADDRESS_2»
«GP_ADDRESS_3»
«GP_ADDRESS_4»
«GP_POSTCODE»

DERBYSHIRE JAPC SHARED CARE AGREEMENT LETTER

Dear «GP_TITLE» «GP_SURNAME»

«FORENAME_1» «SURNAME» «DATE_OF_BIRTH»
«CURRENT_ADDRESS_1» «CURRENT_ADDRESS_2» «CURRENT_ADDRESS_3» «CURRENT_ADDRESS_4» «CURRENT_POSTCODE»

Your patient was seen on ***{Insert date}*** with a diagnosis of ***{Insert diagnosis}***. I have initiated the following medication ***{Insert drug name}*** and am writing to ask you to participate in the shared care for this patient.

This medication has been accepted as suitable for shared care by the Derbyshire Joint Area Prescribing Committee (JAPC). I agree to the secondary care responsibilities set out in the shared care agreement for this medication (available from www.derbyshiremedicinesmanagement.nhs.uk/clinical_guidelines/shared_care_guidelines). I am therefore requesting your agreement to share the care of this patient. Where preliminary tests are set out in the agreement I have carried these out and results are below.

Dose Regimen	Date ***{Insert medicine name}*** started	Date for GP to start prescribing ***{Insert medicine name}*** from
The baseline test results are (if applicable):		

I can confirm that the following has happened with regard to this treatment:

	Specialist to complete
The patient has been initiated on this therapy and has been on an optimised dose for the following period of time:	
Baseline investigation and monitoring as set out in the shared care documents have been completed and were satisfactory	*Yes / No*
The condition being treated has a predictable course of progression and the patient can be suitably maintained by primary care	*Yes / No*
The risks and benefits of treatment have been explained to the patient	*Yes / No*
The roles of the specialist/specialist team/ Primary Care Prescriber / Patient and pharmacist have been explained and agreed	*Yes / No*
The patient has agreed to this shared care arrangement, understands the need for ongoing monitoring, and has agreed to attend all necessary appointments	*Yes / No*
I have enclosed a copy of the shared care protocol which covers this treatment/the SCP can be found here (insert electronic/ web link)	*Yes / No*
I have included with the letter copies of the information the patient has received	*Yes / No*

I have provided the patient with sufficient medication to last until	
I have arranged a follow up with this patient in the following timescale	

If you do **NOT** wish to participate in shared care for this patient, usually under clinical grounds, please complete the attached form.

Yours sincerely

{Consultant name}

GP RESPONSE TO SHARED CARE (only complete & send if **NOT** participating in shared care)

Shared care is produced by GPs and specialists knowledgeable in the field of that drug usage. The shared care has been approved by the JAPC. This allows a more convenient service to the patient and cost effective use of NHS resources.

Patient:	NHS No:
Consultant:	Medicine requested for shared care:

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

		Tick which apply
1.	**The prescriber does not feel clinically confident in managing this individual patient's condition, and there is a sound clinical basis for refusing to accept shared care** As the patients primary care prescriber I do not feel clinically confident to manage this patient's condition because *[insert reason]*. I have consulted with other primary care prescribers in my practice who support my decision. This is not an issue which would be resolved through adequate and appropriate training of prescribers within my practice. **I have discussed my decision with the patient and request that prescribing for this individual remain with you as the specialist, due to the sound clinical basis given above.**	
2.	**The medicine or condition does not fall within the criteria defining suitability for inclusion in a shared care arrangement** As the medicine requested to be prescribed is not included on the national list of shared care drugs as identified by RMOC or is not a locally agreed shared care medicine I am unable to accept clinical responsibility for prescribing this medication at this time. **Until this medicine is identified either nationally or locally as requiring shared care the responsibility for providing this patient with their medication remains with you**	
3.	**A minimum duration of supply by the initiating clinician** As the patient has not had the minimum supply of medication to be provided by the initiating specialist I am unable to take clinical responsibility for prescribing this medication at this time. Therefore can you please contact the patient as soon as possible in order to provide them with the medication that you have recommended. ***Until the patient has had the appropriate length of supply the responsibility for providing the patient with their medication remains with you.***	
4.	**Initiation and optimisation by the initiating specialist** As the patient has not been optimised on this medication I am unable to take clinical responsibility for prescribing this medication at this time. Therefore can you please contact the patient as soon as possible in order to provide them with the medication that you have recommended. ***Until the patient is optimised on this medication the responsibility for providing the patient with their medication remains with you.***	
5.	**Shared Care Protocol not received** As legal responsibility for clinical care lies with the clinician who signs the prescription, I need to ensure that I am in possession of sufficient clinical information for me to be confident to prescribe this treatment for my patient and it is clear where each of our responsibilities lie to ensure the patient is safely managed. For this reason I am unable to take clinical responsibility for prescribing this medication at this time, therefore would you please contact the patient as soon as possible in order to provide them with the medication that you have recommended. ***Until I receive the appropriate SCP, responsibility for providing the patient with their medication remains with you.***	
6.	**Other (Primary Care Prescriber to complete if there are other reasons why shared care cannot be accepted)**	

Please do not hesitate to contact me if you wish to discuss any aspect of my letter in more detail and I hope to receive more information regarding this shared care agreement as soon as possible.

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 Medicines Management and Clinical Policies and Decisions Team, 1st Floor East Point, Cardinal Square, 10 Nottingham Road, Derby, DE1 3QT or E-MAIL: ddccg.medicinesmanagement@nhs.net

(Sending a copy of this form to the Medicines Management and Clinical Policies and Decisions Team 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 prescribing group of the reasons shared care is not being undertaken allowing for changes to be made in future updates to improve patient care).