**Request to Share Care and Agreement Form**

**Riluzole for the treatment of the Amyotrophic Lateral Sclerosis (ALS) form of**

**Motor Neurone Disease (MND)**

**Shared Care Protocol: Guideline No 7; Version 1.1**

**This Request to Share Care provides Key Primary Care Information on responsibilities and monitoring. The aim is to support the GP to agree to share care arrangements. Refer to Full Shared Care Protocol for further information (page 5 onwards).**

**GP to review and must respond to provider Trust request to share care within 2 weeks using form provided on page 4.**

**For Completion by Specialist (with page 4 Shared Care Agreement Form)**

Addressograph label

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| **Patient name** |       |  |
| **DOB** |       | **OR** |
|  **NHS number** |       |  |

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| **Drug(s) Dose and Route at handover:**  |       |
| **Indication:**  |       |
| **Date of first prescription by specialist:**  |       |
| **Patient weight (kg):** |       |
| **Estimated date for prescribing to be continued by the GP:**  |       |
| **Next monitoring tests due and dates if not at 12 weekly monitoring:**  |       |
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| **Specialist additional comments/advice:**  |       |
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| **Key Primary Care Information (refer to Full Shared Care Protocol for further information)****GP RESPONSIBILITIES*** Consider request to shared care arrangements and prompt completion and emailed return of signed response to the specialist using the Shared Care Agreement Form within 14 days of its receipt.
* If shared care accepted prescribe riluzole once patient is clinically stable in line with protocol.
* Arrange, record and share ongoing monitoring and take appropriate action as per protocol and advised by specialist (see monitoring table), ensuring GP practice systems are in place to recall patients for monitoring blood tests.
* Re-iterating with the patient that non-attendance for blood testing may lead to withdrawal of the medication. Further help and advice can be sought from the hospital specialist team.
* Ascertaining the reason for non-completion of routine blood testing, if one test is missed.
* Appropriately prompt notification to the hospital specialist of any significant and relevant changes in the patient’s condition, medication dose, or of an adverse reaction, according to the protocol and if the patient fails to attend for blood monitoring.
* Ensure no drug interactions with other medicines.
* Stop riluzole if neutropenia develops. Arrange for immediate hospital assessment if neutropenic sepsis is suspected.
* Stop riluzole and make an urgent referral to the specialist if ALT rises to 5 times the ULN or if chest x-ray finding are suggestive of interstitial lung disease.
* Refer the management back to the specialist if the patient becomes or plans to become pregnant.
* Stop treatment as advised by the specialist

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| **MONITORING AND ACTIONS TO BE TAKEN****Monitoring Table**

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| **Monitoring table** | **Hospital specialist** | **Hospital specialist** | **Hospital specialist**  | **GP**  | **Hospital specialist**  |
| Test | Indication | Pre-treatment baseline | During Treatment Initiation (during the first 3 months) | Following Treatment Initiation | Ongoing | Annual review |
| U&E | Baseline and ongoing assessment for disease and drug dose assessment | √ | Not required | Not routinely required | Not required by GP | As part of annual review or as clinically indicated  |
| LFTs  | √ including serum transaminases, bilirubin and/or gamma-glutamyl transferase. | Monthly  | Not routinely required | 3 monthly for the first year then annually  | As part of annual review or as clinically indicated  |
| FBC | √ | Monthly  | Not routinely required | 3 monthly for the first year then annually | As part of annual review or as clinically indicated  |
| WCC | √ | Monthly  | Not routinely required | 3 monthly for the first year then annually | As part of annual review or as clinically indicated  |

**Action to be taken if Abnormal Result**Normal reference range may vary slightly between labs. Results should be recorded in the patient’s shared care monitoring record booklet (where in use). Please note an unusual fall or rise or a consistent downward or upward trend in any value should prompt review of the patient and extra vigilance. Some patients may have abnormal baseline values, specialist will advise.

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| **Abnormal Result** | **Action to be taken by GP** |
| Altered LFTsElevated LFTs up to 5 times ULN | Continue riluzole and discuss with specialist. Increase monitoring frequency if ALT is elevated. |
| ALT rises to 5 times ULN or more | Stop riluzole and inform specialist. Riluzole should not normally be re-started. |
| Decreased WCC to below lower limit of local reference range | If clinical evidence of febrile illness/neutropenia, stop riluzole and treat or refer according to local pathways, as appropriate. Arrange for immediate hospital assessment if neutropenic sepsis is suspected.In the absence of febrile illness or clinical signs of neutropenia, seek advice from specialist. |

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* The expectation is that this information along with the full protocol provides sufficient information to enable GPs to be confident to take on the clinical & legal responsibility for prescribing and monitoring.
* Prescribing and monitoring responsibility will only be transferred under this shared care protocol when:
* Specialist has initiated treatment and prescribed/monitored treatment for initial stabilisation period.
* Specialist has provided pre-treatment counselling and discussed patient responsibilities, preferences and obtained consent to shared care arrangements.
* Specialist and patient have completed and signed the shared care agreement form (page 4).

**Shared Care Agreement Form**

**This form is used to agree shared care between the specialist, patient and GP.**

**Specialist and patient agreement**

**By signing below we accept:**

* the HWE [shared care principles](https://www.hweclinicalguidance.nhs.uk/all-clinical-areas-documents/download?cid=1739&checksum=752d25a1f8dbfb2d656bac3094bfb81c) and
* the requirements and responsibilities defined in this drug specific shared care protocol

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| **Specialist name:**       | **Patient name or addressograph label:**      |
| **Designation:**       |
| **Provider Trust:**       |
| **Direct telephone number:**       |
| **Email:**      **Email (for use by GP to respond to request to share care):**       |
| **Date:**            | **Specialist Signature:**       |
| **Date:**            | **Patient signature or specialist confirmation of patient agreement to shared care arrangement:**            |

**GP response to shared care**

**Please return to specialist within two weeks of receipt of request to share care.**

***This form is to be completed by the GP who is requested to share care.***

I agree to accept shared care for this patient as set out in this shared care protocol and HWE [shared care principles](https://www.hweclinicalguidance.nhs.uk/all-clinical-areas-documents/download?cid=1739&checksum=752d25a1f8dbfb2d656bac3094bfb81c)[ ]

I do not accept shared care for this patient [ ]

My reason(s) for not prescribing are given below: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Please note that GP agreement is voluntary, with the right to decline to share care if for any reason you do not feel confident in accepting clinical responsibility. Refusal should not be for financial reasons.

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| **GP name:**       | **Practice address /stamp:**       |
| **Direct telephone number:**       |
| **Email:**       |
| **Date:**       | **GP Signature:**       |

**Please return a copy of the completed form to the requesting specialist within two weeks of receipt of request to share care (preferably by email).**

1. Specialist to retain copy in patient’s hospital records.
2. Copy to be given to patient.
3. GP to retain copy in patient’s notes.

**Full Shared Care Protocol**

**RILUZOLE FOR THE TREATMENT OF THE AMYOTROPHIC LATERAL**

**SCLEROSIS (ALS) FORM OF MOTOR NEURONE DISEASE (MND)**

**Shared Care Protocol: Guideline No 7; Version 1.1**

**This full protocol provides prescribing and monitoring guidance. It should be read in conjunction with** [**HWE shared care principles**](https://www.hweclinicalguidance.nhs.uk/all-clinical-areas-documents/download?cid=1739&checksum=752d25a1f8dbfb2d656bac3094bfb81c)**,** [**Summary of Product Characteristics (SPC)**](https://www.medicines.org.uk/emc) **and the** [**BNF**](http://www.bnf.org/bnf/index.htm)**.**

**BACKGROUND AND INDICATION(S) FOR USE**

Riluzole is indicated for extending life or the time to mechanical ventilation for patients with the amyotrophic lateral sclerosis (ALS) variant of motor neurone disease (MND). ALS is a progressive neurodegenerative disease that causes the loss of motor neurones resulting in a gradual increase in muscle weakness and muscle wasting.

Riluzole is recommended by NICE technology appraisal guidance (TA20: Guidance on the use of Riluzole (Rilutek) for the treatment of Motor Neurone Disease) as an option for treatment of people with ALS. It should be initiated by a neurological specialist with expertise in the management of MND.

The safety and efficacy of riluzole has only been studied in ALS, therefore riluzole should not be use in any other form of MND.

Riluzole is not recommended for use in children

**Licensed indications:**

To extend life or the time to mechanical ventilation for patients with amyotrophic lateral sclerosis (ALS).

**DOSAGE, ROUTE OF ADMINISTRATION AND DURATION OF TREATMENT**

**Adult dosage and administration**

50mg twice daily

Riluzole tablets can be crushed and dispersed in water for enteral tube administration or mixed with soft food e.g. yoghurt or puree. Give immediately or within 15 minutes. Riluzole may block enteral feeding tubes, so ensure that the tube is flushed well after each dose. Crushed tablets may have a local anaesthetic effect in the mouth. Crushing or splitting riluzole tablets is unlicensed.

The oral suspension is suitable for administration via enteral feeding tubes. The suspension must be manually gently shaken for at least 30 seconds by rotating the bottle by 180° and the homogeneity should be visually verified.

**Preparations available:** Riluzole 50mg tablets, 5mg in 1ml oral suspension

Swallowing difficulties

Please refer to the [‘specials’ alternative guidance](https://gbr01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.hweclinicalguidance.nhs.uk%2Fall-clinical-areas-documents%2Fdownload%3Fcid%3D2274%26checksum%3D95f8d9901ca8878e291552f001f67692&data=05%7C02%7Cheernamehta%40nhs.net%7Ccba67ac584344a90298108dcafcc3bcd%7C37c354b285b047f5b22207b48d774ee3%7C0%7C0%7C638578538908037976%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C0%7C%7C%7C&sdata=drWPIVzT4RkMn0VJJa96%2F2dIm19xPNtqcc0yghL%2FsEA%3D&reserved=0) for a list of commonly prescribed medicines and alternative methods of administration for patients with swallowing difficulties, feeding tubes or for patients prescribed unlicensed ‘specials’ medication. Each entry takes into account alternative medicines, formulations, cost and licensing. This list is not exhaustive. As not all medicines are listed, please contact the initiating specialist if required for individual patient advice if a patient has a swallowing difficulty.

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| **SPECIALIST RESPONSIBILITIES INCLUDING PRE-TREATMENT ASSESSMENT*** Assess if patient is suitable for treatment with riluzole and initiate treatment. Counsel
* Undertake pre-treatment counselling and document discussion in patient’s records. Provide patient/carer with relevant (preferably written) information on use, side effects, need for monitoring of medication and precautions including that no new medicines are started (including over the counter preparations). Provide advice to patients.
* Obtain agreement and consent to share care. Complete and sign Specialist and patient agreement section of Shared Care Agreement form. Document in patient’s notes and transfer once patient stabilised.
* Request for GP confirmation of acceptance of shared care by secure emailing of request to share care, protocol and completed agreement form, allowing 2 weeks for response.
* Receipt and recording in patient records/notes that GP has / has not accepted shared care and ensuring appropriate action if not (specialist to continue to prescribe/monitor).
* Prescribe and monitor for initial stabilisation period of 12 weeks.
* Undertake baseline and ongoing tests as indicated in the monitoring table. Review results of safety monitoring and request additional tests as required.
* Continue to review the patient at agreed specified intervals, sending a written summary to the GP whenever the patient is reviewed.
* Monitor disease response and adverse effects to treatment and need to continue therapy. Notify the GP of any changes to dose or cessation of therapy.
* Notify GP if patient does not attend clinic repeatedly and advise on action to take.
* Provide any other advice, information or support for the GP if required. Communicate any clinically important issues and action to be taken.
* Ensure no drug interactions with other medicines
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**GP RESPONSIBILITIES**

Refer to page 1&2 and GP Considerations for Shared Care page 9.

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| **PATIENT RESPONSIBILITIES IN COOPERATION WITH SPECIALIST AND GP*** Confirm their agreement with the decision to move to a shared care model for their ongoing care and their understanding of the shared care agreement.
* Consent to share care and complete/sign Specialist and patient agreement section of Shared Care Agreement form.
* Confirm their understanding of the treatment and agreeing to contact the specialist/GP if they subsequently do not have a clear understanding of the treatment (patient to be provided with relevant contact details for GP/specialist in and out of hours).
* Attending for blood monitoring and follow up hospital or GP appointments.
* Ensuring a list of all medications are brought to all GP surgery, outpatient and A&E consultations.
* Reporting any change in symptoms and adverse effects promptly to the clinician who is currently prescribing.
* Confirm that no new medicines are started (including over the counter preparations) unless this has been discussed with the GP, specialist or pharmacist.
* Alert GP and/or specialist of any changes of circumstance which could affect management of disease e.g. plans for pregnancy; plans to move/change GP practice.
* Not to drive or operate heavy machinery if riluzole affects their ability to do so safely.
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| **DISPENSING PHARMACIST RESPONSIBILITIES*** Confirming that the patient has received verbal and written patient counselling / information and provide additional counselling should this be required.
* Check the patient is being monitored regularly, e.g. using the patient held monitoring booklet where available, to ensure that it is safe before issuing or dispensing prescriptions.
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| **MONITORING AND ACTIONS TO BE TAKEN*** Refer to page 2&3.
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| **SIDE EFFECTS AND ACTIONS TO BE TAKEN (REFER TO** [**BNF**](http://www.bnf.org/bnf/index.htm) **AND** [**SPC**](http://www.medicines.org.uk/emc) **for full details)*** GP to liaise with specialist if any side effects are a cause for concern
* Patients should be instructed to report immediately any evidence of infection, unexpected bruising or bleeding or other manifestations of bone marrow depression - also refer to monitoring section.

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| **SIDE EFFECTS** | **Action to be taken by GP** |
| Respiratory functionDry cough or dyspnoea | Order chest x-ray. Stop riluzole immediately if findings are suggestive of interstitial lung disease. Inform specialist of findings. |
| Haematological parametersFebrile illness | Check WCC. Treat febrile illness according to local pathways. Arrange for immediate hospital assessment if neutropenic sepsis is suspected. |
| Confirmed neutropenia | Stop riluzole and inform specialist. Review patient for signs and symptoms of infection and treat or refer according to local pathways, as appropriate. Arrange for immediate hospital assessment if neutropenic sepsis is suspected. |

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**CONTRAINDICATIONS AND PRECAUTIONS (REFER TO** [**BNF**](http://www.bnf.org/bnf/index.htm) **AND** [**SPC**](http://www.medicines.org.uk/emc) **for full details)**

**Contraindications:**

* + - * + 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 (ULN)
				+ Pregnancy or breast-feeding
				+ Acute porphyria’s

Cautions:

* + - * + Liver impairment: riluzole should be prescribed with care in patients with:
				+ a history of abnormal liver function
				+ slightly elevated serum transaminases (up to 3 times 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
				+ Interstitial lung disease has been reported in patients treated with riluzole
				+ Neutropenia or febrile illness.
				+ Renal Impairment (due to lack of data)

**NOTABLE DRUG INTERACTIONS (REFER TO** [**BNF**](http://www.bnf.org/bnf/index.htm) **AND** [**SPC**](http://www.medicines.org.uk/emc) **for full details)**

**Common drug interactions**

Riluzole is metabolised by cytochrome P450 isoform 1A2 (CYP1A2) and has the potential to interact with drugs which inhibit or induce CYP1A2. The clinical relevance of these interactions has not been established, and some of these medicines are frequently used with riluzole without incident. Discuss with specialist team if there are any concerns.

* + - * + CYP1A2 inhibitors include caffeine, diclofenac, diazepam, clomipramine, imipramine, fluvoxamine, phenacetin, theophylline, amitriptyline, quinolones, mexiletine, nicergoline, rucaparib, vemurafenib, combined hormonal contraceptives
				+ CYP1A2 inducers include cigarette smoke, charcoal-grilled food, rifampicin, omeprazole

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| **ADVICE TO PATIENTS AND CARERS**The patient should be advised to report any of the following signs or symptoms to their primary care prescriber without delay: * + - * + Signs or symptoms of infection, such as fever, chills or shivering, flu-like symptoms, sore throat, rashes, or mouth ulcers.
				+ Dry cough and/or dyspnoea.
				+ Signs or symptoms of liver problems, such as yellow skin or eyes (jaundice), itching all over, nausea or vomiting.

The patient should be advised:* + - * + Not to stop taking riluzole without talking to their doctor and not to share their medicines with anyone else.
				+ Tell their prescriber if their smoking status changes, since this may affect their medicine
				+ Not to drive or operate machines if riluzole affects their ability to do so safely, e.g. by causing dizziness or drowsiness, and to inform the DVLA if their ability to drive safely is affected. See <https://www.gov.uk/driving-medical-conditions> and <https://www.gov.uk/motor-neurone-disease-and-driving>
				+ Patient information
				+ MND association riluzole information leaflet <https://www.mndassociation.org/app/uploads/2015/07/5A-Riluzole.pdf>
				+ MND Scotland riluzole fact sheet <https://www.mndscotland.org.uk/media/1824/22-riluzole-2017.pdf>
				+ NHS.uk. Low white blood cell count <https://www.nhs.uk/conditions/low-white-blood-cell-count/>
				+ Patient information leaflets are also available from <https://www.medicines.org.uk/emc/search?q=riluzole>
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* **REFERENCES** **NICE TA20:**
* Guidance on the use of Riluzole (Rilutek) for the treatment of Motor Neurone Disease. January 2001. Accessed via <https://www.nice.org.uk/guidance/ta20>
* NICE NG42: Motor neurone disease: assessment and management.. Accessed via <https://www.nice.org.uk/guidance/ng42>
* Riluzole 50 mg film-coated tablets (Rilutek®) Date of revision of the text 01/01/2021. Accessed via [https://www.medicines.org.uk/emc/product/1101/smpc on 21/05/21](https://www.medicines.org.uk/emc/product/1101/smpc%20on%2021/05/21)
* Handbook of Drug Administration via Enteral Feeding Tubes. Riluzole. Accessed via <https://www.medicinescomplete.com/#/content/tubes/c330>

**GP Considerations for Shared Care**

This shared care agreement outlines suggested management for the prescribing of the specified drug(s) and indication(s) when the responsibility is shared between the specialist and general practitioner (GP). Sharing of care assumes communication between the specialist, GP and patient. It is important that patients are consulted about treatment and are in agreement with it. The intention to share care should be explained to the patient by the doctor initiating treatment and consent obtained.

Prescribing is to be initiated in secondary care by a provider Trust specialist and will usually be prescribed for 12 weeks unless otherwise stated within the agreed individual shared care protocol**. The expectation is that these shared care guidelines should provide sufficient information to enable GPs to be confident to take on the clinical and legal responsibility for the prescribing and the monitoring of this / these drug(s) in stable patients.** The questions below will help you confirm this:

* Is the patient’s condition predictable or stable?
* Do you have the relevant knowledge, skills and access to equipment to allow you to monitor treatment as indicated in this shared care document?
* Have you been provided with relevant clinical details including monitoring data?
* Have this document and BNF/SPC provided sufficient information for you to feel confident in accepting clinical and legal responsibility for prescribing?

**If you can answer YES to all of these questions (after reading this shared care guideline), then it is appropriate for you to accept the prescribing responsibility. GPs need to formally accept shared care by completing and returning the form provided within this protocol to the specialist within two weeks of receipt of request to share care.**

If the answer is NO to any of these questions, you should not accept prescribing responsibility. You should respond back to the consultant outlining your reasons for NOT prescribing on the agreement form within two weeks of receiving the request to share care. If you do not have the confidence to prescribe, you still have the right to decline. In such an event, the total clinical responsibility for prescribing the medication and any monitoring required remains with the specialist. Please note that medication cost is not an acceptable reason for refusal to take on shared care.

The prescribing doctor legally assumes clinical responsibility for the drug and the consequences of its useas well as responsibility of monitoring (securing and reviewing blood test results).

Prescribing and monitoring responsibility will only be transferred when the consultant and the GP agree that the patient’s condition is stable or predictable. This will usually be 12 weeks of treatment unless otherwise stated within the agreed individual shared care protocol.

**Approval Information**

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| Version  | V1.1 Updated with wording on swallowing difficulties September 2024V1  |
| Developed by | HWE ICB PMOT |
| Approved by | HWE APC |
| Date approved/updated | November 2023 |
| Review date:  | The recommendation is based upon the evidence available at the time of publication. This recommendation will be reviewed upon request in the light of new evidence becoming available.  |
| Superseded version | n/a |