Royal Cornwall Hospitals
NHS Trust

Riluzole for Amyotrophic Lateral Sclerosis Shared Care Guideline

V5.0

August 2025

1. Aim/Purpose of this Guideline

1.1. This guideline applies to medical, nursing and pharmacy staff in the safe and appropriate prescription and administration of Riluzole for amyotrophic lateral sclerosis.

1.2. This shared care guideline sets out details for the sharing of care of adults with Amyotrophic Lateral Sclerosis form of Motor Neurone Disease prescribed Riluzole. These guidelines provide additional limited information necessary to aid in the treatment these patients. As with all shared care guidelines they highlight relevant prescribing issues but should be used in conjunction with relevant NICE guidance, the BNF, ABPI summary of product characteristics and do not replace them.

1.3. This version supersedes any previous versions of this document.

Data Protection Act 2018 (UK General Data Protection Regulation – GDPR) Legislation.

The Trust has a duty under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed, and documented. We cannot rely on opt out, it must be opt in.

Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 please see the Information Use Framework Policy or contact the Information Governance Team.

Royal Cornwall Hospital Trust rch-tr.infogov@nhs.net

2. The Guidance

2.1. Amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig's disease, is a form of motor neurone disease. It is a progressive neurodegenerative disease causing degeneration of corticospinal neurones in the motor cortex (upper motor neurones) and brain stem and spinal cord motor neurones (lower motor neurones). Amyotrophic Lateral Sclerosis (ALS) is characterised by both upper and lower motor neurone signs and is the most common form of Motor Neurone Disease (MND), accounting for 65% to 85% of all cases.

2.2. In mainland Europe, the terms MND and ALS are often used interchangeably. ALS is the terminology used in the current product licence for Riluzole.

2.3. Commonly patients present with limb weakness, often beginning with foot drop, rapid muscle weakness becoming progressively worse and death is usually from respiratory failure as a result of diaphragmatic weakness which may be precipitated by aspiration pneumonia. Average life expectancy is between two to four years. Until the introduction of Riluzole treatment was supportive only.

2.4. Riluzole is a glutamate receptor antagonist. Glutamate acts as an excitatory amino-acid neurotransmitter, excess activity of which is thought to be neurotoxic and may be involved in the pathogenesis of MND.

2.5. Based on 2 multi centre double blind, placebo controlled trials there was a clear statistical benefit on survival at 12 to 18 months using Riluzole at 100mg daily. Patients enrolled in these studies already had advanced disease and had an increase in median tracheotomy free survival of 2 months compared to the placebo group. There was no significant improvement in functional measures used such as muscle strength.

2.6. The indication for the purpose of this guideline is to extend life or the time to mechanical ventilation for patients with ALS.

2.7. NICE recommendation states that 'Riluzole therapy should be initiated by a neurological specialist with expertise in the management of MND'.

2.8. **Preparations and Dosage**

50mg tablets taken 12 hourly. There is anecdotal information to indicate that the tablets may be crushed if necessary (see notes section).

2.9. **Contraindications and Precautions**

2.9.1. Contraindications are:

- Hepatic disease or baseline transaminases greater than 3 times the upper limit of normal or raised bilirubin.
- Renal impairment, (no formal studies have been carried out on patients in this group).
- Pregnancy and breastfeeding.

2.9.2. Riluzole should be used with caution in history of abnormal hepatic function.

2.9.3. 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 dyspnoea, 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 medicinal product discontinuation and symptomatic treatment.

2.10. **Monitoring**

2.10.1. Regular hepatic function blood tests and Full Blood Count (baseline then every month for 3 months, then every 3 months for a further 9 months and annually thereafter) are recommended to monitor tolerability.

2.10.2. ALT levels should be measured more frequently in patients who develop elevated ALT levels >2x upper limit of normal e.g. weekly until level stabilises or falls.

2.10.3. If patient presents with febrile illness then monitoring white blood cell count for neutropenia is strongly recommended.

2.11. **STOP AND REFER TO THE NEUROLOGY TEAM IF:**

- Liver function tests – ALT greater than 5 times the upper limit of normal.
- Blood disorders - WBC <3.5 x 10^9/l, Neutrophils <2 x 10^9/l.

2.12. **Side Effects**

Very common > [1 in 10] > Common > [1 in 100] > Uncommon > [1 in 1000] > Rare > [1 in 10000] > Very rare.

- **Very Common:**
  Asthenia, Nausea.
- **Common:**
  Alterations in liver function tests, Headache, Abdominal pain, Pain, Vomiting, Dizziness, Tachycardia, Somnolence, Circumoral paraesthesia.
- **Uncommon:**
  Neutropenia, Angioedema, Pancreatitis.

2.13. **Significant Drug Interactions**

No clinical data are available but since Riluzole is extensively metabolised by the liver there is a possibility of interactions with a number of drugs.

Potential cytochrome P450 1A2 isoenzyme interactions of Riluzole	
Rate of Riluzole excretion decreased by:	Rate of Riluzole excretion increased by:
Caffeine. Diclofenac. Diazepam. Clomipramine. Imipramine. Fluvoxamine. Theophylline. Amitriptyline. Quinolones.	Cigarette smoke. Charcoal-grilled food. Rifampicin. Omeprazole.

2.14. **Notes**

2.14.1. **DRIVING:** Dizziness or vertigo may affect performance of skilled tasks (e.g. driving).

2.14.2. **Crushing tablets:** Though not recommended in the drug licence there is supporting information for the practice of crushing or dispersing tablets to facilitate administration in those patients that cannot take the solid dose form. The drug has been administered in puree, yoghurt or a thick beverage via a nasogastric tube. Water is not a suitable diluent as the drug can sediment reducing the dose received and also cause oral anaesthesia. Administration by this route must follow nationally recognised guidelines on the covert administration of medicines.

2.14.3. 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; white blood cell counts should be determined in febrile illness; neutropenia requires discontinuation of Riluzole.

2.15. **Discontinuation**

2.15.1. There are likely to be three main reasons for discontinuing Riluzole.

2.15.2. Adverse drug reactions including those listed above.

2.15.3. Patient choice, usually because of lack of perceived benefit in the face of inexorable deterioration of the underlying illness.

2.15.4. Major clinical deterioration. It is likely that, depending on individual patient characteristics, there may come a point in the clinical course of the disease when continuation of Riluzole is no longer considered appropriate.

2.16. **Patient information**

For newly diagnosed patients, a booklet from the Motor Neurone Disease Association on practical management of the disease will be sent to the GP. A printable copy of the booklet can be found at:

http://www.mndassociation.org/downloads/Guide.pdf

2.17. **References:**

Summaries of Product Characteristics.

NICE reviewed for new evidence January 2004 and deferred until January 2006 and again to an unspecified future date as no new evidence was available that would change the 2001 advice.

2.18. **Areas of Responsibility for the Sharing of Care**

2.18.1. These are suggested ways in which the responsibilities for the management of adult patients with who are prescribed **Riluzole** can be shared between the specialist and the general practitioners. The expectation is that these guidelines should provide sufficient information to enable GPs to be confident to take clinical and legal responsibility for prescribing these drugs. If a specialist asks the GP to prescribe this drug the GP should reply to this request as soon as practical. Sharing of care assumes communication between the specialist, GP and patient. The intention to share care should be explained to the patient and be accepted by them.

2.18.2. **In the NHS E guidelines on responsibility for prescribing (January 2018) between hospitals and GPs, it is advised that legal responsibility for prescribing lies with the doctor who signs the prescription.**

2.18.3. **Specialist:**

2.18.3.1. Diagnosis of Amyotrophic Lateral Sclerosis after appropriate investigations.

2.18.3.2. Ensure that a baseline liver function test is recommended or carried out as a reference for subsequent monitoring. Any results from liver function test taking place in hospital should be copied to the GP.

2.18.3.3. Provide the patient or patient's parents/guardians/carers with suitable written and/or verbal information about the drug prior to starting medication e.g. patient information leaflet and the benefits, realistic outcomes and side effects of treatment (including how to recognize signs of neutropenia) and to confirm the main points of the discussion by letter to the patient. This may need to be repeated at a subsequent visit, as all the relevant information may not have been remembered.

2.18.3.4. Start drug treatment providing the first prescription and ensuring the patient's condition is stabilized (usually requires three month's treatment prescribed by the specialist).

2.18.3.5. Ensure monitoring of the patient with regard to side effects and liver function tests and FBC in the first 3 months of treatment.

2.18.3.6. Monitoring the progress of the disease.

2.18.3.7. Assessment of the continuing need for treatment including advice to GPs on when to stop treatment.

2.18.3.8. Ask the GP whether they are willing to participate in shared care using the suggested wording template (Appendix 3).

2.18.3.9. Specify review dates at clinically relevant time intervals for both the GP and the consultant.

2.18.3.10. Prompt communication with GP of any changes in treatment, results of monitoring undertaken and assessment of adverse events.

2.18.3.11. Provide the GP with relevant contact information with clear arrangements for back-up advice and support should further assistance be required relating to this drug.

2.18.3.12. Reporting adverse events to the MHRA.

2.18.4. **General Practitioner:**

2.18.4.1. To respond to the shared care request from the consultant in writing without undue delay. Prescribing of Riluzole after communication with specialists regarding the need for treatment.

2.18.4.2. Undertake monitoring of side effects and liver function tests and FBC as outlined in the shared care guideline (as per 2.10).

2.18.4.3. Prompt referral to a specialist if there is a change in the patient's status, liver function or troublesome side effect.

2.18.4.4. Reporting to and seeking advice from a specialist on any aspect of patient care which is of concern to the GP and may affect treatment.

2.18.4.5. Reporting adverse events to specialist and MHRA.

2.18.4.6. Stopping treatment in the case of a severe adverse event or as per shared care guideline.

2.18.5. **Patient / parent / guardian / carer:**

- Report any adverse effects to their GP and/or specialist regarding their treatment.
- Ensure that they have a clear understanding of their treatment and relevant potential side effects.
- Ensure they attend for monitoring requirements as per shared care guideline.
- Awareness that treatment may be stopped under certain conditions.

2.18.6. **Back-Up Advice and Support is Available from the Relevant Clinical Team.**

3. Monitoring compliance and effectiveness

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	Compliance with prescribing and administration in accordance with this guideline (or other safe practice).
Lead	Head of Prescribing Support Unit.
Tool	Audit and review tool using patient documentation.
Frequency	As required according to clinical incident reports.
Reporting arrangements	Via Cornwall Area Prescribing Committee / Medication Practice Committee.
Acting on recommendations and Lead(s)	Relevant Clinical Staff.
Change in practice and lessons to be shared	Lessons and changes in practice will be communicated through various channels to relevant staff.

4. Equality and Diversity

4.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the Equality Diversity And Inclusion Policy or the Equality and Diversity website.

4.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Information Category	Detailed Information
Document Title:	Riluzole for Amyotrophic Lateral Sclerosis Shared Care Guideline V5.0
This document replaces (exact title of previous version):	Riluzole for Amyotrophic Lateral Sclerosis Shared Care Guideline V4.0
Date Issued/Approved:	August 2025
Date Valid From:	August 2025
Date Valid To:	August 2028
Directorate / Department responsible (author/owner):	Neurology Team / Pharmacy - Head of Prescribing Support Unit
Contact details:	01872 253548
Brief summary of contents:	Some clinical issues and details of prescribing responsibilities for GP and specialists.
Suggested Keywords:	Riluzole, Shared Care.
Target Audience:	**RCHT:** Yes **CFT:** No **CIOS ICB:** Yes
Executive Director responsible for Policy:	Chief Medical Officer
Approval route for consultation and ratification:	Cornwall Area Prescribing Committee
Manager confirming approval processes:	Richard Andrzejuk
Name of Governance Lead confirming consultation and ratification:	Kevin Wright
Links to key external standards:	None
Related Documents:	No
Training Need Identified?	No
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet

Information Category	Detailed Information
Document Library Folder/Sub Folder:	Clinical / Pharmacy

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
March 2013	V1.0	Minor updating	M Wilcock, Head of Prescribing Support Unit
May 2016	V2.0	Renewal	M Wilcock, Head of Prescribing Support Unit
May 2019	V3.0	New format and slight text amendments to and inclusion of shared care agreement letter.	M Wilcock, Head of Prescribing Support Unit
March 2020	V3.1	Appendix 3 added following FRG approval - CHA4215 Shared Care Agreement Letter Consultant Request.	Demi Louise Kent, Corporate records Manager
September 2021	V3.2	Substitution of Shared Care Agreement Letter with suggested wording template instead (Appendix 3).	M Wilcock, Head of Prescribing Support Unit
May 2022	V4.0	Full Update and Transposed to latest Trust template.	M Wilcock, Head of Prescribing Support Unit
July 2025	V5.0	Renewal and minor correction to 2.18.4.2.	M Wilcock, Head of Prescribing Support Unit

All or part of this document can be released under the Freedom of Information Act 2000.

All Policies, Strategies and Operating Procedures, including Business Plans, are to be kept for the lifetime of the organisation plus 6 years.

This document is only valid on the day of printing.

Controlled Document

This document has been created following the Royal Cornwall Hospitals NHS Trust The Policy on Policies (Development and Management of Knowledge Procedural and Web Documents Policy). It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2. Equality Impact Assessment

Section 1: Equality Impact Assessment (EIA) Form

The EIA process allows the Trust to identify where a policy or service may have a negative impact on an individual or particular group of people.

For guidance please refer to the Equality Impact Assessment Policy (available from the document library) or contact the Equality, Diversity and Inclusion Team rcht.inclusion@nhs.net

Information Category	Detailed Information
Name of the strategy / policy / proposal / service function to be assessed:	Riluzole for Amyotrophic lateral sclerosis Shared Care Guideline V4.0
Directorate and service area:	Pharmacy
Is this a new or existing Policy?	Existing
Name of individual completing EIA (Should be completed by an individual with a good understanding of the Service/Policy):	Mike Wilcock, Pharmacy RCHT
Contact details:	01872 253548

Information Category	Detailed Information
1. Policy Aim - Who is the Policy aimed at? (The Policy is the Strategy, Policy, Proposal or Service Change to be assessed)	To provide information on prescribing of Riluzole to enable General Practitioners to take over prescribing responsibility from secondary care.
2. Policy Objectives	To promote a consistent level of shared care between primary and secondary care (in relation to RCHT catchment area)
3. Policy Intended Outcomes	Confident and competent prescribers, enabling medicines to be access in a primary care setting.
4. How will you measure each outcome?	Six monthly review
5. Who is intended to benefit from the policy?	General practitioners, hospital specialists and community pharmacists – from understanding local guidance around use of these medicines. Patients/carers, from being able to access medicines from their GP.

Information Category	Detailed Information
6a. Who did you consult with? (Please select Yes or No for each category)	• Workforce: Yes • Patients/ visitors: No • Local groups/ system partners: No • External organisations: No • Other: No
6b. Please list the individuals/groups who have been consulted about this policy.	**Please record specific names of individuals/ groups:** Cornwall Area Prescribing Committee.
6c. What was the outcome of the consultation?	Agreed.
6d. Have you used any of the following to assist your assessment?	**National or local statistics, audits, activity reports, process maps, complaints, staff or patient surveys:** No.

7. The Impact

Following consultation with key groups, has a negative impact been identified for any protected characteristic? Please note that a rationale is required for each one.

Where a negative impact is identified without rationale, the key groups will need to be consulted again.

Protected Characteristic	(Yes or No)	Rationale
Age	No	
Sex (male or female)	No	
Gender reassignment (Transgender, non-binary, gender fluid etc.)	No	
Race	No	
Disability (e.g. physical or cognitive impairment, mental health, long term conditions etc.)	No	
Religion or belief	No	
Marriage and civil partnership	No	

Protected Characteristic	(Yes or No)	Rationale
Pregnancy and maternity	No	
Sexual orientation (e.g. gay, straight, bisexual, lesbian etc.)	No	

A robust rationale must be in place for all protected characteristics. If a negative impact has been identified, please complete section 2. If no negative impact has been identified and if this is not a major service change, you can end the assessment here.

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

Name of person confirming result of initial impact assessment:
Dan Thomas, Pharmaceutical Services Contracting Team, NHS Kernow

If a negative impact has been identified above OR this is a major service change, you will need to complete section 2 of the EIA form available here:
Section 2. Full Equality Analysis

Appendix 3. Suggested wording for Specialist communication re commencement of shared care

This patient is suitable for treatment with (insert drug name) for the treatment of (insert indication) which has been accepted for Shared Care. I am therefore requesting your agreement to share the care of this patient, as they are now stable on the treatment. Where baseline investigations are set out in the shared care protocol, I have carried these out.

Treatment was started on (insert date started) (insert dose).

If you are in agreement, please undertake monitoring and treatment from (insert date). (please note: date must be at least 1 month from stabilisation of treatment.)

Baseline tests: (insert information)

Next review with this department: (insert date)

You will be sent a written summary within (XX) days. The medical staff of the department are available at all times to give you advice. The patient will not be discharged from out-patient follow-up while taking (insert drug name).

Please could you reply to this request for shared care and initiation of the suggested medication to either accept or decline within 14 days.