SHARED CARE GUIDELINE

RILUZOLE FOR MOTOR NEURONE DISEASE

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of **RILUZOLE** can be shared between the specialist, the patient and the patient's general practitioner (GP).

The patient's GP has been invited to participate in the shared care agreement. Sharing of care assumes positive communication and a decision between the clinical specialist (usually from secondary care, the GP based in primary care, patient (and their carers where applicable). Note that not all treatments will be suitable for a shared care agreement.

Shared care criteria
Patients will have been stabilised, receiving a therapeutic dose of the drug with time allowed for common adverse events and side effects to have occurred before referral to the GP.

Response to shared care request
The patient's GP must agree in writing to the request for shared care within **14 days** of receiving the request. Shared care should **not** be assumed if a response is not received. The specialist should contact the patient's GP practice directly or the North East London Pharmacy and Medicines Optimisation Team (nelondonicb.prescribingqueries@nhs.net) if they do not receive a response within the expected timeframe.

Document control	
Version	1.0
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This document should be read in conjunction with the NHSE policy – Responsibility for prescribing between Primary & Secondary/Tertiary Care

1. Indications

State whether licensed or unlicensed locally agreed use

To extend life or the time to mechanical ventilation for patients with amyotrophic lateral sclerosis (ALS) variant of motor neurone disease

2. Patient pathway

Brief summary of the patient pathway

Indication/specialty	Prescribing initiated by	When prescribing would be transferred to primary care	Monitoring responsibilities	Treatment duration
Motor neurone Disease/Neurology	Consultant Neurologist experienced in the management of motor neurone disease	When dose is optimised with satisfactory investigation results for at least 4 weeks	Hospital Specialist and GP	The duration of treatment & frequency of review will be determined by the specialist, based on clinical response and tolerability

Please see below for detailed prescribing information and specific monitoring parameters

3. Initiation and ongoing dose regime

Note

- ***Transfer of monitoring and prescribing to primary care is normally once the patient is on a stable dose and investigation results are satisfactory/ stable.***
- ***The duration of treatment & frequency of review will be determined by the specialist, based on clinical response and tolerability.***
- ***All dose or formulation adjustments will be the responsibility of the initiating specialist unless directions have been discussed and agreed with the GP.***
- ***Termination of treatment will be the responsibility of the specialist.***

Initial stabilisation ***The loading period must be prescribed by the initiating specialist***
50mg twice daily

	Maintenance dose (following initial stabilisation) ***The initial maintenance dose must be prescribed by the specialist until GP agrees to take over shared care***
	50mg twice daily
	Conditions requiring dose adjustment (and adjusted doses)
	None

4. Contraindications and cautions

Please note only **key cautions and contraindications should be listed here.**

This does not replace the Summary of Product Characteristics (SPC) and should be read in conjunction with it.

The following list is not exhaustive; please see the BNF or SPC for comprehensive information and recommended management.

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 porphyrias

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)

	Route of administration	Oral

5. Pharmaceutical aspects	**Formulation**	50mg tablets 50mg orodispersible films 5mg/mL oral suspension
	Administration details	The orodispersible films and oral suspension may be used in primary care, for patients unable to take solid formulation. Riluzole orodispersible films and oral suspension should be used as the first line option, although tablets may be crushed (if necessary) immediately prior to administration (unlicensed use). Riluzole tablets when crushed, may block enteral feeding tubes, so ensure that the tube is flushed well after each dose. Crushing tablets may have a local anaesthetic effect in the mouth. The orodispersible films should only be handled with clean dry hands and should not be folded. They should not be taken with liquids or chewed and whilst the film dissolves the patient should avoid talking. Food or other medication should be taken with caution after administration due to the local anaesthetic effect (slight numbing of mouth). After administration hand should be washed. 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.
	Other important information	Patients should be warned about the potential for dizziness or vertigo, and advised not to drive or operate machinery if these symptoms occur.
6. Significant medicine interactions Please note only key interactions should be listed here	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. **The following list is not exhaustive; please see the BNF or SPC for comprehensive information and recommended management.** • 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	
7. Baseline investigations, initial monitoring and ongoing	**Baseline investigations**	• Liver function tests (LFTs), including serum transaminases, bilirubin and/or gamma-glutamyl transferase • Full blood count (FBC) including a differential white cell count (WCC) • Urea and electrolytes

monitoring to be undertaken by the specialist	**Initial monitoring**	• LFTs, including alanine aminotransferase (ALT), should be measured every month during the first 3 months of treatment, every 3 months during the remainder of the first year, or until transferred to primary care • FBC and WCC every month during the first 3 months of treatment and every 3 months during the remainder of the first year until transferred to primary care
	Ongoing monitoring	Routine review to assess effectiveness and ongoing appropriateness of treatment every 6 months, or as clinically indicated. After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in 8 remains appropriate.
	Other important information	

8. Ongoing monitoring requirements to be undertaken by primary care

Monitoring parameter	Frequency
LFTs, FBC & WCC	Every month during the first 3 months of treatment, then every 3 months for the remainder of the first year. NB: where monthly or quarterly monitoring is performed in secondary care prior to transfer, there is no need to repeat individual tests. Annually after the first year

Please see below section for further guidance on management of adverse effects/out of range test results

9. Management of adverse effects/ out of range test results

Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme

Adverse effect/out of range test result	Action for GP
Altered LFTs: Elevated LFTs up to 5 times ULN	Continue riluzole and discuss with specialist. Increase monitoring frequency if ALT is elevated.
Altered LFTs: ALT rises to 5 times ULN	Stop riluzole and inform specialist. Riluzole should not normally be re-started

www.mhra.gov.uk/yellowcard For information on incidence of ADRs see relevant summaries of product characteristics	**Respiratory function:** Dry cough or dyspnoea	Order chest x-ray. Stop riluzole immediately if findings are suggestive of interstitial lung disease. Inform specialist of findings.
	Haematological parameters: Febrile 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.
	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.

10. Advice to patients and carers

The specialist will counsel the patient with regard to the benefits and risks of treatment and will provide the patient with any relevant information and advice, including patient information leaflets on individual medicines.

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

11. Pregnancy, paternal exposure and breast feeding

It is the responsibility of the specialist to provide advice on the need for contraception to male and female patients on initiation and at each review but the ongoing responsibility for providing this advice rests with both the GP and the specialist.

Pregnancy	Riluzole is contraindicated in pregnancy.
Breastfeeding	Riluzole is contraindicated in breast-feeding women. Very limited published evidence indicates low levels in breast milk. The UK Drugs in Lactation Advisory Service recommends caution if used, and infants should be monitored for adverse effects associated with adult use. Information for healthcare professionals: https://www.sps.nhs.uk/medicines/riluzole/
Paternal exposure / Effect of fertility	Fertility studies in rats indicate slight impairment of reproductive performance and fertility at doses of 15 mg/kg/day (which is higher than the therapeutic dose), probably due to sedation and lethargy. The relevance of this to human fertility is not known.

12. Contact information

The list contains contact details for all five trusts in NEL, please ensure the correct specialist team from the hospital that initiated treatment is contacted (e.g. only contact Whipps Cross Hospital team if patient

Barts Health NHS Trust	
Main switchboard	02073777000
Consultant Secretary	02035941202, forem.khilochia@nhs.net
MND Co-ordinator	Mon -Tue (Shegofeta Ali): 07825-935187, shegofeta.ali4@nhs.net Wed - Fri (Colette Bloomfield): 07825-935187, colettebloomfield@nhs.net
Neurology Registrar on-call out of hours – Aircall via switchboard	

initiated by Whipps Cross Hospital).	**Barking Havering and Redbridge University Hospitals NHS Foundation trust** |
	Neurology team | 01708 435 000 ext. 6836 (On-call registrar)
	Neurology pharmacy team | 01708 435 000 ext. 6809 Email: bhrut.neuropharmacy@nhs.net
13. Additional information	**Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed.**
14. References	• MND association accessed via: https://www.mndassociation.org/about-mnd/what-is-mnd/basic-facts-about-mnd/ on 20/05/21 • MND Scotland accessed via https://www.mndscotland.org.uk/ 21/05/21 • 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 on 21/05/21 • Riluzole 50 mg film coated tablets (Glentek®). Date of revision of the text 29/04/2020. Accessed via https://www.medicines.org.uk/emc/product/10060/smpc on 21/05/21 • 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 • Riluzole 50 mg film-coated tablets (Ranbaxy UK Ltd). Date of revision of the text 15/02/2018. Accessed via https://www.medicines.org.uk/emc/product/5185/smpc on 21/05/21 • Riluzole 50mg Film-Coated Tablet (Accord-UK Ltd). Date of revision of the text 18/07/2019. Accessed via https://www.medicines.org.uk/emc/product/2831/smpc on 21/05/21 • Riluzole 5 mg/ml oral suspension (Teglutik®). Date of revision of the text 10/11/2019. Accessed via https://www.medicines.org.uk/emc/product/5060/smpc on 21/05/21 • Handbook of Drug Administration via Enteral Feeding Tubes. Riluzole. Last updated 15/02/18. Accessed via https://www.medicinescomplete.com/#/content/tubes/c330 on 20/05/21 • NEWT Guidelines. Riluzole. Last updated October 2020. Accessed via https://access.newtguidelines.com/R/Riluzole.html on 20/05/21 • Specialist Pharmacy Service. Riluzole Lactation Safety Information. Last updated 3 August 2020. Accessed via https://www.sps.nhs.uk/medicines/riluzole/ on 10/06/21 NICE Clinical Knowledge Summaries. Neutropenic sepsis: management. Last revised March 2020. Accessed via https://cks.nice.org.uk/topics/neutropenic-sepsis/management/management/ on 11/06/21
15. Shared care responsibilities	**Specialist Team** • Ensure that the patient/carer is an informed recipient in therapy. • Ensure that the patient/carer understands their treatment regimen and any monitoring or follow up that is required (using advocacy if appropriate). Issue any local patient information leaflets where appropriate. • Ensure baseline investigations (if applicable) are normal before commencing treatment.

- Initiate treatment and prescribe until the GP formally agrees to share care.
- Send a letter to the GP requesting shared care for the patient.
- Clinical and laboratory supervision of the patient by blood monitoring (if applicable) and routine clinic follow-up on a regular basis.
- 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. Note that GPs within NEL may be able to access results via ELPR.
- Evaluation of any reported adverse events by GP or patient.
- 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.
- Inform GP of patients who do not attend clinic appointments.
- Ensure that backup advice is available during working hours. The GP/patient should contact on-call/A&E out of hours or during an emergency.

Primary Care Prescriber

- Ensure that the patient understands 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.
- Monitor patient's overall health and well-being.
- Report any adverse events to the consultant, where appropriate.
- Report any adverse events to the MHRA via the Yellow Card Scheme, where appropriate.
- Help in monitoring the progression of disease.
- Prescribe the drug treatment as described.

North East London Pharmacy and Medicines Optimisation Team

- To provide feedback to acute trusts via the FPG (or dedicated working group of the FPG).
- To support GPs to make the decision whether or not to accept clinical responsibility for prescribing.
- To support acute/mental health trusts in resolving issues that may arise as a result of shared care.

Patient/Carer

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