PAN MERSEY APC

PAN MERSEY AREA PRESCRIBING COMMITTEE
SHARED CARE FRAMEWORK
REF: SC16 FINAL
APC BOARD DATE: 27 SEP 2017

NHS Pan Mersey Area Prescribing Committee

RILUZOLE

Background	Riluzole is licensed to extend life or the time to mechanical ventilation for patients with amyotrophic lateral sclerosis (ALS), a variant of Motor Neuron Disease (MND). Safety and efficacy of riluzole has only been studied in ALS. Riluzole has not been shown to be effective in late stages of ALS. Progressive bulbar palsy (PBP) is considered by NICE to be a form of ALS and eligible for treatment with riluzole. Riluzole should only be initiated by a neurological specialist with expertise in the management of MND and routine supervision of therapy can be managed locally by GPs as indicated in this policy (as per NICE TA 20, 2001).	
Licensed Indications	Riluzole is licensed to extend life or the time to mechanical ventilation for patients with amyotrophic lateral sclerosis (ALS).	
Locally agreed off- label indications	None	
Initiation and dose regime	50mg twice daily. No significant increased benefit can be expected from daily doses higher than 100mg.	
Baseline investigations and initial monitoring arrangements.	Baseline monitoring: FBC and LFT including serum transaminases undertaken by specialist centre. This will be followed by monthly monitoring for the first 3 months. No dose titration required. The specialist centre may request that the GP takes over prescribing and monitoring after the first month for patients who have difficulty travelling to the hospital for the first three months of treatment. Termination of treatment will be the responsibility of the specialist.	
Ongoing monitoring requirements to be undertaken in Primary Care	**Monitoring**	**Frequency**
	LFTs	After the initial monitoring period, every 3 months for the first year of therapy. To be continued at 3 monthly intervals unless specified differently by the specialist.
	FBC	After the initial monitoring period, every 3 months for the first year of therapy. To be continued at 3 monthly intervals unless specified differently by the specialist.
Pharmaceutical aspects	Route of administration	Oral
	Formulation	50mg film coated tablets Oral solution 5mg in 1mL Only use when liquid is essential as it is much more expensive than tablets.

	Administration details	Absorption can be reduced by fatty food
	Other information	Tablets can be crushed and mixed with soft food to aid swallowing. Once crushed tablets should be taken immediately
Contraindications	Patient will be assessed for contraindications at initiation by the specialist, see SPC for up to date list.	
Significant Drug Interactions	For a comprehensive list consult the BNF or Summary of Product Characteristics.	
Adverse Effects and management.	**Adverse result**	**Management**
	Raised serum transaminase	Discuss with specialist, patient should be advised to stop riluzole if ALT is raised to 5 times the upper limit of normal
	Febrile illness	Check WBC, discontinue riluzole in case of neutropenia
	Development of new dry cough/dyspnoea	Dyspnoea may be due to MND or a rare adverse effect of riluzole. New cough or dyspnoea can be discussed with the MND team, or the respiratory team if involved, who will advise on need for chest X-ray (CXR). Any CXR showing changes suggestive of interstitial lung disease (e.g. bilateral diffuse lung opacities) should lead to discontinuation of riluzole immediately
Advice to patient/carers	Patients should be advised to report any febrile illness	
Pregnancy and breast feeding	Riluzole is contraindicated in pregnancy and breast feeding due to lack of available data.	
Specialist contact information	See clinic letter for contact details	
Additional information	N/A	
References	1. National Institute for Health and Care Excellence. Guidance on the use of Riluzole (Rilutek) for the treatment of Motor Neurone Disease. Technology Appraisal Guidance (TA) 20. Accessed 14 September 2017 at: https://www.nice.org.uk/guidance/ta20 2. NEWT Guidelines for the administration of medications to patients with enteral feeding tubes or swallowing difficulties. Accessed 14 September 2017	
To be read in conjunction with the following documents	N/A	

Appendix 1

Policy for Shared Care

Shared care is only appropriate if it provides an optimum solution for the patient and it meets the criteria outlined in the Shared Care section of the Pan Mersey **Definitions and Criteria for Categorisation of Medicines in the Pan Mersey Formulary** document.

Before prescribing responsibilities are transferred to primary care:

- Prescribing responsibility will only be transferred when the consultant and the patient's GP agree that the patient's condition is stable.
- All information required by the shared care framework for the individual medicine has been provided to the patient's GP.
- Patients will only be referred to the GP once the GP has agreed to the Shared Care Agreement and returned signed copies.

Inherent in any shared care agreement is the understanding that participation is at the discretion of the GP, subject to the availability of sufficient information to support clinical confidence.

Specialist Responsibilities in Shared Care

- To initiate the medicine, prescribing and monitoring toxicity and efficacy as required until the patient is stabilised and reviewed as described by the shared care framework.
- To ensure the patient or their carer is counselled with regard to the medicine.
- To provide any necessary written information to the patient with regard to the individual medicine.
- To be familiar with the shared care framework.
- To provide all information to the patient's GP as required by the shared care framework when prescribing responsibility is initially transferred and at any subsequent times as necessary for safe and effective treatment of the patient.
- To assess the patient regularly as necessary for the duration of therapy as specified in the individual medicine shared care framework.
- To review the patient promptly if required by the GP concerned.

- To meet any additional requirements as required by the individual medicine shared care framework.
- To communicate failure of a patient to attend a routine hospital review and advise the GP of appropriate action to be taken.
- Following the addition of a new drug to an existing regime covered by a Shared Care Agreement, the Specialist must recall the patient for re-titration, stabilisation and subsequent review and inform the GP of this. A new Shared Care Agreement must then be initiated.

Primary Care Responsibilities in Shared Care

- To reply to a written request for Shared Care within 21 days ensuring both copies of the Shared Care Agreement are signed if appropriate.

If agreeing to shared care, the GP is asked to:

- To provide prescribe or manage and monitor the medicine as advised by the Specialist and in line with the individual Shared Care Framework.
- To review the patient as required by the Shared Care Framework
- To make appropriate and contemporaneous records of prescribing and/or monitoring and to note the existence of the Shared Care Agreement on the patient`s clinical record. A READ code of “6652 Shared Care- Specialist/GP” can be used.
- To be familiar with the individual Shared Care Framework.
- To report any adverse effects of treatment to the consultant
- To inform the Specialist of any relevant change in the patient’s circumstances.
- To seek Specialist advice as appropriate.
- To meet any additional requirements as required by the individual Shared Care Framework.
- To respond to Specialist communication relating to any change or addition to the patient’s treatment covered by the Shared Care Agreement.

Appendix 2: Shared Care Agreement

Request by Specialist Clinician for the patient's GP to enter into a shared care agreement for riluzole

Part 1
To be signed by Consultant / Associate Specialist / Specialist registrar or Specialist Nurse (who must be a prescriber)

Date _____

Name of patient_____

Address _____

_____

Patient NHS No _____

Patient hospital unit No _____

Diagnosed condition _____

If using addressograph label please attach one to each copy

Dear Dr_____

I request that you prescribe

(1) _____

(2) _____

for the above patient in accordance with the enclosed shared care framework.

Last Prescription Issued: ….. / ….. / ….. Next Supply Due: ….. / ….. / …..

I confirm that the patient has been stabilised and reviewed on the above regime in accordance with the Shared Care Framework and Policy. ☐

I confirm that if this is a Shared Care Agreement for a drug indication which is unlicensed or off label, informed consent has been received. ☐

Details of Specialist Clinicians

Name _____Date_____

Consultant / Associate Specialist / Specialist Registrar / Specialist Nurse ***circle or underline as appropriate***

Signature _____

In all cases, please also provide the name and contact details of the Consultant.

When the request for shared care is made by a Specialist Nurse, it is the supervising consultant who takes medico-legal responsibility for the agreement.

Consultant: _____

Contact details*:*

Telephone number: _____Ext:_____

Address for return of documentation _____

_____

_____

Part 2
To be completed by Primary Care Clinician

I agree to prescribe _____for the above patient in accordance with the enclosed shared care framework.

GP signature _____Date _____

GP name _____Please print

GP: *Please sign and return a copy* ***within 21 calendar days*** *to the address above*

OR

GP- If you do not agree to prescribe, please delete the section above and provide any supporting information as appropriate below:

Part 3 Other Relevant Information

Part 4 **Monitoring Requirements**

Monitoring requirements are detailed in section 5 of the attached Shared Care Framework.

Details of most recent Monitoring results:

Previous Investigations Completed	**Date**	**Result**	**Next date due**