SHARED CARE AGREEMENT

Name of medicine Riluzole

Indication for amyotrophic lateral sclerosis (ALS) motor neurone disease

Version: 4.0 Approval date: September 2024 Review Date: September 2027

The Shared Care Agreement (SCA) is intended to facilitate the accessibility and safe prescribing of complex treatments across the secondary/primary care interface. It does not contain all of the relevant product information, which should be sought using the current British National Formulary and manufacturer's Summary of Product Characteristics. The SCA must be used in conjunction with the NHS Lothian Procedure for the Shared Care of Medicines, available here.

Roles and Responsibilities

Listed below are specific responsibilities that are additional to those included in the NHS Lothian Policy and Procedures for Shared Care. Please refer to the policy for core roles and responsibilities that apply to all Shared Care Agreements.

Consultant Neurologist

- Diagnosis of ALS and assessment of suitability of patients for riluzole treatment
- Undertake baseline U&Es and LFTs
- Initiate therapy by prescribing and supplying the first month's treatment
- Monitor and evaluate response to riluzole therapy and decide in conjunction with patient and all medical attendants on discontinuation
- Monitor and evaluate adverse drug reactions

General Practitioner

- Check LFTs monthly for first three months, three monthly for next nine months, then periodically as clinically indicated thereafter
- Check renal function where clinically indicated
- Check white blood cell counts in febrile illness and stop riluzole if patient found to be neutropenic
- Interstitial lung disease has been reported in patients treated with riluzole; arrange for chest x-ray if patient reports dry cough and/or dyspnoea

Patient, Relatives, Carers

- As listed in NHS Lothian Policy and Procedures for the Shared Care of Medicines

Support and Advice for the GP

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Consultants
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Key information on the medicine

Please refer to the current edition of the British National Formulary available at www.bnf.org, and Summary of Product Characteristics (SPC), available at www.medicines.org.uk for detailed product and prescribing information and specific guidance.

Background to disease and use of drug for the given indication
Riluzole is used to extend life in patients with motor neurone disease (MND) who have amyotrophic lateral sclerosis. Treatment should be initiated by a specialist in MND but can then be supervised under a shared care arrangement involving the GP. (Refer to British National Formulary www.bnf.org and NICE 'Guidance on the use of riluzole for the

treatment of motor neurone disease', January 2001. www.nice.org.uk/TA20)

There is no evidence that riluzole exerts a therapeutic effect on motor function, lung function, fasciculations, muscle strength and motor symptoms. Riluzole has not been shown to be effective in the late stages of ALS. Safety and efficacy of riluizole has only been studied in ALS; therefore, riluzole should not be used in patients with any other form of motor neurone disease.

Excessive stimulation of glutamate receptors may cause or play an important role in the destruction of motor neurones in MND. In vitro riluzole inhibits the release of glutamate, thereby decreasing the firing of motor neurones induced by glutamate receptor agonists and thus protecting cells from glutamate-mediated damage.

Indication
Riluzole is licensed for the amyotrophic lateral sclerosis (ALS) form of MND. It should be started once the diagnosis has been established by a consultant neurologist or pending investigations where clinical suspicion of ALS is high. It should be stopped if side effects become unacceptable or as agreed mutually between patient and their medical attendants.

Dosage and Administration
The recommended daily dose in adults or older people is 100 mg (50 mg every 12 hours). No significant increased benefit can be expected from higher daily doses. High fat meals reduce the extent and rate of absorption and should be avoided.

If patient is unable to swallow tablets the liquid preparation may be a suitable alternative. Alternatively, tablets may be crushed and mixed with a soft food product to aid swallowing although this is an off-label use. Care should be taken when using crushed tablets as they may produce a local anaesthetic effect in the mouth. For enteral tube administration liquid or crushed tablets dispersed in water may be used (off-label use).

Monitoring
Routine supervision to be performed by general practitioners as follows:

Test	Frequency	Action
LFTs	Monthly for first three months, three monthly for next nine months then periodically as clinically indicated thereafter	Increase frequency of LFTs if ALT levels begin to rise. Stop riluzole if ALT rises to greater than five times upper limit of normal
Renal function	As clinically indicated	Manufacturer does not have data and therefore do not recommend riluzole in renally impaired patients. Obtain specialist opinion on risk versus benefit.
WBC	Check if patient reports febrile illness	Stop riluzole if patient is neutropenic (neutrophils $<1x10^{-9}$/l)
Chest x-ray	Check if patient reports dry cough and/or dyspnoea	If findings are suggestive of interstitial lung disease riluzole should be discontinued immediately

Cautions, contraindications - Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

Adverse effects - Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

Drug interactions - Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

The presence of this SCA does not compel a primary care prescriber to prescribe if they feel that it is out with the scope of their competencies (as per GMC guidance on safe prescribing) or resources, as ultimate responsibility lies with the prescribing, not the recommending, clinician.

For office use only:

Approved by the General Practice Prescribing Committee (GPPC) on 10th September 2024