SHARED CARE AGREEMENT FOR

RILUZOLE

in the treatment of

Amyotrophic Lateral Sclerosis form of Motor Neurone Disease

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Shared Care Agreement for Riluzole in the treatment of amyotrophic lateral sclerosis (ALS) form of Motor Neurone Disease

Introduction and purpose
This shared care agreement has been produced following NICE guidance issued in 2001 on the use of riluzole (https://www.nice.org.uk/guidance/ta20). Shared Care has been defined as the mechanism of sharing patient care between primary and secondary care providers. This document therefore sets out these responsibilities from initial diagnosis to ongoing support.

Disease background
ALS is a progressive, fatal neurodegenerative disorder with a median survival of 37 to 49 months. It is characterised by progressive deterioration of muscle tissue (amyotrophy) and specific effects on lateral columns of the spinal cord, including fibre loss and fibrillary gliosis (lateral sclerosis). Glutamate toxicity has been implicated as a factor causing neuronal damage. Death is due to respiratory failure.

Drug covered by the policy and it’s place in treatment

Riluzole

This is a glutamate antagonist, which inhibits the release of presynaptic glutamic acid in the central nervous system, and interferes with the effects of excitatory amino acids post-synaptically. The dose of riluzole is 50mg twice a day and is available as a tablet, or liquid preparation (Teglutik 5mg/ml).

Riluzole is indicated to extend life or time to mechanical ventilation for patients with amyotrophic lateral sclerosis (riluzole should not be used in any other form of motor neurone disease).

Contra-indications:
- Patients with a history of hypersensitivity to Riluzole or any of the tablet components
- Patients who have hepatic disease or who have baseline transaminases greater than 3 times the upper limit of normal
- Patients with renal impairment
- Patients who are pregnant or lactating

Cautions For Use:
- Patients should be warned about the potential for dizziness or vertigo, and advised not to drive or operate machinery if these symptoms occur
- Riluzole should be prescribed with care in patients with a history of abnormal liver function, or in patients with slightly elevated serum transaminases, bilirubin and/or gamma-glutanyl transferase levels. (See responsibilities above).
- If respiratory symptoms develop such as cough and/or dyspnoea, chest radiography should be performed to rule out interstitial lung disease.
For more information about riluzole including side effects and interactions please see BNF and spc.

**Hospital Clinician Responsibilities:**

- Assess need for and appropriateness of riluzole
- Due to the potential for hepatic damage and blood disorders the Consultant should perform a full blood count and check serum transaminases before therapy commences and monthly until the end of the first three months of treatment
- Recommend a treatment regime and prescribe for the first three months
- Liaise with GP to agree to share patient’s care after first three months using the [Shared Care Request Form](#)
- Evaluating ADR’s noted by GP or patients to their carer and reporting them to the MHRA if appropriate
- Overall monitoring of disease status
- Discussing treatment discontinuation with carers
- Advise patients or their carers how to recognise signs of neutropenia – advise to seek immediate medical attention if symptoms such as fever occurs
- Neutropenia requires discontinuation of riluzole
- Riluzole should be discontinued if ALT levels increase to 5 times the upper limit of normal
- Provides back up advice whenever necessary

**GP Responsibilities:**

- Confirm or decline request to share patient’s care as soon as possible, using the shared care request form
- Report signs of disease progression
- Laboratory supervision of the patient after the first three months. Full blood count and liver function tests every three months up to the end of the first year then every twelve months
- Prescribing Riluzole after the initial first three months
- Reporting any suspected adverse events to the Consultant in charge and any serious suspected adverse events to the MHRA
- Advise patients or their carers how to recognise signs of neutropenia – advise to seek immediate medical attention if symptoms such as fever occurs
- Neutropenia requires discontinuation of Riluzole
- Riluzole should be discontinued if ALT levels increase to 5 times the upper limit of normal
- Symptomatic management of minor adverse effects
Contact for support and advice

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References

1. Summary of Product Characteristics (SPC) - Rilutek® (Sanofi Aventis), eMC, reviewed December 2013
3. BNF https://bnf.nice.org.uk/drug/riluzole.html

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<tr>
<th>Version</th>
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<tr>
<td>3.1</td>
<td></td>
<td>Reference to shared care agreement form added</td>
<td>June 2011</td>
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<td>3.2</td>
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<td>Shared care agreement form changed to shared care request form. ALS clarified as a form of motor neurone disease</td>
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<td>3.3</td>
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<td>Members reviewed by updated Spelling of amyotrophic corrected Available preparations and brands updated Contacts for support and advice updated Web link to full NICE TA guidance added Information on cautions and side effects updated Additional reference added</td>
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