Brighton and Sussex University Hospitals NHS Trust

WORKING IN PARTNERSHIP WITH

NHS
Brighton and Hove Clinical Commissioning Group
Crawley Clinical Commissioning Group
Horsham and Mid Sussex Clinical Commissioning Group
High Weald Lewes Havens Clinical Commissioning Group

OPT-OUT SHARED CARE GUIDELINE

It is assumed that shared care **will** be accepted unless the specialist is informed otherwise within 28 days of receipt of the request at the end of this document.

DRUG NAME: **Riluzole**

INDICATION(S) COVERED **Amyotrophic Lateral Sclerosis in Adult Patients**

NHS Brighton and Hove CCG, Crawley CCG, Horsham and Mid-Sussex CCG and High Weald Lewes Havens CCG Traffic Light System Classification: Amber

NOTES to the general practitioner (GP) or primary care prescriber

For medicines which require specialist initiation and/or dose titration and specific ongoing monitoring. For initiation, dose stabilisation and prescribing (including monitoring) by a specialist until the patient is stabilised (usually for 3 months) after which the GP may be asked to work under shared care through the use of approved shared care guidelines.
The expectation is that these guidelines should provide sufficient information to enable GPs or primary care prescribers to be confident to take clinical and legal responsibility for prescribing these medicines.

The questions below will help you confirm this:

- Is the patient currently under your care (e.g. shared care should not be agreed if the patient is currently in intermediate care following hospital discharge)?
- Do you have the relevant knowledge, skills and access to equipment to allow you to monitor treatment as indicated in this shared care guideline?
- Have you been provided with relevant clinical details including monitoring data?

If you can answer YES to all these questions (after reading this shared care guideline), then it is appropriate for you to accept prescribing responsibility. It is assumed that shared care will be accepted unless the specialist is informed otherwise within 28 days of receipt of this request.

If the answer is NO to any of these questions, you should not accept prescribing responsibility. You should inform the consultant or specialist within 28 days, outlining your reasons for NOT prescribing. If you do not have the confidence to prescribe, we suggest you discuss this with your local Trust or specialist service, who will be willing to provide training and support. If you still lack the confidence to accept clinical responsibility, you still have the right to decline. Your CCG medicines management pharmacist will assist you in making decisions about shared care if you are unsure.

Prescribing unlicensed medicines or medicines outside the recommendations of their marketing authorisation alters (and probably increases) the prescriber's professional responsibility and potential liability. The prescriber should be able to justify and feel competent in using such medicines.

The GP or primary care prescriber has the right to refuse to agree to shared care, in such an event the total clinical responsibility will remain with the consultant or specialist.

Reason for update: due for review	**Prepared by:** Gill Yates	**Updated by:** Gill Yates and Jade Tomes (on behalf of APC)
Approved by (Specialist or Consultant): Prof P Nigel Leigh, Dr Jonathan Knibb **Agreed by:** Dr Romi Saha, Dr Sarah Cooper, Dr Julia Aram, Dr Norman Kock, Dr Waqar Rashid, Dr Leonora Fisniku, Dr Basil Ridha		
Approved by (Chief Trust Pharmacist): Mike Cross		
Approved by (CCG Medicines Management Pharmacist): Stewart Glaspole		
Approved by Brighton and Hove and High Weald Lewes Havens CCG on: 07.2018		
Approved by Crawley CCG, Horsham and Mid-Sussex CCG on: 07.2018		

Information

This page should include general information relevant to the specific drug and indication/s. It should include information on the dose of the drug for the indication, cautions, contraindications, common side effects and interactions to look out for. This section should have input from a specialist consultant in the field.

This information sheet does not replace the Summary of Product Characteristics (SPC), which should be read in conjunction with this guidance. Prescribers should also refer to the appropriate paragraph in the current edition of the BNF.

1. Link to the relevant SPC website:

Riluzole SPCs: https://www.medicines.org.uk/emc/search?q=riluzole
Teglutik® SPC: http://www.medicines.org.uk/medicine/31219

2. Background to use for the indication/s, including licence status:

Indication: Riluzole is indicated to extend life or the time to mechanical ventilation for patients with amyotrophic lateral sclerosis (ALS). ALS is also known as Motor Neurone Disease (or MND)

Prescribing: A specialist neurologist with expertise in ALS should initiate this drug. Routine supervision of therapy should be managed by locally agreed shared care protocols undertaken by General Practitioners. NICE TA 20 Jan 2001

Therapeutic effect: Riluzole inhibits the release of glutamate *in vitro*. It is thought that excessive stimulation of glutamate receptors on neurones may cause or play an important role in the destruction of motor neurones

3. Dose & administration:

Dose: 50mg taken orally twice a day. Tablets to be used if patient has a safe swallow or if riluzole is being administered via a feeding tube. Riluzole 5mg/ml oral suspension (Teglutik®) is licensed in patients with ALS who have bulbar symptoms and who are at risk of dysphagia. NB Riluzole oral suspension has a 'thickened liquid' consistency and at the time of writing is not licensed for administration via feeding tubes.

Administration:
For patients using a feeding tube to administer medicines: First choice is to use tablets which may be crushed for administration via a PEG or NG tube (unlicensed but accepted practice). The manufacturer of (Teglutik®) can provide information from in-house studies on the administration of Riluzole 5mg/ml oral suspension (Teglutik®) through feeding tubes upon request.

For patients with an impaired swallow: SALT to assess safest option. Riluzole oral suspension 5mg/ml can be considered, or riluzole tablets may be crushed and mixed with a soft food product such as yoghurt (unlicensed)

Duration: Until patient reaches later stages of their disease and /or wishes to stop treatment.

4. Cautions (including for pregnancy & lactation where relevant):

Cautions: Liver impairment, neutropenia, interstitial lung disease. Not recommended for use in patients with impaired renal function

Pregnancy and lactation: Riluzole is contraindicated in pregnancy; clinical experience in pregnant women is lacking. Riluzole is contraindicated in breast-feeding women. It is not known whether riluzole is excreted in human milk

5. 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. Patients who are pregnant or breast-feeding

6. Side effects:

Please refer to Summary of Product Characteristics for riluzole tablets and Teglutik® oral suspension

Very common: abnormal liver function tests, usually transient, asthenia, nausea.
Common: diarrhoea, abdominal pain, vomiting, headache, dizziness, oral paraesthesia, somnolence, tachycardia, pain

7. Notable drug interactions:

There are no reports of interactions between riluzole and other drugs. It is principally metabolised by cytochrome P450 1A2 enzyme. Other drugs that affect this enzyme may have an effect on riluzole clearance
Inhibitors of cytochrome P450 1A2 (caffeine, diclofenac, diazepam, clomipramine, imipramine, fluvoxamine, phenacetin, theophylline, amitriptylline and quinolones) could decrease the rate of excretion of riluzole
Inducers (cigarette smoke, charcoal-broiled food, rifampicin and omeprazole) could increase the rate of excretion of riluzole
However, as these are only theoretical interactions treatment should only be monitored and no advice on dosage adjustments exists

8. Criteria for use:

In accordance with NICE TA20 Jan 2001: https://www.nice.org.uk/guidance/ta20

9. Any further information (e.g. supporting therapies):

None

10. References: Riluzole SPC, NICE TA20, Teglutik® SPC, Information from Martindale Pharma 18.3.2016

RESPONSIBILITIES and ROLES

Consultant or specialist responsibilities

1 Confirm diagnosis and indication for treatment with riluzole.
2 To discuss fully the aims, benefits, risks and side effects of treatment and a treatment plan with the patient and/or carer and for written information to be supplied to the patient and/or carer.
3 Inform GP when initiating treatment so the GP is aware what is being prescribed and can add to GP clinical record.
4 Undertake baseline monitoring as required (specific to the medication).
5 Record other medications and address potential medicine interactions before starting therapy.
6 To discuss the potential implications of pregnancy and breastfeeding in women of child bearing potential and agree a risk minimisation strategy where appropriate.
7 To initiate treatment by prescribing and monitoring usually for a minimum of 3 months.
8 Undertake monitoring if dose changed.
9 Monitor and prescribe according to guidelines until handover is appropriate (including when dose changes are made).
10 Discuss the possibility of shared care with the patient and/or carer and ensure that they understand the plan for their subsequent treatment.
11 Supply GP with a summary of the patient's review (including anticipated length of treatment) and a link to, or a copy of, the shared care guideline when requesting transfer of prescribing to GP or primary care prescribers.
12 Advise GP if treatment dose changes or treatment is discontinued.
13 Inform GP if patient does not attend planned follow-up.
14 Refer to Community Based Motor Neurone Disease support services

GP or primary care prescriber responsibilities

1 Continue prescribing of riluzole at the dose recommended and undertake monitoring requirements.
2 Undertake all relevant monitoring as outlined in the monitoring requirements section below, and take appropriate action as set out in this shared care guideline.
3 Monitor for adverse effects throughout treatment and check for medicine interactions on initiating new treatments.
4 Add information about the medicine to the patient record, initially as "hospital prescribed", and highlight the importance that this medicine is only to be prescribed under a shared care guideline in primary care.
5 Inform the consultant or specialist of any issues that may arise.
6 Refer patient back to the Consultant/Specialist if any concerns.
7 Ensure that if care of the patient is transferred to another prescriber, that the new prescriber is made aware of the shared care guideline (e.g. ensuring the patient record is correct in the event of a patient moving surgery).

Monitoring requirements and appropriate dose adjustments (if relevant to specific medication)

Note: The Hospital Specialist will initiate treatment and monitor blood tests at baseline and for the first 3 months of treatment

Test	Frequency	Action
ALT	Monthly for first 3 months, then 3 monthly At 1 year can reduce to 6 monthly	**STOP** if ALT > 5x upper limit of normal (ULN). **Seek specialist advice**
Renal function	6 monthly	Not recommended in renal impairment due to lack of data **Seek specialist advice**
WBC	Check FBC if patient febrile	Stop if neutropenic (neutrophils < 1 x 10^{-9}/l) **Seek specialist advice**
Chest x-ray	Check if dry cough/dyspnoea develops	Stop if interstitial lung disease **Seek specialist advice**

Liver function tests
Riluzole commonly causes an elevation of ALT to more than 3x ULN. Increases are usually transient and ALT levels fall to below 2x ULN within 6 months of treatment. In some patients ALT increases to more than 5 x ULN. In these patients riluzole should be stopped and re-administration is not recommended

Neutropenia
Patients will be warned about the risk of neutropenia by the hospital specialist, and advised on how to recognise signs of neutropenia (including febrile illness)

Interstitial Lung Disease
Patients will be warned by the hospital specialist to report any signs of dry cough or dyspnoea. Seek specialist advice if this occurs, to arrange urgent chest radiography. Riluzole should be stopped if interstitial lung disease is diagnosed. Symptoms may be reversible on discontinuation of riluzole
Renal Impairment - there is no data available about the use of riluzole in renal impairment. Discontinue in renal impairment

Patient and/or carer role

1 Make sure that you understand the treatment and ask for more information, if needed.
2 Share any concerns in relation to treatment with whoever is prescribing this medicine for you.
3 Tell the prescriber of this medication about any other medication being taken, including over-the-counter products.
4 Read the patient information leaflet included with your medication and report any side effects or concerns you have to whoever is prescribing this medicine for you.
5 Attend any follow up appointments with the consultant or specialist.
6 Attend any monitoring appointments (eg blood tests).
7 Report any febrile illness or new respiratory symptoms to your doctor

SHARED CARE GUIDELINE

MEDICATION NAME: Riluzole

INDICATION: Amyotrophic Lateral Sclerosis

DATE OF REQUEST:

Agreement to transfer prescribing to general practice or primary care prescriber:

Patient details:

Name:

Address:

DoB:

NHS No:

Hospital No:

Medication name, form and strength:

The following tests and investigations have been carried out:

Date treatment initiated:

At the last patient review the medication appeared to be effectively controlling symptoms or providing benefit:
Yes/No

The patients has now been stabilised on a dose of:

The patient has been given written information about their medication:
Yes/No

The patient understands that this medication is being prescribed under a shared care agreement between their GP and specialist and that they have responsibilities under the agreement to ensure they attend their GP to be regularly monitored.
Yes/No

The patient has been informed that the GP can opt-out of taking on prescribing responsibility if they do not feel clinically able to prescribe or if the patient persistently does not attend for monitoring:
Yes/No

Date of next clinic appointment:

If the practice declines shared care, then the named consultant or specialist should be informed within 28 days of receipt of this request. Forms used to decline prescribing can be found here:

Brighton and Hove CCG and High Weald Lewes Havens CCG:
http://www.gp.brightonandhoveccg.nhs.uk/prescribing/joint-formulary-supporting-information
Crawley CCG, Horsham and Mid Sussex CCG:
http://www.horshamandmidsussexccg.nhs.uk/EasySiteWeb/GatewayLink.aspx?alId=415216

BACK-UP ADVICE AND SUPPORT

	Name and position	Telephone	Email
Specialist or Consultant	Medical secretaries for the following Consultant Neurologists can be contacted via the hospital switchboards: Dr Sarah Cooper, Dr Romi Saha, Dr Waqar Rashid, Dr Leonora Fisniku, Dr Jonathan Knibb, Dr Julia Aram, Dr Norman Kock, Dr Basil Ridha	Hospital Switchboards RSCH 01273 696955 PRH 01444 441881	firstname.surname@bsuh.nhs.uk
Alternative specialist (e.g. departmental contact)	Professor P Nigel Leigh		peterleigh@nhs.net
Specialist pharmacist	Gill Yates	01444 441881 x 8143	gill.yates@bsuh.nhs.uk gill.yates1@nhs.net
Out of hours (e.g. medical team on call)	On-call neurologist via hospital switchboard	Hospital Switchboards RSCH 01273 696955 PRH 01444 441881	

Link to full SCG:
http://www.gp.brightonandhoveccg.nhs.uk/prescribing/shared-care-guidelines