BNSSG Shared Care Guidance
Please complete all sections

Section 1: Heading

Drug	Riluzole
Amber *three months*	
Indication	To extend life or the time to mechanical ventilation for patients with amyotrophic lateral sclerosis (ALS).
Speciality / Department	Neurosciences
Trust(s)	North Bristol NHS Trust
	Click here to enter details
	Click here to enter details

Section 2: Treatment Schedule

Usual dose and frequency of administration	Dose is 50mg every 12 hours. No significant benefit can be expected from higher daily doses.
Route and formulation	Riluzole is available as 50mg tablets to be administered orally. If the patient has swallowing difficulties, the tablets may be crushed and mixed with soft food e.g. yoghurt or puree. When crushed the drug can produce a temporary numbing effect in the mouth. If crushing for tube administration then crushed tablets may be dissolved in water, but flush well as may block tubes. Give immediately once crushed. For those where crushing tablets is not appropriate and use of the licensed liquid (Teglutik®) would be preferable to prevent PEG/RIG complications or where a PEG/RIG has been declined. Riluzole liquid would usually be initiated by a Consultant, specialist registrar or specialist nurse who is involved in the care of patients with motor neurone disease.
Duration of treatment	Treatment may be continued indefinitely or until review by the specialist. The patient will ordinarily have routine review appointments with their specialist but the GP may refer back to the specialist any patient whose condition declines or who reports symptoms suggestive of side effects.

Section 3: Monitoring

Please give details of any tests that are required before or during treatment, including frequency, responsibilities (please state whether they will be undertaken in primary or secondary care), cause for adjustment and when it is required to refer back to the specialist.

Baseline tests - where appropriate

Baseline tests will be performed by secondary care prior to treatment inititation. Because of the risk of hepatitis, serum transaminases including ALT should be measured prior to treatment initiation. Riluzole is contraindicated in patients with hepatic disease or baseline trasaminases greater than 3 times the upper limit of normal. Women of child bearing potential should have a negative pregnancy test prior to treatment initiation as riluzole is contraindicared in pregnancy.
Subsequent tests - where appropriate
1. Subsequent test will be performed by primary care and advice sought from specialist if the results are deranged. 2. ALT should also be measured every month during the first three months of treatment, every three months during the remainder of the first year and annually thereafter. ALT levels should be measured more frequently in patients who develop elevated ALT levels. Riluzole should be discontinued if the ALT levels increase to five times the upper limit of normal. 3. Patients should be warned to report any febrile illness to their GP. The report of a febrile illness should prompt the GP to check white blood cell counts and to contact the specialist with regard to treatment discontinuation of riluzole in case of neutropenia.

Section 4: Side Effects

Please list the most common side effects and management. Please provide guidance on when the GP should refer back to the specialist.

Side effects and management	Very common (>1/10) Nausea,asthenia, abnormal liver function tests (see management as above) Common (>1/100 to <1/10) Headache, dizziness, oral paraesthesia, somnolence, tachycardia, diarrhoea, abdominal pain, vomiting, pain Uncommon (>1/1000) Anaemia, anaphylactoid reaction, angioedema, interstitial lung disease, pancreatitis. Not known: Severe neutropenia, hepatitis.
Referral back to specialist	If liver function tests are raised above 2x the upper limit of normal If respiratory symptoms develop such as a dry cough/ dyspnoea, chest radiography should be performed in case of findings of interstitial lung disease (in which case riluzole should be stopped immediately). If the patient is found to be neutropenic or pancytopenic immediate advice should be sought from the specialist.

Section 5: Drug Interactions

Please list clinically significant drug interactions (eMC link please click here)

Significant Drug Interactions	No studies have been carried out on interactions of riluzole with other medications. In vitro studies using human liver microsomal preparations suggest that CYP1A2 is the principal isoenzyme involved in the metabolism of riluzole.In theory, inhibitors of CYP1A2 (e.g. caffeine, diclofenac, diazepam, nicergoline, clomipramine, imipramine, fluvoxamine,

	theophylline, amitriptyline and quinolones) could potentially decrease the rate of riluzole elimination. Inducers of CYP1A2 (e.g. cigarette smoke, charcoal-broiled food, rifampicin and omeprazole) could increase the rate of riluzole elimination
Reminder to ask patient about specific problems	Patients should be warned about the potential for dizziness or vertigo and advised not to drive or operate machinery if these symptoms occur. If respiratory symptoms occur (such as dry cough/ dyspnoea) then attend GP as chest radiography may be required.

Section 6: Contra-indications, Cautions and Special Recommendations

Please list

1. Contraindicated if hypersensitive to active substance or any of the excipients
2. Contraindicated in hepatic disease or with baseline transaminases more than three times the upper limit of normal
3. Contraindicated in patients who are pregnant or breast feeding.
4. Contraindicated in acute porphyria
5. Caution in those with history of abnormal hepatic function.
6. Riluzole is not recommended for use in those with impaired renal function as studies have not been conducted in this population.

Section 7: Advice to the patient

Advice for prescribing clinician to inform patient

1. Patients (or their carers) should be told how to recognise signs of neutropenia and advised to seek immediate medical attention if symptoms such as fever occur; white blood cell counts should be determined in febrile illness as neutropenia requires discontinuation of riluzole.
2. Perform chest radiography if symptoms such as dry cough or dyspnoea develop; discontinue if interstitial lung disease is diagnosed.
3. If dizziness or vertigo occur, patient should be informed not to drive and that it may affect their performance of skilled tasks.
4. For patients with swallowing difficulties the tablets may be crushed and mixed with soft food such as yoghurt or puree and eaten. It is not recommended that the powder be mixed with water as sedimentation may occur. This could result in an incomplete dose being given. When crushed riluzole can cause local anaesthesia in the mouth.

Section 8: Responsibilities for Secondary Care

Core responsibilities

1. Initiating treatment and prescribing for the first three months
2. Undertaking the clinical assessment and monitoring for the first month.
3. Communicate details of the above in 1 and 2 to GP within the first month of treatment. This information should be transferred in a timely manner.
4. Refer patients to GP and provide information of further action where appropriate e.g. blood test is due.
5. To provide advice to primary care when appropriate.
6. Review concurrent medications for potential interaction prior to initiation of riluzole.
7. Stopping treatment where appropriate or providing advice on when to stop.
8. Reporting adverse events to the MHRA.
9. Reminder to ask patients about particular problems see section 5.

Other specific to drug

1. Ensure patient is aware of how to obtain supplies of Riluzole during the first three months of treatment, whether this be by contacting the MND service co-ordinator or consultant via their secretary.

Section 9: Responsibilities for Primary Care

Core responsibilities 1. Responsible for taking over prescribing after the first three months 2. Responsible for the clinical assessment and monitoring after the first month 3. Review of any new concurrent medications for potential interactions. 4. Reporting adverse events to the MHRA. 5. Refer for advice to specialist where appropriate. 6. Reminder to ask patients about particular problems see section 5.
Other specific to drug
1. To check FBC, U&Es, Cr and LFTs monthly for first three months and then every three months for the first year thereafter. To contact the specialist if blood results are out of range- as per guidance in section 4.

Section 10: Contact Details

Name	Organisation	Telephone Number	E mail address
Neurology Consultant	North Bristol NHS Trust	Via switchboard 0117 9505050 (24 hours)	Click here to enter details
Neurology Registrar	North Bristol NHS Trust	Via switchboard 0117 9505050 (24 hours)	Click here to enter details
Neurology Pharmacist	North Bristol NHS Trust	Via switchboard 0117 9505050 Bleep 1767 (09.00- 17.15)	Click here to enter details
MND Service Co-ordinator	North Bristol NHS Trust	Via Switchboard (0117 9505050)	Click here to enter details
Click here to enter details	Click here to enter details	Click here to enter details	Click here to enter details
Click here to enter details	Click here to enter details	Click here to enter details	Click here to enter details
Click here to enter details	Click here to enter details	Click here to enter details	Click here to enter details

Section 11: Document Details

Date prepared	September 2016 amended January 2018
Prepared by	Kimberley Jefferson amended Kirsty Brisker

Date approved by JFG	November 2016
Date of review	January 2020
Document Identification: Version	2.2

Section 12: Collaboration

Specialists in any one discipline are encouraged to collaborate across the health community in preparing shared care guidance. Please give details

1. Click here to enter details

Section 13: References

Please list references

1. BNSSG Shared Care Guidelines – Riluzole dated April 2014
2. Summary of Product Characteristics for Rilutek, last updated on the eMC 06/01/2014, accessed January 2014
3. BNF September 2016 accessed via medicines complete September 2016
4. Stockleys Drug Interactions accessed via medicines complete September 2016
5. NEWT Guidelines for administration of medication to patients with enteral feeding tubes or swallowing difficulties. Riluzole monograph updated May 2010. Accessed September 2016.