NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Technology Appraisals and Guidance Information Services

Static List Review (SLR) report

Title and TA publication number of static topic:	TA20; Riluzole for the treatment of Motor Neurone Disease
Final decision:	The guidance will remain on the 'static guidance list'.

1. Publication date:	January 2001.
2. Date added to static list:	February 2006.
3. Date the last searches were run:	28 November 2005.
4. Current guidance:	1.1 Riluzole is recommended for the treatment of individuals with the amyotrophic lateral sclerosis (ALS) form of Motor Neurone Disease (MND). 1.2 Riluzole therapy should be initiated by a neurological specialist with expertise in the management of MND. Routine supervision of therapy should be managed by locally agreed shared care protocols undertaken by general practitioners.
5. Research recommendations from original guidance:	6.1 Further trials of riluzole are required to examine the relative effectiveness of differing dosing regimens.

	6.2 Methods for the early diagnosis of MND require development as they may enable earlier treatment and enhanced clinical outcomes.
6. Current cost of technology/ technologies:	50mg tablets, 56-tab pack – net price: £320.33 (BNF 65).
7. Cost information from the TA (if available):	"The license dosage of riluzole is 100mg per day (50mg twice per day). The NHS list price (excluding VAT) of riluzole is £286 per treatment course [56 tablets], which amounts to an annual cost of £3718. An additional cost, incurred for monitoring liver enzymes, has been estimated to be a maximum of £24 per year, giving a total annual cost of treatment with riluzole of £3742."
8. Alternative manufacturers:	Actavis UK; Teva; Sun; Generics (UK) Ltd (Mylan).
9. Changes to the original indication:	No change. Note that riluzole is only licensed people with amyotrophic lateral sclerosis (ALS) and not for other forms of motor neurone disease.
10. New relevant trials:	Nothing relevant found.
11. Relevant NICE guidance (published or in progress):	CG105: Motor neurone disease: The use of non-invasive ventilation in the management of motor neurone disease. Issued: July 2010. Review date: July 2013. The above guideline makes no reference to riluzole. In trials of non-invasive ventilation (NIV) people taking riluzole have continued their treatment whilst receiving NIV.
12. Relevant safety issues:	None.
13. Any other additional relevant information or comments:	Miller, R G et al. (2012) Riluzole for amyotrophic lateral sclerosis (ALS)/motor neuron disease (MND). *Cochrane Database of Systematic Reviews* 2012, Issue 3. This review includes 4 studies, only 1 of which (Bensimon et al, 2002) was published

	after the original NICE TA. This study was identified during the 2005/6 RPP process and so would have been considered at the time. The Cochrane review concludes: *"…riluzole 100 mg probably prolongs median survival in people with ALS by two to three months and the safety of the drug is not a major concern. The evidence from randomized controlled trials indicates that participants taking riluzole probably survive longer than participants taking placebo. The beneficial effects are very modest and the drug is expensive".*
14. Technical Lead comments and recommendation:	Based on the lack of new published evidence related to this appraisal a review proposal at this stage is unnecessary. Therefore this guidance should remain on the static list.

Appendix 1 – explanation of options

Options	Consequence	Selected – 'Yes/No'
The guidance will remain on the 'static guidance list'	The guidance will remain in place, in its current form, unless NICE aware of substantive information which would make it reconsider. Literature searches are carried out every 5 years to check whether any of the Appraisals on the static list should be flagged for review.	Yes
The decision to review the guidance will be deferred to specify date or trial	NICE will consider whether a review is necessary at the specified date. NICE will actively monitor the evidence available to ascertain when a consideration of a review is more suitable.	No
A full consideration of a review will be carried out through the Review Proposal Process	There is evidence that could warrant a review of the guidance. NICE will schedule a consideration of a review, including a consultation with relevant consultees and commentators.	No
The guidance will be withdrawn	The guidance is no longer relevant and an update of the existing recommendations would not add value to the NHS. NICE will schedule a consideration of a review, including a consultation with relevant consultees and commentators.	No

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