NOTIFICATION

PHARMAC
Pharmaceutical Management Agency

11 September 2013

Approval of proposal to fund riluzole for amyotrophic lateral sclerosis (motor neurone disease)

PHARMAC is pleased to announce the approval of an agreement with Sanofi-Aventis to fund riluzole (Rilutek) for the treatment of amyotrophic lateral sclerosis (ALS, also known as motor neurone disease) from 1 October 2013 subject to the restrictions outlined below.

The proposal was the subject of a consultation letter dated 8 August 2013 which can be found on PHARMAC's website at www.pharmac.health.nz/news/item/riluzole-for-motor-neurone-disease

Details of the decision

- Riluzole 50 mg tablets (Rilutek) will be listed in Section B, and in the Hospital Medicines List (HML, Part II of Section H), of the Pharmaceutical Schedule from 1 October 2013 at a price and subsidy of $400.00 per pack of 56 tablets (ex-manufacturer, excluding GST). A confidential rebate will apply to Rilutek, reducing its net price.

- Riluzole will be listed subject to the following Special Authority restrictions in Section B of the Pharmaceutical Schedule. Similar restrictions will apply in the HML.

  Special Authority for Subsidy
  Initial application only from a neurologist or respiratory specialist. Approvals valid for 6 months for applications meeting the following criteria:
  All of the following:
  1 The patient has amyotrophic lateral sclerosis with disease duration of 5 years or less; and
  2 The patient has at least 60 percent of predicted forced vital capacity within 2 months prior to the initial application; and
  3 The patient has not undergone a tracheostomy; and
  4 The patient has not experienced respiratory failure; and
  5 Any of the following:
  5.1 The patient is ambulatory; or
  5.2 The patient is able to use upper limbs; or
  5.3 The patient is able to swallow.

  Renewal from any relevant practitioner. Approvals valid for 18 months for applications meeting the following criteria:
  All of the following:
  1 The patient has not undergone a tracheostomy, and
  2 The patient has not experienced respiratory failure; and
  3 Any of the following:
  3.1 The patient is ambulatory; or
  3.2 The patient is able to use upper limbs; or
  3.3 The patient is able to swallow.

- Rilutek will have protection from subsidy reduction and delisting until 1 July 2015.

- The wastage rule will apply to riluzole, so pharmacies will be able to claim for any unused stock from partly dispensed packs at expiry.

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Feedback received

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses were considered in their entirety in making a decision on the proposed changes. Most responses were supportive of the proposal, and the following issues were raised in relation to specific aspects of the proposal:

Theme	Comment
Several responders requested changes to the proposed access criteria.	We note that the criteria were recommended by the Pharmacology and Therapeutics Advisory Committee (PTAC) and reviewed by the Neurological Subcommittee of PTAC. They are also essentially the same as the access criteria that apply in Australia. After considering the consultation feedback we have made some minor formatting changes to the criteria and made a change to allow any relevant practitioner to make renewal applications. We will be taking advice from the Neurological Subcommittee of PTAC at its next meeting on 20 September 2013 regarding the other requested changes.
Some responders were concerned about the potential for pharmacies to bear the cost of expired stock from partly dispensed packs, given the high cost of riluzole and the low expected patient numbers.	After reviewing this feedback a decision was made to apply the wastage rule to riluzole so that pharmacies will be able to claim for any unused stock from partly dispensed packs at expiry.

More information

If you have any questions about this decision, you can call our toll free number (9 am to 5 pm, Monday to Friday) on 0800 66 00 50.