NOTIFICATION

PHARMAC
Pharmaceutical Management Agency

13 January 2014

Approval of proposals for atomoxetine, sugammadex and baclofen injection

PHARMAC is pleased to announce the approval of proposals to amend access to sugammadex and atomoxetine and to fund baclofen injection in the community. These proposals were the subject of a consultation letter dated 29 November 2013 which can be found on PHARMAC's website at http://www.pharmac.health.nz/news#consultation.

The proposals were approved as consulted on except for some minor changes to the atomoxetine and baclofen restrictions which were made after considering responses to consultation (see the 'Feedback received' section on the next page for more details). The decisions are summarised as follows, all with an implementation date of 1 February 2014:

- Funding for atomoxetine (Strattera) in the community and in hospitals will be widened to include its first-line use for Attention Deficit and Hyperactivity Disorder (ADHD) in patients with a history of psychoses or who have a first-degree relative with schizophrenia.

- Funding for sugammadex (Bridion) in hospitals will be widened to include severe neuromuscular degenerative disease where the use of neuromuscular blockade is required.

- Baclofen injection (Lioresal Intrathecal) will be funded in the community, subject to a prescription endorsement, for use in a programmable pump in patients where oral antispastic agents have been ineffective or have caused intolerable side effects.

Details of the decisions

- The initial Special Authority criteria for atomoxetine (Strattera) cap 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg and 100 mg will be amended in Section B of the Pharmaceutical Schedule from 1 February 2014 as outlined below (additions in bold). The Hospital Medicines List (HML; Part II of Section H of the Pharmaceutical Schedule) restrictions will be similarly amended from 1 February 2014.

  SAXXXX Special Authority for Subsidy
  Initial application from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:
  All of the following:
  1 Patient has ADHD (Attention Deficit and Hyperactivity Disorder) diagnosed according to DSM-IV or ICD 10 criteria; and
  2 Once-daily dosing; and
  3 Any of the following:
  3.1 Treatment with a subsidised formulation of a stimulant has resulted in the development or worsening of serious adverse reactions or where the combination of subsidised stimulant treatment with another agent would pose an unacceptable medical risk; or

Level 9, 40 Mercer Street, PO Box 10-254, Wellington 6143, New Zealand
Phone: 64 4 460 4990 - Fax: 64 4 460 4995 - www.pharmac.govt.nz

3.2 Treatment with a subsidised formulation of a stimulant has resulted in worsening of co-morbid substance abuse or there is a significant risk of diversion with subsidised stimulant therapy; or
3.3 An effective dose of a subsidised formulation of a stimulant has been trialled and has been discontinued because of inadequate clinical response; **or**
3.4 Treatment with a subsidised formulation of a stimulant is considered inappropriate because the patient has a history of psychoses or has a first-degree relative with schizophrenia; and

4 The patient will not be receiving treatment with atomoxetine in combination with a subsidised formulation of a stimulant, except for the purposes of transitioning from subsidised stimulant therapy to atomoxetine.

- The restrictions applying to sugammadex (Bridion) inj 100 mg per ml, 2 ml and 5 ml vials, will be amended in the HML from 1 February 2014 as follows (additions in bold):

Any of the following:
1 Patient requires reversal of profound neuromuscular blockade following a rapid sequence induction that has been undertaken using rocuronium (i.e. suxamethonium is contraindicated or undesirable); or
2 Severe neuromuscular degenerative disease where the use of neuromuscular blockade is required; or
3 Patient has an unexpectedly difficult airway that cannot be intubated and requires a rapid reversal of anaesthesia and neuromuscular blockade; or
4 The duration of the patient's surgery is unexpectedly short; or
5 Neostigmine or a neostigmine/anticholinergic combination is contraindicated (for example the patient has ischaemic heart disease, morbid obesity or COPD); or
6 Patient has a partial residual block after conventional reversal.

- Baclofen inj 0.05 mg per ml, 1 ml ampoule and inj 2 mg per ml, 5 ml ampoule (Lioresal Intrathecal) will be listed in Section B of the Pharmaceutical Schedule from 1 February 2014, fully funded at a price and subsidy of $11.55 and $209.29 per injection, respectively, subject to the following prescription endorsement for subsidy:

Subsidy by Endorsement
Subsidised only for use in a programmable pump in patients where oral antispastic agents have been ineffective or have caused intolerable side effects and the prescription is endorsed accordingly.

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
Responders requested that the indications proposed in the consultation letter (severe chronic spasticity of spinal or cerebral origin) not be specified in the baclofen injection subsidy endorsement, as there is a very small number of patients with other conditions who could similarly benefit from treatment.	We have considered this feedback and the specific indication has not been included in the subsidy endorsement.

Theme	Comment
One responder considered that the wording for the new atomoxetine criterion proposed in the consultation letter ("The patient has existing or previous psychoses and/or has a first-degree relative with schizophrenia, and treatment with a subsidised stimulant is considered inappropriate") was not clear and requested that it be made clear.	After considering this feedback we have reworded the criterion to read: "Treatment with a subsidised stimulant is considered inappropriate because the patient has a history of psychoses or has a first-degree relative with schizophrenia."
One responder had a number of queries relating to the status of the proposals in the Application Tracker on PHARMAC's website.	We have written separately to this responder but would like to take this opportunity to note that, while we try our best to keep the Application Tracker up to date, it will not necessarily be completely up to date for every proposal we consult on. In cases where we are aware that the Tracker is not fully up to date we endeavour to include any additional relevant information in the consultation letter – as was the case for these proposals.

More information

If you have any questions about these decisions, you can email us at enquiry@pharmac.govt.nz or call our toll free number (9 am to 5 pm, Monday to Friday) on 0800 66 00 50.