

30 January 2013

Proposal to list sugammadex (Bridion) for reversal of neuromuscular blockade

PHARMAC is seeking feedback on a proposal to list sugammadex (Bridion) in Section H of the Pharmaceutical Schedule (the national Preferred Medicines List (PML)), subject to the restrictions outlined below, from 1 July 2013, through a provisional agreement with Merck Sharp & Dohme as follows:

Chemical	Presentation	Brand	Pack size	Price (ex-man, ex GST)
Sugammadex	Inj 100 mg per ml, 2 ml vial	Bridion	10	\$1,200.00
Sugammadex	Inj 100 mg per ml, 5 ml vial	Bridion	10	\$3,000.00

Sugammadex would be subject to prescribing restrictions in Section H restricting its use in DHB hospitals to patients with an unexpectedly difficult airway that can be ventilated but not intubated and in whom the anaesthetist plans a rapid reversal of anaesthesia and neuromuscular blockade.

As detailed in the background section of this consultation, PHARMAC is aware of other uses for sugammadex. We would be willing to consider widening access subject to a commercially acceptable agreement being reached with the supplier and sufficient funding being available.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **Friday, 15 February 2013** to:

Geraldine MacGibbon
 Therapeutic Group Manager
 PHARMAC

Email: geraldine.macgibbon@pharmac.govt.nz
 Fax: 04 460 4995
 Post: PO Box 10 254, Wellington 6143

All feedback received before the closing date will be considered by PHARMAC's Board (or Chief Executive acting under delegated authority) prior to making a decision on this proposal.

We are not able to treat any part of your feedback as confidential unless you specifically request that we do. If you would like us to withhold any commercially sensitive, confidential proprietary, or personal information included in your submission, please clearly state this in your submission and identify the relevant sections of your submission that you would like withheld.

Feedback we receive is subject to the Official Information Act 1982 (OIA) and we will consider any request to have information withheld in accordance with our obligations under the OIA.

Background

Sugammadex is a selective relaxant binding agent used in hospitals to reverse neuromuscular block induced by rocuronium or vecuronium. An application from the supplier for sugammadex to be funded in DHB hospitals was reviewed by the Analgesic Subcommittee of the Pharmacology and Therapeutics Advisory Committee (PTAC) at its April 2012 meeting. In summary, the Subcommittee recommended that sugammadex be funded with a high priority for five indications as follows:

- patients who require reversal of profound neuromuscular blockade following a rapid sequence induction that has been undertaken using rocuronium (ie suxamethonium contraindicated or undesirable);
- patients with an unexpectedly difficult airway that can be ventilated but not intubated and in whom the anaesthetist plans a rapid reversal of anaesthesia and neuromuscular blockade;
- unexpected short surgical duration;
- patients in whom neostigmine or the neostigmine/anticholinergic combination is contraindicated, such as those with ischaemic heart disease, morbid obesity or COPD; and
- patients with a partial residual block after conventional reversal.

The minutes of the Analgesic Subcommittee meeting were reviewed by the Hospital Pharmaceuticals Subcommittee of PTAC at its September 2012 meeting. The Subcommittee considered that the access restrictions that had been proposed by the Analgesic Subcommittee were very broad, given its current use in DHB hospitals, and that the criteria would position the agent as one for routine use, rather than as an emergency option. The Subcommittee considered that, while sugammadex should be included in a national PML, the overall expenditure on sugammadex under the Analgesic Subcommittee's proposed access criteria would be large, and recommended that PTAC give consideration to refining these criteria further.

The application for funding along with the view of the Analgesic Subcommittee was also reviewed by PTAC at its November 2012 meeting. The Committee considered that the clinical benefits from sugammadex are unclear, but that the benefit in terms of theatre time could be significant, depending on the extent to which sugammadex is used. The Committee agreed with the recommendation to list sugammadex in a national PML, and gave a medium priority to this recommendation for all indications listed above. Members noted that there may be a potential to use sugammadex in other situations, such as patients with myasthenia gravis or muscular dystrophy.

Relevant minutes are available on PHARMAC's website at www.pharmac.govt.nz/2012/11/19/Nervous%20System%20Group%20Web%20Minutes.pdf