Analgesic Subcommittee of PTAC meeting held 24 April 2012

(minutes for web publishing)

Analgesic Subcommittee minutes are published in accordance with the *Terms of Reference for the Pharmacology and Therapeutics Advisory Committee (PTAC) and PTAC Subcommittees 2008*.

Note:

- that this document is not necessarily a complete record of the Analgesic Subcommittee meeting; only the relevant portions of the minutes relating to Analgesic Subcommittee discussions about an Application or PHARMAC staff proposal that contain a recommendation are published.
- that any part of the minutes relating to hospital pharmaceuticals and the establishment of a national Preferred Medicines List (PML) will be released, in a complete publication with the original Hospital Pharmaceuticals Subcommittee minutes and final recommendations made by PTAC, once PTAC have reviewed each therapeutic group.

The Analgesic Subcommittee may:

(a) recommend that a pharmaceutical be listed by PHARMAC on the Pharmaceutical Schedule and the priority it gives to such a listing;
(b) defer a final recommendation, and give reasons for the deferral (such as the supply of further information) and what is required before further review; or
(c) recommend that PHARMAC decline to list a pharmaceutical on the Pharmaceutical Schedule.

These Subcommittee minutes were reviewed by PTAC at its meeting on 2 & 3 August 2012, the record of which will be made available in September 2012.

Contents

1 Phenobarbitone

1.1 The Subcommittee considered a request from the Palliative Care Medications Working Group for phenobarbitone to be funded for use in terminal agitation. Members noted that this had been considered by the Subcommittee in 2009.

1.2 Members considered that the evidence in support of the application was relatively weak, and consisted of review articles rather than clinical trials.

1.3 The Subcommittee considered that phenobarbitone would be used if other agents, such as midazolam and levomepromazine, had proven ineffective. Members considered that in this case, phenobarbitone may provide some benefit.

1.4 The Subcommittee **recommended** that phenobarbitone be listed in the Pharmaceutical Schedule, and gave a high priority to this recommendation.

1.5 The Subcommittee considered that phenobarbitone should be restricted to use in terminal agitation that is unresponsive to other agents, and that it be utilised within a multidisciplinary team working in palliative care.

1.6 The Subcommittee considered that the Decision Criteria particularly relevant to this recommendation are: *(i) the health needs of all eligible people within New Zealand; (iii) the availability and suitability of existing medicines, therapeutic medical devices and related products and related things; (iv) the clinical benefits and risks of pharmaceuticals; and (v) The cost-effectiveness of meeting health needs by funding pharmaceuticals rather than using other publicly funded health and disability support services.*

2 Pregabalin (Lyrica) for neuropathic pain

Application

2.1 The Subcommittee considered a proposal from PHARMAC staff, following PTAC's review of a funding application from Pfizer for pregabalin (Lyrica), for the treatment of neuropathic pain. The Subcommittee considered the appropriate Special Authority criteria and treatment sequencing for pregabalin.

Recommendation

2.2 The Subcommittee **recommended** that pregabalin be listed in the Pharmaceutical Schedule with a medium priority. The Subcommittee recommended that the following Special Authority criteria apply to pregabalin (Lyrica) should it be funded:

> **Initial application** – (neuropathic pain) from any relevant practitioner. Approvals valid for 3 months where the patient has, been unresponsive or unable to tolerate treatment following a reasonable trial with therapeutic doses of tricyclic antidepressant therapy.
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> **Renewal** – from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:
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> Either:
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> a. The patient has demonstrated a marked improvement in their pain control (prescriber determined); or

b. The patient has previously demonstrated clinical responsiveness to pregabalin and has now developed neuropathic pain in a new site.

Note: Not to be used in combination with gabapentin

Discussion

2.3 The Subcommittee noted PTAC's review of the funding application from Pfizer for pregabalin for the treatment of neuropathic pain and its recommendation that the Subcommittee consider appropriate Special Authority criteria and treatment sequencing should pregabalin be funded.

2.4 The Subcommittee noted that four randomised controlled trials (van Seventer et al. Curr Med Res Opin 2006; 22(2): 375-84, Stacey et al. J Pain 2008; 9: 1006-1017, Moon et al. Clin Ther 2010;32(14):2370-85, van Seventer et al. Eur J Neurol 2010; 17: 1082-9) and several cohort studies (Stacey et al. Pain Med 2008; 9(8): 1202-8, Freynhagen et al. Int J Clin Pract. 2007 Dec;1989-96, Toth et al. Pain Med. 2010 Mar;11(3):456-65, Lampl et al. J Neurol. 2010;257:1265-73) formed the basis of the evidence in the application. The Subcommittee considered that the studies had a high drop-out rate in both arms, and that efficacy was only achieved at higher dose ranges (600mg daily); however these patients noted a higher rate of dizziness and somnolence.

2.5 The Subcommittee noted that the NICE guidelines (NICE clinical guideline 96; www.nice.org.uk/guidance/CG96) recommend that pregablin be used as second line therapy for neuropathic pain and that gabapentin does not feature in its recommendations.

2.6 The Subcommittee considered that pregabalin has a similar effect to gabapentin, however pregabalin has slightly different pharmacokinetics. The Subcommittee considered the benefits of pregablin to be more complete absorption and faster onset time and decreased incidence of side effects such as leg swelling.

2.7 The Subcommittee considered that it is likely that if funded, pregabalin is likely to be prescribed in preference to gabapentin. The Subcommittee considered that there is little evidence to show that patients who do not respond to gabapentin would respond to pregabalin and therefore would not consider pregabalin as a third line treatment.

2.8 The Subcommittee considered that pregabalin would have similar market dynamics to gabapentin with patients taking treatment for similar duration. The Subcommittee considered that treatment would continue for some months for the treatment of post herpetic neuralgia and some years for peripheral diabetic neuropathy.

2.9 The Subcommittee considered that restricting pregabalin for peripheral diabetic neuropathy and post herpetic neuralgia could be difficult, and considered that if listed as a second line agent, it should be subject to the same access criteria as gabapentin. The Subcommittee noted that there may be a risk of indication creep if pregabalin was listed for indications such as fibromyalgia or neuropathic pain of malignant origin.