

30 September 2009

Funding for mirtazapine (Avanza) approved

PHARMAC is pleased to announce the approval of an agreement with Schering-Plough to fund the antidepressant mirtazapine (Avanza), subject to Special Authority restrictions, from 1 November 2009.

Details of the decision

Mirtazapine (Avanza) tablets will be listed in Section B, and in Part II of Section H, of the Pharmaceutical Schedule from 1 November 2009 at the following prices and subsidies (expressed ex-manufacturer, excluding GST):

Pharmaceutical	Brand	Form and Strength	Pack Size	Price and subsidy
Mirtazapine	Avanza	Tablet 30 mg	30	\$22.00
Mirtazapine	Avanza	Tablet 45 mg	30	\$35.00

Schering-Plough does not intend to register a 15 mg tablet strength of Avanza in New Zealand; however, we note that the 30 mg tablet is scored.

The Special Authority criteria that will apply to the funding of mirtazapine are as follows (bold text indicates changes made following consultation on the proposed criteria, as explained later in this notification letter):

Initial application from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Both:

- 1 The patient has a severe major depressive episode; and
- 2 Either:
 - 2.1 The patient must have had a trial of two different antidepressants and **was unable to tolerate the treatments or** failed to respond to an adequate dose over an adequate period of time (usually at least four weeks); or
 - 2.2 Both:
 - 2.2.1 The patient is currently a hospital in-patient as a result of an acute depressive episode; and
 - 2.2.2 The patient must have had a trial of one other antidepressant and **either could not tolerate it or** failed to respond to an adequate dose over an adequate period of time.

Renewal from any relevant practitioner. Approvals valid for 2 years where the patient has a high risk of relapse (prescriber determined).

Avanza will have protection from subsidy reduction and delisting until 1 July 2012.

Feedback received

We appreciate all of the feedback that we received and acknowledge the time people took to respond. Most responses were supportive of the proposal; however some responders requested changes to the Special Authority criteria that were originally proposed.

We sought advice from the Mental Health Subcommittee of the Pharmacology and Therapeutics Advisory Committee about these requests. As advised on the first page of this notification letter, some changes were subsequently made to the wording of the approved Special Authority criteria as a result of the Subcommittee's recommendations. The relevant excerpt from the minutes of the July 2009 meeting of the Subcommittee is as follows:

The Subcommittee noted that during consultation on a proposal to fund mirtazapine PHARMAC had received requests from several consultation responders to change the proposed access criteria, to include patients with moderate depression and patients intolerant to other antidepressants and to allow the use of mirtazapine as a first-line option in psychogeriatric patients and those in whom the presence of significant co-morbidities such as cancer and HIV infection would preclude the use of other antidepressants.

The Subcommittee considered that, given the significant price differential between mirtazapine and most other funded antidepressants, restricting its use to patients with severe depression was appropriate at this time.

The Subcommittee considered that the request to include patients intolerant to other antidepressants was reasonable and, accordingly, **recommended** that the relevant criteria be amended to the following (additions in bold):

Initial application from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Both:

The patient has a severe major depressive episode; and

Either:

The patient must have had a trial of two different antidepressants and **was unable to tolerate the treatments or** failed to respond to an adequate dose over an adequate period of time (usually at least four weeks); or

Both:

The patient is currently a hospital in-patient as a result of an acute depressive episode; and

The patient must have had a trial of one other antidepressant **and either could not tolerate it or** failed to respond to an adequate dose over an adequate period of time.

Renewal from any relevant practitioner. Approvals valid for 2 years where the patient has a high risk of relapse (prescriber determined).

The Subcommittee considered that there were other, less expensive, first-line antidepressant treatment options, for example selective serotonin reuptake inhibitors, moclobemide, and tricyclic agents, that it would be reasonable to consider for psychogeriatric patients or those with significant co-morbidities and, therefore, there was no compelling reason to change the criteria for mirtazapine to allow first-line use in these patient groups. The Subcommittee noted that it would be willing to reconsider the issue if evidence was provided in support of the use of mirtazapine instead of the other treatment options as a first-line agent in these patient groups.

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.