

8 June 2011

Funding of olanzapine depot injection, raloxifene and teriparatide approved

PHARMAC is pleased to announce the approval of an agreement with Eli Lilly and Company (NZ) Limited to fund a new depot antipsychotic injection and two new treatments for osteoporosis from 1 July 2011.

This was the subject of a consultation letter dated 5 April 2011, which can be found on PHARMAC's website at www.pharmac.govt.nz/2011/04/05.

In summary, the effect of the decision is as follows (all changes from 1 July 2011):

- olanzapine depot injection (Zyprexa Relprevv) will be funded subject to Special Authority restrictions for patients with schizophrenia who are non compliant with oral medications and who have been admitted to hospital or treated in respite care, or intensive outpatient or home-based treatment, for 30 days or more in the last 12 months;
- teriparatide (Forteo) will be funded subject to Special Authority restrictions as a last-line treatment for osteoporosis; and
- raloxifene (Evista) will be funded for patients with osteoporosis subject to Special Authority restrictions similar to those that currently apply to alendronate and zoledronic acid.

Details of the decision and consultation feedback information can be found below and on the following pages.

Details of the decision

Olanzapine depot injection

- Olanzapine depot injection (Zyprexa Relprevv) will be listed in Section B, and in Part II of Section H, of the Pharmaceutical Schedule from 1 July 2011 at the following prices and subsidies (ex-manufacturer, excluding GST):

Chemical	Form	Strength	Brand	Pack size	Price and subsidy
Olanzapine pamoate monohydrate	Injection	210 mg	Zyprexa Relprevv	1	\$280.00
Olanzapine pamoate monohydrate	Injection	300 mg	Zyprexa Relprevv	1	\$460.00
Olanzapine pamoate monohydrate	Injection	405 mg	Zyprexa Relprevv	1	\$560.00

- Olanzapine depot injection listed in Section B of the Pharmaceutical Schedule will be funded subject to the following Special Authority restrictions:

Initial application from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 The patient has schizophrenia; and
- 2 The patient has tried but failed to comply with treatment using oral atypical antipsychotic agents; and
- 3 The patient has been admitted to hospital or treated in respite care, or intensive outpatient or home-based treatment for 30 days or more in the last 12 months.

Renewal from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Either:

- 1 Both:
 - 1.1 The patient has had less than 12 months' treatment with olanzapine depot injection; and
 - 1.2 There is no clinical reason to discontinue treatment; or
- 2 The initiation of olanzapine depot injection has been associated with fewer days of intensive intervention than was the case during a corresponding period of time prior to the initiation of olanzapine depot injection.

Note: The patient should be monitored for post-injection syndrome for at least three hours after each injection.

- Zyprexa Relprevv will be subject to a confidential rebate.

Teriparatide

- Teriparatide (Forteo) injection 250 µg per ml, 2.4 ml will be listed in Section B, and in Part II of Section H, of the Pharmaceutical Schedule from 1 July 2011 at a price and subsidy of \$490.00 per injection cartridge (ex-manufacturer, excluding GST).
- Teriparatide listed in Section B of the Pharmaceutical Schedule will be funded subject to the following Special Authority restrictions:

Initial application from any relevant practitioner. Approvals valid for 18 months for applications meeting the following criteria:

All of the following:

- 1 The patient has severe, established osteoporosis; and
- 2 The patient has a documented T-score less than or equal to -3.0 (see Notes); and
- 3 The patient has had two or more fractures due to minimal trauma; and
- 4 The patient has experienced at least one symptomatic new fracture after at least 12 months' continuous therapy with a funded antiresorptive agent at adequate doses (see Notes).

Notes:

- a) The bone mineral density (BMD) measurement used to derive the T-score must be made using dual-energy x-ray absorptiometry (DXA). Quantitative ultrasound and quantitative computed tomography (QCT) are not acceptable.
- b) Antiresorptive agents and their adequate doses for the purposes of this Special Authority are defined as: alendronate sodium tab 70 mg or tab 70 mg with cholecalciferol 5,600 iu once weekly; raloxifene hydrochloride tab 60 mg once daily; zoledronic acid 5 mg per year. If an intolerance of a severity necessitating permanent treatment withdrawal develops during the use of one antiresorptive agent, an alternate antiresorptive agent must be trialed so that the patient achieves the minimum requirement of 12 months' continuous therapy.
- c) A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that

- body, or a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.
- d) A maximum of 18 months of treatment (18 cartridges) will be subsidised.

- Forteo will be subject to a confidential rebate.

Raloxifene

- Raloxifene hydrochloride (Evista) 60 mg tablets will be listed in Section B, and in Part II of Section H, of the Pharmaceutical Schedule from 1 July 2011 at a price and subsidy of \$53.76 per 28 tablets (ex-manufacturer, excluding GST).
- Raloxifene hydrochloride listed in Section B of the Pharmaceutical Schedule will be funded subject to the following Special Authority restrictions:

Initial application from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Any of the following:

- 1 History of one significant osteoporotic fracture demonstrated radiologically and documented bone mineral density (BMD) ≥ 2.5 standard deviations below the mean normal value in young adults (i.e. T-Score ≤ -2.5) (see Notes); or
- 2 History of one significant osteoporotic fracture demonstrated radiologically, and either the patient is elderly, or densitometry scanning cannot be performed because of major logistical, technical or pathophysiological reasons. It is unlikely that this provision would apply to many patients under 75 years of age; or
- 3 History of two significant osteoporotic fractures demonstrated radiologically; or
- 4 Documented T-Score ≤ -3.0 (see Notes); or
- 5 A 10-year risk of hip fracture $\geq 3\%$, calculated using a published risk assessment algorithm (e.g. FRAX or Garvan) which incorporates BMD measurements (see Notes); or
- 6 Patient has had a prior Special Authority approval for zoledronic acid (Underlying cause – Osteoporosis) or alendronate (Underlying cause - Osteoporosis).

Notes:

- a) BMD (including BMD used to derive T-Score) must be measured using dual-energy x-ray absorptiometry (DXA). Quantitative ultrasound and quantitative computed tomography (QCT) are not acceptable.
- b) Evidence used by the UK National Institute for Health and Clinical Excellence (NICE) in developing its guidance indicates that patients aged 75 years and over who have a history of significant osteoporotic fracture demonstrated radiologically are very likely to have a T-Score ≤ -2.5 and, therefore, do not require BMD measurement for raloxifene funding.
- c) Osteoporotic fractures are the incident events for severe (established) osteoporosis, and can be defined using the WHO definitions of osteoporosis and fragility fracture. The WHO defines severe (established) osteoporosis as a T-score below -2.5 with one or more associated fragility fractures. Fragility fractures are fractures that occur as a result of mechanical forces that would not ordinarily cause fracture (minimal trauma). The WHO has quantified this as forces equivalent to a fall from a standing height or less.
- d) A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

- Evista will be subject to a confidential rebate.

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. Some common themes were raised in relation to specific aspects of the proposal, which are summarised below along with PHARMAC's comments.

Theme of Response	Comment
Given the requirement for three-hour monitoring for post-injection syndrome following administration of olanzapine depot injection, responders considered that the most appropriate place to administer this pharmaceutical would be a community mental health centre or similar. However, the funding rules currently prevent community-funded medicines from being administered in hospital outpatient centres, which includes community mental health centres.	We are aware of this issue and understand that it is not unique to olanzapine depot injection. We will be working with DHBs to address this issue in the coming months.
Some responders were concerned that prescribers may not be sufficiently aware of the requirement for three-hour monitoring for post-injection syndrome following administration of olanzapine depot injection, which could potentially cause safety problems.	A note has been added to the Special Authority for olanzapine depot injection advising that patients should be monitored for post-injection syndrome for at least three hours after each injection.
Some responders considered that the proposed Special Authority criteria for teriparatide were not clinically appropriate for a variety of reasons.	The Special Authority criteria have been revised in consultation with the Osteoporosis Subcommittee of PTAC and other specialists. We note that the high cost of teriparatide relative to other funded treatments is a key reason for the requirement for other treatments to be tried prior to teriparatide.
Although generally supportive of the funding of olanzapine depot injection, some responders were concerned that funding olanzapine depot injection would preclude consideration of funding another new depot antipsychotic, paliperidone depot injection.	The decision to fund olanzapine depot injection does not preclude PHARMAC from considering the funding of paliperidone depot injection – or indeed the funding of any other pharmaceutical. Interested parties can monitor the status of the funding application for paliperidone depot injection using the Application Tracker on PHARMAC's website at www.pharmac.govt.nz . The status of the paliperidone depot injection application remains unchanged following the decision to fund olanzapine depot injection.

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.