November 2006 PBAC OUTCOMES – Results of Independent Review

Drug And Form	Listing Requested By Sponsor	Sponsor's Reasons For Seeking Review	Results Of Independent Review	Pbac Outcome And Comments
TERIPARATIDE, cartridge 3 mL, 250 micrograms/mL, Forteo®. Eli Lilly Australia Pty Ltd <u>TGA INDICATION</u> For the treatment of osteoporosis in postmenopausal women and the treatment of primary osteoporosis in men when other agents are considered unsuitable and when there is a high risk of fractures.	Authority required listing for Treatment by a specialist/ consulting physician treating osteoporosis for severe established vertebral osteoporosis in men and postmenopausal women who: 1. have evidence of one or more severe painful osteoporotic vertebral fracture and 2. have received at least 6 continuous months of anti-resorptive therapy of proven efficacy and safety at the time of the SQ3 vertebral fracture. A severe vertebral fracture is defined as 40% reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, greater than 40% reduction in any of these heights compared to the vertebral body above or below the affected vertebral body. Evidence of the fracture/deformity must be demonstrated radiologically and the year of plain x-ray or CT-	The issues upon which review is sought are: (a) PBAC concern that the indirect comparison and subgroup analysis does not support the claim of superiority, (b) PBAC's claim that the submission provides no evidence to suggest any biologically plausible reason to explain the claimed difference between teriparatide and the comparator. (c) PBAC concern with regard to continuing use of the same utility values in spite of the sponsor's efforts to address these concerns in its responses.	"The deficiencies in the cost utility analysis are amenable to correction with further work and analysis. However, the correction of the utility analysis will not overcome the inherent problems in the primary clinical outcome analysis, which forms the basis for the cost utility analysis. There is insufficient rigor in the clinical trial data analysis to recommend acceptance of the material presented in the submissions. In particular, the validity and robustness of the post-hoc subgroup analysis is a major deficiency. This results in an interpretation of unclear therapeutic benefit for teriparatide over comparator therapy."	The PBAC acknowledged the findings of the independent review. The PBAC considered that the review provided no new basis to warrant reconsideration of the PBAC's previous recommendation in March 2006. The PBAC acknowledged the reviewer's comments regarding the new Guidelines and requested they be referred to the Economic Sub-Committee.

	scan or MRI scan must be included in the authority application. Antiresorptive therapies for osteoporosis which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg/day or 70 mg QW, risedronate sodium 5 mg/day or 35 mg QW; raloxifene hydrochloride 60 mg/day (women only); etidronate 200 mg with calcium carbonite 1.25 g/day. Patients with 6 months continuous prior treatment with strontium ranelate will also be eligible under the administration of this listing. If treatment with the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use, the patient is exempted form the requirement to complete 6 continuous months of therapy with that particular agent or class of agents. Details of the contraindication or intolerance must be provided at the time of application.			
			Sponsor's comments:	The sponsor will be considering its position regarding any future course of action, but refers you to its own website (www.lilly.com.au) for further information.

	Continuing treatment where the patient has previously been issued with an authority prescription for this drug. Teriparatide is available with a lifetime maximum of 18 months teriparatide therapy (18 pens), a maximum of 18 pens will be reimbursed through the PBS.			