

**March 2006 PBAC OUTCOMES - "Subsequent" Decisions not to Recommend**

DRUG AND FORM	TGA INDICATION	CURRENT PBS LISTING	LISTING REQUESTED BY SPONSOR	PBAC OUTCOME AND COMMENTS
<p>FENTANYL CITRATE, lozenge with applicator, 200 microgram, 400 microgram, 600 microgram, 800 microgram, 1200 microgram, 1600 microgram, Actiq® Orphan Australia</p> <p>Minor Submission</p>	<p>For the management of breakthrough cancer pain in patients with malignancies who are already receiving and are tolerant to opioid therapy for their underlying persistent cancer pain.</p>	<p>Not PBS-listed</p>	<p>Authority required for the management of breakthrough cancer pain in palliative care patients who are receiving opioids for their underlying persistent cancer pain where morphine is contraindicated due to: renal impairment defined as estimated glomerular filtration rate of less than 50 mL/min; or documented adverse reaction to other S8 opioids which require cessation or change of therapy.</p>	<p>The PBAC is sympathetic to the need of palliative care patients for an alternative to morphine for use in breakthrough pain and acknowledged that the overall patient population is likely to be small. However the Committee considered that the current minor submission does not provide sufficient information to enable it to reach a decision on the cost-effectiveness of fentanyl. As required by the Guidelines, a major re-submission would need to be submitted for evaluation for consideration by the PBAC.</p> <p>The submission was therefore rejected.</p>
			<p><i>Sponsor's comments</i></p>	<p>The sponsor disagrees with the decision.</p>
<p>RISPERIDONE, powder for I.M. injection, 25 mg, 37.5 mg and 50 mg (modified release) with 2 mL diluent in pre-filled syringe,</p>	<p>For the treatment of schizophrenia and related psychoses</p>	<p>Authority required for schizophrenia.</p>	<p>List under section 100 highly specialised drug (HSD) program for the treatment of schizophrenia in patients whose illness requires supervision and treatment at hospital outpatient clinics or affiliated mental health centres.</p>	<p>The PBAC noted that the Highly Specialised Drugs Working Party (HSDWP) continues not to support listing under the section 100 HSD program, in spite of the survey presented to the HSDWP and in this submission.</p>

<p>Risperdal Consta<sup>®</sup>, Janssen-Cilag Pty Ltd</p>			<p>NB. The submission requested listing under section 100 in addition to the existing authority required listing</p>	<p>The PBAC was not convinced that availability under section 100 would address the submission's claimed problems with patient access. The survey submitted did not provide sufficient evidence to support the extension of the listing under section 100. The PBAC therefore rejected the submission.</p>
<p>TERIPARATIDE, cartridge 3 mL, 250 micrograms/mL, Forteo<sup>®</sup>. Eli Lilly Australia Pty Ltd</p> <p>Major Submission</p>	<p>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.</p>	<p>Not PBS listed</p>		<p>The PBAC accepted there is a strong clinical need for an effective treatment for patients with osteoporosis who continue to have symptomatic vertebral fractures whilst receiving a bisphosphonate, with calcium and vitamin D supplementation, but rejected the submission because of uncertain clinical benefit and the resulting uncertain and unacceptable cost-effectiveness.</p>
			<p>Authority required Treatment by a specialist/consulting physician treating osteoporosis for severe established vertebral osteoporosis in men and postmenopausal women who:</p> <ol style="list-style-type: none"> <li>1. have evidence of one or more severe painful osteoporotic</li> </ol>	<p>Accepted</p>
			<p><i>Sponsor's comments</i></p>	<p>The sponsor has no comment.</p>

			<p>vertebral fracture and</p> <p>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.</p> <p>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.</p> <p>Evidence of the fracture/deformity must be demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be included in the authority application.</p> <p>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 carbonate 1.25 g/day. Patients with 6 months continuous prior treatment with strontium ranelate will also be eligible under the administration of this listing.</p>	
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			Comparator: Alendronate sodium	Accepted
			Clinical claim: Teriparatide has significant clinical advantages over alendronate.	Not accepted. The PBAC noted that the submission relied on an indirect comparison across placebo-controlled trials to infer the superiority claim for teriparatide over alendronate rather than a

				<p>head-to-head randomised trial. Further, the submission used the results of the post hoc sub-group analysis in place of the overall ITT results for teriparatide to support the clinical claim and the economic claim.</p>
			Economic claim: Cost-effectiveness	<p>Not accepted. In addition to the use of the post hoc sub-group analysis instead of the overall ITT results noted above, there was further uncertainty because of the continuing use of the same utilities and disutilities as in the previous submission in the model, where the sensitivity analyses indicate the model is sensitive to the assumptions used to derive the incremental utility estimates from the trial-based outcome measures.</p>
			Sponsor's comments:	<p>The sponsor disagrees with the decision and is considering its position regarding any future course of action, but refers you to its website (<a href="http://www.lilly.com.au">www.lilly.com.au</a>) for further information.</p>