

March 2006 PBAC OUTCOMES - Deferrals

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC OUTCOME AND COMMENT
<p>DORNASE ALFA, solution for inhalation, 2.5 mg (2,500 units) in 2.5 mL ampoule, Pulmozyme[®], Roche Products Pty Ltd Minor submission</p>	<p>Treatment for cystic fibrosis</p>	<p>A change to the restriction to allow children less than 5 years of age to receive treatment.</p>	<p>The PBAC considered that an alternative means of assessing clinical response would need to be defined in this younger age group, as younger children are not able to perform spirometry adequately. The PBAC decided to defer the submission to seek expert advice from paediatric respiratory specialist physicians on any appropriate measure of clinical response to dornase alfa. It was also suggested that advice be sought on the suitability of the current restriction from both paediatric and adult respiratory physicians.</p>
		<p><i>Sponsor's comments</i></p>	<p>The sponsor has no comment.</p>

March 2006 PBAC OUTCOMES - "Subsequent" Decisions to Defer

DRUG AND FORM	TGA INDICATION	CURRENT PBS LISTING	LISTING REQUESTED BY SPONSOR	PBAC OUTCOME AND COMMENTS
<p>INSULIN DETEMIR (rys) cartridge 3mL (Penfill[®]), prefilled device 3 mL (FlexPen[®]), 100 U/mL, Levemir[®],</p> <p>Novo Nordisk Pty Ltd</p> <p>Major submission</p>	<p>Treatment of diabetes mellitus where used as basal insulin in combination with meal-related short- or rapid-acting insulin. Not recommended for diabetes mellitus type 2 patients who still respond to oral hypoglycaemic agents.</p>	<p>Not listed on the PBS</p>	<p>Restricted Benefit listing for treatment of type 1 or type 2 diabetes patients requiring intensive insulin therapy with 3 or more injections of insulin per day with one of the insulins being a short acting insulin. Type 1 or Type 2 patients with a documented protamine allergy.</p>	<p>The PBAC again acknowledged the clinical need for an insulin product that reduces hypoglycaemic events without compromising long-term diabetic control as measured using HbA1c. The PBAC was concerned that the submission had applied undue status to the outcomes of the stakeholder meeting in October 2005. The meeting was conducted without prejudice and was not binding on any party.</p> <p>The Committee noted that the indirect comparison provided in the submission showed that there was no statistically significant difference between insulin detemir and insulin glargine for change in HbA1c, FPG and weight, and reductions in hypoglycaemic events, for Type I and II patients combined and Type I patients alone.</p> <p>The PBAC did not consider the price advantage requested over insulin NPH in the submission was justified. The PBAC made a pricing offer consistent with this consideration. The submission was therefore deferred to seek comment</p>

				<p>from the sponsor on the proposal. The PBAC agreed to consider the matter again out of session if the sponsor agreed this proposal. Any update to this information will be posted on this website.</p>
			<i>Sponsor's comments:</i>	The sponsor is considering the PBAC proposal.
<p>INSULIN GLARGINE, injection, 100 units per mL, 10 mL vials and 3 mL x 5 cartridges, Lantus®</p> <p>Sanofi-Aventis Group</p> <p>Major submission</p>	<p>For once daily subcutaneous administration in the treatment of type 1 diabetes mellitus in adults and children and type 2 diabetes mellitus in adults who require insulin for the control of hyperglycaemia</p>	<p>Not listed on the PBS.</p>	<p>The submission requested one of two options for a Restricted Benefit listing:</p> <p><u>Either:</u> For the treatment of Type 1 diabetes; For the treatment of Type 2 diabetes when used in combination with three or more prandial doses of insulin per day; For the treatment of patients with diabetes who have documented systemic protamine hypersensitivity.</p> <p><u>or:</u> For the treatment of diabetes when used in combination with three or more prandial doses of</p>	<p>The PBAC again acknowledged the clinical need for an insulin product that reduces hypoglycaemic events without compromising long-term diabetic control as measured using HbA1c. The PBAC did not consider the price advantage requested over insulin NPH in the submission was justified. The PBAC made a pricing offer consistent with this consideration. The submission was therefore deferred to seek comment from the sponsor on this proposal. The PBAC agreed to consider the matter again out of session if the sponsor agreed the proposal.</p> <p>Link to further decision by the PBAC.</p>

			insulin per day; For the treatment of patients with diabetes who have documented systemic protamine hypersensitivity.	
			<i>Sponsor's comments</i>	sanofi-aventis will continue to work with the PBAC to find a way forward for patients with diabetes.