

March 2011 PBAC MEETING OUTCOMES - "Subsequent" decisions not to recommend

DRUG AND FORM	TGA INDICATION	CURRENT PBS LISTING	LISTING REQUESTED BY SPONSOR	PBAC OUTCOME AND COMMENTS
<p>Amino acids - synthetic, formula, compound powder, 400 g, Neocate Nutra®</p> <p>Nutricia Australia Pty Ltd</p> <p>Minor submission</p>	<p>Neocate Nutra is not a therapeutic good and does not require registration with the TGA. It is classified with Food Standards Australia New Zealand as a 'food for special medical purposes'.</p>	<p>Not currently PBS listed</p>		<p>The PBAC rejected the submission on the basis of uncertain clinical need and uncertain but likely high and inappropriate utilisation.</p>
			<p>Listing requested: <u>Authority required</u> Use in a child meeting certain criteria in the following conditions: - combined intolerance (not infant colic) to cow's milk protein, soy protein and protein hydrosylate formulas - severe intolerance (not infant colic) to cows' milk protein - severe intestinal malabsorption including short bowel syndrome.</p>	<p>The PBAC was concerned about utilisation outside of the restriction, such as use in infants with reflux and eosinophilic oesophagitis, neither of which would be PBS-subsidised.</p>
			<p>Clinical claim: An amino acid based product suitable for weaning which aims to ensure normality in the diet by providing an alternative format to liquid formulations.</p>	<p>The PBAC considered there was potential for Neocate Nutra to be used as a substitute for other non-prescription forms of semi-solids (e.g. rice cereal).</p>
			<p>Economic claim: Nil</p>	<p>The PBAC also considered that there was potential for overuse or misuse of the product, which would result in increased costs to the Government.</p>
			<p>Sponsor's comments:</p>	<p>Although disappointed with the outcome of the March 2011 PBAC meeting, Nutricia Australia Pty Ltd will continue to make Neocate Nutra available to patients with Cow's Milk Protein Allergy (CMPA), multiple food allergies (MFPA) and severe malabsorption, subject to the</p>

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<p>Paricalcitol, capsule, 1 microgram and 2 microgram, Zemplar®</p> <p>Abbott Australasia Pty Ltd</p> <p>Major submission</p>	<p>Treatment for the biochemical manifestations of secondary hyperparathyroidism associated with chronic kidney disease, stages 3, 4 and 5.</p>	<p>Not currently PBS listed.</p>	<p>advice/recommendation of a healthcare professional.</p>	<p>The PBAC rejected the submission because of uncertain clinical benefit and uncertain cost effectiveness.</p>
			<p>Listing requested: <u>Authority Required</u> Treatment of secondary hyperparathyroidism in patients with chronic kidney disease where treatment with calcitriol is not appropriate.</p>	
			<p>Comparator: Placebo</p>	<p>Accepted in those patients with chronic kidney disease (CKD) who are not receiving dialysis for the proposed restriction – ‘...where treatment with calcitriol is not appropriate’.</p>
			<p>Clinical claim: Paricalcitol is superior in terms of comparative effectiveness and equivalent in terms of comparative safety over placebo.</p>	<p>Accepted. However, the PBAC noted that although paricalcitol is highly effective at reducing levels of iPTH, it is unclear whether this translates to final outcomes such as reduction in fractures, cardiovascular events or improved survival.</p>
			<p>Economic claim: Cost-effectiveness</p>	<p>Not accepted. A number of uncertainties were identified with modelled economic evaluation, such as modelling the difference in overall survival, non-fatal cardiovascular events and fractures between paricalcitol and standard care when no causal relationship between reducing iPTH and reducing the risk</p>

				of mortality had been demonstrated. Therefore, the PBAC considered the incremental cost-effectiveness ratio remained uncertain.
			Sponsor's comments:	The sponsor has no comment.