

**14.03 AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED  
with LONG CHAIN POLYUNSATURATED FATTY ACIDS  
and MEDIUM CHAIN TRIGLYCERIDES  
oral liquid: powder for, 400 g,  
Alfamino® and Alfamino® Junior, Nestlé Health Science  
(Nestlé Australia Ltd)**

**1 Purpose of Application**

- 1.1 For Alfamino®, the minor submission requested an Authority Required listing for patients with eosinophilic oesophagitis and patients with severe intestinal malabsorption including short bowel syndrome.
- 1.2 For Alfamino® Junior, the minor submission requested an Authority Required listing for patients with eosinophilic oesophagitis.

**2 Requested listing**

- 2.1 The submission requested restrictions in line with comparable products.

**3 Background**

- 3.1 The sponsor of Alfamino® and Alfamino® Junior has previously confirmed that they meet the requirements for foods that have medical purposes as set out under *The Australia New Zealand Food Standards Code — Standard 2.9.5: Food for Special Medical Purposes*.
- 3.2 At its July 2013 meeting, the PBAC recommended listing Alfamino® as an Authority required benefit for the same indications as those applying to Neocate® Gold, on a cost-minimisation basis compared to Neocate Gold and at an equivalent price per gram of protein.
- 3.3 At its March 2015 meeting, the PBAC recommended an Authority Required listing for Alfamino® Junior for the same conditions as the existing Alfamino® product listed on the PBS, as well as for severe intestinal malabsorption including short bowel syndrome.

**4 Comparator**

- 4.1 For Alfamino®, the minor submission nominated Neocate® Gold as the comparator.
- 4.2 For Alfamino® Junior, the minor submission nominated Neocate® Advance, which the PBAC has previously accepted is similar to Neocate Advance Vanilla (a flavoured version of Neocate® Advance) and EleCare®. As a minor submission, there was no economic comparison.
- 4.3 The PBAC has previously accepted that these comparators are appropriate.

## **5 Consideration of the evidence**

### ***Sponsor hearing***

5.1 There was no hearing for this item as it was a minor submission.

### ***Consumer comments***

5.2 The PBAC noted that no consumer comments were received for this item.

### ***Clinical trials***

5.3 No clinical data was provided in this submission.

5.4 In consideration of the submission, the Nutritional Products Working Party (NPWP) noted:

- Alfamino® Junior was recommended by the NPWP and PBAC for listing at the March 2015 meeting, but that this listing has not yet been implemented, as of 1 October.
- The addition of indications for eosinophilic oesophagitis and severe intestinal malabsorption including short bowel syndrome would bring the listing for Alfamino® and Alfamino Junior® in line with listings for comparable products.
- The PBAC has previously stated that Alfamino® is a comparable product to Neocate Gold®, and Alfamino® Junior is a comparable product to Neocate Advance®, which PBAC has concluded is in turn similar to Neocate Advance® Vanilla and Elecare®.
- No changes to current pricing arrangements were requested, and the submission was therefore considered to be cost neutral to the PBS.

### ***Estimated PBS usage & financial implications***

5.5 The submission proposed no changes to current pricing arrangements, and the listing of these items for additional conditions is expected to be cost-neutral to the PBS.

## **6 PBAC Outcome**

6.1 The PBAC recommended the listing of Alfamino® as an Authority Required Benefit for patients with eosinophilic oesophagitis and patients with severe intestinal malabsorption, with no changes to current pricing arrangements.

6.2 The PBAC recommended the listing of and Alfamino® Junior as an Authority Required Benefit for patients with eosinophilic oesophagitis, with no changes to current pricing arrangements.

6.3 The PBAC noted the advice of the Nutritional Products Working Party that supported the listing of Alfamino® and Alfamino® Junior on the PBS for the requested indications.

- 6.4 The PBAC recommended that the restriction wording for these indications align with currently listed products, and that the following Administrative Advice apply: “Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.”
- 6.5 The PBAC noted that the submission estimated a nil cost to the PBS.
- 6.6 For the requested indications, the PBAC recommended that Alfamino® and Alfamino® Junior are suitable for inclusion in the PBS medicines for prescribing by nurse practitioners within collaborative arrangements.
- 6.7 The PBAC recommended that the Safety Net 20 Day Rule should not apply as it has been the PBAC’s view that general nutrients be exempt.

**Outcome:**

Recommended

**7 Recommended listing**

- 7.1 Add additional indications to existing listings as follows:

Eosinophilic oesophagitis

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer	
AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES oral liquid: powder for, 400 g	8	5	Alfamino®	Nestlé Australia Ltd
AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES oral liquid: powder for, 400 g	8	5	Alfamino® Junior	Nestlé Australia Ltd

<b>Category / Program</b>	GENERAL – General Schedule (Code GE)
<b>Prescriber type:</b>	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
<b>PBS Indication:</b>	Eosinophilic oesophagitis
<b>Treatment phase:</b>	Initial treatment for up to 3 months
<b>Restriction Level / Method:</b>	<input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required - In Writing <input checked="" type="checkbox"/> Authority Required - Telephone <input checked="" type="checkbox"/> Authority Required – Emergency <input checked="" type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined

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<b>Treatment criteria</b>	Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.
<b>Clinical criteria:</b>	Patient must require an amino acid based formula as a component of a dietary elimination program.
<b>Population criteria:</b>	Patient must be 18 years of age or less.
<b>Prescriber Instructions</b>	<p>Treatment with oral steroids should not be commenced during the period of initial treatment.</p> <p>Eosinophilic oesophagitis is demonstrated by the following criteria:</p> <p>(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and</p> <p>(ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and</p> <p>(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.</p> <p>The date of birth of the patient must be included in the authority application.</p>
<b>Administrative Advice</b>	Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

<b>Category / Program</b>	GENERAL – General Schedule (Code GE)
<b>Prescriber type:</b>	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
<b>PBS Indication:</b>	Eosinophilic oesophagitis
<b>Treatment phase:</b>	Continuing treatment
<b>Restriction Level / Method:</b>	<input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required - In Writing <input checked="" type="checkbox"/> Authority Required - Telephone <input checked="" type="checkbox"/> Authority Required – Emergency <input checked="" type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined
<b>Treatment criteria</b>	Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.
<b>Clinical criteria:</b>	Patient must have responded to an initial course of PBS-subsidised treatment.
<b>Population criteria:</b>	Patient must be 18 years of age or less.
<b>Prescriber Instructions</b>	Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.
<b>Administrative Advice</b>	Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

Severe intestinal malabsorption including short bowel syndrome

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES oral liquid: powder for, 400 g	8	5	Alfamino®	Nestlé Australia Ltd

<b>Category / Program</b>	GENERAL – General Schedule (Code GE)
<b>Prescriber type:</b>	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
<b>Episodicity:</b>	-
<b>Severity:</b>	-
<b>Condition:</b>	Severe intestinal malabsorption including short bowel syndrome
<b>PBS Indication:</b>	Severe intestinal malabsorption including short bowel syndrome
<b>Treatment phase:</b>	-
<b>Restriction Level / Method:</b>	<input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required - In Writing <input checked="" type="checkbox"/> Authority Required - Telephone <input checked="" type="checkbox"/> Authority Required – Emergency <input checked="" type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined
<b>Treatment criteria</b>	-
<b>Clinical criteria:</b>	Patient must have failed to respond to protein hydrolysate formulae; OR Patient must have been receiving parenteral nutrition.
<b>Administrative Advice</b>	Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**8 Context for Decision**

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

**9 Sponsor's Comment**

Nestle Health Science welcomes the PBAC's recommendation of additional indications for Alfamino® in patients with eosinophilic oesophagitis and patients with severe intestinal malabsorption and Alfamino® Junior in patients with eosinophilic oesophagitis.