

**5.10 AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS, MEDIUM CHAIN TRIGLYCERIDES, 2'-FUCOSYLLACTOSE AND LACTO-N-NEOTETRAOSE,
Oral powder 400 g,
Alfamino[®],
Nestle Australia Ltd.**

1 Purpose of Submission

1.1 The Category 3 submission requested a General Schedule Authority Required listing of amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids, medium chain triglycerides, 2'-fucosyllactose (2'FL) and lacto-N-neotetraose (LNnT), oral powder 400 g (Alfamino[®], hereafter referred to as Alfamino HMO) for the treatment of:

- Cows' milk protein enteropathy
- Severe cows' milk protein enteropathy with failure to thrive
- Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae
- Cows' milk anaphylaxis
- Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein
- Severe intestinal malabsorption including short bowel syndrome
- Eosinophilic oesophagitis (EoE)

2 Background

2.1 The current Pharmaceutical Benefits Scheme (PBS) listed Alfamino product, amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides (Alfamino[®], hereafter referred to as Alfamino), does not contain human milk oligosaccharides (HMOs), 2'FL and LNnT.

2.2 Alfamino HMO has not been previously considered by the PBAC.

2.3 The submission confirmed Alfamino HMO meets the requirements for infant formula products as set out under the Australia New Zealand Food Standards Code – Standard 2.9.1 – Infant Formula Products.

3 Requested listing

- 3.1 The submission requested listing Alfamino HMO under the same conditions as the currently listed Alfamino. Due to the number of items and indications required for the listing the full restrictions have not been reproduced.

Add new medicinal product as follows:

MEDICINAL PRODUCT Medicinal Product Pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS, MEDIUM CHAIN TRIGLYCERIDES, 2'-FUCOSYLLACTOSE AND LACTO-N-NEOTETRAOSE					
amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids, medium chain triglycerides, 2'-fucosyllactose and lacto-N-neotetraose powder for oral liquid, 400 g	NEW	8	8	5	Alfamino
amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids, medium chain triglycerides, 2'-fucosyllactose and lacto-N-neotetraose powder for oral liquid, 400 g	NEW	8	8	5	Alfamino
Concept ID (for internal Dept. use)					
Administrative Advice: Special Pricing Arrangements apply.					

- 3.2 The submission stated that Alfamino HMO will replace the currently listed Alfamino from July 2023 in Australia as Alfamino is being phased out globally. The submission stated that most markets have transitioned or are already planning to transition to the HMO version.

- 3.3 The submission requested a Special Pricing Arrangement (SPA) for Alfamino HMO with a proposed published approved ex-manufacturer price (AEMP) of \$|per 400 g can.

For more detail on PBAC's view, see section 7 PBAC outcome.

4 Comparator

- 4.1 The submission nominated Alfamino as the comparator. The PBAC considered that Alfamino was an appropriate comparator, and Neocate® Gold and EleCare® LCP are also considered to be alternative therapies.

For more detail on PBAC's view, see section 7 PBAC outcome.

5 Consideration of the evidence

Sponsor hearing

- 5.1 There was no hearing for this item.

Consumer comments

- 5.2 The PBAC noted and welcomed the input from ausEE Inc. via the Consumer Comments facility on the PBS website. The comments described the benefits of having an

additional amino acid formula available on the PBS for children with EoE, highlighting that an increase in treatment options with amino acid formulae allows a patient to find a suitable formula in terms of taste, tolerance, and availability leading to improved treatment adherence and better health outcomes, especially when a patient is reliant on a formula as a sole source or main source of nutrition.

Nutritional profile

5.3 The submission stated that Alfamino HMO is nutritionally very similar to Alfamino. The details of the nutritional profile of Alfamino HMO and the comparator, Alfamino are provided in Table 1.

Table 1: Nutritional composition of Alfamino HMO and Alfamino

	Units	Alfamino HMO		Alfamino	
		Average quantity per 100 g	Average quantity per 100 mL made up formula ^a	Average quantity per 100 g	Average quantity per 100 mL made up formula ^b
Energy	kcal	498	66	503	70
	kJ	2085	277	2105	293
Protein ^c (11% kcal)	g	13.3	1.8	13.3	1.9
Fat (44% kcal)	g	24.6	3.3	24.6	3.4
- Monounsaturated	g	9.1	1.2	9.5	1.3
- Polyunsaturated	g	5.4	0.72	4.5	0.63
- DHA	mg	80.0	10.6	50.0	7.0
- ARA	mg	80.0	10.6	50.0	7.0
- MCT	g	6.0	0.80	6.0	0.84
- α -Linolenic Acid	g	0.4	0.06	0.4	0.06
- Linoleic Acid	g	4.6	0.61	3.5	0.49
Carbohydrate	g	55.3	7.3	57.0	7.9
- sugars	g	4.4	0.6	4.0	0.6
Vitamin A	μ g RE	450	60	580	81
Vitamin B6	mg	0.4	0.1	0.38	0.05
Vitamin B12	μ g	3.5	0.5	1.30	0.18
Vitamin C	mg	90	12	70	10
Vitamin D	μ g	8.0	1.1	6.6	0.9
Vitamin E	mg α -TE	11.0	1.5	12.3	1.7
Vitamin K	μ g	50	6.6	44	6.1
Biotin	μ g	14	1.9	11.3	1.6
Niacin	mg NE	5.5	0.7	4.1	0.57
Folic Acid	μ g	100	13	60.0	8.4
Pantothenic Acid	mg	3.5	0.47	3.9	0.54
Riboflavin	mg	1.10	0.15	1.10	0.15

	Units	Alfamino HMO		Alfamino	
		Average quantity per 100 g	Average quantity per 100 mL made up formula ^a	Average quantity per 100 g	Average quantity per 100 mL made up formula ^b
Thiamine	mg	0.47	0.06	0.50	0.07
Calcium	mg	540	72	410	57
Copper	µg	400	53	380	53
Iodine	µg	100	13	76	11
Iron	mg	5.0	0.7	5.0	0.7
Magnesium	mg	50	6.6	46	6.4
Manganese	µg	75	10	50.0	7.0
Phosphorous	mg	360	49	280	39
Selenium	µg	15	2.0	11.9	1.7
Zinc	mg	5.0	0.7	5.0	0.7
Chloride	mg	420	56	420	58
Potassium	mg	570	76	570	79
Sodium	mg	210	30	180	25
Taurine	mg	43	5.7	35.0	4.9
L-Carnitine	mg	8.1	1.1	7.5	1.0
Choline	mg	52	7.0	43.8	6.1
Inositol	mg	55	7.3	30.6	4.3
2'-Fucosyllactose	mg	752	100	-	-
Lacto-N-Neotetraose	mg	376	50	-	-

Source: Table 1-5 of the submission main document.

ARA: arachidonic acid; DHA: Docosahexaenoic acid; MCT: Medium-chain triglycerides; RE: Retinol-Equivalents; TE: Tocopherol-Equivalent

Notes:

- a. 1 Litre = 133 g powder + 900 mL water
- b. 1 Litre = 139 g powder + 900 mL water
- c. Represents the sum of added amino acids

Clinical trials

- 5.4 The submission presented 3 trials in support of the listing of Alfamino HMO. Details of the trials presented in the submission are provided in Table 2.
- 5.5 The submission stated that results of the primary outcome showed infants receiving HMO containing formula had non-inferior weight gain per day and similar growth and development to infants receiving non-HMO containing formula. The submission also claimed that, based on key secondary outcomes in the trials, HMO containing formula demonstrated immune-related benefits, including reductions in infection rates (e.g. respiratory tract infection and otitis media) and antibiotic use, and improvements in gut microbiota.

Table 2: Trials presented in the submission

Trial ID	Protocol title/ Publication title	Publication citation
CINNAMON (NCT03085134)	Vandenplas et al. Effects of an Extensively Hydrolyzed Formula Supplemented with Two Human Milk Oligosaccharides on Growth, Tolerability, Safety and Infection Risk in Infants with Cow's Milk Protein Allergy: A Randomized, Multi-Center Trial	Nutrients 2022, 14(3): 530
Puccio 2017 (NCT01715246)	Puccio et al. Effects of Infant Formula With Human Milk Oligosaccharides on Growth and Morbidity: A Randomized Multicenter Trial	J Pediatr Gastroenterol Nutr 2017, 64(4): 624-631
PLATYPUS (NCT03661736)	Gold et al. Effects of an Amino Acid-Based Formula Supplemented with Two Human Milk Oligosaccharides on Growth, Tolerability, Safety, and Gut Microbiome in Infants with Cow's Milk Protein Allergy	Nutrients 2022, 14(11): 2297

Source: Table 2-5, pp28-30 of the submission main document

5.6 As a Category 3 submission, no evaluation of the clinical evidence was undertaken.

Clinical claim

5.7 The submission claimed Alfamino HMO provides superior efficacy by reducing the risk of infections (e.g. respiratory tract infection, otitis media) measured at up to 12 months due to the addition of HMOs. The PBAC considered this claim was not adequately supported by the evidence in the submission.

5.8 The submission also claimed non-inferior efficacy in terms of growth and development (mean weight gain per day at month 4) and non-inferior safety of Alfamino HMO compared with the comparator, Alfamino. The PBAC considered this was reasonable.

Cost analysis

5.9 The submission presented a cost analysis of Alfamino HMO compared with Alfamino, based on the energy equivalent (EE) at the AEMP.

5.10 The submission requested a price premium (effective AEMP of \$ [REDACTED] per 400 g can) for Alfamino HMO compared to the AEMP of \$34.14 per 400 g can for the comparator. The requested price premium ([REDACTED]% increase) for Alfamino HMO was based on estimated healthcare cost savings due to a claimed reduction in the occurrence of bronchitis, otitis media, crying and fussing, and regurgitation. Further details on the price are provided in **Error! Reference source not found.3**.

Table 3: Results of the cost analysis

Component	Alfamino HMO (effective)	Alfamino
Energy (kJ) per 100 g	2085	2105
Energy equivalent (EE) ^a	0.00405	0.00405
AEMP per 400 g can ^b	\$	\$34.14
DPMQ (at cost-minimised price)	\$	\$315.50
DPMQ for 6 months ^c (A)	\$	\$1,893.00
Healthcare cost savings for 6 months		
Cost offset – reduced Bronchitis (RTI)	\$	-
Cost offset – reduced Otitis Media	\$	-
Cost offset – reduced crying and fussing	\$	-
Cost offset – reduced regurgitation	\$	-
Total healthcare cost savings (B)	\$	-
Adjusted DPMQ for 6 months (A) + (B)	\$	-
Price premium for claimed health benefits per 400 g can at AEMP	\$	-
Proposed AEMP per 400 g can	\$	\$34.14

Source: Table 3-2, Section 3 Economic Evaluation, pp77-87 of the submission main document

^a Energy equivalent (EE) was calculated as AEMP of Alfamino per 400 g can (\$34.14) divided by total energy per can (2105 x 4) = 0.00405.

^b AEMP of Alfamino HMO per 400 g can was calculated as total energy per can (2085 x 4) x EE (0.00405) then rounded to the first decimal point.

^c Calculated as the Dispensed Price for Maximum Quantity (DPMQ) x 6

RTI: respiratory tract infection

Estimated PBS utilisation and financial implications

- 5.11 The submission adopted a market share approach to estimate the utilisation and financial implications of listing Alfamino HMO.
- 5.12 The submission assumed that Alfamino HMO will substitute for Alfamino, applying a script equivalence of 1:1 between Alfamino HMO and Alfamino to derive the expected script volume of Alfamino HMO.
- 5.13 The submission estimated a net cost to the PBS of \$255,000 to < \$355,000 in Year 6 of listing, with a total net cost to the PBS of \$0 to < \$10 million over the first 6 years of listing at the effective price, excluding the estimated MBS savings. The net increase in costs to the PBS was due to the requested price premium for Alfamino HMO over Alfamino. This is summarised in Table 4.

Table 4: Estimated use and financial implications

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated extent of use						
Number of scripts dispensed	1	1	1	1	1	1
Estimated financial implications of Alfamino HMO						
Cost to PBS/RPBS less co-payment	\$2	\$2	\$2	\$2	\$2	\$2
Estimated financial implications of Alfamino						
Number of scripts displaced	-3	-3	-3	-3	-3	-3
Cost to PBS/RPBS less co-payment	4	4	4	4	4	4
Net financial implications						
Net cost to PBS/RPBS	\$2	\$2	\$2	\$2	\$2	\$2

Note: requested published DPMQ of Alfamino HMO is \$█.

Source: Section 4 financial workbook of the submission

The redacted values correspond to the following ranges:

¹ 5,000 to < 10,000

² \$0 to < \$10 million

³ < 500

⁴ Net cost saving

5.14 As a Category 3 submission, the financial estimates have not been independently evaluated.

For more detail on PBAC’s view, see section 7 PBAC outcome.

6 NPWP Consideration

6.1 The Nutritional Products Working Party (NPWP) supported the General Schedule Authority Required listing of Alfamino HMO under the same circumstances as the currently listed Alfamino.

6.2 The NPWP advised that the nutritional values for Alfamino HMO meet the Australian requirements.

6.3 The NPWP advised that the currently listed Alfamino is an appropriate comparator, and Neocate Gold and EleCare LCP are also considered to be alternative therapies.

6.4 The NPWP advised that the claim of superior efficacy for Alfamino HMO over Alfamino in terms of the reduced risk of infections (e.g. bronchitis) is not adequately supported by the studies presented in the submission, noting that the claim of superiority for Alfamino HMO was made on the secondary outcomes (e.g. infection rates), based on parental report and a relatively small number of patients. The NPWP advised that more evidence obtained from well-designed controlled trials with larger sample sizes would be required to demonstrate the health benefits of HMOs and to justify a price premium for Alfamino HMO.

6.5 The NPWP considered that, if recommended, it would be appropriate to list Alfamino HMO on the PBS under the same brand name as the currently listed Alfamino for a

transition period, noting that Alfamino HMO and Alfamino are clinically substitutable at a patient level.

7 PBAC Outcome

- 7.1 The PBAC recommended the General Schedule Authority Required listing of amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids, medium chain triglycerides, 2'-fucosyllactose and lacto-n-neotetraose (Alfamino®) for the treatment of cows' milk protein enteropathy, severe cows' milk protein enteropathy with failure to thrive, combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae, cows' milk anaphylaxis, proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein, severe intestinal malabsorption including short bowel syndrome, and eosinophilic oesophagitis. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of Alfamino HMO would be acceptable if it were cost-minimised to the currently listed Alfamino.
- 7.2 The PBAC recommended that Alfamino HMO (13.3 g of protein per 100 g) be listed at the same price per gram of protein as Alfamino (13.3 g of protein per 100 g).
- 7.3 The PBAC noted and agreed with the NPWP's advice detailed in Section 6 NPWP consideration. The PBAC considered that, although Alfamino was an appropriate comparator, there were also other alternative therapies, such as Neocate Gold and EleCare LCP.
- 7.4 The PBAC considered that Alfamino HMO was non-inferior to Alfamino in terms of effectiveness and safety. The PBAC noted the submission's claim of superior efficacy for Alfamino HMO in terms of the reduced risk of infections (e.g. bronchitis) was made on the secondary outcomes, based on parental report and a relatively small number of patients. The PBAC noted the NPWP's advice and considered that the claim of superior efficacy for Alfamino HMO over Alfamino was not adequately supported by the evidence in the submission.
- 7.5 The PBAC accepted the proposed market share approach that Alfamino HMO would substitute for Alfamino on a 1:1 basis.
- 7.6 In accordance with section 101 (3BA) of the Act, the PBAC advised that on the basis of the material available to its November 2022 meeting, Alfamino HMO be treated as interchangeable on an individual patient basis with similar nutritional products.
- 7.7 The PBAC advised that Alfamino HMO is suitable for prescribing by nurse practitioners.
- 7.8 The PBAC recommended that the Early Supply Rule should not apply, as it has been the PBAC's view that general nutrients be exempt.
- 7.9 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because Alfamino HMO is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over Alfamino, or not expected to address a high and urgent unmet clinical need given the presence of

an alternative therapy, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2022* for Pricing Pathway A were not met.

7.10 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

8 Recommended listing

8.1 Add new item:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS, MEDIUM CHAIN TRIGLYCERIDES, 2'-FUCOSYLLACTOSE AND LACTO-N-NEOTETRAOSE					
amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids, medium chain triglycerides, 2'-fucosyllactose and lacto-N-neotetraose powder for oral liquid, 400 g	NEW	8	8	5	Alfamino
Restriction Summary [new] / Treatment of Concept:					
Concept ID (for internal Dept. use)	Category / Program: GENERAL – General Schedule (Code GE)				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system) <input checked="" type="checkbox"/> Authority Required (in writing)				
	Indication: Cows' milk protein enteropathy				
	Treatment Phase: Initial treatment for up to 6 months				
	Clinical criteria:				
	The condition must not be isolated infant colic or reflux; and				
	Patient must be intolerant to both soy protein and protein hydrolysate formula, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.				
	Treatment criteria: Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.				
	Population criteria: Patient must be up to the age of 24 months.				
	Prescribing Instructions: The name of the specialist and the date of birth of the patient must be included in the authority application.				
	Administrative Advice:				
	No increase in the maximum quantity or number of units may be authorised; and				
	No increase in the maximum number of repeats may be authorised.				

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Indication: Severe cows' milk protein enteropathy with failure to thrive
Treatment Phase: Initial treatment for up to 6 months
Clinical criteria: The condition must not be isolated infant colic or reflux.
Treatment criteria: Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.
Population criteria: Patient must be up to the age of 24 months.
Prescribing Instructions: The name of the specialist and the date of birth of the patient must be included in the authority application
Administrative Advice:
No increase in the maximum quantity or number of units may be authorised; and
No increase in the maximum number of repeats may be authorised.

Indication: Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formula
Treatment Phase: Initial treatment for up to 6 months
Clinical criteria: The condition must not be isolated infant colic or reflux.
Treatment criteria: Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.
Population criteria: Patient must be older than 24 months of age.
Prescribing Instructions: The name of the specialist and the date of birth of the patient must be included in the authority application
Administrative Advice:
No increase in the maximum quantity or number of units may be authorised; and
No increase in the maximum number of repeats may be authorised.

Indication: Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein
Treatment Phase: Initial treatment for up to 6 months
Clinical criteria: Patient must have failed a trial of protein hydrolysate formula (with or without medium chain triglycerides)
Treatment criteria: Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.
Population criteria: Patient must be up to the age of 24 month
Prescribing Instructions: The name of the specialist and the date of birth of the patient must be included in the authority application
Administrative Advice:
No increase in the maximum quantity or number of units may be authorised; and
No increase in the maximum number of repeats may be authorised.

Indication: Eosinophilic oesophagitis
Treatment Phase: Initial treatment for up to 3 months
Clinical criteria: Patient must require an amino acid based formula as a component of a dietary elimination program.
Treatment criteria: Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.
Population criteria: Patient must be 18 years of age or less.
Prescribing Instructions:
Treatment with oral steroids should not be commenced during the period of initial treatment.
Eosinophilic oesophagitis is demonstrated by the following criteria:

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	(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and
	(ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and
	(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.
	The date of birth of the patient must be included in the authority application.
	Administrative Advice: Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

	Indication: Cows' milk protein enteropathy
	Treatment Phase: Continuing treatment
	Clinical criteria:
	The condition must not be isolated infant colic or reflux; and
	Patient must be intolerant to both soy protein and protein hydrolysate formula, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.
	Treatment criteria: Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.
	Population criteria: Patient must be up to the age of 24 months.
	Prescribing Instructions: The name of the specialist and the date of birth of the patient must be included in the authority application.
	Administrative Advice: Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

	Indication: Severe cows' milk protein enteropathy with failure to thrive
	Treatment Phase: Continuing treatment
	Clinical criteria:
	The condition must not be isolated infant colic or reflux; and
	Patient must have had failure to thrive prior to commencement with initial treatment.
	Treatment criteria: Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.
	Population criteria: Patient must be up to the age of 24 months.
	Prescribing Instructions: The name of the specialist and the date of birth of the patient must be included in the authority application.
	Administrative Advice: Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

	Indication: Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formula
	Treatment Phase: Continuing treatment
	Clinical criteria: The condition must not be isolated infant colic or reflux.
	Treatment criteria: Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.
	Population criteria: Patient must be older than 24 months of age.
	Prescribing Instructions: The name of the specialist and the date of birth of the patient must be included in the authority application.

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	Administrative Advice: Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.
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	Indication: Cows' milk anaphylaxis
	Treatment criteria: Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.
	Population criteria: Patient must be up to the age of 24 months.
	Prescribing Instructions:
	Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction; and
	The name of the specialist and the date of birth of the patient must be included in the authority application.
	Administrative Advice: Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

	Indication: Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein
	Treatment Phase: Continuing treatment
	Clinical criteria: Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.
	Treatment criteria: Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.
	Population criteria: Patient must be up to the age of 24 month
	Prescribing Instructions: The name of the specialist and the date of birth of the patient must be included in the authority application.
	Administrative Advice: Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

	Indication: Severe intestinal malabsorption including short bowel syndrome
	Clinical criteria:
	Patient must have failed to respond to protein hydrolysate formulae; or
	Patient must have been receiving parenteral nutrition.
	Administrative Advice: Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

	Indication: Eosinophilic oesophagitis
	Treatment Phase: Continuing treatment
	Clinical criteria: Patient must have responded to an initial course of PBS-subsidised treatment.
	Treatment criteria: Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.
	Population criteria: Patient must be 18 years of age or less.
	Prescribing Instructions: 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.
	Administrative Advice: Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

These restrictions may be subject to further review. Should there be any changes made to the restriction the Sponsor will be informed.

9 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

10 Sponsor's Comment

The sponsor had no comment.