

**5.26 AMINO ACID FORMULA WITH FAT, CARBOHYDRATE,
VITAMINS, MINERALS, TRACE ELEMENTS AND
MEDIUM CHAIN TRIGLYCERIDES,
Oral powder 400 g (Essential Care Jr)
Essential Care Jr
CORTEX HEALTH PTY LTD**

1 Purpose of Submission

- 1.1 The Committee Secretariat submission requested a General Schedule Authority Required (Telephone/Online) listing of a 400 g pouch of amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides oral powder (Essential Care Jr) with a new formulation, for the same indications as the current PBS listings for the 800 g pouch of Essential Care Jr.
- 1.2 Listing was requested on a cost-minimisation basis versus the currently PBS-listed Essential Care Jr, 800 g.

2 Background

- 2.1 At its March 2021 meeting, the PBAC recommended the General Schedule Authority Required (Telephone/Online) listing of Essential Care Jr, 800 g for the following indications:
- 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
 - Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein
 - Eosinophilic oesophagitis (EoE)
 - Cows' milk anaphylaxis
 - Severe intestinal malabsorption including short bowel syndrome.
- 2.2 The submission stated that the change in pack size is a result of the 800 g pouch no longer being manufactured globally. A separate delisting request for the 800 g pouch was considered by the PBAC at its November 2024 meeting.
- 2.3 The submission stated the minor adjustments to the formulation, particularly to the levels of Vitamin A and Vitamin D, were made in response to updated Canadian requirements. The submission claimed that, overall, the composition of the new

formulation remains unchanged from the previously considered formulation in March 2021, providing comparable levels of nutrients.

Registration status

- 2.4 The sponsor of Essential Care Jr previously confirmed it meets the requirements for foods for medical purposes as set out under *The Australia New Zealand Food Standards Code – Standard 2.9.5: Food for Special Medical Purposes* (Essential Care Jr Public Summary Document (PSD), March 2021).
- 2.5 As Essential Care Jr is marketed as a nutritional product and not a therapeutic good, it is not registered in the Australian Register of Therapeutic Goods.

3 Requested listing

- 3.1 The submission requested the listing of the new pack with the same criteria as the currently listed pack size (initial treatment 12643K, and continuing treatment 12650T).

Add new medicinal product pack as follows:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES					
amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides oral powder, 800 g	12643K	4	4	5	Essential Care Jr
amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides oral powder, 400 g	NEW	8	8	5	Essential Care Jr
Restriction Summary / Treatment of Concept:					
Category / Program: <input checked="" type="checkbox"/> 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)					
Indication: Cows' milk protein enteropathy					
Treatment Phase: Initial treatment for up to 6 months					
Restriction Summary / Treatment of Concept:					
Indication: Severe cows' milk protein enteropathy with failure to thrive					
Treatment Phase: Initial treatment for up to 6 months					
Restriction Summary / Treatment of Concept:					
Indication: Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein					
Treatment Phase: Initial treatment for up to 6 months					
Restriction Summary / Treatment of Concept:					
Indication: Cows' milk protein enteropathy					

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	Treatment Phase: Continuing treatment
Restriction Summary / Treatment of Concept:	
	Indication: Severe cows' milk protein enteropathy with failure to thrive
	Treatment Phase: Continuing treatment
Restriction Summary / Treatment of Concept:	
	Indication: Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein
	Treatment Phase: Continuing treatment
Restriction Summary / ToC:: Authority Required	
	Indication: Cows' milk anaphylaxis

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES					
amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides oral powder, 800 g	12650T	4	4	5	Essential Care Jr
amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides oral powder, 400 g	NEW	8	8	5	Essential Care Jr

Restriction Summary / Treatment of Concept:	
	Category / Program: <input checked="" type="checkbox"/> 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)
	Indication: Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae
	Treatment Phase: Initial treatment for up to 6 months
Restriction Summary / Treatment of Concept:	
	Indication: Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae
	Treatment Phase: Continuing treatment
Restriction Summary / Treatment of Concept:	
	Indication: Severe intestinal malabsorption including short bowel syndrome
Restriction Summary / Treatment of Concept:	
	Indication: Eosinophilic oesophagitis
	Treatment phase: Initial treatment for up to 3 months
Restriction Summary / Treatment of Concept:	
	Indication: Eosinophilic oesophagitis
	Treatment Phase: Continuing treatment

3.2 The submission requested listing the new 400 g pouch with a maximum quantity pack/unit of 8 to equally provide the same amount of oral powder per dispensing as

the 800 g pouch listing (maximum quantity pack/unit of 4). No other changes to the current 60-pack listing were requested.

4 Comparator

- 4.1 The submission nominated Essential Care Jr, 800 g as the main comparator. The pre-PBAC response reiterated that the currently listed 800 g pack was the reasonable comparator, as the new 400 g pack is expected to substitute for the current 800 g pack of Essential Care Jr, if recommended for listing.
- 4.2 Other brands of amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides in 400 g powder for oral liquid (Neocate® Junior and Alfamino® Junior) are currently PBS listed.

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 comment supported the continuous supply and availability of Essential Care Jr and emphasized the importance of having a variety of amino acid formula options for children with Eosinophilic Oesophagitis and other PBS-listed indications.

Nutritional profile

- 5.3 A comparison of the new and current formulations of Essential Care Jr is provided in Table 1. The new formulation presented in this submission is for unflavoured Essential Care Jr. The submission noted that Essential Care Jr is also available in a vanilla flavour.

Table 1: Comparison of nutritional composition

Nutrient	Unit	Essential Care Jr (per 100 g powder)	
		New formulation (400 g) November 2024 PBAC	Previous formulation (800 g) March 2021 PBAC
Energy, protein, carbohydrate, salt, fat, fibre:			
Energy	kJ	2068	1946
Energy	calories	494	465
Protein	g	19	19
Carbohydrate	g	45	44.2
Fat	g	25	24.2
Saturated fat	g	11	0
Monounsaturated fat	g	4.7	NR
Polyunsaturated fat	g	8.8	NR
Linoleic acid	mg	3878	3786
α-Linoleic acid	mg	898	879.1
DHA	mg	68	65.1

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Fibre	g	0	2.7
Vitamins:			
Vitamin A	mcg retinol equivalents	290	209
Vitamin D	mcg of cholecalciferol	9.8	10.4
Vitamin E	mg α-tocopherol equivalents	6.7	6.5
Vitamin K1	mcg	24	23.3
Vitamin K2 (MK-7)	mcg	24	23.3
Thiamin / B1	mg	1.0	0.930
Riboflavin / B2	mg	1.9	1.861
Vitamin B6	mg	0.7	0.698
Vitamin B12	mcg	1.0	0.9
Niacin	mg niacin equivalents	12	10.776
Folate, DFE	mcg	97	96.8
Folic acid	mcg	57	56.9
Pantothenic acid / B5	mg	1.9	1.861
Biotin	mcg	19	18.6
Vitamin C	mg	48	46.5
Minerals, trace elements			
Choline	mg	143	140
Inositol	mg	95	93
Lutein	mcg	181	174.4
Calcium	mg	588	577
Phosphorous	mg	382	373
Magnesium	mg	81	79.2
Iron	mg	6.2	5.8
Zinc	mg	3.8	3.7
Manganese	mcg	610	590.7
Copper	mg	476	465.1
Iodine	mcg	71	69.8
Molybdenum	mcg	17	16.5
Chromium	mcg	14	14.1
Selenium	mcg	14	14.1
Sodium	mg	430	419
Potassium	mg	481	479
Chloride	mg	308	306.1
Amino acids			
L-alanine	mg	1333	1302.3
L-arginine	mg	952	930.2
L-aspartate	mg	714	697.7
L-carnitine	mg	29	27.9
L-cystine	mg	238	232.6
L-glutamine	mg	0	790.7
L-glycine	mg	1333	1302.3
L-histidine	mg	667	651.2
L-isoleucine	mg	1238	1209.3
L-leucine	mg	2476	2418.6
L-lysine	mg	2190	2139.5
L-methionine	mg	238	232.6
L-phenylalanine	mg	952	930.2
L-proline	mg	810	790.7
L-serine	mg	1333	1302.3
L-taurine	mg	67	65.1
L-threonine	mg	2857	2790.7

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L-tryptophan	mg	476	465.1
L-tyrosine	mg	952	930.2
L-valine	mg	1667	1627.9
Other			
Osmolality	mOsm/kg H2O	711	750
pH		7.0	6.7

Source: Table 2 of the submission main body, p 3-4

Abbreviations: NR: not reported, DHA: docosahexaenoic acid

- 5.4 In the pre-PBAC response, the sponsor confirmed that the Essential Care Jr information sheet on its website will be updated following the listing of the 400 g pack size.
- 5.5 The sponsor provided comparisons of the new nutritional profile against the *Australia New Zealand Food Standards Code Standard 2.9.1 Schedule 2* requirements and the *Standard 2.9.5 Schedule 2* requirements as well as adequate intake (AI) and recommended daily intake (RDI) requirements. The submission noted that overall, the formula is largely unchanged from the original listed one, providing very similar, adequate levels of nutrients across the different patient groups.
- 5.6 The sponsor stated that there are no major allergens present in Essential Care Jr 400 g.

Economic analysis

- 5.7 The submission did not present an economic analysis. The submission requested the same dispensed price for maximum quantity (DPMQ) of \$336.55 as the currently PBS-listed Essential Care Jr 800 g.
- 5.8 In March 2021, the PBAC recommended Essential Care Jr 800 g on a cost-minimisation basis compared with Neocate Junior and Alfamino Junior at an equivalent cost per kilojoule at the March 2021 PBAC meeting (paragraph 7.01, Essential Care Jr, PSD, March 2021 PBAC meeting). The energy content and proposed price of Essential Care Jr 400 g in comparison to these products is presented in Table 2.

Table 2: Energy equivalent contents and prices of Essential Care Jr, Neocate Junior and Alfamino Junior

Brand Name	PBS item number	kJ/100 g powder	Pack size	Max qty packs	Maximum dispensed qty	AEMP ^c	DPMQ ^c
Essential Care Jr	<i>New</i>	2068	400 g	8	3200 g	\$36.33	\$336.55
	12643K; 12650T	1946 ^a	800 g	4	3200 g	\$72.66	\$336.55
Neocate Junior	11161K	1992 ^b	400 g	8	3200 g	\$37.19	\$344.35
Alfamino Junior	10522T; 10527C	1900 ^b	400 g	8	3200 g	\$37.19	\$344.35

Source: compiled by the Secretariat during the evaluation

^aBased on previous formulation (March 2021).

^bEnergy contents for Neocate Junior and Alfamino Junior were obtained from the respective sponsors' websites accessed on 2 August 2024.

^cBased on AEMPs and DPMQs as of August 2024

AEMP = approved ex-manufacturer price, DPMQ = dispensed price for maximum quantity, kJ = kilojoules

Estimated cost/patient/year: \$4038.60

- 5.9 The estimated cost/patient per year would be \$4038.60, based on 12 scripts per year (DPMQ of \$336.55 x 12). The actual cost may vary due to variations in individual patient needs.

Estimated PBS usage and financial implications

- 5.10 The submission did not present an analysis of the estimated PBS usage and financial implications. However, the submission claimed that the new pack size with the new formulation is not expected to have financial implications to the PBS/RPBS, as the total maximum quantity and price remain unchanged.

6 NPWP consideration

- 6.1 The NPWP supported listing the new 400 g pack size of Essential Care Jr with the new formulation on the PBS, for the same indications as the current PBS listings for the 800 g pack size of Essential Care Jr on a cost-minimisation basis to the lowest cost comparator, at an equivalent cost per kilojoule.
- 6.2 The NPWP advised that the currently listed Essential Care Jr was an appropriate comparator for the new 400 g pack size of Essential Care Jr with the new formulation, and that Neocate Junior and Alfamino Junior are also appropriate comparators.
- 6.3 The NPWP accepted that the new formulation is expected to provide non-inferior clinical benefits and safety for the listed indications compared to the current formulation of Essential Care Jr.
- 6.4 The NPWP accepted the claim that the new pack size with the new formulation for Essential Care Jr is not expected to have financial implications to the PBS/RPBS.

7 PBAC Outcome

- 7.1 The PBAC recommended a General Schedule Authority Required (Telephone/Online) listing of a 400 g pouch of amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides oral powder (Essential Care Jr) with a new formulation, for the same indications as the current PBS listings for the 800 g pouch of Essential Care Jr.
- 7.2 The PBAC considered that the new 400 g pack size of Essential Care Jr with the new formulation should be cost-minimised to the lowest cost comparator accepted by the NPWP (the current 800 g pack of Essential Care Jr, Neocate Junior, and Alfamino Junior) at an equivalent cost per kilojoule.
- 7.3 The PBAC considered the nominated main comparator, the 800 g pouch of Essential Care Jr, to be reasonable and considered that Neocate Junior and Alfamino Junior are appropriate comparators.

- 7.4 The PBAC noted and supported the NPWP advice that the new formulation is expected to provide non-inferior clinical benefits and safety for the listed indications compared to the current formulation of Essential Care Jr.
- 7.5 The PBAC considered that the estimated nil net financial impact to the PBS/RPBS over 6 years was reasonable.
- 7.6 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because the new 400 g pack size of Essential Care Jr is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over the 800 g pouch of Essential Care Jr, 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.
- 7.7 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 FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES					
amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides oral powder, 400 g	NEW	8	8	5	Essential Care Jr
Restriction Summary / Treatment of Concept:					
Category / Program: <input checked="" type="checkbox"/> 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)					
Administrative Advice: No increase in the maximum quantity or number of units may be authorised.					
Administrative Advice: No increase in the maximum number of repeats may be authorised.					
Administrative Advice: Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.					
Indication: Cows' milk protein enteropathy					
Treatment Phase: Initial treatment for up to 6 months					
Treatment criteria:					

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	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
	AND
	Clinical criteria:
	The condition must not be isolated infant colic or reflux
	AND
	Clinical criteria:
	Patient must be intolerant to both soy protein and protein hydrolysate formulae, 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
	AND
	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.
Restriction Summary / Treatment of Concept:	
	Category / Program: <input checked="" type="checkbox"/> 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)
	Indication: Severe cows' milk protein enteropathy with failure to thrive
	Treatment Phase: Initial treatment for up to 6 months
	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
	AND
	Clinical criteria:
	The condition must not be isolated infant colic or reflux
	AND
	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.
Restriction Summary / Treatment of Concept:	
	Category / Program: <input checked="" type="checkbox"/> 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)
	Indication: Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein
	Treatment Phase: Initial treatment for up to 6 months
	Treatment criteria:

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	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
	AND
	Clinical criteria:
	Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides)
	AND
	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.
Restriction Summary / Treatment of Concept:	
	Category / Program: <input checked="" type="checkbox"/> 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)
	Indication: Cows' milk protein enteropathy
	Treatment Phase: Continuing treatment
	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
	AND
	Clinical criteria:
	The condition must not be isolated infant colic or reflux
	AND
	Clinical criteria:
	Patient must be intolerant to both soy protein and protein hydrolysate formulae, 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
	AND
	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.
Restriction Summary / Treatment of Concept:	
	Category / Program: <input checked="" type="checkbox"/> 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)
	Indication: Severe cows' milk protein enteropathy with failure to thrive
	Treatment Phase: Continuing treatment
	Treatment criteria:

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	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
	AND
	Clinical criteria:
	The condition must not be isolated infant colic or reflux
	AND
	Clinical criteria:
	Patient must have had failure to thrive prior to commencement with initial treatment
	AND
	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.
Restriction Summary / Treatment of Concept:	
	Category / Program: <input checked="" type="checkbox"/> 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)
	Indication: Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein
	Treatment Phase: Continuing treatment
	Treatment criteria:
	Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist
	AND
	Clinical criteria:
	Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment
	AND
	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.
Restriction Summary / ToC:: Authority Required	
	Category / Program: <input checked="" type="checkbox"/> 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)
	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

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	Prescribing Instructions: Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.
	Prescribing Instructions: The name of the specialist and the date of birth of the patient must be included in the authority application.

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES					
amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides oral powder, 400 g	NEW	8	8	5	Essential Care Jr

Restriction Summary / Treatment of Concept:

	Category / Program: <input checked="" type="checkbox"/> 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)
	Administrative Advice: Authority approval for an increased maximum quantity, up to 3 times the stated quantity (in packs), may be sought.
	Administrative Advice: Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.
	Indication: Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae
	Treatment Phase: Initial treatment for up to 6 months
	Treatment criteria: Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist
	AND
	Clinical criteria: The condition must not be isolated infant colic or reflux
	AND
	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.

Restriction Summary / Treatment of Concept:

	Category / Program: <input checked="" type="checkbox"/> 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)
	Indication: Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae
	Treatment Phase: Continuing treatment
	Treatment criteria: Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months
	AND
	Clinical criteria:

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	The condition must not be isolated infant colic or reflux
	AND
	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.
Restriction Summary / Treatment of Concept:	
	Category / Program: <input checked="" type="checkbox"/> 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)
	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
Restriction Summary / Treatment of Concept:	
	Category / Program: <input checked="" type="checkbox"/> 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)
	Indication: Eosinophilic oesophagitis
	Treatment phase: Initial treatment for up to 3 months
	Treatment criteria:
	Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist
	AND
	Clinical criteria:
	Patient must require an amino acid based formula as a component of a dietary elimination program
	AND
	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.
	Prescribing Instructions: Eosinophilic oesophagitis is demonstrated by the following criteria: (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.
9476	Prescribing Instructions: The date of birth of the patient must be included in the authority application.
Restriction Summary / Treatment of Concept:	
	Category / Program: <input checked="" type="checkbox"/> 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)
	Indication: Eosinophilic oesophagitis
	Treatment Phase: Continuing treatment

	Treatment criteria:
	Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist
	AND
	Clinical criteria:
	Patient must have responded to an initial course of PBS-subsidised treatment
	AND
	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.

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.