

**5.19 AMINO ACID FORMULA WITH FAT,  
CARBOHYDRATE, VITAMINS, MINERALS, TRACE  
ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES  
Oral powder 800 g,  
Essential Care Jr<sup>®</sup>,  
Cortex Health Pty Ltd**

**1 Purpose of Application**

1.1 The minor submission requested an Authority Required listing of amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides (Essential Care Jr) 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 Background**

2.1 This was the first Essential Care Jr submission.

2.2 Amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides in the form of [powder for oral liquid, 400 g] with the current trade products of [Neocate Junior, Alfamino Junior] was first considered in March 2015 PBAC meeting and listed 1 November 2015 [Alfamino Junior].

**3 Requested listing**

3.1 The requested restrictions were almost identical to the comparator, Neocate Junior (PBS codes: 11183N, 11161K) with the exception that the sponsor wanted to remove the population criterion: 'Patient must be up to the age of 24 months', for the reason that it did not consider treatment should be age-limited.

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

## 4 Comparator

- 4.1 The submission nominated Neocate Junior (PBS item codes: 11183N, 11161K) as the main comparator as it is the most-used similar formula that contains medium chain triglycerides.
- 4.2 In March 2017, the PBAC recommended listing Neocate Junior as an Authority Required benefit on a cost-minimisation basis against Alfamino Junior (Neocate Junior, Public Summary Document, March 2017 PBAC Meeting).

*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 an individual/organisation received via the consumer comment facility on the website. The comment described the benefits of treatment with Essential Care Jr for children with eosinophilic oesophagitis and food allergies, including reduced symptoms and inflammation leading to better health outcomes and quality of life.

### ***Clinical evidence***

- 5.3 As a minor submission, no clinical trials were presented in the submission.
- 5.4 The submission stated Essential Care Jr provides an important therapeutic alternative for children with poor tolerance to corn by-products; constipation and gastrointestinal (GI) intolerance; diarrhoea and/or malabsorption; risk for vitamin and mineral deficiencies; inflammation of the GI tract; and poor growth.
- 5.5 The submission mentioned Essential Care Jr is low fermentable oligo-, di-, mono-saccharides and polyols (FODMAP) fibre (psyllium fibre, cellulose), reducing the risk of inadequate absorption of sugars in the gut, leading to lower risk of gas, bloating, abdominal discomfort and more normalised stool patterns thereby reducing diarrhoea or constipation.
- 5.6 The submission indicated Essential Care Jr has a low FODMAP Prebiotic (acacia gum) that ferments at a slower rate compared to the high FODMAP oligosaccharides used in some other formulas (e.g. inulin used in Neocate Junior) that may result in less digestive discomfort.
- 5.7 The submission stated the proposed product contains a unique fibre blend of soluble and insoluble fibres, including psyllium fibre, a stool softener that helps normalise stools in those with IBS.

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- 5.8 The submission specified Essential Care Jr contains higher calcium, vitamin D3 and magnesium (compared with Elecare Jr and Neocate Junior) and is the only amino acid (AA)-based formula with Vitamin K2, a fat soluble vitamin effective in supporting strong bones. The submission also stated Essential Care Jr has lower potential renal acid load (compared with Alfamino Jr and Neocate Junior, Elecare Jr) which may lead to reduced renal acid excretion and calcium retention which may support bone health.
- 5.9 The submission stated the proposed product contains lutein, an antioxidant found in fruits/vegetables often limited in children’s diets (compared with Elecare Jr, Neocate Junior, Alfamino Junior that do not contain lutein).
- 5.10 The submission mentioned the proposed product provides approximately 60% more essential AAs per calorie compared with other products (Elecare Jr, Neocate Junior, Alfamino Junior) and more natural ingredients: contains no artificial sweeteners, flavours or colours (some other products, e.g. Elecare Jr, Neocate Jr, contain these).
- 5.11 The sponsor stated that Essential Care Jr provides more leucine per serving than other PBS-listed formulas as it supports protein synthesis.
- 5.12 The sponsor stated that Essential Care Jr is higher in protein per serving than other PBS-listed formulas which may promote muscle building, healing and growth.
- 5.13 The submission claimed Essential Care Jr provides a hypoallergenic infant formula that supports appropriate nutritional intake to allow optimal brain and body system development.
- 5.14 The submission also claimed Essential Care Jr 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.
- 5.15 The nutrient content of the Essential Care Jr and the comparator (Neocate Junior) are presented in the table below.

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**Table 1: Nutrient contents of Essential Care Jr and the comparator Neocate Junior**

Nutritional Information	Essential Care Jr (per 100 g)	Neocate Junior (per 100g)
Energy, protein, carbohydrate, salt, fat, fibre:		
Energy (kJ)	1946	1992
Energy (calories)	465	475
Protein (g)	19	13.3
Carbohydrate (g)	44.2	5
Sugar, g	NR	5
Sugar alcohols (g)	0.0	NR
Fat (g)	24.2	22
Saturated fat (g)	0	9.4
Monounsaturated fat (g)	NR	7.7
Polyunsaturated fat (g)	NR	4
Linoleic acid (mg)	3786	3608
$\alpha$ -Linoleic acid (mg)	879.1	358.7
DHA (mg)	65.1	NR
Fibre (g)	2.7	0
Vitamins:		
Vitamin A (mcg retinol equivalents)	209	214
Vitamin D (mcg of cholecalciferol)	10.4	6.2
Vitamin E (mg $\alpha$ -tocopherol equivalents)	6.5	6.7
Vitamin K (mcg)	46.6	19
Vitamin K1 (mcg)	23.3	NR
Vitamin K2 (MK-7) (mcg)	23.3	NR
Thiamin / B1 (mg)	0.930	0.48
Riboflavin / B2 (mg)	1.861	0.95
Vitamin B6 (mg)	0.698	0.48
Vitamin B12 (mcg)	0.9	1.2
Niacin (mg niacin equivalents)	10.776	9
Folate, DFE (mcg)	96.8	NR
Folic acid (mcg)	56.9	71.3
Pantothenic acid / B5 (mg)	1.861	1.9
Biotin (mcg)	18.6	14.3
Vitamin C (mg)	46.5	47.5
Minerals, trace elements		
Choline (mg)	140	95
Inositol (mg)	93	26.1
Lutein (mcg)	174.4	NR
Calcium (mg)	577	428
Phosphorous (mg)	373	309
Magnesium (mg)	79.2	66.5
Iron (mg)	5.8	5.7
Zinc (mg)	3.7	5.2
Manganese (mcg)	590.7	290
Copper (mg)	465.1	480
Iodine (mcg)	69.8	71.3
Molybdenum (mcg)	16.5	21.4
Chromium (mcg)	14.1	7.6
Selenium (mcg)	14.1	15.2
Sodium (mg)	419	285

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<b>Nutritional Information</b>	<b>Essential Care Jr (per 100 g)</b>	<b>Neocate Junior (per 100g)</b>
Potassium (mg)	479	546
Chloride (mg)	306.1	437
<b>Amino acids</b>		
L-alanine (mg)	1302.3	NR
L-arginine (mg)	930.2	NR
L-aspartate (mg)	697.7	NR
L-carnitine (mg)	27.9	NR
L-cystine (mg)	232.6	NR
L-glutamine (mg)	790.7	NR
L-glycine (mg)	1302.3	NR
L-histidine (mg)	651.2	NR
L-isoleucine (mg)	1209.3	NR
L-leucine (mg)	2418.6	NR
L-lysine (mg)	2139.5	NR
L-methionine (mg)	232.6	NR
L-phenylalanine (mg)	930.2	NR
L-proline (mg)	790.7	NR
L-serine (mg)	1302.3	NR
L-taurine (mg)	65.1	NR
L-threonine (mg)	2790.7	NR
L-tryptophan (mg)	465.1	NR
L-tyrosine (mg)	930.2	NR
L-valine (mg)	1627.9	NR
<b>Other</b>		
Osmolality (mOsm/kg H <sub>2</sub> O)	750	600
pH	6.7	NR

Source: Table 1.5.3, pg 26 of the submission.

***Clinical claim***

5.16 The PBAC noted the submission described Essential Care Jr as non-inferior in terms of both effectiveness and safety to Neocate Junior. The PBAC considered this was reasonable, on the basis that Essential Care Jr provides the same amount of energy in comparison to Neocate Junior.

***Economic analysis***

5.17 As a minor submission, an economic analysis was not presented. The submission sought listing based on an equivalent cost per kilojoule of energy compared with Neocate Junior. The sponsor stated Essential Care Jr will directly substitute for Neocate Junior based on energy content (kilojoules), consistent with pricing of the existing products.

5.18 The proposed approved ex-manufacturer price (AEMP) \$39.15 per 400 g is consistent with the comparator and other amino acid products listed for the same indication. The submission stated that for simplicity and consistency with other listed products, the

proposed price of Essential Care Jr is the same per weight. Since Essential Care Jr comes as an 800 g pouch, the proposed AEMP is  $2 \times \$39.15 = \$78.30$ .

- 5.19 The price of the Essential Care Jr in comparison to the nominated comparators are presented in the table below.

**Table 2: Energy equivalent content of Essential Care Jr, Neocate Junior and similar products**

Brand Name	PBS Item number	Kilojoules per 100g powder	AEMP for 400g can	DPMQ
Essential Care Jr	-	1946	Proposed: \$78.30 for 800 g	\$360.62
Neocate Junior	11183N, 11161K	1992	\$39.15	\$360.54
Alfamino Junior	10522T, 10527C	1900	\$39.15	\$360.54

Source: Data on kilojoule equivalents is obtained from the product data sheets (Attachment 1 & 2) and PBS website.

- 5.20 As a minor submission, the economic analysis has not been independently evaluated.

***Estimated cost/patient/year: \$4327.44***

- 5.21 The estimated cost/patient per year would be \$4327.44, based on a 12 scripts per year for the maximum quantity requested at DPMQ of \$360.62. *The actual cost will vary due to variations in individual patient needs.*

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

- 5.22 The submission used a market share approach for the utilisation and cost model of Essential Care Jr. The submission stated that all usage of Essential Care Jr is a substitute of usage for other relevant PBS-listed nutritional products for the same indications, with no market growth expected due to PBS listing of Essential Care Jr.
- 5.23 The submission estimated a net cost to the PBS of \$0 to < \$10 million 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. This is summarised in the table below as well as the expected patient and prescription numbers.

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Table 3: Estimated use and financial implications

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
<b>Estimated extent of use</b>						
Number of scripts dispensed <sup>a</sup>	■ <sup>1</sup>	■ <sup>1</sup>	■ <sup>1</sup>	■ <sup>2</sup>	■ <sup>2</sup>	■ <sup>2</sup>
<b>Estimated financial implications of Essential Care Jr</b>						
Cost to PBS	\$■ <sup>3</sup>	\$■ <sup>3</sup>	\$■ <sup>3</sup>	\$■ <sup>3</sup>	\$■ <sup>3</sup>	\$■ <sup>3</sup>
Copayments	\$■ <sup>3</sup>	\$■ <sup>3</sup>	\$■ <sup>3</sup>	\$■ <sup>3</sup>	\$■ <sup>3</sup>	\$■ <sup>3</sup>
Cost to PBS less copayments	\$■ <sup>3</sup>	\$■ <sup>3</sup>	\$■ <sup>3</sup>	\$■ <sup>3</sup>	\$■ <sup>3</sup>	\$■ <sup>3</sup>
<b>Estimated financial implications for Neocate Junior</b>						
Cost to PBS	-\$■ <sup>3</sup>	-\$■ <sup>3</sup>	-\$■ <sup>3</sup>	-\$■ <sup>3</sup>	-\$■ <sup>3</sup>	-\$■ <sup>3</sup>
Copayments	\$■ <sup>3</sup>	\$■ <sup>3</sup>	\$■ <sup>3</sup>	\$■ <sup>3</sup>	\$■ <sup>3</sup>	\$■ <sup>3</sup>
Cost to PBS/RPBS less copayments	-\$■ <sup>3</sup>	-\$■ <sup>3</sup>	-\$■ <sup>3</sup>	-\$■ <sup>3</sup>	-\$■ <sup>3</sup>	-\$■ <sup>3</sup>
<b>Net financial implications to PBS</b>						
Net cost to PBS/RPBS	\$■ <sup>3</sup>	\$■ <sup>3</sup>	\$■ <sup>3</sup>	\$■ <sup>3</sup>	\$■ <sup>3</sup>	\$■ <sup>3</sup>

Source: Tablet 4.2.7 of the submission and Section 4 of the submission.

The redacted values correspond to the following ranges:

<sup>1</sup> < 500

<sup>2</sup> 500 to < 5,000

<sup>3</sup> \$0 to < \$10 million

5.24 As a minor 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 NPWP supported the listing of Essential Care Jr as an additional treatment option for proposed indications (paragraph 1.1) on a cost-minimisation basis with the nominated comparator.
- 6.2 The NPWP considered Neocate Junior was an appropriate comparator.
- 6.3 The NPWP had concerns about Essential Care Jr containing “negligible protein” rather than no protein, as intact protein presents a risk of allergic reaction and requested further clarification from the sponsor. In the pre-PBAC response, the sponsor stated that Essential Care Jr is composed of 100% amino acids; it does not contain intact protein and is free from food allergens.
- 6.4 The NPWP also had concerns about the source of fibre (psyllium) in Essential Care Jr, as psyllium is an intact allergen, which may be unsafe for children with increased risk of allergy and requested further clarification from the sponsor. The pre-PBAC response stated that psyllium has recently been removed from the original formulation, hence it cannot be an allergen source.
- 6.5 The NPWP advised that it is not appropriate to remove the population criterion ‘Patient must be up to the age of 24 months’ from the restrictions for Essential Care

Jr; and advised that Essential Care Jr should have the same restrictions for the relevant indications as its proposed comparator, Neocate Junior. The pre-PBAC response stated that Cortex Health accepted the NPWP advice and overview recommendation on the consistency of the age restriction, and are amenable to the PBAC's view on this.

- 6.6 The NPWP noted that there was no clinical data to support the clinical claim and requested clinical data. The pre-PBAC response stated that 'it is not standard for nutritional foods to have randomised, controlled trial data to support effectiveness and safety, rather that the formulation provides a comprehensive ingredient profile to support required energy, protein, fat, carbohydrate needs while meeting recommended daily intakes of important vitamins, minerals, trace elements and other nutrients'.
- 6.7 The NPWP supported listing Essential Care Jr on the PBS following consideration of the submission and the pre-PBAC response.

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

## **7 PBAC Outcome**

- 7.1 The PBAC recommended the Authority required listing of amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements and medium chain triglycerides on an equivalent cost per kilojoule of energy compared with Neocate Junior 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.
- 7.2 The PBAC agreed with the NPWP advice detailed in Section 5 NPWP consideration. In particular, the PBAC agreed with the NPWP advice that the restrictions of Essential Care Jr be consistent with its comparator, Neocate Junior.
- 7.3 The PBAC advised that Essential Care Jr is suitable for prescribing by nurse practitioners.
- 7.4 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because Essential Care Jr is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over alternative therapies, or not expected to address a high and urgent unmet clinical need given the

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presence of alternative therapies, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2009* for Pricing Pathway A were not met.

- 7.5 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 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, powder for oral liquid, 800 g	NEW	4	4	5	Essential Care Jr
<b>Concept ID</b> (for internal Dept. use)	<b>Category / Program:</b> GENERAL – General Schedule (Code GE)				
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners				
	<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (immediate/real time assessment by Services Australia)				
<b>Restriction Summary 11212 / Treatment of concept: 4323</b> (as at 1 March 2021 from PBS item code: 11161K)					
	<b>Indication:</b> Cows' milk protein enteropathy				
	<b>Treatment Phase:</b> Initial treatment for up to 6 months				
	<b>Treatment criteria:</b>				
	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				
	<b>AND</b>				
	<b>Clinical criteria:</b>				
	The condition must not be isolated infant colic or reflux				
	<b>AND</b>				
	<b>Clinical criteria:</b>				
	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				
	<b>AND</b>				
	<b>Population criteria:</b>				
	Patient must be up to the age of 24 months				
	<b>Prescribing Instructions:</b>				
	The name of the specialist and the date of birth of the patient must be included in the authority application.				
	<b>Administrative Advice:</b> No increase in the maximum quantity or number of units may be authorised.				

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	<b>Administrative Advice:</b> No increase in the maximum number of repeats may be authorised.
	<b>Administrative Advice:</b> Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see <a href="http://www.servicesaustralia.gov.au/HPOS">www.servicesaustralia.gov.au/HPOS</a> ) or by telephone by contacting Services Australia on 1800 888 333.
<b>Restriction Summary 11217 / ToC: 4337</b> (as at 1 March 2021 from PBS item code: 11183N)	
	<b>Indication:</b> Cows' milk protein enteropathy
	<b>Treatment Phase:</b> Continuing treatment
	<b>Treatment criteria:</b>
	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
	<b>AND</b>
	<b>Clinical criteria:</b>
	The condition must not be isolated infant colic or reflux
	<b>AND</b>
	<b>Clinical criteria:</b>
	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
	<b>AND</b>
	<b>Population criteria:</b>
	Patient must be up to the age of 24 months
	<b>Prescribing Instructions:</b> The name of the specialist and the date of birth of the patient must be included in the authority application.
	<b>Administrative Advice:</b> Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see <a href="http://www.servicesaustralia.gov.au/HPOS">www.servicesaustralia.gov.au/HPOS</a> ) or by telephone by contacting Services Australia on 1800 888 333.
	<b>Administrative Advice:</b> Authority approval for an increased maximum quantity, up to 3 times the stated quantity (in packs), may be sought
<b>Restriction Summary 11211 / ToC: 4352</b> (as at 1 March 2021 from PBS item code: 11161K)	
	<b>Indication:</b> Severe cows' milk protein enteropathy with failure to thrive
	<b>Treatment Phase:</b> Initial treatment for up to 6 months
	<b>Treatment criteria:</b>
	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
	<b>AND</b>
	<b>Clinical criteria:</b>
	The condition must not be isolated infant colic or reflux
	<b>AND</b>
	<b>Population criteria:</b>
	Patient must be up to the age of 24 months
	<b>Prescribing Instructions:</b>

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	The name of the specialist and the date of birth of the patient must be included in the authority application.
	<b>Administrative Advice:</b> No increase in the maximum quantity or number of units may be authorised.
	<b>Administrative Advice:</b> No increase in the maximum number of repeats may be authorised.
	<b>Administrative Advice:</b> Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see <a href="http://www.servicesaustralia.gov.au/HPOS">www.servicesaustralia.gov.au/HPOS</a> ) or by telephone by contacting Services Australia on 1800 888 333.
<b>Restriction Summary 11213 / ToC: 4345:</b> (as at 1 March 2021 from PBS item code: 11183N)	
	<b>Indication:</b> Severe cows' milk protein enteropathy with failure to thrive
	<b>Treatment Phase:</b> Continuing treatment
	<b>Treatment criteria:</b>
	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
	<b>AND</b>
	<b>Clinical criteria:</b>
	The condition must not be isolated infant colic or reflux
	<b>AND</b>
	<b>Clinical criteria:</b>
	Patient must have had failure to thrive prior to commencement with initial treatment
	<b>AND</b>
	<b>Population criteria:</b>
	Patient must be up to the age of 24 months
	<b>Prescribing Instructions:</b>
	The name of the specialist and the date of birth of the patient must be included in the authority application.
	<b>Administrative Advice:</b> Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see <a href="http://www.servicesaustralia.gov.au/HPOS">www.servicesaustralia.gov.au/HPOS</a> ) or by telephone by contacting Services Australia on 1800 888 333.
	<b>Administrative Advice:</b> Authority approval for an increased maximum quantity, up to 3 times the stated quantity (in packs), may be sought
<b>Restriction Summary 11218 / ToC: 4305:</b> (as at 1 March 2021 from PBS item code: 11161K)	
	<b>Indication:</b> Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae
	<b>Treatment Phase:</b> Initial treatment for up to 6 months
	<b>Treatment criteria:</b>
	Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist
	<b>AND</b>
	<b>Clinical criteria:</b>
	The condition must not be isolated infant colic or reflux
	<b>AND</b>
	<b>Population criteria:</b>
	Patient must be older than 24 months of age
	<b>Prescribing Instructions:</b>
	The name of the specialist and the date of birth of the patient must be included in the authority application.

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	<b>Administrative Advice:</b> No increase in the maximum quantity or number of units may be authorised.
	<b>Administrative Advice:</b> No increase in the maximum number of repeats may be authorised.
	<b>Administrative Advice:</b> Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see <a href="http://www.servicesaustralia.gov.au/HPOS">www.servicesaustralia.gov.au/HPOS</a> ) or by telephone by contacting Services Australia on 1800 888 333.
<b>Restriction Summary 11214 / ToC: 4338</b> (as at 1 March 2021 from PBS item code: 11183N)	
	<b>Indication:</b> Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae
	<b>Treatment Phase:</b> Continuing treatment
	<b>Treatment criteria:</b>
	Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months
	<b>AND</b>
	<b>Clinical criteria:</b>
	The condition must not be isolated infant colic or reflux
	<b>AND</b>
	<b>Population criteria:</b>
	Patient must be older than 24 months of age
	<b>Prescribing Instructions:</b>
	The name of the specialist and the date of birth of the patient must be included in the authority application.
	<b>Administrative Advice:</b> Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see <a href="http://www.servicesaustralia.gov.au/HPOS">www.servicesaustralia.gov.au/HPOS</a> ) or by telephone by contacting Services Australia on 1800 888 333.
	<b>Administrative Advice:</b> Authority approval for an increased maximum quantity, up to 3 times the stated quantity (in packs), may be sought

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<b>Restriction Summary 11210 / ToC: 4312</b> (as at 1 March 2021 from PBS item code: 11161K)	
	<b>Indication:</b> Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein
	<b>Treatment Phase:</b> Initial treatment for up to 6 months
	<b>Treatment criteria:</b>
	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
	<b>AND</b>
	<b>Clinical criteria:</b>
	Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides)
	<b>AND</b>
	<b>Population criteria:</b>
	Patient must be up to the age of 24 months
	<b>Prescribing Instructions:</b>
	The name of the specialist and the date of birth of the patient must be included in the authority application.
	<b>Administrative Advice:</b> No increase in the maximum quantity or number of units may be authorised.
	<b>Administrative Advice:</b> No increase in the maximum number of repeats may be authorised.
	<b>Administrative Advice:</b> Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see <a href="http://www.servicesaustralia.gov.au/HPOS">www.servicesaustralia.gov.au/HPOS</a> ) or by telephone by contacting Services Australia on 1800 888 333.

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<b>Restriction Summary 11215 / ToC: 4339</b> (as at 1 March 2021 from PBS item code: 11183N)	
	<b>Indication:</b> Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein
	<b>Treatment Phase:</b> Continuing treatment
	<b>Treatment criteria:</b>
	Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist
	<b>AND</b>
	<b>Clinical criteria:</b>
	Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment
	<b>AND</b>
	<b>Population criteria:</b>
	Patient must be up to the age of 24 months
	<b>Prescribing Instructions:</b> The name of the specialist and the date of birth of the patient must be included in the authority application.
	<b>Administrative Advice:</b> Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see <a href="http://www.servicesaustralia.gov.au/HPOS">www.servicesaustralia.gov.au/HPOS</a> ) or by telephone by contacting Services Australia on 1800 888 333.
	<b>Administrative Advice:</b> Authority approval for an increased maximum quantity, up to 3 times the stated quantity (in packs), may be sought
<b>Restriction Summary 11219 / ToC: 5945</b> (as at 1 March 2021 from PBS item code: 11161K)	
	<b>Indication:</b> Eosinophilic oesophagitis
	<b>Treatment Phase:</b> Initial treatment for up to 3 months
	<b>Treatment criteria:</b>
	Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist
	<b>AND</b>
	<b>Clinical criteria:</b>
	Patient must require an amino acid based formula as a component of a dietary elimination program
	<b>AND</b>
	<b>Population criteria:</b>
	Patient must be 18 years of age or less
	<b>Prescribing Instructions:</b> Treatment with oral steroids should not be commenced during the period of initial treatment.
	<b>Prescribing Instructions:</b> 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.
	<b>Prescribing Instructions:</b> The date of birth of the patient must be included in the authority application.

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	<b>Administrative Advice:</b> Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see <a href="http://www.servicesaustralia.gov.au/HPOS">www.servicesaustralia.gov.au/HPOS</a> ) or by telephone by contacting Services Australia on 1800 888 333.
	<b>Administrative Advice:</b> Authority approval for an increased maximum quantity, up to 3 times the stated quantity (in packs), may be sought
<b>Restriction Summary 5974 / ToC: 5974</b> (as at 1 March 2021 from PBS item code: 11183N)	
	<b>Indication:</b> Eosinophilic oesophagitis
	<b>Treatment Phase:</b> Continuing treatment
	<b>Treatment criteria:</b>
	Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist
	<b>AND</b>
	<b>Clinical criteria:</b>
	Patient must have responded to an initial course of PBS-subsidised treatment
	<b>AND</b>
	<b>Population criteria:</b>
	Patient must be 18 years of age or less
	<b>Prescribing 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> Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see <a href="http://www.servicesaustralia.gov.au/HPOS">www.servicesaustralia.gov.au/HPOS</a> ) or by telephone by contacting Services Australia on 1800 888 333.
	<b>Administrative Advice:</b> Authority approval for an increased maximum quantity, up to 3 times the stated quantity (in packs), may be sought
<b>Restriction Summary 11216 / ToC: 4330</b> (as at 1 March 2021 from PBS item code: 11183N)	
	<b>Indication:</b> Cows' milk anaphylaxis
	<b>Treatment Phase:</b> [blank]
	<b>Treatment criteria:</b>
	Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist
	<b>AND</b>
	<b>Population criteria:</b>
	Patient must be up to the age of 24 months
	<b>Prescribing Instructions:</b> Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.
	<b>Prescribing Instructions:</b> The name of the specialist and the date of birth of the patient must be included in the authority application.
	<b>Administrative Advice:</b> Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see <a href="http://www.servicesaustralia.gov.au/HPOS">www.servicesaustralia.gov.au/HPOS</a> ) or by telephone by contacting Services Australia on 1800 888 333.

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	<b>Administrative Advice:</b> Authority approval for an increased maximum quantity, up to 3 times the stated quantity (in packs), may be sought
<b>Restriction Summary 4415 / ToC: 4415</b> (as at 1 March 2021 from PBS item code: 11183N)	
	<b>Indication:</b> Severe intestinal malabsorption including short bowel syndrome
	<b>Treatment Phase:</b> [blank]
	<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> Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see <a href="http://www.servicesaustralia.gov.au/HPOS">www.servicesaustralia.gov.au/HPOS</a> ) or by telephone by contacting Services Australia on 1800 888 333.
	<b>Administrative Advice:</b> Authority approval for an increased maximum quantity, up to 3 times the stated quantity (in packs), may be sought

***This restriction 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.