

**5.17 AMINO ACID FORMULA SUPPLEMENTED WITH
PREBIOTICS, PROBIOTICS AND LONG CHAIN
POLYUNSATURATED FATTY ACIDS
Oral powder, 400g (Neocate Syneo),
Neocate Syneo[®], Nutricia Australia Pty Ltd**

1 Purpose of Application

1.1 The minor submission requested an Authority Required listing of a new drug for the following indications:

- Cows' milk anaphylaxis;
- 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;
- Severe intestinal malabsorption including short bowel syndrome; and
- Eosinophilic oesophagitis (EoE).

2 Requested Listing

2.1 The submission requested that Neocate Syneo[®] be listed for the same indications as the existing listings for Neocate Gold[®] (item codes 5466Q, 5467R and 1545H):

Public Summary Document – July 2017 PBAC Meeting

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Manufacturer	Name and
AMINO ACID FORMULA SUPPLEMENTED WITH PREBIOTICS, PROBIOTICS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS power for oral liquid, 400g	8	5	\$ [REDACTED]	Neocate Syneo®	Nutricia Australia Pty Ltd

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Restriction Level / Method:	<input checked="" type="checkbox"/> Authority Required - In Writing <input checked="" type="checkbox"/> Authority Required - Telephone <input checked="" type="checkbox"/> Authority Required – Emergency <input checked="" type="checkbox"/> Authority Required - Electronic

PBS 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. 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.

PBS Indication:	Cows' milk protein enteropathy
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.
Clinical criteria:	The condition must not be isolated infant colic or reflux, AND 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.
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. No increase in the maximum number of repeats may be authorised.

Public Summary Document – July 2017 PBAC Meeting

PBS 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.
Clinical criteria:	The condition must not be isolated infant colic or reflux, AND 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.
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.

PBS 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.
Clinical criteria:	The condition must not be isolated infant colic or reflux
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. No increase in the maximum number of repeats may be authorised.

PBS Indication:	Severe cows' milk protein enteropathy with failure to thrive
Treatment phase:	Continuing 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.
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.
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.

Public Summary Document – July 2017 PBAC Meeting

PBS 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.
Clinical criteria:	The condition must not be isolated infant colic or reflux
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. No increase in the maximum number of repeats may be authorised.

PBS 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.
Clinical criteria:	The condition must not be isolated infant colic or reflux
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	Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

PBS 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:	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.
Clinical criteria:	Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).
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. No increase in the maximum number of repeats may be authorised.

Public Summary Document – July 2017 PBAC Meeting

PBS 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.
Clinical criteria:	Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.
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.

PBS 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.

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Manufacturer	Name and
AMINO ACID FORMULA SUPPLEMENTED WITH PREBIOTICS, PROBIOTICS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS power for oral liquid, 400g	12	5	\$ [REDACTED]	Neocate Syneo®	Nutricia Australia Pty Ltd

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Restriction Level / Method:	<input checked="" type="checkbox"/> Authority Required - In Writing <input checked="" type="checkbox"/> Authority Required - Telephone <input checked="" type="checkbox"/> Authority Required – Emergency <input checked="" type="checkbox"/> Authority Required - Electronic
PBS Indication:	Eosinophilic oesophagitis (EoE)
Treatment phase:	Initial treatment for up to 3 months
Treatment criteria:	Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.
Clinical criteria:	Patient must require an amino acid based formula as a component of a dietary elimination program.
Population criteria:	Patient must be 18 years of age or less.

Prescribing Instructions	<p>Treatment with oral steroids should not be commenced during the period of initial treatment.</p> <p>Eosinophilic oesophagitis is demonstrated by the following criteria:</p> <ul style="list-style-type: none"> (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. <p>The date of birth of the patient must be included in the authority application.</p>
Administrative Advice	<p>Authorities for increased maximum quantities, up to a maximum of 52, may be authorised.</p>

PBS Indication:	Eosinophilic oesophagitis (EoE)
Treatment phase:	Continuing treatment
Treatment criteria:	Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.
Clinical criteria:	Patient must have responded to an initial course of PBS-subsidised treatment.
Population criteria:	Patient must be 18 years of age or less.
Prescribing Instructions	<p>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.</p>
Administrative Advice	<p>Authorities for increased maximum quantities, up to a maximum of 52, may be authorised.</p>

For more detail on PBAC's view, see section 6 "PBAC outcome".

3 Background

- 3.1 Neocate Syneo® does not require registration with the TGA. The sponsor of Neocate Syneo® confirms that it meets the requirements for foods that have medical purposes as set out under *The Australia New Zealand Food Standards Code – Standard 2.9.5: Food for Special Medical Purposes*.
- 3.2 The Secretariat noted that Neocate Syneo® does not meet Standard 2.9.5 of the Australian New Zealand Food Standards Code (ANZFSC) for manganese and molybdenum. The sponsor claimed that the lower amounts of these minerals were of no nutritional concern and were directly comparable with the currently listed comparator Neocate Gold®.

- 3.3 Neocate Syneo® has not been previously considered by the PBAC.

4 Comparator

- 4.1 The minor submission nominated Neocate Gold® as the comparator. The submission claimed that Neocate Gold® would be the therapy that prescribers would most replace in clinical practice.
- 4.2 The Secretariat noted that there is slightly less energy per gram in Neocate Syneo® (1941 kJ per 100g) than Neocate Gold® (2020 kJ per 100g), due to the addition of synbiotics and nucleotides in the form of dietary fibre. The sponsor claimed that this is not considered to be nutritionally significant.

For more detail on PBAC's view, see section 6 "PBAC outcome."

5 Consideration of the evidence

Sponsor hearing

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

Consumer comments

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

Clinical trials

- 5.3 The basis for listing Neocate Syneo® presented in the minor submission is that it will meet a clinical need for the treatment of cow's milk allergy and multiple food protein intolerance in infants, and eosinophilic oesophagitis and severe malabsorption including short bowel syndrome in children 18 year of age or less. The minor submission claimed that whilst Neocate Syneo® is nutritionally similar to Neocate Gold®, it contains the addition of synbiotics (Syneo blend scFOS/lcFOS/*B. breve* M-16V) which fosters a gut microbiota composition in allergic infants similar to that seen in breast fed infants. The sponsor claimed that Neocate Syneo® would provide an additional choice for physicians and patients.
- 5.4 The minor submission claimed that Neocate Syneo® has been shown to foster a gut microbiota composition in allergic infants similar to that seen in breast fed infants when breast feeding is not possible. To support its claim of an effect on gut microbiota, the minor submission presented the following trials:

Table 1: Clinical trials presented in the submission

Trial ID	Publication title	Publication citation
Direct randomised trials		
NCT00664768	Effects on growth and tolerance and hypoallergenicity of an amino acid-based formula with synbiotics	Pediatr Res. 2014 Feb;75(2):343-51 (Harvey et al. (2014)
NCT00664768	Synbiotics-supplemented amino acid-based formula supports adequate growth in cow's milk allergic infants	Pediatr Allergy Immunol 2015; 26: 316-322.
NTR3979	An amino acid-based formula with synbiotics affects faecal microbiota in Non-IgE mediated cow's milk allergic infants	European Academy of Allergy and Clinical Immunology Congress Oral Abstract Session OAS 19-114

Source: Table 9 of the minor submission

5.5 As a minor submission, the studies presented in the submission have not been independently evaluated.

5.6 In consideration of the submission, the NPWP noted that:

- The sponsor provided a suitable comparison against the requirements of the *Australia New Zealand Food Standards Code - Standard 2.9.5: Food for Special Medical Purposes*.
- Neocate Syneo® does not meet Standard 2.9.5 for manganese and molybdenum but does meet Standard 2.9.1, which is appropriate given the age group most likely to use the product (infants).
- Neocate Syneo® has slightly less energy (1941 kJ) per 100g than the comparator Neocate Gold® (2020 kJ per 100g), due to the addition of synbiotics and nucleotides in the form of dietary fibre.
- The proposed additional \$ [REDACTED] per can (at the AEMP level), although a small cost, was not justified, as the evidence presented in the submission did not support any additional clinical benefits in relation to the addition of symbiotic flora over the comparator.
- The product is not suitable for use for short bowel syndrome in infants without a risk/benefit analysis from a health care professional and unless the patient is monitored.

The NPWP supported the Authority required listing of Neocate Syneo® on a cost-minimisation basis against Neocate Gold® for the dietary management of cow's milk allergy (CMA), multiple protein food intolerance (MPFI) and other medical conditions

where an elemental diet is required (e.g. eosinophilic oesophagitis), at an equivalent price per kilojoule (kJ) of energy to the nominated comparator Neocate Gold®. The NPWP considered that an administrative note should be added to the restriction for short bowel syndrome advising clinicians of the need to complete a risk/benefit analysis prior to treatment and of a need to monitor the patient.

Estimated PBS usage & financial implications

- 5.7 The proposed DPMQs of Neocate Syneo® is \$ [REDACTED] for 8 cans and \$ [REDACTED] for 12 cans. These proposed DPMQs are based on the cost-minimised price to Neocate Gold® plus an additional \$ [REDACTED] per can (at the AEMP level) to account for the increased manufacturing costs from the addition of the synbiotics.
- 5.8 It is noted that the AEMP per kJ is \$ [REDACTED] for Neocate Gold® and \$ [REDACTED] for Neocate Syneo®.
- 5.9 The minor submission estimated a minimal financial impact to the PBS, reflective of the increased cost of manufacturing, associated with the added synbiotics and nucleotides in Neocate Syneo®.
- 5.10 The total net cost to the PBS is estimated to be substantially less than \$10 million dollars by year five. No other costs or cost offsets to the Government were anticipated by the sponsor.

For more detail on PBAC's view, see section 6 "PBAC outcome."

6 PBAC Outcome

- 6.1 The PBAC recommended the Authority Required listing of Neocate Syneo®, 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 formula; proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein; eosinophilic oesophagitis (EoE); cows' milk anaphylaxis and; severe intestinal malabsorption including short bowel syndrome; on a cost-minimisation basis to Neocate Gold®, at an equivalent price per kilojoule of energy.
- 6.2 The PBAC noted the advice of the NPWP supported the listing of Neocate Syneo® on the PBS.
- 6.3 The PBAC considered that Neocate Gold® was the appropriate main comparator.

- 6.4 The PBAC noted that the proposed maximum quantity and number of repeats is consistent with the main comparator Neocate Gold® currently listed on the PBS.
- 6.5 The PBAC agreed with the NPWP's advice that the product is not suitable for use for short bowel syndrome in infants without a risk/benefit analysis from a health care professional and unless the patient is monitored. The PBAC advised that an administrative note should be added to the restriction for short bowel syndrome advising clinicians of this issue.
- 6.6 The PBAC noted that the Pre-PBAC response claimed the proposed additional manufacturing cost of \$ [REDACTED] per can was attributed to manufacturing costs associated with added synbiotics and nucleotides only and not to a claim of additional benefit. However, the PBAC considered that any additional cost in addition to the cost minimised price in the absence of supportive evidence of additional benefit was not justified.
- 6.7 The PBAC recommended that the Early Supply Rule should not apply as it has been the PBAC's view that general nutrients should be exempt.
- 6.8 The PBAC recommended that Neocate Syneo® is suitable for prescribing by nurse practitioners, as nutritional products are currently included for prescribing by nurse practitioners.
- 6.9 In accordance with Section 101 (3BA) of the National Health Act, the PBAC advised that on the basis of the material available to its March 2017 meeting, Neocate Syneo® should be treated as interchangeable on an individual patient basis with any other similar nutritional product.
- 6.10 The PBAC noted that this submission was not eligible for an Independent Review, as it had received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

Add new item:

Public Summary Document – July 2017 PBAC Meeting

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AMINO ACID FORMULA SUPPLEMENTED WITH PREBIOTICS, PROBIOTICS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS power for oral liquid, 400g	8	5	Neocate Syneo®	Nutricia Australia Pty Ltd

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Restriction Level / Method:	<input checked="" type="checkbox"/> Authority Required - In Writing <input checked="" type="checkbox"/> Authority Required - Telephone <input checked="" type="checkbox"/> Authority Required – Emergency <input checked="" type="checkbox"/> Authority Required - Electronic

PBS 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. 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.

PBS Indication:	Cows' milk protein enteropathy
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.
Clinical criteria:	The condition must not be isolated infant colic or reflux, AND 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.
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. No increase in the maximum number of repeats may be authorised.

Public Summary Document – July 2017 PBAC Meeting

PBS 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.
Clinical criteria:	The condition must not be isolated infant colic or reflux, AND 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.
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.

PBS 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.
Clinical criteria:	The condition must not be isolated infant colic or reflux
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. No increase in the maximum number of repeats may be authorised.

PBS Indication:	Severe cows' milk protein enteropathy with failure to thrive
Treatment phase:	Continuing 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.
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.
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.

Public Summary Document – July 2017 PBAC Meeting

PBS 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.
Clinical criteria:	The condition must not be isolated infant colic or reflux
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. No increase in the maximum number of repeats may be authorised.

PBS 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.
Clinical criteria:	The condition must not be isolated infant colic or reflux
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	Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

PBS 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:	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.
Clinical criteria:	Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).
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. No increase in the maximum number of repeats may be authorised.

Public Summary Document – July 2017 PBAC Meeting

PBS 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.
Clinical criteria:	Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.
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.

PBS 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. A risk/benefit analysis from a health care professional and patient monitoring is required for the use of this product for this indication.

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
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Restriction Level / Method:	<input checked="" type="checkbox"/> Authority Required - In Writing <input checked="" type="checkbox"/> Authority Required - Telephone <input checked="" type="checkbox"/> Authority Required – Emergency <input checked="" type="checkbox"/> Authority Required - Electronic
PBS Indication:	Eosinophilic oesophagitis (EoE)
Treatment phase:	Initial treatment for up to 3 months
Treatment criteria:	Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.
Clinical criteria:	Patient must require an amino acid based formula as a component of a dietary elimination program.
Population criteria:	Patient must be 18 years of age or less.

Prescribing Instructions	<p>Treatment with oral steroids should not be commenced during the period of initial treatment.</p> <p>Eosinophilic oesophagitis is demonstrated by the following criteria:</p> <ul style="list-style-type: none"> (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. <p>The date of birth of the patient must be included in the authority application.</p>
Administrative Advice	<p>Authorities for increased maximum quantities, up to a maximum of 52, may be authorised.</p>

PBS Indication:	Eosinophilic oesophagitis (EoE)
Treatment phase:	Continuing treatment
Treatment criteria:	Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.
Clinical criteria:	Patient must have responded to an initial course of PBS-subsidised treatment.
Population criteria:	Patient must be 18 years of age or less.
Prescribing Instructions	<p>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.</p>
Administrative Advice	<p>Authorities for increased maximum quantities, up to a maximum of 52, may be authorised.</p>

8 Context for Decision

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

9 Sponsor's Comment

The sponsor had no comment.