5.27 AMINO ACID SYNTHETIC FORMULA

oral liquid: powder for, 400 g Alfamino® Junior, Nestle Australia Ltd

1. Purpose of Application
   1. The minor submission sought listing of a new formulation suitable for children aged 1 year and older for the same indications as the existing Alfamino® product listed on the PBS, as well as for severe intestinal malabsorption including short bowel syndrome.
2. Requested listing
   1. The submission sought listing for the same PBS indications as Neocate Advance with the exception of the eosinophilic oesophagitis indication. These are summarised as the following:

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| Name, Restriction,  Manner of administration and form | Max.  Qty | №.of  Rpts | Dispensed Price for Max. Qty | Proprietary Name and Manufacturer | |
| AMINO ACID SYNTHETIC FORMULA  amino acid synthetic formula oral liquid: powder for, 400 g | 8 | 5 | $361.48 | Alfamino Junior | NT |

* Cows’ milk protein enteropathy - Initial treatment (for up to 6 months)
* Cows’ milk protein enteropathy – Continuing treatment
* Severe cows’ milk protein enteropathy with failure to thrive – Initial treatment (for up to 6 months)
* Severe cows’ milk protein enteropathy with failure to thrive – Continuing treatment
* Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae - Initial (for up to 6 months)
* Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae – Continuing treatment
* Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein - Initial treatment (for up to 6 months)
* Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein – Continuing treatment
* Cow’s milk anaphylaxis – Initial and Continuing treatment
* Severe intestinal malabsorption including short bowel syndrome

1. Background
   1. Alfamino Junior did not require registration with the TGA. It is classified as a “Food for Special Medical Purpose” regulated under the Australia New Zealand Food Standards Code and complies with this standard.
   2. Alfamino Junior had not previously been considered by the PBAC.
   3. In July 2013, the PBAC recommended listing Alfamino as an Authority required benefit for the same indications as those applying to Neocate Gold, on a cost-minimisation basis compared to Neocate Gold and at an equivalent price per gram of protein.
2. **Comparator**
   1. The minor submission nominated Neocate Advance as the main comparator as it is the most similar preparation to Alfamino Junior, containing amino acid synthetic formula and medium chain triglycerides.
   2. The PBAC noted the following products are listed for the requested indications:

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| **PBS Item** | **Major components** | **Label Age Range** |
| Elecare | AAF+MCT | Infants and Children |
| Elecare LCP | AAF+LCP | Infants and Children |
| Neocate Advance Vanilla | AAF | 12 months+ |
| Neocate Advance | AAF+MCT | 12 months+ |
| Neocate LCP | AAF+LCP | 0-12 months |
| Neocate Gold | AAF+LCP+MCT | 0-12 months |
| Alfamino | AAF+LCP+MCT | From birth onwards |

Source: Table 5, p11 of the minor submission

LCP=Long chain polyunsaturated fatty acids

MCT=Medium chain triglycerides

AAF=Amino acid synthetic formula

1. Consideration of evidence
   1. The minor submission did not present any clinical trials.
   2. The premise of the submission was that the product would fulfil a clinical need for a more nutritionally targeted formula for patients aged 1 year and older, compared to the existing Alfamino product which is suitable for use from birth.

**Estimated PBS usage & financial implications**

* 1. The submission sought listing at the same price per gram of protein equivalent as Neocate Advance.
  2. The minor submission therefore claimed that there would be no financial implications to the PBS as the submission expected Alfamino Junior to substitute directly for Neocate Advance, Neocate Advance Vanilla and EleCare® in practice.

1. PBAC Outcome
   1. The PBAC noted advice from the Nutritional Products Working Party and recommended listing Alfamino Junior as an Authority Required benefit for the same indications as Neocate Advance with the exception of eosinophilic oesophagitis on a cost-minimisation basis against Neocate Advance at an equivalent price per gram of protein.
   2. The PBAC noted the NPWP’s support for the listing of Alfamino Junior and advice that Alfamino Junior would provide a more nutritionally targeted product for patients aged 1 year and older compared to the existing Alfamino product which is suitable for use from birth.
   3. The PBAC recommended that Alfamino Junior be suitable for inclusion in the PBS medicines for prescribing by nurse practitioners within collaborative arrangements.
   4. The PBAC recommended that the Safety Net 20 Day Rule should not apply as it has been the PBAC’s view that general nutrients be exempt.

**Outcome:**

Recommended

1. Recommended listing
   1. Add new items:

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| Name, Restriction,  Manner of administration and form | | Max.  Qty | №.of  Rpts |  | Proprietary Name and Manufacturer | |
| AMINO ACID SYNTHETIC FORMULA  amino acid synthetic formula oral liquid: powder for, 400 g | | 8 | 5 |  | Alfamino Junior | NT |
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| **Category / Program** | GENERAL – General Schedule (Code GE) | | | | | |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists Midwives | | | | | |
| **Episodicity:** | - | | | | | |
| **Severity:** | - | | | | | |
| **Condition:** | Cows’ milk protein enteropathy | | | | | |
| **PBS Indication:** | Cows’ milk protein enteropathy | | | | | |
| **Treatment phase:** | Initial (for up to 6 months) | | | | | |
| **Restriction Level / Method:** | Restricted benefit  Authority Required - In Writing  Authority Required - Telephone  Authority Required – Emergency  Authority Required - Electronic  Streamlined | | | | | |
| **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. | | | | | |
| **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. | | | | | |
| **Prescriber Instructions:** | The name of the specialist and the date of birth of the patient must be included in the authority application. | | | | | |
| **Administrative Advice:** | NOTE:  No increase in the maximum quantity or number of units may be authorised.  NOTE:  No increase in the maximum number of repeats may be authorised. | | | | | |

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| **Category / Program** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists Midwives |
| **Episodicity:** | - |
| **Severity:** | - |
| **Condition:** | Cows’ milk protein enteropathy |
| **PBS Indication:** | Cows’ milk protein enteropathy |
| **Treatment phase:** | Continuing |
| **Restriction Level / Method:** | Restricted benefit  Authority Required - In Writing  Authority Required - Telephone  Authority Required – Emergency  Authority Required - Electronic  Streamlined |
| **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. |
| **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. |
| **Prescriber Instructions:** | The name of the specialist and the date of birth of the patient must be included in the authority application. |
| **Administrative Advice:** | NOTE:  Authorities for increased maximum quantities, up to a maximum of 20, may be authorised. |

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| **Category / Program** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists Midwives |
| **Episodicity:** | - |
| **Severity:** | Severe |
| **Condition:** | cows’ milk protein enteropathy with failure to thrive |
| **PBS Indication:** | Severe cows’ milk protein enteropathy with failure to thrive |
| **Treatment phase:** | Initial (for up to 6 months) |
| **Restriction Level / Method:** | Restricted benefit  Authority Required - In Writing  Authority Required - Telephone  Authority Required – Emergency  Authority Required - Electronic  Streamlined |
| **Clinical criteria:** | The condition must not be isolated infant colic or reflux. |
| **Population criteria:** | Patient must be up to the age of 24 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. |
| **Prescriber Instructions:** | The name of the specialist and the date of birth of the patient must be included in the authority application. |
| **Administrative Advice:** | NOTE:  No increase in the maximum quantity or number of units may be authorised.  NOTE:  No increase in the maximum number of repeats may be authorised. |

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| **Category / Program** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists Midwives |
| **Episodicity:** | - |
| **Severity:** | Severe |
| **Condition:** | cows’ milk protein enteropathy with failure to thrive |
| **PBS Indication:** | Severe cows’ milk protein enteropathy with failure to thrive |
| **Treatment phase:** | Continuing |
| **Restriction Level / Method:** | Restricted benefit  Authority Required - In Writing  Authority Required - Telephone  Authority Required – Emergency  Authority Required - Electronic  Streamlined |
| **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. |
| **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. |
| **Prescriber Instructions:** | The name of the specialist and the date of birth of the patient must be included in the authority application. |
| **Administrative Advice:** | NOTE:  Authorities for increased maximum quantities, up to a maximum of 20, may be authorised. |

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| **Category / Program** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists Midwives |
| **Episodicity:** | - |
| **Severity:** | - |
| **Condition:** | Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae |
| **PBS Indication:** | Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae |
| **Treatment phase:** | Initial (for up to 6 months) |
| **Restriction Level / Method:** | Restricted benefit  Authority Required - In Writing  Authority Required - Telephone  Authority Required – Emergency  Authority Required - Electronic  Streamlined |
| **Clinical criteria:** | The condition must not be isolated infant colic or reflux. |
| **Population criteria:** | Patient must be older than 24 months of age. |
| **Treatment criteria:** | Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist. |
| **Prescriber Instructions:** | The name of the specialist and the date of birth of the patient must be included in the authority application. |
| **Administrative Advice:** | NOTE:  No increase in the maximum quantity or number of units may be authorised.  NOTE:  No increase in the maximum number of repeats may be authorised. |

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| **Category / Program** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists Midwives |
| **Episodicity:** | - |
| **Severity:** | - |
| **Condition:** | Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae |
| **PBS Indication:** | Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae |
| **Treatment phase:** | Continuing |
| **Restriction Level / Method:** | Restricted benefit  Authority Required - In Writing  Authority Required - Telephone  Authority Required – Emergency  Authority Required - Electronic  Streamlined |
| **Clinical criteria:** | The condition must not be isolated infant colic or reflux. |
| **Population criteria:** | Patient must be older than 24 months of age. |
| **Treatment criteria:** | Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months. |
| **Prescriber Instructions:** | The name of the specialist and the date of birth of the patient must be included in the authority application. |
| **Administrative Advice:** | NOTE:  Authorities for increased maximum quantities, up to a maximum of 20, may be authorised. |

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| **Category / Program** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists Midwives |
| **Episodicity:** | - |
| **Severity:** | - |
| **Condition:** | Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein |
| **PBS Indication:** | Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein |
| **Treatment phase:** | Initial (for up to 6 months) |
| **Restriction Level / Method:** | Restricted benefit  Authority Required - In Writing  Authority Required - Telephone  Authority Required – Emergency  Authority Required - Electronic  Streamlined |
| **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. |
| **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. |
| **Prescriber Instructions:** | The name of the specialist and the date of birth of the patient must be included in the authority application. |
| **Administrative Advice:** | NOTE:  No increase in the maximum quantity or number of units may be authorised.  NOTE:  No increase in the maximum number of repeats may be authorised. |

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| **Category / Program** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists Midwives |
| **Episodicity:** | - |
| **Severity:** | - |
| **Condition:** | Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein |
| **PBS Indication:** | Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein |
| **Treatment phase:** | Continuing |
| **Restriction Level / Method:** | Restricted benefit  Authority Required - In Writing  Authority Required - Telephone  Authority Required – Emergency  Authority Required - Electronic  Streamlined |
| **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. |
| **Treatment criteria:** | Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist. |
| **Foreword** | - |
| **Definitions** | - |
| **Prescriber Instructions:** | The name of the specialist and the date of birth of the patient must be included in the authority application. |
| **Administrative Advice:** | NOTE:  Authorities for increased maximum quantities, up to a maximum of 20, may be authorised. |

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| **Category / Program** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists Midwives |
| **Episodicity:** | - |
| **Severity:** | - |
| **Condition:** | Cow’s milk anaphylaxis |
| **PBS Indication:** | Cow’s milk anaphylaxis |
| **Treatment phase:** | Initial and Continuing |
| **Restriction Level / Method:** | Restricted benefit  Authority Required - In Writing  Authority Required - Telephone  Authority Required – Emergency  Authority Required - Electronic  Streamlined |
| **Clinical criteria:** | - |
| **Population criteria:** | Patient must be up to the age of 24 months. |
| **Treatment criteria:** | Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist. |
| **Foreword** | - |
| **Definitions** | Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction. |
| **Prescriber Instructions:** | The name of the specialist and the date of birth of the patient must be included in the authority application. |
| **Administrative Advice:** | NOTE:  Authorities for increased maximum quantities, up to a maximum of 20, may be authorised. |

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| **Category / Program** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists Midwives |
| **Episodicity:** | - |
| **Severity:** | - |
| **Condition:** | Severe intestinal malabsorption including short bowel syndrome |
| **PBS Indication:** | Severe intestinal malabsorption including short bowel syndrome |
| **Treatment phase:** | Initial and Continuing |
| **Restriction Level / Method:** | Restricted benefit  Authority Required - In Writing  Authority Required - Telephone  Authority Required – Emergency  Authority Required - Electronic  Streamlined |
| **Clinical criteria:** | Patient must have failed to respond to protein hydrolysate formulae; OR  Patient must have been receiving parenteral nutrition. |
| **Treatment criteria:** | Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist. |
| **Administrative Advice:** | NOTE:  Authorities for increased maximum quantities, up to a maximum of 20, may be authorised. |

1. 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.

1. Sponsor’s Comment

The sponsor had no comment.