



☒ 29<sup>th</sup> January 2024

**AMINO ACID FORMULA SUPPLEMENTED WITH PREBIOTICS, PROBIOTICS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS - Neocate® Syneo:** 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; Cows' milk anaphylaxis; Severe intestinal malabsorption including short bowel syndrome; Eosinophilic oesophagitis

## PBAC public consultation survey

The PBAC welcomes input from anyone with an interest in the medicine proposed to be listed on the Pharmaceutical Benefits Scheme (PBS). You can submit input by answering the five (5) questions below and/or by uploading a file. You can choose to answer as many of the questions as you like but providing as much detail as you can will be most helpful for the PBAC. Your input will be saved so you can come back at any time to your response before the consultation close date. A copy of your submission will be emailed to the contact email address provided.

### 1 Please outline your experience with the medical/health condition

The National Allergy Council is a partnership between the Australasian Society of Clinical Immunology and Allergy (ASCIA) and Allergy & Anaphylaxis Australia (A&AA), working in consultation with key stakeholder organisations. This submission supports the approval of Neocate Syneo (new formulation) for the treatment of IgE mediated cow's milk allergy including those at risk of anaphylaxis, cow's milk enteropathy, and Eosinophilic Oesophagitis (EoE) in infants and children.

Allergy & Anaphylaxis Australia (A&AA) is a charitable, non-profit organisation established in 1993 to support those affected by allergic disease including food allergy. A&AA is dedicated to assisting individuals, their caregivers and all in the community in the management of allergic conditions. A&AA's aim is to enable individuals and their families to enjoy an optimal quality of life whilst minimising risk to their health and wellbeing.

A&AA strives to raise awareness of allergic disease in the community and provides evidence-based information, resources and services to support children and adults living with allergic disease and those who care for them. A&AA has members across all states and territories of Australia. We have a Medical Advisory Board that consists of clinical immunology/allergy specialists who are also members of Australia's peak medical body ASCIA.

#### **Points for individual consumers to consider**

- *What is the impact of your health condition on your life? Try to be as specific as possible including impacts on your everyday activities, work, family, friends, mental and emotional health.*

Please provide your comments

### 2 How is the medical/health condition currently treated?

Complete avoidance of cow's milk is the only treatment for cow's milk allergy. For infants with IgE and non IgE mediated cow's milk allergy, breast feeding is the preferred mode of feeding; sometimes maternal elimination of cow's milk is required.

Infants with cow's milk allergy who are unable to breast feed or who need supplementary infant formula require a cow's milk free formula. Amino acid formula is well established as the best choice of formula for infants at risk of anaphylaxis to cows' milk, or infants who are symptomatic with formulae based on soy protein or extensively hydrolysed milk protein. For cow's milk enteropathy (a form of non-IgE mediated food allergy), amino acid formula is required where the infant's growth is faltering or when they are unable to tolerate hydrolysed or soy formula.

In eosinophilic oesophagitis, amino acid formula is required for infants and children during trial or maintenance of dietary elimination therapy.

In all cases, supplementation with an appropriate amino acid based formula facilitates resolution of symptoms and promotes normal growth, development and acquisition of normal feeding skills.

**Points for individual consumers to consider**

- What is the effect of your current treatment on your health condition?
- Are there any symptoms which cannot be controlled with the current treatment?
- What side-effects have you experienced with current treatments? Are these manageable?
- Do you have any issues accessing your current treatment? (For example, where or how it is given, how it is funded, whether you fit the criteria to qualify for access)

Please provide your comments

**3 What do you see as the advantages of this proposed medicine, in particular for those with the medical condition and/or family and carers?**

There are several amino acid formulae listed on the PBS, including the current formulation of Neocate Syneo. Continuing to list this formula on the PBS provides Australian families with choice in amino acid formulae, particularly if a formula with probiotics and prebiotics including Human Milk Oligosaccharides is considered beneficial for the infant by the treating clinician.

Importantly, in recent years there have been supply issues and shortages with all brands of amino acid formula currently listed on the PBS. It is therefore necessary to include a range of formula from different manufacturers to ensure access for an essential medical food for infants and children with cow's milk allergy or Eosinophilic Oesophagitis.

**Points for individual consumers to consider**

- What are the specific positive impacts that you hope this treatment will have on your health condition? (for example, reducing pain)
- What impact would you like it to have on your quality of life? (for example, enabling you to return to work)
- If you have used this medicine what was your experience? What changed for you?
- Are there advantages in the way the medicine is delivered? (For example, where it is delivered (for example, home, GP, hospital), or how it is given (for example, tablets rather than injection))

Please provide your comments

**4 What do you see as the main disadvantages of this proposed medicine?**

We do not see any disadvantages to this formula being listed on the PBS.

**Points for individual consumers to consider**

- Are there disadvantages in how you can access the medicine, for example whether you meet the criteria, where it is delivered (for example, home, GP, hospital), or how it is given (for example, tablets rather than injection)?
- Have you heard of any side effects from this medicine? Do you consider these to be manageable?
- What side effects would stop you from taking this medicine?
- If you have used this medicine, what did you consider to be the disadvantages?

Please provide your comments

**5 Please provide any additional comments you would like the PBAC to consider.**

Whilst the National Allergy Council and A&AA support the listing for severe intestinal malabsorption and short bowel syndrome, our expertise relates to the field of allergic diseases.

It is also noteworthy that with the discontinuation of Alfare to the Australian market there is now only one extensively hydrolysed formula (eHF) available on the PBS. If there is any supply issue with the current listed extensively hydrolysed formula, patients will be prescribed amino acid formula as a safe alternative. This will be an increased demand for amino acid formulae until supply of eHF is reinstated, so having a range of formulae for this contingency is necessary.

## Declaration of interests

### Declaration of Interest Statement

The purpose of this declaration is to discover any financial, professional or personal interest on the part of a person, or on the part of their immediate family, who is providing consumer input to the PBAC.

### Information on declaration of interests

For example, a patient has an interest in a particular medicine, because they are currently using it, and wish to see it listed on the PBS. A doctor may be providing comments and has also been involved in clinical trials investigating this medicine. A family member may want to provide comments on a particular medicine that another relative is using, and separately may also have shares in the company which manufactures a number of pharmaceutical drugs, including this specific item.

Such interests may affect or have the appearance of affecting a person's view on the merits of a drug, vaccine or medicinal preparation being considered by the PBAC. The existence of such interests may be a 'conflict of interest'. A conflict of interest is declared so that information provided can be assessed fairly and in a transparent manner. The declarations are confidential to the PBAC, and do not prevent anyone from providing their comments.

A conflict of interest can be declared, but does not mean a person should not still provide their comments.

A **financial interest** may include, but is not limited to, any of the following involvement with companies or other organisations engaged in the development, manufacture, marketing or distribution of vaccines, drugs and medicinal preparations:

1. current shareholdings;
2. board memberships or other offices;
3. paid employment or contracting work;
4. grants
5. hospitality (including conferences, travel).

A **professional interest** may include, but is not limited to, involvement in any of the following:

1. development, manufacture or marketing and distribution of vaccines, drugs and medicinal preparations;
2. making a public statement about that company or a drug or other product of that company.

A **personal interest** may include, but is not limited to, any of the following:

1. where you are writing to support a drug being listed on the PBS, because you have a condition or illness for which that drug may be being considered by the PBAC;
2. an immediate family is aware that a relative close to them suffers from a condition for which a drug before the PBAC may be being considered by the PBAC;
3. where you or your immediate family has strong personal or religious beliefs about a drug or treatment under consideration by the PBAC.

Please include any declarations you wish to make regarding the PBAC submission upon which you are commenting.

*(Required)*

*Please select all that apply*

- ☐ No conflicts
- ☒ Financial conflicts (describe below)
- ☐ Professional conflicts (describe below)
- ☐ Personal conflicts (describe below)

Conflicts Explained:

The National Allergy Council has received unrestricted education grants in the past from companies that make infant formula including Nutricia.

A&AA receives unrestricted educational grants from companies that make infant formula including Nutricia.

The National Allergy Council's and A&AA's informed response is focused on choice, availability and improved health and well-being of infants.