

14.03(c) AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE
Sachets containing oral powder 27.8 g, 30
PKU Lophlex[®],
Nutricia Australia Pty Ltd

1 Purpose of Application

- 1.1 The Committee Secretariat listing requested amending the Pharmaceutical Benefits Scheme (PBS), Section 85 Restricted Benefit listing of amino acid formula with vitamins and minerals without phenylalanine (PKU Lophlex), for the dietary management of phenylketonuria (PKU) due to a product reformulation. The submission requested:
- a change in the formulation composition;
 - amending the form from PKU Lophlex powder 30 x 27.8 g sachets to PKU Lophlex powder 28 g stick pack; and
 - a change to the age indication from 8+ years of age to 3+ years of age.

2 Background

- 2.1 PKU Lophlex was listed on the PBS on 1 April 2005.
- 2.2 The submission requested a change to the formulation and a revised age guideline to align with other PKU Lophlex products.
- 2.3 The sponsor of PKU Lophlex confirmed it meets the requirements for foods for medical purposes as set out under The Australia New Zealand Food Standards Code — Standard 2.9.5: Food for Special Medical Purposes.
- 2.4 There is no change to the level of protein equivalent (PE).

3 Requested listing

- 3.1 The submission did not request changes to existing listing of PKU Lophlex (item 8804J), however suggested the inclusion of an age restriction to patients aged 3 and over.

4 Consideration of the evidence

Sponsor hearing

- 4.1 There was no hearing for this item as it was a Committee Secretariat submission.

Consumer comments

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

Clinical trials

4.3 As a Committee Secretariat submission, no clinical trials were presented in the submission.

Other relevant matters

4.4 The key differences between the current and new formulation of PKU Lophlex in meeting the product upgrade were:

- addition of Docosahexaenoic acid (DHA);
- increases in the level of vitamin C and D;
- decrease in the level of folic acid;
- change the PKU Lophlex powder 27.8 g sachet to PKU Lophlex powder 28 g stick pack for ease of use; and
- Change the flavour description from berry to berries (reflecting the presence of multiple berry flavours).

4.5 The main changes to formulation are presented in Table 1 below.

Table 1: Changes to the nutritional profile of PKU Lophlex powder:

Nutrients	Current PKU Lophlex powder per 20 g PE sachet	New PKU Lophlex powder per 20 g PE stick pack	Rationale
Energy kcal	86-91	98-99	Result of including organic acids in the energy calculation and the addition of encapsulated DHA.
Docosahexaenoic acid DHA (mg)	-	150	Added to optimize dietary management and potentially long term neurodevelopmental outcomes.
Vitamin D (µg)	3.6	8.2	Following recommendations for increased intake of Vitamin D.
Folic acid (µg)	249	100	Following the recommendations for the general population.
Vitamin C (mg)	17.8	36.6	Benefits as an antioxidant.

Estimated PBS usage & financial implications

4.6 The submission did not request a price change for the amended listing.

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

5 NPWP Consideration (and sponsor's further clarification)

- 5.1 The Nutritional Products Working Party (NPWP) supported retaining the listing of the PKU Lophlex powder (including its new packaging), for the dietary management of phenylketonuria (PKU). The NPWP had no concerns that the changes to formulation would pose a risk to the health and safety of patients.
- 5.2 The NPWP considered the addition of an age restriction to patients aged 3+ years old was not required as the current listing does not have an age restriction and agreed use of the product would be adequately guided by clinical judgement.

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

6 PBAC Outcome

- 6.1 The PBAC recommended continuing the Restricted Benefit listing of amino acid formula with vitamins and minerals without phenylalanine (PKU Lophlex), for the dietary management of phenylketonuria (PKU) and amending the listing to reflect the change in sachet size from 27.8 g to 28 g to reflect the amended dose size.
- 6.2 The PBAC noted there is no change to the level of protein equivalent (PE) with the new dose size.
- 6.3 The PBAC noted the NPWP supported the proposed listing of PKU Lophlex for the dietary PKU. The PBAC agreed with the NPWP that the addition of an age restriction to patients aged 3+ years old was not required as the current listing does not have an age restriction and considered that use of the product is guided by clinical judgement.
- 6.4 The PBAC advised that its previous advice for amino acid formula with vitamins and minerals without phenylalanine regarding Nurse Practitioner Prescribing, the Early Supply Rule and interchangeability advice under Section 101 (3BA) of the *National Health Act 1953* remained appropriate.
- 6.5 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

7.1 Amend listing (8804J) as follows:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE Powder for oral liquid 27.8 28 g, 30	4	5	PKU Lophlex	Nutricia Australia Pty Ltd
Category / Program	Section 85 – General Schedule			
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			
PBS Indication: [9229]	Phenylketonuria			
Restriction Level / Method:	<input checked="" type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined			

This restriction may be subject to further review. Should there be any changes made to the restriction the Sponsor will be informed.

8 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.

9 Sponsor's Comment

The sponsor had no comment.