

6.05 AMINO ACID FORMULA WITH VITAMINS AND MINERALS, WITHOUT PHENYLALANINE
Oral liquid 125 mL, 30 (PKU Lophlex LQ 20)
PKU Lophlex LQ 20[®]

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

1 Purpose of Application

- 1.1 The minor submission sought to increase the maximum quantity per script for PKU Lophlex LQ 20[®] and Lophlex[®] from three to four to be consistent with the listings of PKU Cooler 20[®] and PKU Express 20[®]
- 1.2 The minor submission also requested that the brand Lophlex[®] be changed to PKU Lophlex[®] to keep branding consistent with the current Nutricia Pty Ltd PKU range.

2 Requested Listing

- 2.1 The minor submission requested the following changes to the existing listing:
- 2.2 Requested changes appear in *italics*.
- 2.3 No changes to the proposed listing were suggested by the Secretariat.

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Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Manufacturer	Name and
AMINO ACID FORMULA WITH VITAMINS AND MINERALS, WITHOUT PHENYLALANINE oral liquid, 30 x 125 mL cans	4	5	\$1954.22	PKU Lophlex LQ 20®	Nutricia Australia Pty Ltd
AMINO ACID FORMULA WITH VITAMINS AND MINERALS, WITHOUT PHENYLALANINE powder for oral liquid, 30 x 27.8 g sachets	4	5	\$1954.22	PKU Lophlex®	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"/> 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
Condition:	Phenylketonuria

3 Background

- 3.1 PKU Lophlex LQ 20® and Lophlex® are currently listed on the PBS as Restricted Benefits for the dietary management of phenylketonuria. Both PKU Lophlex LQ 20® and Lophlex® are nutritionally incomplete products for patients from the age of four years and patients from the age of eight years respectively.
- 3.2 The sponsor of PKU Lophlex LQ 20® and Lophlex® 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.
- 3.3 The Secretariat noted that based on the Australian and New Zealand Nutrient Reference Values (NRV), some micronutrient levels in PKU Lophlex LQ 20® and Lophlex® are exceeded when 85% of Protein Equivalent (PE) requirements are met. Nutrients exceeding the upper limit are magnesium and folate; the sponsor claims that this is of no nutritional concern as dietary intake of magnesium and folate will be limited in these patients.

4 Comparator

- 4.1 The minor submission nominated PKU Cooler 20[®] as the main comparator for PKU Lophlex LQ 20[®]. Both products are a liquid protein substitute in 125 mL cans containing 20 g protein equivalent (PE).
- 4.2 The minor submission nominated PKU Express 20[®] as the main comparator for Lophlex[®]. Both products are a powdered protein substitute in sachet form containing 20 g PE.
- 4.3 The main comparators, PKU Cooler 20[®] and PKU Express 20[®], contain a higher PE (2400 g PE) per script with a maximum quantity of four than PKU Lophlex LQ 20[®] and Lophlex[®] (1800 g PE).

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.

Basis for submission

- 5.3 The sponsor stated that the minor was submitted in response to feedback from a metabolic dietician stating that the maximum quantities of PKU Lophlex LQ 20[®] and Lophlex[®] do not provide patients with phenylketonuria with the appropriate protein requirements, and that patients subsequently have to fill their prescription more frequently than once a month. The sponsor also claimed that there are occasions when patients may require a higher amount of protein substitute to control their condition (i.e. rapid growth, illness and metabolic decompensation).
- 5.4 The sponsor proposed an increase to the maximum quantity per script to four so that the total PE per script would be consistent with those of PKU Cooler 20[®] and PKU Express 20[®].

Clinical trials

- 5.5 As a minor submission, no clinical trials were presented in the submission.
- 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*.
 - The nominated comparators PKU cooler 20[®] and PKU express [®] were currently listed with a maximum quantity of four.
 - The NPWP advised that the sponsor may wish to investigate a further name change request for PKU Lophlex[®] to PKU Lophlex 20[®], because clinicians find the addition of the grams of protein equivalent in the product name to be helpful in avoiding confusion in prescribing and for patients.

Estimated PBS usage & financial implications

- 5.7 The sponsor claimed there will be limited impact on the cost to Government and product use. The sponsor claimed that increasing maximum script quantity will decrease the number of scripts that will be required per year to meet protein requirements, consequently decreasing patient co-payments as well, and that patients will not switch from the comparators to these products.
- 5.8 The submission included the current DPMQ for both products as \$1,466.73 (maximum quantity of 3 cartons). The Secretariat noted that since 1 July 2017, the DPMQ for both products was now \$1,467.25 due to an update of mark-up fees. The submission calculated the DPMQ for a maximum quantity of 4 cartons to be \$1,954.22 based on \$0.81 per gram PE (calculated based on the DPMQ). The Secretariat noted that this calculation was incorrect as the cost per gram PE should be calculated using the AEMP rather than the DPMQ. The Secretariat noted that the correct DPMQ for a maximum quantity of 4 cartons, with current mark-up fees would be \$1,930.63. The sponsor estimated that increasing the maximum script quantity will result in 12 rather than 16 scripts needed to meet required protein intake, and an annual PBS cost per patient of \$23,450.64 opposed to \$23,467.69 currently.
- 5.9 The submission stated that the proposed change to the listing of PKU Lophlex LQ 20[®] and Lophlex[®] is expected to be cost neutral to the PBS, as both products will remain priced per PE at the same price as existing listings for the same indication (\$0.81 per

gram PE) and it will not result in any new patients using this product for the treatment of PKU.

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

6 PBAC Outcomes

- 6.1 The PBAC recommended the request to increase the maximum quantities of PKU Lophlex LQ 20[®] and PKU Lophlex[®] for the dietary management of phenylketonuria to four.
- 6.2 The PBAC noted the advice of the Nutritional Products Working Party (NPWP) that supported the changes to the listings of PKU Lophlex LQ 20[®] and Lophlex[®].
- 6.3 The PBAC noted the request to change the brand name of Lophlex[®] to PKU Lophlex[®]. The PBAC considered that a further change request for PKU Lophlex[®] to PKU Lophlex 20[®] may also be appropriate noting that clinicians find the addition of the grams of protein equivalent in the product name to be helpful in avoiding confusion in prescribing and for patients.
- 6.4 The PBAC noted that this submission is not eligible for an Independent Review. Independent Review is not available in response to a request to modify or extend an existing listing.

Outcome:

Recommended

7 Recommended listing

- 7.1 Amend existing listings as follows:

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Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
AMINO ACID WITH VITAMINS AND MINERALS,WITHOUT PHENYLALANINE, Oral liquid, 30 × 125 mL cans	4	5	PKU Lophlex LQ 20®	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
Condition:	Phenylketonuria
PBS Indication:	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

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
AMINO ACID WITH VITAMINS AND MINERALS,WITHOUT PHENYLALANINE, Powder for oral liquid, 30 × 27.8 g sachets	4	5	PKU Lophlex®	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
Condition:	Phenylketonuria
PBS Indication:	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

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.