

5.22 AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE

Oral liquid: powder for, 30 x 20 g sachets;
PKU Go, Orpharma Pty Ltd.

1 Purpose of Application

1.1 The minor submission requested a restricted benefit listing for phenylketonuria

2 Requested listing

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 Amino acid formula with vitamins and minerals without phenylalanine containing 15 g protein oral liquid: powder, 30, 20g sachets	4	5	\$ [REDACTED]	PKU Go	To be confirmed

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
Episodicity:	-
Severity:	-
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

Background

- 2.1 PKU Go does not require registration with the TGA. The sponsor has confirmed 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.
- 2.2 PKU Go has not been considered by the PBAC previously.

3 Comparator

- 3.1 The submission nominates PKU Gel and PKU Anamix Junior as the main comparator. All 3 products are supplied as a powder sachet and contain 10g protein equivalent per single use pack.

4 Consideration of the evidence

Sponsor hearing

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

Consumer comments

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

Clinical trials

- 4.3 As a minor submission, no clinical trials were presented in the submission.
- 4.4 In consideration of the submission, the Nutritional Products Working Party (NPWP) noted:
 - This product has a similar proportion of amino acids to the comparators, PKU Gel® and PKU Anamix Infant®; but it does not contain choline. There is an RDI level for choline, and patients on a PKU-suitable diet are likely to have low levels of choline. The sponsor was therefore encouraged to consider adding choline to future formulations of the product.
 - This product can be used across the age range of 6 months to 10 years of age.
 - Although the sponsor stated that this product meets “Australia New Zealand Food Standards Code - Standard 2.9.5 - Food for Special Medical Purposes”, the NPWP noted that the submission, for a formula proposed to be used in infants younger than 12 months, did not provide a comparison with the requirements of the “Australia New Zealand Food Standards Code - Standard 2.9.1 - Infant Formula Products”, as recommended in the PBAC Guidelines.
 - The sponsor did not provide any information about the osmolality when this product is mixed with 20mL of water. This is important in clinical practice as high levels can cause gastrointestinal upsets in young children (for example, the 3000 mOsm/kg per 30mL water measured in PKU Gel®).
 - The sponsor presented different vitamin and mineral levels in Table A.17 (p. 10) and Attachment 3.
 - At the price proposed, the submission estimated no net cost to the PBS.

- 4.5 The NPWP deferred its consideration of this submission until such time that clarification from the sponsor can be sought regarding:
- whether the product meets “Australia New Zealand Food Standards Code - Standard 2.9.1 - Infant Formula Products”; and
 - the vitamin and mineral values for the product (which differed between Table A.17 on p. 10 and Attachment 3).
- 4.6 The PBAC noted that the sponsor provided the requested information in its Pre-PBAC Response, however it was not possible in the available time for the NPWP to fully evaluate the information prior to the PBAC meeting.

Estimated PBS usage & financial implications

- 4.7 The DPMQ (\$████████) has been calculated based on the same cost per protein equivalent of the comparator PKU Anamix Junior, consistent with the pricing of all similar nutritional products for PKU.
- 4.8 The submission assumes ██████ dispensing per year for this product.
- 4.9 Based on the DPMQ in the submission, there was estimated to be no net cost to the PBS as the submission expects PKU Go to only replace the use of other PBS listed nutritional products for PKU.

5 PBAC Outcome

- 5.1 The PBAC noted that the Nutritional Products Working Party (NPWP) deferred its consideration of the submission until further information could be provided. The PBAC therefore deferred its recommendation until further advice could be provided by the NPWP on this submission in view of the additional information received from the sponsor.

Outcome:

Deferred

6 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.

7 Sponsor’s Comment

The Sponsor thanks the PBAC for their considerations and looks forward to being able to list PKU Go in the near future.