

5.19 GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS

oral liquid: powder for, 30 x 51 g sachets

PKU BETTERMILK Lite[®], Cortex Health Pty Ltd

1 Purpose of Application

- 1.1 The minor submission requested a restriction benefit listing for phenylketonuria (PKU).

2 Requested Listing:

- 2.1 The submission requested the following new listing:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Manufacturer	Name and
GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS oral liquid: powder for, 30 x 51 g bottles	4	5	\$2067.73	PKU BETTERMILK Lite [®]	Cortex Health 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

3 Background

- 3.1 The sponsor of PKU BETTERMILK Lite[®] 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.
- 3.2 The product has a lower carbohydrate and fat content compared to the similar PBS-listed product Camino Pro[®] Bettermilk. PKU BETTERMILK Lite[®] has a Protein

Equivalent (PE) amount of 20g and 295 calories per 100 g, while Camino Pro[®] Bettermilk contains 15 g PE and 326 calories per 100 g.

- 3.3 The submission stated that the product can be used by children aged from 12 months, as well as pregnant or lactating women.
- 3.4 PKU BETTERMILK Lite[®] had not been considered by the PBAC previously.

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

4 Comparator

- 4.1 The minor submission nominated Camino Pro[®] Bettermilk as the main comparator, as it is also a glycomacropeptide (GMP) powder for use by patients in the same age groups.
- 4.2 The sponsor also proposed that the product could replace, or be used in combination with, other amino acid supplements or GMP-containing products for PKU.

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.

Clinical trials

- 5.3 The comparative clinical trial data on the use of GMP products for PKU was previously presented in the July 2012 minor submissions for Camino Pro[®] BetterMilk, Complete, and Restore.
- 5.4 The sponsor updated the literature search from 2012 to 2014 which identified an ongoing clinical study, which was provided in the March 2015 submission for PKU Glytactin[®] RTD. As of April 2016, there were no available outcomes for the ongoing study.
- 5.5 In consideration of the submission, the Nutritional Products Working Party (NPWP) noted:
- The proposed listing was clinically and nutritionally appropriate, with suitable restriction criteria. The NPWP stated that there were no indicated safety concerns over the product's proposed patient cohort in children from 12 months, pregnant or lactating women, and all adults.
 - The sponsor estimated a nil financial impact to the PBS, as PKU BETTERMILK Lite[®] would likely substitute, or be used in combination with, currently listed products for PKU patients.

- The product has a reduced carbohydrate and fat content compared to similar PBS-listed PKU products. Based on the comparator, Camino Pro Bettermilk[®], the product also contains higher amounts of nutrients and amino acids. The NPWP noted that these elements are advantageous for PKU patient adherence, as the new brand will add variety to the existing treatments available to patients.

5.6 The NPWP supported the listing of PKU BETTERMILK Lite[®] as a Restricted Benefit for phenylketonuria on a cost-minimisation basis against Camino Pro Bettermilk[®] at an equivalent price per gram of protein.

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

Estimated PBS usage & financial implications

5.7 The proposed dispensed price for maximum quantity for PKU BETTERMILK Lite[®] (DPMQ = \$2,067.73) was derived based on an equivalent cost per gram of protein equivalent (PE) compared with the comparator (\$0.80).

5.8 The submission estimated dispensing ■■■ scripts of PKU BETTERMILK Lite[®] in the first year, assuming that the use of the product will replace the comparator. The submission also assumes an annual ■% dispensing increase applied to subsequent years.

5.9 All nutritional products PBS-listed as "*Glycomacropeptide and essential amino acids with vitamins and minerals*" are listed on a cost-minimisation basis, based on protein equivalent content.

5.10 The sponsor estimated a nil financial cost to the PBS, as the use of PKU BETTERMILK Lite[®] was expected to substitute for currently PBS-listed nutritional therapies for phenylketonuria.

6 PBAC Outcome

6.1 The PBAC recommended the listing of PKU BETTERMILK Lite[®] as a Restricted Benefit for phenylketonuria on a cost-minimisation basis against Camino Pro[®] Bettermilk at an equivalent price per gram of protein.

6.2 The PBAC noted the advice of the NPWP that supported the listing of PKU BETTERMILK Lite[®] on the PBS.

6.3 The PBAC accepted Camino Pro[®] Bettermilk as an appropriate comparator for PKU BETTERMILK Lite[®].

6.4 The PBAC noted that the submission estimates a nil cost to the PBS as it was expected to substitute for existing products.

6.5 The PBAC agreed with the NPWP's statement that there are no safety concerns over the product's proposed patient cohort.

- 6.6 In accordance with subsection 101(3BA) of the *National Health Act* the PBAC advised that, on the basis of the material available to its July 2016 meeting, PKU BETTERMILK Lite[®] should be treated as interchangeable on an individual patient basis with any other nutritional product .
- 6.7 The PBAC recommended that PKU BETTERMILK Lite[®] is suitable for inclusion in the PBS medicines for prescribing by nurse practitioners, as nutritional products are currently included for prescribing by nurse practitioners.
- 6.8 The PBAC recommended that the Early Supply Rule should not apply as it has been the PBAC’s view that general nutrients be exempt.
- 6.9 The PBAC noted that this submission was not eligible for an Independent Review, as it had received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

7.1 Add new item:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS oral liquid: powder for, 30 x 51 g bottles	4	5	PKU BETTERMILK Lite [®]	Cortex Health 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.