

**5.22 GLYCOMACROPEPTIDE and ESSENTIAL AMINO ACIDS with VITAMINS and MINERAL Sachet containing oral powder 35 g, 30, Pku Sphere<sup>®</sup>, Vitaflo Australia Pty Ltd.**

**1 Purpose of Application**

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

**2 Requested Listing**

2.1 The submission requested the following new listing:

2.2 Secretariat suggested changes to ensure consistency with the current PBS restriction for the main comparator are indicated in italics for additions and strikethrough for deletions.

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Name and Manufacturer
GLYCOMACROPEPTIDE FORMULA WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND DOCOSAHEXAENOIC ACID AND LOW IN PHENYLALANINE Powder for oral liquid, 30 x 35 g sachets	4	5	\$ [REDACTED]	PKU SPHERE <sup>®</sup> Vitaflo Australia Pty Ltd

<b>Category / Program</b>	GENERAL – General Schedule (Code GE)
<b>Prescriber type:</b>	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
<b>Condition:</b>	<del>Patients with proven diagnosis of Phenylketonuria</del>
<b>PBS Indication:</b>	<del>Patients with proven diagnosis of Phenylketonuria</del>
<b>Restriction Level / Method:</b>	<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

*For more detail on PBAC’s view, see section 6 “PBAC outcome”*

**3 Background**

3.1 The sponsor of PKU SPHERE<sup>®</sup> confirmed that it met 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 PKU SPHERE<sup>®</sup> had not been considered by PBAC previously.

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

#### **4 Comparator**

4.1 The minor submission nominated Camino Pro<sup>®</sup> Bettermilk as the main comparator as it was also presented in powdered form requiring addition of water prior to consumption. PKU Glylactin RTD 10 and PKU Glylactin RTD 15 were nominated as secondary comparators.

4.2 The product contained a higher protein equivalent per sachet than Camino Pro<sup>®</sup> Bettermilk (20 g versus 15 g protein equivalents).

4.3 The product had lower fat and carbohydrate content than Camino Pro<sup>®</sup> Bettermilk. The product has 45% less calories per gram of protein equivalents than Camino Pro<sup>®</sup> Bettermilk.

*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.

##### **Clinical trials**

5.3 As a minor submission, no clinical trials were presented in the submission.

5.4 In consideration of the submission, the NPWP noted that:

- The comparator suggested by the sponsor, Camino Pro Bettermilk<sup>®</sup>, was appropriate.
- There was a higher amount of phenylalanine at 24 mg per 100 mL than the comparator (14.4 mg per 100 mL). However, the NPWP considered that this level did not lead to a clinical manifestation in increased blood levels.
- The product contained a low level of manganese. However, this was consistent with other similar products.

- The product has fewer calories and a lower volume than the comparator, which may be advantageous for some people.
  - The clinical data was only available for patients over 10 years; therefore, the sponsor's request for an age restriction to patients over 10 years was considered appropriate.
  - The submission was considered to be cost neutral as it was on a cost-minimisation basis against Camino Pro Bettermilk®, at an equivalent price per gram of protein.
- 5.5 The NPWP supported the listing of PKU Sphere® as a Restricted Benefit for phenylketonuria for patients 10 years and older, on a cost-minimisation basis against Camino Pro Bettermilk®, at an equivalent price per gram of protein.

### **Estimated PBS usage & financial implications**

- 5.6 The submission sought to list the product on a cost minimisation basis at the same AEMP per gram of protein equivalent (PE) compared to Camino Pro® Bettermilk.
- 5.7 The cost per patient per year was estimated to be \$ [REDACTED] in the submission. However, this calculation used the price to pharmacy and not the DPMQ. The PBAC noted that the actual cost per patient per year was calculated by, 4 cartons per month = 35g × 30 × 4 at a DPMQ of \$ [REDACTED] × 12 months = \$ [REDACTED].
- 5.8 The PBAC noted that PKU SPHERE® would substitute for the currently PBS-listed items Camino Pro® Bettermilk and PKU Glylactin RTD at the same price per gram PE. However, the PBAC noted that due to the higher concentration of protein in PKU Sphere over the comparator, Camino Pro Bettermilk, that the proposed DPMQ for the maximum quantity was \$ [REDACTED] higher than the comparator for 1 month of supply. On the basis of the patient number estimates in the submission, this would result in a cost to government of \$ [REDACTED] over five years (table 1).

**Table 1. Cost to government of listing PKU sphere**

Year	2017	2018	2019	2020	2021
No. patients	█	█	█	█	█
Net cost to PBS	\$ █	\$ █	\$ █	\$ █	\$ █

The redacted table above shows that at year 5, the estimated cost to PBS would be \$10 - \$20 million.

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

## **6 PBAC Outcomes**

- 6.1 The PBAC recommended the listing of PKU SPHERE<sup>®</sup> as a Restricted Benefit for phenylketonuria for patients 10 years and older, on a cost-minimisation basis against Camino Pro<sup>®</sup> Bettermilk, at an equivalent price per gram of protein.
- 6.2 The PBAC noted the advice of the Nutritional Products Working Party (NPWP) that supported the listing of PKU SPHERE<sup>®</sup> on the PBS.
- 6.3 The PBAC noted the requested maximum quantity of 30 × 35 g sachets × 4 with 5 repeats was consistent with the main comparator Camino Pro<sup>®</sup> Bettermilk and PKU Glylactin RTD formulas currently listed on the PBS.
- 6.4 The PBAC considered the comparator nominated by the sponsor, Camino Pro<sup>®</sup> Bettermilk, to be appropriate.
- 6.5 The PBAC noted there was a higher amount (24 mg per 100 mL) of phenylalanine compared to Camino Pro<sup>®</sup> Bettermilk (14.4 mg per 100 mL) however also noted the advice of the NPWP that this was not likely to lead to a clinical manifestation in increased levels of phenylalanine in blood.
- 6.6 The PBAC noted that the product contained a low level of manganese but that this was consistent with similar products.
- 6.7 The PBAC acknowledged that the product contained fewer calories and a lower volume than the comparator, which may be preferable in some people.
- 6.8 The PBAC considered the sponsor's request for an age restriction to patients over 10 years to be appropriate as clinical data was only available for patient over 10 years.
- 6.9 In accordance with subsection 101(3BA) of the Act, the PBAC advised it was of the opinion that, on the basis of the material available to it at its November 2016 meeting, PKU Sphere<sup>®</sup> should be treated as interchangeable on an individual patient basis with similar nutritional products.

- 6.10 The PBAC advised that PKU SPHERE<sup>®</sup> was suitable for prescribing by nurse practitioners, as nutritional products are currently included for prescribing by nurse practitioners.
- 6.11 The PBAC recommended that the Early Supply Rule should not apply, as it has been the PBAC's view that general nutrients be exempt.
- 6.12 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	
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**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.