

**5.24 GLYCOMACROPEPTIDE FORMULA WITH LONG CHAIN
POLYUNSATURATED FATTY ACIDS AND
DOCOSAHEXAENOIC ACID AND LOW PHENYLALANINE
Sachets containing oral powder 27 g, 30 (PKU
Sphere15)
PKU Sphere15[®]**

**GLYCOMACROPEPTIDE FORMULA WITH LONG CHAIN
POLYUNSATURATED FATTY ACIDS AND
DOCOSAHEXAENOIC ACID AND LOW PHENYLALANINE
Sachets containing oral powder 35 g, 30 (PKU
Sphere20)
PKU Sphere20[®],
Vitaflo Australia Pty Ltd**

1 Purpose of Application

- 1.1 The minor submission requested a Restricted Benefit listing for a new form of glycomacropeptide formula with long chain polyunsaturated fatty acids and docosahexanoic acid and low phenylalanine for the treatment of phenylketonuria.
- 1.2 The minor submission also requested that the currently listed PKU Sphere[®] be changed to PKU Sphere20[®] to better reflect the amount of protein equivalent per sachet.

2 Requested Listing

- 2.1 The submission requested the following new listing of an additional strength and change to existing listing:
- 2.2 Suggested changes are shown in *italics* and deletions are shown in ~~strikethrough~~.

2.3 No changes to the proposed listing are suggested by the Secretariat.

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Manufacturer	Name and
GLYCOMACROPEPTIDE FORMULA WITH DOCOSAHEXAENOIC ACID AND LOW PHENYLALANINE powder for oral liquid, 30 x 27 g sachets	4	5	\$1,612.74 (calculated)	PKU Sphere15®	Vitaflo Australia Pty Ltd
GLYCOMACROPEPTIDE FORMULA WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND DOCOSAHEXAENOIC ACID AND LOW PHENYLALANINE GLYCOMACROPEPTIDE FORMULA WITH DOCOSAHEXAENOIC ACID AND LOW PHENYLALANINE powder for oral liquid, 30 x 35 g sachets	4	5	\$2067.90	PKU Sphere PKU Sphere20®	

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 PKU Sphere® was listed on the PBS on 1 April 2017 as a Restricted Benefit for the dietary management of phenylketonuria.
- 3.2 PKU Sphere15® has not previously been considered by the PBAC.
- 3.3 The sponsor of PKU Sphere15® 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*.

4 Comparator

- 4.1 The minor submission nominated Camino Pro Bettermilk® and PKU Sphere® as the main comparators.
- 4.2 PKU Sphere15® has an equivalent nutritional profile per gram to PKU Sphere®.

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 claimed that an additional sachet size will allow the product to be used in patients depending on their protein requirement. The sponsor also claimed that an additional pack size will allow for interchangeability with the sponsor's other listed products including PKU cooler15®, PKU cooler20®, PKU air15®, PKU express15®, PKU express20® which may assist with compliance.

Clinical trials

- 5.4 As a minor submission, no clinical trials were presented in the submission.
- 5.5 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 NPWP considered that the nominated comparators Camino Pro Bettermilk® and PKU Sphere® were appropriate.

- The minor submission proposed an approved ex-manufacturer price (AEMP) of \$371.03 per carton and claimed this was calculated using an identical price per gram of protein as the nominated comparators. It was noted that the correct cost minimised AEMP at an equivalent price per gram of protein should be \$360.72. The NPWP considered that PKU Sphere 15[®] should be costed at the same price per gram of protein as the nominated comparators.

The NPWP supported the request to list PKU Sphere15[®] as a Restricted Benefit for phenylketonuria on a cost-minimisation basis against the nominated comparators; Camino Pro Bettermilk[®] and PKU Sphere[®], at an equivalent price per gram of protein.

Estimated PBS usage & financial implications

- 5.6 The minor submission proposed an AEMP of \$371.03 per carton and claimed this was calculated using an identical price per gram of protein equivalent as the nominated comparators. However, the Department noted that this was incorrect and the correct cost minimised AEMP at an equivalent price per gram of protein should be \$360.72.
- 5.7 The minor submission claimed that the listing of PKU Sphere15[®] would result in no additional cost to the PBS.

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

6 PBAC Outcome

- 6.1 The PBAC recommended the listing of PKU Sphere15[®] as a Restricted Benefit for the treatment of phenylketonuria on a cost-minimisation basis to Camino Pro Bettermilk[®] at an equivalent cost per gram of protein equivalent.
- 6.2 The PBAC noted that the NPWP supported the listing of PKU Sphere15[®] on the PBS.
- 6.3 The PBAC considered that Camino Pro Bettermilk[®] was an appropriate main comparator.
- 6.4 PBAC noted the requested maximum quantity of 4 cartons with 5 repeats is consistent with the current listings of the main comparators Camino Pro Bettermilk[®] and PKU Sphere[®].

- 6.5 The PBAC recommended that the Early Supply Rule should not apply as it has been the PBAC's view that general nutrients should be exempt.
- 6.6 The PBAC recommended that PKU Sphere15® be made available for PBS prescribing by nurse practitioners, as nutritional products are currently included for prescribing by nurse practitioners.
- 6.7 In accordance with Section 101 (3BA) of the National Health Act, the PBAC advised that on the basis of the material available to its July 2017 meeting, PKU Sphere15® be treated as interchangeable on an individual patient basis with any other similar nutritional product.
- 6.8 The PBAC noted the request to change the brand name of PKU Sphere® to PKU Sphere20®.
- 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 FORMULA WITH DOCOSAHEXAENOIC ACID AND LOW PHENYLALANINE powder for oral liquid, 30 x 27 g sachets	4	5	PKU Sphere15®	Vitaflo 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

7.2 Amend existing listing as follows:

The proposed changes to the existing listing are shown in italics:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
GLYCOMACROPEPTIDE FORMULA WITH DOCOSAHEXAENOIC ACID AND LOW PHENYLALANINE <i>powder for oral liquid, 30 x 35 g sachets</i>	4	5	PKU Sphere20®	Vitaflo 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.