

5.30 GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS
oral liquid, 30 x 250 mL cartons;
PKU Glytactin® RTD 10, PKU Glytactin® RTD 15; Cortex Health Pty Ltd.

1 Purpose of Application

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

2 Requested listing

2.1 The submission’s requested listing is shown below:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Name and Manufacturer
GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS				
glycomacropeptide and essential amino acids with vitamins and minerals containing 10 g protein oral liquid, 28 x 250 mL carton	4	5	\$ [REDACTED]	PKU Glytactin RTD 10 QH
glycomacropeptide and essential amino acids with vitamins and minerals containing 15 g protein oral liquid, 28 x 250 mL carton	4	5	\$ [REDACTED]	PKU Glytactin RTD 15 QH

* Correct DPMQ, an error was identified in Section E of the submission wherein an incorrect formula was used to calculate the DPMQ.

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
Treatment phase:	-
Restriction 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

2.2 Following lodgement of the submission, the sponsor further requested an amendment in the proposed listing from 28 units per carton to 30 units per carton.

3 Background

- 3.1 PKU Glytactin RTD did not require registration with the TGA. It is classified as a “Food for Special Medical Purpose” regulated under the Australia New Zealand Food Standards Code and complies with this standard.
- 3.2 This dose form presentation (ready prepared oral liquid in 250 mL cartons) had not been considered by the PBAC previously.
- 3.3 In July 2012, the PBAC recommended listing glycomacropeptide and essential amino acids with vitamins and minerals, available as ready-to-eat bars (Camino Pro Complete[®]) and powder (Camino Pro[®] Bettermilk), and glycomacropeptide and essential amino acids, available as oral liquid and powder (Camion Pro Restore[®]) on the PBS as Restricted Benefits for the treatment of phenylketonuria.

4 Comparator

- 4.1 The minor submission nominated Camino Pro Bettermilk as the main comparator, as PKU Glytactin RTD contains the same ‘milk-like’ formulation and nutritional composition with Camino Pro Bettermilk. The minor submission claimed that PKU Glytactin RTD is similar to PKU Cooler.

5 Consideration of evidence

- 5.1 The submission presented a summary of the clinical trial data for glycomacropeptide-containing supplements, which was presented in the minor submissions for Camino Pro Bettermilk, Complete and Restore considered by the PBAC in July 2012. The submission claimed that such products are shown to provide at least equivalent efficacy to amino acid products in terms of controlling plasma phenylalanine concentrations.

Estimated PBS usage & financial implications

- 5.2 The price requested was based on the same price per gram of protein unit as Camino Pro Bettermilk.
- 5.3 The minor submission estimated there to be no financial implications to the PBS as the submission expected PKU Glytactin RTD to only substitute for other products PBS-listed under ‘glycomacropeptide and essential amino acids with vitamins and minerals’, particularly Camino Pro Bettermilk. The submission also stated that some substitution of ‘amino acid formula with vitamins and minerals without phenylalanine’ ready to drink such as PKU Cooler 10 and PKU Cooler 15 may occur.

6 PBAC Outcome

- 6.1 The PBAC recommended the listing of PKU Glytactin RTD as a Restricted Benefit for the treatment of phenylketonuria on a cost-minimisation basis with Camino Pro Bettermilk at the same price per gram of protein unit.

- 6.2 The PBAC noted advice from the Nutritional Products Working Party (NPWP) that supported the listing of PKU Glytactin RTD on the PBS.
- 6.3 The PBAC noted advice from the NPWP that the new product contains a higher vitamin A concentration compared to other glycomacropeptide products. In view of this, the PBAC supported the addition of an administrative note to the listing which would potentially assist in alerting prescribers of this difference.
- 6.4 Advice to the Minister under subsection 101(3BA) of the Act
In accordance with subsection 101(3BA) of the Act the PBAC advised that it is of the opinion that, on the basis of the material available to it at its March 2015 meeting, glycomacropeptide and essential amino acids with vitamins and minerals should not be treated as interchangeable on an individual patient basis with any other drugs.
- 6.5 The PBAC recommended that PKU Glytactin is suitable for inclusion in the PBS medicines for prescribing by nurse practitioners within collaborative arrangements.
- 6.6 The PBAC recommended that the Safety Net 20 Day Rule should not apply as it has been the PBAC's view that general nutrients be exempt.

Outcome:

Recommended

7 Recommended listing

7.1 Add new items:

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				
glycomacropeptide and essential amino acids with vitamins and minerals containing 10 g protein oral liquid, 30 x 250 mL carton	4	5	PKU Glytactin RTD 10	QH
glycomacropeptide and essential amino acids with vitamins and minerals containing 15 g protein oral liquid, 30 x 250 mL carton	4	5	PKU Glytactin RTD 15	QH

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

Treatment phase:	-
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
Administrative Advice:	<u>NOTE:</u> This product contains higher vitamin A levels than other PBS-listed glycomacropptide products.

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.