

5.14 GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS, 15 g protein oral liquid, 30 x 250 mL tetrapack, Tylactin® RTD 15, Cortex Health Pty Ltd

1 Purpose of Application

1.1 The minor submission requested a restricted benefit listing of Tylactin RTD® 15 as a medicinal food for adults and children (over one year) for tyrosinaemia.

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	4	5	\$ [REDACTED]	Tylactin® RTD QH 15

glycomacropeptide and essential amino acids with vitamins and minerals containing 15 g protein oral liquid, 30 x 250 mL carton

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:	Tyrosinaemia
PBS Indication:	Tyrosinaemia
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

3 Background

- 3.1 Tylactin[®] RTD 15 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) has not been considered by the PBAC previously for tyrosinaemia.
- 3.3 In July 2007 and in November 2009, PBAC recommended listing of TYR Cooler[®] and TYR Anamix Junior[®] LQ respectively for the treatment of tyrosinaemia as ready prepared oral liquid on an equivalent cost per gram of protein basis compared with the other PBS-listed synthetic amino acid formulations for tyrosinaemia.
- 3.4 Phenylketonuria: 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. In March 2015, the PBAC recommended listing of glycomacropeptide and essential amino acids with vitamins and minerals, available as ready prepared oral liquid in 250 mL cartons (PKU Glytactin[®]) on the PBS as Restricted Benefit for the treatment of phenylketonuria.

4 Comparator

- 4.1 The minor submission nominated TYR Cooler[®] 20 and TYR Cooler[®] 15 as the main comparator, as they are the most used amino acid supplements without phenylalanine and tyrosine used for tyrosinaemia and are also ready-to-drink formulations.

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.

Consideration of the evidence

- 5.3 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. While there are no studies done in patients with tyrosinaemia, the

submission claims the evidence is applicable since the diet for tyrosinaemia is a similar protein and phenylalanine restricted diet.

- 5.4 The advice from the Nutritional Products Working Party (NPWP) noted the most informative evidence to compare Tylactin® RTD 15 with the comparator was the comparison of the nutritional content with recommended dietary intake (RDI). This comparison per gram of protein was against TYR Cooler® 20, not TYR Cooler® 15 which would have been a more appropriate comparator.

Estimated PBS usage & financial implications

- 5.5 The price requested was based equivalent cost per gram of protein equivalent compared with the comparators TYR Cooler 15 and 20.
- 5.6 The submission presents the calculated cost to the PBS of Tylactin® RTD 15 over the first full 5 years of listing in the table below. The cost to the PBS of Tylactin® RTD 15 was calculated based on the dispensed price for the maximum quantity (DPMQ) and the DPMQ with patient co-payments removed, as required by the Guidelines. The 2010-2014 total usage of relevant PBS products for tyrosinaemia by the different PBS patient categories was used to predict the DPMQ with co-payments removed.

Table 1: Cost of Tylactin to the PBS over the first five years of listing

	Year 1	Year 2	Year 3	Year 4	Year 5
Total units*	■	■	■	■	■
Cost at DPMQ	\$■	\$■	\$■	\$■	\$■
Cost at DPMQ with average co-payment removed	\$■	\$■	\$■	\$■	\$■

* 1 unit = proposed PBS maximum quantity

- 5.7 The minor submission estimates there to be no financial implications to the PBS as the submission expects Tylactin® RTD to only replace the use of other PBS-listed amino acid formula at the same daily dose of protein equivalents for each patient.

6 PBAC Outcome

- 6.1 The PBAC recommended the restricted benefit listing of glycomacropeptide and essential amino acids with vitamins and minerals, Tylactin RTD® 15 for the treatment of tyrosinaemia on a cost-minimisation basis against TYR Cooler® 20 and TYR Cooler® 15 on an equivalent price per gram of protein basis.
- 6.2 The PBAC noted advice from the Nutritional Products Working Party (NPWP) that supported the listing of Tylactin RTD® 15 on the PBS, including:
- Tylactin® RTD 15 can be used from 12 months of age, while TYR Cooler® 20 and TYR Cooler® 15 can be used from three years of age.
 - In the one to three year age group, the amount of a number of vitamins and minerals in Tylactin® RTD 15 was below the specific RDI. For example, Tylactin® RTD 15 contained approximately 47% of the RDI for iron. In practice, diet choice or supplements may be used to meet the RDI.

- Listing would give patients more variety and choice.
- 6.3 The PBAC noted that the submission estimated a nil cost to the PBS as it is expected to replace existing products.
- 6.4 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 Tylactin RTD[®] 15 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

Add new item:

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Restriction Method:	Level /	<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
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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.