

5.21 GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS

Bars 81 g, 14 (Tylactin Complete), Tylactin Complete[®], Cortex Health

1 Purpose of Application

- 1.1 The minor submission requested a Restricted Benefit listing of a new form of glycomacropeptide and essential amino acids with vitamins and minerals (Tylactin Complete) for the dietary management of tyrosinaemia.

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 for Max. Qty	Price	Proprietary Manufacturer	Name and
GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS 15 g protein equivalent bar 81 g, 14	8	5	\$ [REDACTED]		Tylactin Complete	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:	Tyrosinaemia
PBS Indication:	Tyrosinaemia
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 Tylactin Complete confirms 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 Tylactin Complete has not previously been considered by the PBAC.

4 Comparator

- 4.1 The minor submission nominated Tylactin RTD as the main comparator as it is the only glycomacropeptide containing formula for the dietary management of tyrosinaemia currently listed on the PBS. Tylactin RTD contains an equivalent amount of protein equivalent (PE) per serving (one carton) as Tylactin Complete (one bar).
- 4.2 The Secretariat noted that Tylactin Complete® has a similar nutritional content compared with Tylactin RTD. The Secretariat noted that Tylactin Complete® contains double the amount of carbohydrate (45g) compared with Tylactin RTD® (24g) per serve and therefore a higher energy content (1340 kilojoules per serve compared with 837 kilojoules per serve).

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 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 comparator Tylactin RTD® was appropriate.
 - The NPWP considered that Tylactin Complete® would be used as a component of the overall dietary regimen for patients with tyrosinaemia and would not completely replace other nutritional products.
 - The proposed maximum quantity of 8 packs (14 bars per pack) would provide for over one month's supply at one bar per day but NPWP considered that this would not pose a quality use of medicines issue through wastage as scripts would only be presented as needed.
 - The submission presented an acceptable cost-minimisation against Tylactin RTD® on a cost per gram of protein equivalent.

The NPWP supported the request to list Tylactin Complete® as a Restricted Benefit for the dietary management of tyrosinaemia on a cost-minimisation basis against the nominated comparator Tylactin RTD®, at an equivalent price per gram of protein equivalent.

Estimated PBS usage & financial implications

- 5.5 The minor submission proposed an AEMP of \$ [REDACTED] per pack based on an equivalent price per gram of protein as the comparator Tylactin RTD®. The proposed DPMQ is \$ [REDACTED].
- 5.6 The minor submission stated that the listing of Tylactin Complete® is expected to be cost neutral to the PBS as it is expected to substitute for the currently listed Tylactin RTD.

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

6 PBAC Outcome

- 6.1 The PBAC recommended the listing of Tylactin Complete® as a Restricted Benefit for the dietary management of tyrosinaemia on a cost-minimisation basis to Tylactin RTD® at an equivalent cost per gram of protein equivalent (PE).
- 6.2 The PBAC noted Tylactin Complete® provides a comparable amount of PE per maximum quantity (1,680 g) to Tylactin RTD® (1,800 g).
- 6.3 The PBAC noted that the NPWP supported the Restricted Benefit listing of Tylactin Complete® on the PBS.
- 6.4 The PBAC noted that the submission estimated a nil cost to the PBS as Tylactin Complete® was expected to substitute for currently listed products on an equivalent cost per gram of PE.
- 6.5 In accordance with subsection 101(3BA) of the *National Health Act*, the PBAC advised that, on the basis of the material available to it at its November 2017 meeting, Tylactin Complete® should be treated as interchangeable on an individual patient basis with similar nutritional products. Similar products may include Tylactin RTD®.
- 6.6 The PBAC advised that Tylactin Complete® was suitable for prescribing by nurse practitioners, as nutritional products are currently included for prescribing by nurse practitioners.

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 8 MINERALS 15 g protein equivalent bar 81 g, 14	8	5	Tylactin Complete®	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
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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.