

14.03 GLYCOMACROPEPTIDE FORMULA WITH DOCOSAHEXAENOIC ACID AND LOW PHENYLALANINE Oral liquid 250 mL, 18 PKU GMPro LQ[®], Nutricia Australia Pty Ltd.

1 Purpose of Application

- 1.1 The minor submission sought to list a liquid formulation of the recommended (but not yet listed) PKU GMPro powder formulation for the dietary management of phenylketonuria (PKU).

2 Requested listing

- 2.1 The submission requested an identical listing to the recommended powder presentation of PKU GMPro, as a Restricted Benefit listing for phenylketonuria, as outlined below.

Name, Restriction, Manner of administration and form	Max. Qty	Nº.of Rpts	Dispensed Price Max. Qty	Proprietary Name and Manufacturer	
GLYCOMACROPEPTIDE FORMULA WITH DOCOSAHEXAENOIC ACID AND LOW PHENYLALANINE ORAL LIQUID 250 mL, 18	10	5	\$1,570.79	PKU GMPro LQ [®]	NUTRICIA AUSTRALIA PTY LTD

Category / Program	Section 85 – General Schedule
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
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
Administrative Advice	This product contains higher vitamin A levels than other PBS-listed glycomacropeptide products.

3 Background

- 3.1 The sponsor of PKU GMPro LQ (Nutricia Australia Pty Ltd) confirmed the product meets the requirements for foods for medical purposes as set out under *The Australia*

New Zealand Food Standards Code — Standard 2.9.5: Food for Special Medical Purposes.

- 3.2 At its November 2018 meeting, the PBAC recommended the listing of a powder presentation of PKU GMPro for the dietary management of PKU. The sponsor advised it is currently unable to guarantee supply of the powder formulation, and PBS listing of the liquid formulation will ensure the continued supply of PKU GMPro in Australia, under a different formulation.

4 Consideration of the evidence

Sponsor hearing

- 4.1 There was no hearing for this item as it was a minor submission.

Consumer comments

- 4.2 The PBAC noted there were no consumer comments received for this item.

Comparison with similar products

- 4.3 The sponsor provided a summary comparing PKU GMPro LQ with the powder formulation and established comparators from the November 2018 submission¹. The product contains the same amount of protein equivalent (PE), slightly lower calorific content, and has a similar nutritional profile to the powder form.

Estimated PBS usage & financial implications

- 4.4 The submission requested a price based on cost minimisation with PKU GMPro powder at the same price per gram of PE (\$0.8016). The submission requested an approved ex-manufacturer price for the maximum quantity (1,800g PE) of \$1,570.79, equivalent to other products with the same quantity of PE. The submission assumed PKU GMPro LQ would be the only substitute for PKU.

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

5 NPWP Consideration

- 5.1 The NPWP noted the requested listing of a liquid formulation of the PKU GMPro for the dietary management of phenylketonuria. The PBAC recommended PBS listing of PKU GMPro powder formulation at its November 2018 meeting, but the sponsor was unable to supply the product at the time of this minor submission. The NPWP noted the similarities in nutritional profiles between the liquid and powder formulations, and supported a listing at the same price-per-gram of PE as similar alternatives. The NPWP noted that at the requested maximum quantities, younger patients may receive a

¹ November 2018 PBAC, Glycomacropeptide formula (PKU GMPro) Public Summary Document

substantial supply (3-4 months), which raised a modest concern regarding wastage if the product were to expire before being consumed, due to the shorter shelf-life of the liquid formulation.

6 PBAC Outcome

- 6.1 The PBAC agreed with the listing of the glycomacropeptide formula, PKU GMPPro® LQ, for the dietary management of phenylketonuria (PKU) processed by the Secretariat. The PBAC advised that the pricing of the previously recommended powder and new liquid formulations should be set at the same cost per gram of protein equivalent (PE). The PBAC noted it had recommended the powder formulation of PKU GMPPro on a cost minimisation basis with PKU Glytactin RTD 10 at the same cost per gram of PE.
- 6.2 Noting the NPWP advice, the PBAC agreed the nutritional profiles of the powder and liquid forms of PKU GMPPro were similar, and the listings and restrictions should be the same, including the administrative note regarding vitamin A content.
- 6.3 The PBAC agreed PKU GMPPro LQ is suitable for inclusion in the PBS medicines for prescribing by nurse practitioners, similar to other nutritional product listings for PKU.
- 6.4 The PBAC advised the Early Supply Rule should not apply to PKU GMPPro LQ as it has generally been its view that nutritional product listings be exempt.
- 6.5 The PBAC advised under Section 101(3BA) of the *National Health Act 1953* that PKU GMPPro LQ should be treated as interchangeable with similar nutritional products on an individual patient basis.
- 6.6 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because PKU GMPPro LQ is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity over PKU GMPPro or not expected to address a high and urgent unmet clinical need over similar nutritional products for dietary management of PKU, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2009* for Pricing Pathway A were not met.
- 6.7 The submission is not eligible for independent review as it received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

- 7.1 Add new item:

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Administrative Advice	This product contains higher vitamin A levels than other PBS-listed glycomacropeptide 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.