

## 5.22 GLYCOMACROPEPTIDE FORMULA WITH DOCOSAHEXAENOIC ACID WITH LOW PHENYLALANINE

**Sachets containing oral powder 33.3 g, 16,  
PKU GMP<sup>®</sup>, Nutricia Australia Pty Ltd**

### 1 Purpose of Application

- 1.1 The minor submission requested a Restricted Benefit listing of a new form of glycomacropeptide formula with docosahexaenoic acid with low phenylalanine (PKU GMP<sup>®</sup>) for the treatment of phenylketonuria (PKU) in patients aged 3 years or older.

### 2 Requested Listing

- 2.1 The submission requested the following new listing:
- 2.2 Suggestions by the Secretariat are shown in italics and deletions are shown in strikethrough in the proposed restriction.

Name, Restriction, Manner of administration and form	Max. Qty	Nº.of Rpts	Dispensed for Max. Qty	Price	Proprietary Name and Manufacturer
GLYCOMACROPEPTIDE FORMULA WITH DOCOSAHEXAENOIC ACID WITH LOW PHENYLALANINE glycomacropeptide formula with docosahexaenoic acid with low phenylalanine powder for oral liquid, 16 × 33.3 sachets	14	5	\$1935.97		PKU GMP <sup>®</sup> Nutricia Australia Pty Ltd

<b>Category / Program</b>	GENERAL – General Schedule (Code GE)
<b>Prescriber type:</b>	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
<b>Condition:</b>	phenylketonuria
<b>PBS Indication:</b>	phenylketonuria
<b>Population criteria:</b>	<del>Patient must be aged 3 years or older.</del>
<b>Foreword</b>	<i>This product contains higher vitamin A levels than other PBS-listed glycomacropeptide products.</i>

- 2.3 The Secretariat considered it appropriate to align the listing of PKU GMP with the nominated comparator (below), which does not have an age restriction.

For more detail on PBAC's view, see section 7 PBAC outcome.

### **3 Background**

- 3.1 The sponsor of PKU GMPPro<sup>®</sup> 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.
- 3.2 PKU GMPPro<sup>®</sup> has not been previously considered by the PBAC.

### **4 Comparator**

- 4.1 The minor submission nominated PKU Glytactin RTD 10 as the main comparator.

**\*\*\* Committee in Confidence Information \*\*\***



**\*\*\* End Committee in Confidence information \*\*\***

For more detail on PBAC's view, see section 7 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 there was no consumer comment for this submission.

#### ***Clinical trials***

- 5.3 As a minor submission, no clinical trials were presented in the submission.

#### ***Estimated PBS usage & financial implications***

- 5.4 The submission stated that the listing of PKU GMPPro<sup>®</sup> is expected to be cost neutral to the PBS as it would be listed on an equivalent price per gram of protein as PKU Glytactin RTD 10. The submission considered there may be a marginal saving to the PBS (less than \$5,000 over 6 years) as a result of fewer dispensing fees due to the larger maximum quantity than the comparator.

For more detail on PBAC's view, see section 7 PBAC outcome.

## 6 NPWP consideration

- 6.1 The Nutritional Product Working Party (NPWP) considered there is a need to have alternative products available for patients providing this amount of protein per serve should [REDACTED]. The NPWP considered the submission likely overestimated utilisation, and hence the estimated savings may not be realised. The NPWP advised the requested listing should have a maximum quantity of 8 instead of 14 to avoid unnecessary wastage and to align with similar listings (based on grams of protein per month).

*For more detail on PBAC's view, see section 7 PBAC outcome.*

## 7 PBAC Outcome

- 7.1 The PBAC recommended the Restricted Benefit listing of a new form of glycomacropeptide formula with docosahexaenoic acid with low phenylalanine (PKU GMP<sup>®</sup>) on a cost-minimisation basis to the comparator PKU Glytactin RTD 10 for the treatment of phenylketonuria (PKU) at an equivalent cost per gram of protein equivalent (PE).
- 7.2 The PBAC noted that the Nutritional Product Working Party (NPWP) supported the decision to list PKU GMP<sup>®</sup> on the PBS.
- 7.3 The PBAC considered PKU Glytactin RTD 10 an appropriate comparator for PKU GMP<sup>®</sup>.
- 7.4 The submission claimed the requested maximum quantity (MQ) is based on providing 85% of the total daily protein requirement for adult males with severe PKU (Table 1). The PBAC noted that the proposed MQ is approximately double that of PKU Glytactin RTD 10. The PBAC supported the NPWP's advice, and considered that the MQ should be 8 instead of 14 to avoid unnecessary wastage and to align with the comparator.

**Table 1. Comparison between PKU GMP<sup>®</sup> and PKU Glytactin RTD 10<sup>®</sup>, the comparator.**

	Pack size	MQ	Total protein equivalent per MQ (g)	AEMP per box	AEMP per MQ	DPMQ
PKU Glytactin RTD 10 (comparator)	30	4	1200	240.48	961.92	1073.01
PKU GMP <sup>®</sup>	16	14	2240	128.26	1795.64	1935.97

Abbreviation: AEMP= approved ex-manufacture price; MQ=maximum quantity; DPMQ=dispensed price for maximum quantity.

Source: Extract from page 18 of the submission

- 7.5 The submission suggested adding a criterion to the restrict PKU GMPro to patients aged 3 or older. Based on the advice of NPWP and the listing of the comparator, the PBAC recommended removing this criterion to align with the listing of PKU Glytactin RTD 10.
- 7.6 The PBAC considered that the Early Supply Rule should not apply as it has been the PBAC’s view that general nutrients be exempt.
- 7.7 Nutritional products are currently included for prescribing by nurse practitioners.
- 7.8 In accordance with Section 101 (3BA) of the National Health Act, the PBAC advised it is of the opinion that, on the basis of the material available to it at its November 2018 meeting, PKU GMPro® should be treated as interchangeable on an individual patient basis with similar nutritional products. Similar product in this case may include the comparator, PKU Glytactin RTD 10.
- 7.9 The PBAC noted that this submission was not eligible for an Independent Review, as it received a positive recommendation.

**Outcome:**

Recommended

## 8 Recommended listing

8.1 Add new item:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer
GLYCOMACROPEPTIDE FORMULA WITH DOCOSAHEXAENOIC ACID WITH LOW PHENYLALANINE glycomacropptide formula with docosahexaenoic acid with low phenylalanine powder for oral liquid, 16 × 33.3 sachets	8	5	PKU GMPro® Nutricia Australia Pty Ltd

<b>Category / Program</b>	GENERAL – General Schedule (Code GE)
<b>Prescriber type:</b>	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
<b>Condition:</b>	phenylketonuria
<b>PBS Indication:</b>	phenylketonuria
<b>Restriction Level / Method:</b>	Restricted benefit
<b>Population criteria:</b>	NA
<b>Administrative Advice</b>	This product contains higher vitamin A levels than other PBS-listed glycomacropptide products.

## **9 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.

## **10 Sponsor's Comment**

The sponsor had no comment.