

**5.31 GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS  
WITH VITAMINS AND MINERALS,  
Sachets containing oral powder 15 g, 30 (PKU Build  
10)  
PKU Build 10  
CORTEX HEALTH PTY LTD**

**1 Purpose of Submission**

- 1.1 The Committee Secretariat submission requested a General Schedule Restricted Benefit listing of a 30-pack of glycomacropeptide and essential amino acids with vitamins and minerals sachets containing oral powder 15 g (PKU Build 10) for the dietary management of phenylketonuria (PKU).
- 1.2 Listing was requested on the basis that the 30-pack size of PKU Build 10 be priced at the same dispensed price for maximum quantity (DPMQ) as the currently PBS-listed 60-pack size of PKU Build 10.

**2 Background**

- 2.1 At its November 2017 meeting, the PBAC recommended the General Schedule Restricted Benefit listing of PKU Build 10 for the dietary management of PKU (paragraph 6.1, PKU Build, Public Summary Document (PSD), November 2017 PBAC).
- 2.2 In November 2019, the PBAC recommended that PKU Build 10 with the new formulation and amended sachet size (15 g) continue to be listed on the PBS (paragraph 7.1, PKU Build, PSD, November 2019 PBAC). The PBAC noted the Nutritional Product Working Party (NPWP) was concerned by several changes to the vitamin, mineral and micronutrient profile of the formulation, specifically the reduction in levels of choline and methionine, and the below recommended daily intake (RDI) levels of folate (measured in dietary folate equivalents) (paragraph 7.2, PKU Build, PSD, November 2019 PBAC).
- 2.3 As PKU Build 10 is marketed as a nutritional product and not a therapeutic good, it is not registered in the Australian Register of Therapeutic Goods.
- 2.4 The submission stated that the manufacturer of PKU Build 10 is transitioning globally to supply only the 30-pack size, while the currently listed 60-pack will no longer be available. A separate delisting request for the 60-pack PKU Build 10 was considered by the PBAC at its November 2024 meeting.

### 3 Requested listing

- 3.1 The submission requested the listing of the new pack size based on the current listing of the 60-pack PKU Build 10 (PBS item code 11287C).

Add new medicinal product pack as follows:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS					
glycomacropeptide and essential amino acids with vitamins and minerals containing 10 g of protein equivalent powder for oral liquid, 60 x 16 g sachets	11287C	2	2	5	PKU Build 10
glycomacropeptide and essential amino acids with vitamins and minerals containing 10 g of protein equivalent powder for oral liquid, 30 x 15 g sachets	NEW	4	4	5	PKU Build 10
<b>Restriction Summary 10089 / Treatment of Concept: 4295</b>					
Concept ID (for internal Dept. use)	<b>Category / Program:</b> <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)				
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners				
	<b>Restriction type:</b> <input checked="" type="checkbox"/> Restricted benefit				
	<b>Indication:</b> Phenylketonuria				
	<b>Administrative advice:</b> This product is low in folic acid, choline and methionine and is not intended as a sole source of nutrition.				

- 3.2 The submission requested listing the 30-pack with a maximum quantity pack/unit of 4 to provide the same amount of oral powder per dispensing as the 60-pack listing (maximum quantity pack/unit of 2). No other changes to the current 60-pack listing were requested.
- 3.3 The proposed 30-pack listing includes an administrative note to advise of the low levels of folate, choline and methionine, consistent with the November 2019 PBAC recommendation for PKU Build (paragraph 7.2, PKU Build, PSD, November 2019 PBAC).

### 4 Comparator

- 4.1 The submission did not nominate a comparator but indicated that the 30-pack of PKU Build 10 will substitute for the currently listed 60-pack size.
- 4.2 Other brands of glycomacropeptide and essential amino acids with vitamins and minerals in oral power sachets and oral liquid cartons (PKU Build 20, Camino Pro® Bettermilk, PKU Restore, and PKU Glytactin RTD 15) are also listed on the PBS.

### 5 Consideration of the evidence

#### Sponsor hearing

- 5.1 There was no hearing for this item.

### Consumer comments

5.2 The PBAC noted that no consumer comments were received for this item.

### Nutritional profile

5.3 The submission stated that no changes have been made to the formulation of PKU Build 10 since the revisions to the nutritional composition were considered by the PBAC at its November 2019 meeting.

### Economic analysis

5.4 The submission did not present an economic analysis. The submission requested the same DPMQ of \$1,075.35 as the currently PBS-listed 60-pack size.

5.5 PKU Build 10 was recommended on a cost-minimisation basis against the nominated comparators Camino Pro® Bettermilk and PKU Bettermilk Lite® at an equivalent price per gram of protein equivalent (paragraph 6.1, PKU Build, PSD, November 2017 PBAC meeting). PKU Bettermilk Lite was delisted from the PBS on 1 February 2023. The protein equivalent content and proposed price of PKU Build 10 30-pack in comparison to other PBS-alternative therapies are presented in Table 1.

Table 1: Protein equivalent contents and prices of PKU Build 10 and alternative therapies

Brand Name	PBS item number	PE/ 100 g <sup>a</sup>	Pack size <sup>a</sup>	Max qty packs	Maximum dispensed qty	AEMP <sup>c</sup> (\$)	DPMQ <sup>c</sup> (\$)
PKU Build 10	New	67	30 x 15 g	4	1800 g	240.48	1075.35
	11287C	67	60 x 15 g	2	1800 g	480.97	1075.35
PKU Build 20	11279P	64	30 x 31 g	4	3720 g	480.97	2085.39
Camino Pro Bettermilk	13714T	38	30 x 40 g	4	4800 g	360.73	1580.39
PKU Restore	11084J	25	60 x 20 g	5	6000 g	238.58	1317.87
PKU Glytactin RTD 15	10332T	6 <sup>d</sup>	30 x 250 mL	4	7500 mL	360.72	1580.35

Source: compiled by the Secretariat during the evaluation

<sup>a</sup> Data obtained from the respective sponsors' websites accessed on 29 August 2024

<sup>b</sup> PKU Restore is an alternative brand of glycomacropeptide and essential amino acids with vitamins and minerals in oral power sachets

<sup>c</sup> Based on AEMPs and DPMQs as of August 2024

<sup>d</sup> per 100 mL

AEMP = approved ex-manufacturer price, DPMQ = dispensed price for maximum quantity, PE = protein equivalent (g)

### Estimated cost/patient/year: \$12,904.20

5.6 The estimated cost/patient per year would be \$12,904.20, based on 12 scripts per year (DPMQ of \$1,075.35 x 12). The actual cost will vary due to variations in individual patient needs.

### Estimated PBS usage and financial implications

5.7 The submission did not present financial analysis. The submission requested no changes to the current pricing arrangements. The new pack is expected to directly substitute for the currently listed 60-pack size. If recommended, the listing of the 30-pack is not expected to impact the utilisation or costs to the PBS/RPBS.

## 6 NPWP consideration

- 6.1 The NPWP supported listing the new 30-pack of PKU Build 10 on the PBS for the dietary management of PKU on a cost-minimisation basis to the lowest cost comparator, at an equivalent cost per gram of PE.
- 6.2 The NPWP advised that the currently listed 60-pack size of PKU Build 10 was an appropriate comparator for the new 30-pack of PKU Build 10, and that other PBS-listed brands of glycomacropeptide and essential amino acids with vitamins and minerals in oral powder sachets (PKU Build 20, Camino Pro<sup>®</sup> Bettermilk, and PKU Restore) and oral liquid (PKU Glytactin RTD 15) are also alternative comparators.
- 6.3 The NPWP accepted the claim that listing the new pack size for PKU Build 10 would not have financial implications to the PBS/RPBS.

## 7 PBAC Outcome

- 7.1 The PBAC recommended a General Schedule Restricted Benefit listing of a 30-pack of glycomacropeptide and essential amino acids with vitamins and minerals sachets containing 15 g of oral powder (PKU Build 10) under the same conditions as the currently listed 60-pack size of PKU Build 10, except for the maximum quantity, for the dietary management of phenylketonuria (PKU).
- 7.2 The PBAC considered that the new 30-pack of PKU Build 10 should be cost-minimised to the lowest cost comparator accepted by the NPWP (60-pack PKU Build 10, PKU Build 20, Camino Pro Bettermilk, PKU Restore, and PKU Glytactin RTD 15) at an equivalent price per gram of protein equivalent.
- 7.3 The PBAC noted and accepted the currently listed 60-pack size of PKU Build 10 as an appropriate comparator and considered that PKU Build 20, Camino Pro Bettermilk, PKU Restore and PKU Glytactin RTD 15 are also alternative comparators.
- 7.4 The PBAC considered the estimated use and estimated nil net financial impact to the PBS/RPBS over 6 years was reasonable.
- 7.5 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because the new 30-pack of PKU Build 10 is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over the currently listed 60-pack size of PKU Build 10, or not expected to address a high and urgent unmet clinical need given the presence of an alternative therapy, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2022* for Pricing Pathway A were not met.
- 7.6 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

### Outcome:

Recommended

## 8 Recommended listing

### 8.1 Add new item:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS					
glycomacropeptide and essential amino acids with vitamins and minerals containing 10 g of protein equivalent powder for oral liquid, 30 x 15 g sachets	NEW	4	4	5	PKU Build 10
<b>Restriction Summary 10089 / Treatment of Concept: 4295</b>					
Concept ID (for internal Dept. use)	Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners				
	Restriction type: <input checked="" type="checkbox"/> Restricted benefit				
	Indication: Phenylketonuria				
	Administrative advice: This product is low in folic acid, choline and methionine and is not intended as a sole source of nutrition.				

***These restrictions may be subject to further review. Should there be any changes made to the restriction the sponsor will be informed.***

## 9 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

## 10 Sponsor's Comment

The sponsor had no comment.