

5.16 AMINO ACID FORMULA with VITAMINS and MINERALS without METHIONINE

oral liquid: powder for, 30 x 36 g sachets,
HCU Anamix Junior®, Nutricia Australia Pty Ltd

1 Purpose of Application

- 1.1 The minor submission requested a Restricted Benefit listing for pyridoxine non-responsive homocystinuria.

2 Requested listing

- 2.1 The submission requested the following new listing. Suggested deletions proposed by the Secretariat are crossed out with ~~strikethrough~~.

Name, Restriction, Manner of administration and form	Max. Qty packs	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Name and Manufacturer
AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE oral liquid: powder for, 30 x 36 g sachets	4	5	\$ [REDACTED]	HCU Anamix Junior® Nutricia Australia 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
Episodicity:	-
Severity:	Proven
Condition:	Pyridoxine non-responsive homocystinuria
PBS Indication:	Proven pyridoxine non-responsive homocystinuria
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 The sponsor of HCU Anamix Junior® 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 HCU Anamix Junior® has not been considered by the PBAC previously.

4 Comparator

- 4.1 The minor submission nominated HCU Gel® and XMET Maxamaid® as comparators, as they are all powdered, amino acid based protein substitutes indicated for the dietary management of children with homocystinuria. As a minor submission, there was no economic comparison.

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 No clinical data was provided in the submission.
- 5.4 In consideration of the submission, the Nutritional Products Working Party (NPWP) noted:
- The proposed listing is clinically and nutritionally appropriate, with suitable restriction criteria.
 - This product will likely substitute currently listed products for a very small number of patients and/or may improve compliance so is expected to be cost neutral to the PBS. However, the submission did slightly underestimate the current total patient population since it did not consider patients using all HCU protein supplements. For example, patients using HCU Anamix Junior LQ® were not included in estimates.
 - The NPWP viewed the listing of additional products as beneficial to this patient population.
 - In Appendix B (p. 34), there is an error in the calculation of the percentage of Recommended Dietary Intake (% RDI) for Niacin. Calculations were based on a Niacin content of 0.72 mg-Niacin Equivalent (mg-NE) per 36 g sachet. However, in the Product Data Sheet in Appendix C (p. 39), it states that there is actually 3.7 mg-NE per 36 g sachet. Consequently, the Niacin content appears low (44% RDI).
- 5.5 The NPWP supported the listing of HCU Anamix Junior® as a Restricted Benefit for pyridoxine non-responsive homocystinuria on a cost-minimisation basis against HCU Gel® and XMET Maxamaid® at an equivalent price per gram of protein.

Estimated PBS usage & financial implications

- 5.6 The proposed PBS dispensed price for maximum quantity (DPMQ = \$██████) is based on the equivalent cost per gram of protein equivalent compared with the comparators (\$██████). Although the approved ex-manufacturer price is correct, the proposed DPMQ has been miscalculated due to an error in the application of

Administration, Handling and Infrastructure fees. The correct DPMQ is therefore \$ [REDACTED].

- 5.7 The submission assumes 1 to 2 patients per year will move to this product from comparator products.
- 5.8 Based on the proposed DPMQ in the submission, in year 5, the estimated net cost to the PBS is expected to be cost-neutral if HCU Anamix Junior® completely replaces HCU Gel® or a saving to the PBS of \$ [REDACTED] if XMET Maxamaid® were replaced by HCU Anamix Junior®.

6 PBAC Outcome

- 6.1 The PBAC recommend the listing of HCU Anamix Junior® as a Restricted Benefit for pyridoxine non-responsive homocystinuria on a cost-minimisation basis against HCU Gel® and XMET Maxamaid® at an equivalent price per gram of protein.
- 6.2 The PBAC noted the advice of the Nutritional Products Working Party that supported the listing of HCU Anamix Junior® on the PBS.
- 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 November 2015 meeting, HCU Anamix Junior® should not be treated as interchangeable on an individual patient basis with any other drugs.
- 6.5 The PBAC recommended that HCU Anamix Junior® 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

- 7.1 Add new item:

Public Summary Document – November 2015 PBAC Meeting

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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.