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

# Purpose of Application

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

# Requested listing

* 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** | **№.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 | $'''''''''''''''''' | HCU Anamix Junior® | Nutricia Australia Pty Ltd |
|  |
| **Category /** **Program** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | [ ] Dental [x] Medical Practitioners [x] Nurse practitioners [ ] Optometrists[ ] Midwives |
| **Episodicity:** | - |
| **Severity:** | ~~Proven~~ |
| **Condition:** | Pyridoxine non-responsive homocystinuria |
| **PBS Indication:** | ~~Proven~~ pyridoxine non-responsive homocystinuria |
| **Treatment phase:** | - |
| **Restriction Level / Method:** | [x] Restricted benefit[ ] Authority Required - In Writing[ ] Authority Required - Telephone[ ] Authority Required – Emergency[ ] Authority Required - Electronic[ ] Streamlined |

# Background

* 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.*
	2. HCU Anamix Junior® has not been considered by the PBAC previously.

# Comparator

* 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.

# Consideration of the evidence

## Sponsor hearing

* 1. There was no hearing for this item as it was a minor submission.

## Consumer comments

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

## Clinical trials

* 1. No clinical data was provided in the submission.
	2. 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).
	1. 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

* 1. 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 $''''''''''''''''''''.

* 1. The submission assumes 1 to 2 patients per year will move to this product from comparator products.
	2. 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 $'''''''''''''''' if XMET Maxamaid® were replaced by HCU Anamix Junior®.

# PBAC Outcome

* 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.
	2. The PBAC noted the advice of the Nutritional Products Working Party that supported the listing of HCU Anamix Junior® on the PBS.
	3. The PBAC noted that the submission estimated a nil cost to the PBS as it is expected to replace existing products.
	4. In accordance with subsection 101(3BA) of the Act the PBAC advised that it is of the opinion that, on the basis if 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.
	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. 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

# Recommended listing

* 1. Add new item:

|  |  |  |  |
| --- | --- | --- | --- |
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| **PBS Indication:** | Pyridoxine non-responsive homocystinuria |
| **Treatment phase:** | - |
| **Restriction Level / Method:** | [x] Restricted benefit[ ] Authority Required - In Writing[ ] Authority Required - Telephone[ ] Authority Required – Emergency[ ] Authority Required - Electronic[ ] Streamlined |

# 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.

# Sponsor’s Comment

The Sponsor had no comment.