

**5.20 AMINO ACID FORMIULA with VITAMINS and MINERALS
without LYSINE and LOW IN TRYPTOPHAN
oral liquid: powder for, 30 x 18 g sachets,
GA1 Anamix Junior®, Nutricia Australia Pty Ltd**

1 Purpose of Application

1.1 The minor submission requested a Restricted Benefit listing for glutaric aciduria type 1.

2 Requested listing

2.1 The submission requested the following new listing.

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 LYSINE AND LOW IN TRYPTOPHAN oral liquid: powder for, 30 x 18g sachets	8	5	\$ [REDACTED]	GA1 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:	Glutaric aciduria type 1
PBS Indication:	Proven glutaric aciduria type 1
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 GA1 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 GA1 Anamix Junior® has not been considered by the PBAC previously.

4 Comparator

- 4.1 The minor submission nominated GA Gel® and XLYS LOW TRY Maxamaid® as the comparators, as they are all powdered, amino acid based protein substitutes indicated for the dietary management of young children with glutaric aciduria type 1 (GA1). 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 this submission. GA1 is a rare condition with an estimated prevalence of 1:100,000 worldwide.

- 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.
- The essential amino acid composition of this product is similar to that of the comparator GA1 Gel®.
- The sachet size of this product is potentially beneficial since lower amounts of currently listed products are required for patients with glutaric aciduria type 1, than for those with other metabolic conditions.
- The fat content of this product is potentially beneficial, given the risk of catabolism and the need to provide adequate energy intake in the proposed patient group.
- The submission estimated a small save to the PBS depending on how this product substitutes with currently listed products.
- The Nutrient Reference Values (NRV) comparison (Appendix B, pp. 33-7) is based on the product meeting 100% of protein requirements, but the NPWP agreed with the submission that this product is more likely to meet 60-80% of requirements.

- 5.5 The NPWP supported the listing of GA1 Anamix Junior® as a Restricted Benefit for glutaric aciduria type 1 on a cost-minimisation basis against GA Gel® and XLYS LOW TRY 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 (\$████). The approved ex-manufacturer price (AEMP) requires further review by the Pricing Section, Pharmaceutical Benefits Division. Based on the stated AEMP, the proposed DPMQ has been miscalculated due to an error in the application of Administration, Handling and Infrastructure fees. The correct DPMQ is therefore \$████.

- 5.7 The submission assumes 1 to 4 patients per year will move to this product from comparator products.
- 5.8 Based on the DPMQ in the submission, in year 5, the submission expects if GA1 Anamix Junior® completely replaced GA Gel®, the net cost to the PBS would be zero. Alternatively, there would be a saving to the PBS of \$████ per year, if XLYS LOW TRY Maxamaid® were replaced by GA1 Anamix Junior®.

6 PBAC Outcome

- 6.1 The PBAC recommended the listing of GA1 Anamix Junior® as a Restricted Benefit for glutaric aciduria type 1 on a cost-minimisation basis against GA Gel® and XLYS LOW TRY 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 GA1 Anamix Junior® on the PBS.
- 6.3 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, GA1 Anamix Junior® should not be treated as interchangeable on an individual patient basis with any other drugs.
- 6.4 The PBAC recommended that GA1 Anamix Junior® is suitable for inclusion in the PBS medicines for prescribing by nurse practitioners within collaborative arrangements.
- 6.5 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.