

5.18 AMINO ACID FORMULA with VITAMINS and MINERALS without METHIONINE, THREONINE and VALINE and LOW IN ISOLEUCINE

oral liquid: powder for, 30 x 18 g sachets, MMA/PA Anamix Junior®, Nutricia Australia Pty Ltd

1 Purpose of Application

1.1 The minor submission requested a Restricted Benefit listing for methylmalonic acidaemia and propionic acidaemia.

2 Requested listing

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

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, THREONINE AND VALINE AND LOW IN ISOLEUCINE liquid: powder for, 30 x 18g sachets	8	5	\$ [REDACTED]	MMA/PA 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:	Methylmalonic acidaemia Propionic acidaemia
PBS Indication:	Proven methylmalonic acidaemia Proven propionic acidaemia
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 MMA/PA 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 MMA/PA Anamix Junior® has not been considered by the PBAC previously.

4 Comparator

- 4.1 The minor submission nominated MMA/PA Gel® and XMTVI Maxamaid® as the comparators, as they are all powdered, amino acid based protein substitutes indicated for the dietary management of young children with methylmalonic acidaemia and propionic acidaemia. 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.
 - In Appendix B (pp. 33-7), 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 0.45 mg-Niacin Equivalent (mg-NE) per 18 g sachet. However, in the Product Data Sheet in Appendix C (p. 39), it states that there is actually 2.5 mg-NE per 18 g sachet.
 - The smaller sachet size of this product is potentially beneficial since lower amounts of the currently listed products are required for patients with methylmalonic acidaemia and propionic acidaemia, than for those with other metabolic conditions.
 - The amino acid composition of this product is similar to that of the comparator MMA/PA Gel®.
 - The submission estimated a low update of the product (1 patient per year) be reflected in clinical practice. The NPWP considered there may be some offset in

use of other products, such as Energivit®, due to the higher fat and energy content of this product, given the risk of catabolism and the need to provide adequate energy intake in the proposed patient group.

- 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.

5.5 The NPWP supported the listing of MMA/PA Anamix Junior® as a Restricted Benefit for methylmalonic acidaemia and propionic acidaemia on a cost-minimisation basis against MMA/PA Gel® and XMTVI 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 █████ patient 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 that if MMA/PA Anamix Junior® completely replaces MMA/PA Gel®, the net cost to the PBS would be zero. Alternatively, there would be a saving to the PBS of \$██████████/year if XMTVI Maxamaid® were replaced by MMA/PA Anamix Junior.

6 PBAC Outcome

6.1 The PBAC recommended the listing of MMA/PA Anamix Junior® as a Restricted Benefit for methylmalonic acidaemia and propionic acidaemia on a cost-minimisation basis against MMA/PA Gel® and XMTVI 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 MMA/PA 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, MMA/PA Anamix Junior® should not be treated as interchangeable on an individual patient basis with any other drugs.

6.5 The PBAC recommended that MMA/PA 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:

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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:	-
Condition:	Methylmalonic acidaemia
PBS Indication:	Methylmalonic acidaemia
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

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:	-
Condition:	Propionic acidaemia
PBS Indication:	Propionic acidaemia

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

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.