

**6.07 ESSENTIAL AMINO ACIDS FORMULA WITH VITAMINS
AND MINERALS,
Sachets containing oral powder 12.5 g, 30 (EAA
Supplement),
EAA Supplement[®],
Vitaflo Australia Pty Limited**

1 Purpose of Submission

- 1.1 The Category 4 submission sought to request essential amino acids formula with vitamins and minerals (EAA Supplement) with new formulation (herein referred to as new EAA Supplement) continue to be listed on the PBS, with changes to the maximum quantity due to the pack size change.

2 Background

- 2.1 EAA Supplement is listed on the PBS for urea cycle disorders (UCDs) and gyrate atrophy (GA) of the choroid and retina.
- 2.2 The submission confirmed the new EAA Supplement meets the requirements for foods for medical purposes as set out under the Australia New Zealand Food Standards Code – Standard 2.9.5: Food for Special Medical Purposes.

For more detail on PBAC's view, see section 7 PBAC outcome.

3 Requested listing

- 3.1 The submission requested the following changes:
- 1) Replacing the current medicinal product pack (MPP) with the new MPP of 'essential amino acids formula with vitamins and minerals powder for oral liquid, 30 x 12.5 g sachets'
 - 2) Listing EAA Supplement with a maximum quantity (packs/units) of six.
- 3.2 Suggested additions are in italics and deletions are in strikethrough.

Public Summary Document – November 2021 PBAC Meeting

MEDICINAL PRODUCT Medicinal Product Pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Proprietary Name and Manufacturer
ESSENTIAL AMINO ACIDS FORMULA WITH VITAMINS AND MINERALS essential amino acids formula with vitamins and minerals powder for oral liquid, 50 x 12.5 g sachets	9385 Y	4	4	5	EAA Supplement Vitaflo Australia Pty Limited
ESSENTIAL AMINO ACIDS FORMULA WITH VITAMINS AND MINERALS essential amino acids formula with vitamins and minerals powder for oral liquid, 30 x 12.5 g sachets	NEW	6	6	5	EAA Supplement Vitaflo Australia Pty Limited

3.3 The currently PBS-listed EAA Supplement provides 200 sachets per month. As a result of the reduction in pack size of the new EAA Supplement, the submission proposed to change the maximum number of units from four to six, providing 180 sachets per month.

3.4 Although the submission did not request de-listing the currently PBS-listed EAA Supplement, it is expected that the sponsor will engage the Department through the de-listing process to remove the currently PBS-listed EAA Supplement (PBS item code 9385 Y) from the PBS, if the new EAA Supplement was recommended. This is because a new item code will be required for the new pack size and the new EAA Supplement is expected to replace the currently PBS-listed EAA Supplement.

For more detail on PBAC's view, see section 7 PBAC outcome.

4 Comparator

4.1 The submission nominated Dialamine (essential amino acids formula with minerals and vitamin C) as the main comparator. The PBAC considered this was appropriate.

For more detail on PBAC's view, see section 7 PBAC outcome.

5 Consideration of the evidence

Sponsor hearing

5.1 There was no hearing for this item.

Consumer comments

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

Other relevant matters

5.3 The submission claimed that the new EAA Supplement reflects the latest scientific knowledge of dietary requirements and management of UCDs and the general population.

Public Summary Document – November 2021 PBAC Meeting

- 5.4 The submission claimed the new EAA Supplement formulation aligns with current international nutritional recommendations, including the European Food Safety Authority's Dietary Reference Values and national recommendations, the Australian Nutrient Reference Values. The submission noted that although international and national reference nutrient intakes for healthy populations are not directly transferable to UCDs and GA, they provide a very useful reference point.
- 5.5 When comparing the new EAA Supplement to the currently PBS-listed EAA Supplement, the submission claimed that new EAA Supplement has less micronutrient amounts per 100 g, except:
- Vitamin D of 39 mcg, which was 14 mcg more than the currently PBS-listed EAA Supplement
 - Choline of 600 mg, which was not included in the currently PBS-listed EAA Supplement.
- 5.6 The submission claimed that the amount of Vitamin D in the new EAA Supplement is in line with recently published *European Food Safety Authority's Dietary Reference Values Guidelines*.
- 5.7 The new EAA Supplement contains 530 mg Docosahexaenoic Acid (DHA), which was not included in the currently PBS-listed EAA Supplement.
- 5.8 The new EAA Supplement contains more leucine (1.6 g more) and isoleucine (0.97 g) to support an adequate intake of these amino acids as low plasma levels have been observed in patients with UCDs prescribed nitrogen scavenging drugs (Mol Genet Metab. 2010). The submission claimed that this change aligns with the World Health Organisation amino acid requirements.
- 5.9 The detailed key differences between the currently PBS-listed and the new EAA Supplement are shown in Table 1 below.

Public Summary Document – November 2021 PBAC Meeting

Table 1: Nutritional changes to EAA Supplement (currently PBS-listed and New) and the comparator Dialamine per 100g powder.

Nutrient per 100g	EAA Supplement (New)	EAA Supplement (currently PBS-listed)	Dialamine
Energy kJ	1314	1224	1530
Kcal	310	288	360
Protein Equivalent g	40	40	25
Carbohydrate g	31	31.8	65
O/W sugars	19	24	59
Fat g	2.9	0.1	Nil added
DHA mg	530	0	0
Amino Acid Profile			
L-Cystine g	1.43	1.8	1.2
L-Histidine g	1.71	1.8	1.2
L-Isoleucine g	6.84	5.7	3.3
L-Leucine g	11.41	9.8	5.13
L-Lysine g	6.24	6.6	4.2
L-Methionine g	1.8	1.8	1.2
L-Phenylalanine g	2.14	3.4	1.8
L-Threonine g	3.91	4.1	3.6
L-Tryptophan g	1.23	1.3	0.75
L-Tyrosine g	3.71	4.7	3
L-Valine g	6.85	7.2	4.62
L-Carnitine mg	130	130	0
Vitamins			
Vitamin A RE	1000	2030	0
Vitamin D3 mcg	39	25	0
Vitamin E mg	21	31	0
Vitamin C mg	145	218	125
Vitamin K mcg	94	203	0
Thiamin mg	2.6	4.1	0
Riboflavin mg	2.9	4.6	0
Niacin mg/ (mg NE)	13/ (33)	51/ (73)	0
Vitamin B6 mg	3.6	5.8	0
Folacin mcg	390	812	0
Vitamin B12 mcg	5.9	9.4	0
Biotin mcg	48	377	0
Pantothenic Acid mg	7.3	16	0
Choline mg	600	0	0
Minerals			
Sodium mg	52	15	<10
Potassium mg	40	35	<10

Public Summary Document – November 2021 PBAC Meeting

Nutrient per 100g	EAA Supplement (New)	EAA Supplement (currently PBS-listed)	Dialamine
Chloride mg	0	0	<20
Calcium mg	2200	2326	<5
Phosphorus mg	1400	2265	<5
Magnesium mg	500	837	<5
Trace Elements			
Iron mg	28	44	0
Copper mg	2.3	4.4	0
Zinc mg	22	44	0
Manganese mg	2.1	6.4	0
Iodine mcg	320	508	0
Molybdenum mcg	90	290	0
Selenium mcg	102	174	0
Chromium mcg	54	174	0

Source: Appendix 1 of the submission

Pricing consideration

5.10 The submission presented the following table (Table 2) to show the pricing structure for EAA supplement.

Table 2: Pricing Structure for EAA supplement

	EAA Supplement Pricing (New)	EAA Supplement Pricing (currently PBS-listed)
AEMP per Pack	\$177.25 (12.5g x 30) (150g PE)	\$295.41 (12.5g x 50) (250g PE)
AEMP per Max. Quantity	\$1063.50 (12.5g x 30 x 6) (150g PE x 6 = 900g PE)	\$1181.64 (12.5g x 50 x 4) (250g PE x 4 = 1000g PE)
DPMQ	\$1180.50	\$1304.66

Source: p11 of the submission.

5.11 The submission claimed that it did not request a change to the established price per gram of Protein Equivalent (PE) for the new EAA Supplement. Due to the reduction in pack size of the new EAA Supplement, the AEMP will reduce from \$1181.64 to \$1063.50. The AEMP is based on the established \$1.1817 per gram of PE.

Estimated PBS usage & financial implications

5.12 The submission estimated the number of scripts of new EAA Supplement using a market share approach. The submission predicted that the use of New EAA Supplement will substitute the use of currently PBS-listed EAA Supplement.

Public Summary Document – November 2021 PBAC Meeting

5.13 The submission estimated a net cost to the PBS of \$0 to < \$10 million in Year 6 of listing, with a total net cost to the PBS of \$0 to < \$10 million over the first 6 years of listing. This is summarised in Table 3 below.

Table 3: Estimated use and financial implications

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Script volume						
EAA Supplement 30 x 12.5g sachets x 6	■ ¹	■ ¹	■ ¹	■ ¹	■ ¹	■ ¹
9385Y - EAA Supplement 50 x 12.5g sachets x 4	-■ ¹	-■ ¹	-■ ¹	-■ ¹	-■ ¹	-■ ¹
EAA Supplement 30 x 12.5g sachets x 6 - new EAA Supplement						
Cost to PBS	■ ²	■ ²	■ ²	■ ²	■ ²	■ ²
Less co-payments	-■ ²	-■ ²	-■ ²	-■ ²	-■ ²	-■ ²
Net cost to PBS	■ ²	■ ²	■ ²	■ ²	■ ²	■ ²
Net cost to RPBS	■ ²	■ ²	■ ²	■ ²	■ ²	■ ²
Net cost PBS / RPBS	■ ²	■ ²	■ ²	■ ²	■ ²	■ ²
EAA Supplement 50 x 12.5g sachets x 4 -- PBS code 9385Y - currently PBS-listed EAA Supplement						
Cost to PBS	-■ ²	-■ ²	-■ ²	-■ ²	-■ ²	-■ ²
Less co-payments	■ ²	■ ²	■ ²	■ ²	■ ²	■ ²
Net cost to PBS	-■ ²	-■ ²	-■ ²	-■ ²	-■ ²	-■ ²
Net cost to RPBS	■ ²	■ ²	■ ²	■ ²	■ ²	■ ²
Net cost PBS / RPBS	-■ ²	-■ ²	-■ ²	-■ ²	-■ ²	-■ ²
Estimated net financial implications						
New listing	■ ²	■ ²	■ ²	■ ²	■ ²	■ ²
Changed listing	-■ ²	-■ ²	-■ ²	-■ ²	-■ ²	-■ ²
Net cost to PBS	■ ²	■ ²	■ ²	■ ²	■ ²	■ ²

Source: EAA Supplement WorkSheet PBS August 2021 of the submission document

The redacted values correspond to the following ranges:

¹ < 500

² \$0 to < \$10 million

5.14 As a Category 4 submission, the financial estimates have not been independently evaluated.

For more detail on PBAC's view, see section 7 PBAC outcome.

6 NPWP Consideration

6.1 The NPWP supported the new EAA Supplement continue to be listed on the PBS, with changes to the maximum quantity due to the pack size change.

- 6.2 The NPWP considered that there is a clinical need for the new EAA Supplement, noting that it is a useful product for a very small number of patients.
- 6.3 The NPWP considered the proposed change to the maximum quantity from four units to six units appropriate, noting that the price per gram of protein equivalent remains unchanged.
- 6.4 The NPWP considered Dialamine an appropriate comparator noting that it was originally used as a comparator for the currently PBS-listed EAA Supplement.
- 6.5 The NPWP noted that the micronutrient supplementation in new EAA Supplement has been reduced for most vitamins and minerals except vitamin D and calcium. The NPWP considered that paediatric patients who use new EAA Supplement will require extra monitoring by dietitians in dietary assessments due to the reduction in vitamin and minerals.
- 6.6 The NPWP considered the addition of choline and (DHA appropriate, noting that patients who require dietary management of UCDs and GA of the choroid and retina are likely to have low dietary intake in choline and DHA. The NPWP considered the changes in amino acid pattern beneficial.

For more detail on PBAC's view, see section 7 PBAC outcome.

7 PBAC Outcome

- 7.1 The PBAC recommended the listing of essential amino acids formula with vitamins and minerals (EAA Supplement) with new formulation, pack size and maximum quantity to replace the current PBS listed EAA Supplement.
- 7.2 The PBAC agreed with the NPWP advice detailed in Section 6 'NPWP consideration'. The PBAC noted that the submission did not request de-listing the currently PBS-listed EAA Supplement. However, it did not have any objection to de-list the currently PBS listed EAA Supplement, noting that the new EAA Supplement will replace the currently PBS listed EAA Supplement.
- 7.3 The PBAC noted that its recommendation was based on EAA Supplement with new formulation replacing the current PBS listed EAA Supplement on a cost neutral basis. The PBAC advised the new EAA Supplement is 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 2009* for pricing Pathway A were not met.
- 7.4 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

8 Recommended listing

- 1) Remove the current medicinal product pack (MPP) of: ‘essential amino acids formula with vitamins and minerals (EAA Supplement) powder for oral liquid, 50 x 12.5 g sachets; apply ‘Supply Only’ arrangements to enable any remaining repeat prescriptions to remain valid for a period of 12 months following removal from the PBS;
- 2) Replace the removed MPP with the new MPP of: ‘essential amino acids formula with vitamins and minerals (EAA Supplement) powder for oral liquid, 30 x 12.5 g sachets; and
- 3) List EAA Supplement with a maximum quantity (packs/units) of six and five repeats.

MEDICINAL PRODUCT Medicinal Product Pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Proprietary Name and Manufacturer
ESSENTIAL AMINO ACIDS FORMULA WITH VITAMINS AND MINERALS essential amino acids formula with vitamins and minerals powder for oral liquid, 50 x 12.5 g sachets	93857	4	4	5	EAA Supplement Vitafo Australia Pty Limited
ESSENTIAL AMINO ACIDS FORMULA WITH VITAMINS AND MINERALS essential amino acids formula with vitamins and minerals powder for oral liquid, 30 x 12.5 g sachets	NEW	6	6	5	EAA Supplement Vitafo Australia Pty Limited

This restriction 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.