

5.11 AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE, Sachets containing oral powder 34g, 30 (TYR Express20), TYR Express20[®], Vitaflo Australia Pty Ltd

1 Purpose of Application

1.1 The minor submission requested a Restricted Benefit listing of a new form of amino acid formula with vitamins and minerals without phenylalanine and tyrosine (TYR Express20[®]) for the dietary management of tyrosinaemia.

2 Requested Listing

2.1 The submission requested the following new listing:

2.2 No changes to the proposed listing were suggested by the Secretariat.

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Manufacturer	Name and
AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE powder for oral liquid, 30 x 34 g sachets	4	5	\$ [REDACTED]	TYR Express20 [®]	Vitaflo 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
Condition:	Tyrosinaemia
Restriction Level / Method:	<input checked="" type="checkbox"/> Restricted benefit

3 Background

3.1 The sponsor of TYR Express20[®] confirmed 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 The submission has not been considered by the PBAC previously.

4 Comparator

4.1 The minor submission nominated TYR Express15[®] as the main comparator, as TYR Express20[®] was a new form of the existing listing, TYR Express15[®].

- 4.2 The submission also proposed another comparator, TYR Cooler20®, which was also used in this indication and has the same amount of protein equivalent (PE) as TYR Express20®.

For more detail on PBAC’s view, see section 6 “PBAC outcome”

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 trials were presented in the submission.
- 5.4 In consideration of the submission, the Nutritional Products Working Party (NPWP) noted that:
- The formulation is a larger sachet size of the comparator TYR Express 15®, which would align it with other 20 g/sachet products.
 - The proposed listing would allow for ease of switching between products for tyrosinaemia in adult patients.
 - Patients would be under the care of a specialist and as such no age stipulation was required in the proposed restriction.
- 5.5 The NPWP supported the listing of TYR Express20® as a Restricted Benefit for the dietary management of tyrosinaemia on a cost-minimisation basis against TYR Express15® at an equivalent price per gram of PE.

Estimated PBS usage & financial implications

- 5.6 The minor submission proposed that TYR Express 20® be cost minimised at an equivalent price per gram of PE as TYR Express 15®. TYR Express 15® and TYR Cooler 20® are currently PBS listed based on an equivalent price per gram of protein. On the proposed basis for listing of an equivalent price per gram of protein as TYR Express 15®, the Secretariat calculated the Approved Ex-Manufacturer Price (AEMP) and Dispensed Price for Maximum Quantity (DPMQ) to be the same as for TYR Cooler20® (see Table 1).

Table 1: Price comparison of TYR Express 20® and its comparators

Brand	PE per Sachet (g)	PE per carton (g)	AEMP per carton	Price per gram PE	PE per max qty (g)	DPMQ
TYR Express15	15	450	\$701.10	\$1.558	1800	\$2,952.30
TYR Cooler20	20	600	\$934.80	\$1.558	2400	\$3,887.10
TYR Express20	20	600	\$934.80	\$1.558	2400	\$3,887.10

PE = protein equivalent; AEMP = Approved Ex-Manufacturer Price; DPMQ = Dispensed Price for Maximum Quantity

- 5.7 The submission claimed that there would be no net cost to the PBS as a result of listing this product as it would directly replace existing products.

For more detail on PBAC's view, see section 6 "PBAC outcome"

6 PBAC Outcome

- 6.1 The PBAC recommended the Restricted Benefit listing of TYR Express20® on a cost-minimisation basis to TYR Express15® for the treatment of tyrosinaemia at an equivalent cost per gram of protein equivalent (PE).
- 6.2 The PBAC noted that the NPWP supported the decision to list TYR Express20® on the PBS.
- 6.3 The PBAC considered TYR Express15® an appropriate comparator for TYR Express20®.
- 6.4 The PBAC noted that the submission estimated a nil cost to the PBS upon listing of TYR Express20®, as it was expected to substitute for currently listed products on an equivalent cost per gram PE basis.
- 6.5 In accordance with subsection 101(3BA) of the *National Health Act 1953*, the PBAC advised it is of the opinion that, on the basis of the material available to it at its March 2017 meeting, TYR Express20® should be treated as interchangeable on an individual patient basis with similar nutritional products. Similar products may include TYR Cooler20, TYR Anamix Junior, TYR Gel and TYR Express15.
- 6.6 The PBAC advised that TYR Express20® was suitable for prescribing by nurse practitioners, as nutritional products are currently included for prescribing by nurse practitioners.
- 6.7 The PBAC recommended that the Early Supply Rule should not apply as it has been the PBAC's view that general nutrients be exempt.
- 6.8 The PBAC noted that this submission was not eligible for an Independent Review, as it had received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

7.1 Add new item:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE powder for oral liquid, 30 × 34 g sachets	4	5	TYR Express20®	Vitaflo 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
Condition:	Tyrosinaemia
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.