

5.17 AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE

Oral liquid: powder for, 30 x 34g bottles,
TYR Easy Shake & Go[®], Orpharma Pty Ltd

1. Purpose of Application

1.1 The minor submission requested a restricted benefit listing for tyrosinaemia (TYR)

2. Requested Listing:

2.1 The submission requested the following new listing:

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 oral liquid: powder for, 30 x 34 g bottles	4	5	\$ [REDACTED]	TYR Easy Shake & Go [®]	Orpharma 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
PBS Indication:	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

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

3. Background

- 3.1 The sponsor of TYR Easy Shake & Go[®] 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 product contains a different Protein Equivalent (PE) amount of 15 g PE per 34 g powder, compared to similar PBS-listed products, such as TYR Cooler[®] 10 or 20 (10 g and 20 g PE respectively), Lophlex[®] (20 g PE) or TYR Anamix Junior[®] (10 g PE).
- 3.3 TYR Easy Shake & Go[®] had not been considered by PBAC previously.

4. Comparator

- 4.1 The minor submission nominated TYR Express 15[®] as the main comparator. The comparator is also a powder for an oral liquid formulation, and contains the same amount (15 g PE) per dosing unit and per PBS maximum quantity (4 x 30 bottles).
- 4.2 The sponsor also proposed that TYR Easy Shake & Go[®] could replace, or be used in combination with, other amino acid formulas for thyrosinaemia, as listed in paragraph 3.2. As a minor submission, there was no economic comparison included.

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 As a minor submission, no clinical trials were presented in the submission.
- 5.4 In consideration of the submission, the Nutritional Products Working Party (NPWP) noted that:
 - The proposed listing was clinically and nutritionally appropriate, with suitable restriction criteria.
 - The product would likely substitute or be used in combination with currently listed products for TYR patients. Therefore, the submission estimated that the product would be cost neutral to the PBS.

- The sponsor claimed a more palatable taste due to the product having a unique coating, which the NPWP noted could increase patient adherence to the treatment.
- A new TYR product would add to the variety of treatments available to patients, which could also contribute to patient adherence/compliance.
- In Attachment 3 (nutritional content comparison) of the submission, TYR Easy Shake & Go[®] does not contain choline, whereas the comparator, TYR Express 15[®], does contain choline. The NPWP noted that there is a Recommended Daily Intake (RDI) level for choline, and patients on a TYR-suitable diet are likely to have low intake of choline. The NPWP recalled a similar submission from the sponsor in September 2015, PKU Easy Shake and Go[®], which also did not contain choline. Although the submission was supported by the NPWP for PBS listing, the NPWP encouraged the sponsor to consider adding choline to future formulations of the product.

5.5 The NPWP supported the listing of TYR Easy Shake & Go[®] as a Restricted Benefit for tyrosinaemia on a cost-minimisation basis against TYR Express 15[®] at an equivalent price per gram of protein. However, the NPWP recommend that future products should contain an amount of choline which is consistent with the RDI.

Estimated PBS usage & financial implications

5.6 The proposed PBS dispensed price for maximum quantity for TYR Easy Shake & Go[®] (DPMQ = \$██████) was derived based on an equivalent cost per gram of protein equivalent (PE) compared with the comparator (\$██████).

5.7 The submission estimated dispensing 870 scripts of TYR Easy Shake & Go[®] in the first year, with an annual 18% increase applied to subsequent years.

5.8 The sponsor estimated a nil financial cost to the PBS, as the use of TYR Easy Shake & Go[®] was expected to substitute for currently PBS-listed nutritional therapies for tyrosinaemia.

6. PBAC Outcome

6.1 The PBAC recommended the listing of TYR Easy Shake & Go[®] as a Restricted Benefit for tyrosinaemia on a cost-minimisation basis against TYR Express 15[®] at an equivalent price per gram of protein equivalent.

6.2 The PBAC noted the advice of the Nutritional Products Working Party (NPWP) that supported the listing of TYR Easy Shake & Go[®] on the PBS.

6.3 The PBAC accepted TYR Express 15[®] as an appropriate comparator for TYR Easy Shake & Go[®].

6.4 The PBAC noted that the submission estimated a nil cost to the PBS as it was expected to substitute for existing products.

- 6.5 The PBAC noted that TYR Easy Shake & Go[®] does not contain choline, and that the NPWP recommended to the sponsor that future formulations should contain an amount of choline that is consistent with the RDI. In the Pre-PBAC response the sponsor stated that they have provided the NPWP's advice to the manufacturer. The sponsor stated that the amount of choline in the product will be equivalent to TYR Express 15[®] and other similar products, and will be in line with the RDI.
- 6.6 In accordance with Section 101 (3BA) of the *National Health Act*, the PBAC advised that, on the basis of the material available at the July 2016 meeting, TYR Easy Shake & Go[®] should be treated as interchangeable on an individual patient basis with any other nutritional product.
- 6.7 The PBAC advised that TYR Easy Shake & Go[®] was suitable for prescribing by nurse practitioners, as nutritional products are currently included for prescribing by nurse practitioners.
- 6.8 The PBAC recommended that the Early Supply Rule should not apply, as it has been the PBAC's view that general nutrients be exempt.
- 6.9 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	№.of Rpts	Proprietary Name and Manufacturer	
AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE oral liquid: powder for, 30 x 34 g bottles	4	5	TYR Easy Shake & Go [®]	Orpharma Pty Ltd

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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.