

## 5.17 AMINO ACID FORMULA WITH FAT, CARBOHYDRATE WITHOUT PHENYLALANINE AND TYROSINE

Tablets 0.91 g, 462

TYR Easy Tablet<sup>®</sup>, Orpharma Pty Ltd

### 1 Purpose of Application

- 1.1 The minor submission requested a Restricted Benefit listing for a new form of amino acid formula with fat, carbohydrate without phenylalanine and tyrosine (TYR Easy Tablet<sup>®</sup>) for the dietary management of tyrosinaemia (TYR).

### 2 Requested listing

- 2.1 The submission requested the following new listing.
- 2.2 *Suggestions and additions proposed by the Secretariat to the requested listing are added in italics and suggested deletions are crossed out with strikethrough.*

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Name and Manufacturer
AMINO ACID FORMULA WITH FAT, CARBOHYDRATE WITHOUT PHENYLALANINE AND TYROSINE	4	5	\$2,392.31*	TYR Easy Tablet <sup>®</sup> Orpharma Pty Ltd

*Tablet: modified release, 6 x 77 g*

\* The DPMQ proposed in the minor submission for TYR Easy Tablet (\$2,910.11) is derived from the AEMP for TYR Cooler 15 for the dietary management of TYR prior to the application of any relevant Statutory Price Reductions. In the overview, the relevant F1 Statutory Price Reductions have been applied to the requested listing to enable a relevant comparison to be made with TYR Cooler 15 (see paragraphs 5.4-6).

<b>Category / Program:</b>	GENERAL – General Schedule (Code GE)
<b>Prescriber type:</b>	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
<b>PBS Indication:</b>	Tyrosinaemia
<b>Restriction Level / Method:</b>	<input checked="" type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required – In Writing <input type="checkbox"/> Authority Required – Telephone/Electronic/Emergency <input type="checkbox"/> Streamlined
<b>Administrative Advice:</b>	<i>This product does not contain any vitamins, minerals or trace elements</i>

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

### 3 Background

- 3.1 The sponsor of TYR Easy confirmed it 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*.

- 3.2 The submission claimed that TYR Easy provides a convenient, palatable treatment option that will enhance adherence to therapy and is likely to provide economic benefits that flow-on from the clinical benefits observed from improved phenylalanine and tyrosine control.

## **4 Comparator**

- 4.1 The minor submission nominated TYR Cooler 15 as the main comparator stating that it is the most commonly used oral liquid formulation for treatment of TYR, and is therefore the most likely to be replaced by TYR Easy.
- 4.2 There are no similar tablet formulations currently listed on the PBS. Current treatments for TYR are oral liquids and powders to be made into liquids.

*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 as it was a minor submission.

### ***Consumer comments***

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

### ***Drug cost/patient/year: \$28,707.72***

- 5.3 The submission determined the proposed DPMQ based on a cost minimisation analysis versus TYR Cooler 15 based on cost per protein equivalent content (see Table 1).
- 5.4 The estimated nutritional product cost/patient/year would be \$28,484.16, based on a DPMQ of \$2,392.31 and 12 scripts per year.

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**Table 1: Calculation of DPMQ based on equivalent cost per gram of protein to comparator**

Product	PBS pack size	PE per PBS pack (g)	PE in PBS max qty (g)	AEMP <sup>a</sup>	PBS Max. Qty.	DPMQ	DPMQ with average co-pay removed
TYR Easy tablets	Tablet, 0.91 g PE per tablet, 77 tablets x 6 packs	420	1682	\$560.04	4	\$2,392.31	\$2,373.68
TYR Cooler 15	Cans, 30 x 130 mL	450	1800	\$599.44	4	\$2,549.91	\$2,531.28

<sup>a</sup>Cost-minimised to price of TYR Cooler 15 on 1 August 2019.

PE: Proteien equivalent

Source: TYR Easy – Attachment 4 – financial estimates Microsoft Excel spreadsheet.

- 5.5 The submission sought TYR Easy Tablet to be considered under the pricing arrangements agreed under Clause 5.7 of the Strategic Agreement between Medicines Australia and the Commonwealth of Australia (the Strategic Agreement). The submission requested that TYR Easy Tablets not be subject to any statutory price reductions that have previously been applied to TYR Cooler 15.
- 5.6 The application of Clause 5.7 of the Strategic Agreement is a matter for the Minister (or delegate) and is not a matter for the PBAC. In Table 2 the relevant F1 Statutory Price Reductions have been applied to the requested listing to enable a relevant comparison to be made with TYR Cooler 15.
- 5.7 The DPMQ proposed in the submission for TYR Easy Tablet (\$2,910.11) is derived from the AEMP for TYR Cooler 15 for the dietary management of TYR prior to the application of any relevant Statutory Price Reductions.

***Estimated PBS usage & financial implications***

- 5.8 The submission projected 5% yearly growth in the market during the first six years of listing. It also projected no displacement of TYR Cooler 15 in the first year, then 10% displacement from the second to sixth year of listing.
- 5.9 The submission argued that there would be no significant cost to the PBS listing of TYR Easy as the cost will be offset by a reduction in the cost of other relevant treatments for TYR. It also stated that the sponsor was taking into account that F1 price reductions would eventually flow on to TYR Easy when calculating financial implications.
- 5.10 Based on the estimates of utilisation in the minor submission and a DPMQ of \$2,392.31, listing of TYR Easy is expected to be cost-neutral to the PBS.

**Table 2: Estimated use and financial implications**

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
<b>Estimated extent of use</b>						
Number of scripts dispensed <sup>a</sup>						
<b>Estimated financial implications of TYR Easy</b>						
Cost to PBS						
Copayments						
Cost to PBS less copayments						
<b>Estimated financial implications for TYR Cooler 15</b>						
Cost to PBS						

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	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Copayments	█	█	█	█	█	█
Cost to PBS less copayments	█	█	█	█	█	█
<b>Net financial implications</b>						
Net cost to PBS	█	█	█	█	█	█

<sup>a</sup> Assuming 4/5 scripts per year as estimated by the submission.

<sup>b</sup> The relevant F1 Statutory Price Reductions have been applied to the price of the requested listing to enable a relevant comparison to be made with TYR Cooler 15 (see paragraphs 5.5-7). The submission estimated that if TYR Easy Tablet is listed at the DPMQ proposed in the submission (of \$2,910.11), the net cost to the PBS over the first 6 years of listing would be \$2,488.

Source: TYR Easy – Attachment 4 - financial analyses Microsoft Excel spreadsheet

The redacted table shows that at Year 6, the estimated number of scripts dispensed was less than 10,000 and the net cost to the PBS would be less than \$10 million.

5.11 As a minor submission, the financial estimates have not been independently evaluated.

*For more detail on PBAC’s view, see section 7 PBAC outcome*

## **6 NPWP Consideration (and sponsor’s further clarification)**

6.1 The Nutritional Products Working Party (NPWP) accepted TYR Cooler 15 as the comparator for TYR Easy.

6.2 The NPWP noted TYR Easy did not contain any vitamins, minerals or trace elements and therefore patients would have to achieve their recommended daily intake (RDI) of these by other means, such as through diet or supplements. Some of these vitamin, mineral and trace element supplements, such as Phlexy-Vits or Paediatric Seravit (and other alternatives), are subsidised on the PBS. Therefore, the NPWP considered that while the requested cost minimisation may be an appropriate basis for listing, this did not necessarily mean a listing would be cost neutral to either patients or the PBS as some patients would require PBS-subsidised supplements.

6.3 The NPWP considered the use of the tablet formulation was likely to be low because of the large number of tablets patients had to take and the need to obtain vitamins and minerals from other sources

6.4 The NPWP supported the listing of TYR Easy as an additional treatment option for the dietary management of tyrosinaemia on a cost-minimisation bases with TYR Cooler 15 per gram of protein equivalent.

6.5 The NPWP supported a note be added to the listing to state that, ‘This product does not contain any vitamins, minerals or trace elements’.

*For more detail on PBAC’s view, see section 7 PBAC outcome*

## 7 PBAC Outcome

- 7.1 The PBAC recommended the Restricted Benefit listing of amino acid formula with fat, carbohydrate without phenylalanine and tyrosine, TYR Easy Tablet for the dietary management of tyrosinaemia on a cost-minimisation basis to the cheapest currently listed amino acid formula for the treatment of tyrosinaemia at an equivalent price per protein equivalent.
- 7.2 The PBAC noted the NPWP supported the proposed listing as a treatment option for the dietary management of tyrosinaemia. The PBAC noted the NPWP advice that TYR Easy does not contain any vitamins, minerals or trace elements and therefore patients would have to meet their dietary needs through other sources, which may include use of PBS-subsidised vitamin, mineral and trace element supplements included Phlexy-vits and Paediatric Seravit.
- 7.3 The PBAC accepted TYR Cooler 15 was a relevant comparator for TYR Easy, however also considered other amino acid formulas for the treatment of tyrosinaemia are also be relevant comparators.
- 7.4 The PBAC noted that use of the only similar PBS-listed formulation of amino acid formula tablets, Phlexy-10 (for dietary management of phenylketonuria) was very low. Given the large number of tablets in the standard dosage and low use of other amino acid tablet formulations, the PBAC considered it was likely the use of TYR Easy would be low.
- 7.5 Given the likely low use of this product, the PBAC considered that while there may be an additional per-patient cost impact to the PBS if additional vitamin, mineral and trace element supplements are prescribed, any additional overall cost to the PBS was likely to be low. On balance, the PBAC considered the requested price was reasonable and that TYR Easy was a suitable alternative amino acid formula for some patients.
- 7.6 The PBAC recommended that TYR Easy should be treated as interchangeable on an individual patient basis with similar nutritional products on the PBS indicated to treat TYR.
- 7.7 The PBAC advised that TYR Easy is suitable for prescribing by nurse practitioners, as is the case with other nutritional products.
- 7.8 The PBAC recommended that the Early Supply Rule should not apply, since it has previously been the PBAC's view that in general, nutritional products be exempt.
- 7.9 The PBAC noted that this submission is not eligible for Pricing Pathway A under *National Health (Pharmaceutical and Vaccines – Cost Recovery) Regulations 2009* because TYR Easy is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over any alternative therapy and is not expected to address a high and urgent unmet clinical need.,
- 7.10 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

**Outcome:**

Recommended

## 8 Recommended listing

### 8.1 Add new item:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
AMINO ACID FORMULA WITH FAT, CARBOHYDRATE WITHOUT PHENYLALANINE AND TYROSINE Tablet: modified release, 6 x 77 g	4	5	TYR Easy	Orpharma Pty Ltd

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<b>Administrative Advice:</b>	This product does not contain any vitamins, minerals or trace elements.

*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.