

5.18 GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS

Sachets containing oral powder 35 g, 30

TYR Sphere 20®, Vitaflo Australia Pty Limited.

1 Purpose of Application

- 1.1 The minor submission sought listing of a new glycomacropeptide (GMP) formula for the dietary management of tyrosinaemia.

2 Requested listing

- 2.1 The submission requested a new Restricted Benefit listing of TYR Sphere 20 aligned with existing listings for nutritional products currently listed for tyrosinaemia.

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Name and Manufacturer
GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS				
Sachets containing oral powder 35 g, 30	4	5	██████████	TYR Sphere 20® Vitaflo Australia Pty Ltd

Category / Program:	Section 85 – General Schedule
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
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

3 Background

- 3.1 The sponsor of TYR Sphere 20 (Vitaflo Australia Pty Ltd) confirmed the product 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*.

4 Consideration of the evidence

Sponsor hearing

4.1 There was no hearing for this item as it was a minor submission.

Consumer comments

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

Clinical trials

4.3 As a minor submission, no clinical trials were presented, however the submission stated that TYR Sphere 20 was therapeutically equivalent to similar glycomacropeptide formulas used in the dietary management of tyrosinaemia.

Other matters

4.4 The submission stated that TYR Sphere 20 represents a suitable dietary management option for people with tyrosinaemia and claimed that the product offers a number of advantages over currently listed products, including:

- TYR Sphere has a lower calorific content than alternative GMP formulas for tyrosinaemia, and is 54% lower in calories than Tylactin RTD per gram of protein equivalent (PE). The submission argued that obesity is a specific issue in phenylketonuria (PKU); and that obesity, as well as metabolic disorders, tend to be greater with PKU than in the general population. This is due to a higher need to use carbohydrates for energy intake in a low tyrosine and/or phenylalanine diet.
- TYR Sphere has a higher concentration of PE, meaning patients need to consume 58% less volume of prepared formula per day.
- TYR Sphere is enriched with docosahexaenoic acid (DHA) meaning alternative sources are not required.

4.5 Based on these claimed benefits, the submission requested a price premium of 5% over the price-per-gram of protein equivalent, at the approved ex-manufacturer price (AEMP) level. The submission derived a requested price-per-gram of PE with the named comparator(s) (Tylactin RTD/Tylactin Complete¹) of \$1.722, with a resultant AEMP of [REDACTED] per carton.

¹ Based on the 1 May 2019 PBS schedule, Tylactin RTD has an AEMP of \$738.00 per pack of 30 cartons each containing 15g of protein equivalent (PE), for a per gram PE price of \$1.64. TYR Sphere 20 contains 30 cartons each containing 20g of PE, with a 5% premium on the price per gram PE of \$1.64

Drug cost/patient/year: \$51,406.08.

4.6 The above calculation of nutritional product cost per patient per year is derived from the DPMQ for one month’s supply (██████████) for 12 months, and assumes that a patient would receive the maximum quantity (4 packs) per dispensing, however this may not occur in practice due to variations in individual patient needs.

Estimated PBS usage & financial implications

4.7 The submission argued the listing of TYR Sphere was unlikely to grow the market and would only substitute for existing GMP formulations for tyrosinaemia. It also argued a disproportionate number of comparator scripts were expected to be replaced due to differences in the amount of PE per carton (TYR Sphere 20 provides 2,400g of PE per maximum quantity (MQ) whilst Tylactin RTD has 1,800g of PE per MQ). Table 1 includes utilisation and financial estimates over six years as estimated in the submission.

Table 1: Estimated PBS utilisation and financial estimates

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
TYR Sphere 20 scripts	█	█	█	█	█	█
Cost at DPMQ (\$4,283.84)	██████████	██████████	██████████	██████████	██████████	██████████
Minus Co-pays (average \$18.67)	\$131	\$261	\$261	\$392	\$392	\$392
Net cost to PBS/RPBS	██████████	██████████	██████████	██████████	██████████	██████████

Source: Utilisation and financial estimates and associated calculations in Appendix 8 of the submission.

The redacted table shows that the estimated number of scripts over 6 years is less than 10,000 and the net cost to the PBS is less than \$10 million.

4.8 Accounting for replaced prescriptions, there would be a modest cost of approximately \$148 per patient per equivalent quantity of PE, attributable to the requested price premium.

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

5 NPWP Consideration (and sponsor’s further clarification)

5.1 The NPWP noted the requested listing of TYR Sphere 20® as an alternative to other glycomacropeptide (GMP) formulas listed on the PBS for dietary management of tyrosinaemia, including Tylactin RTD and Tylactin Complete. The NPWP noted the product was lower in calories than the current alternatives and the product appeared to be nutritionally complete. It considered having additional GMP formula options for tyrosinaemia would be beneficial, and that a low calorie alternative may be useful for some patients.

5.2 The NPWP noted the submission proposed listing on a cost minimisation basis, and requested a 5% premium at the price-per-gram of protein equivalent (PE) compared

to the alternative products, primarily based on added docosahexaenoic acid (DHA). However, it also noted that arachidonic acid (AA) was not included in the formula.

- 5.3 The NPWP supported the listing of TYR Sphere 20 for the dietary management of tyrosinaemia, however considered a price premium was not justified. The NPWP considered the majority of use was likely to be in patients aged 4 years and over and there was little evidence to support the submission's argument that DHA supplementation offers a distinct advantage over the alternatives in this context. The NPWP also noted the sponsor presented the nutritional comparison with alternatives to TYR Sphere 20 per units of energy (kcal) expressed a strong preference for sponsors to present the nutritional profiles of products and comparisons per gram of PE.

6 PBAC Outcome

- 6.1 The PBAC recommended the Restricted Benefit listing of a new form of glycomacropeptide formula, TYR Sphere 20[®], for the dietary management of tyrosinaemia on a cost minimisation basis to the lowest cost alternative glycomacropeptide formula listed on the PBS for the same condition, at an equivalent cost per gram of protein equivalent. Tylactin RTD and Tylactin Complete are similar GMP formulas listed on the PBS for dietary management of tyrosinaemia.
- 6.2 The PBAC agreed with the NPWP advice that a price premium was not justified as the addition of docosohexaenoic acid was unlikely to offer a distinct advantage over alternative products in the target patient population.
- 6.3 The PBAC agreed TYR Sphere 20 is suitable for inclusion in the PBS medicines for prescribing by nurse practitioners, similar to other nutritional products for tyrosinaemia.
- 6.4 The PBAC advised the Early Supply Rule should not apply to TYR Sphere 20 as it has generally been its view that nutritional product listings be exempt.
- 6.5 The PBAC advised under Section 101(3BA) of the *National Health Act 1953* that TYR Sphere 20 should be treated as interchangeable with similar nutritional products on an individual patient basis. Similar products in this case may include Tylactin RTD and Tylactin Complete.
- 6.6 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because TYR Sphere 20 is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over similar nutritional products for tyrosinaemia, or not expected to address a high and urgent unmet clinical need over these alternatives, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2009* for Pricing Pathway A were not met.
- 6.7 The submission is not eligible for independent review as it received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

7.1 Add new item:

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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

Vitaflo Australia notes that PBAC has accepted the amendments to the PSD.