

5.37 TRIGLYCERIDES MEDIUM CHAIN FORMULA
oral liquid, 8 x 500 mL cartons;
Nutrini Peptisorb®, Nutricia Australia Pty Ltd

1 Purpose of Application

1.1 The minor submission requested a Restricted benefit listing for the dietary management of conditions requiring a source of medium chain triglycerides limited to fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis, gastrointestinal disorders, radioenteritis, chemotherapy or bone marrow transplant.

2 Requested listing

2.1 The submission’s requested listing is shown below:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Name and Manufacturer
TRIGLYCERIDES MEDIUM CHAIN FORMULA				
triglycerides medium chain oral liquid, 8 x 500 mL cartons	8	5	\$ [REDACTED]	Nutrini Peptisorb SB

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
Episodicity:	-
Severity:	-
Condition:	Dietary management of conditions requiring a source of medium chain triglycerides
PBS Indication:	Dietary management of conditions requiring a source of medium chain triglycerides
Treatment phase:	-
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
Clinical criteria:	Patient must have fat malabsorption due to liver disease; OR Patient must have fat malabsorption due to short gut syndrome; OR Patient must have fat malabsorption due to cystic fibrosis; OR Patient must have fat malabsorption due to gastrointestinal disorders; OR Patient must have fat malabsorption due to radioenteritis, chemotherapy treatment or bone marrow transplant

2.2 The PBAC noted that the requested indications are currently listed for the existing triglycerides medium chain formula products with the brands ‘Monogen[®]’, ‘Peptamen Junior[®]’ and ‘Lipistart[®]’ with the exception of the indication of ‘fat malabsorption due to radioenteritis, chemotherapy treatment or bone marrow transplant’.

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

3 Background

- 3.1 Nutrini Peptisorb did not require registration with the TGA. It is classified as a “Food for Special Medical Purpose” regulated under the Australia New Zealand Food Standards Code and complies with this standard.
- 3.2 Nutrini Peptisorb had not been considered by the PBAC previously.

4 Comparator

- 4.1 The minor submission nominated Peptamen Junior as the main comparator.

5 Consideration of evidence

- 5.1 The submission presented case studies from the United Kingdom on the acceptability and tolerance of Nutrini Peptisorb.
- 5.2 The submission also presented a summary of survey results from key Australian dietitians (n=5) involved in the care of patients. The survey results show the current dietary management options for this patient group in Australia and estimated number of patients who would use Nutrini Peptisorb.

Estimated PBS usage & financial implications

- 5.3 The price requested was based on the equivalent price per gram of energy equivalent as Peptamen Junior.
- 5.4 The minor submission estimated there to be no financial implications to the PBS for the requested indications which are currently listed on the PBS as the submission expects Nutrini Peptisorb to substitute for Peptamen Junior only in patients requiring alternative enteral tube feeding regimen. Peptamen Junior is used either as a tube feed or taken orally whilst Nutrini Peptisorb is suitable for tube feeding only.
- 5.5 However, for patients with malabsorption due to cancer treatment, the submission noted that there will be an addition cost to the PBS in listing Nutrini Peptisorb. The submission stated that this cost would be small as the patient numbers are small, and the use of Nutrini Peptisorb for these patients would be for a short time frame (i.e. 1 to 2 months as opposed to continuous use) and for a limited patient age range of 1 – 6 years. The submission’s estimates of patient numbers and financial implications for this specific patient population are shown below:

Estimated patient numbers (all sources of malabsorption)

	Year 1	Year 2	Year 3	Year 4	Year 5
Estimated patient numbers expected to use Nutrini Peptisorb	■	■	■	■	■

Source: Submission, pg. 39, Table 14

Percentage of patients by medical condition who would be recommended Nutrini Peptisorb

Malabsorption source:	Percentage breakdown (%)
Cancer treatment	50%
Short bowel syndrome and other GI disorders	40%
Liver disease or cystic fibrosis	10%

Source: Submission, pg. 40, Table 10

Estimated cancer related patient numbers and cost to the PBS

	Year 1	Year 2	Year 3	Year 4	Year 5
Estimated patients with malabsorption due to cancer treatment	█	█	█	█	█
PBS cost based on \$ █ per box of 8 x 500 mL	\$ █	\$ █	\$ █	\$ █	\$ █

Source: Submission, pg. 45, Table 19.

- 5.6 The Nutritional Products Working Party (NPWP) advised that the submission’s estimates of use and financial estimates particularly in the chemotherapy setting were significantly underestimated. The NPWP’s view was that there would be a ten-fold difference between the submission’s estimate of use in cancer patients and what is likely to be occurring in practice, based on anecdotal evidence and the experience of clinicians on the NPWP.
- 5.7 The pre-PBAC response provided further estimates of the potential number of patients who may use Nutrini Peptisorb for cancer related malabsorption. The pre-PBAC response noted that there are approximately 625 children under 15 years of age in Australia diagnosed with cancer each year (Childhood Cancer Institute, 2014). Further to this, the pre-PBAC response noted that acute lymphoblastic leukemia (ALL) is the most common childhood cancer. The pre-PBAC response claimed that each year in Australia, over 300 people are diagnosed with ALL and 60% of all cases are children 0 – 14 years (Leukaemia Foundation, Australia). This would equate to 180 children diagnosed with ALL each year. Of these, about less than half of this number (i.e. <90) could be estimated to be children 1 – 6 years of age and hence potentially requiring the use of Nutrini Peptisorb (Nutrini Peptisorb is indicated for ages 1 – 6 years). The pre-PBAC response claimed that the number of patients reported by the Australian Bone Marrow Transplant Recipient Registry receiving a bone marrow transplant over a year is 117 children between the ages of 0 to 15 (Leukemia Foundation, 2008). Hence, the potential number of patients that would be suited in age to use Nutrini Peptisorb (for 1- 6 years only) could be estimated to be less than half this patient number of 117 (i.e. <60 per year who would be undergoing bone marrow transplant treatment between ages of 1 – 6 years hence potentially requiring the use of Nutrini Peptisorb due to impaired gastrointestinal absorption).

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

6 PBAC Outcome

- 6.1 The PBAC recommended listing Nutrini Peptisorb as a Restricted Benefit for the dietary management of conditions requiring a source of medium chain triglycerides involving fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis and gastrointestinal disorders on a cost-minimisation basis against Peptamen Junior with the same price per gram of energy equivalence between Nutrini Peptisorb and Papatmen Junior.

- 6.2 The PBAC noted advice from the Nutritional Products Working Party (NPWP) that it supported listing Nutrini Peptisorb on the PBS for all the requested indications.
- 6.3 However, with respect to the additional indications sought for this product in paediatric cancer patients, the PBAC held concerns that the submission's estimates of use and financial implications to the PBS were likely to be significantly underestimated in this patient population. Additionally, the PBAC was also concerned that listing for this patient population would create a risk of inappropriate use in a patient population which did not necessarily have fat malabsorption, which in turn could contribute to an increase in obesity in children. The PBAC noted that submissions seeking the addition of a new indication/s on the PBS would usually require a major submission.
- 6.4 Advice to the Minister under subsection 101(3BA) of the Act
In accordance with subsection 101(3BA) of the Act the PBAC advised that it is of the opinion that, on the basis of the material available to it at its March 2015 meeting, triglycerides medium chain formula should not be treated as interchangeable on an individual patient basis with any other nutritional products.
- 6.5 The PBAC recommended that Nutrini Peptisorb is suitable for inclusion in the PBS medicines for prescribing by nurse practitioners within collaborative arrangements.
- 6.6 The PBAC recommended that the Safety Net 20 Day Rule should not apply as it has been the PBAC's view that general nutrients be exempt.

Outcome:

Recommended

7 Recommended listing

7.1 Add new items:

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Administrative Advice:	<p><u>NOTE:</u> No increase in the maximum number of repeats may be authorised.</p> <p><u>NOTE:</u> No increase in the maximum quantity or number of units may be authorised.</p> <p><u>NOTE:</u> Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.</p>

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.