

## **5.26 TRIGLYCERIDES MEDIUM CHAIN FORMULA**

**Oral liquid solution, 500mL, 8 pouches**

**Nutrini Peptisorb Energy<sup>®</sup>,**

**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.

### **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 were added in italics and suggested deletions were crossed out with strikethrough.

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Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Manufacturer	Name and
TRIGLYCERIDES MEDIUM CHAIN FORUMLA oral liquid solution, 500mL, 8 pouch	10	5	\$ [REDACTED]	Nutrini Peptisorb Energy	Nutricia Australia Pty Ltd

<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>Condition:</b>	Dietary management of conditions requiring a source of medium chain triglycerides
<b>PBS Indication:</b>	Dietary management of conditions requiring a source of medium chain triglycerides
<b>Restriction Level / Method:</b>	<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
<b>Clinical criteria:</b>	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.
<b>Administrative Advice</b>	<i>No increase in the maximum quantity or number of repeats may be authorised</i> <del>Note: Authorities for increased maximum quantities, up to a maximum of 15, may be authorised.</del> <i>Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.</i>

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

### **3 Background**

- 3.1 The sponsor of Nutrini Peptisorb Energy<sup>®</sup> (NPE) 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 NPE has not been considered by PBAC previously

### **4 Comparator**

- 4.1 The minor submission nominated Peptamen<sup>®</sup> Junior powder as the main comparator. However, Nutrini Peptisorb was also considered to be a comparator.
- 4.2 As a minor submission, there was no economic comparison submitted.

*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 requested age range of 1–14 years has not previously been presented to the NPWP for these products. The age ranges, recommended by Nutricia, of similar PBS listed brands are as follows: Nutrini Peptisorb<sup>®</sup> for 1–6 years or 8-20kg; Peptamen Junior<sup>®</sup> for 1–10 years and Nutrini Energy<sup>®</sup> for 1–6 years or 8-20kg.
  - The product does not meet the nutritional requirements of patients aged 14 years old; in particular, protein and vitamin A. These nutrients are particularly important in children with Cystic Fibrosis. Therefore, the NPWP agreed that an age range is necessary.
  - The quantity is appropriate for a 10 year old patient with a high energy requirement.

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- The sponsor requested a maximum quantity of 10 × 8 pouches with 5 repeats, as well as a note for authorisation of up to 15 × 8 pouches per month. However, the NPWP did not agree with the requested note, as this quantity is based on figures for a 14 year old patient.
  - There is a clinical need for the product, as patients with higher energy requirements who require a tube feed often find it difficult to obtain the appropriate amount of nutritional energy through high volume products.
  - The product is nutritionally dense, containing 1.5 times more calories per mL than the comparator, Peptamen Junior®.
  - The sponsor incorrectly calculated the dispensed price per maximum quantity (DPMQ), as the price was based on a maximum quantity of 8, rather than the requested MQ of 10.
- 5.5 The NPWP supported the listing of Nutrini Peptisorb Energy® as a Restricted Benefit for the dietary management of conditions requiring a source of medium chain triglycerides for patients aged 1–10 years old. The NPWP did not support the requested note for authorisation of up to 15 × 8 pouches. The NPWP supported the listing on a cost-minimisation basis against Peptamen Junior® at an equivalent price per kilojoule of energy.
- 5.6 The Pre-PBAC response from the sponsor clarified that the DPMQ was calculated on the basis of 10 × (8 × 500 mL) which is the maximum quantity requested in the submission.

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

- 5.7 The submission based on all the economic and financial analyses on the assumption that approximately █% of scripts from Peptamen® Junior powder will switch to NPE. This will equate to █ scripts of NPE based on the energy (kJ) provided at maximum quantity.
- 5.8 Under this assumption, this equated to an annual cost of █ scripts x DPMQ of \$█ = \$█ per year.
- 5.9 The sponsor stated that approval of listing of NPE will not result in any new patients commencing dietary treatment of conditions requiring a source of medium chain triglycerides. Based on the assumption that the cost of NPE will be the same on a per kJ of energy basis, there should be no net cost to the PBS.

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

## **6 PBAC Outcome**

- 6.1 The PBAC recommended the listing of Nutrini Peptisorb Energy<sup>®</sup> (NPE) as a Restricted Benefit for the dietary management of conditions requiring a source of medium chain triglycerides for patients aged 1-10 years old.
- 6.2 The PBAC noted the advice of the Nutritional Products Working Party (NPWP) that supported the listing of NPE on the PBS.
- 6.3 The PBAC accepted Peptamen Junior powder and Nutrini Peptisorb as appropriate comparators for NPE.
- 6.4 The PBAC noted that the submission requested a lower DPMQ/kJ than both Peptamen Junior and Nutrini Peptisorb however, on an AEMP per kJ basis NPE was costed at a higher rate.
- 6.5 The PBAC agreed with the advice of the NPWP that supported the listing of NPE on the PBS on a cost-minimisation basis against Peptamen Junior at an equivalent price per kilojoule of energy.
- 6.6 The PBAC noted that the maximum quantity requested is 10 × 8 × 500 mL pack, with a request to include a note for authorisation of up to 15 x 8 x 500 mL pack NPE per month to fulfil a higher estimated energy requirements for certain medical conditions. The PBAC agreed with the advice from the NPWP that the maximum quantity should be limited to 10 × 8 × 500 mL pack as this was sufficient for a month's supply for a child up to 10 years.
- 6.7 The PBAC agreed with the NPWP's advice that an age restriction (1-10 years) should be included, as the product does not meet the nutritional requirements of patients aged up to 14 years old. The Sponsor, acknowledged in the Pre-PBAC response that the NPE is appropriate for this age group.
- 6.8 In accordance with subsection 101(3BA) of the National Health Act the PBAC advised that, on the basis of the material available to its July 2016 meeting, Nutrini Peptisorb Energy<sup>®</sup> should be treated as interchangeable on an individual patient basis with any other similar nutritional product.
- 6.9 The PBAC recommended that NPE is suitable for prescribing by nurse practitioners, as nutritional products are currently included for prescribing by nurse practitioners.
- 6.10 The PBAC recommended that the Early Supply Rule should not apply as it has been the PBAC's view that general nutrients be exempt.
- 6.11 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	
TRIGLYCERIDES MEDIUM CHAIN FORUMLA oral liquid solution, 500mL, 8 pouch	10	5	Nutrini Peptisorb Energy	Nutricia Australia Pty Ltd

<b>Category / Program</b>	GENERAL – General Schedule (Code GE)
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<b>PBS Indication:</b>	Dietary management of conditions requiring a source of medium chain triglycerides
<b>Restriction Level / Method:</b>	<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
<b>Clinical criteria:</b>	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.
<b>Population criteria</b>	Patient must be aged from 1 to 10 years inclusive.
<b>Administrative Advice</b>	No increase in the maximum quantity or number of repeats may be authorised Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

## 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.