

**5.26 TRIGLYCERIDES MEDIUM CHAIN FORMULA  
500 g pouch, Peptamen® Junior Liquid,  
500 g pouch, Peptamen® Junior Advance,  
Nestle Health Science**

**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 or gastrointestinal disorders.

**2 Requested listing**

2.1 The submission requested the following new listing, with Secretariat additions marked in italics.

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Manufacturer	Name and
TRIGLYCERIDES MEDIUM CHAIN FORMULA Triglycerides medium chain formula oral liquid 12 x 500mL pouches	5	5	\$ [REDACTED] \$ [REDACTED]	Peptamen® Junior Liquid	Nestle Health Science
TRIGLYCERIDES MEDIUM CHAIN FORMULA Triglycerides medium chain formula oral liquid 12 x 500ml pouches	4	5	\$ [REDACTED] \$ [REDACTED]	Peptamen® Junior Advance	Nestle Health Science

<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>Treatment phase:</b>	-
<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>Treatment criteria:</b>	-
<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>	<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>
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### **3 Background**

- 3.1 The sponsor of triglycerides medium chain formula confirms 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 Peptamen® Junior Liquid and Peptamen® Junior Advance have not been previously considered by the PBAC.

### **4 Comparator**

- 4.1 The minor submission nominated is Peptamen Junior powder. The submission identified Nutrini Peptisorb as the therapy most likely to be replaced but it was not nominated as the main comparator because it does not meet relevant PBAC Guidelines as it not been utilised through the PBS at the time of the submission. There are no PBS listed products for this indication which are specifically intended for administration via enteral feeding. Nutrini Peptisorb was listed on 1 August 2015.
- 4.2 The PBAC noted the reason in the submission for the proposed comparator. The PBAC noted that in the Guidelines, a comparator may include non-PBS subsidised standard medical management. The PBAC also recalled that there are examples of other submissions to the PBAC have used a product as a comparator that has been recommended by the Committee but not yet PBS listed.

### **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:
- The proposed place in therapy for the products was clinically and nutritionally appropriate.
  - The products are largely nutritionally similar to the nominated comparator products, Peptamen® Junior powder formula and another potential comparator, Nutrini Peptisorb®, although:
  - Manganese levels are relatively low (0.1% RDI); and

- Table 6 (p. 16) shows that neither product contains linoleic acid, while Peptamen® Junior Advance tube feed does not contain alpha linoleic acid. Given these products contain soy oil, the NPWP viewed that the stated levels of these essential fatty acids may have been a typographical error, but sought confirmation from the sponsor.
- The proposed pricing of this product at the same price per kilojoule as comparable products was considered appropriate and almost cost-neutral. Although the NPWP noted a slight overall increase in cost to the PBS, depending on the rate of substitution from other products. This was considered reasonable.
- The headers in Table 3 (p. 12) appeared mislabelled, with the correct Column 4 label assumed to be “Peptamen® Junior Advanced tube feed”. In this table, the total “kilojoule per dispensing” appeared also incorrectly calculated for Peptamen® Junior Liquid tube feed (Column 3) as 135,360 kJ when it may have been 126,900 kJ, based on the calculation of 60 units x 2,115 kJ.
- Under the manner of administration for the requested restriction, the NPWP considered that “enteral liquid” rather than “oral liquid” was more appropriate terminology.

5.5 The NPWP deferred its consideration of this submission until such time that clarification from the sponsor as to the accurate essential fatty acid composition and kilojoule per dispensing of Peptamen® Junior Liquid and Peptamen® Junior Advance can be sought.

5.6 The PBAC noted that the sponsor provided the requested information in its Pre-PBAC Response, however it was not possible in the available time for the NPWP to fully evaluate the information prior to the PBAC meeting.

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

5.7 The proposed PBS dispensed price for maximum quantity (DPMQ) is \$ [REDACTED] for Peptamen Junior liquid and \$ [REDACTED] for Peptamen Junior Advanced. This is the equivalent AEMP per kJ of energy as the comparator. Based on AEMPs provided, DPMQs in submission are incorrect due to calculation errors - correct DPMQs are Peptamen Junior Liquid \$ [REDACTED] and Peptamen Junior Advance \$ [REDACTED].

5.8 The submission assumes [REDACTED] items processed per year for these products.

5.9 Based on the DPMQ in the submission with substitution from the comparator, Peptamen Junior powder, the overall net cost to the PBS is expected to be \$ [REDACTED] in year 5.

**6 PBAC Outcome**

- 6.1 The PBAC deferred its recommendation until further advice could be provided by the NPWP on this submission in view of the additional information that was received from the sponsor.
- 6.2 The PBAC recalled that at the July 2015 PBAC meeting the Committee recommended the note 'Authorities for increased maximum quantities, up to a maximum of 20, may be authorised' for the listing of Peptamen Junior. The PBAC noted that the comparison of kilojoules per maximum dispensed was based on 20 cans of Peptamen Junior, rather than the listed maximum quantity of 8 cans. The PBAC considered, with the proposed comparator in the submission, that a listing should include a lower number of maximum quantity packs to align with the listing for Peptamen Junior (8 cans) and include the note: 'Authorities for increased maximum quantities, up to a maximum of 5 (Peptamen® Junior Liquid)/4 (Peptamen® Junior Advance), may be authorised'.

**Outcome:**

Deferred

**7 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.

**8 Sponsor's Comment**

Nestle Health Science has provided the details of the essential fatty acid composition requested by the Nutritional Products Working Party (NPWP), provided a scale error correction to manganese levels and looks forward to the PBAC's consideration of the submission in March 2016.