

4.04 TRIGLYCERIDES MEDIUM CHAIN FORMULA
oral liquid 12 x 500 mL pouches, Peptamen® Junior Liquid,
oral liquid 12 x 500 mL pouches, 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]	Peptamen® Junior Liquid	Nestle Health Science
TRIGLYCERIDES MEDIUM CHAIN FORMULA Triglycerides medium chain formula oral liquid 12 x 500mL pouches	4	5	\$ [REDACTED]	Peptamen® Junior Advance	Nestle Health Science

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
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.
Administrative Advice	<p><u>Note:</u> No increase in the maximum number of repeats may be authorised.</p> <p><u>Note:</u> <i>No increase in the maximum quantity or number of units may be authorised.</i></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>

3 Background

- 3.1 The sponsor of Peptamen® Junior Liquid and Peptamen® Junior Advance confirmed that these products meet 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 were previously considered by the Nutritional Products Working Party (NPWP) in September 2015 and the PBAC in November 2015.
- In September 2015, the NPWP deferred its consideration of the submission until such time that clarification from the sponsor could be sought regarding the accurate essential fatty acid composition and kilojoule per dispensing of the products. The NPWP had also noted the low manganese levels in these products (0.1% RDI).
 - In November 2015, the PBAC noted that the sponsor provided additional information post-submission to address the NPWP concerns. The PBAC then deferred its recommendation until further advice could be provided by the NPWP on the submission in view of this additional information. At that time, the PBAC also “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’.”
- 3.3 The NPWP considered the additional information for this submission in January 2016, and its updated advice is noted below under ‘Consideration of the evidence’.

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 September 2015, in consideration of the submission, the 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 In January 2016, in consideration of information received post-submission, the NPWP noted that:

- The corrected levels of essential fatty acids, which were considered acceptable.
- The corrected kilojoule per dispensing for Peptamen® Junior Liquid tube feed, which was considered acceptable.
- The corrected manganese levels are relatively low, but acceptable. The NPWP acknowledged that there is considerable variation in recommendations for manganese intake across guidelines in Australia, the United States of America, the United Kingdom and Europe.
- That the sponsor requested a maximum quantity in line with the ‘maximum authorised quantity’ for Peptamen® Junior powder formula, which is 20 cans. The NPWP noted that Peptamen® Junior powder formula is listed with a maximum quantity of 8 cans, with a note that ‘Authorities for increased maximum quantities, up to a maximum of 20, may be authorised’. The NPWP considered it reasonable to list Peptamen® Junior Liquid and Peptamen® Junior Advance in a consistent manner – that is, with a maximum quantity of 2 (packs of 12 pouches) and a note allowing authorisation of increased maximum quantities, up to a maximum of 5 (Peptamen® Junior Liquid)/4 (Peptamen® Junior Advance).

5.6 The NPWP supported the listing of Peptamen® Junior Liquid and Peptamen® Junior Advance as a Restricted Benefit for dietary management of conditions requiring a source of medium chain triglycerides limited to fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis and gastrointestinal disorders on a cost-minimisation basis against Peptamen® Junior powder formula at an equivalent price per gram of energy. The NPWP supported listing these products with a maximum quantity of 2 (packs of 12 pouches), and a note allowing authorisation to increase the maximum quantity up to 5 (Peptamen® Junior Liquid)/4 (Peptamen® Junior Advance).

Estimated PBS usage & financial implications

5.7 The submission assumed less than 10,000 items processed per year for these products.

5.8 Based on the DPMQ in the submission with substitution from the comparator, Peptamen Junior powder, the overall net cost to the PBS was expected to be less than \$10 million in year 5.

6 PBAC Outcome

6.1 The PBAC recommended listing triglycerides medium chain formula, oral liquid 500 mL, 12 (Peptamen Junior Liquid) and triglycerides medium chain formula, oral liquid

500 mL, 12 (Peptamen Junior Advance) as a Restricted Benefit for dietary management of conditions requiring a source of medium chain triglycerides limited to fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis and gastrointestinal disorders on a cost-minimisation basis against triglycerides medium chain formula, oral powder 400 g (Peptamen Junior) at an equivalent price per gram of energy.

- 6.2 The PBAC noted the advice of the NPWP that supported the listing of Peptamen® Junior Liquid and Peptamen® Junior Advance on the PBS, following its consideration of additional information received from the sponsor post-submission.
- 6.3 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’.
- 6.4 In accordance with subsection 101(3BA) of the Act the PBAC advised that it is of the opinion that, on the basis if the material available to it at its March 2016 meeting, Peptamen® Junior Liquid and Peptamen® Junior Advance should not be treated as interchangeable on an individual patient basis with any other drugs.
- 6.5 The PBAC recommended that Peptamen® Junior Liquid and Peptamen® Junior Advance are suitable for inclusion in the PBS medicines for prescribing by nurse practitioners within collaborative arrangements.
- 6.6 The PBAC recommended that the Early Supply 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:

Name, Restriction, Manner of administration and form	Max. Qty	No.of Rpts	Proprietary Manufacturer	Name and
TRIGLYCERIDES MEDIUM CHAIN FORMULA Triglycerides medium chain formula oral liquid 12 x 500mL pouches	2	5	Peptamen® Junior Liquid	Nestle Health Science

Category / Program	GENERAL – General Schedule (Code GE)
-----------------------	--------------------------------------

Public Summary Document – March 2016 PBAC Meeting

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
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
Treatment criteria:	-
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.
Administrative Advice	<u>Note:</u> A maximum number of repeats may be authorised. <u>Note:</u> Authorities for increased maximum quantities, up to a maximum of 5, may be authorised. <u>Note:</u> Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Manufacturer	Name and
TRIGLYCERIDES MEDIUM CHAIN FORMULA Triglycerides medium chain formula oral liquid 12 x 500mL pouches	2	4	Peptamen® Junior Advance	Nestle Health Science

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
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
Treatment criteria:	-

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.
Administrative Advice	<u>Note:</u> A maximum number of repeats may be authorised. <u>Note:</u> Authorities for increased maximum quantities, up to a maximum of 4, may be authorised. <u>Note:</u> 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.