6.15 TRIGLYCERIDES MEDIUM CHAIN FORMULA 400 g powder, Peptamen® Junior, Nestle Health Science

1 Purpose of Application

1.1 The sponsor's submission seeks a change to the current PBS listing note, allowing an increased supply of Peptamen® Junior from the listed maximum quantity of 8 cans up to a maximum of 20 cans to allow a one month supply for an infant or child at an appropriate dose to meet the total nutritional requirements for their respective age range.

2 Requested listing

2.1 The submission seeks the following changes to the existing listing:

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Dispensed Price for Max. Qty	Proprietary Name and Manufacturer	
TRIGLYCERIDES MEDIUM CHAIN FORMULA Triglycerides medium chain formula oral liquid Powder for, 400 g	8	5	$411.80	Peptamen® Junior	Nestle Health Science

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	☐Dental ☒Medical Practitioners ☒Nurse practitioners ☐Optometrists ☐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:	☒Restricted benefit ☐Authority Required - In Writing ☐Authority Required - Telephone ☐Authority Required – Emergency ☐Authority Required - Electronic ☐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:	Note: No increase in the maximum number of repeats may be authorised. Note: ~~No increase in the maximum quantity or number of units may be authorised~~ Authorities for increased maximum quantities, up to a maximum of 20, may be authorised. Note: Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet

3 Background

3.1 Peptamen® Junior does 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 Peptamen® Junior has been considered by the PBAC previously at the July 2014 meeting. The PBAC recommended the listing of Peptamen® Junior with the same restriction wording as the comparator Monogen® on advice from the Nutritional Products Working Party. The PBAC also recommended that the restriction of Peptamen® Junior should include the same administrative notes as currently apply to the listings of Monogen® and Lipstart®.

3.3 At its March 2012 meeting, the PBAC recommended the listing of Lipistart® on a cost-minimisation basis to Monogen®. Lipistart® and Monogen® were considered to be therapeutically equivalent and are presented as 400g X 8 tins.

4 Consideration of the evidence

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

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

4.3 As a minor submission, no new clinical trials are presented in the re-submission.

4.4 The submission claims that an increase of up to 20 cans would allow 30 days of treatment. The submission provides:

- a supporting letter from a senior clinician from The Royal Children's Hospital Melbourne, that a patient, exclusively meeting their entire nutritional requirements from Peptamen® Junior, requires the equivalent of 1 can per day.
- a table showing that to provide total nutrition, 14 to 25 cans are required for children weighting between 11.0 -25.6 kg.

4.5 The sponsor claims the proposed change to the listing condition for Peptamen® Junior would facilitate more convenient access to patients and result in a decrease in items processed by pharmacies and the Government, resulting in reduced mark-ups and dispensing fees. Consequently, a patient's maximum of five repeats would last longer, reducing the need for unnecessary visits to the doctor for the sole purpose of obtaining further prescriptions. This claim was not been evaluated.

Estimated PBS usage & financial implications

4.6 The submission does not analyse/quantify any possible reduction in costs as a replacement for other products in the medium chain triglycerides (MCT) market ie. Monogen® and Lipistart®, nor the reduction in visits to the doctor for prescriptions.

4.7 There is no change to Approved Ex-Manufacturer Price (AEMP) with the requested increase in maximum quantity.

4.8 There is an error in the calculation to Dispensed Price Maximum Quantity (DPMQ), likely due to rounding. The correct DPMQ for the supply of 20 cans is $1,013.16 (compared to $1,015.42 stated in the submission).

Cost of supplying 8 cans or 20 cans of Peptamen® Junior

	Peptamen® Junior	
Cans supplied	8 cans	20 cans
DPMQ	$411.80	~~$1,015.42~~ $1,013.16
Dispensing fee	$6.76	$6.76
Pharmacist mark-up	$18.00	$38.79
PTP	$387.04	$969.87
Wholesaler mark-up	$27.07	$69.94
AEMP	$359.97	$899.93

AEMP per can	$45.00	$45.00
DPMQ per can	$51.48	$50.77

4.9 Based on the DPMQ in the submission and the assumption of [redacted]% of the estimated Peptamen® Junior market will be supplied through patient's accessing 20 cans of Peptamen® per item processed, the impact to the PBS is claimed to be $[redacted] over 5 years. However the cost will be slightly over-estimated due to the error in the calculation of the DPMQ. The submission presented a sensitivity analysis that if the assumption of patient's accessing 20 cans is [redacted]%, the cost to the PBS was estimated to be $[redacted] over 5 years.

5 PBAC Outcome

5.1 The PBAC noted advice from the Nutritional Products Working Party and recommended to amend the current administrative advice note, allowing an increased supply of Peptamen® Junior from the listed maximum quantity of 8 cans up

to a maximum of 20 cans to allow a one month supply for an infant or child at an appropriate dose to meet the total nutritional requirements for their respective age range.

5.2 The PBAC noted that if Peptamen® Junior powder was the sole source of nutrition for an eight to ten year old child, they would require approximately 300 grams of powder per month to meet their nutrition requirements. This amount of powder equates to approximately 22 cans of Peptamen® Junior. The value of 20 cans would align with a number of other nutritional formulas on the PBS (including other Nestle products, such as Alfamino®) that allows increase of maximum quantities to 20.

5.3 The PBAC noted that the submission claimed the change to the note would have a small financial impact on the Commonwealth.

5.4 The PBAC noted that Peptamen® Junior was listed on the same basis as Lipistart® and Monogen® for fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis or gastrointestinal disorders. Lipistart® and Monogen® are also listed for hyperlipoproteinaemina type 1, long chain fatty acid oxidation disorders, chylous ascites and chylothorax. The PBAC noted the advice from the Nutritional Products Working Party that in practice, Lipistart® and Monogen® tended to be mostly used in infants and that overall, without specific evidence, different clinical conditions and the age groups treated with the products, the Working Party could not currently advise if a similar change in the administrative note should be applied for the listing of Lipistart® and Monogen®.

Outcome:
Recommended

6 Recommended listing

Amend administrative note as follows:

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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:	Note: No increase in the maximum number of repeats may be authorised. Note: Authorities for increased maximum quantities, up to a maximum of 20, may be authorised. Note: Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet

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

The sponsor had no comment.