**14.2 TRIGLYCERIDES MEDIUM CHAIN FORMULA,**

**triglycerides medium chain formula oral liquid, powder for, 400 g,**

**Peptamen® Junior, Nestle Health Science (Nestle Australia Ltd)**

1. **Purpose of application**
   1. To request a Restricted Benefit listing for fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis and gastrointestinal disorders.
2. **Requested listing**

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| Name, Restriction,  Manner of administration  and form | | Max.  Qty | №.of  Rpts |  | Proprietary Name and Manufacturer | |
| TRIGLYCERIDES MEDIUM CHAIN FORMULA  Triglycerides medium chain oral liquid, powder for 8 x 400g | | 8 | 5 |  | Peptamen® Junior | NT |
| **Condition/Indication:** | Dietary management of conditions requiring a source of medium chain triglycerides | | | | | |
| **Restriction:** | Restricted benefit | | | | | |
| **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 | | | | | |

1. **PBAC Outcome**
   1. The PBAC recalled that it recommended listing Lipistart® in March 2012, on a cost-minimisation basis to Monogen®. Lipistart® and Monogen® were considered to be therapeutically equivalent and are presented as 400g X 8 tins.
   2. Peptamen Junior is nutritionally comparable to Monogen but contains a lower amount of total fat. This enables Peptamen Junior to meet the nutritional management of children with conditions leading to fat malabsorption. Additionally the submission claims other advantages over its comparator, Monogen: the potential for the formulation to be used as a sole source of nutrition in children since it contains the daily requirements for the essential fatty acids, linoleic acid and alpha linoleic acid and the use of 100% hydrolysed whey protein compared to Monogen’s whole whey protein source.
   3. The submission claimed a cost saving to the PBS if Peptamen Junior were to be listed on the PBS as Peptamen Junior will substitute for the comparator Monogen, the most commonly prescribed medium chain triglyceride formula (MCT). Peptamen Junior was proposed at a lower price than Monogen.
   4. Monogen and Lipistart are also PBS-listed for the following additional indications: hyperlipoproteinaemia type 1, long chain fatty acid oxidation disorders, chlylous ascites and chylothorax. The submission did not request listing for Peptamen Junior for these indications.
   5. The Nutritional Products Working Party (NPWP) noted that the product name “Peptamen Junior” was very similar to another product “Pepti Junior” (Karicare Aptamil Pepti Junior Gold), a protein hydrolysate formula with MCT, which has PBS-listing for a number of different indications including cows’ milk protein enteropathy and intolerance to soy protein, IgE mediated allergy to cows’ milk protein and soy protein, and other fat malabsorption indications. The NPWP were concerned that there was potential for confusion with these two similarly named products.
   6. The PBAC noted that the NPWP supportedthe listing of Peptamen Junior with the same restriction wording as that of the comparator, Monogen. The PBAC recommend the listing of Peptamen Junior as advised. The PBAC also recommended that the restriction for Peptamen Junior should include the same administrative notes as currently apply to the listings of Monogen and Lipistart.

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| Name, Restriction,  Manner of administration  and form | | Max.  Qty | №.of  Rpts | Proprietary Name and Manufacturer | |
| TRIGLYCERIDES MEDIUM CHAIN FORMULA  Triglycerides medium chain oral liquid, powder for 8 x 400g | | 1 | 5 | Peptamen® Junior | NT | |
| **Condition/Indication:** | Dietary management of conditions requiring a source of medium chain triglycerides | | | | |
| **Restriction:** | Restricted benefit | | | | |
| **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 quantity of number of units may be authorised*  *Note*  *No increase in the maximum number of repeats may be authorised*  *Note:*  *Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal; fluid glucose transporter defect requiring a ketogenic diet.* | | | | |

1. **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.

1. **Sponsor’s Comment**

The sponsor had no comment.