

**5.23 HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN CARBOHYDRATE**

**Oral semi-solid, 100g, 48, tubs,  
Keyo<sup>®</sup>,  
Vitaflo Australia Pty Ltd.**

**1 Purpose of Application**

1.1 The minor submission requested a Restricted Benefit listing for a Ketogenic diet.

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

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Manufacturer	Name and
HIGH FAT FORMULA with VITAMINS, MINERALS and TRACE ELEMENTS and LOW in PROTEIN CARBOHYDRATE oral semi-solid, 100g, 48, tubs	4	5	\$ [REDACTED]	Keyo®	Vitaflo Australia Pty Ltd

<b>Category / Program</b>	GENERAL – General Schedule (Code GE)
<b>Prescriber type:</b>	<input type="checkbox"/> Dental <input type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
<b>PBS Indication:</b>	Ketogenic diet
<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>	Patients <i>must have intractable seizures</i> requiring a ketogenic diet for the treatment of intractable seizures;  OR  Patients <i>must have a glucose transport protein defect</i> ;  OR  Patient <i>must have pyruvate dehydrogenase deficiency</i>
<b>Prescriber Instructions</b>	<i>Keyo should only be used under strict supervision of a dietician, together with a metabolic physician and/or neurologist</i>
<b>Administrative Advice</b>	<i>Authorities for increased maximum quantities, up to a maximum of 11, may be authorised.</i>

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

### 3 Background

- 3.1 The sponsor of Keyo® 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 The submission has not been considered by the PBAC previously.

#### **4 Comparator**

- 4.1 The minor submission nominated KetoCal 4:1 LQ<sup>®</sup> as the main comparator, as the product most closely resembling the nutritional composition and presentation of Keyo.
- 4.2 As a minor submission, there was no economic comparison.

*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 sponsor's proposed comparator, KetoCal<sup>®</sup>, was considered suitable.
  - The sponsor used a ratio of fat to protein and carbohydrate when comparing Keyo<sup>®</sup> to KetoCal<sup>®</sup>. The NPWP suggested that the sponsor use a percentage of calories from fat rather than the ratio.
  - The product is a nutritionally complete formula for patients aged 1–10 years old. However, the NPWP noted that older patients will require further supplementation.
  - The NPWP noted that the product contained less docosahexanoic acid (DHA) and amino acids (AA) than the nominated comparator.
  - As some patients require other sources of nutritional support, Keyo<sup>®</sup> may not fully replace the use of KetoCal<sup>®</sup>, as the sponsor claimed. Therefore, the listing of Keyo<sup>®</sup> on the PBS may increase the cost to the Government.
  - The requested maximum quantity of 4 × 48 tubs is considered large for the particular age range. The NPWP suggested the MQ be lowered to 3 × 48 tubs per month.
- 5.5 The NPWP supported the listing of Keyo<sup>®</sup> as a Restricted Benefit for patients requiring a Ketogenic diet on a cost-minimisation basis against KetoCal<sup>®</sup> at an equivalent price per calorie. The NPWP suggested that the product be listed at a maximum quantity of 3 × 48 tubs.

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

- 5.6 The submission sought to list the product on a cost minimisation basis at the same AEMP per kJ compared to KetoCal 4:1 LQ<sup>®</sup>.
- 5.7 The submission had based all the economic and financial analysis on the assumption that patients would consume 4 tubs per day which is equivalent to 120 tubs per month or 2.5 cartons per month.
- 5.8 Under the assumption of patient uses average of 2.5 cartons per month, the cost per patient per month was reported as \$████████. However, this was calculated using the price to the pharmacy not the DPMQ. Upon recalculation using the DPMQ the price per month was \$████████ (based on the calculation: \$████████ ÷ 4 cartons × 2.5 cartons per month) this would give a cost per patient per year of \$████████ (\$████████ × 12 months).
- 5.9 The financial estimation in the submission was calculated using the Price to Pharmacy, when using the DPMQ the financial implication to the Government would be expected to be higher. The sponsor did not overtly state that the product would substitute for currently listed products for the patients that require a ketogenic diet, however this would be expected and would lessen the financial impact on 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 Keyo<sup>®</sup> as a Restricted Benefit for patients requiring a Ketogenic diet.
- 6.2 The PBAC noted the advice of the Nutritional Products Working Party (NPWP) that supported the listing of Keyo<sup>®</sup> on the PBS.
- 6.3 The PBAC accepted KetoCal 4:1 LQ<sup>®</sup> as an appropriate comparator for Keyo<sup>®</sup>.
- 6.4 The PBAC noted that the product has a higher protein concentration (24 %) and a lower fat to protein plus carbohydrate ratio (3:1 vs 4:1) than the comparator.
- 6.5 The PBAC also noted that maximum quantity requested of 4 cartons of 48 tubs would provide more than one month's supply, using the sponsor's assumption of patients using 4 tubs per day (equivalent to 2.5 cartons per month).
- 6.6 The PBAC agreed with the NPWP that the Maximum Quantity be restricted to 3 cartons as this was sufficient for one month of treatment.
- 6.7 The PBAC noted that the product Keyo<sup>®</sup> (1280 kJ per 100 g) is therapeutically equivalent to its main comparator KetoCal 4:1 LQ (620 kJ per 100 mL), and the submission requested a higher DPMQ than KetoCal 4:1 LQ<sup>®</sup>, which is currently listed on PBS based on a price per kJ basis.
- 6.8 The PBAC agreed with the advice of the NPWP that the price should be on a cost minimisation basis with the comparator KetoCal 4:1LQ.

- 6.9 In accordance with Section 101 (3BA) of the *National Health Act*, the PBAC advised that, on the basis of the material available at the November 2016 meeting, Keyo® should be treated as interchangeable on an individual patient basis with similar nutritional products.
- 6.10 The PBAC recommended that Keyo® is suitable for prescribing by nurse practitioners, as nutritional products are currently included for prescribing by nurse practitioners.
- 6.11 The PBAC recommended that the Early Supply Rule should not apply as it has been the PBAC's view that general nutrients be exempt.
- 6.12 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	
HIGH FAT FORMULA with VITAMINS, MINERALS and TRACE ELEMENTS and LOW in PROTEIN CARBOHYDRATE oral semi-solid, 100g, 48, tubs	3	5	Keyo®	Vitaflo Australia Pty Ltd

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<b>PBS Indication:</b>	Ketogenic diet
<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>	Patients must have intractable seizures requiring a ketogenic diet;  OR  Patients must have a glucose transport protein defect;  OR  Patient must have pyruvate dehydrogenase deficiency
<b>Prescriber Instructions</b>	Keyo should only be used under strict supervision of a dietician, together with a metabolic physician and/or neurologist
<b>Administrative Advice</b>	Authorities for increased maximum quantities, up to a maximum of 11, may be authorised.

## **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.