

## **14.03b HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE**

**Oral semi-solid, 100g, 36**

**K.Yo<sup>®</sup>,**

**Vitaflo Australia Pty Ltd**

### **1 Purpose of Application**

- 1.1 The Committee secretariat submission requested listing a new brand (K.Yo<sup>®</sup>) to replace the PBS-listed Keyo<sup>®</sup>.
- 1.2 The submission also requested de-listing Keyo<sup>®</sup> (PBS code 11108P) from the PBS.

### **2 Background**

- 2.1 In November 2016, the PBAC recommended listing Keyo as a Restricted Benefit for patients requiring a Ketogenic diet on a cost minimisation basis at the same AEMP per kilojoules compared to KetoCal 4:1 LQ<sup>®</sup>.

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

### **3 Requested listing**

- 3.1 The submission requested listing K.Yo under the same circumstances of the PBS-listed Keyo.
- 3.2 Secretariat suggested additions are in italics and deletions are in strikethrough.

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MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE					
<del>high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate oral semi-solid, 48 x 100 g tubs [Supply Only]</del>	11108P	3	3	5	Keye
high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate oral semi-solid, 36 x 100 g tubs	NEW	4	4	5	K. Yo
<b>Restriction Summary 6858 / Treatment of Concept: 6858</b>					
<b>Category / Program:</b> GENERAL – General Schedule (Code GE)					
<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners					
<b>Restriction type:</b> <input checked="" type="checkbox"/> Restricted benefit					
<b>Indication:</b> Ketogenic diet					
<b>Clinical criteria:</b>					
Patient must have intractable seizures requiring treatment with a ketogenic diet; or					
Patient must have a glucose transport protein defect; or					
Patient must have pyruvate dehydrogenase deficiency					
<b>Treatment criteria:</b>					
Patient must be undergoing treatment under the strict supervision of a dietitian, together with at least one of: (i) a metabolic physician, (ii) a neurologist					
<b>Prescribing instructions:</b>					
Keye should only be used under strict supervision of a dietitian, 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.					
<b>Administrative Advice:</b> Authorities for increased maximum quantities, up to a maximum of 15, may be authorised.					

- 3.3 The Secretariat advised that under existing administrative arrangements, authority approvals seeking increases in the maximum quantity need to be a multiple of the stated maximum quantity (packs) for Services Australia to be able to administer correctly.

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

## 4 Consideration of the evidence

### **Sponsor hearing**

- 4.1 There was no hearing for this item.

### **Consumer comments**

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

### **Other relevant matters**

- 4.3 The submission stated the following changes to the fat profile:

- The Docosahexaenoic acid (DHA) source in K.Yo is oil from microalgae *Schizochytrium sp.*, whilst the DHA source in Keyo is tuna oil. This is to make K.Yo suitable for patients following a vegetarian diet and to achieve Halal certification.
- K.Yo has a DHA content of 20mg per 100g, whilst Keyo's DHA content is 10mg per 100g. Keyo's DHA content is below the limit of detection, which has caused analytical issues. The increase has resolved these issues and is nutritionally appropriate.
- K.Yo does not contain Arachidonic acid (ARA), whilst Keyo contains ARA and DHA. ARA is not an essential fatty acid. ARA does become essential if a deficiency of Linoleic Acid (LA) exists or if an inability to convert LA to ARA occurs. K.Yo has a LA content of 5.5g per 100g and so a deficiency of ARA attributable to inadequate LA intake is not expected.

4.4 The nutrient content of the proposed product, K.Yo and the comparator (KetoCal 4:1 LQ RTF) are presented in the table below.

Table 1: Nutrient contents of K.Yo and Keyo and comparator

Nutrient per 100g/ml	K.Yo Chocolate/ Vanilla	Keyo Chocolate	KetoCal 4:1 LQ RTF
Energy kJ Kcal	1280/ <b>1272</b> 310/ <b>308</b>	1280 310	620 150
Protein g	8	8	3.1
Carbohydrate g Of which (O/W) sugars	2/ <b>1.5</b> 1.5	2 1.5	0.6 0.4
Fat g O/W saturates g O/W polyunsaturates g O/W monounsaturates g O/W DHA mg/AA mg	30 2.7 8.0 18 20/ <b>0</b>	30 2.2 8.6 18.6 10/20	14.8 2.2 3.7 8.3 55/55
Fibre g	Nil Added	Nil added	1.1
Osmolality mOsm/kg	N/A	N/A	280
<b>Vitamins</b>			
Vitamin A mcg RE	160	160	79.2
Vitamin D3 mcg	5	5	2.3
Vitamin E mg	4	4	1.5
Vitamin C mg	14	14	9.3
Vitamin K mcg	20	16	5.6
Thiamin mg	0.25	0.25	0.2
Riboflavin mg	0.3	0.3	0.2
Niacin mg / (mg NE)	2.9/ <b>(4.9)</b>	4.9	2.3
Vitamin B6 mg	0.3	0.3	0.2
Folacin mcg	64	64	28.7
Vitamin B12 mcg	0.5	0.5	0.17
Biotin mcg	4.8	4.8	4.1
Pantothenic Acid mg	0.9	0.95	0.6
Choline mg	88	88	51.5
<b>Minerals</b>			
Sodium mg	115	115	113
Potassium mg	290/ <b>246</b>	290	182
Chloride mg	180	150	170
Calcium mg	160	160	97.2
Phosphorus mg	190	190	97.2
Magnesium mg	29	29	24.9
<b>Trace Elements</b>			
Iron mg	3.5	3.5	1.7
Zinc mg	2.5	2.5	1.4
Copper mcg	230	230	140
Manganese mg	0.31	0.31	0.2
Iodine mcg	37	37	18.5
Molybdenum mcg	14	14	6.8
Selenium mcg	13	13	7.8
Chromium mcg	20/ <b>14</b>	14	3.5

Note: K.Yo chocolate and K.Yo vanilla provide several nutrients, in differing amounts. These amounts, per 100g of product, are highlighted above in **bold blue**. It was necessary to add a slightly different amount of each of these nutrients to each of the two flavours to ensure product stability during the manufacturing process. These differences are not expected to have any significant nutritional impact.

Source: Appendix 1-1a of the submission

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

- 4.5 The PBAC noted that the submission stated the net cost to the PBS would be the same as Keyo as K.Yo's listed price was based on currently PBS-listed Keyo's cost per calorie of energy (\$0.015603 per kcal/energy).

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

## **5 NPWP Consideration**

- 5.1 The Nutritional Products Working Party (NPWP) noted that K.Yo is the replacement product for Keyo (which will be delisted) and is nutritionally complete.
- 5.2 The NPWP considered the formulation changes are minor and continue to meet the ketogenic diet requirements as per existing Keyo PBS listing.
- 5.3 The NPWP supported listing K.Yo on the PBS and advised that it had no concerns on de-listing Keyo from the PBS, noting that there are other comparable nutritional products available from the PBS.
- 5.4 The NPWP advised that it is appropriate to increase the proposed maximum quantity of K.Yo from 3 to 4 to ensure the new listing provides the same amount of energy (kilojoules) as the current Keyo PBS listing.

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

## **6 PBAC Outcome**

- 6.1 The PBAC recommended the listing of high fat formula with vitamins, minerals, and trace elements and low in protein and carbohydrate (K.Yo) to replace the current PBS listed brand Keyo.
- 6.2 The PBAC agreed with the NPWP advice detailed in Section 5 'NPWP consideration'. The PBAC noted the sponsor has requested to delist the current PBS listed brand Keyo and had no objection to this de-listing, noting that Keyo will be replaced by K.Yo.
- 6.3 The PBAC noted that its recommendation was based on (K.Yo) replacing the current PBS listed brand Keyo and on a cost neutral basis. The PBAC advised K.Yo is not expected to address a high and urgent unmet clinical need given the presence of an alternative therapy, the criteria prescribed by the National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2009 for pricing Pathway A were not met.
- 6.4 The PBAC advised that this submission is not eligible for an Independent Review as it received a positive recommendation.

### **Outcome:**

Recommended

## 7 Recommended listing

- 1) Remove the current trade product pack (TPP) of Keyo; apply 'Supply Only' arrangements to enable any remaining repeat prescriptions to remain valid for a period of 12 months following removal from the PBS;
- 2) Replace the deleted TPP with the new TPP 'K.Yo';
- 3) Remove the current medicinal product pack (MPP) of: 'high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate oral semi-solid, 48 x 100 g tubs';
- 4) Replace the removed MPP with the new MPP of: 'high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate oral semi-solid, 36 x 100 g tubs'; and
- 5) List K.Yo with a maximum quantity (packs/units) of four.

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
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<del>high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate oral semi-solid, 48 x 100 g tubs [Supply Only]</del>	41108P	3	3	5	Keyo
high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate oral semi-solid, 36 x 100 g tubs	NEW	4	4	5	K.Yo
		Max.Qty multiplier = 4 Repeat increases: nil			
<b>Edit Restriction Summary 6858 / Treatment of Concept: 6858 for the new K.Yo product only:</b>					
<b>Category / Program:</b> GENERAL – General Schedule (Code GE)					
<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners					
<b>Restriction type:</b> <input checked="" type="checkbox"/> Restricted benefit					
<b>Indication:</b> Ketogenic diet					
<b>Clinical criteria:</b>					
Patient must have intractable seizures requiring treatment with a ketogenic diet; or					
Patient must have a glucose transport protein defect; or					
Patient must have pyruvate dehydrogenase deficiency					
<b>Treatment criteria:</b>					
Patient must be undergoing treatment under the strict supervision of a dietitian, together with at least one of: (i) a metabolic physician, (ii) a neurologist					
<b>Prescribing Instructions:</b>					
Keyo should only be used under strict supervision of a dietitian, 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.					
<b>Administrative Advice:</b> Requests seeking an increased maximum quantity (packs) up to 4 times that stated, may be authorised.					

***This restriction may be subject to further review. Should there be any changes made to the restriction the Sponsor will be informed.***

## **8 Context for Decision**

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

## **9 Sponsor's Comment**

The sponsor had no comment.