

**14.03 TRIGLYCERIDES, LONG CHAIN**  
**Oral liquid 250 mL, 18 (carbzero),**  
**CarbZero®**

**TRIGLYCERIDES, MEDIUM CHAIN**  
**Oral liquid 250 mL, 18 (betaquik),**  
**Betaquik®**

**Vitaflo Australia Pty Ltd**

**1 Purpose of Application**

1.1 The minor submission sought to amend the current Restricted Benefit listing for Carbzero® and the Authority Required (Streamlined) listing for Betaquik® by changing the product forms from cartons to bottles, and changing the electrolyte profile in both formulations. No changes to the current pricing were proposed.

**2 Requested Listing**

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

2.2 Additions are in italics and deletions are in strikethrough.

No changes to the proposed listing are suggested by the Secretariat.

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Manufacturer	Name and
TRIGLYCERIDES LONG CHAIN; <i>triglycerides long chain oral liquid, 250 mL, 18 bottles</i> <del>triglycerides long chain oral liquid, 18 x 250 mL cartons</del>		5	\$289.30	Carbzero®	Vitaflo Australia Pty Ltd

<b>Category / Program</b>	GENERAL – General Schedule (Code GE)
<b>Prescriber type:</b>	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
<b>Condition:</b>	Ketogenic diet
<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

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<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>Prescriber Instructions</b>	Carbzero should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.
<b>Administrative Advice</b>	Carbzero is not nutritionally complete and is not intended for use as a sole source of nutrition.

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Manufacturer	Name and
MEDIUM CHAIN TRIGLYCERIDES, <i>triglycerides medium chain oral liquid, 250 mL, 18 bottles</i> <i>triglycerides medium chain oral liquid, 18 x 250 mL cartons</i>	2	5	\$357.34	Betaquik®	Vitaflo Australia Pty Ltd

<b>Category / Program</b>	GENERAL – General Schedule (Code GE)
<b>Prescriber type:</b>	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
<b>Condition:</b>	Ketogenic diet
<b>PBS Indication:</b>	Ketogenic diet
<b>Restriction Level / Method:</b>	<input 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 checked="" type="checkbox"/> Streamlined
<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>Administrative Advice</b>	No increase in the maximum quantity or number of units may be authorised.  No increase in the maximum number of repeats may be authorised.

<b>Condition:</b>	Dietary management of conditions requiring a source of medium chain triglycerides
<b>PBS Indication:</b>	Dietary management of conditions requiring a source of medium chain triglycerides
<b>Restriction Level / Method:</b>	<input 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 checked="" type="checkbox"/> Streamlined

<b>Clinical criteria:</b>	Patient must have chylous ascites; OR Patient must have chylothorax; OR Patient must have hyperlipoproteinaemia type 1; OR Patient must have long chain fatty acid oxidation disorders; OR 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.
<b>Administrative Advice</b>	No increase in the maximum quantity or number of units may be authorised. No increase in the maximum number of repeats may be authorised.

### 3 Background

- 3.1 The sponsor of Betaquik® and Carbzero® confirmed that they 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 The PBAC previously recommended the listing of Carbzero® as a Restricted Benefit and Betaquik® as an Authority Required (STREAMLINED) benefit at the November 2013 meeting.

### 4 Pricing considerations

- 4.1 The sponsor stated that there will be no change to the current DPMQs (\$357.34 for Betaquik® and \$289.30 for Carbzero®). Therefore there will be nil impact to the PBS.

### 5 Other relevant factors

- 5.1 The submission also requested an amendment to the electrolyte composition of the formulations as outlined in Table 1 below. These changes were not considered to impact the nutritional value of the products affected.

**Table 1. Proposed formulation change.**

CarbZero/Betaquik	Current Formulation	New Formulation	Units
Sodium	45	52	mg/100 mL
Chloride	57	60	mg/100 mL

### 6 PBAC Outcome

- 6.1 The PBAC noted the change to the listings processed by the secretariat.

**Outcome:**

Recommended

**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.