**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. 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**
	1. The submission requested the following changes to the existing listing:
	2. Additions are in italics and deletions are in strikethrough.

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

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| **Name, Restriction,****Manner of administration and form** | **Max.****Qty** | **№.of****Rpts** | **Dispensed Price for Max. Qty** | **Proprietary Name and Manufacturer** |
| TRIGLYCERIDES LONG CHAIN;*triglycerides long chain oral liquid, 250 mL, 18 bottles*~~triglycerides long chain oral liquid, 18 x 250 mL cartons~~ | 2 | 5 | $289.30 | Carbzero**®** | Vitaflo Australia Pty Ltd |
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| **Category /** **Program** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | [ ] Dental [x] Medical Practitioners [x] Nurse practitioners [ ] Optometrists[ ] Midwives |
| **Condition:** | Ketogenic diet |
| **PBS Indication:** | Ketogenic diet |
| **Restriction Level / Method:** | [x] Restricted benefit[ ] Authority Required - In Writing[ ] Authority Required - Telephone[ ] Authority Required – Emergency[ ] Authority Required - Electronic[ ] Streamlined |
| **Clinical criteria:** | Patient must have intractable seizures requiring treatment with a ketogenic diet; ORPatient must have a glucose transport protein defect; ORPatient must have pyruvate dehydrogenase deficiency. |
| **Prescriber Instructions** | Carbzero should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist. |
| **Administrative Advice** | Carbzero is not nutritionally complete and is not intended for use as a sole source of nutrition. |

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| **Name, Restriction,****Manner of administration and form** | **Max.****Qty** | **№.of****Rpts** | **Dispensed Price for Max. Qty** | **Proprietary Name and Manufacturer** |
| MEDIUM CHAIN TRIGLYCERIDES,*triglyerides medium chain oral liquid, 250 mL, 18 bottles**~~triglycerides medium chain oral liquid, 18 x 250 mL cartons~~* | 2 | 5 | $357.34 | Betaquik**®** | Vitaflo Australia Pty Ltd |
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| **Category /** **Program** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | [ ] Dental [x] Medical Practitioners [x] Nurse practitioners [ ] Optometrists[ ] Midwives |
| **Condition:** | Ketogenic diet |
| **PBS Indication:** | Ketogenic diet |
| **Restriction Level / Method:** | [ ] Restricted benefit[ ] Authority Required - In Writing[ ] Authority Required - Telephone[ ] Authority Required – Emergency[ ] Authority Required - Electronic[x] Streamlined |
| **Clinical criteria:** | Patient must have intractable seizures requiring treatment with a ketogenic diet; ORPatient must have a glucose transport protein defect; ORPatient must have pyruvate dehydrogenase deficiency. |
| **Administrative Advice** | No increase in the maximum quantity or number of units may be authorised.No increase in the maximum number of repeats may be authorised. |

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| **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 |
| **Restriction Level / Method:** | [ ] Restricted benefit[ ] Authority Required - In Writing[ ] Authority Required - Telephone[ ] Authority Required – Emergency[ ] Authority Required - Electronic[x] Streamlined |
| **Clinical criteria:** | Patient must have chylous ascites; ORPatient must have chylothorax; ORPatient must have hyperlipoproteinaemia type 1; ORPatient must have long chain fatty acid oxidation disorders; ORPatient must have fat malabsorption due to liver disease; ORPatient must have fat malabsorption due to short gut syndrome; ORPatient must have fat malabsorption due to cystic fibrosis; ORPatient must have fat malabsorption due to gastrointestinal disorders. |
| **Administrative Advice** | No increase in the maximum quantity or number of units may be authorised.No increase in the maximum number of repeats may be authorised. |

1. **Background**
	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.*
	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.
2. **Pricing considerations**
	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.
3. **Other relevant factors**
	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 |

1. **PBAC Outcome**
	1. The PBAC noted the change to the listings processed by the secretariat.

**Outcome:**

Recommended

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.