

6.18 TRIGLYCERIDES, MEDIUM CHAIN
Oral liquid 225 mL, 15 (Betaquik)
BetaQuick®, Vitaflo Australia Pty Ltd.

TRIGLYCERIDES, LONG CHAIN
Oral liquid 225 mL, 15 (Carbzero),
Carbzero®, Vitaflo Australia Pty Ltd.

1 Purpose of Application

- 1.1 The minor submission sought to amend the current form and maximum quantity of cartons per script from two to three of both the listed products Betaquik® and Carbzero® for the treatment of patients requiring a diet high in medium chain triglyceride and for patients who require a ketogenic diet respectively.

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.
- 2.3 No changes to the indication or wording of the criteria were proposed and no changes to the proposed listing are suggested by the Secretariat.

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed for Max. Qty	Price	Proprietary Manufacturer	Name and
MEDIUM CHAIN TRIGLYCERIDES						
Oral liquid, 18 x 250 mL cartons (Betaquik)	2	5	\$357.87		Betaquik	Australia
<i>Oral liquid, 15 x 225 mL cartons (Betaquik)</i>	3		<i>\$401.38</i>		Vitaflo Pty Ltd	

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed for Max. Qty	Price	Proprietary Manufacturer	Name and
TRIGLYCERIDES LONG CHAIN						
Oral liquid, 18 x 250 mL cartons (Carbzero)	2	5	\$289.83		Carbzero	Australia
<i>Oral liquid, 15 x 225 mL cartons (Carbzero)</i>	3		<i>\$325.90</i>		Vitaflo Pty Ltd	

3 Background

- 3.1 The sponsor of Betaquik® and Carbzero® has previously 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. At its March 2017 meeting, the PBAC noted a minor change to electrolyte content of both products along with a change to the packaging of the products from a carton to a bottle.

4 Pricing considerations

- 4.1 The minor submission provided minimal information on the proposed changes to the dispensed price for the maximum quantity (DPMQ) other than to indicate that no change in the price per mL of product was requested (i.e that the 225 mL volumes of Carbzero® and Betaquik® be determined at the same cost per mL of product as the 250 mL volumes). While this is not the correct way to compare these formulations, the end result is the same as costing on a price per kilojoule (kJ) basis.
- 4.2 The proposed decrease in pack/carton size from 18 bottles of 250 mL to 15 bottles of 225 ml with a subsequent request to increase the maximum quantity of cartons from 2 to 3 would result in an increase in volume of liquid dispensed per script from 9 L to 10.125 L. This increase in volume of product per script would result in an equivalent increase in the DPMQ.

Estimated PBS usage & financial implications

- 4.3 The minor submission did not provide any estimated financial implications.
- 4.4 The PBAC noted that the requested increase in the DPMQ will result in an overall increase in the cost to the PBS, however the magnitude of this was not clear.
- 4.5 In consideration of the submission, the Nutritional Products Working Party (NPWP) noted:
 - The sponsor of Betaquik® and Carbzero® confirms 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*.
 - The change in container size for Betaquik® and Carbzero® from 250 mL to 225 mL and a change in the number of containers per carton from 18 to 15. The sponsor also requested an increase in the maximum quantity of cartons per script from two to three due to the change in the packaging of the products.

- Increasing the number of cartons per script would increase the dispensed maximum quantity per script from 9 L to 10.125 L of product.
- The minor submission incorrectly presented a cost-minimisation against the current listing on a cost per mL of product, however it was noted that this would result in a same costing outcome as a cost-minimisation on a cost per kilojoule (kJ) basis.

The NPWP did not consider that the request for an increase in the maximum quantity was clinically appropriate and recommended to the PBAC that the maximum quantity per script for Betaquik® and Carbzero® remain at two cartons. The NPWP did not support the proposed amendment to the maximum quantity and number of repeats of both Betaquik® and Carbzero® for the dietary management of conditions requiring a source of medium chain triglycerides and for patients who require a ketogenic diet respectively. The NPWP proposed to leave the maximum quantity at two with five repeats while noting the change to container size and a decrease in the number of containers per carton. The NPWP considered that the cost per maximum quantity should be calculated on a cost per kJ basis to the currently listed packaging.

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 There PBAC noted that no consumer comments were received for this item.

6 PBAC Outcome

- 6.1 The PBAC decided not to recommend amending the maximum quantity of cartons per script from two to three of both Betaquik® and Carbzero®, for the dietary management of conditions requiring a source of medium chain triglycerides and for patients who require a ketogenic diet respectively.
- 6.2 The PBAC also noted the change to container size for Betaquik® and Carbzero® from 250 mL to 225 mL, and the change in number of containers per carton from 18 to 15.
- 6.3 The PBAC noted the advice of the NPWP that did not support the request to increase the maximum quantity of Betaquik® and Carbzero® from two cartons per script to three, as this would increase the total volume per script from 9 L to 10.125 L of product, which was not considered clinically appropriate.
- 6.4 The PBAC considered that the increase in volume per script would result in a higher dispensed maximum quantity per script, and potentially higher costs to the PBS.

6.5 The PBAC agreed with the NPWP that the existing maximum quantity of two cartons with five repeats was appropriate.

6.6 The PBAC noted that this submission was not eligible for an Independent Review as it was a request to modify or extend an existing listing.

Outcome:

Rejected

7 Recommended listing

7.1 Add new items:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer
MEDIUM CHAIN TRIGLYCERIDES Oral liquid, 15 x 225 mL cartons	2	5	Betaquik® Vitaflo Australia Pty Ltd
Category / Program	GENERAL – General Schedule (Code GE)		
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives		
Condition:	Ketogenic diet		
PBS Indication:	Ketogenic diet		
Restriction Level / Method:	<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		
Clinical criteria:	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.		
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.		

Public Summary Document – November 2017 PBAC Meeting

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

Public Summary Document – November 2017 PBAC Meeting

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer
TRIGLYCERIDES LONG CHAIN triglycerides long chain oral liquid, 15 x 2 225 mL cartons	5	Carbzero®	Vitaflo Australia Pty Ltd
Category / Program	GENERAL – General Schedule (Code GE)		
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives		
Condition:	Ketogenic diet		
PBS Indication:	Ketogenic diet		
Restriction Level / Method:	<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		
Clinical criteria:	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.		
Prescriber Instructions	Carbzero should only be used under strict supervision of a dietician, 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.		

7.2 Delete items:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer
MEDIUM CHAIN TRIGLYCERIDES Oral liquid, 18 x 250 mL cartons	2	5	Betaquik® Vitaflo Australia Pty Ltd
Category / Program	GENERAL – General Schedule (Code GE)		
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives		
Condition:	Ketogenic diet		
PBS Indication:	Ketogenic diet		
Restriction Level / Method:	<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		
Clinical criteria:	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.		
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.		

Public Summary Document – November 2017 PBAC Meeting

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

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer
TRIGLYCERIDES LONG CHAIN triglycerides long chain oral liquid, 18 x 2 250 mL cartons	5	Carbzero®	Vitaflo Australia Pty Ltd
Category / Program	GENERAL – General Schedule (Code GE)		
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives		
Condition:	Ketogenic diet		
PBS Indication:	Ketogenic diet		
Restriction Level / Method:	<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		
Clinical criteria:	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.		
Prescriber Instructions	Carbzero should only be used under strict supervision of a dietician, 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.		

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.