

6.09 TRIGLYCERIDES, MEDIUM CHAIN, Oral liquid 225 mL, 15 (K.Quik), K.Quik®, Vitaflo Australia Pty Limited

1 Purpose of Submission

- 1.1 The Committee Secretariat submission requested a General Schedule Authority Required (STREAMLINED) listing of a new form of triglycerides, medium chain oral liquid, 15 x 225 mL bottles (K.Quik®) to replace the PBS-listed Betaquik®.

2 Background

- 2.1 Triglycerides, medium chain oral liquid, 15 x 225 mL bottles (K.Quik), meets the requirements for foods that have special medical purposes as set out under *The Australia New Zealand Food Standards Code – Standard 2.9.5: Food for Special Medical Purposes*.
- 2.2 In November 2013 the Pharmaceutical Benefits Advisory Committee (PBAC) recommended triglycerides, medium chain oral liquid (Betaquik®) as an Authority Required (STREAMLINED) listing for patients requiring a ketogenic diet (KD), and dietary management of conditions requiring a source of medium chain triglycerides.
- 2.3 There is no difference in the nutritional content between K.Quik and Betaquik.
- 2.4 The submission also requested de-listing Betaquik (Pharmaceutical Benefits Scheme (PBS) code 11444H) from the PBS. This was handled in a separate process.

3 Requested listing

- 3.1 The submission requested listing the new brand K.Quik under the same conditions as the currently PBS-listed Betaquik.

Add new medicinal product pack as follows:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
MEDIUM CHAIN TRIGLYCERIDES					
medium chain triglycerides oral liquid, 15 x 225 mL bottles	11444H	2	2	5	Betaquik
<i>medium chain triglycerides oral liquid, 15 x 225 mL bottles</i>	<i>NEW</i>	2	2	5	<i>K.Quik</i>
Restriction Summary / ToC: Authority Required: Streamlined					
Insert New AA1	Administrative Advice: (applies across both restrictions) <i>From [insert listing date here], the brand 'K.Quik' has replaced the brand 'Betaquik'.</i>				
	Indication: Ketogenic diet				
	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.				
	Administrative Advice: No increase in the maximum number of repeats may be authorised.				
Restriction Summary / ToC: Authority Required: Streamlined					
	Indication: Dietary management of conditions requiring a source of medium chain triglycerides				
	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.				
	Administrative Advice: No increase in the maximum number of repeats may be authorised.				

- 3.2 An administrative advice could be added to state that K.Quik has replaced Betaquik from a stated listing date to help prescribers and pharmacists understand the change. It is the sponsor's responsibility to undertake relevant, necessary healthcare professional education activities outside of the PBS listing.

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.

Estimated PBS utilisation and financial implications

4.3 The submission requested K.Quik to have an equivalent dispensed price for maximum quantity (DPMQ) (\$274.70) for the same amount of product as Betaquik.

4.4 The submission considered there to be no financial implications to the PBS usage as the submission expects K.Quik to only substitute for Betaquik assuming 1:1 script equivalence.

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

5 NPWP Consideration

5.1 The Nutritional Products Working Party (NPWP) supported the listing of a new brand K.Quik to replace the currently listed Betaquik brand.

6 PBAC Outcome

6.1 The PBAC recommended the listing of the new form of triglycerides, medium chain – oral liquid 225 mL, 15 (K.Quik®) to replace the PBS-listed Betaquik®.

6.2 The PBAC had no objection to the sponsor-initiated de-listing request of Betaquik.

6.3 The PBAC noted that its recommendation was based on K.Quik replacing the PBS-listed brand Betaquik on a cost neutral basis. The PBAC advised K.Quik 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 noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

7.1 Add new medicinal product pack and brand 'K.Quik'.

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- 7.2 Add new administrative advice (New AA1) to the listing to aid health professional, consumer and administrator awareness.

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	Indication: Dietary management of conditions requiring a source of medium chain triglycerides				
	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				
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	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.				
	Administrative Advice: No increase in the maximum number of repeats 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.

9 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.

8 Sponsor's Comment

The sponsor had no comment.