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Pharmaceutical Benefits Advisory Committee

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The Australian Kidney Foundation
Trading as Kidney Health Australia
ABN 37 008 464 426 | Charity No. CH 0614

Patron-in-Chief
His Excellency General
The Honourable Sir Peter Cosgrove AK MC
(Retired)

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Lady Margaret Brabham
Mr Normie Rowe AM

**Kidney Health Australia Submission
Public Consultation on the Post-market Review of Ezetimibe**

Kidney Health Australia (KHA) is the peak national body representing the needs of those with kidney disease and kidney cancer in Australia. As the lead organisation in the kidney sector, KHA advocates on matters relating to the welfare of kidney stakeholders and the delivery of services to people affected by chronic kidney disease (CKD). Furthermore, KHA has close ties with consumers, the medical community, renal units around the nation and is a member of the Australian Chronic Disease Prevention Alliance (ACDPA) and the National Vascular Disease Prevention Alliance (NVDPA).

In light of our work to support those with kidney disease, KHA is strongly of the view that Australian consumers should have equitable, timely access to the necessary range of subsidised treatment options available internationally.

CKD and cholesterol

Dyslipidaemia is common in people with CKD. The major determinants of dyslipidaemia in people with CKD are the level of kidney function, the presence of diabetes, severity of proteinuria, use of immunosuppressive agents, the modality of renal replacement therapy (if used), comorbid conditions and nutritional status. The primary rationale for pharmacological lipid-lowering treatment in people with CKD is to reduce morbidity and mortality from cardiovascular events. Although the effects of lipid-lowering therapy on cardiovascular outcomes and mortality in the CKD cohort have been less robustly demonstrated (particularly for people with end-stage kidney disease), clinical practice guidelines from the Kidney Disease Improving Global Outcomes Group (KDIGO)¹ recommend that adults with CKD be treated with a statin or statin/ezetimibe combination (evidence grade 1A).

We note the Review advice to the PBAC to include consideration of Absolute Cardiovascular Disease Risk in the ezetimibe PBS criteria. While KHA is supportive of the assessment of absolute cardiovascular risk using the Australian Absolute Cardiovascular Disease Risk Calculator, we emphasise that more prescriber education regarding the use of this risk calculator is required. In a KHA survey of 656 general practitioners, knowledge testing indicated that 32% of respondents were not able to correctly identify when and how to use the absolute cardiovascular risk calculator².

¹ Kidney Disease: Improving Global Outcomes (KDIGO) Lipid Work Group. KDIGO Clinical Practice Guideline for Lipid Management in Chronic Kidney Disease. *Kidney inter., Suppl.* 2013; 3: 259–305.

² Ludlow M, Mathew T, Usherwood T et al. Australian general practitioners' current practice for chronic kidney disease (CKD) detection and management. Manuscript submitted for publication. Copy available upon request.

Statin intolerance

CKD patients already have a high symptom burden, and are likely to have a higher rate of intolerance to high-dose statin therapy. Access to ezetimibe when other statins are not tolerated is therefore highly applicable for people with CKD.

KHA supports the existing criteria for ezetimibe initiation after statin intolerance. KHA also supports initiatives such as improved access to co-packaged statin-ezetimibe combinations which will improve patient acceptance and compliance, a crucial factor in treatment of chronic diseases.

Conclusion

KHA supports the existing criteria for ezetimibe initiation after statin intolerance, as this is an issue of particular relevance for people with CKD. We also welcome improved access to co-packaged statin-ezetimibe combinations that may improve medication adherence. We recommend that any amendments to the ezetimibe listing criteria that incorporate the assessment of absolute cardiovascular risk are accompanied by prescriber education regarding how and when to correctly use the Australian Absolute Cardiovascular Risk Calculator.

We would welcome the opportunity to further elaborate on these views either in person or in writing.

Yours Sincerely,

A handwritten signature in black ink that reads 'Mikaela Stafrace'.

Mikaela Stafrace
Chief Executive Officer
Kidney Health Australia

A handwritten signature in black ink that reads 'Marie Ludlow'.

Dr Marie Ludlow
General Manager Clinical Directorate
Kidney Health Australia