

24 September 2020

PHARMAC

By email: consult@pharmac.govt.nz

Proposal to fund two new medicines for type 2 diabetes

Dear Sir/Madam

The New Zealand Medical Association (NZMA) wishes to provide feedback on the above proposal.

We note that under the proposal, empagliflozin (a SGLT-2 inhibitor) with and without metformin and dulaglutide (a GLP-1 agonist) would be funded for the treatment of people with type 2 diabetes at high risk of heart and kidney complications who meet the proposed Special Authority Criteria. This reflects clinical advice that these treatments provide benefits beyond glycaemic control. For empagliflozin, these include reduced rates of heart failure hospitalisation, all-cause death, progression to macroalbuminuria and initiation of renal replacement therapy. For dulaglutide, benefits include a reduction in the rate of major cardiovascular events and progression to macroalbuminuria.

The NZMA strongly supports this proposal. The proposed Special Authority criteria for the use of these medicines are broadly aligned with recent guidelines by the American Diabetes Association,¹ although left ventricular hypertrophy is omitted from the definitions of pre-existing cardiovascular disease or risk equivalent in PHARMAC's proposed Special Authority criteria. Another point of difference is that the American Diabetes Association states that for patients without established cardiovascular disease, indicators of high risk of cardiovascular disease, chronic kidney disease or heart failure, the choice of a second agent to add to metformin is based on avoidance of side effects, particularly hypoglycaemia and weight gain. We contend that empagliflozin should also be made available for these reasons and ask PHARMAC to amend the proposed Special Authority criteria accordingly.

¹ American Diabetes Association. Pharmacologic Approaches to Glycemic Treatment: Standards of Medical Care in Diabetes. Diabetes Care 2020;43(Suppl. 1):S98–S110.

https://care.diabetesjournals.org/content/diacare/suppl/2019/12/20/43.Supplement_1.DC1/Standards_of_Care_2020.pdf

We have been disappointed at the delay in the funding of new diabetes medicines such as empagliflozin. It should be noted that data on empagliflozin showing a reduction in cardiovascular death, as well as total death, and hospitalisation for heart failure was published in the NEJM in 2015,² and a second publication in the same journal the following year reported reduced incident or worsening nephropathy.³ In the United States, empagliflozin was approved for reduction in cardiovascular death in 2016 by the FDA.

As PHARMAC notes, the prevalence of diabetes in Māori and Pacific populations is estimated to be around three times higher than among other New Zealanders. Furthermore, the occurrence and rate of progression of diabetes complications are notably higher in these populations. The unavailability in New Zealand of medicines such as empagliflozin that have been proven to reduce mortality in patients with type 2 diabetes is lamentable, particularly given the inequities experienced by Māori and Pacific populations. We are very pleased, therefore, that this hitherto unsatisfactory situation is finally being addressed.

We hope our feedback is helpful.

Yours sincerely

A handwritten signature in blue ink that reads "K. Baddock". The signature is written in a cursive style with a long, sweeping tail on the letter "k".

Dr Kate Baddock
NZMA Chair

² Zinman B, et al. Empagliflozin, Cardiovascular Outcomes, and Mortality in Type 2 Diabetes. N Engl J Med 2015 Nov 26;373(22):2117-28.

³ Zinman B, et al. Empagliflozin, Cardiovascular Outcomes, and Mortality in Type 2 Diabetes. N Engl J Med 2015 Nov 26;373(22):2117-28.