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### **Proposal to list nivolumab (Opdivo) for advanced melanoma**

Dear Danae

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

New Zealand has a very high incidence of advanced melanoma for which there is an unmet health need for effective treatment options. We note that PHARMAC has reviewed all the evidence about registered PD-1 inhibitors for advanced melanoma and has received advice from the Cancer Treatments Subcommittee. We concur with PHARMAC's current view that nivolumab (Opdivo) has better quality clinical trials with data showing a more certain survival impact than pembrolizumab (Keytruda).<sup>1</sup> We also note that PHARMAC has been able to negotiate better commercial terms with the supplier, but that the funding application for pembrolizumab (Keytruda) remains open.

The NZMA is supportive of the proposal to list Opdivo for advanced melanoma for the reasons outlined above. We agree that it is appropriate for initial and renewal applications to be limited to a medical oncologist. We understand that this proposal is linked to the recently announced increase in funding for PHARMAC.

While the increase in funding is welcome, we are concerned at the implications of the requirement for DHBs to inject \$11 million towards the PHARMAC budget. There will be considerable resource implications for DHBs to administer Opdivo and monitor patients receiving the drug. Concerns have been raised that the proposal would have a major impact on DHBs' ability to provide other chemotherapy services. Our support for the current

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<sup>1</sup> <https://www.pharmac.govt.nz/assets/ptac-cancer-treatments-subcommittee-minutes-2016-04-nivolumab.pdf>

proposal, therefore, is contingent on DHBs receiving sufficient additional funding to meet the resource implications for administering / monitoring Opdivo without having to reduce the provision of other services. Without such additional funding, this represents a health loss to other patients. If this additional funding is not forthcoming—and/or DHBs have to reduce the provision of other services and thus forgo health gains for other patients—then we would be opposed to this proposal.

As the evidence for both Opdivo and Keytruda is very recent, with long-term survival data and total remission data still unclear, we suggest that PHARMAC consider implementing this proposal for a limited time period, such as two years, after which it could review the evidence of efficacy and tolerability for Opdivo and other PD-1 inhibitors that become available. We understand that some patients with advanced melanoma are receiving Keytruda funded by ACC as delayed diagnosis was accepted as treatment injury. We seek clarification on the impacts of the proposal on ACC funding for the treatment of such patients.

In conclusion, the NZMA is provisionally supportive of the proposal to list Opdivo for advanced melanoma, but subject to DHBs receiving sufficient additional funding to ensure they can meet the requirements for its administration, without having to reduce the provision of other services. Without such additional funding for the necessary relevant DHB services, the NZMA must regretfully oppose the proposal.

We hope that our feedback has been helpful and look forward to learning the outcome of this consultation.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Stephen Child', written in a cursive style.

Dr Stephen Child  
NZMA Chair