bcac breast cancer aotearoa coalition

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Tangata tū pakari tonu

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BCAC Response to Consultation on the Proposal to List Pembrolizumab for the treatment of Advanced Triple Negative Breast Cancer on the Pharmaceutical Schedule

Thank you for the opportunity to respond to this proposal. As you are aware, Breast Cancer Aotearoa Coalition (BCAC) applied for this treatment to be listed on the Pharmaceutical Schedule for two indications in 2022 (Breast Cancer Aotearoa Coalition Inc. November 2022). We're delighted to see the Pharmac proposal to list this vital medicine for advanced triple negative breast cancer (TNBC).

Consistent with the clinical evidence; MEDSAFE approval (MSD 2022); and international (Gennari, André et al. 2021, NICE 2022) and New Zealand guideline recommendations (Breast Cancer Special Interest Group (Breast SIG) New Zealand 2022) we requested listing for:

- High-risk early-stage triple-negative breast cancer (TNBC) in combination with chemotherapy as neoadjuvant treatment, and then continued as monotherapy as adjuvant treatment after surgery.
- In combination with chemotherapy, for the treatment of patients with locally recurrent, unresectable or metastatic TNBC whose tumours express PD-L1 CPS ≥10.

Comments on the Proposed Listing for Advanced Breast Cancer

Pharmac now proposes to list this medicine with special authority access criteria for recurrent and metastatic breast cancer only. This description would perhaps inadvertently exclude those with de novo locally advanced inoperable TNBC. Whether the locally advanced inoperable TNBC is detected de novo or as recurrent, patients have the same clinical need, require exactly the same treatment and should therefore be given access under this special authority. Those with de novo detection are a very small subgroup of patients who urgently require this treatment. It would be inappropriate and indeed unethical to allow their cancer to advance until detected as metastatic disease in order for them to have access to treatment.

We therefore propose that the wording be amended to the following:

Special Authority for Subsidy

*Initial application – (**locally advanced inoperable or metastatic breast cancer**) from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:*

*Criterion a) "**Patient has locally advanced inoperable or metastatic triple-negative breast cancer** (that does not express ER, PR or HER2 IHC3+ or ISH+ [including FISH or other technology]); and ….*

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What's Missing?

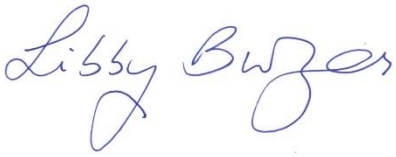
While we are very pleased to see Pharmac proposing to list this medicine for patients with advanced TNBC, we believe there is also a pressing need for patients with high-risk early stage TNBC to be treated early and effectively. The 2022 publication included in our submission of the pivotal KEYNOTE-522 Phase III clinical trial (of neoadjuvant and adjuvant pembrolizumab and chemotherapy combined versus chemotherapy alone) showed significant improvement in pathological complete response (64.5% versus 51.2%; treatment difference 13.6%, 95%CI 5.4-21.8, p<0.001) and improved event free survival (84.5% versus 76.8% at 36 months, HR 0.63, 95%CI 0.48-0.82, p<0.001) irrespective of PD-L1 status (Schmid, Cortes et al. 2020, Schmid, Cortes et al. 2022).

Results from this trial have been used to support access to treatment in similar countries such as the United Kingdom and Australia.

More recently, in May 2024, MSD announced that the Phase 3 KEYNOTE-522 trial met its overall survival (OS) endpoint for the treatment of patients with high-risk early-stage TNBC. At a pre-specified interim analysis conducted by an independent Data Monitoring Committee, pembrolizumab demonstrated a statistically significant and clinically meaningful improvement in OS compared to pre-operative chemotherapy. The safety profile of pembrolizumab was consistent with that observed in previously reported studies; no new safety signals were observed. These results will be presented internationally very soon, expected to be at ESMO in September 2024 (MSD May 28, 2024).

The potential for those with early stage TNBC to be "cancer-free" is extremely important and offers significant benefits to patients and whānau, and to society as a whole. This population has a prospect of complete response with the chance to return to full productivity with such early treatment. Given the vital roles that these patients have in society as mothers, carers, family members and contributors to a wide range of workplaces and community activities, this is an important and relevant finding. Timely access to this treatment for this particular population is an absolute priority.

Ngā mihi,



Libby Burgess

BCAC Chair

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MSD (May 28, 2024). KEYTRUDA® (pembrolizumab) is the first and only immunotherapy-based regimen to show a statistically significant improvement in OS as pre-operative (neoadjuvant) treatment with

chemotherapy and then as a single agent after surgery (adjuvant) compared to pre-operative chemotherapy in patients with high-risk early-stage TNBC. New OS results build on the pathological complete response and event-free survival data previously reported from the KEYNOTE-522 trial.

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