



Together we're stronger
Tangata tū pakari tonu

Geraldine MacGibbon
Senior Therapeutic Group Manager
PHARMAC
VIA EMAIL: consult@pharmac.govt.nz

7 November 2016

Dear Geraldine,

BCAC applauds PHARMAC's decision to fund pertuzumab for HER2+ metastatic breast cancer patients. However, there are some aspects of the proposed Special Authority criteria for access to pertuzumab that we have serious concerns about.

In particular, we refer to the following criteria and commentary:

- 2.1 Patient is chemotherapy naïve; or
- 2.2 Patient has not received prior treatment for their metastatic disease and has had a treatment free interval of at least 12 months between prior (neo) adjuvant chemotherapy treatment and diagnosis of metastatic breast cancer; and
- Note that pertuzumab would not be funded for patients with metastatic breast cancer who have already started trastuzumab treatment prior to 1 January 2017.

Firstly, as a result of these criteria, women who have self-funded pertuzumab to date will be ineligible for public funding. BCAC is aware of eight women in New Zealand who have been self-funding pertuzumab, many of whom obtain this at personal hardship. The set criteria would exclude them from access to funded pertuzumab in January 2017, despite the treatment for these women being absolutely consistent with the treatment protocol in this proposal as is scientifically accepted. They will be discriminated against and disadvantaged solely based on the fact they were able to, at significant cost to their families' financial welfare, fund pertuzumab themselves.

We note that when PHARMAC funded pembrolizumab for metastatic melanoma, patients who had previously self-funded the medicine were provided with funded access. We submit that the same approach must be taken for the patients who currently self-fund pertuzumab.

Secondly, we submit that patients who have received previous chemotherapy with trastuzumab should be able to access the additional benefit of adding pertuzumab to this regime. We note that patients on the CLEOPATRA study who transferred to pertuzumab derived benefit from doing so. The CLEOPATRA study concludes that women who have already received chemotherapy with trastuzumab and crossed over to have pertuzumab gained benefit from doing so. We submit that PHARMAC must fund pertuzumab for all those with metastatic HER2+ breast cancer, even those who have already had chemotherapy and/or trastuzumab.

Further, BCAC considers this an issue of human rights; the withholding of pertuzumab from select groups is unethical and a breach of the International Covenant on Economic Social and Cultural Rights to which New Zealand is a signatory and has ratified. We urge PHARMAC to reconsider its approach in this regard. This covenant refers to the right to the "enjoyment of the highest attainable standard of physical and mental health" including: availability,



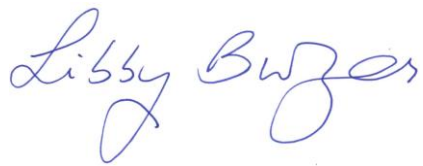
accessibility (non-discrimination, economic accessibility (affordability)), acceptability: respectful of medical ethics and quality: scientifically and medically appropriate. By ratifying the ICESCR New Zealand has made an undertaking to comply with the standards in the Convention.

Lastly, regarding the delay for funding until 1 January, we consider it an unwise delay and urge PHARMAC to begin funding pertuzumab immediately. We are aware of several women newly diagnosed with HER2+ breast cancer who are considering delaying the start of their treatment until January 1st on the basis of the current funding proposal. Any such delay in commencement of treatment for the aggressive HER2+ form of breast cancer could have serious negative impacts on the health and outcomes of these women.

We note that Australian women with HER2+ breast cancer have had funded access to pertuzumab since 1st July 2015 and urge PHARMAC to provide this breakthrough treatment to New Zealanders without further delay.

Again, we reiterate our approval of PHARMAC's proposal to fund pertuzumab, however we urge reconsideration of the criteria as outlined above.

Yours sincerely,

A handwritten signature in blue ink that reads "Libby Burgess". The signature is written in a cursive, flowing style.

Libby Burgess
Chairperson, Breast Cancer Aotearoa Coalition