bcac breast cancer aotearoa coalition

Together we're stronger
Tangata tū pakari tonu

Alexandra Chippy Compton
Therapeutic Group Manager, Oncology
24th October 2021

Dear Chippy

Thank you for seeking BCAC's views on Pharmac's upcoming RFP for trastuzumab biosimilars. We appreciate the opportunity to provide input.

Equivalence

BCAC has consulted Breast Cancer Network Australia (BCNA) colleagues and received input from their policy staff and clinical consultants. As you know, biosimilar forms of trastuzumab have been used in Australia since 2019 and Australia now funds five biosimilars, namely Ogivri, Herzuma, Kanjinti, Ontruzant and Trazimera. BCNA assures us that these are all equivalent from a patient and clinical perspective, i.e. no new side effects have been observed and these products are all efficacious. These biosimilars have all received international regulatory approval. On this basis, we would be confident that all these products could be safely used in NZ. If different products were selected, we would assume equivalence only if the product(s) had been approved by the European Medicines Agency or the US Food and Drug administration and were also approved by Medsafe.

Patient concerns

Some patients will be concerned that their trusted medicine is being switched. In July 2020 BCAC wrote an article to inform patients about the inevitable switch. https://www.breastcancer.org.nz/content/herceptin-biosimilars-when-will-we-see-them-new-zealand We would be happy to update this when biosimilars are introduced. Clear reassurance of equivalence will be needed from Pharmac, clinicians and patient groups, especially for those who have been on long-term treatment for advanced breast cancer. It would be important to provide everyone affected with good information and for patients to be able to consent to change. It would be helpful if patients already under treatment were given the option of remaining on Herceptin. The availability of a second biosimilar as an alternative if side effects occur (as mentioned in your email) would also be a positive move.

Need for sub-cutaneous options to broaden access and improve equity

BCNA noted in our discussions that there are many benefits of having the funded option of sub-cutaneous trastuzumab and this should be introduced for New Zealanders. This would provide access to this important medicine for those with poor venous access and would also support 'hospital in the home' programmes. A subcutaneous option would also save infusion chair time, freeing facilities for other patients and thus enabling more timely cancer treatment for many, reducing pressure on services that are under constant pressure and are struggling to deliver treatment in a consistent and timely manner. In turn patients would benefit from reduced time

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taken to access treatment, reduced travel, reduced parking-related costs and difficulties, and being able to gain whānau support in or closer to home. Sub-cutaneous trastuzumab can be infused in GP clinics, in 'close to home' medical clinics and even at home. Local availability of treatment has been identified by Te Aho o Te Kahu (TAoTK) as an important means of providing greater access to cancer treatment for Māori and Pacific peoples, so this is an ōritetanga/equity opportunity that should be seen as a priority by Pharmac.

Ethnic inequity is highly relevant in the case of trastuzumab, see evidence cited on p145 of the TAoTK report: "Māori and Pacific peoples experience specific inequities when it comes to accessing systemic anti-cancer therapies. Examples include poorer access to trastuzumab and adjuvant chemotherapy in breast cancer (294, 342)…". Easier access through availability of injectable trastuzumab closer to home could help to overcome this unacceptable inequity. This is also highly relevant to Pacific women who have higher rates of HER2 positive disease than other ethnicities and also have the highest rate of de novo metastatic diagnoses.

For the same reasons of ease of access, increased infusion capacity in cancer treatment centres and improved equity, we are very hopeful that Phesgo, a subcutaneous form of trastuzumab and pertuzumab, will soon be approved for HER2 positive breast cancer in the neoadjuvant and post-neoadjuvant setting as well as in the metastatic setting.

I provide in Appendix 1 below a number of relevant quotes from the Systemic Anticancer Therapies (SACT) section of TAoTK's recently released final draft report*, He Mahere Ratonga Mate Pukupuku, Cancer Services Planning: A vision for cancer treatment in the reformed health system*. The report is very clear that a key component of achieving equity and improving access is to deliver care closer to home. The availability of an injectable form instead of an infusible one greatly simplifies and speeds delivery and reduces the number of staff and the facilities required to deliver treatment.

Trastuzumab availability beyond progression in metastatic breast cancer

In many overseas countries including in Australia, trastuzumab, in specific regimens and as deemed appropriate by physician is the normal standard of care as a second and later line treatment for metastatic HER2 positive breast cancer (beyond progression on trastuzumab). It is the backbone on which new treatments for advanced HER2 positive breast cancer are built. The HER2 CLIMB trial demonstrated progression free survival and overall survival (OS) benefits of adding tucatinib and capecitabine to trastuzumab after progression on trastuzumab. The HER2 CLIMB 05 trial is now investigating the addition of pertuzumab to trastuzumab and tucatinib. The TUGETHER trial (Principal Investigator Prof. Sherene Loi, Peter Mac, Melbourne and Breast Cancer Trials (BCT)) adds pembrolizumab to trastuzumab and tucatinib in the later line setting. BCT recently contacted BCAC and the Breast Special Interest Group (BSIG) to discover whether we could find a way for patients to access later line trastuzumab to enable NZ patients to participate in this trial, but without Pharmac funding our participation was not possible. Clearly, NZ should fund trastuzumab after

progression as a standard of care to avoid our falling further behind the world in medicines access and OS for these patients.

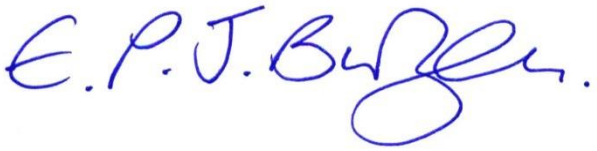
A trastuzumab biosimilar will presumably be significantly less costly than Herceptin. This provides the opportunity to extend access to later line metastatic use where additional treatment options are sorely needed. We are concerned that Pharmac might reject later line trastuzumab use as there have been no specific clinical trials testing new agents without trastuzumab. There are no such trials because trastuzumab is the accepted standard of care. In HER2 CLIMB for example, tucatinib was added to trastuzumab as the two agents block HER2 signalling in different ways and provide a dual blockade. It would have been thought unethical to withhold trastuzumab for patients in this trial. The same applies with the next iteration in TUGETHER, where pembrolizumab will be added to trastuzumab and tucatinib. This is an issue that really needs to be addressed, i.e. approval for later line metastatic access to trastuzumab, beyond progression.

As Prof. Fran Boyle, prominent Australian medical oncologist said to us recently when discussing access to trastuzumab beyond progression, 'Why would you take the foot off the throat of cancer?'

To provide context in considering second and later line treatment options, I refer to the recently published 2nd New Zealand Consensus Guidelines for Advanced Breast Cancer (ABC-NZ2). These are adapted for Aotearoa by a panel of NZ experts led by Marion Kuper-Hommel, chair of BSIG The Guidelines are adapted from the 6th International ABC Consensus Guidelines in consultation with the ABC Global Alliance chair Fatima Cardoso, MD. ABC-NZ2 can be accessed at this link:
https://www.breastcancer.org.nz/content/new-nz-guidelines-treating-advanced-breast-cancer-welcomed
In Section IV, HER2-positive ABC pp 26-29, treatments recommended for 2nd line and beyond include trastuzumab with tucatinib, and trastuzumab with a range of chemotherapy agents.

Other unfunded treatments for metastatic HER2-positive breast cancer recommended in ABC-NZ2 are nab-paclitaxel (in combination with trastuzumab and pertuzumab) and trastuzumab deruxtecan.

Ngā mihi,



Libby Burgess
Chair, Breast Cancer Aotearoa Coalition

Appendix 1: Extracts from TAoTK Cancer Services Planning report 2022

He Mahere Ratonga Mate Pukupuku, Cancer Services Planning: A vision for cancer treatment in the reformed health system

Systemic Anti-Cancer Therapies section

P132 The aim is to see the needs of patients and whānau at the centre of the optimisation of existing models of care and the development of new models of care for SACT and HSCT.

P133 Patients will be able to access SACT in the community closer to where they live.

P139 There is a shortage of trained staff in several key areas which limits the ability to deliver SACT and HSCT.

P142 There is (sic) insufficient, and often inadequate, facilities to support the delivery of services.

P144 The availability of new cancer medicines is a common concern for clinicians and patients, with some cancer medicines that are currently unfunded in Aotearoa having the potential to offer significant clinical benefit.

P145 …the accessibility of medicines for Māori, Pacific peoples and other population groups is influenced by many things in addition to whether they are listed in Pharmac's Pharmaceutical Schedule. These include barriers of cost, time, travel and trust, as well as health system factors. Māori and Pacific peoples experience specific inequities when it comes to accessing systemic anti-cancer therapies. Examples include poorer access to trastuzumab and adjuvant chemotherapy in breast cancer (294, 342), and adjuvant chemotherapy in stage III colon cancer.

P147 "Why is it the sick person that has to do all the travel?" Community Hui participant, 2021

P147 "Being close to whānau when undergoing treatment is rongoā." Community Hui participant, 2021

P149 The ongoing rapid increase in SACT demand and complexity means that services are under constant pressure and are struggling to deliver treatment in a consistent and timely manner. Many of the challenges described above are being made evident and exacerbated by this rapid increase in demand for services.

P151 Equity for Māori
Māori experience significant barriers in receiving high quality SACT. Several studies have found that Māori are less likely to receive chemotherapy than non-Māori, including adjuvant chemotherapy for colon and breast cancer (342, 343, 354). Māori also experience significantly longer delays in receiving adjuvant treatment for breast cancer than non-Māori, with inequities persisting after adjusting for deprivation and

rurality (294). Māori also experience barriers to completing SACT regimens, including adjuvant endocrine therapy for breast cancer (355).

P151 Equity for Pacific peoples
Pacific peoples also experience barriers to accessing SACT and are less likely to receive adjuvant chemotherapy for colon cancer and are more likely to experience delays in receiving treatment than non-Pacific peoples (343, 354). Pacific peoples with breast cancer are less likely to receive adjuvant chemotherapy than non-Māori, non-Pacific and are more likely to experience delays in treatment (294, 342)

P153 Models of care for the delivery of SACT
Internationally many jurisdictions are decentralising less complex SACT to community hospitals, with more complex treatments being provided in regional centres (331). This approach has potential to improve patients' wellbeing by keeping them closer to their support networks during treatment and reduce access barriers by reducing the need to travel. Common mechanisms to implement this include clear role delineation outlining the minimum requirements for services providing different levels of systemic treatment, common treatment guidelines and care pathways across centres, and shared care agreements with clear responsibilities (331, 356-359).

P154 To support the decentralised delivery of SACT, some jurisdictions have also created new workforce roles. One example is general practitioners in oncology (GPOs), which is a growing role in parts of Canada. GPOs can have a wide range of roles as part of the cancer care team, including: clinical supervision of SACT, management of the physical and psychosocial effects of cancer treatment, follow-up and survivorship care and palliative care (360).

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P155 Tele-chemotherapy is a model of care whereby selected patients are able to receive low-risk SACT locally – and often in remote areas – with the support of specialist clinicians in larger centres via telehealth. Several jurisdictions have developed tele-chemotherapy delivery models. One example is the Queensland Remote Chemotherapy Supervision (QReCS) model (361). In this model a rural generalist nurse can administer select SACT under the direct supervision of chemotherapy-proficient nurses at larger centres using videoconferencing technology. Rural generalist medical officers and pharmacists provided local support at rural centres and medical oncologists and oncology pharmacists from larger centres provided support via teleconference (361). Tele-chemotherapy is currently utilised in some regions of Aotearoa, but there is scope for it to be enhanced and more consistent.

Mobile Chemotherapy Units have been in use in the UK since 2007. In this nurseled model, a van is converted to accommodate several treatment chairs. The service includes two nurses and a driver. The driver picks up compounded systemic anti-cancer treatments before parking the van in grounds of community hospitals. The units operate independently of the hospitals where they are parked; however, further assistance is available in the event of a medical emergency. This model has been used to deliver a range of systemic anti-cancer treatments, including cytotoxic compounds, targeted therapies and supportive medications (362).

Home-based delivery is another model to move SACT out of hospital settings by staff travelling to, and delivering care, in patients' homes. Home based therapy has been shown to be safe, patient centred and cost-effective and can reduce the contact time of immunocompromised patients with the hospital environment (363-370). However, there are concerns around home infusion of anticancer therapy, with American Society of Clinical Oncology (ASCO) releasing a policy statement against the routine use of home infusions largely due to safety concerns except in "exceptional circumstances where the benefits of home infusion outweigh the potential risks to patients" (371). The Victoria State Government in Australia has developed a home-based cancer care framework and toolkit to outline the governance, models of care and funding structures to assist Victorian health services in establishing and delivering safe, high-quality SACT treatment in the home (372).

P156 Equity implications: community delivery of SACT is thought to be a powerful tool to remove barriers to accessing care and improve equity.