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Briefing on Breast Cancer Issues and Solutions for New Zealand

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Breast Cancer Issues and Solutions for New Zealand

On behalf of the thousands of New Zealanders diagnosed with breast cancer every year, BCAC is grateful to have the opportunity to discuss some of the key breast cancer issues affecting New Zealanders and suggest solutions.

These issues are of national importance given the widespread reach breast cancer has in our society and its impact on women, men, their families and whānau, their workplaces and the health system.

i. Key facts about breast cancer in New Zealand:

Breast cancer is the most common form of cancer to affect women.

- Breast cancer accounts for more than 30% of all new female cancers.
- Breast cancer is the most common cancer to affect women, with more than 3500 New Zealand women diagnosed each year (1).
- Breast cancer has an overall survival of 89% at 5 years (1), but more than 670 women die each year from breast cancer. The most common breast cancer subtype sees women relapse and die 10 to 20 years following diagnosis (2).
- Breast cancer is the most commonly diagnosed cancer for Māori women, who are 76% more likely to die from the disease after five years than New Zealand European women (3).
- Pasifika women are twice as likely die from the disease after five years than New Zealand European women (4).
- Young women are also affected by breast cancer, with around 400 women under the age of 44 diagnosed each year (5).
- About one per cent of all diagnosed cases of breast cancer in New Zealand will be in men (5).
- Deprivation affects breast cancer survival and access to care is an issue (6, 7).
- Median survival for advanced breast cancer patients in New Zealand is 16 months compared to 32+ months globally (8).
- New Zealanders are more likely to die from breast cancer than Australians (9).

These statistics indicate significant work is needed to improve health outcomes for New Zealanders with breast cancer.

ii. Consultation

Breast Cancer Aotearoa Coalition (BCAC) is an umbrella organisation representing more than 30 breast cancer-related groups in New Zealand. We regularly consult with:

- patients with breast cancer
- our membership groups
- cancer clinicians and researchers.

Issues identified by our members are listed in Appendix One. These provide insights into the day to day challenges faced by New Zealanders with breast cancer. They offer many opportunities to improve the care provided within our health system.

iii. Key issues and solutions

This document identifies three key areas in which a real difference can and should be made in the lives of the thousands of New Zealanders who either have breast cancer or are at risk of developing breast cancer. BCAC considers that these need urgent attention from Government, and we offer meaningful solutions that should be adopted immediately.

1. Manage risk and improve screening so that breast cancers are detected earlier and treatments are less invasive, cheaper and more effective. This is not just about increasing participation in the current screening programme, but modernising it so that it better targets particular groups based on their breast cancer risk.

2. Ensure greater access to new medicines so that oncologists have a 'full toolkit' and can give patients optimal treatments, targeted to their particular breast cancer subtype and stage.

3. Increase precision by using germline testing, genomic sequencing and gene expression profiling to improve breast cancer diagnosis, appropriately target treatments, optimise health outcomes, reduce inequity and ensure efficient use of resources.

Key Issue One: Risk management and targeted screening for early detection and prompt treatment

Currently, all women aged between 45 and 69 are offered a two-yearly mammogram. The Government has committed to progressively extending this to include women aged 70 to 74, although we are concerned that this has been delayed due to Covid-19 and urge the Government to ensure this change is effected immediately.

The frequency and imaging technology used in current public screening is based on a woman with 'average risk'. There is now sufficient evidence that this could be refined so that those at greater risk receive closer surveillance and potentially those at lower risk could receive less. Improvements in imaging technology are providing more sensitive and affordable screening options (see Appendix Two). By tailoring our screening to risk, while building participation rates, we have the opportunity to reduce breast cancer mortality by finding invasive cancers earlier.

The benefits would be that more breast cancers would be detected at an earlier stage, when treatments are less intensive and health outcomes are better. The cost savings to the health system and wider society associated with this are obvious.

Māori and Pasifika women are disproportionately affected by breast cancer, with alarming mortality rates that need to be addressed with better screening and treatment (3). These women tend to be

diagnosed at a younger age and with more advanced disease. Given that ethnicity is a breast cancer risk factor in New Zealand's population, our screening programme should be refined to address this inequity. For example, Māori and Pasifika women could be screened from age 40.

Breast density

Breast density is one risk factor that could be easily incorporated into the current screening system. Up to 50% of women aged 45 to 69 have varying proportions of fibro-glandular tissue, or "dense" breasts, which masks tumours from the view of radiologists reading the mammogram film. Those with dense breasts also have an intrinsically higher risk of breast cancer.

Currently, policy dictates that women are not informed of the density of their breasts. When no evidence of disease is picked up in mammograms, that information is provided without any caveat informing the women that they have dense breasts, and that this raises the chances of receiving a false negative test result. This results in later diagnosis, more invasive treatment (e.g., full mastectomy, chemotherapy, radiotherapy), more advanced cancers. Earlier diagnosis would lead to less invasive treatment and reduced cost to the health system and societal burden. All US states have made it mandatory for screening providers to inform women of their breast density.

Women who have dense breasts benefit from additional forms of screening such as ultrasound and MRI. Women in New Zealand's private healthcare system are more likely to be informed of their breast density, and advised to have more frequent checks and supplemental screening in addition to mammography. This creates another inequity between those who can afford private screening and those who rely on the public screening programme. This disproportionately impacts Māori women, as this population has a higher incidence of dense breasts (10) and is less likely to have health insurance.

This is an inequity that can be swiftly and simply remedied by mandating that women are informed of the density of their breasts and offered additional forms of screening.

Genetic testing (germline)

Some people carry gene mutations in their germline that predispose them to breast cancer. The best known of these are BRCA1 and BRCA2, but there are others (e.g. ATM, PALB2, CHEK2, TP53, PTEN) and more being discovered with recent advances in cancer genetics research. Recent New Zealand and overseas research has shown that current clinical criteria and family-history-based testing misses more than 50% of carriers of currently known gene mutations (11 – 13) and many adopted women are unable to access any information on their family history. Less restrictive testing of breast cancer patients in New Zealand would improve the identification of high-risk individuals, allowing for timely predictive testing and appropriate risk management, while also reducing the impact of hereditary cancer syndromes for these individuals and their whānau. Recent evidence from Australian research (14, 15) indicates that genetic testing in women with breast cancer and their family members is cost-effective and is associated with reduced risk from cancer and improved survival.

Risk assessment tools

There are now a number of breast cancer risk assessment tools available that could be used alongside screening by primary care providers to assess an individual's risk and ensure that they receive

appropriate surveillance and advice. These tools take into account not only genetic and medical history risk factors (e.g. dense breasts, early menarche, late menopause, late or no childbearing, high polygenic risk scores), but also some modifiable behavioural factors (e.g. HRT use, high BMI after menopause, excessive alcohol consumption). Examples of such tests are BODICEA, CanRisk and CRA.

Actions

- Accelerate the roll-out of mammographic screening for 70-74 year-olds.
- Notify all screened women of their breast density and provide appropriate supplemental screening (e.g. ultrasound, contrast enhanced mammography, abbreviated MRI) for those at above average risk of breast cancer.
- Better resource the Genetic Health Service of New Zealand and genetic counselling services to improve access and broaden the testing criteria for germline breast cancer mutations.
- Introduce risk assessment tools at primary care so that at-risk patients may be identified and given appropriate advice and access to strategies such as modified screening and surveillance, lifestyle/behaviour changes, and/or prophylactic surgery.

Key Issue Two: Improved access to medicines

BCAC was pleased to see a handful of medicines with demonstrated efficacy in breast cancer recently approved for two different subtypes of advanced breast cancer, i.e. palbociclib (Ibrance), fulvestrant (Faslodex), and ado-trastuzumab emtansine (Kadcyla). However, this has only gone a small way to addressing the deficit of modern medicines. Appendix Three provides a current list of breast cancer medicines that remain unfunded as well as medicines for which strong evidence is emerging.

New Zealanders continue to have insufficient and slow access to effective medicines. This is impacting quality and length of life for New Zealanders diagnosed with breast cancer and other cancers as well as other treatable diseases. New Zealand ranks last of 20 OECD countries compared for market access to modern medicines (16) and of the 36 OECD countries, only Mexico invests less per capita on medicines than New Zealand (17), at around a third of the average spend within the OECD (18). There is direct correlation between our poor medicines access, poorer outcomes, and the lack of money invested by successive governments into medicines.

Advances in medicine

Around 25,000 New Zealanders are diagnosed with cancer each year and this number will increase in the coming years as our population grows and ages. Globally, personalised treatment has seen an overall drop of 29% in cancer deaths between 1991 and 2017; approximately 2.9 million fewer cancer deaths. Treatment breakthroughs such as immunotherapies and targeted therapies have contributed significantly to this decline (16). Providing New Zealanders access to the most effective treatment for their cancer subtype is a smart investment that will result in savings long term as more precisely targeted medicines are used to treat smaller subgroups of patients and people suffer less morbidity and mortality and are better able to contribute to society.

The current narrative

Commentary from Te Aho o Te Kahu (1), copied in part from PHARMAC's recent briefing to the incoming Minister of Health (19) is concerning and does not fairly represent the state of play:

Te Aho o Te Kahu (1):

> *Some of the challenges facing Te Pātaka Whaioranga and the rest of the cancer sector include the pace at which new treatments are becoming available. Many of these new treatments work in different ways to traditional chemotherapy agents and may present new challenges in terms of administration and management (for example, side effects may be very different to the side effects from traditional chemotherapy).* ***These treatments can also be very expensive, often with limited information available about their effectiveness****.*

PHARMAC (19):

> ***New cancer medicines often come with a significant cost and limited evidence of effectiveness.***

These statements are problematic and demonstrate both a lack of acknowledgement that New Zealanders are missing out on effective treatments and any aspiration to do better. Generally, modern targeted therapies are less toxic and the side effects more tolerable than those of traditional cytotoxic chemotherapy. The scientific advances validated through clinical trials and published in peer reviewed journals are well documented in breast cancer, and frontiers of treatment are moving rapidly. Other countries, such as Australia, Canada and the United Kingdom, adopt this science by funding newer medicines far sooner than New Zealand. It is concerning that PHARMAC continues to question the evidence of efficacy of unfunded medicines that have been recommended with priority by its own specialist committees and that these can languish on a "waiting list" for years while patients continue to suffer and die without access.

The PHARMAC budget

The issue at the crux of our poor access to medicines is simple: PHARMAC (via the DHBs) does not have an adequate budget to keep up with the advances in medicines, leaving us lagging behind the rest of the OECD in terms of access to medicines. PHARMAC's paltry budget and the fact that, unlike other countries, this budget is capped prevent PHARMAC from responding to opportunities for innovation or playing a role in horizon-scanning.

This is a sad indictment on New Zealand.

It is incredibly concerning to read that PHARMAC is forecasting a smaller budget for the following three financial years - 2022 to 2025 (19).

To ensure the long term economic and societal benefits of effectively treating cancer, clinicians need to have a suite of medicines available to optimally treat their patients. While better medicines remain unfunded for many treatable diseases in New Zealand, our knowledge of breast cancer allows us to identify a range of medicines available for use across early and metastatic breast cancer. Simply put, to provide access to modern, effective treatments, New Zealand's medicines budget must substantially increase. To reach the OECD average, the budget would need to triple. As a country we will not be able to make long-term inroads in eradicating cancer if the Government and PHARMAC are unrealistic about the financial investment required.

The equity impact

Lack of medicines access contributes to a growing inequity where New Zealanders face having to pay for the drugs they need or move their entire family to other countries. Less fortunate New Zealanders can only resort to crowdfunding platforms to raise money; this is not a long-term solution for most people and not a solution at all for many. They receive a poorer standard of care and will stay alive only if the Givealittle money allows. This serves to compound ethnic and socioeconomic inequities in our society (6, 7, 20).

Early breast cancer is a curable disease when treated with the appropriate medicines for the subtype and stage, an approach which is the current global standard of care, but New Zealand falls short of that standard.

Globally, metastatic breast cancer is fast becoming a chronic, treatable illness that can be lived with over many years. This is possible when clinicians are able to rapidly and accurately determine the nature of the disease, apply treatments precisely targeted to the subtype and switch to other treatments as needed, depending on individual response.

Without adequate investment into new medicines and allowing swift and early access for patients, New Zealand's cancer mortality statistics will not improve and will fall further behind those of similar countries.

The Government's responsibility

We are pleased to see that the review of PHARMAC will include its objectives as well as the transparency and timeliness of decision making. However, it is disappointing that the capped nature and size of its budget are excluded and that there is no health consumer on the panel.

We note that the Minister of Health has recently stated that the responsibility for setting the medicines budget lies with the Government. New Zealand's response to the Covid-19 crisis has been exemplary. We met this crisis head-on with the focus and investment it deserves. This has no doubt saved countless lives.

We ask that the same urgency as shown in our response to Covid-19 become inherent in our response to the raft of other health crises that our citizens face through lack of access to modern treatments.

Actions

- Increase funding for the medicines budget to the OECD average.
- Explore options to facilitate access to new and innovative medicines, including Early Access Schemes and Cancer Drug Funds.
- Reform PHARMAC's processes to increase transparency, establish defined timelines for funding decisions and involve consumers throughout the decision-making process, including as members of Specialist Advisory Committees and the Pharmacology and Therapeutics Advisory Committee (PTAC).

- Ensure PHARMAC applies new criteria to fund medicines based not only on cost, but on value including the health outcomes and needs of people, whānau and communities, e.g. extending women's lives so that they can continue to work and care for their children for longer.
- Ensure that PHARMAC's decisions take into account their impact on the efficient functioning of other parts of the health system, e.g. an injectable version of a drug that would reduce pressure on infusion services, or drugs that improve survival and reduce palliative care costs.

Key Issue Three: Introduction of precision testing

As noted above, in order to improve and have a real impact on cancer diagnosis and treatments, clinicians need to have the knowledge and proper tools at their disposal to treat each person as an individual with different genetic makeup and cancer subtype. The Te Aho o Te Kahu *State of Cancer in New Zealand* report touches on this but provides no information about how to achieve it.

Below we describe two new testing technologies, genomic tumour sequencing and gene expression profiling, that we believe should be incorporated into routine breast cancer care in New Zealand, with benefits to patients and the health system. Germline testing at the time of diagnosis can also play a role in precisely identifying targeted medicines that will be effective. Private providers and their patients are embracing these technologies, as their use can achieve better risk assessment, more precise diagnosis, better prognosis and in some instances better prediction and active surveillance. These benefits result from patients and clinicians having the genomic and molecular evidence needed to determine which therapies will or will not bring benefit, in what sequence and to assess the risk of a cancer occurring or recurring. The information provided may also determine whether a particular treatment can be avoided and how light or aggressive treatment may need to be. Clearly, patients want to be given only treatments that they know will work for them and avoid those that will not.

Within New Zealand's public system such initiatives are not funded and there is a tendency to treat people as it they are the same when it is clear they are not. We urge the Government to develop the infrastructure and processes for routine DNA/RNA sequencing of patient's tumours and blood samples just as we did in our response to COVID 19, when we understood that an upfront cost would bring a downstream benefit. Adoption of advanced testing technologies will provide our health system with the opportunity to break away from being a reactive 'late follower', and ensure that we take advantage of the cost savings and societal benefits that well selected modern cancer treatments can confer.

Genomic tumour sequencing

Breast cancer is a complex disease, with an increasing number of subtypes being identified through research. The use of therapies that target specific molecular features of a subtype has been largely responsible for reductions in mortality from breast cancer in recent decades (e.g. tamoxifen for oestrogen-receptor positive (ER+) and trastuzumab (Herceptin) for HER2+ breast cancer). New medicines being developed for breast cancer are almost exclusively based on the concept of targeting particular subtypes with greater accuracy and effectiveness.

Genetic research has now shown that the tumours themselves can mutate during the course of the disease, meaning that treatment regimens may need to be altered over time.

Genomic tumour DNA sequencing, at the time of diagnosis and during treatment to monitor the effectiveness of a therapy, allows clinicians to ensure that a patient is being effectively treated, using the best targeted medicines or devices, avoiding unnecessary treatments and resulting in better outcomes.

As noted in the medicines section above, the Government has demonstrated with its Covid-19 response that New Zealand has the capacity and the capability to undertake sophisticated, world-class genomic sequencing. We simply ask that the Government adopt a similar science-based approach in relation to breast cancer diagnosis and treatment.

Gene expression profiling

Gene expression profiling (GEP) tests are increasingly used in clinical practice to identify which patients with early-stage oestrogen receptor-positive (ER+, the most common subtype), lymph node negative breast cancer are likely to have a higher risk of recurrence. These tests provide personalised information based on analysis of the expression of multiple genes in a patient's tumour. Test results are presented with a recurrence score, which is typically a numeric score that is then placed into a risk category. All tests have a low and a high-risk category, with some tests (e.g., Oncotype DX and Prosigna) also having an intermediate risk category. Both low and high scores are used to support treatment decision making, i.e. whether cytotoxic chemotherapy is needed in addition to anti-oestrogen therapy.

A local study has demonstrated the number of low-risk patients in New Zealand with this breast cancer subtype needing to receive chemotherapy each year (380) could be reduced by 70% by using gene expression tests such as MammaPrint, OncotypeDx and Prosigna. Although there is a cost in providing these tests, there is a significant saving of time (institutional and personal including travel and treatment time), facilities (reduced use of infusion facilities) and reduced toxicity and disruption for patients, whānau and communities. In addition, effective prognostic work at the time of diagnosis will also dictate the level of surveillance required to detect metastasis early to guide medical oncology decisions and to optimise overall survival and wellbeing for patients with advanced breast cancer.

GEP tests bring increased precision to medical oncology. This technology is already being used in New Zealand by those who can afford it. Our public health system should be assessing its potential value to the wider population and preparing to implement given the potential health, economic and societal benefits.

Actions

- Introduce genomic sequencing for all breast cancer patients enabling better treatment decisions.
- Introduce gene expression profiling for ER+HER2- lymph node negative patients.
- Resource this initiative and ensure it is supported by the necessary infrastructure to ensure its value and benefit can be achieved.
- Support and fund research and clinical trial projects to ensure these initiatives grow New Zealand's capability and knowledge for translation into the clinic.

Conclusion: Building innovation and readiness into New Zealand's health system

The three key issues raised above by BCAC are in response to the need for a coherent and positive strategy or mechanism for recognising, adopting and adequately resourcing technological innovation within our health system. While 'prioritisation', 'research and innovation' and 'improving cancer diagnosis and treatment outcomes' are among the many goals of Te Aho o Te Kahu, the agency does not appear to have a specific future watch or preparedness function. We ask that Te Aho o Te Kahu be encouraged and resourced to enable an aspirational approach to cancer care to ensure that innovations are adopted early and equity across the motu is achieved at a high, modern standard.

This would give New Zealanders confidence that we have a modern health system providing the level of care we expect and deserve. We look forward to a time when patients do not have to fundraise for their own care, or petition the Government to provide evidence-based effective treatments that they could expect to receive as a matter of course in other countries.

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Appendix One: Issues identified by BCAC members

1. Medicines funding:
    a. Request for increased funding to the medicines budget. Members comment "we do not choose to have cancer and it's ridiculous that some women have to worry about the extra cost of a crucial and possibly life-saving non-Pharmac funded drug".

2. Continuity of care:
    a. At many large teaching hospitals, members report they can go for months without seeing their oncologist and are seen by a revolving door of other doctors. This is unsettling for the patient, and results in a much lower standard of care as the doctors do not have a sense of the patient and are just working from previous notes which can be inaccurate – they also do not appear to have time to prepare thoroughly for each patient.

    b. Request that women see their dedicated oncologist at least every other appointment (this may require more oncologists in the bigger centres).

3. Screening and diagnosis:
    a. There are unacceptable delays between receiving concerning screening results and being seen at the hospital.

    b. There is a reluctance within DHBs to biopsy cancer patients.

    c. Younger women are having to pay for a mammogram when a lump is found. Many young women cannot afford to do this.

    d. Breast Screen Aotearoa has guidelines that outline very strict reporting timeframes to those who are eligible. Younger women fall outside of the eligibility, and can often wait extended periods for the results. The reporting timeframes should be the same – if not with more priority as younger women usually get more aggressive forms of cancer.

    e. Members noted that post mastectomy surveillance mammograms are untaken on the remaining breast. No surveillance is undertaken on the mastectomy/reconstructed side, despite 3-5% risk of recurrence showing up on the mastectomy/reconstructed side. The mastectomy/reconstructed side should also receive ultrasound (private patients routinely have this as part of post cancer follow ups).

4. Follow-up care:
    a. Request that surveillance in the public system includes routine MRI, particularly for women with dense breasts. This is standard surveillance for a high risk patient in the private system.

5. Breast density:
    a. Women should be informed of their breast density as high density can mask breast cancer. A member required a bilateral mastectomy in 2018 due to advanced and aggressive cancer that was not seen by a radiologist on a screening mammogram before it became a palpable lump. Subsequently, the member paid for a private ultrasound and 3D mammogram, and was then told that she had extreme density.

6. Genetic testing:
    a. Adopted women are not receiving genetic testing services because they are unable to access family medical history. This results in many "at risk" women not being tested for gene mutations.

    b. There is an unacceptable delay between women being informed they have a genetic mutation and receiving (recommended) prophylactic surgery, e.g., hysterectomy, mastectomy. There is a points system that identifies risk factors, which in turn places a patient on a priority list, but this is not being communicated to women at the point of learning of the mutation.

7. Travelling to receive treatment:
    a. Members have noted the difficulties they face in the regions because of centralised use of resources, e.g., having to travel from Napier to Wanganui for chemotherapy and radiotherapy. This results in financial concerns, family worries and additional stress on health from the additional travel.

8. Post code lottery cancer care:
    a. Currently some DHBs offer a secondary mastectomy as an equal option to reconstruction. The option to "go flat" should be available to women throughout the country.

    b. Request that cancer care is the same regardless of DHB, e.g., creams and Mepitel (second skin) to reduce skin burns from radiation should be funded in all centres for patients receiving radiation treatment.

    c. Members report issues regarding waiting times for reconstructions in different DHBs, e.g. Hutt Hospital is reported by members as being a number of years. The delays cause mental stress and anxiety.

    d. Women have reported they are offered different levels of testing, scanning, radiation and medical treatments as well as different amounts of nursing and supportive care, depending on which DHB is managing their cancer.

9. Financial support during treatment:
    a. Request for a cancer support scheme to financially help those who are too ill to continue to work (for a period of time), and don't have the sick leave or annual leave

to cover it (similar to ACC). These women DO NOT want to resign their employment and apply for a sickness benefit.

b. Request for free GP visits and prescriptions for patients with advanced breast cancer. Many women are struggling financially and "save up" their pain for one GP visit, rather than going each time they have a singular issue. This is dangerous.

10. Patient communication and consultation:
    a. Members note that DHBs are not adhering to the legal requirement to ensure women are given ALL the information they require to understand their treatment options and give informed consent.

    b. Members note that their right to question what treatments are available are ignored, and that their specialists have refused to compromise on treatments offered.

    c. Members note that some GPs do not take patients' concerns seriously when presenting with symptoms (of cancer and treatment). Members feel brushed off by their GPs.

    d. Request that GPs are provided with more education to recognise signs of cancer.

    e. Request that complementary treatments are made more available, and/or that more information is provided.

    f. Request that better nutritional advice or direction on where to obtain good advice on this during and after treatments.

11. Post-treatment care and support:
    a. Request for more "after care" support for when treatment is finished, e.g.:
        i. Mental health services;
        ii. Dental care post chemotherapy;
        iii. Eye care;
        iv. Physio care for rehabilitation after surgeries and assistance with post treatment exercise programmes
        v. Proper care and guidelines for patients with lymphedema
        vi. Request for funding of lymphedema garments. Some women are paying $650 per sleeve out of their own pocket.

    b. Members noted that they are left dealing with the mental and physical scars with no support. They note that if they had been in a car crash, they would be covered by ACC, but there appears to be nothing available for those who request assistance after receiving cancer treatment (from the Government).

If you would like any further information into any of the points raised above, please let us know.

Appendix Two: Imaging technologies

Breast imaging has gone through technical improvements in the last 20 years to improve sensitivity (can the cancer be detected), specificity (can we tell if it is invasive cancer rather than something more benign), accuracy (fewer false positives, fewer false negatives and interval cancers (those found between screening appointments)) and a desire to reduce cost and improve efficiency.

Digital mammography (4-5 cancers detected per 1000 women screened[1-3]) is currently used in New Zealand's breast screening programme. Compared to screen-film mammography, it has reduced radiation exposure with improved efficiencies and detection. Sensitivity varies depending on the nature of the population screened with overall sensitivity between 50 and 90% (79.9%[4], 84%[5], 86.9%[6], 89.0%[7], 50%[8]) and specificity up to 88.9%[9]. It detects more DCIS than other forms of screening[10] and is preferable for those with a BRCA2 mutation[11]. It is less sensitive for others at above average risk compared to other methods as demonstrated by many international trials. There is growing concern that it is not detecting our most invasive cancers. Individuals with above average risk would benefit from other options. It costs approximately NZ$150-200.

Breast ultrasound (4-7 cancers detected per 1000 screened) has been shown in multiple studies to improve cancer detection in women at elevated risk as a supplemental tool[12]. Automated breast ultrasound has been developed to address poor reproducibility operator issues. Breast ultrasound costs approximately NZ$150-200.

Digital breast tomosynthesis (DBT) (4-8 cancers detected per 1000 screened) has demonstrated an improvement over mammography. Superior for the first screen but subsequently its benefit varies with age and breast density. Research has shown those with extremely dense breasts gain no benefit from DBT[13]. Women aged 50-59 with average density benefit from DBT, (fewer requiring recalls and more cancers being detected than with digital mammography). However, reduction in recall may not significantly reduce interval cancer rates and it is inefficient given the number of images to be reviewed although AI (artificial intelligence) is beginning to be used to assist with this. DBT costs about NZ$300-400.

Contrast-enhanced breast magnetic resonance imaging (CE-MRI)[14] (17-18 cancers detected per 1000 screened) is generally available to clinical practice in the private sector because of its cost or for specific high-risk groups, for screening and diagnostic purposes. By using contrast (gadolinium), it allows for visualisation of early blood vessel formation around small tumours, there is a steep increase in sensitivity for CE-MRI compared to ultrasound, mammography and DBT. CE-MRI sensitivity can range from 75–100% but is often 95- 100%, as demonstrated by large-scale multi-centre trials for high-risk individuals. In NZ it costs about NZ$2,000.

Contrast enhanced mammography (CEM)[15] (14-15 cancers detected per 1000 screened) also exploits the uptake of contrast (iodine). CEM utilises low- and high-energy images and outside of New Zealand has been in use 16 years. Due to its ability to detect form and function of breast tissue, CEM consistently improves diagnostic performance when compared to other forms of screening, frequently matching CE-MRI's overall performance. CEM is often preferred against CE-MRI in high-risk women in both the screening and problem-solving setting. Patients find its shorter examination time and less demanding procedure easier to tolerate when they need to be screened frequently. Mammography machines can be converted at a cost of approximately $8,000. With just four images

to view it is very efficient from a resource perspective. The estimated cost of CEM is about NZ$600-700.

Abbreviated breast MRI (AB-MRI) (9-15 cancers detected per 1,000 screened) has been used globally for several years but is just beginning to be seen in New Zealand. It substantially reduces the MRI screening time to 10 to 15 min compared to 30 to 40 min for conventional CE-MRI. In addition, its reading time is 30 s to 3 min compared to 3 to 9 min for CE-MRI. Preliminary data recently reported[16,17] demonstrated that the sensitivity and specificity of AB-MRI were comparable to those of conventional CE-MRI. Comstock et al.[18] investigated 1444 women of average risk with heterogeneously or extremely dense breasts completed both AB-MRI and DBT. AB-MRI detected 11.8 cancers per thousand women and DBT 4.8. Sensitivity was 95.7% for AB-MRI and 39.1% for DBT. Specificity was 86.7% for AB-MRI versus 97.4% for DBT. In conclusion, women with dense breasts undergoing screening with AB-MRI compared to DBT had a significantly higher rate of detection of invasive breast cancer. This is important because we are concerned that New Zealand's breast screening programme is missing some of these more worrying cancers. A range of studies have reported that AB-MRI could be used in clinical practice, mainly for screening purposes. Compared with CE-MRI, AB-MRI showed no statistically significant differences, with sensitivity of 82% to 100% and specificity of 45% to 97%. Cancer detection rate was 13.3 per 1000 women in a high-risk screening group. AB-MRI costs approximately NZ$800-1000.

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Appendix Three: Breast cancer medicines awaiting funding in New Zealand

In recent years, several innovative new medicines have become available for the treatment of early and advanced breast cancer. However, many of these medicines are not funded in New Zealand. Many are available and publicly funded in Australia. Some are available privately if a patient can pay for them. Pre-Covid a number of New Zealand women travel to other countries to access and pay for medicines they need to extend or improve their lives. This is even more dire now with some women unable to travel due to Covid-19 to access the medicines in other countries.

This can see homes being mortgaged, family lives disrupted and increased stress in an already stressful situation. When surveyed, 51% of New Zealanders said they would consider moving to Australia to access a prescription medicine (16).

All these drugs offer potential advantages in quality and length of life for New Zealanders with breast cancer and would give oncologists additional options for optimising treatment of the different sub-types of breast cancer.

We also list some new medicines that are still being investigated in breast cancer clinical trials for effectiveness and safety.

Medicine name	NZ approval and funding status
Abraxane (nab-paclitaxel) – is used to treat advanced breast cancer in people who have already received other medicines. ● It is a taxane that fights cancer by interfering with cell division. Abraxane is a less toxic formulation of the taxane Taxol (paclitaxel), with the advantage of causing reduced side effects as it is delivered in protein nanoparticles rather than the toxic solvent that Taxol and another taxane Taxotere (docetaxel) are dissolved in. ● Abraxane is particularly helpful for patients who have an allergic reaction to Taxol or Taxotere. Abraxane has been publicly funded in Australia since 2009 and has since become the preferred taxane, with 71% of Australian patients who use a taxane being treated with this drug by September 2011.	Abraxane is available and Medsafe approved, but not publicly funded, in New Zealand. In February 2018 BCAC applied to PHARMAC to have this medicine funded. In May 2019 PTAC recommended it be funded only if "cost-neutral" to weekly paclitaxel (the currently funded option). The potential supplier of nab-paclitaxel has advised BCAC that meeting this price requirement would be extremely difficult because of the higher cost of creating a humanised nanoparticle albumin bound (nab) paclitaxel compared with the other taxanes which are simply dissolved in solvent.

Afinitor (everolimus) – is used in the treatment of hormone-receptor-positive, HER2-negative advanced breast cancer in post-menopausal women, in conjunction with the aromatase inhibitor Aromasin (exemestane) after failure of Femara (letrozole) or Arimidex (anastrozole). ● It is only used in patients whose tumour has tested negative to HER2. ● Afinitor stops a particular protein called mTOR from working properly. mTOR controls other proteins that trigger cancer cells to grow. Afinitor has been funded in Australia since 2014. BCAC has heard that the patent on Afinitor is due to expire soon, potentially leading to a drop in the price, increasing the likelihood that PHARMAC may fund this medicine for breast cancer.	Afinitor is Medsafe registered but not publicly funded for breast cancer in New Zealand.
Bondronat (ibandronate) - is a bisphosphonate used to reduce bone loss in those whose metastatic cancer has moved to their bones. It is funded specifically for breast cancer in Australia but not in New Zealand.	Medsafe approval in NZ has lapsed.
Caelyx (pegylated doxorubicin) – is the chemotherapy drug doxorubicin, contained within a liposomal coating, and is used to treat metastatic breast cancer. Publicly funded in Australia.	Approved by Medsafe in 1997, but not publicly funded in New Zealand.
CDK 4/6 inhibitors - Kisqali® (ribociclib), Verzenio® (abemaciclib) – CDK 4/6 inhibitors are a group of medicines that prevent over-proliferation of cancer cells by inhibiting enzymes that the cells need in order to divide. These drugs offer very promising new treatments for those with advanced oestrogen receptor positive breast cancer. There are several on the market now, and each offers slightly different benefits. Australia has approved funding for all three CDK 4/6 inhibitors – Ibrance, Kisqali and Verzenio - for first- and second-line use with either an aromatase inhibitor or fulvestrant in patients with metastatic hormone receptor positive, HER2-negative breast cancer. All three are also available via the National Health Service throughout the United Kingdom, but with some restrictions depending on which country the patient lives in.	Ibrance® (palbociclib), supplied by Pfizer, is the only CDK 4/6 inhibitor that is funded for breast cancer in New Zealand at present.
Halaven (eribulin) – is used to treat late-stage metastatic breast cancer that is hormone-receptor-positive and HER2-negative that has previously been treated with anthracycline and taxane chemotherapies. It is a "non-taxane microtubule inhibitor" that kills cancer cells by inhibiting cell division. It has been publicly funded in Australia since 2013.	Halaven is not funded in New Zealand.

Keytruda (pembrolizumab) – is an antibody used in cancer immunotherapy. ● It is one of a number of new medicines called checkpoint inhibitors that support the body's immune system to recognise and destroy cancer cells. Some types of cancers have a protein on the cell surface that masks the cancer from the body's immune system. ● Keytruda and other similar new drugs are designed to lock onto and deactivate this protein, exposing the cancer cells to the body's immune system, allowing the body's T-cells to destroy the cancer.	Breast cancer clinical trials currently under way with Keytruda (Keynote trials) and other similar drugs are producing very promising results, particularly in triple negative breast cancers that test positive for the tumour masking protein, PD-L1. Keytruda has recently been funded in New Zealand for treating advanced melanoma.
Perjeta (pertuzumab) – is used for the treatment of HER2-positive metastatic breast cancer in conjunction with Herceptin and the chemotherapy medicine, Taxotere (docetaxel). ● It is used as a "first line" treatment for advanced breast cancer, i.e. as the first treatment to be given once the cancer has advanced. ● It works in a complementary way with Herceptin, inhibiting different proteins that cause Her2-positive breast cancers to grow. ● Results from the CLEOPATRA clinical trial reported in October 2014 showed an extraordinary survival benefit of 15.7 months longer than for patients who did not receive the drug.	Perjeta became publicly funded in New Zealand from January 2017, 18 months after it was funded in Australia. BCAC petitioned PHARMAC to fund the drug for women whose HER2-positive cancers had already advanced, as was done in Australia, but PHARMAC declined to provide funding for this group of around 160 women. Some of those who missed out on Perjeta are fundraising to obtain Perjeta and there has been recent media coverage of their plight.
Tykerb (lapatinib) – Since 1998, Herceptin® (trastuzumab) has been used to successfully treat HER2 positive breast cancers that have spread beyond the breast and the lymph nodes under the arm to other organs within the body (advanced or metastatic breast cancer). ● However, in the majority of patients with advanced HER2 positive breast cancer, the disease will eventually progress despite Herceptin treatment. In some cases, the cancer will spread to the brain probably because Herceptin and other chemotherapy regimens cannot adequately cross the blood-brain barrier. These problems highlight the need for new drug treatments.	Tykerb is only funded in New Zealand for an extremely limited use that oncologists advise makes it inaccessible to the vast majority of patients who need it.

● Tykerb (lapatinib) is an oral therapy that targets the HER2 protein inside the tumour cell (in a different way to Herceptin®). It is a small molecule and can also enter the central nervous system (i.e. cross the blood brain barrier). Tykerb represents an effective way of treating advanced or metastatic HER2 positive breast cancer.	
Xgeva or Prolia (denosumab) is a monoclonal antibody that reduces tumour formation and growth in people whose cancer has spread to the bones. ● Recent Australian research has shown this drug also has the potential to prevent breast cancer in people with a BRCA gene mutation who are at high risk of getting breast cancer. ● It was approved by the US FDA in 2010 for prevention of skeletal events (fractures) in patients with bone metastases from solid tumours. ● It is funded in Australia for elderly patients with low bone density and people with osteoporosis who have had a fracture after minimal trauma.	This medicine is Medsafe registered but not funded in New Zealand.
Tukysa (tucatinib) is a kinase inhibitor for the treatment of adults with advanced unresectable or metastatic HER2-positive breast cancer, including those with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting. ● It was approved by the US FDA in 2020 after early clinical trials showed efficacy in patients with HER2-positive metastatic breast cancer who had prior treatment with trastuzumab (Herceptin), pertuzumab (Perjeta), and ado-trastuzumab emtansine (Kadcyla).	This medicine is not Medsafe registered or funded in New Zealand, but is a promising candidate for an early access scheme.
Nerlynx (neratinib) is indicated for the extended adjuvant treatment of adult patients with early-stage HER2- overexpressed/amplified breast cancer, to follow adjuvant trastuzumab-based therapy. Nerlynx also is used in combination with the chemotherapy medicine capecitabine to treat advanced-stage and metastatic HER2-positive breast cancer in people who have already been treated with at least two HER2 inhibitors for advanced-stage disease.	This medicine was approved by Medsafe in June 2020, and is a promising candidate for an early access scheme.
Tecentriq (atezolizumab) is a monoclonal antibody medication used to treat triple-negative breast cancer (TNBC) as well as other cancers such as lung. ● In March 2019, it was approved in the United States, for adults with unresectable locally advanced or metastatic triple negative breast cancer.	This medicine is Medsafe registered but not funded in New Zealand.
Margenza (margetuximab) is a chimeric IgG monoclonal antibody medication used to treat metastatic HER2+ breast cancer for patients who had received prior treatment with other anti-HER2 therapies.	This medicine is not Medsafe registered or funded in New Zealand, but is a promising

● In December 2020, it was approved for use by the US FDA in combination with chemotherapy, for the treatment of adult patients with metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease.	candidate for an early access scheme.
Enhertu (trastuzumab deruxtecan) is a monoclonal antibody that targets the HER2 receptor on cancer cells and is linked to a topoisomerise inhibitor, which is a chemical compound that is toxic to cancer cells. ● It was granted accelerated approval by the US FDA in December 2019 after early clinical trials showed efficacy in patients with HER2-positive metastatic breast cancer who had received significant previous treatment of their disease.	This medicine is not Medsafe registered or funded in New Zealand, but is a promising candidate for an early access scheme.