Supporting Australians for 15 years

Breast Cancer Network Australia

Submission to the Pharmaceutical Benefits Advisory Committee
Pertuzumab (Perjeta®)
Trastuzumab Emtansine (Kadcyla®)
Trastuzumab (Herceptin®)

8 October 2014

About Breast Cancer Network Australia

Breast Cancer Network Australia (BCNA) is the peak national organisation for Australians personally affected by breast cancer. We support, inform, represent and connect people whose lives have been affected by breast cancer. We work to ensure that Australians diagnosed with breast cancer receive the very best support, information, treatment and care appropriate to their individual needs.

BCNA represents more than 95,000 individual members and 300 member groups from across Australia. More than 3,000 of our members are women who have told us they have had a diagnosis of metastatic (secondary) breast cancer. The actual number is likely to be considerably higher.

We note also that around 125 men are diagnosed with breast cancer in Australia every year, and that some men develop secondary breast cancer. BCNA agrees that men should have equal access to breast cancer treatments that are appropriate for them. As the vast majority of Australians diagnosed with breast cancer are women, this submission refers to women with breast cancer. However we believe the issues and benefits are the same for men with breast cancer.

Submission

Living with advanced breast cancer puts an enormous stress on families. Decisions about whether to pay for an expensive treatment can create conflict when that money also needs to be spent elsewhere. It leaves women feeling guilty that they are spending money on treatments when the family really needs it for other things. – Lynne

Breast Cancer Network Australia welcomes the opportunity to provide comment to the Pharmaceutical Benefits Advisory Committee (PBAC) on the applications to list Perjeta, Kadcyla and Herceptin for women with HER2-positive locally advanced and/or metastatic (secondary) breast cancer on the Pharmaceutical Benefits Scheme (PBS).

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We refer members of the PBAC to our previous submissions in support of PBS listing of Perjeta (12 February 2014) and Kadcyla (12 February 2014 and 12 June 2013), copies attached. Members may also be aware of the campaign BCNA led in 2001 to have Herceptin subsidised for women with secondary breast cancer.

Around 15 to 20 per cent of breast cancers are HER2-positive. For women with these types of cancer, there are currently only two treatments subsidised by the Australian Government: Herceptin (with taxane chemotherapy or as monotherapy) and Tykerb (with Xeloda chemotherapy). The addition of the Perjeta-Herceptin-Taxotere combination and Kadcyla will provide significant new treatment options for these women. BCNA also supports the inclusion on the PBS of Herceptin for women with secondary breast cancer.

BCNA notes that there is good evidence from clinical trials to support the use of Perjeta and Kadcyla in secondary breast cancer. In our previous submissions, we have noted results from the EMILIA and TH3RESA trials for Kadcyla, and the CLEOPATRA trial for Perjeta.

On 28 September 2014, new results from the CLEOPATRA trial were released at the European Society for Medical Oncology (ESMO) conference in Madrid. These results showed the median survival time of women who had received the Perjeta combination was nearly 16 months longer than those in the control group, who did not receive Perjeta. The researchers reported this was the longest survival time for any drug used as a first-line treatment for secondary breast cancer.

Given these remarkable results, BCNA believes that Perjeta should be urgently subsidised by the Australian Government for Australians with HER2-positive secondary breast cancer.

BCNA is concerned by the amount of time it is taking for new drugs to be listed on the PBS. Perjeta was approved by the TGA in May 2013 and Kadcyla in September 2013. Although both have been considered by the PBAC (Kadcyla twice), neither drug has yet received a positive recommendation.

It is important that new drugs for which there is good clinical evidence are made available through the PBS in a timely manner so that all women can have access to them. Currently there is not equal access during the sometimes lengthy approvals process. Only women who can afford to pay can access new drugs prior to their listing on the PBS. This has been the case for both Perjeta and Kadcyla since they were approved by the TGA more than 12 months ago.

Even with the patient access programs which are sometimes offered by pharmaceutical companies, we know that not all women can afford to pay for non-PBS listed drugs. BCNA has taken calls from families who have not been able to afford Perjeta and Kadcyla through the programs offered by Roche, where the patient contribution is between $12,000 and $20,000. This means that these women are missing out on important new treatments that could extend their lives. It puts families in the distressing situation of desperately seeking substantial amounts of money to pay for drugs. Where they can't raise the money, they live knowing there is a drug that may help, but that it is beyond their reach.

We know that many, if not most, women would not be able to afford the full cost of Perjeta (plus Herceptin and Taxotere) and Kadcyla, should they not be PBS-listed and the patient access programs close.

My niece has recently been diagnosed with secondary breast cancer. She starts on Perjeta today, but because it is not on the PBS she will have to contribute nearly $13,000. I'm shocked. She is a public patient. How ridiculous for someone on a low income. I know I could never pay it. – Pam, BCNA Online Network user

In a recent BCNA survey of 582 people living with secondary breast cancer (including three men), sixty per cent (352) reported that their secondary breast cancer had caused some financial difficulty in the last week. One quarter of these (133) described that difficulty as being 'very much' or 'quite a bit'. Treatments not available on the PBS accounted for the greatest out of pocket costs, with an average out of pocket cost per person of $5,277.

We often hear from women, however, whose out-of-pocket costs are significantly higher than this.

Having lived with secondary breast cancer for eight years, my family has incurred significant expense due to my health – more than $50,000 out of pocket. – Karen, BCNA Member

I was diagnosed with secondary breast cancer in November 2012. I've received my treatment mostly in the private system and my out of pocket costs have been about $15,000. This includes costs for specialists, surgery and medicines. I've been exceptionally lucky I haven't needed any of the non-PBS drugs. – Sharon, BCNA Member

I am lucky that I have been able to afford to pay for the first three treatments of Kadcyla under the drug company's patient access scheme. It was almost $15,000; that's a lot of money to find upfront, especially as I've already paid thousands of dollars for other treatments before this one. – Lynne, BCNA Member

In considering the addition of Perjeta, Kadcyla and Herceptin to the PBS, it will be important that the listing restrictions allow flexibility in treatment options. Not all of the HER2 drugs will suit all women with HER2-positive breast cancer, and women will require alternative treatments when their cancer progresses.

Women in the CLEOPATRA trial had access to multiple lines of treatment after their cancer progressed on the Perjeta combination and subsequent treatments, which no doubt contributed to their overall survival. It is important, therefore, that Australian women have access to additional lines of treatment after Perjeta, including Kadcyla, Tykerb and Herceptin options.

Access to Tykerb and Xeloda will need to be maintained as these will suit some women better than the Herceptin combinations, particularly women with brain metastases. Perjeta, Kadcyla and Herceptin have very little brain penetration, and Tykerb is often recommended in this situation. Tykerb and Xeloda may also still be needed for women whose cancer progresses on Kadcyla, and for those who do not tolerate it. The option to return to Herceptin with chemotherapy will also be needed by some women.

In moving Herceptin to the PBS, it will be important that the criteria for its use are extended to allow it to be used with chemotherapies other than taxanes. Under the current arrangements, Herceptin can be used only with a taxane or as a monotherapy. Women receiving Herceptin as a late line treatment are usually prescribed it with chemotherapy, but often not a taxane. Many women will have been treated with at least one taxane during their earlier treatment and may not be suitable for them again, especially if they developed neuropathy as a result of earlier use. For some women, taxane chemotherapy did not work for them, and so would not be prescribed again. It is important therefore, that the new restrictions allow Herceptin to be used with other chemotherapy drugs.

I have had several lines of treatment for my HER2-positive secondary breast cancer, including Kadcyla and, more recently, Tykerb and Xeloda. After several stable months on the Tykerb combination, my breast cancer recently progressed. My oncologist has suggested Herceptin and Navelbine. I have previously had Taxotere [taxane chemotherapy] *and it did not work for me, so I would not have it again. As Navelbine is not approved for use with Herceptin, my oncologist has told me I will have to pay for it, even though it is on the PBS.* – Vanessa, BCNA Member

Conclusion

BCNA strongly urges the PBAC to recommend the inclusion of Perjeta, Kadcyla and Herceptin for treatment of secondary breast cancer on the PBS. These treatments, along with the Tykerb-Xeloda combination, provide women (and men) with HER2-positive secondary breast cancer a flexible range of treatments that can extend their lives and allow them to continue to contribute to their families and communities.

We believe it is vital that new breast cancer drugs are made available through the PBS so that all those who can benefit from them can have equal access to them.

I have had breast cancer since 2008. I have been on many chemotherapy protocols and all have made me so ill I could barely function. The problem was compounded by the fact they were not very effective for me. I accepted a position on a clinical trial for Kadcyla in February 2013. In the eighteen months since starting this drug, my cancer has remained stable and my life has almost returned to normal. I have none of the side effects with Kadcyla that I had with previous treatments. This has given me the opportunity to look after my husband and four children, and work and pay tax. I could not afford to pay for Kadcyla and I urge the PBAC to give this incredible drug its full support. – Liz, BCNA Member

We have included a personal story from BCNA Member Karen about her experience with Kadcyla at the end of this submission.

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Comment from BCNA Member Karen, who has accessed Kadcyla through the patient access program

Thank you for BCNA's continued campaign for patients like me in pushing for Kadcyla to be listed on the PBS. Here is an updated account of my journey now that I have had seven doses of Kadcyla.

Before beginning treatment with Kadcyla, my health had a turn for the worst and, having lived with secondary breast cancer for eight years, my treatment options were running out. Thankfully medical research has provided me with an answer: Kadcyla, a drug that is enabling people like me to live a good life despite having cancer. I emphatically implore the Pharmaceutical Benefits Advisory Committee to make this drug available as it's proving to not only extend people's lives but their quality of life, so they can continue to contribute and live a full life even if it is modified somewhat.

I am fighting not only for me but also for my fellow HER2-positive patients, many of whom have been struck down in their prime with young families. Surely a drug that will not only extend a woman's life expectancy but allow her to continue to be productive for as long as possible is a win/win on all fronts, including humanitarian, society and economics. All of these factors rely on one thing, families. You cannot put a price on the fundamental cornerstone of our society: the family unit of which, more often than not, women are the glue.

With regards to my secondary breast cancer treatment, I have taken different chemotherapies as adjuncts to Herceptin for seven years, and Caelyx which took a toll on my body, causing chronic pain, chronic fatigue, irritable bowel (diarrhoea and gastric reflux), peripheral neuropathy, hand and foot syndrome and migraine. At times I've felt more overwhelmed by the side effects than by the cancer.

I have found Kadcyla very tolerable and thankfully it has halted the progression of my metastatic bone cancer. Together with stereotactic radiosurgery to my brain, my disease is in check.

Emotionally, I no longer feel I'm on a tightrope as Kadcyla is giving me a time of stability. This gives me a lot of comfort and enables me to have some control over my life instead of being dictated by my disease and/or the side effects of treatment.

Being a long term patient, my family has incurred significant expense due to my health – $50,000 out of pocket, including the recent outlay of $15,000 to access Kadcyla through the patient access program. It goes without saying that this is a tremendous financial burden for my family.

My 'normal' has changed because of my disease but I don't let my life be dictated by it. I am still functioning and, thanks to Kadcyla, I have a good quality of life and want to keep it that way. I am still a strong contributor to my immediate and extended family.