Supporting Australians for 15 years

Breast Cancer Network Australia

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Submission to the Medical Services Advisory Committee

Consultation Decision Analytical Protocol 1342 for Gene Expression Profiling (GEP)

23 July 2013

About Breast Cancer Network Australia

Breast Cancer Network Australia (BCNA) is the peak national organisation for Australians personally affected by breast cancer. We empower, inform, represent and link together people whose lives have been affected by breast cancer.

BCNA represents more than 83,000 individual members and 307 Member Groups from across Australia.

BCNA works to ensure that women diagnosed with breast cancer and their families receive the very best information, treatment, care and support possible.

Introduction

Breast Cancer Network Australia (BCNA) welcomes the opportunity to provide feedback to the Medical Services Advisory Committee's Consultation Decision Analytical Protocol (DAP) 1342 regarding gene expression profiling (GEP) of 21 genes in breast cancer assay to quantify the risk of disease recurrence and predict adjuvant chemotherapy benefit.

While we acknowledge that this DAP covers any GEP of 21 genes in breast cancer assay, for the purposes of this submission we will refer to the Oncotype DX gene assay test, which has prompted the DAP.

We also note that around 100 men are diagnosed with breast cancer in Australia every year, and that the wording of the proposed MBS item descriptor will allow men diagnosed with breast cancer and who meet the eligibility criteria access to these gene assay tests. BCNA agrees that men should have equal access to these tests. As the vast majority of Australians diagnosed with breast cancer are women, this submission refers to women with breast cancer. However we believe the benefits are the same for men with breast cancer.

BCNA is a consumer advocacy group, whose functions include representing the views of people affected by breast cancer. Not all questions in the survey fall within the ambit of our expertise. Questions that require clinical expertise have not been answered in this submission.

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Response to Survey Questions

Question 1: Describe your experience with the medical condition (disease) and/or proposed intervention relating to the draft protocol?

Founded in 1998, BCNA is the peak national consumer organisation for Australians affected by breast cancer. We have an excellent reputation as a provider of reliable, high quality information on breast cancer and its treatments, and as an advocate on behalf of women diagnosed and their families.

BCNA actively seeks feedback from our members on issues of relevance to them. We have a strong contingent of active members, all women who have had a diagnosis of breast cancer, who we train to speak about their breast cancer experience and to represent BCNA and women diagnosed in various forums. These women often provide us with feedback on issues affecting women. We are also often contacted directly by women who have been diagnosed with breast cancer regarding issues concerning them, including their breast cancer treatment options.

In recent times we have received a number of inquiries from women regarding the Onctoype DX test, and access to it.

BCNA also works closely with breast cancer clinicians and key industry organisations, such as the Medical Oncology Group of Australia, to help improve the treatment and care of women.

BCNA draws directly on the experience of women who have, or have had, breast cancer and is an excellent position to speak on their behalf.

Question 2: What do you see as the *benefits of this proposed intervention for the person involved and/or their family and carers?*

Chemotherapy is a highly toxic treatment and can cause unpleasant and sometimes debilitating side effects, including nausea and vomiting, diarrhoea, mouth ulcers, hair loss, early menopause, fatigue, peripheral neuropathy and neutropenia. It can cause premature and sometimes permanent infertility, a devastating outcome particularly for young women who may wish to have a family in the future.

For some women, side effects are so severe that they are unable to continue living their normal daily lives. They may have to take time off work, and seek assistance with child care and managing their home. There may be increased financial pressure on them and their families as a result of loss of income, and the cost of treatment and travel for treatment.

> *This round of chemo is horrible. I can't find any energy. I'm so exhausted. I feel like all my muscles are so tired and I ache all over. All I can do is sleep and spend a bit of time on the PC, then back to bed. I so want to get on with life and exercise and be healthy, but it's just impossible at present.* – Terry

The decision on whether or not to accept chemotherapy treatment therefore often causes women, and their families, much angst and grief. This is especially so if there is no clear evidence of the benefit of chemotherapy for them personally.

> *So it has come to this. A raging debate in my head as to whether it is worth undergoing chemo. … Apparently I am in a 'grey area' – it's not clear cut if there will be any benefit from chemo, with most of my benefit to come from hormone treatment. I want to do everything to avoid this coming back. I'm 47.* – Dawn

The availability of a test to assist women, their families and their clinicians to make decisions about chemotherapy treatment is therefore extremely valuable.

The Oncotype DX test is a tool to assist women with certain types of early breast cancer to make their decision on chemotherapy treatment. For this group of women (ER+ and/or PR+, HER2-, and lymph node negative or with a maximum of three positive lymph nodes), there may be some ambiguity about whether or not chemotherapy will be beneficial. The Oncotype DX recurrence score predicts the risk of an individual woman's breast cancer recurring. It can be used by women and their doctors to help them understand whether their personal risk is low (and so chemotherapy will not provide much benefit) or high (in which case chemotherapy is desirable).

A study conducted in Australia by leading breast cancer clinicians found that knowledge of the Oncotype DX recurrence score resulted in a change in treatment recommendations for 24% (36/151) of women who undertook the test. Their treatment recommendations had been made by multidisciplinary teams based on the best information available to them without the Oncotype DX recurrence score.

For 15.9% of the women, the change was to omit chemotherapy and have hormone therapy alone. These women had been recommended chemotherapy treatment by their medical team. As a result of the test, they were able to avoid unnecessary chemotherapy treatment and its toxic side effects. Instead of regular visits over 4-6 months to a chemotherapy unit for intravenous chemotherapy, they were able to be treated with a daily tablet, taken at home. Avoiding chemotherapy may have enabled them to remain well enough to continue to lead their normal life – in the paid workforce, caring for children and/or other family members, running a household or small business, and contributing to their local community. It also provided considerable cost savings to them and to government.

For the 7.9% of women whose treatment recommendation was changed to include chemotherapy, the knowledge that having this treatment is likely to reduce the risk of their breast cancer recurring, and that it may prolong or save their life, gives them confidence that they are making the best treatment decisions for them.

> *I have been so thankful I took the step to undergo chemotherapy and give myself the extra 2-3 per cent nudge against a recurrence when no one in my treatment team could come right out and recommend it because I fell into a 'grey zone'. They left it up to me to decide if it would be worth going through. It was a decision that tore my husband and I apart as we wrestled back and forth with 'I should, I shouldn't, I should'. The fear of what I would have to endure wrestling against the fear of recurrence and statistics, damn statistics.* – Dawn

Question 3: What do you see as the disadvantages of this proposed intervention for the person involved and/or their family and carers?

BCNA does not see any potential disadvantages with the proposal.

We do note, however, that Oncotype DX testing sometimes comes back with an ambiguous result, which can leave the woman tested without definitive advice and so further confused. Explanation will be required by the specialist referring the woman undertaking the test to ensure she understands that this is a possible outcome. Counselling may also be required if an ambiguous result is returned to help her with her decision on chemotherapy treatment.

Question 4: How do you think a person's life and that of their family and/or carers can be improved by this proposed intervention?

Access to the Oncotype DX test will provide eligible women and their treating clinicians with a useful tool to help them in their decision-making around the potential benefits to them of undertaking chemotherapy treatment.

It will provide them, and their families, with additional information to assist them in making this significant decision that will greatly impact their lives.

For women for whom the recurrence score indicates chemotherapy is not required, there are the very definite advantages of avoiding a toxic treatment that may ultimately be of no benefit to them.

For women for whom the recurrence score indicates chemotherapy is recommended, there is the knowledge that they are receiving a treatment based on the best possible information.

Question 5: What other benefits can you see from having this proposed intervention publicly funded on the Medicare Benefits Schedule (MBS)?

The cost to Australian women of the Oncotype DX test is currently $4,000. To our knowledge, no Australian private health insurance fund has yet provided a reimbursement for Onctoype DX testing, although BCNA and others encourage women with private health insurance to make an application to their fund. Women and their families are therefore currently required to cover the full cost of the test themselves.

This puts Oncotype DX out of the reach of some women, particularly as it is a test and not a treatment. It can be difficult for a woman to justify this amount of money for a test which may or may not provide information to guide her in her decision-making. The result is that women who are able to afford the test have access to it; while those who cannot, or cannot justify it, do not. One medical oncologist recently spoke to us about the difficulty she finds in being able to offer the test to her private patients, while knowing that many of her public patients are unable to afford it. This clearly results in an undesirable inequity in access to potentially vital information.

A Medicare rebate for gene assay testing will allow all eligible women (and men) equal access to this testing. As noted previously, the test is recommended only for those who have hormone positive, HER2-negative disease that was either lymph node negative or limited to 1-3 nodes. A Medicare rebate will provide a more equitable system for Australians diagnosed with breast cancer.

It is also possible that, in the future, 21 gene assay tests similar to the Oncotype DX test may be developed and conducted in Australia at a lower cost than Oncotype DX. In wording the item descriptor broadly to allow other 21 gene assays to be subsidised, these tests will be available as an alternative to Oncotype DX.

I had the Oncotype DX test done back in January 2009. It was very expensive as the Aussie dollar was down to 62c to the American dollar and we paid $5,800. My oncologist originally advised me to have chemo 'just in case' but my wonderful surgeon told me about this test and we went ahead. My result was a 6 which indicated no benefit from chemo for my particular breast cancer diagnosis. My Oncologist on seeing the results advised against chemo and said it [Oncotype DX] *was money well spent. I must say though that we were fortunate to have some money set aside (we were going to renovate the bathroom before I was diagnosed). I would think that offering everyone who qualified for this test the possibility of it could cause despair and frustration due to the cost and no Medicare rebate or private health insurance cover. I am extremely grateful for having it available for my decision making.* – Helena

I was recently diagnosed with breast cancer. I had a lumpectomy and initially thought I would need radiotherapy and hormone therapy. At my post-surgical visit it was discussed that as I sat in a 'grey area', 'somewhere in the middle', chemotherapy may be an option. I decided to have an Oncotype DX test. I was hormone positive with no lymph node involvement. My result was I had a low score and wouldn't benefit from chemo. It was an expensive test with no rebate from Medicare or my health fund. I will be writing to both pointing out how much I saved these organisations by having this test. – Julie

Question 6: What other services do you believe need to be delivered before or after this intervention, eg dietitian, pathology.

BCNA understands that the Oncotype DX test does not require any additional services. Women are informed about the test, and the test results, through their breast cancer specialist or treating team. Samples for testing are provided by the pathology laboratory that undertook the woman's breast cancer surgery pathology testing.

It may be appropriate in some circumstances however to refer women for counselling or psychological support following the results of an Oncotype DX test. The decision on whether or not to undergo chemotherapy often involves considerations that are not clinical in nature, such as the emotional and financial burden on families. Some women will receive an ambiguous result from Oncotype DX testing. In these circumstances, it may be appropriate for her medical oncologist to refer her for counselling. BCNA understands that medical oncologists are currently unable to refer their patients for Medicare-reimbursed psychological assistance.

Questions 7 – 12

BCNA does not have the clinical expertise to answer these questions.

BCNA thanks the Medical Services Advisory Committee for the opportunity to provide comment on this proposal. We are pleased to support the application. Should you have any concerns or questions related to this comment, please contact me at kwells@bcna.org.au or (03) 9805 2562.

Yours sincerely

Kathy Wells
National Policy Manager

Personal story from BCNA Member Julie Barnes, NSW

I was diagnosed in December 2012 with hormone positive, lymph node negative breast cancer. I was told after surgery that I sat in a 'grey area' and may benefit from chemotherapy.

I decided to go ahead with the Oncotype DX test. I was very glad I did. My result was that I had a low recurrence score and therefore wouldn't benefit from chemotherapy.

My family and I were happy with the outcome. I ended up with minimal time off work; just a couple of hours each afternoon for radiation.

Had I have had the chemotherapy, there would have been a 'community cost' – time off work for me, for a family member to look after me if I was unwell, their time off work, possible hospital admissions (cost to private health fund or Medicare). I work in a small business and my husband works for himself - so it would have been very costly. There would also have been the emotional cost on all concerned.

In addition, there are the long term effects of the chemotherapy on my body, and the possible risks to my family in sharing a bathroom in the days immediately after a treatment (especially for my eight year old grandson who lives with us).

We should be able to claim from either Medicare or our private health fund for this test, even if we don't have the population to sustain having the test performed here.