Information and frequently asked questions regarding the MammaPrint® (70 gene signature) test for early breast cancer

Purpose

The purpose of this document is to provide information for patients and health professionals about the Medical Services Advisory Committee (MSAC) conclusion in relation to public funding of the MammaPrint® (70 gene signature) test. Information is presented in the form of frequently asked questions to support discussions regarding the test and the MSAC outcome.

Background

- In Australia survival for patients with breast cancer is among the highest in the world, with greater than 95% of patients with early breast cancer surviving at least five years from diagnosis.[1]
- Best practice management of early breast cancer, including surgery, radiotherapy, chemotherapy, hormonal and targeted therapies, is guided by multidisciplinary treatment planning and evidence-based best practice care.
- The decision to use chemotherapy in early breast cancer after local treatments (surgery and radiotherapy) is determined by considering both patient (clinical) and tumour (pathology) characteristics, which are often used in algorithms to guide treatment decisions.
- Gene profile tests are an emerging technology for describing the pattern or grouping of genes in particular breast cancer cells. These tests are intended as an add-on to the clinical and pathology information as a way of further assessing risk of breast cancer recurrence and guiding therapy.
- MSAC is an independent expert committee established by the Australia Government to advise the Minister for Health on evidence relating to the comparative safety, clinical effectiveness and value for money of medical technologies and procedures.
- In March 2018, MSAC considered an application seeking public funding of a gene profile test, the MammaPrint® test, to be used in patients with early breast cancer assessed as being at high clinical risk of cancer recurrence, to guide their decision about the use of additional (adjuvant) chemotherapy.
- After considering safety, clinical effectiveness and cost-effectiveness, MSAC did not support public funding for the MammaPrint® test.
- While international guidance varies, the MSAC conclusion is in line with the 2018 NICE (UK) Guidelines and the 2018 recommendation of the national funding body of the Netherlands (where the MammaPrint® test was developed).

[1] Cancer Australia. https://breast-cancer.canceraustralia.gov.au/statistics. Accessed March 2019.

Information for patients and health professionals

1. What is the MammaPrint® (70 gene signature) test?

MammaPrint® is a gene profile test (a genomic test of breast cancer tumour cells). It examines 70 different genes to look for changes associated with a higher risk of breast cancer recurrence after treatment. The aim of the MammaPrint® test is to help inform decisions about whether to use chemotherapy after local treatment for early breast cancer.

2. What did MSAC conclude about the MammaPrint® test?

MSAC **did not support** public (Government) funding for the MammaPrint® test in Australia. This conclusion was based on a review of the safety, clinical effectiveness and cost-effectiveness.

3. Why did MSAC reach the conclusion not to support public funding of the MammaPrint® test in Australia?

MSAC based its conclusion on its appraisal of a study known as the MINDACT trial which investigated the use of the MammaPrint® test in a clinical trial setting.

The trial aimed to show whether information provided by the MammaPrint® test could be added to existing clinical information to inform decisions about the use of adjuvant chemotherapy for early breast cancer. The trial showed that, overall, breast cancer outcomes were poorer in women who did not have chemotherapy based on the MammaPrint® test, compared with those who received chemotherapy.

"As a result, MSAC had little confidence that the MammaPrint® test could be used to justify withholding chemotherapy without negatively impacting upon important outcomes, including overall survival." http://www.msac.gov.au/1376.1-public

4. Does this MSAC conclusion apply to other gene profile tests?

MammaPrint® is one gene profile test that has been considered by MSAC for public funding. A number of such tests have been developed to assess the risk of breast cancer recurrence after initial treatment, in order to guide a patient's decision about the use of chemotherapy.

To date, none of the tests reviewed by MSAC has been considered to provide sufficient evidence of benefit to be approved for public funding in Australia. However, gene profile tests are an active area of research. MSAC's conclusion in relation to this particular test (MammaPrint®) does not necessarily mean that the Committee would reach the same conclusion for other gene profile tests in the future.

5. Is the MammaPrint® test available in Australia?

Currently no gene profile tests, including MammaPrint® for use in early breast cancer, are publicly funded in Australia, however patients can choose to personally pay for such a test.

Patients who choose to undertake the MammaPrint® test after being informed about the MSAC findings, should be made aware that there is an out of pocket cost for the test. This is called informed financial consent. Patients should also be made aware that breast cancer tissue is sent overseas for testing.

Questions for Patients

6. What should I do if I am considering having the MammaPrint® test to inform my decision about whether to have chemotherapy?

There are many factors considered in the decision whether or not to have chemotherapy in each individual case.

Talk to your specialist treating clinician about the potential benefits and risks of chemotherapy for you, based on available clinical information about you and your breast cancer, and the MSAC conclusion on use of the MammaPrint® test.

In order that you make the decision that is right for you, it is important you understand what is involved, including the cost of having the test.

7. What if I have had the MammaPrint® test?

If you have had the MammaPrint® test, you may have used the results to help you decide whether or not to have chemotherapy. Treatment decisions are based on the best available information at the time. There are many factors considered in the decision whether or not to have chemotherapy in your case, including specific clinical and tumour characteristics.

If you have questions or concerns associated with the use of the MammaPrint® test in your case, speak to your specialist treating clinicians.

Questions for Health Professionals

8. What should I tell a patient considering having the MammaPrint® test?

A clinician's role is to provide advice about treatment options relevant to the individual patient. This advice should consider clinical and patient characteristics and include the potential benefits and risks of treatments. The consideration of the MammaPrint® test should be in the context of providing a clear explanation of the MSAC conclusion based on the MINDACT trial.

http://www.msac.gov.au/1376.1-public

Current clinical practice involves the use of patient and tumour criteria to determine if

chemotherapy is recommended. Patients who choose to undertake the MammaPrint® test after being informed of the MSAC conclusion, should be advised of the out of pocket costs, as part of informed financial consent and the fact that samples are currently sent overseas for testing.

9. What should I tell a patient who has had the MammaPrint® test?

Inform the patient that treatment decisions are based on the best available information at the time. There are many factors considered in the decision about whether or not to have chemotherapy, including specific clinical and tumour characteristics.

Recent assessment undertaken by MSAC of the MammaPrint® test considered the results of a randomised controlled trial, the MINDACT trial. Based on the study, MSAC concluded that withholding chemotherapy on the basis of the MammaPrint® test led overall to poorer breast cancer outcomes for some patients. Further details can be found in the MSAC Public Summary Document at http://www.msac.gov.au/1376.1-public

If you are not the treating specialist, encourage the patient to discuss any concerns they have associated with the use of the MammaPrint® test with their specialist treating clinicians.

If you have treated a patient who decided not to have chemotherapy after using the MammaPrint® test, consider the need to contact the patient and counsel them based on the MSAC conclusion with respect to the particular circumstances of the patient.

For more information on MSAC's conclusion in relation to the MammaPrint® test, visit the MSAC website at http://www.msac.gov.au/1376.1-public