Background report on assessing whether the gene expression test Mammaprint® in the treatment of breast cancer complies with established medical science and medical practice

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Summary

This report describes the assessment of the Dutch Health Insurance Board '*College voor zorgverzekeringen*' (CVZ) regarding the gene expression test Mammaprint® in the treatment of breast cancer.

Breast cancer

Breast cancer involves a malignant tumour in the breast, originating from the milk ducts of breast tissue. These tumours can grow and spread into surrounding tissue and metastasise into the lymph glands or other organs. Adjuvant chemotherapy (CT) is one of the treatment possibilities for preventing the outgrowth of metastases. The selection of patients who benefit from this medication takes place on the basis of risk-profiling.

Mammaprint®

Mammaprint® is a commercially available gene expression test that measures the expression of 70 genes in cancerous breast tissue. It involves drawing up a risk-profile of the chance of developing distant metastases. The claim is that categorising patients into a high-risk or a low-risk group based on the Mammaprint® is more accurate than with the standard risk-estimates in use. Only patients in the high-risk group are indicated for adjuvant CT. This could limit overtreatment.

Indication

The Mammaprint® was developed for patients younger than 61 years with a breast tumour < 5 cm, without lymph gland metastases, both oestrogen receptor-positive and oestorgen receptor-negative types.

Efficacy/clinical utility

CVZ examines interventions for their clinical efficacy, or, in the case of tests, for their clinical utility. This implies that the test affects treatment decisions to such a degree that it results in a health benefit for the patient.

The available literature is based solely on retrospective research that describes the outcomes of the Mammaprint®, the standard risk-profiling tests and actual survival outcomes. An important disadvantage is that the groups of patients included have undergone different treatments that may have affected survival and also therefore the link between the Mammaprint®

outcome and the prognosis on the course of the disease. Prospective research can be used to demonstrate whether opting for or denying adjuvant CT on the basis of the results of the Mammaprint® actually does lead to health benefits. The data are, however, not yet available. This means that the clinical utility of using the Mammaprint® has not yet been demonstrated.
The current MINDACT trial, a prospective, randomised, multicentre study that compares use of the Mammaprint® with standard clinical risk-estimates, will have to demonstrate whether its use really does lead to health benefits.

Not in accordance with established medical science and medical practice

CVZ concludes that using the medical test Mammaprint®, based on the results of the literature search relating to its clinical utility, does not comply with the criterion 'established medical science and medical practice'.