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## Evaluation of international guidelines: Breast cancer



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## **New developments in breast cancer treatment for women, including a special kind of antibody therapy, could play a role in the upcoming revision of the German disease management programme for breast cancer.**

Breast cancer is the most common kind of cancer in women in Germany. Men can get it too, although it is rare. Nowadays breast cancer can be treated at every stage of the disease. More and more people with breast cancer can expect to survive and live for a long time without symptoms.

In breast cancer, cancerous (malignant) tissue starts growing in the mammary glands. When discovered, it can usually be removed in most women. But sometimes it is only discovered at an advanced stage. Advanced cancer is no longer only found in the breast and surrounding tissue, but has travelled to other parts of the body, such as the bones or lymph nodes. These new tumours are called metastases. But even then the disease can still be treated.

After being diagnosed with breast cancer, a time of uncertainty, fears and worries about the future may begin. Friends and relatives often feel helpless too. Breast cancer can be painful and the treatment is often demanding and unpleasant. This can be a great strain, both physically and mentally.

Treatment for breast cancer depends on the kind of tumour, how big it is, whether it has spread, the patient's general state of health and, last but not least, her wishes. It may involve surgery, radiation or medication. These different treatment approaches are often combined.

Breast cancer can affect all areas of a person's life, including their physical ability, psychological wellbeing and social life. That is why it is very important to have detailed information about breast cancer, its symptoms, and what treatment and psychosocial support options there are. You can read about current research on breast cancer here (URL: <http://www.gesundheitsinformation.de/a-z-list.128.56.en.html>) .

### **Structured treatment plans: DMPs**

The statutory health insurances in Germany have developed so-called disease management programmes (DMPs) for certain chronic illnesses. The aim of DMPs is to help people with chronic illnesses to get the best possible care. You can read more about DMPs here (URL:

<http://www.informedhealthonline.org/index.276.en.html>) .

There is a DMP for breast cancer too. It covers a range of areas, including diagnostic procedures, treatment, rehabilitation, aftercare and psychosocial care. All women with breast cancer can participate in the programme, at all stages of the illness.

Doctors who participate in DMPs have to follow defined quality standards when treating their patients. The German Federal Joint Committee (G-BA) determines the medical content and specifications of a DMP. The G-BA is the supreme decision-making self-governance body of physicians, dentists, psychotherapists, hospitals and health insurance funds in Germany.

The treatments offered in DMPs should be evidence-based. In other words, treatment decisions should be based on the best available scientific knowledge. One way in which evidence-based medicine is put into practice is through "evidence-based guidelines". Guidelines are developed to help doctors and patients to make decisions and ensure that patients get the best possible quality-assured treatment. Ideally, evidence-based guidelines should be based on the outcomes of good quality trials.

### **Evaluation of guidelines for breast cancer**

In Germany, the law requires DMPs to be revised regularly. The DMP for breast cancer was last revised in 2005. The Federal Joint Committee (G-BA) commissioned the German Institute for Quality and Efficiency in Health Care (IQWiG) to look for current good quality guidelines, compare their key recommendations with the specifications of the German breast cancer DMP, and point out any changes that may need to be made. The G-BA wanted to use the IQWiG report as a basis for discussion when updating the breast cancer DMP.

Together with researchers from the German Agency for Quality in Medicine (ÄZQ), IQWiG found and systematically evaluated 23 good quality clinical guidelines from different countries. Four of these guidelines had been developed in Germany. One comprehensive set of German guidelines was updated in 2008.

For the report, the researchers summarised the recommendations made in good quality guidelines and

compared them with the German DMP. They did not evaluate the research that the recommendations in the guidelines were based on.

## What they found

The researchers found that the German DMP for breast cancer is largely in line with the recommendations of current good quality guidelines for the treatment of breast cancer. But according to IQWiG's evaluation, some areas of the DMP could be expanded or added to. One important outcome of the evaluation concerns a new development in the area of drug therapy: antibody therapy with the drug trastuzumab.

The growth of tumour cells is influenced by many factors, including a particular protein called the HER2 receptor (human epidermal growth factor receptor). Sometimes there are more of these receptors on breast cancer tumour cells than there are on healthy cells. If there are a lot of HER2 receptors on the tumour cells, it is called HER2-positive breast cancer. In many cases, drugs with the antibody called trastuzumab in them can block the growth-promoting effect of the HER2 receptors and stop the tumour from growing.

Current guidelines recommend that women with HER2-positive breast cancer have antibody therapy with trastuzumab. In the German DMP for breast cancer, HER2 receptor tests and therapy aimed at these receptors are only recommended for certain women who already have metastases.

Compared to the DMP, current guidelines consider a lot of other aspects in more detail. This is not only true for areas like chemotherapy and hormone therapy, but also for diagnostic and surgical procedures, as well as radiotherapy.

The DMP also covers aftercare and follow-up - the care of people after they have had breast cancer treatment. According to the DMP, aftercare should begin following the first treatment, or six months after the diagnosis at the latest. The DMP recommends generally having follow-up examinations every 6 months, and a mammogram once a year. The recommended time intervals between follow-up examinations are different in current guidelines. For example, several guidelines recommend having follow-up examinations every three months in the first three years after being diagnosed with breast cancer, then every six months in the two years that follow, and only once a year after that. The guidelines also provide more information

about the options for diagnosing and treating the pain that can arise after a breast has been removed (mastectomy).

Compared to the DMP, the guidelines also go into more detail about psychosocial care. For example, they include recommendations about patient information, counselling, doctor-patient communication and special kinds of care, such as that given by trained breast care nurses. Last but not least, the researchers at IQWiG found that it may be necessary to include more detailed information in the DMP about advanced breast cancer, its diagnosis and the treatment options.

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**Glossary**

## evidence

Evidence is what we call scientific proof from well-conducted, good-quality scientific trials that have been carefully designed to answer specific questions. Depending on the types of questions, different scientific research methods (types of study) are most appropriate to find reliable answers to these questions. Randomized controlled trials (RCTs), for example, are the best way to get reliable evidence on the effectiveness of medical treatments (interventions). This type of study, however, is not the best form of evidence for all possible questions, and does not provide the best answers to all kinds of questions, either. Epidemiological studies, for example, are very suitable for establishing well-founded proof for the spreading of a disease in the population.

## Sources

German Institute for Quality and Efficiency in Health Care (IQWiG). *Systematic guideline search and evaluation, as well as extraction of new and relevant recommendations, for the DMP "Breast cancer". Final report V06-05. Version 1.0.* Cologne: IQWiG. September 2008. [Full text (URL: [http://www.iqwig.de/download/V06-05\\_AB\\_Leitlinienrecherche\\_und\\_bewertung\\_fuer\\_das\\_DMP\\_Brustkrebs.html](http://www.iqwig.de/download/V06-05_AB_Leitlinienrecherche_und_bewertung_fuer_das_DMP_Brustkrebs.html)) - in German]

## **The German Institute for Quality and Efficiency in Health Care (IQWiG)**

The German Institute for Quality and Efficiency in Health Care (IQWiG) was established by legislation to provide evaluations of the effectiveness, quality and efficiency of healthcare services. This includes the assessment of medicines as well as the publication of health information for consumers and patients.

## **Evidence basis of our health information**

Our information is based primarily on systematic reviews of the effects of health care. Systematic reviews are necessary to gain an objective picture of health care. In order to do this, a clear question is formulated. Researchers then find all the relevant studies that could answer this question. They then evaluate those studies.

You can find a list of the evidence and other scientific literature on which this information is based at [\*\*www.informedhealthonline.org\*\*](http://www.informedhealthonline.org)

## **Disclaimer**

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