

**Guidance on
the use of
trastuzumab
for the
treatment of
advanced
breast cancer**

This leaflet is also available in Welsh, (Ref no. N0067).

Mae'r daflen hon hefyd ar gael yn Gymraeg (rhif cyfeirnod N0067).

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What is NICE guidance?

The National Institute for Clinical Excellence (NICE) is a part of the NHS. It produces guidance for both the NHS and patients on medicines, medical equipment, diagnostic tests and clinical and surgical procedures and under what circumstances they should be used.

When the Institute evaluates these things, it is called an appraisal. Each appraisal involves the manufacturers of the drug or device, the professional organisations and the groups who represent patients and their carers.

NICE was asked to look at the available evidence on trastuzumab (the brand name for this drug is Herceptin) and provide guidance that would help the NHS in England and Wales decide where they should be used in the treatment of advanced breast cancer.

What is advanced breast cancer?

Cancer is a disease of the body's cells. Normally, all cells divide and reproduce themselves in an orderly and controlled manner. In cancer,

the cells multiply without proper control and grow into a lump (which is called a tumour).

Approximately 32,000 new cases of breast cancer were reported in England and Wales in 1996. In 1998, breast cancer caused over 11,000 deaths in England and Wales and was the leading cause of death in women aged 35 to 54 years.

Between 16 and 20 women out of every 100 diagnosed with breast cancer have a disease which has spread to other parts of the body. Around half of the women who are diagnosed with localised breast cancer will eventually develop metastatic cancer. It is called metastatic breast cancer if the cancer cells have spread to other parts of the body.

Some breast cancer involves a naturally produced protein in the body (called the epidermal growth factor). This protein attaches itself to another protein called HER2, which is found on the surface of the breast cancer cell. When combined they stimulate the cancer cells to multiply.

How is breast cancer treated?

The type of treatment given to cancer patients depends on many factors. These include:

- the type of cancer,
- where in the body it started,
- what the cancer cells look like under the microscope,
- how far they have spread, if at all
- the general health of the patient

Patients are often given chemotherapy. Chemotherapy is the use of anti-cancer drugs to destroy cancer cells and usually involves a drug called anthracycline. However, the choice of treatment is influenced by how quickly the disease is developing, how far it has spread and by whether the drugs have been used previously.

What is trastuzumab (Herceptin)?

Trastuzumab is a drug that specifically targets the HER2 protein. It attaches itself to the HER2 protein and prevents the protein that encourages cancer cell growth from reaching the cancer cell.

What has NICE recommended ?

It can be used on its own or in combination with another drug called paclitaxel.

NICE has recommended that trastuzumab (Herceptin) is used in certain circumstances for women with breast cancer:

- Trastuzumab (Herceptin) in combination with paclitaxel is recommended as an option for women with breast cancer who have not had chemotherapy for their metastatic breast cancer and for whom anthracycline treatment is not appropriate. However these women will also have had a test that shows their level of HER2 protein is measured as 3+.
- Trastuzumab by itself is recommended for women with tumours with HER2 at levels of 3+ who have had at least two chemotherapy treatments for metastatic breast cancer. Previous chemotherapy must have included at least an anthracycline drug and a

taxane drug where these treatments are appropriate. It should also have included hormonal therapy in patients sensitive to oestrogen.

HER2 levels should be measured using validated techniques and in accordance with published guidelines. NICE have recommended that laboratories offering these tests should participate in and demonstrate satisfactory performance in a recognised external quality assurance scheme.

What should I do?

If you or someone you care for has advanced breast cancer then you should discuss this guidance with your doctor or consultant.

Will NICE review its guidance?

Yes. The guidance will be reviewed in April 2005.

Further information

Further information on NICE and the full guidance issued to the NHS is available on the NICE website (www.nice.org.uk).

The guidance can also be requested from the NHS Response Line on 0870 1555 455, quoting reference N0064.

If you have access to the internet and would like to find out more about advanced breast cancer, visit the NHS Direct website at www.nhsdirect.nhs.uk.