NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single Technology Appraisal

Bevacizumab in combination with a taxane for the first-line treatment of metastatic breast cancer

Final Scope

Remit/appraisal objective

To appraise the clinical and cost effectiveness of bevacizumab in combination with a taxane within its licensed indication for the first-line treatment of HER2-negative metastatic breast cancer (to include a reinitiation of terminated appraisal TA147).

Background

Breast cancer is the most common malignancy affecting women in the UK. There were over 40,000 women newly diagnosed with breast cancer in England and Wales during 2005. In the UK around 300 men are also diagnosed with breast cancer each year. In 2006, there were around 11,000 deaths in England and Wales, an average rate of 42 deaths per 100,000 females and about 1 death per 100,000 males. Between 16% and 20% of women (an estimated 6,000 to 8,000 women) presenting with breast cancer have advanced disease with distant metastases, and it is estimated that around 50% of those presenting with early or localised breast cancer will eventually develop metastatic breast cancer.

The role of current treatments for metastatic breast cancer is to palliate symptoms, prolong survival and maintain a good quality of life with minimal adverse events. Treatment depends on previous therapy, oestrogen receptor status, HER2 status and the extent of the disease. First-line therapy is usually an anthracycline-based regimen, if an anthracycline is considered appropriate. Where an anthracycline is unsuitable (for example if the person has previously received anthracycline-based adjuvant therapy or has a contraindication to anthracyclines) NICE clinical guideline 81 recommends docetaxel monotherapy. Alternatively, combination therapy may be considered for people in whom a greater probability of response is important (NICE technology appraisal guidance No. 116 recommends gemcitabine in combination with paclitaxel). Vinorelbine or capecitabine should then be considered for subsequent lines of therapy.

The technology

Bevacizumab (Avastin, Roche) is a humanised anti-vascular endothelial growth factor (VEGF) monoclonal antibody that inhibits VEGF-induced signalling and inhibits VEGF-driven angiogenesis. This reduces vascularisation of tumours, thereby inhibiting tumour growth. Bevacizumab is administered by intravenous infusion.

Bevacizumab in combination with paclitaxel or docetaxel has a marketing authorisation for first-line treatment of patients with metastatic breast cancer.

A NICE technology appraisal of bevacizumab in combination with paclitaxel (TA 147) was initiated in 2007. NICE was unable to recommend the use in the NHS of bevacizumab in combination with paclitaxel for the first-line treatment of metastatic breast cancer because no evidence submission was received from the manufacturer or sponsor of the technology.

Intervention(s)	Bevacizumab in combination with a taxane
Population(s)	People with untreated metastatic HER2-negative breast cancer for whom anthracyclines are not appropriate.
Comparators	Bevacizumab in combination with paclitaxel and bevacizumab in combination with docetaxel should be compared with each other. In addition, the interventions should be compared with the following: • docetaxel monotherapy • paclitaxel monotherapy • paclitaxel in combination with gemcitabine
Outcomes	The outcome measures to be considered include: • overall survival • progression-free survival • response rates • adverse effects of treatment • health-related quality of life.
Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared. Costs will be considered from an NHS and Personal Social Services perspective.

Other considerations	Guidance will only be issued in accordance with the marketing authorisation
Related NICE recommendations	Related Technology Appraisals: Technology Appraisal No. 116, January 2007, 'Gemcitabine for the treatment of metastatic breast cancer.' Technology Appraisal No. 147 (terminated appraisal), June 2008, 'Bevacizumab for the first-line treatment of metastatic breast cancer' Related Guidelines: Clinical Guideline CG81, February 2009, Advanced breast cancer: diagnosis and treatment.