NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Proposed Health Technology Appraisal

Bevacizumab in combination with paclitaxel and carboplatin for the first-line treatment of advanced and/or metastatic ovarian cancer

Draft scope (Pre-referral)

Draft remit/appraisal objective

To appraise the clinical and cost effectiveness of bevacizumab within its licensed indication in combination with paclitaxel and carboplatin for the first-line treatment of advanced and/or metastatic ovarian cancer.

Background

Ovarian cancer is a common gynaecological cancer. It is classified in stages, from stage I to stage IV. In stage I, the cancer is confined to one or both ovaries. Stage II ovarian cancer has spread beyond the ovaries to the uterus, fallopian tubes or other areas in the pelvis. In stage III, the cancer has grown outside the pelvis into the abdominal cavity or affects the lymph nodes. Stage IV ovarian cancer is defined by distant metastases, that is, the cancer has spread into other body organs such as the liver or lungs.

Ovarian cancer is often asymptomatic in the early stages and approximately 40% of cases are diagnosed with advanced stage III or stage IV disease, around 2,400 cases per year in England and Wales. For women diagnosed with stage III and IV disease, the five-year survival rates are 27% and 16%, respectively. In 2008 there were 3824 deaths from ovarian cancer in England and Wales. The incidence of ovarian cancer increases with age (four out of five cases are diagnosed in women over 50 years) and is higher in women who have BRCA1 or BRCA2 gene mutations.

Standard treatment for ovarian cancer consists of surgery to determine the type and stage of the disease and to remove as much of the cancer as possible. Following surgery, chemotherapy is used to treat any residual disease. NICE Technology Appraisal No. 55 recommends paclitaxel in combination with a platinum-based compound or platinum-based therapy alone (cisplatin or carboplatin) as options for first-line chemotherapy in the treatment of ovarian cancer.

The technology

Bevacizumab (Avastin, Roche Products) is a humanised anti-vascular endothelial growth factor (VEGF) monoclonal antibody that reduces vascularisation of tumours, inhibiting tumour growth. It is administered by intravenous infusion.

Bevacizumab does not have a UK marketing authorisation for the treatment of metastatic ovarian cancer. It has been studied in clinical trials in combination

with carboplatin and paclitaxel in patients with newly diagnosed stage III or IV ovarian cancer who have not received prior chemotherapy. The addition of bevacizumab to carboplatin and paclitaxel has been compared with carboplatin and paclitaxel without bevacizumab.

Intervention(s)	Bevacizumab in combination with paclitaxel and carboplatin
Population(s)	Women with newly diagnosed, stage III or IV ovarian cancer who have not received prior chemotherapy
Comparators	Platinum-based chemotherapy (cisplatin or carboplatin with or without paclitaxel), without bevacizumab
Outcomes	The outcome measures to be considered include: • overall survival • progression-free survival • response rate • 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. 91, May 2005, 'Topotecan, pegylated liposomal doxorubicin hydrochloride and paclitaxel for the treatment of advanced ovarian cancer' (Review of TA 28, TA 45 and TA 55 [for relapsed disease only]). Review date November 2012 Technology Appraisal No. 55, January 2003, 'Review of the clinical effectiveness and cost effectiveness of paclitaxel for ovarian cancer'. Review date: on static list

	Technology Appraisal in Preparation, 'Trabectedin for the treatment of relapsed ovarian cancer'. Earliest anticipated date of publication October 2010. Related Guidelines: Clinical Guideline in Preparation, 'The recognition and initial management of ovarian cancer'. Earliest anticipated date of publication April 2011.

Questions for consultation

Have the most appropriate comparators for bevacizumab for the treatment of stage III or IV ovarian cancer been included in the scope?

Are there any subgroups of people in whom the technology is expected to be more clinically effective and cost effective or other groups that should be examined separately?

Are there any issues that require special attention in light of the duty to have due regard to the need to eliminate unlawful discrimination and promote equality?

Do you consider the technology to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)?

Do you consider that the use of the technology can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?

Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits.

NICE intends to appraise this technology through its Single Technology Appraisal (STA) Process. We welcome comments on the appropriateness of appraising this topic through this process. (Information on the Institute's Technology Appraisal processes is available at http://www.nice.org.uk/aboutnice/howwework/devnicetech/technologyappraisalprocessguides/technology_appraisal_process_guides.jsp)