NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Proposed Health Technology Appraisal

Bevacizumab for the treatment of recurrent or relapsed advanced ovarian cancer

Draft scope (Pre-referral)

Draft remit/appraisal objective

To appraise the clinical and cost effectiveness of bevacizumab within its licensed indication for the treatment of platinum-sensitive or partially platinum-sensitive recurrent or relapsed advanced ovarian cancer.

Background

Ovarian cancer is a common gynaecological cancer occurring in different parts of the ovary. Ovarian cancer may be asymptomatic in the early stages and symptoms tend to be non-specific such as persistent pelvic and abdominal pain, increased abdominal size/persistent bloating, difficulty eating, and feeling full quickly, on a daily basis.

Ovarian cancer mainly affects women who have had their menopause, with the highest rates of incidence in the age group of 65 and above. In England and Wales in 2007, approximately 6000 women were diagnosed with ovarian cancer and of these, approximately 4500 had stage III or IV (advanced) disease. In 2008 there were 4370 deaths in the UK caused by ovarian cancer.

Ovarian cancer may be categorised according to the response to first-line platinum chemotherapy as follows: platinum-sensitive (disease responds to first-line platinum-based therapy but relapses after 12 months or more); partially platinum-sensitive (disease which responds to first-line platinum-based therapy but relapses between 6 and 12 months); platinum-resistant (disease which relapses within 6 months of completion of initial platinum-based chemotherapy) and platinum-refractory, that is, does not respond to initial platinum-based chemotherapy. Although a significant percentage of women with ovarian cancer respond to initial chemotherapy, between 55% and 75% of women whose tumours respond to first line therapy relapse within 2 years of completing treatment. The overall 5-year survival rate is less than 30%.

Current management of ovarian cancer involves surgery to remove as much of the cancer as possible and chemotherapy. Increasingly chemotherapy is given before surgery. NICE Technology Appraisal No. 55 recommends the use of paclitaxel in combination with a platinum-based compound or platinum-based therapy alone to treat residual disease.

NICE Technology Appraisal No. 91 recommends the following as options for the second-line (or subsequent) treatment of platinum-sensitive or partially platinum-sensitive ovarian cancer:

- paclitaxel in combination with a platinum compound in platinum-sensitive or partially platinum-sensitive disease
- pegylated liposomal doxorubicin hydrochloride in partially platinum-sensitive disease

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 currently have a UK marketing authorisation for the treatment of recurrent or relapsed advanced ovarian cancer. It has been studied in clinical trials in addition to standard treatment (carboplatin in combination with paclitaxel, docetaxel or gemcitabine) for the treatment of women with platinum-sensitive or partially platinum-sensitive recurrent epithelial ovarian carcinoma.

Intervention(s)	Bevacizumab in combination with standard platinum-based therapy
Population(s)	Women with recurrent or relapsed platinum-sensitive or partially platinum-sensitive advanced epithelial ovarian cancer
Comparators	Platinum-sensitive ovarian cancer • Paclitaxel in combination with a platinum compound Partially platinum-sensitive ovarian cancer • Paclitaxel in combination with a platinum compound • Pegylated liposomal doxorubicin hydrochloride

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 decision November 2012. Technology Appraisal No. 55, January 2003. Review of the clinical effectiveness and cost effectiveness of paclitaxel for ovarian cancer. Transferred to the static guidance list. Technology Appraisal in Preparation, 'Trabectedin for the treatment of relapsed ovarian cancer.' Earliest anticipated date of publication April 2011. Technology Appraisal in Preparation, 'Bevacizumab in combination with paclitaxel and carboplatin for the first-line treatment of advanced and/or metastatic ovarian cancer'. Earliest anticipated date of publication TBC. Suspended Technology Appraisal, 'Patupilone for the treatment of recurrent epithelial ovarian cancer.' Suspended Technology Appraisal, 'Gemcitabine for relapsed advanced ovarian cancer.' Related Guidelines: Clinical Guideline in Preparation. The recognition and initial management of ovarian cancer. Earliest anticipated date of publication April 2011.

Questions for consultation

Is the proposed population which includes both women with platinum-sensitive and partially platinum-sensitive disease appropriate?

Have the most appropriate comparators for bevacizumab for the treatment of recurrent or relapsed platinum-sensitive or partially platinum-sensitive advanced ovarian cancer been included in the scope?

- Is pegylated liposomal doxorubicin hydrochloride a relevant comparator or is its use generally limited to women who are allergic to platinum compounds?

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?

Please consider whether in the remit or the scope there are any issues relevant to equality. Please pay particular attention to whether changes need to be made to the remit or scope in order to promote equality, eliminate unlawful discrimination, or foster good relations between people who share a characteristic protected by the equalities legislation and those who do not share it, or if there is information that could be collected during the assessment process which would enable NICE to take account of equalities issues when developing guidance.

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)