NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Proposed Health Technology Appraisal

Pazopanib for maintenance treatment of epithelial ovarian, fallopian and peritoneal cancer

Draft scope (pre-referral)

Draft remit/appraisal objective

To appraise the clinical and cost effectiveness of pazopanib within its licensed indication for maintenance treatment of epithelial ovarian, fallopian and peritoneal cancer in patients whose disease has not progressed after first line therapy.

Background

Ovarian cancer is a common gynaecological cancer which represents a group of different tumours that arise from diverse types of tissue contained in the ovary. Fallopian tube cancer and primary peritoneal cancer are histologically equivalent diseases to epithelial ovarian cancer. The most common type of ovarian cancer arises from epithelial cells (the outside layer of cells) on the surface of the ovary, and can often spread from the ovary to any surface within the abdominal cavity including the fallopian tubes and peritoneal cavity.

Symptoms of ovarian cancer tend to be non-specific and include persistent pelvic and abdominal pain, abdominal bloating, urinary frequency or urgency, loss of appetite, and abnormal or postmenopausal bleeding. It is classified in stages, from stage I to stage IV, according to the FIGO (International Federation of Gynaecology & Obstetrics) system. 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 spread beyond the pelvis into the abdominal cavity or affects the para-aortic 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. Most women are diagnosed with advanced stage disease.

Ovarian cancer predominantly occurs in older women, with over 80% of cases being diagnosed in women over 50 years. In 2010, around 7000 new cases of ovarian cancer were diagnosed and there were approximately 4300 deaths from ovarian cancer in the UK. The overall 5-year survival rate for ovarian cancer is approximately 43%.

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. After surgery, chemotherapy is used to treat any residual disease. Increasingly chemotherapy is given before surgery. NICE technology

appraisal guidance 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. Between 55% and 75% of women whose tumours respond to first-line therapy relapse within 2 years of completing treatment. In people whose disease recurs, NICE technology appraisal guidance 91 recommends paclitaxel in combination with a platinum compound in platinum-sensitive or partially platinum-sensitive disease; pegylated liposomal doxorubicin hydrochloride in partially platinum-sensitive, platinum-resistant or platinum-refractory disease; paclitaxel alone in platinum-refractory or platinum-resistant disease; and topotecan in platinum-refractory or platinum-resistant disease for people for whom pegylated liposomal doxorubicin hydrochloride and single-agent paclitaxel are considered inappropriate.

The technology

Pazopanib (Votrient, GlaxoSmithKline) is a multi-targeted tyrosine kinase receptor inhibitor with anti-tumour activity. It inhibits vascular endothelial growth factor receptor (-1, -2 and -3) and platelet-derived growth factor receptor (alpha and beta) and c-kit, which may result in the inhibition of angiogenesis in tumours in which these receptors are unregulated. It is administered orally.

Pazopanib does not currently have a UK marketing authorisation for the maintenance treatment of epithelial ovarian, fallopian and peritoneal cancer. It has been studied in clinical trials as monotherapy compared with placebo in women with stage II-IV epithelial ovarian, fallopian tube, or primary peritoneal cancer whose disease has not progressed after receiving first line chemotherapy.

Intervention(s)	Pazopanib
Population(s)	People with stage II-IV epithelial ovarian, fallopian tube, or primary peritoneal cancer whose disease has not progressed following first line chemotherapy
Comparators	None

Outcomes	The outcome measures to be considered include: • progression-free survival on maintenance treatment • progression-free survival on next-line therapy • overall 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. The availability of any patient access schemes for the intervention or comparator technologies should be taken into account.
Other considerations	Guidance will only be issued in accordance with the marketing authorisation.

Related NICE recommendations	Related Technology Appraisals: 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, 'Bevacizumab in combination with paclitaxel and carboplatin for the first-line treatment of advanced and/or metastatic ovarian cancer'. Earliest anticipated date of publication April 2013. Technology Appraisal in Preparation, 'Bevacizumab in combination with gemcitabine and carboplatin for treating recurrent advanced ovarian cancer' Earliest anticipated date of publication May 2013 Technology Appraisal in Preparation, 'Topotecan, pegylated liposomal doxorubicin hydrochloride, paclitaxel, trabectedin and gemcitabine for advanced ovarian cancer (for recurrent disease only) (Review of TA 91 and TA 222)' Earliest anticipated date of publication February 2014 Technology Appraisal in Preparation, 'Vintafolide in combination with pegylated liposomal doxorubicin hydrochloride for the treatment of folate receptor positive, platinum resistant ovarian cancer' Earliest anticipated date of publication July 2014 Related Guidelines: Clinical Guideline No. 122, April 2011, 'The recognition and initial management of ovarian cancer'. Review Proposal Date April 2014 Related Quality Standards: Quality Standard No. 18, May 2012, 'Ovarian cancer' Review Proposal Date May 2017 Related NICE Pathways: NICE Pathway: Ovarian cancer, Pathway created: February 2012 http://pathways.nice.org.uk/pathways/ovarian-cancer

Questions for consultation

Are there any comparators for pazopanib for the maintenance treatment of epithelial ovarian, fallopian and peritoneal cancer currently being used in UK clinical practice?

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?

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which pazopanib will be licensed;

- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;

- could have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the Committee to identify and consider such impacts.

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

Where do you consider pazopanib will fit into the existing NICE pathway; Ovarian Cancer (http://pathways.nice.org.uk/pathways/ovarian-cancer)?

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)