NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Olaparib for maintenance treatment of BRCA-mutated ovarian, fallopian tube and peritoneal cancer after response to first-line platinum-based chemotherapy (Review of TA598)

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of olaparib within its marketing authorisation for maintenance treatment of BRCA-mutated ovarian, fallopian tube and peritoneal cancer after response to first-line platinum-based chemotherapy.

Background

Ovarian cancer is a cancerous growth that occurs in the ovary or fallopian tubes. The most common type of ovarian cancer, high-grade serous type, is thought to arise from the peritoneum or fallopian tube and presents after it has spread to the ovary. Ovarian cancer is classified from stage 1 to stage 4. Most people are diagnosed with stage 3 and 4 ('advanced') disease, in which the disease has spread outside of the pelvis. Some people have gene mutations that may increase the risk of ovarian cancer. Mutated inherited genes that increase the risk of ovarian cancer include BRCA 1 and 2.

Ovarian cancer rates in the UK have remained stable since the early 1990s. The incidence of ovarian cancer increases with age, with incidence rates being highest in females aged 75 to 79.[1] In 2020, 6,111 people were diagnosed with ovarian cancer in England and there were 3,564 deaths from ovarian cancer.[2,3] The 5-year survival for women diagnosed with ovarian cancer between 2015 and 2019, in England was 43.8.%.[4]

NICE technology appraisal guidance 55 recommends paclitaxel in combination with a platinum-based compound or platinum-based therapy alone (cisplatin or carboplatin) as alternatives for first-line chemotherapy (usually following surgery) in the treatment of ovarian cancer.

Bevacizumab (including the unlicensed dose of 7.5 mg/kg every 3 weeks and the licenced dose of 15 mg/kg every 3 weeks) in combination with chemotherapy is available in routine commissioning as induction treatment for selected groups of patients with International Federation of Gynaecology and Obstetrics (FIGO) stage 3 and stage 4 disease, and as a maintenance monotherapy after completion of induction chemotherapy at a dose of 7.5mg/kg.

NICE technology appraisal 598 recommends olaparib for use within the Cancer Drugs Fund as an option for the maintenance treatment of BRCA mutation-positive, advanced (FIGO stages 3 and 4), high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer that has responded to first-line platinum-based chemotherapy in adults, while further data are collected. This recommendation is the subject of this evaluation.

NICE technology appraisal 673 recommends niraparib for use within the Cancer Drugs Fund as an option for maintenance treatment for advanced (FIGO stages 3 and 4) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer after response to first-line platinum-based chemotherapy in adults.

NICE technology appraisal 693 recommends olaparib plus bevacizumab for use within the Cancer Drugs Fund as an option for maintenance treatment for advanced (FIGO stages 3 and 4) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer in adults when there has been a complete or partial response after first-line platinum-based chemotherapy plus bevacizumab, and the cancer is associated with homologous recombination deficiency (HRD).

The technology

Olaparib (Lynparza, AstraZeneca) has a marketing authorisation in the UK as monotherapy for the maintenance treatment of adult patients with advanced (FIGO stages 3 and 4) BRCA1/2-mutated (germline and/or somatic) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy.

Olaparib has a related marketing authorisation in the UK in combination with bevacizumab for the maintenance treatment of adults with advanced (FIGO stages III and IV) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy in combination with bevacizumab, and whose cancer is associated with HRD positive status defined by either a BRCA1/2 mutation and/or genomic instability. Olaparib also has a marketing authorisation in the UK as monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy.

Intervention(s)	Olaparib
Population(s)	People with BRCA-mutated advanced ovarian, fallopian tube or peritoneal cancer that has responded (completely or partially) to first-line platinum-based chemotherapy
Comparators	• Routine surveillance • Olaparib plus bevacizumab (subject to NICE evaluation)

Outcomes	The outcome measures to be considered include: • overall survival • progression-free survival • progression-free survival 2 (i.e. progression-free survival on next line of therapy) • time to next line of therapy • 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 will be taken into account. The economic modelling should include the cost associated with diagnostic testing in people with platinum-sensitive ovarian, fallopian tube and peritoneal cancer who would not otherwise have been tested. A sensitivity analysis should be provided without the cost of the diagnostic test. See section 5.9 of the Guide to the Methods of Technology Appraisals
Other considerations	Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator
Related NICE recommendations	**Related technology appraisals:** Olaparib plus bevacizumab for maintenance treatment of advanced ovarian, fallopian tube or primary peritoneal cancer**.** (2021) NICE technology appraisal guidance 693 Niraparib for maintenance treatment of advanced ovarian, fallopian tube and peritoneal cancer after response to first-line platinum-based chemotherapy. (2021) NICE technology appraisal guidance 673

	Olaparib for maintenance treatment of relapsed platinum-sensitive ovarian, fallopian tube or peritoneal cancer. (2020) NICE technology appraisal guidance 620 Olaparib for maintenance treatment of BRCA mutation-positive advanced ovarian, fallopian tube or peritoneal cancer after response to first-line platinum-based chemotherapy (2019) NICE technology appraisal guidance 598 Guidance on the use of paclitaxel in the treatment of ovarian cancer (2003) NICE technology appraisal guidance 55 **Related technology appraisals in development:** Olaparib in combination with bevacizumab for maintenance treatment of advanced ovarian, fallopian tube and peritoneal cancer after response to first-line platinum-based chemotherapy with bevacizumab [Review of TA693]. NICE technology appraisal guidance [ID4066] Publication expected August 2023 **Related Guidelines:** Ovarian cancer: recognition and initial management (2011) NICE guideline CG122. Reviewed November 2017. Tests in secondary care to identify people at high risk of ovarian cancer (2017) NICE guideline DG31. **Related Quality Standards:** Ovarian cancer (2012) NICE quality standard 18. Next review: August 2018
Related National Policy	The NHS Long Term Plan (2019) NHS Long Term Plan NHS England NHS manual for prescribed specialist services 2018/2019 (2018) 105. Specialist cancer services (adults) Department of Health, NHS Outcomes Framework 2016-2017 (2016) Domains 1 and 2

Questions for consultation

Have all relevant comparators for olaparib been included in the scope? Are any routinely commissioned maintenance treatments currently used for BRCA-mutated ovarian, fallopian tube and peritoneal cancer after response to initial platinum-based chemotherapy?

Is olaparib plus bevacizumab (subject to NICE evaluation) a relevant comparator?

Is there a clearly defined population who would be offered first-line platinum-based chemotherapy in combination with bevacizumab compared with first-line platinum-based chemotherapy alone?

Are the outcomes listed appropriate?

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

Do you consider that the use of olaparib can result in any potential 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 committee to take account of these benefits.

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 olaparib is 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.

NICE intends to evaluate this technology through its Single Technology Appraisal process. (Information on NICE's health technology evaluation processes is available at https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/changes-to-health-technology-evaluation).

References

1. Cancer Research UK. Ovarian cancer. Accessed April 2023.

2. NHS Digital (2020) Cancer Registration Statistics, England. Cancer diagnoses (incidence) data tables 2020. Accessed April 2023

3. NHS Digital (2020) Cancer Registration Statistics, England. Cancer deaths (mortality) data tables 2020. Accessed April 2023

4. NHS Digital (2020) Cancer Survival in England, cancers diagnosed 2015 to 2019, followed up to 2020. Adult cancer survival data tables for 2015 to 2019 diagnoses . Accessed April 2023