

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)

Final scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of olaparib within its marketing authorisation for maintenance treatment of adults with advanced BRCA-mutated high-grade 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

For first-line chemotherapy (usually following surgery), [NICE technology appraisal guidance 55](#) recommends paclitaxel in combination with a platinum-based compound or platinum-based therapy alone (cisplatin or carboplatin).

After response to first-line platinum-based chemotherapy, maintenance treatment options include:

- olaparib (recommended for use within the Cancer Drugs Fund for BRCA mutation-positive cancer in [NICE technology appraisal 598](#); subject of this evaluation)
- niraparib (recommended for use within the Cancer Drugs Fund in [NICE technology appraisal 673](#))

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

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

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and stage 4 disease, and as a maintenance monotherapy after completion of induction chemotherapy at a dose of 7.5mg/kg.

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), [NICE technology appraisal 693](#) (currently under review) recommends olaparib plus bevacizumab for use within the Cancer Drugs Fund as an option for maintenance treatment.

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)	Adults with BRCA-mutated advanced high-grade ovarian, fallopian tube or peritoneal cancer that have responded (completely or partially) to first-line platinum-based chemotherapy without bevacizumab
Comparators	<ul style="list-style-type: none"> • Routine surveillance
Outcomes	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> • 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	<p>The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year</p> <p>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</p> <p>Costs will be considered from an NHS and Personal Social Services perspective</p> <p>The availability of any patient access schemes for the intervention or comparator technologies will be taken into account.</p> <p>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</p>
Other considerations	<p>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</p>
Related NICE recommendations	<p>Related technology appraisals:</p> <p>Olaparib plus bevacizumab for maintenance treatment of advanced ovarian, fallopian tube or primary peritoneal cancer. (2021) NICE technology appraisal guidance 693</p> <p>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</p> <p>Olaparib for maintenance treatment of relapsed platinum-sensitive ovarian, fallopian tube or peritoneal cancer. (2020) NICE technology appraisal guidance 620</p> <p>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</p> <p>Guidance on the use of paclitaxel in the treatment of ovarian cancer (2003) NICE technology appraisal guidance 55</p> <p>Related technology appraisals in development:</p> <p>Olaparib in combination with bevacizumab for maintenance</p>

	<p>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</p> <p>Related Guidelines:</p> <p>Ovarian cancer: recognition and initial management (2011) NICE guideline CG122. Reviewed November 2017.</p> <p>Tests in secondary care to identify people at high risk of ovarian cancer (2017) NICE guideline DG31.</p> <p>Related Quality Standards:</p> <p>Ovarian cancer (2012) NICE quality standard 18. Next review: August 2018</p>
Related National Policy	<p>The NHS Long Term Plan (2019) NHS Long Term Plan</p> <p>NHS England NHS manual for prescribed specialist services 2018/2019 (2018) 105. Specialist cancer services (adults)</p> <p>Department of Health, NHS Outcomes Framework 2016-2017 (2016) Domains 1 and 2</p>

References

1. Cancer Research UK. [Ovarian cancer](#). Accessed June 2023.
2. NHS Digital (2020) [Cancer Registration Statistics, England. Cancer diagnoses \(incidence\) data tables 2020](#). Accessed June 2023
3. NHS Digital (2020) [Cancer Registration Statistics, England. Cancer deaths \(mortality\) data tables 2020](#). Accessed June 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 June 2023