NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Niraparib for maintenance treatment of advanced ovarian, fallopian tube and peritoneal cancer after response to first-line platinum-based chemotherapy (review of TA673) [ID6403]

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of niraparib within its marketing authorisation for maintenance treatment of adults with advanced epithelial (FIGO stages 3 and 4) high-grade ovarian, fallopian tube or peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy.

Background

Ovarian cancer is a cancerous growth that occurs in different parts of the ovary or fallopian tubes. The most common type of ovarian cancer, high-grade serous carcinoma, is thought to arise from the fallopian tube and presents after it has spread to the ovary. Ovarian cancer is classified from stage 1 to stage 4. Advanced ovarian cancer falls within stages 2 and 4; in stage 2 the disease has grown outside the ovaries but is still within the pelvic area, stage 3 denotes disease that has spread outside the pelvis into the abdominal cavity, and stage 4 denotes that distant metastasis to other body organs such as the liver and the pleura (two thin layers of tissue that protect and cushion the lungs) has occurred. Most people are diagnosed with advanced stage disease. 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 2022, 7,078 people were diagnosed with ovarian cancer in England. [2] There were 3,564 deaths due to ovarian cancer in 2020.[3] The 5-year survival for women diagnosed with ovarian cancer between 2016 and 2020, in England was 45%.[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).

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.[5]

NICE technology appraisal 962 recommends olaparib as an option for maintenance treatment of BRCA mutation-positive, advanced (FIGO stages 3 and 4), high-grade

© National Institute for Health and Care Excellence 2025. All rights reserved.

epithelial ovarian, fallopian tube or primary peritoneal cancer that has responded to first-line platinum-based chemotherapy in adults.

NICE technology appraisal 673 recommends niraparib within the Cancer Drugs Fund (subject of this evaluation) as an option for the maintenance treatment of 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. This recommendation is the subject of this evaluation.

NICE technology appraisal 946 recommends olaparib with bevacizumab for maintenance treatment of high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer in adults whose cancer has completely or partially responded after first-line platinum-based chemotherapy with bevacizumab, is advanced (FIGO stages 3 and 4) and is homologous recombination deficiency (HRD) positive (defined as having either a BRCA1 or BRCA2 mutation, or genomic instability).

The technology

Niraparib (Zejula, GlaxoSmithKline) has marketing authorisation in the UK as monotherapy for the maintenance treatment of adults with advanced epithelial (FIGO Stages 3 and 4) high-grade ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy.

Intervention(s)	Niraparib
Population(s)	Adults with advanced epithelial (FIGO stages 3 and 4) high-grade ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy
Subgroups	If the evidence allows the following subgroups will be considered: • BRCA mutation status • HRD status
Comparators	• Olaparib plus bevacizumab (if HRD-positive and after complete or partial response to first-line platinum-based chemotherapy with bevacizumab) • Olaparib (if BRCA mutation-positive) • Rucaparib (subject to NICE evaluation) • Bevacizumab monotherapy at a dose of 7.5 mg/kg (after response to first-line platinum-based chemotherapy plus bevacizumab) • Routine surveillance

© National Institute for Health and Care Excellence 2025. All rights reserved.

Outcomes	The outcome measures to be considered include: • overall survival • progression-free survival • progression-free survival 2, that is progression-free survival on next line of therapy • response rate • time to first subsequent 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 commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account. The availability and cost of biosimilar and generic products should be taken into account.
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 with bevacizumab for maintenance treatment of advanced high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer (2024) NICE technology appraisal guidance 946 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

© National Institute for Health and Care Excellence 2025. All rights reserved.

	Olaparib for maintenance treatment of BRCA mutation-positive advanced ovarian, fallopian tube or peritoneal cancer after response to first-line platinum-based chemotherapy (2024) NICE Technology appraisal guidance 962 **Related Technology Appraisals in development:** Rucaparib for maintenance treatment of advanced ovarian, fallopian tube and peritoneal cancer after response to first-line platinum-based chemotherapy (ID5100) Expected publication April 2025 **Related Guidelines:** Suspected cancer: recognition and referral (2015, updated 2023) NICE guideline NG12 Ovarian cancer: recognition and initial management (2011, updated 2023) NICE guideline CG122 Ovarian cancer: identifying and managing familial and genetic risk. (2024) NICE guideline NG241 Tests in secondary care to identify people at high risk of ovarian cancer (2017) NICE guideline DG31 **Related Interventional Procedures:** Maximal cytoreductive surgery for advanced ovarian cancer (2023) NICE interventional procedures guidance 757 **Related Quality Standards:** Suspected cancer (2016, updated 2017) NICE quality standard 124 Ovarian cancer (2012, updated 2025) NICE quality standard 18

Questions for consultation

Have all relevant comparators for niraparib been included in the scope?

Is olaparib (TA962) a relevant comparator for the evaluation of niraparib, particularly in BRCA-mutated populations?

Is olaparib plus bevacizumab (TA946) a relevant comparator for the evaluation of niraparib in people with HRD-positive disease?

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 in the scope appropriate for assessing the clinical and cost effectiveness of niraparib?

© National Institute for Health and Care Excellence 2025. All rights reserved.

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

Do you consider that the use of niraparib 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 niraparib 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 March 2025

2. NHS Digital (2024) Cancer Registration Statistics, England. Cancer diagnoses (incidence) data tables 2022. Accessed March 2025

3. NHS Digital (2020) Cancer Registration Statistics, England. Cancer deaths (mortality) data tables 2020. Accessed March 2025

4. NHS Digital (2023) Cancer Survival in England, cancers diagnosed 2016 to 2020, followed up to 2021 . Accessed March 2025

5. NHS England (2025). Available at: NHS England » National Cancer Drugs Fund list. Accessed March 2025

© National Institute for Health and Care Excellence 2025. All rights reserved.