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]

Final scope

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] NICE guideline NG241 states that the rate of familial ovarian cancer is higher in people from Ashkenazi Jewish backgrounds.

For first-line chemotherapy (usually following surgery), NICE technology appraisal guidance 55 recommends paclitaxel in combination with a platinum-based therapy 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 ovarian, fallopian tube and primary peritoneal cancer.[5] and Bevacizumab as a maintenance monotherapy at a dose of 7.5 mg/kg every 3 weeks is available in routine commissioning after completion of induction chemotherapy in combination with bevacizumab 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 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).

NICE technology appraisal 1055 recommends rucaparib as an option for the maintenance treatment of 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, only if:

- it is BRCA mutation-negative and HRD-positive, or
- it is BRCA mutation-negative, and HRD-negative or unknown, and bevacizumab is not a treatment option because:
    - NHS England's BEV3 and BEV10 commissioning approval criteria for having it are not met, or
    - it is contraindicated or not tolerated.

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 (if BRCA mutation-negative and HRD-positive, or BRCA mutation-negative and HRD-negative or HRD-unknown and bevacizumab is not a treatment option) • Bevacizumab monotherapy at a dose of 7.5 mg/kg (after response to first-line platinum-based chemotherapy plus bevacizumab at a dose of 7.5 mg/kg) • Routine surveillance
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 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 Rucaparib for maintenance treatment of advanced ovarian, fallopian tube and peritoneal cancer after response to first-line platinum-based chemotherapy (2025) NICE Technology appraisal guidance 1055 **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

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