NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Rucaparib for maintenance treatment of advanced ovarian, fallopian tube and peritoneal cancer after response to first-line platinum-based chemotherapy

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of rucaparib within its marketing authorisation as maintenance treatment of advanced ovarian, fallopian tube and peritoneal cancer after complete or partial response to 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 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[a] for BRCA mutation-positive cancer in NICE technology appraisal 598; currently under review)
- 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 and stage 4 disease, and as a maintenance monotherapy after completion of induction chemotherapy at a dose of 7.5mg/kg.[5]

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

Rucaparib (Rubraca, Pharmaand) is already licensed in the UK for maintenance treatment of platinum-sensitive relapsed high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer that has responded (completely or partially) to platinum-based chemotherapy, in adults.

Rucaparib does not currently have a marketing authorisation in the UK for the maintenance treatment of advanced ovarian, fallopian tube and peritoneal cancer after response to first-line platinum-based chemotherapy. However, it has been studied in a double-blind, placebo-controlled phase 3 trial in this indication.

Intervention(s)	Rucaparib
Population(s)	People with advanced ovarian, fallopian tube, or primary peritoneal cancer that has responded (complete or partial) to first-line platinum-based chemotherapy

[a] Products recommended for use in the Cancer Drugs Fund after 1 April 2016 should not be considered as comparators, or appropriately included in a treatment sequence, in subsequent relevant appraisals.

Subgroups	If the evidence allows the following subgroups will be considered: • BRCA mutation status • HRD status
Comparators	• Olaparib monotherapy (if BRCA mutation-positive; subject to NICE evaluation) • Olaparib plus bevacizumab (if HRD-positive; subject to NICE evaluation) • Bevacizumab monotherapy 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.

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 Rucaparib for maintenance treatment of relapsed platinum-sensitive ovarian, fallopian tube or peritoneal cancer (TA611) (2019) NICE Technology appraisal guidance 611 Olaparib for maintenance treatment of BRCA mutation-positive advanced ovarian, fallopian tube or peritoneal cancer after response to first-line platinum-based chemotherapy (TA598) (2019) NICE Technology appraisal guidance 598 **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) [ID4066] Expected publication October 2023 Olaparib for maintenance treatment of BRCA mutation-positive advanced ovarian, fallopian tube or peritoneal cancer after response to first-line platinum-based chemotherapy (review of TA598) [ID6191] Expected publication March 2024 **Related Guidelines:** Suspected cancer: recognition and referral (2015, updated 2023) NICE guideline NG12 Ovarian cancer: recognition and initial management (2011) NICE guideline CG122

	Tests in secondary care to identify people at high risk of ovarian cancer (2017) NICE guideline DG31 **Guidelines in development:** Ovarian cancer: identifying and managing familial and genetic risk. NICE guideline. Publication expected March 2024. **Related Interventional Procedures:** Ultra-radical (extensive) surgery for advanced ovarian cancer (2013) NICE interventional procedures guidance 470 **Related Quality Standards:** Suspected cancer (2016 updated 2017) NICE quality standard 124 Ovarian cancer (2012) NICE quality standard 18
Related National Policy	NHS England (2019) The NHS long term plan NHS England (2021) Highly specialised services 2019 NHS England (2014) NHS standard contract for complex gynaecology- specialist gynaecological cancers. Service Specification No. E10/S/f

Questions for consultation

Where do you consider rucaparib will fit into the existing care pathway for advanced ovarian, fallopian tube and peritoneal cancer?

Would rucaparib be used after both first-line platinum-based chemotherapy with bevacizumab and first-line platinum-based chemotherapy alone?

Would rucaparib be a candidate for managed access?

Do you consider that the use of rucaparib 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 rucaparib 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.

NICE intends to evaluate this technology through its Single Technology Appraisal process. We welcome comments on the appropriateness of appraising this topic through this 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 September 2023.

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

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

5. NHS England (2023). Available at: NHS England » National Cancer Drugs Fund list. Accessed September 2023.