NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Rucaparib for maintenance treatment of relapsed platinum-sensitive ovarian, fallopian tube or peritoneal cancer (Review of TA611)

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of rucaparib within its marketing authorisation for maintenance treatment of relapsed, platinum-sensitive high-grade epithelial ovarian, fallopian tube or peritoneal cancer that has responded to 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. Advanced ovarian cancer falls within stages 2 to 4; in stage 2 the disease has grown outside the ovaries but is still within the pelvic area, stage 3 denotes disease that is locally advanced and has spread outside the pelvis into the abdominal cavity, and stage 4 denotes disease that has spread to other body organs such as the liver or lungs. 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.

The incidence of ovarian cancer increases with age, with incidence rates being highest in females aged 75 to 79[1]. In 2017, 6,236 people were diagnosed with ovarian cancer in England and there were 3,693 deaths from ovarian cancer in 2016[2,3]. The 5-year survival for women diagnosed with ovarian cancer between 2013 and 2018, in England was 42.6%[4].

Ovarian cancer may be categorised according to the response to initial platinum chemotherapy as follows: platinum-sensitive (disease responds to platinum-based therapy but relapses after 6 months or more, which can be subdivided into fully [disease responds to platinum-based therapy but recurs after 12 months or more] and partially platinum-sensitive disease [disease responds to platinum-based therapy but recurs between 6 and 12 months]); platinum-resistant (disease which recurs within 6 months of completion of platinum-based chemotherapy) and platinum-refractory, that is, does not respond to initial platinum-based chemotherapy. Although a significant percentage of people have disease that responds to initial chemotherapy, between 55% and 75% of people whose tumours respond to initial therapy relapse within 2 years of completing treatment.

In people whose disease relapses following initial therapy, NICE technology appraisal guidance 389 recommends paclitaxel as monotherapy or in combination with platinum, and pegylated liposomal doxorubicin hydrochloride as monotherapy or in combination with platinum, for treating recurrent ovarian cancer.

NICE technology appraisal 611 (TA611) recommends rucaparib for use in the cancer drugs fund (CDF) as an option for maintenance treatment of relapsed, platinum-sensitive high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer that has responded to platinum-based chemotherapy in adults, while further data are collected. This recommendation is the subject of this evaluation.

In addition, NICE technology appraisal 784 recommends niraparib as an option for maintenance treatment of relapsed, platinum-sensitive high-grade serous epithelial ovarian, fallopian tube or primary peritoneal cancer that has responded to the most recent course of platinum-based chemotherapy: in people who have a BRCA mutation and have had 2 courses of platinum-based chemotherapy and people who do not have a BRCA mutation and have had 2 or more courses of platinum-based chemotherapy.

NICE technology appraisal 908 (TA908) recommends olaparib as an option for maintenance treatment of relapsed, platinum sensitive ovarian, fallopian tube or peritoneal cancer in adults whose disease has responded to platinum-based chemotherapy, if they have a BRCA1 or BRCA2 mutation and have had 2 or more courses of platinum-based chemotherapy.

The technology

Rucaparib (Rubraca, Pharmaand) has a marketing authorisation in the UK 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)	Rucaparib
Population(s)	People with relapsed, platinum-sensitive high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer that is in response (complete or partial) to platinum-based chemotherapy
Comparators	For people who have a BRCA mutation and have had 2 or more courses of platinum-based chemotherapy • Olaparib • Niraparib For people who do not have a BRCA mutation and have had 2 or more courses of platinum-based chemotherapy. • Niraparib
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. If the technology is likely to provide similar or greater health benefits at similar or lower cost than technologies recommended in published NICE technology appraisal guidance for the same indication, a cost comparison may be carried out. 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 for maintenance treatment of recurrent, platinum-sensitive ovarian, fallopian tube and peritoneal cancer after two or more courses of platinum-based chemotherapy (2023) NICE technology appraisal guidance 908. Niraparib for maintenance treatment of relapsed, platinum-sensitive ovarian, fallopian tube and peritoneal cancer (2022) NICE technology appraisal guidance 784. Olaparib for maintenance treatment of relapsed platinum-sensitive ovarian, fallopian tube or peritoneal cancer (2020) NICE technology appraisal guidance 620. Guidance withdrawn. Rucaparib for maintenance treatment of relapsed platinum-sensitive ovarian, fallopian tube or peritoneal cancer (2019) NICE technology appraisal guidance 611. Currently under review (this evaluation). Topotecan, pegylated liposomal doxorubicin hydrochloride, paclitaxel, trabectedin and gemcitabine for treating recurrent

	ovarian cancer (2016) NICE technology appraisal guidance 389. **Related NICE guidelines:** Ovarian cancer: recognition and initial management (2011) NICE guideline CG122. **Related NICE guidelines in development:** Ovarian cancer: identifying and managing familial and genetic risk. NICE guideline. Publication expected March 2024 **Related quality standards:** Ovarian cancer (2012) NICE quality standard 18
Related National Policy	The NHS Long Term Plan (2019) NHS Long Term Plan NHS England (2018) NHS manual for prescribed specialist services (2018/2019) Department of Health, NHS Outcomes Framework 2016-2017 (2016) Domains 1 and 2

Questions for consultation

Where do you consider rucaparib will fit into the existing care pathway for relapsed platinum-sensitive epithelial ovarian, fallopian tube and peritoneal cancer?

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 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 is considering evaluating this technology through its cost comparison evaluation process.
Please provide 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-tehnology-appraisal-guidance/changes-to-health-technology-evaluation).

Technologies can be evaluated through the cost-comparison process if they are expected to provide similar or greater health benefits, at a similar or lower cost, compared with technologies that have been previously recommended (as an option) in published NICE guidance for the same indication. Companies can propose cost-comparison topics to NICE at any stage during topic selection and scoping. NICE will route technologies for evaluation through the cost-comparison process if it is agreed during scoping that the process is an appropriate route to establish the clinical and cost effectiveness of the technology.

NICE's health technology evaluations: the manual states the methods to be used where a cost comparison case is made.

- Is the technology likely to be similar in its clinical effectiveness and resource use to any of the comparators? Or in what way is it different to the comparators?
- Will the intervention be used in the same place in the treatment pathway as the comparator(s)? Have there been any major changes to the treatment pathway recently? If so, please describe.
- Will the intervention be used to treat the same population as the comparator(s)?
- Overall is the technology likely to offer similar or improved health benefits compared with the comparators?
- Would it be appropriate to use the cost-comparison methodology for this topic?

References

1. Patient (2020). Ovarian Cancer 2020. Accessed August 2023.

2. Office for National Statistics (2017). Cancer Registration Statistics, England 2017. August January 2023.

3. Office for National Statistics (2017) Death Registrations Summary Tables – England and Wales. Accessed August 2023.

4. Office for National Statistics (2019). Cancer survival in England - adults and children diagnosed. 2013 to 2017 and followed up to 2018. Accessed August 2023.

Appendix B