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)

Final scope

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	At least 1 of the following treatments, according to NICE guidance: • Niraparib • Olaparib (only for people who have a BRCA mutation)

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	This technology has been selected to be appraised as a cost-comparison. The time horizon should be sufficient to reflect any differences in costs 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 and comparator 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

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.