NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Appraisal

Olaparib for maintenance treatment of recurrent, platinum-sensitive ovarian, fallopian tube and peritoneal cancer that has responded to platinum-based chemotherapy (CDF review of technology appraisal 620)

Draft scope

Remit/appraisal objective

To appraise the clinical and cost effectiveness of olaparib within its marketing authorisation for maintenance treatment of recurrent, platinum-sensitive ovarian, fallopian tube and 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. 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 and average age at diagnosis is 65 years.[1] In 2017, 6,236 people were diagnosed with ovarian cancer in England.[2] The 5-year survival for women diagnosed with ovarian cancer between 2013 and 2017, in England was 42.9% for all stages and 26.9% for stage 3 and 13.4% for stage 4 cancer respectively.[3] 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, platinum-resistant (disease which relapses within 6 months of completion of platinum-based chemotherapy) and platinum-refractory (disease 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.

In addition, NICE technology appraisal 620 (TA620) 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 3 or more

courses of platinum-based chemotherapy. TA620 also recommends olaparib for use in the cancer drugs fund 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 courses of platinum-based chemotherapy. This latter recommendation is the subject of this partial review of TA620.

The technology

Olaparib (Lynparza; AstraZeneca) is a poly-ADP-ribose polymerase (PARP) inhibitor which inhibits PARP proteins involved in DNA repair. It is administered orally.

Olaparib has a marketing authorisation in the UK for as monotherapy for 'the maintenance treatment of adult patients with advanced (FIGO stages III and IV) BRCA1/2-mutated (germline and/or somatic) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy.'

Intervention	Olaparib
Population	People who have relapsed, BRCA-mutated, platinum-sensitive high-grade epithelial ovarian, fallopian tube or peritoneal cancer that is in response (complete or partial) to the second course of platinum-based chemotherapy
Comparators	• Routine surveillance • Niraparib (subject to ongoing appraisal)
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) • 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. 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 and NICE Pathways	**Related Technology Appraisals:** Olaparib for maintenance treatment of relapsed platinum-sensitive ovarian, fallopian tube or peritoneal cancer (2020) NICE technology appraisal guidance 620. To be partially reviewed in this appraisal Niraparib for maintenance treatment of relapsed, platinum-sensitive ovarian, fallopian tube and peritoneal cancer (2018) NICE technology appraisal guidance 528. Currently under review Rucaparib for maintenance treatment of relapsed platinum-sensitive ovarian, fallopian tube or peritoneal cancer (2019) NICE technology appraisal guidance 611. Review date TBC Topotecan, pegylated liposomal doxorubicin hydrochloride, paclitaxel, trabectedin and gemcitabine for treating recurrent ovarian cancer (2016) NICE technology appraisal guidance 389. Review date TBC. Bevacizumab in combination with gemcitabine and carboplatin for treating the first recurrence of platinum-sensitive advanced ovarian cancer (2013) NICE technology appraisal guidance 285. Reviewed May 2013, guidance on static list. **Appraisals in development** Niraparib for maintenance treatment of relapsed, platinum-sensitive ovarian, fallopian tube and peritoneal cancer (CDF review TA528) NICE technology appraisal guidance

	[ID1644]. Publication date TBC **Related Guidelines** Ovarian cancer: recognition and initial management (2011) NICE guideline CG122. Review date to be confirmed **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 (2018/2019) NHS manual for prescribed specialist services (2018/2019) Department of Health and Social Care, NHS Outcomes Framework 2016-2017: Domains 1,2. https://www.gov.uk/government/publications/nhs-outcomes-framework-2016-to-2017

Questions for consultation

The population specified above is the population for whom olaparib was recommended in the CDF in TA620. **Should the population be broadened to include people without a BRCA mutation?**

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

- Which treatments are considered to be established clinical practice in the NHS for relapsed, BRCA-mutated, platinum-sensitive high-grade epithelial ovarian, fallopian tube or peritoneal cancer that has responded to the second course of platinum-based chemotherapy?

Are the outcomes listed appropriate?

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

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 olaparib 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.

Do you consider olaparib to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)?

Do you consider that the use of olaparib can result in any potential significant and 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 Appraisal Committee to take account of these benefits.

To help NICE prioritise topics for additional adoption support, do you consider that there will be any barriers to adoption of this technology into practice? If yes, please describe briefly.

NICE intends to appraise this technology through its Single Technology Appraisal (STA) Process. We welcome comments on the appropriateness of appraising this topic through this process. (Information on the Institute's Technology Appraisal processes is available at http://www.nice.org.uk/article/pmg19/chapter/1-Introduction).

References

1. Patient (2016). Ovarian Cancer. Accessed January 2022.

2. Office for National Statistics (2017). Cancer registration statistics, England: 2017. Accessed January 2022.

3. Office for National Statistics (2019). Cancer survival in England - adults diagnosed. 2013 to 2017 dataset. Accessed January 2022.

