NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Appraisal

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

Draft scope

Draft remit/appraisal objective

To appraise the clinical and cost effectiveness of niraparib 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 (HGSC) 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 I to stage IV. Advanced ovarian cancer falls within stages III and IV; stage III denotes disease that is locally advanced and has spread outside the pelvis into the abdominal cavity and stage IV 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 or 2.

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.

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 III and 13.4% for stage IV cancer respectively.[3]

NICE technology appraisal guidance 55 recommends paclitaxel in combination with a platinum-based compound or platinum-based therapy alone (cisplatin or carboplatin) as alternatives for first-line chemotherapy (usually following surgery) in the treatment of ovarian cancer. NICE technology appraisal 598 recommends olaparib for use within the Cancer Drugs Fund as an option for the maintenance treatment of BRCA mutation-positive, advanced (International Federation of Gynaecology and Obstetrics [FIGO] stages III and IV), high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer that has responded to first-line platinum-based chemotherapy in adults.[a]

[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. NICE's position statement.

The technology

Niraparib (Zejula, GlaxoSmithKline) is a poly-ADP-ribose polymerase (PARP) inhibitor which inhibits PARP proteins involved in DNA repair. It is administered orally.

Niraparib does not have a marketing authorisation in the UK for the maintenance treatment after response to first-line platinum-based chemotherapy. It has been studied in a clinical trial as maintenance monotherapy, compared with placebo, in adults with advanced (FIGO stages III or IV) high-grade predominantly serous or endometrioid ovarian cancer, fallopian tube cancer or primary peritoneal cancer who have responded (completely or partially) to first-line platinum-based chemotherapy (neoadjuvant or adjuvant).

Niraparib has a marketing authorisation in the UK for the maintenance treatment of adult patients with platinum-sensitive relapsed high-grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy.

Intervention(s)	Niraparib
Population(s)	People with advanced ovarian, fallopian tube, or primary peritoneal cancer that has responded (complete or partial) to first-line platinum-based chemotherapy.
Comparators	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 • 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 patient access schemes for the intervention or comparator technologies will be taken into account.

Other considerations	If the evidence allows the following subgroups will be considered. These include: • subgroups by BRCA mutation status, and • subgroups by homologous recombination deficiency (HRD) status. 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 BRCA mutation-positive advanced ovarian, fallopian tube or peritoneal cancer after response to first-line platinum-based chemotherapy (2019) NICE technology appraisal guidance TA598. Review date December 2023. 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. Bevacizumab in combination with paclitaxel and carboplatin for first-line treatment of advanced ovarian cancer (2013) NICE technology appraisal guidance 284 Guidance on the use of paclitaxel in the treatment of ovarian cancer (2003) NICE technology appraisal guidance 55. Reviewed August 2015 Appraisals in development Olaparib with bevacizumab for maintenance treatment of advanced ovarian, fallopian tube or primary peritoneal cancer NICE technology appraisal guidance [ID1652]. Publication date TBC. Related Guidelines: Ovarian cancer: recognition and initial management (2011) NICE guideline CG122. Review date to be confirmed Tests in secondary care to identify people at high risk of ovarian cancer (2017) NICE diagnostics guidance 31 Related Quality Standards: Ovarian cancer (2012) NICE quality standard 18 Related NICE Pathways: Ovarian cancer (2019) NICE Pathway
Related National	The NHS Long Term Plan, 2019. NHS Long Term Plan

Policy	NHS England NHS manual for prescribed specialist services 2018/2019 (2018) 105. Specialist cancer services (adults) Department of Health, NHS Outcomes Framework 2016-2017 (2016) Domains 1 and 2

Questions for consultation

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

Are the outcomes listed appropriate?

Are the subgroups suggested in 'other considerations' appropriate? Are there any other subgroups of people in whom niraparib is expected to be more clinically effective and cost effective or other groups that should be examined separately?

Which treatments are considered to be established clinical practice in the NHS for advanced ovarian, fallopian tube and peritoneal cancer after response to first-line platinum-based chemotherapy?

Where do you consider niraparib will fit into the existing NICE pathway, Ovarian cancer ?

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 niraparib 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.

Do you consider niraparib 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 niraparib 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 September 2019.

2. Office for National Statistics (2017). Cancer registration statistics, England: 2017. Accessed September 2019.

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