National Institute for Health and Care Excellence

Single Technology Appraisal (STA)

Rucaparib for maintenance treatment of recurrent platinum-sensitive epithelial ovarian, fallopian tube and peritoneal cancer that has responded to platinum-based chemotherapy ID1435

Response to consultee and commentator comments on the draft remit and draft scope (pre-referral)

Please note: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

Comment 1: the draft remit

Section	Consultee/ Commentator	Comments [sic]	Action
Wording	Clovis Oncology	Yes, the wording of the remit reflects the relevant issues.	Comment noted. No action required.
	Target Ovarian Cancer	The draft remit/appraisal objective accurately sets out the group and technology under consideration.	Comment noted. No action required.
Timing Issues	Clovis Oncology	While there are some treatment options already available in current NHS practice for relapsed, platinum-sensitive ovarian cancer patients in the maintenance setting, these are currently restricted to certain patient cohorts. There is a group of patients for whom no effective maintenance treatment is currently available and so an early appraisal of rucaparib in this setting would be important.	Thank you for your comment. NICE aims to provide guidance to the NHS within 6 months of the date when the marketing authorisation for a technology is granted.

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	Ovacom	Currently no PARP inhibitors are available to non-BRCA mutated patients and those with BRCA mutations can only access Olaparib third line. Niraparib will not be routinely available. Rucaparib has the potential to offer maintenance treatment with progression free survival after first relapse. Women with ovarian cancer face a potentially life-limiting disease. Therefore, it is urgent that this technology is appraised	Thank you for your comment. NICE aims to provide guidance to the NHS within 6 months of the date when the marketing authorisation for a technology is granted.
	Target Ovarian Cancer	For women who do not have a BRCA1 or BRCA2 mutation the only drug, apart from chemotherapy, available for recurrent disease is niraparib (Zejula(R)), currently available on the Cancer Drugs Fund. There are no further treatments currently approved by NICE. For women who do have a BRCA1 or BRCA2 mutation and who have responded to the third or subsequent course of platinum based chemotherapy women can access olaparib (Lynparza(R)) which is currently under review.	Thank you for your comment. NICE aims to provide guidance to the NHS within 6 months of the date when the marketing authorisation for a technology is granted.
Additional comments on the draft remit	Clovis Oncology	None	Comment noted. No action required.

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	Clovis Oncology	To avoid any confusion around the niraparib indication, please consider changing the wording in paragraph 4 to reflect the maintenance nature of treatment, for example: *In addition, NICE technology appraisal 528 recommends niraparib for use within the Cancer Drugs Fund 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 germline BRCA mutation and have had 2 courses of platinum-based chemotherapy and people who do not have a germline BRCA mutation and have had 2 or more courses of platinum-based chemotherapy.*	Thank you for your comment. The scope has been revised accordingly.
	Target Ovarian Cancer	The information provided is accurate.	Comment noted. No action required.
	Ovarian Cancer Action	Consider highlighting the huge difference in five-year survival rates between stages one (90%) and four (4%). Consider attaching a figure to the number of ovarian cancers linked to BRCA gene mutations – currently around 15%. Worth mentioning that although Niraparib is approved regardless of BRCA status, it must be known either way whether or not the patient carries a mutation. So patient must have had genetic testing to be eligible for the drug.	Thank you for your comment. The scope aims to give a brief description of the technology and condition. More detailed information will be discussed as part of the appraisal.
The technology/ intervention	Clovis Oncology	Yes, the description of the technology is accurate.	Comment noted. No action required.

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	Target Ovarian Cancer	*Is the description of the technology or technologies accurate?* Yes.	Comment noted. No action required.
Population	Clovis Oncology	Yes. The population defined is in line with the anticipated marketing authorisation for rucaparib in the maintenance setting.	Comment noted. No action required.
	Target Ovarian Cancer	*Is the population defined appropriately? Are there groups within this population that should be considered separately?* Yes – as the scoping document identifies, some women (approximately 15 per cent) women with ovarian cancer carry a mutation in the BRCA1 or BRCA2 gene.	Comment noted. No action required.
Comparators	Clovis Oncology	Yes. The comparators listed are in line with established standard of care in current NHS practice. However, the inclusion of niraparib within the Cancer Drugs Fund (NICE TA528) is a recent advance in the ovarian cancer pathway of care that we believe should be acknowledged and taken into account in the appraisal of rucaparib. Because niraparib is now available in clinical practice across England for specific groups of ovarian cancer patients, it could be a relevant comparator to rucaparib in those patient populations.	Thank you for your comment. Niraparib was not deemed a relevant comparator as it is recommended for use within the Cancer Drugs Fund, and therefore does not reflect the established NHS practice in England, as described in the NICE method guide of technology appraisal
	Target Ovarian Cancer	*Is this (are these) the standard treatment(s) currently used in the NHS with which the technology should be compared? Can this (one of these) be described as 'best alternative care'?* Yes.	Comment noted. No action required.

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Outcomes	Clovis Oncology	Yes, these outcome measures capture the most important health benefits of the technology.	Comment noted. No action required.
	Ovacom	Yes, as long as health-related quality of life takes into account the psychological benefit of having maintenance therapy rather than routine surveillance. The time after treatment whereby women are under routine surveillance can be psychologically very hard to cope with. Having a choice of maintenance treatment and continued input from oncology teams offers a significant psychological benefit as well as physical health benefits.	Comment noted. No action required.
	Target Ovarian Cancer	Yes – it is important that indicators such as progression free survival and overall survival are taken in the context of few treatment advances in recent years for ovarian cancer. In particular the challenge of establishing overall survival data and the time this can take and using progression free survival as an interim proxy.	Comment noted. No action required.
	Ovarian Cancer Action	Include discussion on the ease of administration of Rucaparib – one pill, twice a day.	Thank you for your comment. The scope aims to give a brief description of the technology and condition. More detailed information will be discussed as part of the appraisal.
Economic analysis	Clovis Oncology	• A de novo partitioned survival economic model will be developed. • NICE DSU guidance will be used to guide the choice and implementation of the partitioned survival model.	Comment noted. No action required

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		• Health states in the model will be defined by survival and progression status (progression-free disease and progressed disease). • Health-state utility values will be informed by EQ-5D data from the ARIEL3 study and will be applied by progression status. Adverse event disutilities will be informed by the literature. • Costs will be considered from an NHS and Personal Social Services perspective. • The model will use a lifetime horizon in order to reflect all important differences in costs or outcomes between the technologies being compared. • The standard 3.5% discount rates will be used in the base case. • Sensitivity analyses will be performed to quantify structural and parameter uncertainty.	
	Target Ovarian Cancer	N/A	Comment noted. No action required
Equality and Diversity	Clovis Oncology	No equality concerns are foreseen.	Comment noted. No action required
	Target Ovarian Cancer	Ovarian cancer is more common in women over 50 and cancer is considered a disability under the Equality Act 2010. Therefore age, gender and disability are all relevant protected characteristics for the purpose of this appraisal.	Thank you for your comment. Although the prevalence of ovarian cancer is more common in women over the age of 50 this is not something that can be addressed in a technology appraisal.

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			The committee will consider the impact of any disability when it makes its recommendations..
Other considerations	Clovis Oncology	None	Comment noted. No action required
Innovation	Clovis Oncology	Rucaparib offers broad, universal coverage, that is, it is proven to be effective for patients with platinum-sensitive ovarian cancer, irrespective of BRCA mutation status.	Comment noted. Innovation will be considered by the appraisal committee when formulating its recommendations. No changes to the scope are needed.
	Ovacom	Women with ovarian cancer are most commonly diagnosed at stage III and therefore from the outset know that they have a high chance of recurrence. For women without a BRCA mutation, there are no PARP inhibitors routinely available. For women with a BRCA mutation, Olaparib is available only at third line. Thus once treatment for recurrence finishes women with ovarian cancer are in an extremely difficult position where they can feel they are left waiting for their disease to recur again. Having an available maintenance therapy for recurrent disease offers a further treatment option to extend progression free survival and also provides the psychological support of continued treatment and contact with oncology teams. It has the potential to significantly and substantially benefit quality of life for women with ovarian cancer both physically and psychologically to enable them to lead fulfilling lives between treatments.	Comment noted. Innovation will be considered by the appraisal committee when formulating its recommendations. No changes to the scope are needed.

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Questions for consultation	Clovis Oncology	*Where do you consider rucaparib will fit into the existing NICE pathway, ovarian cancer?* - Rucaparib will fit into the existing NICE pathway as a maintenance treatment following platinum-based chemotherapy at second- or later-line. This is aligned with the anticipated marketing authorisation and pivotal trial data. *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.* - We believe the STA process is the most appropriate appraisal route for rucaparib in line with NICE guidance on processes for assessing technologies (https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/process).	Comment noted. No action required
	Target Ovarian Cancer	*Comparators:* It is right that niraparib has not been included as a comparator as it is currently only available through the Cancer Drugs Fund. *Where do you consider rucaparib will fit into the existing NICE pathway, ovarian cancer?* Rucaparib could serve as an alternative to niraparib or olaparib.	Comment noted. No action required. Niraparib was not deemed a relevant comparator as it is recommended for use within the Cancer Drugs Fund, and therefore does not reflect the established NHS practice in England, as described in the NICE

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			method guide of technology appraisal
Additional comments on the draft scope	Clovis Oncology	None	Comment noted. No action required

The following consultees/commentators indicated that they had no comments on the draft remit and/or the draft scope

Department of Health and Social Care