National Institute for Health and Care Excellence

Health Technology Evaluation

Rucaparib for maintenance treatment of advanced ovarian, fallopian tube and peritoneal cancer after response to first-line platinum-based chemotherapy [ID5100]

Response to stakeholder organisation comments on the draft remit and draft scope

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 and proposed process

Section	Stakeholder	Comments [sic]	Action
Appropriateness of an evaluation and proposed evaluation route	AstraZeneca	AstraZeneca agree that the single technology appraisal (STA) process is the most appropriate route for this appraisal.	Thank you for your comment.
	Pharamaand	pharma& agree that a single technology appraisal is the correct route for evaluation for rucaparib in this indication.	Thank you for your comment.
Wording	AstraZeneca	No comments	Thank you.
	Pharamaand	No comments on the remit.	Thank you.

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	AstraZeneca	No comments	Thank you.
	Pharamaand	No comments.	Thank you.
Population	AstraZeneca	No comments	Thank you.
	Pharmaand	Yes, pharma& agrees that the following population is defined appropriately: People with advanced ovarian, fallopian tube, or primary peritoneal cancer that has responded (complete or partial) to first-line platinum-based chemotherapy.	Thank you for your comment.
Subgroups	AstraZeneca	AstraZeneca suggest that in addition to considering subgroups according to mutation status (i.e. patients with BRCA mutations, and those with HRD positive tumours), it is also important to consider subgroups according to the induction chemotherapy regimen received by patients (i.e. whether they received platinum-based chemotherapy alone, or whether they additionally received bevacizumab in the induction setting). Please see below section on “comparators” for further details and rationale.	Thank you for your comment. The comparators section of the scope has been updated to reflect the treatments available according to induction treatment.
Comparators	AstraZeneca	AstraZeneca broadly agrees with the proposed list of 4 comparators, but feel that the subgroups relevant to each comparator should be more accurately defined. It is important to note that there are key differences in the patients eligible for the SOLO-1 and PAOLA-1 regimens (olaparib monotherapy and olaparib+bevacizumab combination therapy respectively) in terms of both	Thank you for your comment. The comparators section of the scope has been updated to reflect the treatments available according to induction treatment.

Section	Consultee/ Commentator	Comments [sic]	Action
		their mutation status as well as the up-front induction chemotherapy regimens they received: • In the SOLO-1 trial, the eligibility criteria specified that patients had a ***BRCA1/2*** mutation. Patients must also have received induction with platinum-based chemotherapy ***alone.***[1] • The PAOLA-1 regimen is recommended for patients with a ***HRD positive tumour***. In the PAOLA-1 trial, eligibility criteria also specified that patients must have received induction with platinum-based chemotherapy ***in combination with bevacizumab.***[2] The relevant NICE recommendations reflect these differences.[3,4] Through discussion with clinicians, AstraZeneca understands that clinicians tend to offer induction bevacizumab in a distinct group of patients, particularly those who have stage IV disease, or sub-optimal debulking during primary cytoreductive surgery, aligned to the patient group who demonstrated an OS (overall survival) benefit in the ICON7 trial.[5] This therefore represents a distinct subgroup of patients who would be expected to have a different prognosis compared to patients in whom clinicians decided to offer platinum-based chemotherapy alone. For this reason, AstraZeneca suggests that the most appropriate comparators for this appraisal are: • Olaparib monotherapy (if BRCA mutation-positive, *for patients whose induction chemotherapy was platinum-based chemotherapy alone*) • Olaparib plus bevacizumab (if HRD-positive, *for patients whose induction chemotherapy was platinum-based chemotherapy in combination with bevacizumab*)	

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		• Bevacizumab monotherapy at a dose of 7.5mg/kg Routine surveillance	
	Target Ovarian Cancer	Niraparib from the 1st line of treatment should be considered as other comparators are also available in the Cancer Drugs Fund	Thank you for your comment. The comparators included in the scope which are available in the Cancer Drugs Fund are currently undergoing review and therefore may be available within routine commissioning (subject to NICE evaluation) before the appraisal committee meeting for this evaluation. If these technologies were available within routine commissioning at this point, they may be appropriate comparators and therefore have been included in the scope. Based on the timings of review of TA673, niraparib will not be available within routine commissioning for this population within the timeframe for this evaluation. It is therefore not a relevant comparator.

Section	Consultee/ Commentator	Comments [sic]	Action
	Pharmaand	pharma& is currently assessing the relevant comparators of choice.	Thank you for your comment.
Outcomes	AstraZeneca	No comments	Thank you.
	Pharmaand	No comments	Thank you.
Equality	AstraZeneca	No comments	Thank you.
	Pharmaand	No equality issues are envisaged from the proposed remit and scope.	Thank you for your comment.
Other considerations	AstraZeneca	No comments	Thank you.
	Pharmaand	No comments	Thank you.
Questions for consultation	AstraZeneca	No comments	Thank you.
	Target Ovarian Cancer	**Where do you consider rucaparib will fit into the existing pathway for advanced ovarian cancer?** There are currently no maintenance treatments available in the routine commissioning from the first line of treatments. Of the options in the Cancer Drugs Fund only one- niraparib- is available for those who do not have a genetic mutation (BRCA or HRD) meaning around 50 per cent of the eligible patient population do not have a choice of treatment and will be unable to use an alternate treatment if they are not able to tolerate side effects	Thank you for your comment.

Section	Consultee/ Commentator	Comments [sic]	Action
	Pharmaand	*Where do you consider rucaparib will fit into the existing care pathway for advanced ovarian, fallopian tube and peritoneal cancer?* • In the current clinical pathway of care for patients with ovarian, fallopian tube and peritoneal cancer who have responded to first-line platinum-based chemotherapy in NHS England, maintenance treatment in the form of olaparib is available under a managed access agreement for patients with BRCA mutation.[4] • Patients with ovarian, fallopian tube and peritoneal cancer that is associated with HRD who have responded to first-line platinum-based chemotherapy plus bevacizumab can receive maintenance treatment in the form of olaparib plus bevacizumab under a managed access agreement.[5] • Within this treatment setting rucaparib would provide an individual PARP inhibitor maintenance option with a different profile compared to other PARP inhibitor, thereby allowing clinicians to individualise patient therapy and select the most suitable PARP inhibitor.[3,6,7] *Would rucaparib be used after both first-line platinum-based chemotherapy with bevacizumab and first-line platinum-based chemotherapy alone*? • Yes, it is anticipated that rucaparib would be used after both first-line platinum-based chemotherapy with bevacizumab and first-line platinum-based chemotherapy alone. *Would rucaparib be a candidate for managed access?* • Rucaparib is a candidate for managed access in this population because of immature trial data of ATHENA.	Thank you for your comment.

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		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? • Costs, resource use (i.e., staff time equipment use) and patient burden (i.e., time spent travelling to and from clinics and time spent waiting at home for monitoring visits) associated with frequent monitoring would not be captured in a cost-effectiveness analysis. *Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits*. A reduction in patient and caregiver burden associated with travelling to clinics and waiting for monitoring visits is inferred from the lack of weekly blood counts required for patients treated with rucaparib.[3]	

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

Ovarian Cancer Action

Ovacome