

National Institute for Health and Care Excellence

Single Technology Appraisal (STAMTA)

Olaparib for maintenance treatment of BRCA-mutated ovarian, fallopian tube and peritoneal cancer after response to first-line platinum-based chemotherapy ID1124


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	AstraZeneca UK	No comment	-
Timing Issues	AstraZeneca UK	EMA approval for olaparib in the proposed population is anticipated [REDACTED]	Thank you for your comment. No action needed.
	Ovacome	Most women are diagnosed at a late stage and survival rates are poor. There is currently no maintenance treatment available following first line treatment. Women with ovarian cancer face a potentially life-limiting disease. Therefore, it is urgent that this technology is appraised.	Thank you for your comment. The dates of the expected marketing authorisation were taken into account when the topic was planned into the work programme.
Additional comments on the draft remit	AstraZeneca UK	No comment	-

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	AstraZeneca UK	Please note that olaparib is also currently being appraised for use in patients with platinum-sensitive relapsed ovarian, fallopian tube or primary peritoneal cancer (ID1296)	Thank you for your comment. No action needed.
	Ovarian Cancer Action	All accurate. Consider adding survival rates at each stage when talking about the stage of diagnosis, and a figure to “most people are diagnosed with advanced stage disease”	Thank you for your comments. Scope includes only a brief description of the relevant disease area, it will be considered in detail during the appraisal.
The technology/ intervention	AstraZeneca UK	Please update the section on marketing authorisation. Olaparib tablets are indicated for use as monotherapy 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.	Thanks you for your comment. The wording has been updated.
Population	AstraZeneca UK	To avoid ambiguity around the proposed use of olaparib, we suggest referring to “ first line ” platinum-based chemotherapy, instead of “ initial ” platinum-based chemotherapy. The anticipated EMA licence for olaparib tablets is as follows: 	Thank you for your comment. The scope has been updated.

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Comparators	AstraZeneca UK	<p>Routine surveillance is the appropriate comparator for this appraisal of olaparib, as no other maintenance therapies are currently available for the proposed patient population.</p> <p>Bevacizumab is not an appropriate comparator for olaparib as it is not recommended for routine use within the NHS in the proposed population. Bevacizumab is only available in England and Wales for use in a different clinical setting (combination with platinum-based chemotherapy) in a subgroup of patients with sub-optimally debulked advanced disease.</p>	Thank you for your comment. No action needed.
Outcomes	AstraZeneca UK	No comment	-
	Ovarian Cancer Action	Health related quality of life outcome could be expanded upon as this is a vital outcome. Specifically mentioning the impact that significantly reduced hospital visits has, and the ability to take the drug in pill format at home cannot be overstated.	Thank you for your comment. No action needed.
	Ovacome	Yes, as long as health-related quality of life takes into account the psychological benefit of having maintenance therapy where none existed before. The time after first line 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.	Thank you for your comment. Innovation will be considered during the appraisal. No action needed.
Economic analysis	AstraZeneca UK	It is appropriate for the base case economic evaluation to exclude the costs of BRCA testing as no additional diagnostic testing costs are	Thank you for your comments. Germline BRCA testing is done routinely, however testing for somatic

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		<p>anticipated if olaparib is recommended for the proposed patient population.</p> <p>BRCA testing is already considered standard of care in routine UK clinical practice (see NICE Guidelines for recognition and initial management of ovarian cancer [CG122] and NICE Guidelines for familial breast cancer [CG164]).</p>	BRCA mutations is not. No action needed.
Equality and Diversity	AstraZeneca UK	No equality issues are expected to arise from this appraisal.	Thank you for your comment. No action needed.
Other considerations	AstraZeneca UK	No comment	-
Innovation	AstraZeneca UK	Yes. Olaparib is the first PARP inhibitor to be investigated as a first line maintenance treatment for women with BRCA-mutated advanced ovarian, fallopian tube or primary peritoneal cancer. No other maintenance therapies are currently available for the proposed patient population. Instead, patients receive routine surveillance (i.e. watch and wait).	Thank you for your comments. No action needed.
	Ovacome	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. Thus once treatment finishes they are in an extremely difficult position where they can feel they are left waiting for their disease to recur. Having an available maintenance therapy offers a further treatment option to maximise wellness between treatments, extend progression free survival and also provide the psychological support of continued treatment and contact with oncology teams. It has the potential to significantly and substantially benefit quality of life for	Thank you for your comments. No action needed.

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		women with ovarian cancer both physically and psychologically to enable them to lead fulfilling lives between treatments.	
Questions for consultation	AstraZeneca UK	No comment	-

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