

## National Institute for Health and Care Excellence

## Health Technology Evaluation

## Niraparib for maintenance treatment of advanced ovarian, fallopian tube and peritoneal cancer after response to first-line platinum-based chemotherapy (review of TA673) [ID6403]

## 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	Ovarian Cancer Action	Feedback from patients tells us that having access to niraparib as an option at first line is very important to them, and offers hope to women with ovarian cancer and their families. As such we agree it is vital to review this provision to ensure future patients have the greatest number of options open to them.	Thank you for your comment. No action required.
	GlaxoSmithKline UK Limited	<p>Patients with ovarian cancer have poor survival outcomes,<sup>1-3</sup> high relapse rates,<sup>4,5</sup> diminished quality of life,<sup>6,7</sup> and limited treatment options for maintenance therapy following first-line treatment regardless of mutation status.<sup>8-10</sup></p> <p>Niraparib provides a crucial option for maintenance therapy, addressing the unmet need for a treatment that can maintain disease control following initial platinum-based chemotherapy.</p> <p>GSK agree that a single technology appraisal is the correct route for evaluation of niraparib.</p>	Thank you for your comment. No action required.

Section	Stakeholder	Comments [sic]	Action
		<p>Oberaigner W, Minicozzi P, Bielska-Lasota M, et al. Survival for ovarian cancer in Europe: the across-country variation did not shrink in the past decade. <i>Acta Oncol.</i> Apr 2012;51(4):441-53. doi:10.3109/0284186x.2011.653437</p> <p>2. Cabasag CJ, Arnold M, Rutherford M, et al. Shifting incidence and survival of epithelial ovarian cancer (1995-2014): A SurvMark-2 study. <i>Int J Cancer.</i> May 1 2023;152(9):1763-1777. doi:10.1002/ijc.34403</p> <p>3. International Agency for Research on Cancer. Global Cancer Observatory: Cancer Today. Accessed 14 March 2025, 2025. <a href="https://gco.iarc.fr/today/en">https://gco.iarc.fr/today/en</a></p> <p>4. National Cancer Institute. Ovarian Epithelial, Fallopian Tube, and Primary Peritoneal Cancer Treatment (PDQ®)—Health Professional Version. Updated 12 February 2025. Accessed 2025, 17 March 2025.</p> <p>5. Berek JS, Renz M, Kehoe S, Kumar L, Friedlander M. Cancer of the ovary, fallopian tube, and peritoneum: 2021 update. <i>Int J Gynaecol Obstet.</i> Oct 2021;155 Suppl 1(Suppl 1):61-85. doi:10.1002/ijgo.13878</p> <p>6. Tookman L, Green C, Leonard K, et al. Diagnosis, treatment and burden in advanced ovarian cancer: a UK real-world survey of healthcare professionals and patients. <i>Future Oncol.</i> 2024;20(23):1657-1673. doi:10.1080/14796694.2024.2358742</p> <p>7. Matulonis UA, Kornblith A, Lee H, et al. Long-term adjustment of early-stage ovarian cancer survivors. <i>Int J Gynecol Cancer.</i> Nov-Dec 2008;18(6):1183-93. doi:10.1111/j.1525-1438.2007.01167.x</p> <p>8. National Institute for Health and Care Excellence. Olaparib for maintenance treatment of BRCA mutation-positive advanced ovarian, fallopian tube or peritoneal cancer after response to first-line platinum-based chemotherapy. Technology appraisal guidance [TA962]. 2024. 28 March 2024.</p>	

National Institute for Health and Care Excellence

Page 2 of 10

Consultation comments on the draft remit and draft scope for the technology appraisal of Niraparib for maintenance treatment of advanced ovarian, fallopian tube and peritoneal cancer after response to first-line platinum-based chemotherapy (review of TA673) [ID6403]

Issue date:

May 2025

Section	Stakeholder	Comments [sic]	Action
		<p>9. National Institute for Health and Care Excellence. Olaparib with bevacizumab for maintenance treatment of advanced high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer. Technology appraisal guidance [TA962]. 2024. 17 January 2024.</p> <p>10. National Institute for Health and Care Excellence. Rucaparib for maintenance treatment of advanced ovarian, fallopian tube and peritoneal cancer after response to first-line platinum-based chemotherapy [ID5100]. Final Draft Guidance. 2025. February 2025.</p>	
Wording	Target Ovarian Cancer	<p>[Does the wording of the remit reflect the issue(s) of clinical and cost effectiveness about this technology or technologies that NICE should consider? If not, please suggest alternative wording.]</p> <p>Yes</p>	Thank you for your comment. No action required.
	GlaxoSmithKline UK Limited	The wording of the remit reflects the proposed issues of clinical and cost effectiveness that NICE should consider.	Thank you for your comment. No action required.
Timing issues	Ovarian Cancer Action	As soon as possible so as to ensure the greatest number of options for future patients.	Thank you for your comment. This appraisal has been scheduled into the technology appraisal work programme. No action required.

Section	Stakeholder	Comments [sic]	Action
	GlaxoSmithKline UK Limited	<p>Advanced ovarian cancer, the stage most patients are diagnosed,<sup>5,11</sup> remains incurable for the majority patients within the current treatment landscape, with approximately 80% experiencing disease recurrence and progression after standard first-line chemotherapy treatment.<sup>4,5</sup> Initially, most patients respond to systemic treatment with platinum-based chemotherapy, but its effectiveness decreases with each subsequent round, leading to reduced benefit for patients as a result of treatment resistance and increased toxicities.<sup>12</sup></p> <p>A key prognostic factor for epithelial ovarian cancer is BRCA/HRD status and most options for maintenance therapies are limited to a subset of patients based on biomarker status (HRD, HRp, BRCA, BRCAwt).<sup>8-10,13</sup></p> <p>Currently niraparib is recommended in the Cancer Drugs Fund (CDF) as a maintenance treatment for advanced (Federation of Gynecology and Obstetrics [FIGO] stages III and IV) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer after response to first-line platinum-based chemotherapy in adults, irrespective of the biomarker status.<sup>14</sup></p> <p>GSK believes that continued access to this therapy is in the best interest of patients and healthcare professionals.</p> <p>4. National Cancer Institute. Ovarian Epithelial, Fallopian Tube, and Primary Peritoneal Cancer Treatment (PDQ®)–Health Professional Version. Updated 12 February 2025. Accessed 2025, 17 March 2025.</p> <p>5. Berek JS, Renz M, Kehoe S, Kumar L, Friedlander M. Cancer of the ovary, fallopian tube, and peritoneum: 2021 update. Int J Gynaecol Obstet. Oct 2021;155 Suppl 1(Suppl 1):61-85. doi:10.1002/ijgo.13878</p>	Thank you for your comment. No action required.

Section	Stakeholder	Comments [sic]	Action
		<p>8. National Institute for Health and Care Excellence. Olaparib for maintenance treatment of BRCA mutation-positive advanced ovarian, fallopian tube or peritoneal cancer after response to first-line platinum-based chemotherapy. Technology appraisal guidance [TA962]. 2024. 28 March 2024.</p> <p>9. National Institute for Health and Care Excellence. Olaparib with bevacizumab for maintenance treatment of advanced high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer. Technology appraisal guidance [TA962]. 2024. 17 January 2024.</p> <p>10. National Institute for Health and Care Excellence. Rucaparib for maintenance treatment of advanced ovarian, fallopian tube and peritoneal cancer after response to first-line platinum-based chemotherapy [ID5100]. Final Draft Guidance. 2025. February 2025.</p> <p>11. Cortez AJ, Tudrej P, Kujawa KA, Lisowska KM. Advances in ovarian cancer therapy. Cancer Chemother Pharmacol. Jan 2018;81(1):17-38. doi:10.1007/s00280-017-3501-8</p> <p>12. Lord R, Rauniyar J, Morris T, et al. Real world outcomes in platinum sensitive relapsed ovarian, fallopian tube, or peritoneal cancer treated in routine clinical practice in the United Kingdom prior to poly-ADP ribose polymerase inhibitors. Int J Gynecol Cancer. Jul 2020;30(7):1026-1033. doi:10.1136/ijgc-2019-000973</p>	

National Institute for Health and Care Excellence

Page 5 of 10

Consultation comments on the draft remit and draft scope for the technology appraisal of Niraparib for maintenance treatment of advanced ovarian, fallopian tube and peritoneal cancer after response to first-line platinum-based chemotherapy (review of TA673) [ID6403]

Issue date:

May 2025

Section	Stakeholder	Comments [sic]	Action
		<p>13. Chase D, Perhanidis J, Gupta D, Kalilani L, Golembesky A, González-Martín A. Association of Multiple High-Risk Factors on Observed Outcomes in Real-World Patients With Advanced Ovarian Cancer Treated With First-Line Therapy. JCO Clin Cancer Inform. Jun 2023;7:e2200189. doi:10.1200/cci.22.00189</p> <p>14. NHS England. National Cancer Drugs Fund List. 14 March 2025 2025;</p>	
Any additional comments on the draft remit	GlaxoSmithKline UK Limited	No additional comments	Thank you for your comment. No action required.

**Comment 2: the draft scope**

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	GlaxoSmithKline UK Limited	<p>The recent NICE appraisal for rucaparib (ID5100) is not included in the background information. According to the final draft guidance, rucaparib is expected to be recommended as an option for the maintenance treatment of advanced (FIGO stages III and IV) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer after complete or partial response to first-line platinum-based chemotherapy in adults, only for HRd BRCAwt or non-HRD (HRp or HRunknown) for whom bevacizumab is not a treatment option because:</p> <p>1. NHS England's BEV3 and BEV10 and commissioning approval criteria for receiving it are not met or</p>	<p>Thank you for your comment.</p> <p>The scope has been updated to include rucaparib as a comparator.</p>

Section	Consultee/ Commentator	Comments [sic]	Action
		2. It is contraindicated or not tolerated. <sup>10</sup> The final guidance for the rucaparib appraisal is expected to be published imminently (April 2025)	
Population	Target Ovarian Cancer	[Is the population defined appropriately?] Yes	Thank you for your comment. No action required.
	GlaxoSmithKline UK Limited	No comment	Thank you for your comment. No action required.
Subgroups	Target Ovarian Cancer	The subgroups suggested are appropriate but given the recent approval of rucaparib in this setting for those who have are HRD positive but do not have a BRCA mutation should this group also be included?	Thank you for your comment.  The scope has been updated to include rucaparib as a comparator. BRCA mutation status and HRD status are listed as subgroups in the scope, to be considered if the evidence allows.
	GlaxoSmithKline UK Limited	No comment	Thank you for your comment. No action required.

Section	Consultee/ Commentator	Comments [sic]	Action
Comparators	Target Ovarian Cancer	[Are the comparators listed considered to be the standard treatments currently used in the NHS with which the technology should be compared? Have all relevant comparators been included?] Yes	Thank you for your comment. No action required.
	GlaxoSmithKline UK Limited	<p>Poly(ADP-ribose) polymerase (PARP) inhibitors are widely seen as the standard of care for the first-line maintenance treatment of advanced ovarian cancer patients, irrespective of their biomarker status.<sup>5,15</sup> PARP inhibitors are also recommended for routine commissioning in the NHS for the first-line maintenance treatment of advanced ovarian cancer patients across all biomarker subgroups, with specific PARP inhibitors approved for particular subgroups.<sup>8-10</sup></p> <p>Rucaparib is expected to be (ID5100) recommended for patients with HRd BRCAwt and non-HRD (HRp and HRunknown).<sup>10</sup> GSK note the information for rucaparib should be updated based on the recent NICE appraisal (ID5100; see background section).</p> <p>In the rucaparib appraisal (ID5100), niraparib was identified as the standard of care in the non-HRD (HRp and HRunknown) population however, it was not included as a comparator as it was only available via the CDF.<sup>10</sup> Instead, routine surveillance was considered the standard treatment in this setting.<sup>10</sup></p> <p>GSK does not consider routine surveillance to be a relevant comparator for evaluating niraparib, given that rucaparib is now available for routine commissioning as a first-line maintenance therapy for non-HRD patients.<sup>10</sup></p> <p>5. Berek JS, Renz M, Kehoe S, Kumar L, Friedlander M. Cancer of the ovary, fallopian tube, and peritoneum: 2021 update. <i>Int J Gynaecol Obstet</i>. Oct 2021;155 Suppl 1(Suppl 1):61-85. doi:10.1002/ijgo.13878</p> <p>8. National Institute for Health and Care Excellence. <i>Olaparib for maintenance treatment of BRCA mutation-positive advanced ovarian</i>,</p>	Thank you for your comment. The comparator and background section has been updated to include rucaparib. The list of comparators is kept inclusive at this stage. The company will have the opportunity during the evaluation to outline which comparators it considers to be most relevant.



Section	Consultee/ Commentator	Comments [sic]	Action
		<p><i>fallopian tube or peritoneal cancer after response to first-line platinum-based chemotherapy. Technology appraisal guidance [TA962]. 2024. 28 March 2024.</i></p> <p>9. National Institute for Health and Care Excellence. <i>Olaparib with bevacizumab for maintenance treatment of advanced high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer. Technology appraisal guidance [TA962]. 2024. 17 January 2024.</i></p> <p>10. National Institute for Health and Care Excellence. <i>Rucaparib for maintenance treatment of advanced ovarian, fallopian tube and peritoneal cancer after response to first-line platinum-based chemotherapy [ID5100]. Final Draft Guidance. 2025. February 2025.</i></p> <p>15. González-Martín A, Harter P, Leary A, et al. Newly diagnosed and relapsed epithelial ovarian cancer: ESMO Clinical Practice Guideline for diagnosis, treatment and follow-up. <i>Ann Oncol.</i> Oct 2023;34(10):833-848. doi:10.1016/j.annonc.2023.07.011</p>	
Outcomes	GlaxoSmithKline UK Limited	No comment	Thank you for your comment. No action required.
Equality	GlaxoSmithKline UK Limited	GSK do not envisage any equality issues arising from the proposed remit and scope	Thank you for your comment. No action required.
Other considerations	GlaxoSmithKline UK Limited	No comment	Thank you for your comment. No action required.

Section	Consultee/ Commentator	Comments [sic]	Action
Questions for consultation	Target Ovarian Cancer	<p><i>Do you consider that the use of niraparib can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?</i></p> <p>Nirpariab is taken at home in pill form meaning that patients do not need to attend hospital to access the treatment. This means that they may be able to return to normal activities including work and caring responsibilities and this is not captured in the QALY.</p>	Thank you for your comment. The committee will consider the impact of any potential substantial health-related benefits that are unlikely to be included in the QALY calculation during the technology evaluation process. No action required.
	GlaxoSmithKline UK Limited	No comment	Thank you for your comment. No action required.
Additional comments on the draft scope	GlaxoSmithKline UK Limited	No comments	Thank you for your comment. No action required.

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

Not applicable