National Institute for Health and Care Excellence

Health Technology Evaluation

Pembrolizumab with chemotherapy with or without bevacizumab for treating platinum-resistant recurrent ovarian cancer after 1 or 2 treatments [ID6363]

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	MSD UK	MSD consider it appropriate to refer the topic to NICE for evaluation through the Single Technology Appraisal route.	Thank you for your comment. No action required.
	Abbvie	AbbVie agree that the technology should be appraised through the single technology appraisal process.	Thank you for your comment. No action required
Wording	MSD UK	MSD consider the suggested wording to be appropriate.	Thank you for your comment. No action required.
	Abbvie	The wording of the remit reflects the issues of clinical and cost-effectiveness about this technology.	Thank you for your comment.

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			No action required.
Timing issues	MSD UK	Over the past decade, no new treatment option has become available for platinum-resistant ovarian cancer. Patients with ovarian cancer that is platinum-resistant have poor prognosis, with median OS typically ranging from ~9–12 months (https://www.nice.org.uk/guidance/ta389). There is a high unmet need for new treatments that reduce the risk of progression and improve survival outcomes. MSD consider that the current appraisal should be carried out in line with current NICE scheduling, to allow timely patient access after the intervention has obtained regulatory approval for use in the indicated population.	Thank you for your comment. NICE has scheduled this topic into its work programme. This will be appraised within its marketing authorisation. For further details, please see the NICE website: https://www.nice.org.uk/guidance/indevelopment/gid-ta11422
	Ovarian Cancer Action	Additional treatment options for ovarian cancer patients who face recurrence are vital. With ovarian cancer cases set to rise over the coming decades, we support any and all effective options for platinum resistant patients being assessed in a timely manner.	Thank you for your comment. NICE has scheduled this topic into its work programme. This will be appraised within its marketing authorisation. For further details, please see the NICE website: https://www.nice.org.uk/guidance/indevelopment/gid-ta11422

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	MSD UK	The background information is accurate.	Thank you for your comment.
	Abbvie	AbbVie note that based on the percentage of patients with ovarian cancer by stage at diagnosis as reported by the 2022 Cancer Registration Statistics, most patients were diagnosed at stages 3 and 4. This should be clarified in the background information which currently concludes the majority of patients are diagnosed in the early stages.[1] AbbVie believe it important to highlight the severe nature of platinum resistant ovarian cancer, given they experience the worst survival in patients with ovarian cancer with survival typically no more than 12 months.(2-6) Furthermore, in addition to the symptoms of ovarian cancer highlighted, the resulting significant negative impact on a patient's quality of life should be noted. References: 1. NHS Digital (2024). Cancer registration statistics 2022. Cancer incidence by stage. Figure 8: Percentage of staged cancers diagnosed for females by stage at diagnosis (stage 1 & 2 and stage 3 & 4), England, 2022. Accessed: 15 October 2025 2. Davis A, Tinker AV, Friedlander M. "Platinum resistant" ovarian cancer: what is it, who to treat and how to measure benefit? Gynecol Oncol. 2014;133(3):624-31. 3. 6. Xu K, Wang T, Pan S, He J. The efficacy and toxicity of mirvetuximab soravtansine, a novel antibody-drug conjugate, in the treatment of advanced or recurrent ovarian cancer: a meta-analysis. Expert Rev Clin Pharmacol. 2023;16(11):1141-52.	Thank you for your comment. The background section of the scope has been amended to remove reference to most diagnosis of ovarian cancer being in the early stages.

Section	Consultee/ Commentator	Comments [sic]	Action
		4. 7. Pujade-Lauraine E, Banerjee S, Pignata S. Management of Platinum-Resistant, Relapsed Epithelial Ovarian Cancer and New Drug Perspectives. J Clin Oncol. 2019;37(27):2437-48. 5. 8. Aghajanian C, Blank SV, Goff BA, Judson PL, Teneriello MG, Husain A, et al. OCEANS: a randomized, double-blind, placebo-controlled phase III trial of chemotherapy with or without bevacizumab in patients with platinum-sensitive recurrent epithelial ovarian, primary peritoneal, or fallopian tube cancer. J Clin Oncol. 2012;30(17):2039-45. 6. 9. Perren TJ, Swart AM, Pfisterer J, Ledermann JA, Pujade-Lauraine E, Kristensen G, et al. A phase 3 trial of bevacizumab in ovarian cancer. New England Journal of Medicine. 2011;365(26):2484-9 **7.** NICE. Mirvetuximab soravtansine for treating folate receptor alpha-positive platinum-resistant advanced epithelial ovarian, fallopian tube or primary peritoneal cancer [ID6442]. Available at: https://www.nice.org.uk/guidance/indevelopment/gid-ta11424. Accessed: 15 October 2025.	
	Ovarian Cancer Action	Please include that although most patients generally respond well to platinum-based chemotherapy, the majority will face recurrence after recurrence, with shorter and shorter time in between recurrences and end up with few options due to platinum resistance. Platinum resistance is a significant factor impacting overall survival of the disease. This means finding additional treatment options for this population is vital.	Thank you for your comment. The background section of the scope is not intended to be exhaustive and has included reference to recurrence of disease. No action required.
Population	MSD UK	MSD note that the defined population reflects the trial population enrolled into KEYNOTE-B96. [redacted]	Thank you for your comment. Since the

Section	Consultee/ Commentator	Comments [sic]	Action
		[redacted]	exact wording of the marketing authorisation is marked as confidential, the population in the draft scope has been left unchanged to maintain confidentiality. No changes to scope required.
	Abbvie (comparator)	The population is appropriately defined.	Thank you for your comment. No action required.
Subgroups	MSD UK (Company)	The subgroups specified in the NICE scope are: • Number of previous lines of therapy • Previous poly (ADP-ribose) polymerase inhibitor (PARPi) treatment • Previous bevacizumab use • PD-L1 status • BRCA status With the exception of BRCA status, MSD have evidence on clinical efficacy in the requested subgroups: BRCA status was not captured in KEYNOTE-B96. Additionally, all the available subgroup analyses were prespecified within the protocol for KEYNOTE-B96. Stratification factors at randomisation were: • planned bevacizumab use (yes vs no); • region (US vs EU vs ROW); and	Thank you for your comment. The subgroups have been kept inclusive to allow the committee to consider any subgroups it considers relevant. No action required.

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		• PD-L1 status (CPS <1 vs CPS 1 to <10 vs CPS ≥10).	
Comparators	MSD UK (Company)	MSD consider the comparators of pegylated liposomal doxorubicin hydrochloride (PLDH) monotherapy and paclitaxel monotherapy to be appropriate comparators for pembrolizumab plus paclitaxel, with or without bevacizumab. As indicated in the draft scope, mirvetuximab soravtansine (for folate receptor alpha-positive ovarian cancer) is currently under assessment by NICE, and, therefore, is deemed not to be a relevant comparator at this time.	Thank you for your comment. The comparators have been kept inclusive to allow for consideration of any comparators that may be recommended for use by NICE during the evaluation. No action required.
Outcomes	MSD UK (Company)	MSD consider the list of outcomes to be appropriate.	Thank you for your comment. No action required.
	Abbvie (comparator)	AbbVie considers the outcomes listed to be appropriate.	Thank you for your comment. No action required.
Equality	MSD UK (Company)	MSD consider that the proposed remit and scope do not impact Equality, as described in the Notes section.	Thank you for your comment. No action required.
Questions for consultation	MSD UK (Company)	*Where do you consider pembrolizumab with chemotherapy will fit into the existing care pathway for platinum-resistant recurrent ovarian cancer?*	Thank you for your responses to the consultation questions.

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		In line with the anticipated licensed indication, pembrolizumab in combination with paclitaxel, with or without bevacizumab, is expected to be a treatment option for [redacted]. *What chemotherapies would be used at this point in the pathway, and which chemotherapy regimens would be used in combination with pembrolizumab in this indication?* As per the draft scope, and recommendations from TA389 (https://www.nice.org.uk/guidance/ta389), paclitaxel and PLDH, given as monotherapies, are currently available treatment options at the stage in the pathway at which MSD is positioning pembrolizumab plus paclitaxel, and are, therefore appropriate comparators. As per KEYNOTE-B96, MSD anticipate that pembrolizumab will be used in combination with paclitaxel with or without bevacizumab, with bevacizumab being given at the discretion of the treating clinician. *Would best supportive care be a relevant comparator?* MSD do not consider best supportive care to be a relevant comparator. Patients likely to receive treatment with pembrolizumab plus paclitaxel are those who are fit enough to tolerate chemotherapy, and, thus, relevant alternative treatments available to those with platinum-resistant disease are paclitaxel and PLDH monotherapies. *Please select from the following, will pembrolizumab with chemotherapy be:* *A. Prescribed in primary care with routine follow-up in primary care* *B. Prescribed in secondary care with routine follow-up in primary care*	These have been considered while finalising the scope.

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		C. Prescribed in secondary care with routine follow-up in secondary care *D. Other (please give details).* Option C *Would pembrolizumab with chemotherapy be a candidate for managed access?* Given the maturity of the overall survival data derived from KEYNOTE-B96, which underpin MSD's application for reimbursement, MSD do not consider managed access to be an appropriate funding route for pembrolizumab with chemotherapy in platinum-resistant ovarian cancer. *Would pembrolizumab with chemotherapy be a candidate for managed access?* Given the maturity of the overall survival data derived from KEYNOTE-B96, which underpin MSD's application for reimbursement, MSD do not consider managed access to be an appropriate funding route for pembrolizumab with chemotherapy in platinum-resistant ovarian cancer. *Do you consider that the use of pembrolizumab with chemotherapy can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?* No. MSD do not anticipate that the use of pembrolizumab and chemotherapy will be associated with health-related benefits that are not captured by the QALY calculation. *Please indicate if any of the treatments in the scope are used in NHS practice differently than advised in their Summary of Product Characteristics. For*	

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		example, if the dose or dosing schedule for a treatment is different in clinical practice. If so, please indicate the reasons for different usage of the treatment(s) in NHS practice. If stakeholders consider this a relevant issue, please provide references for data on the efficacy of any treatments in the pathway used differently than advised in the Summary of Product Characteristics. As far as MSD is aware, in clinical practice, the relevant comparators of paclitaxel and PLDH monotherapy are administered in line with the dose and treatment schedule set out in their respective Summary of Product Characteristics (SmPCs). Considering the experimental arm of KEYNOTE-B96, for those patients receiving bevacizumab, the drug was administered at the dose and dosing schedule specified in the SmPC for the management of platinum-resistant recurrent ovarian cancer: • When given in combination with paclitaxel, 10 mg/kg of body weight given once every 2 weeks as an intravenous infusion (https://www.medicines.org.uk/emc/product/3885/smpc). In KEYNOTE-B96, paclitaxel was given at a dose of 80 mg/m^2 via intravenous infusion on Days 1, 8, and 15 of each 3-week cycle. The dosing schedule does not match that stipulated in the SmPC of for ovarian cancer of 175 mg/m² administered over 3 hours every 3 weeks (https://www.medicines.org.uk/emc/product/10076/smpc), but is an alternative schedule that is used in clinical practice in the UK for platinum-resistant ovarian cancer (https://www.northerncanceralliance.nhs.uk/wp-content/uploads/2018/11/Paclitaxel-Gynae-Protocol-CRP09-GY003-v1-4-2.pdf; https://www.uhs.nhs.uk/Media/UHS-website-2019/Docs/Chemotherapy-SOPs1/Ovarian-cancer/Paclitaxel-7-day.pdf).	

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		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 pembrolizumab with chemotherapy 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.* MSD do not anticipate any equality issues.	
	Abbvie	**Where do you consider pembrolizumab with chemotherapy will fit into the existing care pathway for platinum-resistant recurrent ovarian cancer?** Pembrolizumab with chemotherapy is expected to be used in line with the population in the draft remit i.e., in patients with platinum-resistant ovarian cancer, after 1 or 2 treatments. **What chemotherapies would be used at this point in the pathway, and which chemotherapy regimens would be used in combination with pembrolizumab in this indication?**	Thank you for your responses to the consultation questions. These have been considered while finalising the scope.

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		Non-platinum, single agent chemotherapies, such as paclitaxel and PLD are the current standard of care in this population. **Please select from the following, will pembrolizumab with chemotherapy be:** **A. Prescribed in primary care with routine follow-up in primary care** **B. Prescribed in secondary care with routine follow-up in primary care** **C. Prescribed in secondary care with routine follow-up in secondary care** **D. Other (please give details):** We would expect option C: prescribed in secondary care with routine follow-up in secondary care. **For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention.** We would not expect the setting to differ.	
Additional comments on the draft scope	MSD UK (Company)	Please find below a list of additional comments/suggestions on the draft scope: • Page 1: Suggest amending one of the sentences below to clarify whether most people are diagnosed with advanced stage of cancer, as suggested in the first sentence, versus early disease as inferred from the second sentence. ○ "*Most people are diagnosed once the cancer has progressed to an advanced stage. Recurrent ovarian cancer is when the cancer returns after primary treatment*".	Thank you for your comment. The scope has been amended to remove reference to most cases of ovarian cancer being diagnosed in the early stages.

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		○ "*In 2022, there were around 7,100 new cases of ovarian cancer in England, mostly in the early stages; around 3,200 of these new cases were diagnosed as stage 3 or 4 cancers*". • Page 1: For clarity, suggest adding a sentence to the text below to clarify that paclitaxel and pegylated liposomal doxorubicin are typically administered as monotherapies for those with platinum-resistant cancer, which would also reflect the comparators of interest specified in the draft scope. "*NICE technology appraisal guidance 389 recommends paclitaxel as monotherapy or in combination with platinum, and pegylated liposomal doxorubicin hydrochloride as monotherapy or in combination with platinum-based chemotherapy, for treating recurrent ovarian cancer*"**.**	
	Abbvie	AbbVie note the estimated publication date stated in the draft scope for mirvetuximab should be updated to March 2026, in line with the NICE website.[7] References: 7. NICE. Mirvetuximab soravtansine for treating folate receptor alpha-positive platinum-resistant advanced epithelial ovarian, fallopian tube or primary peritoneal cancer [ID6442]. Available at: https://www.nice.org.uk/guidance/indevelopment/gid-ta11424. Accessed: 15 October 2025.	Thank you for your comment. The estimated date of publication for the evaluation of mirvetuximab soravtansine has been amended in the scope.

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

Target Ovarian Cancer