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

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of pembrolizumab with chemotherapy with or without bevacizumab, within its marketing authorisation for treating platinum-resistant recurrent ovarian cancer after 1 or 2 treatments.

Background

Ovarian cancer is cancer that occurs in the ovary or fallopian tubes. The most common type, high-grade serous carcinoma, is thought to arise from the fallopian tube and presents after it has spread to the ovary. Ovarian cancer is classified from stage 1 to stage 4. Advanced ovarian cancer falls within stages 2 and 4; in stage 2 the disease has grown outside the ovaries but is still within the pelvic area, stage 3 denotes disease that has spread outside the pelvis into the abdominal cavity, and stage 4 denotes that distant metastasis to other body organs has occurred. Symptoms of ovarian cancer include bloating, pelvic pain, frequent urination, constipation, and loss of appetite. Most people are diagnosed once the cancer has progressed to an advanced stage. Recurrent ovarian cancer is when the cancer returns after primary treatment.

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.[1] The incidence of ovarian cancer increases with age, with rates being highest in women aged 75 to 79.[2] The overall 5-year survival rate for people diagnosed with ovarian cancer at any stage is 45%. People with early-stage ovarian cancer tend to have better survival outcomes. About 16% of people diagnosed with stage 4 ovarian cancer survive for 5 years or longer compared to around 95% diagnosed at stage 1.[3]

Treatment for ovarian cancer typically includes surgery followed by platinum-based chemotherapy. Some people may then be offered a maintenance treatment to delay or prevent the cancer coming back. If the cancer relapses within 6 months of completion of platinum-based chemotherapy, the cancer is defined as platinum-resistant. In people who relapse following initial platinum-based therapy, 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.

The technology

Pembrolizumab (Keytruda, Merck Sharp & Dohme) does not currently have a marketing authorisation in the UK for treating platinum-resistant recurrent ovarian, cancer after 1 or 2 treatments. It has been studied in a clinical trial in adults with

platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal carcinoma, who have received 1 or 2 prior lines of systemic therapy for ovarian cancer (including at least 1 prior platinum-based therapy). The clinical trial compared pembrolizumab plus paclitaxel with or without bevacizumab to placebo plus paclitaxel, with or without bevacizumab.

Intervention(s)	Pembrolizumab with chemotherapy (with or without bevacizumab)
Population(s)	Adults with platinum-resistant epithelial ovarian, fallopian tube, or peritoneal cancer, who have received 1 or 2 prior lines of systemic therapy for ovarian cancer (including at least 1 prior platinum-based therapy)
Subgroups	If the evidence allows the following subgroups will be considered: • Number of previous lines of therapy • Previous poly (ADP-ribose) polymerase inhibitor (PARPi) treatment • Previous bevacizumab use • PD-L1 status • BRCA status
Comparators	• Paclitaxel monotherapy • Pegylated liposomal doxorubicin hydrochloride (PLDH) monotherapy • Mirvetuximab soravtansine (for folate receptor alpha-positive cancer) (subject to NICE evaluation)
Outcomes	The outcome measures to be considered include: • overall survival • progression-free survival • response rate • adverse effects of treatment • health-related quality of life.

Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared. Costs will be considered from an NHS and Personal Social Services perspective. The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account. The availability and cost of biosimilar and generic products should be taken into account.
Other considerations	Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.
Related NICE recommendations	**Related technology appraisals:** Rucaparib for maintenance treatment of advanced ovarian, fallopian tube and peritoneal cancer after response to first-line platinum-based chemotherapy (2025) NICE technology appraisal guidance 1055. Olaparib for maintenance treatment of BRCA mutation-positive advanced ovarian, fallopian tube or peritoneal cancer after response to first-line platinum-based chemotherapy (2024) NICE technology appraisal guidance 962. Olaparib with bevacizumab for maintenance treatment of advanced high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer (2024) NICE technology appraisal guidance 946. Olaparib for maintenance treatment of relapsed, platinum-sensitive ovarian, fallopian tube or peritoneal cancer after 2 or more courses of platinum-based chemotherapy (2023) NICE technology appraisal guidance 908. Niraparib for maintenance treatment of advanced ovarian, fallopian tube and peritoneal cancer after response to first-line platinum-based chemotherapy (2021) NICE technology appraisal guidance 673.

	Topotecan, pegylated liposomal doxorubicin hydrochloride, paclitaxel, trabectedin and gemcitabine for treating recurrent ovarian cancer (2016) NICE technology appraisal guidance 389. Bevacizumab in combination with paclitaxel and carboplatin for first-line treatment of advanced ovarian cancer (2013) NICE technology appraisal guidance 284. Guidance on the use of paclitaxel in the treatment of ovarian cancer (2003) NICE technology appraisal guidance 55. **Related technology appraisals in development:** Mirvetuximab soravtansine for treating folate receptor alpha-positive platinum-resistant advanced epithelial ovarian, fallopian tube or primary peritoneal cancer. NICE technology appraisal guidance [ID6442]. Publication expected January 2026 **Related NICE guidelines:** Ovarian cancer: identifying and managing familial and genetic risk (2024) NICE guideline NG241. Ovarian cancer: recognition and initial management (2011) NICE guideline CG122. Last updated October 2023 **Related diagnostics guidance:** Tests in secondary care to identify people at high risk of ovarian cancer (2017) NICE diagnostics guidance 31 **Related interventional procedures:** Maximal cytoreductive surgery for advanced ovarian cancer (2023) NICE interventional procedures guidance 757 **Related quality standards:** Ovarian cancer (2012) NICE quality standard 18 (last updated 2025)

Questions for consultation

Where do you consider pembrolizumab with chemotherapy will fit into the existing care pathway for platinum-resistant recurrent ovarian cancer?

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?

Would best supportive care be a relevant comparator?

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):

For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention.

Would pembrolizumab with chemotherapy be a candidate for managed access?

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?

Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.

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 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.

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.

Please tell us what evidence should be obtained to enable the committee to identify and consider such impacts.

NICE intends to evaluate this technology through its Single Technology Appraisal process. (Information on NICE's health technology evaluation processes is available at https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/changes-to-health-technology-evaluation).

References

1. NHS Digital (2024). Cancer registration statistics 2022. Accessed August 2025.

2. Cancer Research UK. Ovarian cancer incidence statistics. Accessed August 2025

3. NHS England. Cancer Survival in England, cancers diagnosed 2016 to 2020, followed up to 2021. Accessed August 2025.