NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Mirvetuximab soravtansine for treating folate receptor alpha-positive platinum-resistant advanced epithelial ovarian, fallopian tube or primary peritoneal cancer [ID6442]

Final scope

Remit/evaluation objective

To appraise the clinical and cost effectiveness of mirvetuximab soravtansine within its marketing authorisation for treating folate receptor alpha-positive platinum-resistant advanced epithelial ovarian, fallopian tube or primary peritoneal cancer.

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 I to stage IV. In stage I, the cancer is confined to one or both ovaries. In stage II the disease has grown outside the ovaries but is still within the pelvic area. Stage III denotes disease that is locally advanced and has spread outside the pelvis into the abdominal cavity, and stage IV denotes that distant metastasis to other body organs has occurred. Stages II to IV are considered advanced ovarian cancer. Symptoms of ovarian cancer include bloating, pelvic pain, frequent urination, constipation, and feeling full quickly after eating. In the early stages symptoms can be vague or not noticeable, so most people are diagnosed once the cancer has progressed to an advanced stage.

Folate receptor alpha (FRα)-positive cancer means that the cancer expresses high levels of the folate receptor alpha protein on its surface. Elevated FRα expression may be a negative prognostic factor with respect to chemotherapy response. In the pivotal trial for mirvetuximab soravtansine, a tumour sample was considered FRα positive if at least 75% of viable tumour cells showed moderate and/or strong levels of membrane staining.[1] Approximately 80% of recurrent epithelial ovarian cancer express FRα and approximately 32% are categorised as FRα positive.[1,2]

The incidence of ovarian cancer increases with age, with rates being highest in women aged 75 to 79.[3] Approximately 6,300 people are diagnosed with ovarian cancer in England each year.[3] People with early-stage ovarian cancer tend to have better survival outcomes. The 5-year survival rate for stage I is 94.5% compared to 16% for stage IV.[4] The overall 5-year survival for people diagnosed with ovarian cancer at any stage is 45%.[4]

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-based chemotherapy, and pegylated liposomal doxorubicin hydrochloride as monotherapy or in combination with platinum-based chemotherapy, for treating recurrent ovarian cancer.

The technology

Mirvetuximab soravtansine (Elahere, Abbvie) does not currently have a marketing authorisation in the UK. It has been studied in clinical trials as monotherapy compared with investigator's choice of chemotherapy (that is, paclitaxel, pegylated liposomal doxorubicin or topotecan) in people with platinum-resistant, advanced high-grade epithelial ovarian, primary peritoneal, or fallopian tube cancers with high FRα expression who have received one to three prior systemic treatments.

Intervention(s)	Mirvetuximab soravtansine
Population(s)	Adults with FRα-positive platinum-resistant advanced epithelial ovarian, fallopian tube or primary peritoneal cancer
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 • BRCA status
Comparators	• Pegylated liposomal doxorubicin hydrochloride (PLDH) monotherapy • Paclitaxel monotherapy
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. The use of mirvetuximab soravtansine is conditional on having folate receptor alpha-positive ovarian cancer. In the pivotal trial for mirvetuximab soravtansine, a tumour sample was considered FRα positive if at least 75% of viable tumour cells showed moderate and/or strong levels of membrane staining.[1] The economic modelling should include the costs associated with testing for folate receptor alpha expression in people with ovarian cancer who would not otherwise have been tested. A sensitivity analysis should be provided without the cost of the diagnostic test. See section 4.8 of the guidance development manual (available here: https://www.nice.org.uk/process/pmg36/chapter/introduction-to-health-technology-evaluation).
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:** Topotecan, pegylated liposomal doxorubicin hydrochloride, paclitaxel, trabectedin and gemcitabine for treating recurrent ovarian cancer (2016) NICE technology appraisal guidance 389. **Related NICE guidelines:** Ovarian cancer: recognition and initial management (2011) NICE guideline CG122. Last updated 2023. **Related Interventional Procedures:** Ultra-radical (extensive) surgery for advanced ovarian cancer (2013) NICE interventional procedures guidance 470 **Related Quality Standards:** Ovarian cancer (2012) NICE quality standard 18
Related National Policy	The NHS Long Term Plan (2019) NHS Long Term Plan

	NHS England (2018) Manual for prescribed specialised services 2018/19 Chapter 105: Specialist cancer services (adults) NHS England. 2013/14 NHS Standard Contract for Cancer: Chemotherapy (Adult). B15/S/a. NHS England. 2013/14 NHS Standard Contract for Cancer: Gynaecological. E10/S/f/. Public Health England (2015) Living with and beyond ovarian cancer Independent Cancer Taskforce (2015) Achieving world-class cancer outcomes: a strategy for England 2015-2020

References

1 Moore, K.N. et al, 2023. Mirvetuximab soravtansine in FRα-positive, platinum-resistant ovarian cancer. New England Journal of Medicine, 389(23), pp.2162-2174. Supplementary appendix.

2 OncLive. Evaluating the Role of Folate Receptor Alpha Expression in Ovarian Cancer. Accessed Oct 2024.

3 Cancer Research UK. Ovarian cancer incidence statistics. Accessed Oct 2024

4 NHS England. Cancer Survival in England, cancers diagnosed 2016 to 2020, followed up to 2021. Accessed Oct 2024