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

Draft scope

Draft 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. Approximately 80% of epithelial ovarian cancer express FR-alpha.[1]

The incidence of ovarian cancer increases with age, with rates being highest in women aged 75 to 79.[2] Approximately 6,300 people are diagnosed with ovarian cancer in England each year.[2] 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.[3] The overall 5-year survival for people diagnosed with ovarian cancer at any stage is 45%.[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

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with platinum, and pegylated liposomal doxorubicin hydrochloride as monotherapy or in combination with platinum, 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 platinum-resistant, advanced high-grade epithelial ovarian, primary peritoneal, or fallopian tube cancers with high FRα expression.

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.

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	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. If there is a companion diagnostic that is not already in routine use in the NHS, include the following sentences: 'The use of mirvetuximab soravtansine is conditional on the expression of folate receptor alpha. 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)

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	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

Questions for consultation

Is rechallenge with platinum-based chemotherapy used for people with platinum resistant disease (that is, cancer that has relapsed within 6 months of completion of platinum-based chemotherapy)?

Would paclitaxel with platinum chemotherapy or pegylated liposomal doxorubicin hydrochloride with platinum chemotherapy be relevant comparators for people with platinum resistant cancer?

Where do you consider mirvetuximab soravtansine will fit into the existing care pathway for folate receptor alpha-positive platinum-resistant advanced epithelial ovarian, fallopian tube or primary peritoneal cancer?

Would the treatment pathway for this population be different depending on whether the person had maintenance treatment following chemotherapy?

Please select from the following, will mirvetuximab soravtansine 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 mirvetuximab soravtansine be a candidate for managed access?

Do you consider that the use of mirvetuximab soravtansine 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.

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

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

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

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

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