NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Tisotumab vedotin for treating recurrent or metastatic cervical cancer after chemotherapy ID3753

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of tisotumab vedotin within its marketing authorisation for treating recurrent or metastatic cervical cancer after chemotherapy.

Background

Cervical cancer develops when abnormal cells in the lining of the cervix (the entrance to the womb from the vagina) grow in an uncontrolled way and eventually form a tumour.[1] It can start from different types of cells in different parts of the cervix, which gives rise to 2 main subtypes of cancer. The most common subtype, called squamous cell carcinoma, develops from skin-like cells present on the outer surface of the cervix (ectocervix). The other subtype is called adenocarcinoma and it develops from glandular cells that produce mucus inside the cervix (endocervix). The human papilloma virus (HPV) is the main cause of cervical cancer and has been detected in 99% of cases. HPV types 16 and 18 account for at least two-thirds of cases.[2]

Cervical cancer is said to be recurrent when it has returned following treatment, and metastatic when it has spread beyond the pelvis and pelvic lymph nodes to other places in the body such as the abdomen, liver, intestinal tract, or lungs.[3]

In England in 2022, there were 2,641 newly diagnosed cases of cervical cancer, and 737 recorded deaths from cervical cancer. [4] Around half of people diagnosed with cervical cancer in England survive their disease for 5 years or more.[5]

For people with metastatic or recurrent cervical cancer, the aim of treatment is to prolong survival, relieve symptoms and improve quality of life. Treatment options consist of chemotherapy alone or in combination with immunotherapies. NICE technology appraisal guidance 939 recommends pembrolizumab plus chemotherapy with or without bevacizumab for persistent, recurrent or metastatic cervical cancer in adults whose tumours express PD-L1 with a combined positive score of at least 1. NICE technology appraisal guidance 183 recommends topotecan in combination with cisplatin as an option for treating recurrent or stage IVB cervical cancer in people who have not previously received cisplatin. Other treatment options include surgery and radiotherapy, and some people may receive supportive care.[6]

The technology

Tisotumab vedotin (Tivdak, Genmab) does not currently have a marketing authorisation in the UK for treating recurrent or metastatic cervical cancer. It has

been studied in clinical trials in people with recurrent or metastatic cervical cancer who have had chemotherapy.

Intervention(s)	Tisotumab vedotin
Population(s)	People with recurrent or metastatic cervical cancer that has progressed after chemotherapy
Subgroups	Levels of PD-L1 expression
Comparators	• Platinum chemotherapy (cisplatin or carboplatin) alone or in combination with paclitaxel or topotecan • Pembrolizumab plus chemotherapy with or without bevacizumab (in people with tumours expressing PD-L1 with a combined positive score of at least 1)
Outcomes	The outcome measures to be considered include: • progression free survival • overall survival • response rates • 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 of any managed access arrangement for the intervention 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:** Pembrolizumab plus chemotherapy with or without bevacizumab for persistent, recurrent or metastatic cervical cancer. (2023) NICE technology appraisal guidance 939 Topotecan for the treatment of recurrent and stage IVB cervical cancer (2009) NICE Technology appraisal guidance 183 **Related interventional procedures:** High dose rate brachytherapy for carcinoma of the cervix (2006) NICE interventional procedures guidance 160

Questions for consultation

Where do you consider tisotumab vedotin will fit into the existing care pathway for recurrent or metastatic cervical cancer?

Is etoposide used in clinical practice to treat recurrent or metastatic cervical cancer?

Please select from the following, will tisotumab vedotin 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 tisotumab vedotin be a candidate for managed access?

Do you consider that the use of tisotumab vedotin 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 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 tisotumab vedotin 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. Cancer Research UK (2023). What is cervical cancer? Accessed April 2025.
2. NICE (2022). Clinical knowledge summary on cervical cancer and HPV. Accessed April 2025.
3. Cancer Research UK (2023). Stage 4 cervical cancer. Accessed April 2025.
4. NHS Digital (2024). Cancer registration statistics, England, 2022. Accessed April 2025.
5. Cancer Research UK (2023). Survival for cervical cancer (2023). Accessed April 2025,.
6. BMJ Best Practice (2025). Cervical cancer. Accessed April 2025.