NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Tisotumab vedotin for treating recurrent or metastatic cervical cancer that has progressed on or after systemic treatment [ID3753]

Final scope

Remit/evaluation objective

To appraise the clinical and cost effectiveness of tisotumab vedotin within its marketing authorisation for treating recurrent or metastatic cervical cancer that has progressed on or after systemic treatment.

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] Survival rates for metastatic or recurrent cervical cancer are significantly lower than for early stage cervical cancer. About 15% of people diagnosed with stage 4 (metastatic) disease survive for 5 years or more after diagnosis compared with 95% of people diagnosed at stage 1.[5,6]

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 include 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. There is no standard second-line treatment for people with disease progression on or after systemic treatment. Second line options include single-agent chemotherapy and best supportive care.[7]

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 with disease progression on or after systemic treatment, compared to investigator's choice of chemotherapy (topotecan, vinorelbine, gemcitabine, irinotecan, or pemetrexed).

Intervention(s)	Tisotumab vedotin monotherapy
Population(s)	People with recurrent or metastatic cervical cancer that has progressed on or after systemic treatment
Comparators	• Single-agent chemotherapy (including but not limited to paclitaxel, doxorubicin, gemcitabine and topotecan) • Best supportive care
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

References

1. Cancer Research UK (2023). What is cervical cancer? Accessed June 2025.
2. NICE (2022). Clinical knowledge summary on cervical cancer and HPV. Accessed June 2025.
3. Cancer Research UK (2023). Stage 4 cervical cancer. Accessed June 2025.
4. NHS Digital (2024). Cancer registration statistics, England, 2022. Accessed June 2025.
5. Gennigens C, Jerusalem G, Lapaille L et al. (2022) Recurrent or primary metastatic cervical cancer: current and future treatments. ESMO Open : 7(5):100579.
6. Cancer Research UK (2023). Survival for cervical cancer (2023). Accessed June 2025.
7. BMJ Best Practice (2025). Cervical cancer. Accessed June 2025.