NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Catumaxomab for intraperitoneal treatment of malignant ascites in epithelial cellular adhesion molecule-positive carcinomas when further systemic anticancer treatment is unsuitable ID6580

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost-effectiveness of catumaxomab within its marketing authorisation for treating malignant ascites in epithelial cellular adhesion molecule-positive carcinomas when further systemic anticancer treatment is unsuitable.

Background

Malignant ascites is caused by cancers whose primary tumours may have originated in the stomach, liver, bladder, bowel, pancreas, ovaries, endometrium and uterus. Lung cancer and breast cancer can also develop malignant ascites. Malignant ascites occurs when too much fluid builds up inside of the abdomen (peritoneum) causing swelling and bloating. The cancer cells irritate the lining of the abdomen and make it produce too much fluid. It can also cause lymph glands in the abdomen to become blocked so the fluid cannot drain away. Epithelial cellular adhesion molecule (EpCAM) is a protein which has a role in cell proliferation and differentiation. It is produced in many epithelial cancers (carcinomas).[1]

Approximately 10% of all cases of ascites in the UK are caused by cancer.[2] Ovarian cancer is the most common cause of malignant ascites, and occurs in up to 37% of cases.[3] Malignant ascites is twice as likely to occur in women compared to men.[3]

There are currently no licensed therapies approved for use to treat malignant ascites in EpCAM positive carcinoma in the UK. Supportive care aims to relieve the symptoms caused by malignant ascites and improve quality of life. Management of malignant ascites may involve removing the excess fluid (paracentesis), diuretics or systemic treatment of the underlying cancer. NICE guidance (MTG9) reccomends the PeritX system for drainage of treatment-resistant, recurrent malignant peritoneal ascites.

The technology

Catumaxomab (Korjuny, Pharmanovia) does not currently have a marketing authorisation in the UK for treating malignant ascites in EpCAM positive carcinoma. Catumaxomab with paracentesis has been studied in clinical trials compared with paracentesis in people with malignant ascites and have EpCAM positive carcinoma that cannot be treated with further systemic anticancer therapy.

Intervention(s)	Catumaxomab with paracentesis
Population(s)	Adults with malignant ascites in epithelial cellular adhesion molecule-positive carcinomas when further systemic anticancer treatment is unsuitable
Subgroups	If evidence allows, results by type of primary cancer may be considered.
Comparators	Established clinical management without catumaxomab
Outcomes	The outcome measures to be considered include: • puncture-free survival • overall survival • progression-free survival • 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:** None **Related NICE guidelines:** Suspected cancer: recognition and referral (2015; updated 2025) NICE guideline NG12.

	Ovarian cancer: recognition and initial management (2011; updated 2023) NICE clinical guideline CG122 Metastatic malignant disease of unknown primary origin in adults: diagnosis and management (2010; updated 2023) NICE clinical guideline CG104 **Related medical technology guidance:** PeritX peritoneal catheter drainage system for vacuum-assisted drainage of treatment-resistant, recurrent malignant ascites (2012; updated 2022) NICE medical technologies guidance MTG9.

Questions for consultation

Where do you consider catumaxomab will fit into the existing care pathway for malignant ascites caused by epithelial cellular adhesion molecule-positive carcinoma?

Would the effectiveness of catumaxomab be affected by primary tumour site?

Would catumaxomab be used alongside established clinical management or would be catumaxomab be used with paracentesis only?

Are cancers in England routinely tested for EpCAM expression?

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

Do you consider that the use of catumaxomab 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 catumaxomab 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. Dhotare, PS, Bochi-Layec, AC, Fleming, TP, Gillanders, WE, Bremner, RM, Sonawane, KD, Sankpal, NV (2025) Landscape of cancer associated EpCAM mutations: molecule modelling, predictive insights and impact on patient survival. BMC Cancer 25

2. Ayantunde AA, Parsons SL (2007) Pattern and prognostic factors in patients with malignant ascites: a retrospective study. Annals of Oncology 18: 945-949

3. Ilgen JS, Marr AL, (2009) Cancer Emergencies: The Acute Abdomen. Emergency Medicine Clinics of North America 27: 381-399