NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Enfortumab vedotin with pembrolizumab for neoadjuvant and adjuvant treatment of muscle-invasive bladder cancer ID6607

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of enfortumab vedotin with pembrolizumab within its marketing authorisation for neoadjuvant and adjuvant treatment of muscle-invasive bladder cancer.

Background

Bladder cancer is where a growth of abnormal tissue, known as a tumour, develops in the bladder lining. Muscle-invasive bladder cancer is when cancerous cells spread beyond the lining into the surrounding bladder muscle. Common symptoms of bladder cancer include blood in the urine, passing urine often, pain or burning sensation when passing urine, fatigue, pain in lower back or abdomen and unexplained weight loss.

In 2023, 18,389 new bladder cancer cases were diagnosed in England.[1] At diagnosis, 30% of bladder cancers are muscle-invasive bladder cancer.[2] Most cases are in people over 75 but bladder cancer can affect young people too.[3] Bladder cancer is more common in men than in women.[3] Smoking is a significant risk factor for bladder cancer.[4]

NICE guideline NG2 recommends people with muscle-invasive bladder cancer may have surgery or radiotherapy. Cisplatin combination chemotherapy is recommended before surgery (neoadjuvant). Surgery consists of radical cystectomy (removal of the bladder) with urinary stoma or a continent urinary diversion. After surgery, some people with high risk of recurrence (for example positive lymph-node involvement) or for whom neoadjuvant chemotherapy was not suitable may receive cisplatin-based adjuvant therapy to improve survival. Where adjuvant platinum-based chemotherapy is not suitable, NICE technology appraisal 817 recommends nivolumab as an option for the adjuvant treatment of muscle-invasive urothelial cancer that is at high risk of recurrence after radical resection in adults whose tumours express PD-L1 at a level of 1% or more.

The technology

Enfortumab vedotin (Padcev, Astellas) does not currently have a marketing authorisation in the UK for neoadjuvant and adjuvant treatment of muscle-invasive bladder cancer. It has been studied in clinical trials with pembrolizumab for perioperative treatment of muscle-invasive bladder cancer, both in people who can have and cannot have or decline cisplatin.

Enfortumab vedotin does have a marketing authorisation in the UK for the first-line treatment of unresectable or metastatic urothelial cancer in adults.

Intervention	Enfortumab vedotin with pembrolizumab
Population	People with muscle-invasive bladder cancer who are having radical cystectomy
Comparators	For neoadjuvant treatment: • Cisplatin-based chemotherapy • Best supportive care • Durvalumab with gemcitabine and cisplatin (subject to NICE evaluation) For adjuvant treatment: • Cisplatin-based chemotherapy • Nivolumab (for muscle-invasive urothelial cancer that is at high risk of recurrence after radical resection in adults whose tumours express PD-L1 at a level of 1% or more, and when platinum-based chemotherapy is unsuitable) • Best supportive care • Durvalumab with gemcitabine and cisplatin (subject to NICE evaluation)
Outcomes	The outcome measures to be considered include: • event-free survival • disease-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 and 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:** Nivolumab for adjuvant treatment of invasive urothelial cancer at high risk of recurrence. (2022) NICE technology appraisal guidance 817 **Related technology appraisals in development:** Durvalumab with gemcitabine and cisplatin before surgery (neoadjuvant) then alone after surgery (adjuvant) for treating muscle-invasive bladder cancer. NICE technology appraisal guidance [ID6168] Publication date to be confirmed. Nivolumab with BMS-986205 and chemotherapy for neoadjuvant treatment of muscle-invasive bladder cancer. NICE technology appraisal guidance [ID6321] Publication date to be confirmed **Related NICE guidelines:** Bladder cancer: diagnosis and management (2015) NICE guideline NG2. Suspected cancer: recognition and referral (2023) NICE guideline NG12 **Related quality standards:** Bladder cancer (2015) NICE quality standard 106.

Questions for consultation

Where do you consider enfortumab vedotin with pembrolizumab will fit into the existing care pathway for muscle-invase bladder cancer?

Please select from the following, will enfortumab vedotin with pembrolizumab 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 enfortumab vedotin with pembrolizumab be a candidate for managed access?

Do you consider that the use of enfortumab vedotin with pembrolizumab 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 enfortumab vedotin with pembrolizumab 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 registration statistics (2023). Cancer registration statistics in England (Accessed November 2025)

2. Saginala, K. et al (2020) Epidemiology of bladder cancer, Med. Sci 8(1): 15

3. Cancer Research UK Bladder cancer incidence statistics. (Accessed November 2025)

4. Cancer Research UK Bladder cancer risk (Accessed November 2025)