NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Nogapendekin alfa inbakicept with intravesical BCG for previously treated non-muscle-invasive bladder cancer unresponsive to BCG ID6582

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of nogapendekin alfa inbakicept with intravesical BCG (Bacillus Calmette-Guérin) within its marketing authorisation for previously treated non-muscle-invasive bladder cancer unresponsive to BCG.

Background

Cancer arising from the transitional cells which form the inner lining the bladder is called urothelial or transitional cell cancer. Urothelial cancer accounts for approximately 90% of bladder cancers.[1] This type of bladder cancer can be described as non-muscle-invasive or muscle-invasive depending on how far the cancer has grown into the bladder. There are two types of non-muscle-invasive bladder cancer. Papillary cancers often grow towards the hollow part of the organ (for example the bladder and ureter), without going into deeper layers. Papillary cancer is classified as stage Ta when it is confined to the bladder lining and stage T1 when it has spread into the connective tissue layer between the bladder lining and the muscle wall. It can be graded from G1 (low grade, least aggressive) to G3 (high grade, most aggressive). Carcinoma in situ (CIS) is aggressive cancer that has spread within the surface lining of the bladder and appears flat. The most common symptom of bladder cancer is blood in urine, which is usually painless.

In 2022, 18,325 new bladder cancers were diagnosed in England.[2] Most cases are in those over the age of 75 and it is more common among men than women (3 males for every 1 female).[2 3] Bladder cancer has a high recurrence rate, with around 70% of cases returning within 5 years of initial treatment, of whom up to 30% develop muscle invasive bladder cancer.[4] The presence of CIS increases the change of recurrence and around 50% of people with CIS will developing muscle invasive cancer.[6] Smoking is a major factor in the cause of bladder cancer.[2]

NICE's clinical guideline 2 recommends a transurethral resection of a bladder tumour (TURBT) as first line treatment for non-muscle-invasive bladder cancer. For high-risk cancers, Bacille Calmette-Guérin (BCG) immunotherapy may also be given into the bladder for 1 to 3 years. Alternatively, people may have their bladder removed (radical cystectomy). For people whose cancer does not respond to BCG, radical cystectomy is the preferred option. People who cannot or do not want to have a radical cystectomy can be offered further intravesical chemotherapy with or without BCG.

The technology

Nogapendekin alfa inbakicept (Anktiva, ImmunityBio) with intravesical BCG does not currently have a marketing authorisation in the UK for treating non-muscle invasive

bladder cancer. It is being studied in a phase 2/3 clinical trial in adults with CIS or high grade papillary non-muscle-invasive bladder cancer that is unresponsive to BCG.

Intervention(s)	Nogapendekin alfa inbakicept with intravesical BCG
Population(s)	People with previously treated high-risk non-muscle-invasive bladder cancer unresponsive to BCG

Comparators	• Radical cystectomy
	• Intravesical chemotherapy including:
	  ○ Mitomycin C with or without BCG
	  ○ Gemcitabine with or without docetaxel

Outcomes	The outcome measures to be considered include: • overall survival • progression-free survival • response rates • avoidance of cystectomy • 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 in development:** Sasanlimab with BCG for treating high-risk non-muscle-invasive bladder cancer with papillary tumours or carcinoma in situ untreated with BCG. NICE technology appraisal guidance [ID6454]. Publication date tbc Pembrolizumab with BCG for treating high-risk non muscle-invasive bladder cancer. NICE technology appraisal guidance [ID6271]. Publication date tbc Durvalumab with BCG for treating high-risk non muscle-invasive bladder cancer after resection of papillary tumours in people previously untreated with BCG. NICE technology appraisal guidance [ID5080]. Publication date tbc **Related NICE guidelines:** Bladder cancer: diagnosis and management (2015) NICE guideline NG2. Reviewed July 2024 Improving outcomes in urological cancers (2002) NICE Cancer service guideline CSG2 **Related interventional procedures:** Transurethral laser ablation for recurrent non-muscle-invasive bladder cancer (2019) NICE interventional procedures guidance 656 Electrically stimulated intravesical chemotherapy for non-muscle-invasive bladder cancer (2019) NICE interventional procedures guidance 638 Intravesical microwave hyperthermia and chemotherapy for non-muscle-invasive bladder cancer (2018) NICE interventional procedures guidance 628 **Related quality standards:** Bladder cancer (2015) NICE quality standard 106 **Related medical technology guidance** Synergo for non-muscle-invasive bladder cancer (2021) NICE medical technologies guidance 61. Review date not stated

Questions for consultation

Where do you consider nogapendekin alfa inbakicept with intravesical BCG will fit into the existing care pathway for non-muscle-invasive bladder cancer unresponsive to BCG?

Would people with intermediate risk non-muscle invasive bladder cancer have BCG in the NHS? If yes, is it expected that nogapendekin alfa inbakicept with intravesical BCG would be used in these people?

Would people who are unresponsive to BCG be re-challenged with intravesical BCG alone?

Is gemcitabine with or without docetaxel used to treat people with high-risk non-muscle invasive bladder cancer that is unresponsive to BCG in the NHS? Are any other intravesical chemotherapies used?

Would nogapendekin alfa inbakicept with intravesical BCG be used in people with both papilliary and CIS non-muscle invasive bladder cancer?

Please select from the following, will nogapendekin alfa inbakicept with intravesical BCG 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 nogapendekin alfa inbakicept with intravesical BCG be a candidate for managed access?

Do you consider that the use of nogapendekin alfa inbakicept with intravesical BCG 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.

Please indicate if any of the treatments in the scope are used in NHS practice differently than advised in their Summary of Product Characteristics. For example, if the dose or dosing schedule for a treatment is different in clinical practice. If so, please indicate the reasons for different usage of the treatment(s) in NHS practice. If stakeholders consider this a relevant issue, please provide references for data on the efficacy of any treatments in the pathway used differently than advised in the Summary of Product Characteristics.

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 nogapendekin alfa inbakicept with intravesical BCG 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. Types of bladder cancer. https://www.cancerresearchuk.org/about-cancer/bladder-cancer/types-stages-grades/types Accessed July 2025

2. Cancer Research UK. Bladder cancer incidence statistics. https://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/bladder-cancer/incidence#heading-One. Accessed July 2025

3. NHS Digital. Cancer Registrations Statistics, England 2022 https://digital.nhs.uk/data-and-information/publications/statistical/cancer-registration-statistics/england-2022 Accessed July 2025.

4. Chamie, K., et al. (2013). Recurrence of high-risk bladder cancer: a population-based analysis. Cancer, 119(17), 3219-3227.

5. Aldousari S, Kassouf W (2010). Update on the management of non-muscle invasive bladder cancer. Can Urol Assoc J. 4 (1), 56-64.