NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Sasanlimab with BCG for treating high-risk non-muscle-invasive bladder cancer with papillary tumours or carcinoma in situ untreated with BCG ID6454

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of sasanlimab with BCG within its marketing authorisation for high-risk non-muscle-invasive bladder cancer with papillary tumours or carcinoma in situ untreated with BCG.

Background

Cancer arising from the transitional cells which form the inner lining of 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. NMIBC is divided into three risk groups: low, intermediate (medium) and high based on tumour stage, grade, size, recurrence history, and presence of CIS. High risk NMIBC means the cancer is more likely to spread or come back after treatment.[2]The most common symptom of bladder cancer is blood in urine, which is usually painless.

There were 9,401 diagnoses of bladder cancer in 2021 in England.[3] Bladder cancer is the 11th most common cancer in the UK and it is more common among men than women. Each year, almost three-fifths of all new bladder cancer cases in the UK are diagnosed in people aged 75 and over.[4] 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.[5] The presence of CIS increases the chance of recurrence and around 50% of people with CIS will develop muscle invasive cancer.[6] Smoking is a major factor in the cause of bladder cancer.[7]

Treatment for non-muscle-invasive bladder cancer usually depends on what risk level the tumour is. NICE's clinical guideline 2 recommends a transurethral resection of a bladder tumour (TURBT) as first line treatment for non-muscle-invasive bladder cancer. A second TURBT if offered (within 6 weeks of the first procedure) if the first TURBT shows high risk NMIBC. Intravescial Bacille Calmette-Guérin (BCG) or radical cystectomy is also offered to adults with high-risk NMIBC bladder cancer. Adjuvant chemotherapy may be offered following radical cystectomy.

The technology

Sasanlimab (brand name unknown, Pfizer Limited UK) with BCG does not currently have a marketing authorisation in the UK for treating bladder cancer. It is currently being studied in a phase 3 clinical trial in which sasanlimab in combination with BCG is compared with BCG alone in adults with BCG-naive high-risk NMIBC.

BCG currently has marketing authorisation in the UK for treatment of primary or concurrent carcinoma-in-situ of the urinary bladder and for the prevention of recurrence of high grade and/or relapsing superficial papillary transitional cell carcinoma of the urinary bladder (Stage Ta (grade 2 or 3) or T1 (grade 1, 2 or 3)) after transurethral resection.

Intervention(s)	Sasanlimab with BCG
Population(s)	Adults with high-risk non-muscle-invasive bladder cancer with papillary tumours or carcinoma in situ untreated with BCG
Subgroups	If the evidence allows the following subgroups will be considered: • People with papillary tumours • People without papillary tumours • People for whom radical cystectomy is unsuitable
Comparators	Best Supportive Care (BSC) including: • Transurethral resection of bladder tumour (TURBT) • Intravescial BCG • Radical cystectomy
Outcomes	The outcome measures to be considered include: • overall survival • progression-free 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.

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:** Nogapendekin alfa inbakicept with intravesical BCG for previously treated non-muscle-invasive bladder cancer with carcinoma in situ that is unresponsive to BCG. NICE technology appraisal guidance [ID6582]. Publication expected September 2026. Pembrolizumab with BCG for treating high-risk non muscle-invasive bladder cancer. NICE technology appraisal guidance [ID6271]. Publication date to be confirmed. 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 to be confirmed. **Related NICE guidelines:** Bladder cancer: diagnosis and management (2015) NICE guideline NG2. Reviewed September 2025 Improving outcomes in urological cancers (2002) NICE cancer service guidance. Published September 2002. **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. Published December 2015. **Related medical technology guidance** Synergo for non-muscle-invasive bladder cancer (2021) NICE medical technologies guidance 61. Review date not stated

Questions for consultation

What is established clinical management for adults with high-risk non-muscle-invasive bladder cancer with papillary tumours or carcinoma in situ untreated with BCG?

Where do you consider sasanlimab with BCG will fit into the existing care pathway for high-risk non-muscle-invasive bladder cancer?

What would be considered relevant comparators to sasanlimab with BCG? Would transurethral resection of bladder tumour (TURBT) be a comparator?

Are there any subgroups of people in whom sasanlimab with BCG is expected to be more clinically and cost effective or other groups that should be examined separately?

Please select from the following, will sasanlimab with 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 sasanlimab with BCG be a candidate for managed access?

Do you consider that the use of sasanlimab with 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.

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 [the treatment(s)] is/are/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. 2025. Accessed October 2025

2. Cancer Research UK. Non muscle invasive bladder cancer staging. 2025. Accessed September 2025

3. NHS Digital (Oct 2023). Cancer Registrations Statistics, England 2021- First release, counts only. Accessed September 2025

4. Bladder cancer statistics. Bladder cancer statistics | Cancer Research UK. Accessed September 2025

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

6. Lamm, D.L. (1992) Carcinoma in situ. Urol Clin North Am. 19: 499.

7. Cancer Research UK. Risks and causes of bladder cancer. 2025. Accessed October 2025