

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Health Technology Evaluation

### **Nogapendekin alfa inbakicept with intravesical BCG for non-muscle-invasive bladder cancer with carcinoma in situ that is unresponsive to BCG [ID6582]**

#### **Final scope**

#### **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 adults with BCG-unresponsive non-muscle-invasive bladder cancer with carcinoma in situ (CIS) with or without papillary tumours.

#### **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.<sup>1</sup> 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). 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.<sup>2</sup> 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).<sup>2,3</sup> 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.<sup>4</sup> The presence of CIS increases the chance of recurrence and around 50% of people with CIS will develop muscle invasive cancer.<sup>6</sup> Smoking is a major factor in the cause of bladder cancer.<sup>2</sup>

[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.

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### The technology

Nogapendekin alfa inbakicept (Anktiva, ImmunityBio) with intravesical BCG has a marketing authorisation in the UK for the treatment of adults with BCG-unresponsive non-muscle-invasive bladder cancer with CIS with or without papillary tumours.

<b>Intervention(s)</b>	Nogapendekin alfa inbakicept with intravesical BCG
<b>Population(s)</b>	Adults with BCG-unresponsive non-muscle-invasive bladder cancer with CIS with or without papillary tumours
<b>Subgroups</b>	<p>If the evidence allows the following subgroups will be considered:</p> <ul style="list-style-type: none"><li>• People with papillary tumours</li><li>• People without papillary tumours</li><li>• People for whom radical cystectomy is unsuitable</li></ul>
<b>Comparators</b>	<ul style="list-style-type: none"><li>• Radical cystectomy</li><li>• Intravesical chemotherapy including:<ul style="list-style-type: none"><li>○ Mitomycin C with or without BCG</li><li>○ Gemcitabine with or without docetaxel</li></ul></li><li>• BCG re-challenge</li><li>• Best Supportive Care (BSC) including:<ul style="list-style-type: none"><li>○ transurethral resection of bladder tumour (TURBT)</li><li>○ transurethral laser ablation (TULAR)</li><li>○ fulguration of the bladder.</li></ul></li></ul>
<b>Outcomes</b>	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"><li>• overall survival</li><li>• progression-free survival</li><li>• response rates</li><li>• avoidance of cystectomy</li><li>• adverse effects of treatment</li><li>• health-related quality of life.</li></ul>

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<b>Economic analysis</b>	<p>The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.</p> <p>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.</p> <p>Costs will be considered from an NHS and Personal Social Services perspective.</p> <p>The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account.</p> <p>The availability and cost of biosimilar and generic products should be taken into account.</p>
<b>Other considerations</b>	<p>Guidance will only be issued in accordance with the marketing authorisation</p> <p>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.</p>
<b>Related NICE recommendations</b>	<p><b>Related technology appraisals in development:</b></p> <p><a href="#">Sasanlimab with BCG for treating high-risk non-muscle-invasive bladder cancer with papillary tumours or carcinoma in situ untreated with BCG</a>. NICE technology appraisal guidance [ID6454]. Publication date tbc</p> <p><a href="#">Pembrolizumab with BCG for treating high-risk non muscle-invasive bladder cancer</a>. NICE technology appraisal guidance [ID6271]. Publication date tbc</p> <p><a href="#">Durvalumab with BCG for treating high-risk non muscle-invasive bladder cancer after resection of papillary tumours in people previously untreated with BCG</a>. NICE technology appraisal guidance [ID5080]. Publication date tbc</p> <p><b>Related NICE guidelines:</b></p> <p><a href="#">Bladder cancer: diagnosis and management</a> (2015) NICE guideline NG2. Reviewed September 2025</p> <p><a href="#">Improving outcomes in urological cancers</a> (2002) NICE Cancer service guideline CSG2</p> <p><b>Related interventional procedures:</b></p> <p><a href="#">Transurethral laser ablation for recurrent non-muscle-invasive bladder cancer</a> (2019) NICE interventional procedures guidance 656</p>

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	<p><a href="#">Electrically stimulated intravesical chemotherapy for non-muscle-invasive bladder cancer</a> (2019) NICE interventional procedures guidance 638</p> <p><a href="#">Intravesical microwave hyperthermia and chemotherapy for non-muscle-invasive bladder cancer</a> (2018) NICE interventional procedures guidance 628</p> <p><b>Related quality standards:</b></p> <p><a href="#">Bladder cancer</a> (2015) NICE quality standard 106</p> <p><b>Related medical technology guidance</b></p> <p><a href="#">Synergo for non-muscle-invasive bladder cancer</a> (2021) NICE medical technologies guidance 61. Review date not stated</p>
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## References

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<https://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/bladder-cancer/incidence#heading-One>. Accessed July 2025
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<https://digital.nhs.uk/data-and-information/publications/statistical/cancer-registration-statistics/england-2022> Accessed July 2025.
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