

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Tarlatamab for previously treated advanced small-cell lung cancer

Draft scope

**Draft remit/evaluation objective**

To appraise the clinical and cost effectiveness of tarlatamab within its marketing authorisation for previously treated advanced small-cell lung cancer.

**Background**

There are two types of lung cancer: non-small-cell lung cancers and small-cell lung cancers. Small-cell lung cancer (SCLC) is a type of lung cancer that grows rapidly and spreads quickly to other parts of the body. Limited disease is when the cancer has not spread beyond one lung or nearby lymph nodes and extensive disease is when the cancer has spread beyond one lung.<sup>1</sup> Common symptoms of SCLC include weight loss, malaise, bone pain, breathlessness and haemoptysis.

Lung cancer is the 3rd most common cancer in the UK, accounting for 13% of all new cancer cases.<sup>2</sup> In 2021, there were 34,478 people diagnosed with lung cancer in England, of which 7.4% were SCLC.<sup>3</sup> The prognosis for patients with extensive-stage SCLC is poor, with a 5-year survival rate of 10%.<sup>4</sup>

Surgical intervention has limited use in SCLC because most patients present with advanced disease.<sup>5</sup> The NICE guideline 'Lung cancer: diagnosis and management (NG122)' recommends that relapsed SCLC is treated with an anthracycline-containing regimen or retreated with a platinum-based regimen to a maximum of six cycles. Radiotherapy can be offered for the palliation of local symptoms. In addition, NICE technology appraisal guidance 184 recommends oral topotecan as an option only for people with relapsed SCLC when re-treatment with the first-line regimen is not considered appropriate and the combination of cyclophosphamide, doxorubicin and vincristine is contraindicated.

**The technology**

Tarlatamab (Imdelltra, Amgen) does not currently have a marketing authorisation in the UK for the treatment of small-cell lung cancer. Tarlatamab is being studied in:

- an ongoing phase 2 clinical trial in people with relapsed/refractory small cell lung cancer after 2 or more prior lines of treatment and
- an ongoing phase 3 clinical trial in people with relapsed small cell lung cancer after platinum-based first-line chemotherapy

<b>Intervention(s)</b>	Tarlatamab
<b>Population(s)</b>	Adults with advanced small-cell lung cancer with disease progression on or after prior therapy
<b>Comparators</b>	<p>Established clinical management without tarlatamab, which may include:</p> <ul style="list-style-type: none"> <li>• Chemotherapy, including anthracycline-containing or platinum-based regimen</li> <li>• Oral topotecan (when re-treatment with the first-line regimen is not considered appropriate and the combination of cyclophosphamide, doxorubicin and vincristine is contraindicated)</li> <li>• Best supportive care</li> <li>• Lurbinectedin (subject to NICE evaluation)</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>• adverse effects of treatment</li> <li>• health-related quality of life.</li> </ul>
<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. 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>

<p><b>Related NICE recommendations</b></p>	<p><b>Related technology appraisals:</b></p> <p><a href="#">Topotecan for the treatment of relapsed small-cell lung cancer</a> (2009). NICE technology appraisal 184. On static list</p> <p><a href="#">Atezolizumab with carboplatin and etoposide for untreated extensive-stage small-cell lung cancer</a> (2020). NICE technology appraisal 638. Review date 2023</p> <p><b>Related technology appraisals in development:</b></p> <p><a href="#">Lurbinectedin for treating advanced small-cell lung cancer on or after platinum-based chemotherapy</a>. NICE technology appraisal guidance [ID3872]. Publication date to be confirmed.</p> <p><b>Related NICE guidelines:</b></p> <p><a href="#">Lung cancer: diagnosis and management</a> (2019) NICE guideline NG122. Updated 2023</p> <p><b>Related quality standards:</b></p> <p><a href="#">Lung cancer in adults</a> (2012). NICE quality standard 17.</p>
<p><b>Related National Policy</b></p>	<p>The NHS Long Term Plan (2019) <a href="#">NHS Long Term Plan</a></p> <p>NHS England (2023) <a href="#">Manual for prescribed specialist services (2023/2024)</a>, Chapter 105 Specialist cancer services (adults)</p>

### Questions for consultation

What treatments are established clinical management in the NHS for previously treated advanced small cell lung cancer?

Which combinations of chemotherapy are established clinical management in the NHS for previously treated advanced small cell lung cancer?

Where do you consider tarlatamab will fit into the existing care pathway for advanced small cell lung cancer?

Have all relevant comparators for tarlatamab been included in the scope?

Are the outcomes listed appropriate?

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

Would tarlatamab be a candidate for managed access?

Do you consider that the use of tarlatamab 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

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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 tarlatamab 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, [Lung cancer: Stages, types and grades](#) (Accessed December 2023)
2. Cancer Research UK, [Lung cancer statistics](#) (Accessed December 2023)
3. Royal College of Surgeons of England (2023), [National Lung Cancer Audit: State of the Nation Report](#) (Accessed December 2023)
4. Khakwani A, Rich AL, Tata LJ et al. Small-Cell Lung Cancer in England: Trends in Survival and Chemotherapy Using the National Lung Cancer Audit. [PLOS ONE. 2014. 9 \(2\) e89426](#) (Accessed December 2023)
5. BMJ, [BMJ Best Practice: Small cell lung cancer](#) (Accessed December 2023)