NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Lurbinectedin with atezolizumab for maintenance treatment of extensive-stage small-cell lung cancer

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of lurbinectedin with atezolizumab within its marketing authorisation for maintenance treatment of extensive-stage small-cell lung cancer.

Background

Lung cancer falls into two main histological categories: non-small-cell lung cancers and small-cell lung cancers. Small-cell lung cancer (SCLC) is a type of cancer that grows rapidly and spreads quickly to other parts of the body. It can be classified as limited or extensive disease. Extensive disease is when the cancer has spread beyond one lung and nearby lymph nodes, making radiotherapy unsuitable.[1] 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 between 2017 and 2019.[2] In 2022, 36,886 people were diagnosed with lung cancer in England, of which 6.8% were SCLC.[3] The prognosis for patients with extensive-stage SCLC is poor, with a 5-year survival rate of 10%.[4]

Surgical intervention has limited use in SCLC because most patients present with advanced disease.[5] The NICE guideline 'Lung cancer: diagnosis and management (NG122)' recommends platinum-based combination chemotherapy for first-line treatment of SCLC, up to a maximum of six cycles. In addition, NICE recommends the following treatments as an option for untreated extensive-stage SCLC in adults who have an Eastern Coopoerative Oncology Group performance status of 0 or 1:

- atezolizumab with carboplatin and etoposide (NICE technology appraisal guidance 638)
- durvalumab with etoposide and either carboplatin or cisplatin (NICE technology appraisal guidance 1041).

The NICE guideline on lung cancer diagnosis and management (NG122) recommends that maintenance treatment for SCLC should only be offered in the context of a clinical trial.

The technology

Lurbinectedin (Zepzelca, Immedica Pharma) does not currently have a marketing authorisation in the UK for maintenance treatment of extensive-stage small-cell lung cancer. It is being studied in a clinical trial in combination with atezolizumab compared with atezolizumab alone in people with extensive stage small cell lung

cancer, following first-line induction therapy with atezolizumab plus carboplatin and etoposide.

Intervention(s)	Lurbinectedin with atezolizumab
Population(s)	Adults with extensive-stage small-cell lung cancer whose disease has not progressed after first-line induction with atezolizumab, carboplatin and etoposide
Comparators	• Standard clinical management with or without maintenance treatment.
Outcomes	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. 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:** Durvalumab with etoposide and either carboplatin or cisplatin for untreated extensive-stage small-cell lung cancer (2025). NICE technology appraisal ID6404

	Atezolizumab with carboplatin and etoposide for untreated extensive-stage small-cell lung cancer (2020). NICE technology appraisal 638. **Related technology appraisals in development:** Serplulimab with carboplatin and etoposide for untreated extensive-stage small-cell lung cancer. NICE technology appraisal ID6346. Pembrolizumab–vibostolimab with etoposide and platinum-based chemotherapy for untreated extensive-stage small-cell lung cancer. NICE technology appraisal ID6361 **Related NICE guidelines:** Lung cancer: diagnosis and management (2019) NICE guideline NG122. Updated 2024. **Related quality standards:** Lung cancer in adults (2012). NICE quality standard 17. Updated 2019.

Questions for consultation

Where do you consider lurbinectedin with atezolizumab will fit into the existing care pathway for extensive-stage small-cell lung cancer?

What is established standard clinical management for the maintenance treatment of extensive-stage small-cell lung cancer after first-line induction with atezolizumab, carboplatin and etoposide?

Please select from the following, will lurbinectedin with atezolizumab 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 lurbinectedin with atezolizumab be a candidate for managed access?

Do you consider that the use of lurbinectedin with atezolizumab 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 lurbinectedin 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 (2023), Limited and extensive stage (small cell lung cancer) (Accessed August 2024)

2. Cancer Research UK, Lung cancer statistics (Accessed August 2024)

3. National Lung Cancer Audit (2024), National Lung Cancer Audit State of the Nation 2024, version 2 (Accessed August 2024)

4. Khakwani A, Rich AL, Tata LJ et al. (2014) Small-Cell Lung Cancer in England: Trends in Survival and Chemotherapy Using the National Lung Cancer Audit. PLOS ONE. 2014. 9 (2) e89426 (Accessed August 2024)

5. American Cancer Society, Surgery for Small Cell Lung Cancer (Accessed August 2024)