NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Serplulimab with carboplatin and etoposide for untreated extensive-stage small-cell lung cancer ID6346

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of serplulimab with carboplatin and etoposide within its marketing authorisation for untreated extensive-stage 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. SCLC staging can be described as limited or extensive disease. Limited disease is when the cancer has not spread beyond one lung and nearby lymph nodes. Extensive disease is when the cancer has spread beyond one lung and nearby lymph nodes, beyond a single area that can be treated with radiotherapy.[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 technology appraisal guidance 638 recommends atezolizumab with carboplatin and etoposide as an option for untreated extensive-stage SCLC in adults who have an Eastern Coopoerative Oncology Group performance status of 0 or 1.

The technology

Serplulimab (Accord Healthcare, Hansizhuang) does not currently have a marketing authorisation in the UK for the treatment of small-cell lung cancer (SCLC). Serplulimab with carboplatin and etoposide has been studied in a phase 3 clinical trial in people with previously untreated extensive-stage SCLC compared with carboplatin and etoposide alone. It is alsobeing studied in an ongoing phase 3 clinical trial for the same population compared with atezolizumab with carboplatin and etoposide.

Intervention(s)	Serplulimab with carboplatin and etoposide
Population(s)	Adults with untreated extensive-stage small-cell lung cancer
Comparators	• Platinum-based combination chemotherapy • Atezolizumab with carboplatin and etoposide (for people with Eastern Cooperative Oncology Group performance status of 0 or 1)
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. The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will 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:** Atezolizumab with carboplatin and etoposide for untreated extensive-stage small-cell lung cancer (2020). NICE technology appraisal 638. **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.
Related National Policy	The NHS Long Term Plan (2019) NHS Long Term Plan NHS England (2023) Manual for prescribed specialist services (2023/2024), Chapter 105 Specialist cancer services (adults)

Questions for consultation

Where do you consider serplulimab will fit into the existing care pathway for extensive stage SCLC?

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

Please select from the following, will serplulimab 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 serplulimab be a candidate for managed access?

Do you consider that the use of serplulimab 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 serplulimab 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)