NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Lurbinectedin for treating advanced small-cell lung cancer on or after platinum-based chemotherapy

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of lurbinectedin within its marketing authorisation for treating advanced small-cell lung cancer on or after platinum-based chemotherapy.

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 lung cancer that grows rapidly and spreads quickly to other parts of the body. SCLC can be classified as limited disease (cancer has not spread beyond one lung or nearby lymph nodes) or extensive disease (the cancer has spread beyond one lung)[1]. Common symptoms of SCLC include weight loss, malaise, bone pain, breathlessness and haemoptysis.

In 2017 there were 38,906 cases of lung cancer registered in England[2]. Around 15-20% of lung cancer cases are SCLC[1]. The prognosis for patients with extensive-stage SCLC is poor, with a 5-year survival rate of 10%[3].

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, TA184 recommends oral topotecan as an option only for people with relapsed small-cell lung cancer when re-treatment with the first-line regimen is not considered appropriate and the combination of cyclophosphamide, doxorubicin and vincristine (CAV) is contraindicated.

The technology

Lurbinectedin (Zepzelca, Pharma Mar) does not currently have a marketing authorisation in the UK for the treatment of small-cell lung cancer. Lurbinectedin has been studied in clinical trials alone, in combination with doxorubicin, and in combination with irinotecan, in people with relapsed SCLC.

Intervention(s)	Lurbinectedin
Population(s)	Adults with advanced small-cell lung cancer with disease progression on or after prior platinum-based chemotherapy

Comparators	Established clinical management without lurbinectedin, which may include: • Chemotherapy, including anthracycline-containing or platinum-based regimen • Oral topotecan (when re-treatment with the first-line regimen is not considered appropriate and the combination of cyclophosphamide, doxorubicin and vincristine is contraindicated)
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. The availability and costs 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:** Topotecan for the treatment of relapsed small-cell lung cancer (2009). NICE technology appraisal 184. On static list. **Related Guidelines:** Lung cancer: diagnosis and management (2019) NICE guideline NG122. Update in development. **Related Interventional Procedures:** None **Related Public Health Guidance/Guidelines:**

	None **Related Quality Standards:** Lung cancer in adults (2012). NICE quality standard 17.
Related National Policy	The NHS Long Term Plan, 2019. NHS Long Term Plan NHS England (2018/2019) NHS manual for prescribed specialist services (2018/2019). Chapter 105: Specialist cancer services (adults).

Questions for consultation

Have all the relevant comparators for lurbinectedin for advanced small-cell lung cancer with disease progression on or after prior platinum-based chemotherapy been included in the scope?

Which treatments are considered to be established clinical practice in the NHS for advanced small-cell lung cancer with disease progression on or after prior platinum-based chemotherapy?

Are the outcomes listed appropriate?

Would lurbinectedin be a candidate for managed access?

Do you consider that the use of lurbinectedin 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. We welcome comments on the appropriateness of appraising this topic through this 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).

NICE's health technology evaluations: the manual states the methods to be used where a cost comparison case is made.

- Would it be appropriate to use the cost-comparison methodology for this topic?
- Is the new technology likely to be similar in its clinical efficacy and resource use to any of the comparators?
- Is the primary outcome that was measured in the trial or used to drive the model for the comparator(s) still clinically relevant?
- Is there any substantial new evidence for the comparator technology/ies that has not been considered? Are there any important ongoing trials reporting in the next year?

References

1. Cancer Research UK, Lung cancer: Stages, types and grades (Accessed July 2022)
2. Office for National Statistics (2019) Cancer Registration Statistics, England 2017 (Accessed July 2022)
3. 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 July 2022)