NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Durvalumab for treating limited-stage small-cell lung cancer after chemoradiation ID5073

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of durvalumab within its marketing authorisation for treating limited-stage small-cell lung cancer (SCLC) after chemoradiation.

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.

There were around 37,000 new lung cancer cases and 27,000 deaths from lung cancer in England in 2020.[2] Most lung cancers are diagnosed at an advanced stage, when the cancer has spread to lymph nodes and other organs in the chest (locally advanced disease; stage 3) or to other parts of the body (metastatic disease; stage 4).[3] In 2022, 7% (around 2,600) of people diagnosed with lung cancer in England had SCLC.[3]

It is estimated that over half of all NSCLCs express the programmed cell death ligand-1 (PD-L1) biomarker.[4] Cancer cells expressing PD-L1 are believed to suppress certain immune responses which results in a weaker anti-tumour response.[3,4]

As a result of the NHS targeted Lung Health Check programme which is being rolled out in the UK, it is expected that lung cancer will increasingly be diagnosed at an earlier stage, when treatment may be more successful.

NICE's Lung cancer: diagnosis and management guideline recommends several options for people with limited-stage SCLC. These include combination chemotherapy, radiotherapy twice or once daily or sequential or concurrent chemoradiotherapy. If the SCLC is early stage then surgery may be offered.

The technology

Durvalumab (Imfinzi, AstraZeneca) does not currently have a marketing authorisation in the UK for maintenance treatment of SCLC after concurrent chemoradiation therapy.

Durvalumab has a marketing authorisation for the treatment of locally advanced, unresectable non-small-cell lung cancer in adults whose tumours express

programmed cell death ligand 1 (PD-L1) on 1% or more of tumour cells and whose disease has not progressed following platinum-based chemoradiation therapy.

Intervention(s)	Durvalumab
Population(s)	People with limited-stage SCLC whose disease has not progressed after concurrent chemoradiotherapy.
Subgroups	If the evidence allows the following subgroups may be considered: • PD-L1 expression • disease stage
Comparators	Established clinical management without durvalumab maintenance: • Active monitoring
Outcomes	The outcome measures to be considered include: • overall survival • progression-free survival • disease-free survival • 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:** Atezolizumab with carboplatin and etoposide for untreated extensive-stage small-cell lung cancer (2020) NICE technology appraisal 638. Review date 2023. Topotecan for the treatment of relapsed small-cell lung cancer (2009) NICE technology appraisal guidance 184. Review date February 2013 **Related technology appraisals in development:** Lurbinectedin for treating advanced small-cell lung cancer on or after platinum-based chemotherapy NICE technology appraisal guidance ID3872 Publication date to be confirmed Durvalumab with tremelimumab for treating limited-stage small-cell lung cancer after chemoradiation NICE technology appraisal guidance ID5097. Publication date to be confirmed Pembrolizumab–vibostolimab with etoposide and platinum-based chemotherapy for untreated extensive-stage small-cell lung cancer NICE technology appraisal guidance [ID6361] Publication date to be confirmed Tarlatamab for previously treated advanced small-cell lung cancer NICE technology appraisal guidance [ID6364] Publication date to be confirmed **Related NICE guidelines:** Lung cancer: diagnosis and management (2019, updated 2022) NICE guideline NG122. Review date not stated **Related interventional procedures:** Irreversible electroporation for treating primary lung cancer and metastases in the lung (2013) NICE interventional procedures guidance 441. Review date not stated Microwave ablation for treating primary lung cancer and metastases in the lung (2022) NICE interventional procedures guidance 716. Review date February 2025 **Related quality standards:** Lung cancer in adults (2012 updated 2019) NICE quality standard 17
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 durvalumab will fit into the existing care pathway for limited-stage SCLC?

Would durvalumab be a candidate for managed access?

Do you consider that the use of durvalumab can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?

Are the outcomes suggested above complete and appropriate?

Is disease-free or progression-free survival more appropriate for this appraisal?

Are the comparators suggested above complete and appropriate?

Is active monitoring an accurate comparator and what does it involve?

Would topotecan as recommended in TA184 be used as a maintenance treatment after chemoradiotherapy in NHS clinical practice?

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 durvalumab 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. 1. Cancer Research UK, Lung cancer: Stages, types and grades (Accessed May 2024)

2. NHS England. Cancer Registration Statistics, England 2020. Accessed March 2024

3. Royal College of Surgeons of England (2024). National Lung Cancer Audit: State of the Nation Report 2024. Accessed May 2024

4. Skov, B., Rørvig, S., Jensen, T. et al. (2020) The prevalence of programmed death ligand-1 (PD-L1) expression in non-small cell lung cancer in an unselected, consecutive population. Mod Pathol 33, 109–117

5. Han Y, Liu D, Li L. PD-1/PD-L1 pathway: current researches in cancer. Am J Cancer Res. 2020 Mar 1;10(3):727-742. PMID: 32266087; PMCID: PMC7136921.