NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Tislelizumab for treating advanced non-small-cell lung cancer after platinum-based chemotherapy ID6161

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of tislelizumab within its marketing authorisation for treating advanced non-small-cell lung cancer (NSCLC) after platinum-based chemotherapy.

Background

In 2022 lung cancer was the third most common cancer in men and second most common cancer in women in England, accounting for 12% of all cancer diagnoses. It was the most common cause of cancer death for both (around 20% of all deaths caused by cancer).[1]

There are 2 main types of lung cancer: 92% are NSCLC and the rest are small-cell lung cancers.[1] NSCLC is divided into squamous and non-squamous cell carcinoma.

In 2022, 38,475 people were diagnosed with NSCLC in England. Of these 7.9% had stage 3B or 3C cancer, and 40.1% stage 4 cancer.[2] Around 15% of people with stage 3 lung cancer will survive for 5 years or more after they're diagnosed. For stage 4 lung cancer this is around 5%.[3]

Current clinical management for locally advanced or metastatic (stage 3 or 4) NSCLC aims to control the cancer for as long as possible and help with symptoms. Treatment choices are based on cancer stage and line of treatment. They also depend on the presence of biological markers (including PD-L1 status), oncogenic driver genetic alterations, histology (squamous or non-squamous) and previous treatment.

For untreated NSCLC, NICE's guideline on diagnosing and managing lung cancer recommends platinum based chemotherapy. NICE technology appraisal guidance also recommends a range of systemic anticancer therapies, depending on the exact nature of the NSCLC, including immunotherapy with platinum based chemotherapy (TA770, TA683) or in combination with bevacizumab, carboplatin and paclitaxel TA584) and immunotherapy alone (TA705 and TA531).

For previously treated NSCLC a range of options are available depending on the characteristics of the disease. For NSCLC without a targetable genetic alteration, these include:

- pembrolizumab monotherapy (after chemotherapy, TA428)
- atezolizumab monotherapy (after chemotherapy, TA520)
- nivolumab monotherapy (after chemotherapy, TA655 and TA713)
- docetaxel alone or docetaxel with nintedanib (TA347)

- datopotamab deruxtecan (subject to NICE evaluation, ID6241)

For previously treated NSCLC with a targetable genetic alteration people may be offered:

- selpercatinib (RET fusion positive NSCLC, subject to NICE evaluation, TA760)
- sotorasib (KRAS G12C positive NSCLC, subject to NICE evaluation, TA781)
- adagrasib (KRAS G12C positive NSCLC, subject to NICE evaluation, ID6339).

The technology

Tislelizumab (Tevimbra, Beigene) does not currently have a marketing authorisation in the UK for treating advanced non-small-cell lung NSCLC after platinum-based chemotherapy. It has been studied in a clinical trial compared with docetaxel in people with stage 3B or 4 NSCLC that has progressed after platinum-based chemotherapy.

Intervention	Tislelizumab
Population	Adults with locally advanced or metastatic NSCLC whose cancer has progressed on platinum based chemotherapy
Subgroups	If the evidence allows, the following subgroups will be considered: • disease stage • line of therapy (second or third) • histology (squamous or non-squamous) • previous treatment • PD-L1 expression • mutation status
Comparators	NSCLC without a targetable genetic alteration • atezolizumab • datopotamab deruxtecan (subject to NICE evaluation) • docetaxel (with or without nintedanib) • nivolumab • pembrolizumab (PD-L1 positive). NSCLC with a targetable genetic alteration • adagrasib (KRAS G12C mutation-positive; subject to NICE evaluation) • selpercatinib (RET fusion positive; subject to NICE evaluation) • sotorasib (KRAS C12C positive; subject to NICE evaluation).
Outcomes	The outcome measures to be considered include: • progression free survival

	• overall survival • response rates • adverse effects of treatment • health-related quality of life • adverse effects of treatment.
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. If the technology is likely to provide similar or greater health benefits at similar or lower cost than technologies recommended in published NICE technology appraisal guidance for the same indication, a cost comparison may be carried out. 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:** Sotorasib for previously treated KRAS G12C mutation-positive advanced non-small-cell lung cancer (2022). NICE technology appraisal guidance 781. Selpercatinib for previously treated RET fusion-positive advanced non-small-cell lung cancer (2022). NICE technology appraisal guidance 760. Nivolumab for advanced non-squamous non-small-cell lung cancer after chemotherapy (2021). NICE technology appraisal guidance 713. Nivolumab for advanced squamous non-small-cell lung cancer after chemotherapy (2020). NICE technology appraisal guidance 655.

	Atezolizumab for treating locally advanced or metastatic non-small-cell lung cancer after chemotherapy (2018). NICE technology appraisal guidance 520. Pembrolizumab for treating PD-L1-positive non-small-cell lung cancer after chemotherapy (2017). NICE technology appraisal guidance 428. **Related technology appraisals in development:** Sotorasib for previously treated KRAS G12C mutation-positive advanced non-small-cell lung cancer (review of TA781) NICE technology appraisal guidance ID6287. Publication expected February 2025. Adagrasib for previously treated KRAS G12C mutation-positive advanced non-small-cell lung cancer. NICE technology appraisal guidance ID6339. Publication expected July 2025. Datopotamab deruxtecan for treating advanced non-small-cell lung cancer after platinum-based chemotherapy. NICE technology appraisal guidance ID6241. Publication expected August 2025. **Related NICE guidelines:** Lung cancer: diagnosis and management (2019) NICE guideline NG122. **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 2013/2014 NHS Standard Contract for Cancer: Chemotherapy (Adult)

Questions for consultation

Where do you consider tislelizumab will fit into the existing care pathway for advanced NSCLC that has been treated with platinum based chemotherapy?

Are the subgroups listed in the draft scope appropriate, are any subgroups missing?

Are the comparators listed in the draft scope appropriate? Are any treatment options for people with advanced NSCLC after platinum based chemotherapy missing?

In NHS clinical practice would people with advanced NSCLC be offered immunotherapy second line? And if so, what proportion?

If tislelizumab was recommended, would it displace lorlatinib (TA628), brigatinib (TA571), ceritinib (TA395), crizotinib (TA422) or osimertinib (TA653)?

Would tislelizumab be a candidate for managed access?

Do you consider that the use of tislelizumab 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 tislelizumab 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).

NICE is considering evaluating this technology through its cost comparison evaluation process.
Please provide 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).

Technologies can be evaluated through the cost-comparison process if they are expected to provide similar or greater health benefits, at a similar or lower cost, compared with technologies that have been previously recommended (as an option) in published NICE guidance for the same indication. Companies can propose cost-comparison topics to NICE at any stage during topic selection and scoping. NICE will route technologies for evaluation through the cost-comparison process if it is agreed during scoping that the process is an appropriate route to establish the clinical and cost effectiveness of the technology.

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

- Is the technology likely to be similar in its clinical effectiveness and resource use to any of the comparators? Or in what way is it different to the comparators?

- Will the intervention be used in the same place in the treatment pathway as the comparator(s)? Have there been any major changes to the treatment pathway recently? If so, please describe.
- Will the intervention be used to treat the same population as the comparator(s)?
- Overall is the technology likely to offer similar or improved health benefits compared with the comparators?
- Would it be appropriate to use the cost-comparison methodology for this topic?

References

1. NHS Digital Cancer registration statistics, England, 2022 [accessed November 2024]
2. National Lung Cancer Audit State of the nation 2024 report version 2 [accessed November 2024]
3. Cancer Research UK Survival for lung cancer [accessed November 2024]