NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Appraisal

Atezolizumab for adjuvant treatment of resected non-small-cell lung cancer

Draft scope

Draft remit/appraisal objective

To appraise the clinical and cost effectiveness of atezolizumab within its marketing authorisation for adjuvant treatment of resected non-small-cell lung cancer.

Background

Lung cancer is the third most common cancer and the most common cause of cancer death in the UK, accounting for 13% of all new cancer cases and 21% of all cancer deaths in 2017.[1] There are around 38,900 new lung cancer cases and 27,700 deaths from lung cancer in the England every year. Up to 85% of lung cancers are non-small-cell lung cancers (NSCLC).[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 III) or to other parts of the body (metastatic disease; stage IV). Less than 30% of lung cancers are diagnosed at an early stage (stage I or II).

NICE guideline Lung cancer: diagnosis and management recommends surgery, radiotherapy, chemoradiotherapy or a combination of these for early stage disease.[4] Around 18% of people with NSCLC had surgical resection with curative intent in England and Wales in 2017.[3] If well enough, people may be offered a cisplatin-based chemotherapy (adjuvant treatment) after surgery.[4] People are actively monitored for cancer recurrence. If the cancer comes back, treatment options and prognosis depend on the site of the recurrence. Despite the curative intent of treatment for early-stage lung cancer, survival is poor, with only about 57% people with stage I, 34% with stage II and 13% with stage III surviving for 5 years after diagnosis.[1]

It is estimated that over half of all NSCLCs express the programmed cell death ligand-1 (PD-L1) biomarker.[5] Cancer cells expressing PD-L1 are believed to suppress certain immune responses and cause increased tumor aggressiveness.

The technology

Atezolizumab (Tecentriq, Roche) is a humanised, monoclonal antibody that targets PD-L1 resulting in reactivation of T cells that are attacking the cancer cells. It is administered intravenously.

Atezolizumab does not currently have a marketing authorisation in the UK as adjuvant treatment for NSCLC after surgery and adjuvant cisplatin-based chemotherapy. It is being studied in a clinical trial compared with best supportive care, in adults with resectable (stage IB to stage IIIA) NSCLC after surgery and adjuvant cisplatin-based chemotherapy.

Intervention(s)	Atezolizumab (as an adjuvant treatment)
Population(s)	Adults with fully resected NSCLC after adjuvant cisplatin-based chemotherapy
Comparators	Established clinical management without atezolizumab (that is, active monitoring)
Outcomes	The outcome measures to be considered include: • overall survival • progression-free survival • response rate • 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 of any managed access arrangement for the intervention will be taken into account.
Other considerations	If evidence allows, subgroup analysis by level of PD-L1 expression will be considered. 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 and NICE Pathways	**Related Technology Appraisals:** Atezolizumab for treating locally advanced or metastatic non-small-cell lung cancer after chemotherapy (2018). NICE Technology Appraisals guidance TA520. Review date 2021. Atezolizumab in combination for treating metastatic non-squamous non-small-cell lung cancer (2019) NICE Technology Appraisal guidance TA584. Review date 2022.

	Terminated appraisals Atezolizumab with carboplatin and nab-paclitaxel for untreated advanced non-squamous non-small-cell lung cancer (terminated appraisal) (2020). NICE Technology appraisal TA618. **Appraisals in development (including suspended appraisals):** Atezolizumab monotherapy for untreated PD-L1 positive metastatic non-small-cell lung cancer. NICE technology appraisals guidance [ID1678]. Publication expected June 2021. Osimertinib for adjuvant treatment of EGFR mutation-positive non-small-cell lung cancer after complete tumour resection. NICE technology appraisals guidance [ID3835]. Publication expected September 2021. Atezolizumab in combination for untreated squamous non-small-cell lung cancer. [ID1481] (suspended).**Related Guidelines:** Lung cancer: diagnosis and management (2019). NICE guideline NG122. **Related Interventional Procedures** Microwave ablation for treating primary lung cancer and metastases in the lung (2013). NICE interventional procedures guidance 469. **Related Quality Standards:** Lung cancer in adults (2019). NICE quality standard 17 **Related NICE Pathways:** Lung cancer (2021) NICE pathway
Related National Policy	The NHS Long Term Plan, 2019. NHS Long Term Plan NHS England (2018) Manual for prescribed specialised services 2018/19 Chapter 105: Specialist cancer services (adults). Department of Health, NHS Outcomes Framework 2016-2017 (published 2016): Domain 1

Questions for consultation

Have all relevant comparators for atezolizumab for adjuvant treatment of fully resected non-small-cell lung cancer after cisplatin-based chemotherapy been included in the scope?

Are all people with fully resected stage IB, II or IIIA NSCLC suitable for adjuvant therapy?

Are there any other technologies for adjuvant treatment of fully resected NSCLC after cisplatin-based chemotherapy?

How should 'established clinical management without atezolizumab' be defined?

Is there a routine test to detect the biomarker PD-L1 in resected samples?

Are the outcomes listed appropriate?

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

Where do you consider atezolizumab will fit into the existing NICE pathway, Lung Cancer?

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 atezolizumab 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.

Do you consider atezolizumab to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)?

Do you consider that the use of atezolizumab can result in any potential significant and 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 Appraisal Committee to take account of these benefits.

To help NICE prioritise topics for additional adoption support, do you consider that there will be any barriers to adoption of this technology into practice? If yes, please describe briefly.

NICE intends to appraise this technology through its Single Technology Appraisal (STA) Process. We welcome comments on the appropriateness of appraising this topic through this process. (Information on the Institute's Technology Appraisal processes is available at http://www.nice.org.uk/article/pmg19/chapter/1-Introduction).

References

1. Lung cancer statistics. Cancer Research UK. Accessed February 2021
2. Types of lung cancer. Cancer Research UK. Accessed February 2021
3. National Lung Cancer Audit: Annual report 2018 (for the audit period 2017) (2020). Royal College of Physicians. Accessed February 2021.
4. Lung cancer: diagnosis and management. (2019) NICE guideline 122
5. 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