NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal

Durvalumab for maintenance treatment of unresectable non-small cell lung cancer after platinum-based chemoradiation [ID1175]

Final scope

Remit/appraisal objective

To appraise the clinical and cost effectiveness of durvalumab within its marketing authorisation for the maintenance treatment of locally advanced unresectable non-small-cell lung cancer that has not progressed following platinum-based chemoradiation therapy.

Background

Lung cancer falls into two main histological categories: around 85–90% are non-small-cell lung cancers (NSCLC) and the remainder are small cell lung cancers. NSCLC can be further classified into 3 histological sub-types of large-cell undifferentiated carcinoma, squamous cell carcinoma and adenocarcinoma. 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).

Cancer cells expressing an immunologic marker called programmed cell death 1 ligand (PD-L1) are believed to suppress certain immune responses and cause increased tumor aggressiveness. The proportion of NSCLC that is PD-L1 positive in England is unknown.

In 2015, around 33,000 people were estimated to be diagnosed with NSCLC in England.[1,2] Around 21% had stage III disease.[1] The prognosis for people with non-small-cell lung cancer is generally poor. Between 2011 and 2015 around 39% of people with lung cancer survived for 1 year or longer and only 15% survived for 5 years or longer.[2]

NICE clinical guideline 121 (CG121) recommends chemoradiotherapy as an option for people with stage II or III unresectable non-small-cell lung cancer. There is currently no national clinical guidance on maintenance therapy for people who do not progress following chemoradiation therapy.

The technology

Durvalumab (Imfinzi, AstraZeneca) is a human monoclonal antibody that targets the 'programmed death ligand-1' (PD-L1) protein. Durvalumab blocks PD-L1 interaction with both PD-1 and CD80 on T cells, countering the

tumour's immune-evading tactics and activating the patient's immune system to attack the cancer. It is administered by intravenous infusion.

Durvalumab does not currently have a marketing authorisation for treating unresectable non-small-cell lung cancer after platinum-based chemoradiation. It has been studied in clinical trials as monotherapy compared with placebo in people with locally advanced, unresectable non-small cell lung cancer (Stage III) whose disease has not progressed following at least 2 cycles of platinum-based chemoradiotherapy.

Intervention(s)	Durvalumab
Population(s)	Adults with locally advanced, unresectable non-small cell lung cancer whose disease has not progressed after platinum-based chemoradiation therapy
Comparators	Best supportive care
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.

Other considerations	Guidance will only be issued in accordance with the marketing authorisation. If the evidence allows, consideration will be given to subgroups based on biological markers (for example, PD-L1 expression) 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: None Related Guidelines: The diagnosis and treatment of lung cancer (2011). NICE clinical guideline 121. Review date TBC. Related Quality Standards: 'Quality standard for lung cancer (2012). NICE quality standard 17. http://www.nice.org.uk/guidance/qualitystandards/qualitystandards.jsp Related NICE Pathways: Lung cancer. Pathway created: Mar 2012. http://pathways.nice.org.uk/pathways/lung-cancer
Related National Policy	NHS England (2016) Manual for Prescribed Specialised Services 2016/17. See section 105 – specialist cancer services, pp 228-. NHS England (2015) Non-small-cell lung cancer. National chemotherapy algorithm. This is commercial in confidence NHS England. 2013/14 NHS Standard Contract for Radiotherapy (All ages). B01/S/a NHS England. 2013/14 NHS Standard Contract for Chemotherapy (All ages). B15/S/a NHS England (April 2013). Clinical Commissioning Policy: Stereotactic Ablative Body Radiotherapy for Non-Small-Cell Lung Cancer (Adult). NHSCB/B01/P/a

	Department of Health (2016) NHS outcomes framework 2016 to 2017 Independent Cancer Taskforce (2015) Achieving world-class cancer outcomes: a strategy for England 2015-2020 Department of Health (2014) The national cancer strategy: 4th annual report Department of Health (2011) Improving outcomes: a strategy for cancer Department of Health (2009) Cancer commissioning guidance Department of Health (2007) Cancer reform strategy

References

1. National lung cancer audit 2016 (2017) Royal college of Physicians. Accessed October 2017.

2. 2 Cancer survival in England: adult, stage at diagnosis and childhood-patients followed up to 2016 (2017) Office for National Statistics. Accessed October 2017