NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE
Health Technology Evaluation

Osimertinib for maintenance treatment of EGFR mutation-positive locally advanced unresectable non-small-cell lung cancer after platinum-based chemoradiation [ID6223]

Final scope

Remit/evaluation objective

To appraise the clinical and cost effectiveness of osimertinib within its marketing authorisation as maintenance treatment of EGFR mutation-positive (exon 19 deletion or exon 21 (L858R) substitution, either alone or in combination with other EGFR mutations) locally advanced, unresectable non-small-cell lung cancer (NSCLC) which has not progressed after platinum based chemoradiation.

Background

Lung cancer is the fourth most common cancer and the most common cause of cancer death in the UK, accounting for 12% of all new cancer cases and 19.5% of all cancer deaths in 2021.[1] There were around 40,000 new lung cancer cases and 26,000 deaths from lung cancer in England in 2021.[1,2] 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, 92% (around 33,000) of people diagnosed with lung cancer in England had NSCLC.[3]

As a result of the targeted NHS 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. Around 15% of non-small-cell lung cancers harbour an EGFR mutation.[4]

NICE's Lung cancer: diagnosis and management guideline recommends several options for people with unresectable locally advanced non-small-cell lung cancer. These include chemoradiation which can be either concurrent (chemotherapy given alongside radiotherapy) or sequential (chemotherapy followed by radiotherapy) and radiotherapy alone. NICE guidance (TA798) recommends durvalumab as maintenance treatment for people whose NSCLC is PD-L1 positive and has not progressed after concurrent platinum based chemoradiation. Some people may have best supportive care.

The technology

Osimertinib (Tagrisso, AstraZeneca) does not currently have a marketing authorisation in the UK as a maintenance treatment for NSCLC after platinum-based chemotherapy. It is being studied in a phase 3 clinical trial compared with placebo in people who have locally advanced, unresectable NSCLC with one of the two common EGFR mutations, exon 19 deletion or exon 21 (L858R) substitution, either alone or in combination with other EGFR mutations.

Osimertinib does have a marketing authorisation for use as an adjuvant treatment of EGFR genetic alteration (exon 19 deletion or exon 21 L858R substitution) positive

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NSCLC after complete tumour resection and for treating untreated and previously treated EGFR mutation positive locally advanced or metastatic NSCLC.

Intervention(s)	Osimertinib
Population(s)	Adults with EGFR mutation-positive (exon 19 deletion or exon 21 (L858R) substitution, either alone or in combination with other EGFR mutations) locally advanced unresectable NSCLC whose disease has not progressed after platinum based chemoradiation
Subgroups	If the evidence allows then the following subgroups will be considered: • people who had concurrent or sequential chemoradiation therapy • PD-L1 expression • disease stage • newly diagnosed or recurrent NSCLC (including post-surgery recurrence) • treatments had at previous stages (if any) • type of EGFR mutation.
Comparators	• Durvalumab (for people who had concurrent chemoradiation therapy and have PD-L1 positive NSCLC) • Best supportive care.
Outcomes	The outcome measures to be considered include: • overall survival • progression-free survival • CNS progression-free survival • disease free survival • response rates • adverse effects of treatment • health-related quality of life.

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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.
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:** Durvalumab for maintenance treatment of unresectable non-small-cell lung cancer after platinum-based chemoradiation (2022) NICE technology appraisal guidance 798 Osimertinib for adjuvant treatment of EGFR mutation-positive non-small-cell lung cancer after complete tumour resection (2022) NICE technology appraisals guidance 761. **Related NICE guidelines:** Lung cancer: diagnosis and management (2023) NICE guideline 122 **Related diagnostics guidance:** EGFR-TK mutation testing in adults with locally advanced or metastatic non-small-cell lung cancer (2013) NICE diagnostics guidance 9. **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 (2023) Manual for prescribed specialist services (2023/2024) Chapter 105: Specialist cancer services (adults).

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References

1. NHS England. Cancer Registration Statistics, England, 2022 - NHS England Digital. Accessed October 2024

2. Office for National Statistics. Deaths registered in England and Wales - Office for National Statistics (ons.gov.uk). Accessed October 2024

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

4. Prevalence of Epidermal Growth Factor Receptor Exon 20 Insertion Mutations in Non-small-Cell Lung Cancer in Europe: A Pragmatic Literature Review and Meta-analysis. Van Sanden. S, Murton. M et al (2022). Accessed January 2024

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