NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Final draft guidance

Alectinib for adjuvant treatment of ALK-positive non-small-cell lung cancer

1 Recommendation

1.1 Alectinib is recommended, within its marketing authorisation, as an option for the adjuvant treatment of stage 1B (tumours 4 cm or larger) to 3A ALK-positive non-small-cell lung cancer (NSCLC) after complete tumour resection in adults. It is only recommended if the company provides it according to the commercial arrangement (see section 2).

Why this recommendation was made

Usual treatment for stage 1B to 3A ALK-positive NSCLC after surgery (adjuvant treatment) is active monitoring or chemotherapy.

Clinical trial evidence suggests that when people have alectinib after surgery the cancer is less likely to come back than if they have chemotherapy after surgery. But the trial has not been going for long enough to tell if people having alectinib live for longer than those having chemotherapy.

Despite the uncertainties in the clinical evidence, exploratory analyses show that all likely cost-effectiveness estimates are within the range that NICE considers an acceptable use of NHS resources. So alectinib is recommended.

The external assessment group's base case is considered the most likely estimate for decision making. This evaluation used the seventh edition of the Union for International Cancer Control (UICC) and the American Joint Committee on Cancer

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(AJCC) staging system, because this was used in the clinical trial and marketing authorisation. For all the evidence, see the committee papers.

2 Information about alectinib

Marketing authorisation indication

2.1 Alectinib is indicated for 'adjuvant treatment for adult patients with Stage IB (tumours ≥4cm) to IIIA (7th edition of the UICC/AJCC-staging system) anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC) following complete tumour resection'.

Dosage in the marketing authorisation

2.2 The dosage schedule is available in the summary of product characteristics for alectinib.

Price

2.3 The list price of 150 mg alectinib is £5,032 per 224-capsule pack (excluding VAT; BNF online, accessed August 2024). The cost of a course of treatment is £172,068.

2.4 The company has a commercial arrangement (simple patient access scheme). This makes alectinib available to the NHS with a discount. The size of the discount is commercial in confidence.

3 Implementation

3.1 Section 7 of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 requires integrated care boards, NHS England and, with respect to their public health functions, local authorities to comply with the recommendations in this evaluation within 3 months of its date of publication.

3.2 Chapter 2 of Appraisal and funding of cancer drugs from July 2016 (including the new Cancer Drugs Fund) – A new deal for patients, taxpayers and industry states that for those drugs with a draft recommendation for routine commissioning, interim funding will be available (from the overall Cancer Drugs Fund budget) from the point of marketing authorisation, or from release of positive draft guidance, whichever is later. Interim funding will end 90 days after positive final guidance is published (or 30 days in the case of drugs with an Early Access to Medicines Scheme designation or cost comparison evaluation), at which point funding will switch to routine commissioning budgets. The NHS England Cancer Drugs Fund list provides up-to-date information on all cancer treatments recommended by NICE since 2016. This includes whether they have received a marketing authorisation and been launched in the UK.

3.3 The Welsh ministers have issued directions to the NHS in Wales on implementing NICE technology appraisal guidance. When a NICE technology appraisal guidance recommends the use of a drug or treatment, or other technology, the NHS in Wales must usually provide funding and resources for it within 2 months of the first publication of the final draft guidance.

3.4 When NICE recommends a treatment 'as an option', the NHS must make sure it is available within the period set out in the paragraphs above. This means that, if a patient has completely resected stage 1B to 3A NSCLC, and the healthcare professional responsible for their care thinks that alectinib is the right treatment, it should be available for use, in line with NICE's recommendations.

4 Evaluation committee members and NICE project team

Evaluation committee members

The 4 technology appraisal committees are standing advisory committees of NICE. This topic was considered by the lead team of committee A, which includes the chair and vice-chair.

Committee members are asked to declare any interests in the technology being evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

NICE project team

Each evaluation is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the evaluation), a technical adviser, a project manager and an associate director.

Samuel Slayen
Technical lead

Michelle Green
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Kate Moore
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DISBN: [to be added at publication]