SMC2749

alectinib hard capsules (Alecensa®)

Roche Products Ltd

07 March 2025

The Scottish Medicines Consortium (SMC) has completed its assessment of the above product and, following review by the SMC executive, advises NHS Boards and Area Drug and Therapeutic Committees (ADTCs) on its use in NHSScotland. The advice is summarised as follows:

ADVICE: following a full submission

alectinib (Alecensa®) is accepted for use within NHSScotland.

Indication under review: as monotherapy as adjuvant treatment for adult patients with Stage IB (tumours ≥ 4 cm) 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.

In an open-label phase III study, alectinib was associated with a statistically significant improvement in disease-free survival compared with platinum-based chemotherapy following surgery in patients with early ALK-positive NSCLC.

This advice applies only in the context of approved NHSScotland Patient Access Scheme (PAS) arrangements delivering the cost-effectiveness results upon which the decision was based, or PAS/ list prices that are equivalent or lower.

Chair
Scottish Medicines Consortium

1. Clinical Context

1.1. Medicine background

Alectinib is an anaplastic lymphoma kinase (ALK) and rearranged during transfection (RET) tyrosine kinase inhibitor (TKI). Inhibition of ALK tyrosine kinase activity leads to blockage of downstream signalling pathways and induction of tumour cell death. The recommended dose of alectinib is 600 mg taken twice daily with food (total daily dose of 1200 mg). Treatment with alectinib should be continued until disease recurrence, unacceptable toxicity, or for 2 years. Further details, including appropriate dose modifications, are included in the summary of product characteristics.[1]

1.2. Disease background

Approximately 50% of patients with non-small cell lung cancer (NSCLC) receive a diagnosis with early-stage or locally advanced disease (stage I, III, or III). Around 5% of patients with NSCLC have the ALK fusion gene (resulting from chromosomal inversion at 2p21 and 2p23) which makes an ALK fusion protein that contributes to increased cell proliferation and survival in tumours expressing these genes. ALK-positive tumours tend to be associated with younger patients, adenocarcinoma histology and history of never or light smoking, with relatively higher incidence in females. ALK-positive NSCLC has a high risk of central nervous system (CNS) metastases, and the CNS is the most common site for disease progression. There is substantial morbidity associated with CNS metastases, and their treatment.[2, 3]

1.3. Treatment pathway and relevant comparators

In patients with Stage I to III ALK-positive resectable NSCLC, the initial treatment is surgery. The standard of care treatment for patients with resected ALK-positive NSCLC is adjuvant chemotherapy or, in a small proportion of patients, active monitoring. Recommended platinum-based chemotherapy regimens include cisplatin plus vinorelbine or cisplatin plus pemetrexed[4]; cisplatin can be switched to carboplatin if required. Some patients, such as those with stage IB and possibly stage IIA disease, may not receive adjuvant chemotherapy and may be actively monitored instead. The role of immunotherapy in ALK-positive disease remains unclear and is generally not recommended at present.[2, 5] Alectinib has previously been accepted for use by SMC as monotherapy for the first-line treatment of adult patients with ALK-positive advanced NSCLC (SMC2012).

2. Summary of Clinical Evidence

2.1. Evidence for the licensed indication under review

Evidence to support the efficacy and safety of alectinib for the adjuvant treatment of resected ALK-positive NSCLC comes from ALINA. Details are summarised in Table 2.1.

Table 2.1. Overview of relevant studies

Criteria	ALINA[3]
Study design	International, randomised, open-label, phase III study.
Eligible patients	• Adult patients with completely resected, histologically confirmed stage IB (tumours ≥4 cm), II, or IIIA NSCLC (as classified according to the 7th edition of the UICC/AJCC *Cancer Staging Manual* of the American Joint

	Committee on Cancer and Union for International Cancer Control) • Documented ALK-positive disease • Eligible for platinum-based chemotherapy • ECOG performance status of 0 or 1 • No previous systemic anticancer therapy
Treatments	Alectinib orally 600 mg twice daily (n=130) or intravenous platinum-based chemotherapy in four 21-day cycles (n=127). Investigators could choose between three platinum-based regimens: cisplatin 75 mg/m^2 on day 1 plus vinorelbine 25 mg/m^2 on days 1 and 8; cisplatin 75 mg/m^2 on day 1 plus gemcitabine 1,250 mg/m^2 on days 1 and 8; cisplatin 75 mg/m^2 on day 1 pemetrexed 500 mg/m^2 on day 1. Cisplatin could be replaced by carboplatin in cases of intolerability. Treatment was to continue until completion of the treatment period (24 months for alectinib and four 21-day cycles for chemotherapy), disease recurrence, unacceptable toxicity, withdrawal of consent, or death, whichever occurred first.
Randomisation	Patients were randomised equally. Randomisation was stratified according to disease stage (IB versus II versus IIIA) and race (Asian versus non-Asian).
Primary outcome	DFS, defined as the time from randomisation to the first documented recurrence of disease or new primary NSCLC as determined by the investigator or to death from any cause.
Secondary outcomes	Overall survival, time to CNS recurrence or death.
Statistical analysis	Efficacy analyses were performed in the ITT population, which included all patients who underwent randomisation, and in the subgroup of patients with stage II or IIIA NSCLC. A testing hierarchy was used to control the overall type I error rate at 5% with regard to DFS firstly in the Stage II-IIIA subpopulation and then in the ITT population. A pre-planned interim analysis was to be conducted after approximately 67% of events (59 events) were observed in the stage II to IIIA subgroup.

Abbreviations: ALK = anaplastic lymphoma kinase; CNS = central nervous system; DFS = disease-free survival; ITT = intention-to-treat; NSCLC = non-small cell lung cancer; OS = overall survival; UICC/AJCC = Cancer Staging Manual of the American Joint Committee on Cancer and Union for International Cancer Control.

At the preplanned interim analysis, alectinib demonstrated significant improvements in disease-free survival (DFS) compared with platinum-based chemotherapy in both the subgroup of patients with stage II to IIIA disease and in the intention-to-treat (ITT) population. Since pre-specified stopping boundaries were crossed, the interim analysis became the primary analysis and no further hypothesis testing was performed. Results for the ITT population, which reflects the licensed indication, are presented in Table 2.2.

Table 2.2. Key results from ALINA (ITT population) (data cut-off 26 June 2023).[2, 3]

	Alectinib (n=130)	**Chemotherapy (n=127)**
Median duration of follow-up	27.8 months	28.4 months
Primary outcome: DFS (investigator-assessed)		
Events (n)	15	50
Median DFS	NE	41.3 months
Hazard ratio (95% CI)	0.24 (0.13 to 0.43) p<0.001	
Event free rate at 24 months	94%	64%
Secondary outcome: overall survival		
Events (n)	2	4
Median OS	NE	NE

Hazard ratio (95% CI)	0.46 (0.08 to 2.52)	
Exploratory outcome: time to CNS recurrence or death		
Events (n)	5	18
Median time to CNS recurrence	NE	NE
Hazard ratio (95% CI)	0.22 (0.08 to 0.58)	
Event free rate at 24 months	98%	86%

Abbreviations: CI = confidence interval; CNS = central nervous system; DFS = disease-free survival; NE = not estimable; OS = overall survival.

2.2. Health-related quality of life outcomes

Health-Related Quality of Life (HRQoL) was assessed as an exploratory outcome using the Short Form-36 version 2 (SF-36V2) health survey, which assesses functional health and wellbeing across eight domains and two summary scores: the physical component summary (PCS) and mental component summary (MCS). Patients completed the SF-36v2 at baseline, every 3 weeks to week 12, then every 12 weeks until disease recurrence, withdrawal of consent, death, or week 96 (or equivalent post-chemotherapy follow-up visit). Patients in the alectinib group had an improvement in five domains of HRQoL by week 12 (mean change from baseline met or exceeded minimal important differences), followed by maintenance of HRQoL in all eight domains, MCS, and PCS to week 96. Patients in the chemotherapy group had low HRQoL during treatment but improved in the post-chemotherapy period; in the final assessment, minimal important differences were met or exceeded in five domains, MCS, and PCS.[6]

3. Summary of Safety Evidence

In the ALINA study at data cut-off 26 June 2023, the median duration of treatment in the alectinib group was 23.9 months and in the chemotherapy group was 2.1 months. Any adverse event (AE) was reported by 98% (126/128) of patients in the alectinib group and 93% (112/120) in the chemotherapy group and these were considered treatment-related in 94% and 89% respectively. In the alectinib and chemotherapy groups respectively, patients reporting a grade 3 or higher AE were 30% versus 31%, patients with a reported serious AE were 13% versus 8.3%, patients with a dose modification/interruption due to AEs were 43% versus 22%, and patients discontinuing therapy due to an AE was 5.5% versus 12%.[2, 3]

The most frequently reported AEs of any grade with an incidence ≥25% in either the alectinib group or the chemotherapy group were: nausea (7.8% versus 72%); increased creatine kinase (43% versus 0.8%); constipation (42% versus 25%); increased aspartate aminotransferase (41% versus 5.0%); increased alanine aminotransferase (34% versus 9.2%); increased blood bilirubin (34% versus 0.8%); decreased appetite (5.5% versus 29%); COVID-19 (29% versus 0.8%); myalgia (28% versus 1.7%); anaemia (23% versus 26%); vomiting (7.0% versus 25%); increased alkaline phosphatase (25% versus 3.3%).[3]

The safety profile of adjuvant alectinib based on data from ALINA is consistent with the known safety profile of alectinib in NSCLC. One new adverse drug reaction was identified (hyperuricaemia, which was reported in 9.4% of patients in the alectinib group).[2]

4. Summary of Clinical Effectiveness Considerations

4.1. Key strengths

- Alectinib is the first targeted medicine licensed for the adjuvant treatment of early ALK-positive NSCLC following complete resection.
- ALINA is a phase III randomised controlled study that compared alectinib with platinum-based chemotherapy in patients with resected ALK-positive NSCLC. Platinum-based chemotherapy is the most relevant comparator.
- Alectinib was associated with a statistically significant and clinically meaningful improvement in DFS. The hazard ratio of 0.24 corresponds to a 76% lower risk of disease recurrence or death with alectinib versus chemotherapy.[3]
- Exploratory analysis from ALINA appears to suggest that alectinib prolongs time to CNS recurrence or death compared with chemotherapy. This is particularly relevant for patients with ALK-positive NSCLC since the CNS is the most common site for disease progression and is associated with substantial morbidity.[2]

4.2. Key uncertainties

- DFS is a well-established efficacy outcome in studies of adjuvant therapy in resectable NSCLC and can be considered appropriate. However, DFS is not a direct measure of health benefit, and is a surrogate for overall survival. While a large benefit in DFS is generally expected to translate to an effect on overall survival, the magnitude of this benefit may be less certain. DFS and overall survival data from ALINA are immature.[3, 7, 8]
- Further data are required to confirm persistence of treatment effect of alectinib following treatment discontinuation.[2]
- No direct or indirect evidence is available comparing alectinib with active monitoring. A small number of patients may not receive adjuvant chemotherapy and may be actively monitored instead.
- ALINA is an open-label study which may introduce bias, the primary outcome of DFS was assessed by investigators. A scenario analysis using blinded independent central review of DFS from November 2023 was provided to regulators, the results of which were broadly consistent with the primary findings (HR 0.30 [95% CI: 0.17 to 0.54]).[2, 3]
- In ALINA, there were some differences between the alectinib and chemotherapy groups at baseline including: female patients (58% versus 46%); patients who had never smoked (65% versus 55%); and patients aged <65 years (79% versus 73%).[3] The study population is likely to differ to the eligible Scottish population. Patients in ALINA may be younger (median age of 56 years), and there was a high proportion of Asian patients (56% of study population) and low representation of Black patients (0.4% of study population).[2] It is not clear what impact this could have on the generalisability of the study results to patients in Scotland.

4.3. Clinical expert input

Clinical experts consulted by SMC considered that alectinib fills an unmet need in this area and consider it to be a therapeutic advancement. At present, there are no adjuvant targeted treatment options for patients with resected ALK-positive NSCLC.

4.4. Service implications

There are no major service implications anticipated with the introduction of alectinib for the treatment of resected ALK-positive NSCLC. The number of patients with completely resected ALK-positive NSCLC is limited. Alectinib is an oral medication which provides a convenient route of administration for patients and would be advantageous for chemotherapy day units.

Diagnostic testing required to identify patients eligible for treatment: contact local laboratory for information.

5. Summary of Patient and Carer Involvement

The following information reflects the views of the specified Patient Groups.

- We received patient group submissions from ALK Positive Lung Cancer UK, Roy Castle Lung Cancer Foundation and Scottish Lung Cancer Nurses Forum. ALK Positive Lung Cancer UK and the Roy Castle Lung Cancer Foundation are registered charities. The Scottish Lung Cancer Nurses Forum is an unincorporated organisation.
- ALK Positive Lung Cancer UK received has received 20% pharmaceutical company funding in the past two years, including from the submitting company. Roy Castle Lung Cancer Foundation has received 7.6% pharmaceutical company funding in the past two years, including from the submitting company. The Scottish Lung Cancer Nurses Forum has not received any pharmaceutical company funding in the past two years.
- Lung Cancer is the leading cause of cancer related mortality in the UK. Living with a diagnosis of lung cancer brings a high level of stress and anxiety to both patients and their families. Troublesome symptoms include breathlessness, fatigue and a cough that can have a big impact on day-to-day functioning. Patients with ALK-positive NSCLC are prone to developing brain metastases. Apart from the medical consequences of brain metastases, patients lose their driving licence which can have a major impact on their independence, affecting not only the patient but also their families.
- Currently in Scotland, there are no targeted therapies given as adjuvant treatment after surgery for those with ALK-positive NSCLC. The aim of early targeted treatment with alectinib is that it may prevent recurrence of the cancer, and reduce the risk of spread to the brain.
- Having access to alectinib as adjuvant treatment after surgery could offer an improvement in the treatment pathway for those with ALK-positive NSCLC. It may offer better long-term outcomes.
- Patients surveyed by one of the patient groups indicated that alectinib was well-tolerated with fewer side effects than chemotherapy.

6. Summary of Comparative Health Economic Evidence

6.1. Economic case

The submitted economic case is summarised in Table 6.1.

Table 6.1 Description of economic analysis

Criteria	Overview
Analysis type	Cost-utility analysis
Time horizon	40 years.
Population	Patients with Stage IB to IIIA ALK-positive NSCLC following complete tumour resection.
Comparators	Alectinib was compared against platinum-based chemotherapy. Chemotherapy regimen included in the model were cisplatin plus vinorelbine, cisplatin plus gemcitabine and cisplatin plus pemetrexed.
Model description	An eight state semi-Markov model was used to conduct the economic analysis. Patients started in the disease-free state before progressing through non-metastatic recurrence, metastatic recurrence (first-line) and metastatic recurrence (second line) stages. Each of the recurrence stages was split between treatment and non-treatment model states. The final state was an absorbing death state. The model used a cycle length of one month with a half-cycle correction.
Clinical data	The primary clinical data source was the ALINA study.[3] This informed the risk of recurrence in the disease-free state.
Extrapolation	To model the occupancy of the disease-free state, jointly fitted log-logistic curves were estimated based on Kaplan Meier (KM) data from the ALINA study. The destination of events between non-metastatic recurrence, metastatic recurrence and death states were matched to the proportions observed in the ALINA study. These proportions were fixed and treatment dependent. A cure rate was applied to those patients who remained alive and disease-free at 10 years. Those proportions were 92% in the chemotherapy arm and 94% in the alectinib arm and were based on clinical opinion. Upon cure, patients were subject to a mortality rate estimated from general population data, to which a standardised mortality ratio of 1.25 was applied. Occupancy of the subsequent recurrence states could not be based on data observed as part of the ALINA study. Baskets of treatment at each stage were estimated. Pseudo-patient level survival and progression data were generated by digitising KM graphs from secondary sources. Exponential curves were fitted to that pseudo-patient level data.
Quality of life	Quality of life data were collected as part of the ALINA study using the EQ-5D-5L instrument. These data were mapped to the EQ-5D-3L instrument before being entered into a mixed-effects regression to estimate utility values in the disease-free state. Utility values were treatment arm and treatment status dependent. Utility values for the alectinib arm were 0.83 when on treatment and 0.86 when off treatment. Utility values in the chemotherapy arm were 0.81 when on treatment and 0.86 when off treatment. No adverse event disutilities were included as these were assumed to be captured in the on treatment values. Utility in the non-metastatic recurrence and metastatic recurrence were estimated as 0.77 and 0.70 respectively, based on a secondary source.[9]
Costs and resource use	Medicine costs included acquisition costs (initial and subsequent lines of treatment), administration costs and adverse event costs. Wider resource use included in the model were for monitoring, consultations and scans. There was a one-off cost of death.
PAS	A Patient Access Scheme (PAS) was submitted by the company and assessed by the Patient Access Scheme Assessment Group (PASAG) as acceptable for implementation in NHSScotland. Under the PAS, a discount was offered on the list price. A PAS discount is in place for crizotinib, brigatinib, lorlatinib and ceritinib, which are used in subsequent treatment lines, and these were included in the results used for decision-making by using estimates of the comparator PAS price.

6.2. Results

SMC considered results for decision-making that took into account all relevant PAS. SMC is unable to present these results due to competition law issues.

The estimated incremental quality-adjusted life year gain was 3.00.

6.3. Sensitivity analyses

A range of sensitivity and scenario analyses were considered and descriptions of these key scenarios are provided in Table 6.2 below.

Table 6.2 Scenario analysis

	Parameter	Base case	Scenario	Incr. QALYs
-	Base case	-	-	3.00
1	Time horizon	40 years	20 years	2.28
2			30 years	2.88
3	DFS distributions (jointly fitted)	Log-logistic	Exponential	3.64
4			Log-normal	2.77
5			Gompertz	3.10
6	DFS distributions (independently fitted – matched across arms)	N/A	Exponential	4.15
7			Log-logistic	3.17
8			Gompertz	1.30
9	Standardised Mortality Ratio	1.25	1.0	3.20
10			1.70	2.71
11			2.30	2.40
12	Active monitoring as a comparator	Excluded as a comparator	Includes as a comparator	3.00
13	Recurrence proportions in DFS state	Estimated separately across arms	Estimated jointly across arms	2.98
14	Assessed of DFS	Investigator	Independent	2.51

Abbreviations: Incr, incremental; QALYs, quality-adjusted life years; DFS, disease-free survival; BNF, British National Formulary

6.4. Key strengths

- The population in the model matched the licensed indication.
- The model structure appears to be appropriate given data limitations.
- The ALINA study compared alectinib against a relevant comparator and found a significant improvement in DFS.

6.5. Key uncertainties

- The extrapolation of DFS in the alectinib arm was seen as a large area of uncertainty due to the immaturity of the data. The lack of progression events in the alectinib arm meant that there was little evidence to distinguish between alternative parametric survival curves. While the submitting company did receive clinical input while selecting the parametric functions, DFS projection was still seen as a large area of uncertainty within the model,

particularly as the main driver of improved health in the alectinib arm was greater occupancy of the disease-free state. However, under plausible assumptions the range of economic results was relatively modest.

- The OS data collected as part of the ALINA study were highly immature and was not used in the model. Mortality was pieced based on external estimates on a state-by-state basis. This raises some uncertainties on how effective alectinib would be at improving OS.
- ALINA was an open-label study, which may have introduced bias in some outcomes, and within the base case progression status was assessed by the investigators. Independently reviewed progression status can often be viewed as more robust and less subject to bias. A scenario utilising independently assessed progression status led to a small increase in the ICER (scenario 14). Another area of concern with an open-label study can be the estimated utility values, however within this submission the estimated values seem consistent with those used in other SMC submissions for resected NSCLC.
- The submitting company included a comparison with active monitoring within the economics (Scenario 12). This relied on an assumption of equal efficacy between active monitoring and chemotherapy so was not viewed as insightful for decision-making. However, it was acknowledged that only a small proportion of patients are likely to receive active monitoring in Scottish practice.

*Other data were also assessed but remain confidential.**

7. Conclusion

After considering all the available evidence, the Committee accepted alectinib for use in NHSScotland.

8. Guidelines and Protocols

The National Institute for Health and Care Excellence (NICE) published Lung cancer: diagnosis and management (NG 122) in March 2019, which was updated in March 2023.[10]

The European Society for Medical Oncology (ESMO) published "ESMO Consensus Conference on Lung Cancer: early-stage non-small-cell lung cancer consensus on diagnosis, treatment and follow-up" in August 2014.[11]

9. Additional Information

9.1. Product availability date

11 July 2024.

Table 9.1 List price of medicine under review

Medicine	Dose regimen	Cost per year (£)
alectinib	**600 mg orally twice daily**	**£65,416**

Costs from BNF online on 11 December 2024. Costs do not take any patient access schemes into consideration.

10. Company Estimate of Eligible Population and Estimated Budget Impact

The submitting company estimates that there will be around eight patients eligible for treatment with alectinib in year one rising to 19 in year five. The uptake rate was estimated to be 30% in year one (two patients) and 85% in year five (16 patients).

SMC is unable to publish the with PAS budget impact due to commercial in confidence issues. A budget impact template is provided in confidence to NHS health boards to enable them to estimate the predicted budget with the PAS. This template does not incorporate any PAS discounts associated with subsequent lines of treatment.

*Other data were also assessed but remain confidential.**

References

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This assessment is based on data submitted by the applicant company up to and including 14 February 2025.

**Agreement between the Association of the British Pharmaceutical Industry (ABPI) and the SMC on guidelines for the release of company data into the public domain during a health technology appraisal:*https://www.scottishmedicines.org.uk/about-us/policies-publications/

Medicine prices are those available at the time the papers were issued to SMC for consideration. SMC is aware that for some hospital-only products national or local contracts may be in place for comparator products that can significantly reduce the acquisition cost to Health Boards. These contract prices are commercial in confidence and cannot be put in the public domain, including via

the SMC Detailed Advice Document. Area Drug and Therapeutics Committees and NHS Boards are therefore asked to consider contract pricing when reviewing advice on medicines accepted by SMC.

Patient access schemes: A patient access scheme is a scheme proposed by a pharmaceutical company in order to improve the cost-effectiveness of a medicine and enable patients to receive access to cost-effective innovative medicines. A Patient Access Scheme Assessment Group (PASAG), established under the auspices of NHS National Services Scotland reviews and advises NHSScotland on the feasibility of proposed schemes for implementation. The PASAG operates separately from SMC in order to maintain the integrity and independence of the assessment process of the SMC. When SMC accepts a medicine for use in NHSScotland on the basis of a patient access scheme that has been considered feasible by PASAG, a set of guidance notes on the operation of the scheme will be circulated to Area Drug and Therapeutics Committees and NHS Boards prior to publication of SMC advice.

Advice context:

No part of this advice may be used without the whole of the advice being quoted in full.

This advice represents the view of the Scottish Medicines Consortium and was arrived at after careful consideration and evaluation of the available evidence. It is provided to inform the considerations of Area Drug & Therapeutics Committees and NHS Boards in Scotland in determining medicines for local use or local formulary inclusion. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.