Zorginstituut Nederland

National Health Care Institute
Research, Development and Medicinal Products
Medicinal Products Team

Willem Dudokhof 1
1112 ZA Diemen
PO Box 320
1110 AH Diemen
www.zorginstituutnederland.nl
info@zinl.nl

T +31 (0)20-7978227

Contact
Ms A. Waal
vragen@zinl.nl

Our reference
2026013907

> Return address PO Box 320, 1110 AH Diemen

To the Minister of Health, Welfare and Sport
P.O. Box 20350
2500 EJ THE HAGUE

2026013907

Date: 9 July 2026
Re: Reimbursement advice lock procedure medicinal product amivantamab in combination with lazertinib for non-small cell lung cancer (NSCLC)

Dear Ms Hermans,

The National Health Care Institute advises you about the assessment of amivantamab (Rybrevant®) + lazertinib (Lazcluze®) for the first-line treatment of certain patients with advanced non-small cell lung cancer (NSCLC). This advice was prompted by the placement of amivantamab and lazertinib in the lock procedure for expensive medicinal products. The National Health Care Institute advises you not to include amivantamab + lazertinib for the mentioned indication in the basic health insurance package, unless, after successful price negotiations, the net treatment costs do not exceed the net treatment costs of osimertinib + chemotherapy.

In lung cancer, there is a malignant tumour in the lungs. There are two forms of lung cancer: small cell (SCLC) and non-small cell (NSCLC). In NSCLC, the cells usually grow slowly. In the Netherlands, more than 10,000 patients were diagnosed with NSCLC in 2023. If the cancer has spread further into the chest (locally advanced) or has spread through the rest of the body (metastatic), this is called advanced lung cancer. Cure is then no longer possible. In patients with metastatic NSCLC, the 5-year survival rate is only 9%. Approximately 10-15% of patients with lung cancer have an EGFR mutation. At the present time, the standard treatment for patients with advanced NSCLC with an EGFR mutation is osimertinib as monotherapy. In the second line, patients usually receive chemotherapy.

However, very recently, the National Health Care Institute concluded that osimertinib + chemotherapy has an added value compared to osimertinib monotherapy[1]. As a result, osimertinib + chemotherapy has become the new preferred treatment for patients with NSCLC with EGFR exon-19 deletions or

[1] Advice - only reimburse osimertinib (Tagrisso®) in combination with pemetrexed and chemotherapy for the treatment of advanced non-small cell lung cancer after a price decrease | National Health Care Institute

exon-21 (L858R) substitution mutations. The treatment combination is not (yet) reimbursed, as price negotiations are still ongoing.

National Health Care Institute
Research, Development and Medicinal Products
Medicinal Products Team

Date
9 July 2026

Our reference
2026013907

Registered indication
Amivantamab (Rybrevant®) is indicated in combination with lazertinib (Lazcluze®) for the first-line treatment of adult patients with advanced NSCLC with EGFR exon-19 deletions or exon-21 (L858R)substitution mutations.

Amivantamab has been registered for multiple forms of NSCLC in different treatment lines and medicinal product combinations. Another assessment of amivantamab is currently ongoing at the National Health Care Institute, namely as first-line treatment in combination with chemotherapy for patients with NSCLC and activating EGFR insertion mutations in the exon-20 gene. Lazertinib is not registered for other indications.

Claim by the marketing authorisation holder (MAH)
Amivantamab + lazertinib has added value compared to osimertinib monotherapy for the registered indication.

Reimbursement advice
The National Health Care Institute advises you not to include amivantamab + lazertinib for the first-line treatment of NSCLC in patients whose tumours exhibit epidermal growth factor receptor (EGFR) exon-19 deletions or exon-21 (L858R) substitution mutations in the basic health insurance package, unless the net treatment costs after successful price negotiations do not exceed the net treatment costs of osimertinib + chemotherapy. The National Health Care Institute has determined that amivantamab + lazertinib for this indication meets the criterion of 'established medical science and medical practice' and that its therapeutic value is comparable with that of the standard treatment with osimertinib + chemotherapy.

We explain the preparation of this reimbursement advice below.
General
At your request, the National Health Care Institute assesses whether care should be part of the standard health insurance package from the perspective of the health insurance package paid from joint premiums.

The National Health Care Institute makes its assessments on the basis of four package criteria[2]: effectiveness[3], cost-effectiveness[4], necessity[5] and feasibility[6]. Stakeholders are consulted during the process.

[2] Real-world package management 4 (2023). National Health Care Institute, Diemen. Via www.zorginstituutnederland.nl.

[3] Assessment of the established medical science and medical practice (2023). National Health Care Institute. Via www.zorginstituutnederland.nl.

[4] Healthcare cost-effectiveness report (2024) National Health Care Institute, Diemen. Via www.zorginstituutnederland.nl.

[5] Necessity is related to both the medical need due to the severity of a disease for the patient (burden of disease) and the need to insure something. See the report on real-world package management 4 (2023).

[6] The package criterion of feasibility deals with whether it is feasible or sustainable to include a specific type of care in the basic health insurance package. It is therefore mainly a test of a number of implementation aspects, such as the healthcare organisation, the support base, ethical and legal aspects, budget impact, etc. See the report on real-world package management 4 (2023).

National Health Care Institute
Research, Development and Medicinal Products
Medicinal Products Team

Date
9 July 2026

Our reference
2026013907

Comprehensive weighting of reimbursement criteria

Effectiveness

Established medical science and medical practice

The National Health Care Institute recently concluded that osimertinib + chemotherapy has an added value compared to osimertinib monotherapy. The physicians' association has indicated that both combinations are positioned at the same place in the treatment algorithm. Amivantamab + lazertinib was therefore compared to osimertinib + chemotherapy in this assessment.

Both amivantamab + lazertinib and osimertinib + chemotherapy were studied in a randomised study (RCT) that directly compared them to osimertinib monotherapy in patients with advanced NSCLC with EGFR exon-19 deletions or exon-21 (L858R) substitution mutations, namely in the MARIPOSA and FLAURA2 studies, respectively. There is no direct comparative study available. The MARIPOSA and FLAURA2 studies showed that there are no clinically relevant differences between the two treatment combinations in the effects on patients' survival and quality of life. Both treatment combinations also have more adverse effects than osimertinib monotherapy. However, there are differences in the type of adverse effects of the treatment combinations. In addition, amivantamab can be administered either subcutaneously or intravenously, as opposed to chemotherapy that can only be administered intravenously. Lazertinib and osimertinib are both administered orally. Thus, in practice, a decision whether a patient will be treated with amivantamab + lazertinib, osimertinib + chemotherapy, or osimertinib monotherapy will be made based on individual patient characteristics and preferences.

The National Health Care Institute has concluded that amivantamab + lazertinib for this indication meets the established medical science and medical practice and has a value comparable with that of the standard treatment with osimertinib + chemotherapy.

Cost-effectiveness

Due to its comparable value, the National Health Care Institute has not assessed its cost-effectiveness.

Feasibility

Budget impact analysis

Because osimertinib + chemotherapy is not currently included in the health insurance package and price negotiations are still ongoing, 2 scenarios have been developed in the budget impact analysis for amivantamab + lazertinib: a scenario in which only amivantamab + lazertinib becomes available (scenario 1) and a scenario in which both treatment combinations become available (scenario 2).

In scenario 1, the National Health Care Institute estimates that 743 patients will be treated with amivantamab + lazertinib for the aforementioned indication in year 3 after inclusion in the package. The total average treatment costs per patient within the first 3 years are €283,133 (of which €145,067 is for amivantamab and €138,066 for lazertinib). This results in macro costs of €74.4 million in the third year. When substitution of osimertinib as monotherapy is also taken into account, the budget impact in year 3 will be €38.9 million based on list prices.

National Health Care Institute
Research, Development and Medicinal Products
Medicinal Products Team

Date
9 July 2026

Our reference
2026013907

In scenario 2, the National Health Care Institute estimates that 371 patients will be treated with amivantamab + lazertinib for the aforementioned indication in year 3 after inclusion in the package. This results in macro costs of €37.2 million in the third year. When substitution of osimertinib + chemotherapy is also taken into account, the budget impact in year 3 will be €16.0 million based on list prices.

There is uncertainty about the actual treatment durations of all treatment options and about the proportion of patients receiving each treatment option. Also, the actual budget impact will be different given the price agreements already made for osimertinib monotherapy and those that will be made for both combination treatments.

Should you need any further information, please do not hesitate to contact us.

Yours sincerely,

M.J. Janssen
Chairperson of the Executive Board

Appendices:
- Pharmacotherapeutic report
- Budget impact analysis