Zorginstituut Nederland

> Return address PO Box 320, 1110 AH Diemen

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

2025029513

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)20 797 85 55

Contact
E. De Groot
warcg@zinl.nl

Our reference
2025029513

Date: 19 December 2025
Re: Reimbursement advice lock procedure medicinal product nemolizumab (Nemluvio®) for atopic eczema and prurigo nodularis

Dear Mr Bruijn,

The National Health Care Institute advises you on the assessment of nemolizumab (Nemluvio®) for the treatment of moderate-to-severe atopic dermatitis and moderate-to-severe prurigo nodularis. This advice was prompted by the placement of nemoluzimab in the package lock procedure for expensive medicinal products.

Condition

Atopic eczema

Atopic dermatitis, or atopic eczema, is a skin disorder. It is a chronic inflammatory disease of the skin, with itching and (severe) broken skin as the main symptoms. Eczema can have a (major) influence on the quality of life of the patient and, in the event that it occurs in children, on daily family life as well. In the Netherlands, approximately 400,000 people have eczema and this is more common in men than in women.
Eczema is initially treated with an ointment and may be treated with topical corticosteroids (TCS) or topical calcineurin inhibitors (TCI). Only when this does not offer sufficient relief should systemic treatment with immunosuppressive medicinal products be considered. As a final option, biologicals (dupilumab, tralokinumab, lebrikizumab) or JAK inhibitors (abrocitinib, baricitinib, upadacitinib) are used.
Based on its mechanism of action and form of administration, the National Health Care Institute compares nemolizumab with the other biologicals used for atopic eczema.

Prurigo nodularis

Prurigo nodularis (PN) is a skin condition with severely itching lumps, usually on the arms and legs. The condition is maintained by a vicious circle of itching and scratching, leading to thickening and hardening of the skin. PN can occur in all age groups, but is mainly seen in middle-aged adults. PN is a condition associated with a significant physical and psychological burden of disease caused by itching, sleep deprivation, social isolation, and depressive or anxious feelings.
The incidence of PN is estimated to be 1,676 new cases per year. The prevalence is estimated between 5,886 and 29,980 patients in the Netherlands.

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

Date
19 December 2025

Our reference
2025029513

The treatment of PN is mainly aimed at relieving the itching and rash, and the severity of the condition determines how the condition is treated. In general, TCS and topical TCIs are used as first therapy. If these topical therapies fail, systemic administration of these medical products is initiated. In addition, off-label treatment may include antihistamines, antidepressants, light therapy and immunosuppressants.

Patients with moderate-to-severe PN who do not respond well to intensive topical therapies (possibly in combination with light therapy), at least one off-label systemic therapy, and who have been treated for at least 4 months, are eligible for dupilumab.

Licensed indication
Nemolizumab (Nemluvio®) is indicated for:
- use in patients aged 12 years and older with moderate-to-severe atopic dermatitis who are eligible for systemic treatment
- use in adults with moderate-to-severe prurigo nodularis who are eligible for systemic treatment.

Claim by the marketing authorisation holder
Nemolizumab (Nemluvio®) has a similar value to dupilumab for the registered indications.

Reimbursement advice
The National Health Care Institute advises you to include nemolizumab (Nemluvio®) in the basic healthcare package, provided that inclusion in the package does not result in additional costs.
The National Health Care Institute has determined that nemolizumab, for the treatment of both patients with moderate-to-severe atopic dermatitis who are eligible for systemic treatment, and patients with moderate-to-severe prurigo nodularis who are eligible for systemic treatment, meets the legal criterion of 'established medical science and medical practice' and that there is an equal value compared to the standard treatments in these indications.

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 basic healthcare package paid from joint premiums.

The National Health Care Institute assesses on the basis of the four package

criteria[1]: effectiveness[2], cost-effectiveness[3], necessity[4] and feasibility[5]. Stakeholders are consulted during the process.

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

Date
19 December 2025

Our reference
2025029513

Comprehensive weighting of reimbursement criteria

Effectiveness

Established medical science and medical practice

Atopic dermatitis (eczema)

The effectiveness and safety of nemolizumab have been evaluated in two Phase 3 randomised clinical studies (RCTs), ARCADIA 1 and 2, and compared to placebo. The National Health Care Institute assessed how nemolizumab compares to the other biologicals used for the treatment of atopic eczema. An indirect naive comparison of the relevant studies did not reveal clinically relevant differences in the beneficial effects of itching, severity of the condition and quality of life. These beneficial effects were measured using different measurement methods, namely the Peak Pruritis Numeric Rating Scale (PP-NRS), Eczema Area and Severity Index (EASI), the Investigator Global Clinical Assessment (IGA) and the Dermatology Life Quality Index (DLQI). The adverse effects profiles vary, but based on these, no clear clinically relevant benefit for a medicinal product can be determined. Therefore, the National Health Care Institute concludes that nemolizumab is equivalent to the other biologicals dupilumab, lebrikizumab and tralokinumab for the treatment of patients with moderate-to-severe atopic dermatitis who are eligible for systemic treatment.

Pruritis nodularis

The effectiveness and safety of nemolizumab have been evaluated in two Phase 3 RCTs, OLYMPIA 1 and 2, and compared to placebo. An indirect naive comparison of nemolizumab and dupilumab did not reveal clinically relevant differences in the beneficial effects on itching (PP-NRS), severity of the condition (EASI, IGA) and quality of life (DLQI). Again, the adverse reactions profiles differ, but based on these, no clear clinically relevant benefit for one medicinal product can be determined. Therefore, the National Health Care Institute concludes that nemolizumab and dupilumab have an equal value in the treatment of patients with moderate-to-severe PN who are eligible for systemic treatment.

Cost-effectiveness

Due to its equal value, the National Health Care Institute has not assessed its cost-effectiveness. It is not known whether the compared treatments are cost-effective.

---

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

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

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

[4] 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).

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

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

Date
19 December 2025

Our reference
2025029513

Budget impact analysis
Atopic dermatitis (eczema)
The National Health Care Institute estimates that 1,216 patients per year will receive nemolizumab for eczema in year 3 after inclusion in the package. The total cost per patient per year amounts to €18,508 in the first year and €12,030 in every subsequent year. This results in possible macro costs of €17.5 million in the third year. If substitution is also taken into account, the budget impact in year 3 will be savings of € 1 million.

Based on the equal value, the introduction of nemolizumab for the treatment of atopic dermatitis should not result in additional costs.
There is uncertainty about the budget impact, change in the market shares of the different biologicals may lead to additional costs instead of savings upon the introduction of nemolizumab.

Pruritis nodularis
The National Health Care Institute estimates that 171 patients per year will be treated with nemolizumab for pruritis nodularis in year 3 after inclusion in the package. The total cost per patient per year amounts to €33,055 in the first year and €29,353 in every subsequent year. This results in possible macro costs of €5.3 million in the third year. When dupilumab substitution is also taken into account, the budget impact in year 3 will amount to € 2.7 million.
In particular, there is uncertainty about the number of patients with PN in the Netherlands, including the number of patients eligible for nemolizumab treatment for PN. For this reason, the National Health Care Institute has calculated a scenario analysis that also includes less growth.
Based on the equal value, introduction of nemolizumab for PN should not result in additional costs.

The calculations in the BIA used list prices.

Appropriate care
Currently, conditions as described in the Dutch Association of Dermatology and Venereology Guideline apply for the prescription of biologicals for atopic dermatitis and pruritis nodularis. These conditions should also apply for nemolizumab.

Should you need any further information, please do not hesitate to contact us.
The assessment reports have been added as annexes (pharmacotherapeutic report and budget impact analysis).

Yours sincerely,

M.J. Janssen
Chairperson of the Executive Board