[Date]

[Patient’s name]

[Date of birth]

[Case identification]

Re: Appeal of Coverage Denial for NEMLUVIO® (nemolizumab-ilto)

To Whom It May Concern:

I am writing this in support of my request to review a denied claim for my patient, [patient name]. On [date of denial], your organization denied this claim for NEMLUVIO, an FDA-approved medication indicated for the treatment of patients ≥12 years old with moderate-to-severe atopic dermatitis (AD) in combination with topical corticosteroids and/or calcineurin inhibitors when the disease is not adequately controlled with topical prescription therapies.

The reason(s) for denial [is/are] stated as [list reason(s) for the denial from the health insurance plan denial letter]. I disagree with this decision because [reason(s) you disagree with the denial]. This letter [and the attached documentation] provide support for the use of NEMLUVIO for this patient.

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| **Clinical Records** |
| Patient diagnosis: [Include ICD-10 diagnosis code] |
| Disease severity: [Include information such as body surface area involvement, IGA score, and failure or intolerance with prior therapies]  |
| Quality of life measures: [Include information such as patient occupation and impact on daily activities] |

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| **Treatment History** |
| Drug/dose/therapy | Treatment dates | Reason(s) for discontinuation or contraindication |
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NEMLUVIO is the first and only neuroimmune-targeted treatment to directly block IL-31RA—blocking the signaling that drives itch, inflammation, skin barrier dysfunction, and fibrosis.1,2 The other FDA-approved treatment options for AD target IL-4, IL-13, and JAKis.2,3

NEMLUVIO has been shown to be safe and effective based on the two ARCADIA phase 3 trials. In the clinical trials, NEMLUVIO monotherapy was administered every 4 weeks in combination with topical corticosteroids and/or calcineurin inhibitors to patients ≥12 years old with moderate-to-severe AD, which my patient suffers from. Treatment with NEMLUVIO showed significant and rapid itch relief as early as 1 week compared to control in these trials. In addition to this, NEMLUVIO displayed significant skin clearance, symptom improvement, and reductions in sleep disturbance compared to control, which my patient could benefit from.1,4

[Summarize treatment recommendation here].

Given the patient’s history, their current condition, and the emerging data of the effects of NEMLUVIO in patients with AD, I believe that treatment of NEMLUVIO with [patient name] is warranted, appropriate, and medically necessary, and the claim should be covered and reimbursed. The totality of the data available to date supports the potential benefit of [treatment/continuing treatment] with NEMLUVIO.

Please feel free to contact me, [HCP name], at [office phone number] for any additional information you may require. We look forward to receiving your timely response and approval of this claim.

Sincerely,

[Physician’s name and signature, medical specialty, and contact information]

Attachments: [Include list of supporting information provided with letter such as patient medical records, referenced publications, and/or NEMLUVIO Prescribing Information]

FDA, Food and Drug Administration; [HCP, healthcare professional; ICD-10, International Classification of Diseases, Tenth Revision; IGA, Investigator’s Global Assessment;] IL, interleukin; JAKi, Janus kinase inhibitor; RA, receptor antagonist.

References:

1. NEMLUVIO. Prescribing Information. Galderma Laboratories, L.P.
2. Nemmer JM et al. *Front Med (Lausanne)*. 2021;8:639097.
3. Datsi A et al. *Allergy*. 2021;76(10):2982-2997.
4. Silverberg JI et al. *Lancet*. 2024;404(10451):445-460.