[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 adults with prurigo nodularis (PN).

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 number of nodules, duration of pruritus, and history or signs of repeated itch-scratch cycle] |
| Quality of life measures: [Include information such as patient occupation and impact on daily activities] |

|  |  |  |
| --- | --- | --- |
| **Treatment History** | | |
| Drug/dose/therapy | Treatment dates | Reason(s) for discontinuation or contraindication |
|  |  |  |
|  |  |  |
|  |  |  |

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 only other FDA-approved treatment option for PN is dupilumab, an IL-4/-13 inhibitor.2

NEMLUVIO has been shown to be safe and effective based on the two OLYMPIA phase 3 trials. In the clinical trials, NEMLUVIO monotherapy was administered every 4 weeks in adults with moderate-to-severe PN, which my patient suffers from. Treatment with NEMLUVIO showed significant and rapid itch relief as early as 1 week compared to placebo in these trials. In addition to this, NEMLUVIO displayed significant skin clearance and reductions in sleep disturbance compared to placebo, which my patient could benefit from.1,3

[Summarize treatment recommendation here].

Given the patient’s history, their current condition, and the emerging data of the effects of NEMLUVIO in patients with PN, 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.v

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;] IL, interleukin; RA, receptor antagonist.

**References:**

1. NEMLUVIO. Prescribing Information. Galderma Laboratories, L.P.
2. Nemmer JM et al. *Front Med (Lausanne)*. 2021;8:639097.
3. Kwatra SG, et al. *N Engl J Med*. 2023;389(17):1579-1589.