[Date]

[Patient’s name]

[Date of birth]

[Case identification]

Re: Letter of Medical Necessity for NEMLUVIO® (nemolizumab-ilto)

To Whom It May Concern:

I am a [board certified dermatologist] with [#] years of experience writing to provide additional information to support the need for [patient’s name]’s NEMLUVIO [dose and directions] 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. In brief, treatment with NEMLUVIO is medically necessary based on the patient’s confirmed diagnosis of AD, severity of symptoms, [impact to quality of life,] and ineffective response to prior treatments. This letter includes the patient’s medical history, previous treatments, and evidence from published articles that support the need for NEMLUVIO.

**Diagnosis and Medical History**

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| --- |
| **Patient Demographics** |
| 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, ie, school bus driver who is not getting enough sleep] |

|  |  |  |
| --- | --- | --- |
| **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 in AD compared to control, which my patient could benefit from.1,4

[Summarize treatment recommendation here].

Please feel free to contact me, 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.