GPS for nemluvio™

GALDERMA PATIENT SERVICES

Navigating Access for NEMLUVIO

Disclaimer: Galderma Laboratories, L.P. cannot guarantee insurance coverage or reimbursement. Coverage or reimbursement may vary significantly by payer, plan, patient, and setting of care. It is the sole responsibility of the health care provider (HCP) to ensure the accuracy of all statements made in seeking coverage and reimbursement for an individual patient.

IMPORTANT SAFETY INFORMATION

Indications: NEMLUVIO® (nemolizumab-ilto) is an interleukin-31 receptor alpha antagonist indicated for:

- the treatment of adults and pediatric patients 12 years of age and older with moderate-to-severe atopic dermatitis in combination with topical corticosteroids and/or calcineurin inhibitors when the disease is not adequately controlled with topical prescription therapies.
- the treatment of adults with prurigo nodularis.

Contraindication: Known hypersensitivity to nemolizumab-ilto or to any of the excipients in NEMLUVIO. **Warnings/Precautions:** Hypersensitivity reactions have been reported with NEMLUVIO use. If a clinically significant hypersensitivity reaction occurs, immediately institute appropriate therapy, and discontinue NEMLUVIO. Avoid use of live vaccines during treatment with NEMLUVIO. **Adverse Events:** Most common adverse reactions (incidence ≥1%) are:

- **Atopic Dermatitis:** headache (including migraine), arthralgia, urticaria, and myalgia.
- **Prurigo Nodularis:** headache, dermatitis atopic, eczema, and eczema nummular.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit *www.fda.gov/medwatch* or call 1-800-FDA-1088.

Please see accompanying Prescribing Information or click here for full Prescribing Information including Patient Information.

Table of Contents

The purpose of this resource is to equip you with information to support patient access to NEMLUVIO. It includes information on how to get patients started on treatment, navigating common payer restrictions with a focus on prior authorizations, and best practices for appealing a specific denial.

Please see Important Safety Information on page 1 and accompanying Prescribing Information or click here for full Prescribing Information including Patient Information.

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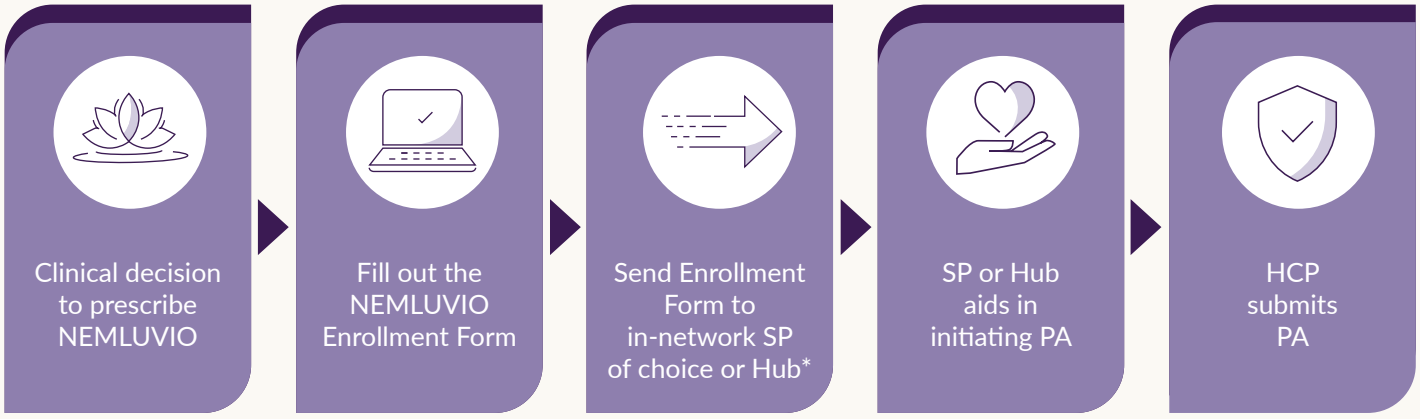
Getting Started

Pathway to Initiate NEMLUVIO



Enrollment Form

Every patient prescribed NEMLUVIO is encouraged to enroll in Galderma Patient Services (GPS) for NEMLUVIO by completing a NEMLUVIO Enrollment Form with the aid of your office. Enrolling the patient in GPS for NEMLUVIO helps support you and your patient by streamlining the benefits verification and PA processes. Please scan or click the code to the right to access the NEMLUVIO Enrollment Form.

Galderma Field Access Managers

The Galderma Field Access Managers play an important role in providing support and education to reduce non-clinical barriers for patient access. They can help with:

- Providing in-depth overview of services
- Navigating NEMLUVIO Enrollment Forms
- Understanding what is required for the benefits investigation and PA/appeal requirements
- Streamlining the Quick Start process and patient onboarding to NEMLUVIO

*The NEMLUVIO Enrollment Form serves as the prescription for NEMLUVIO.
HCP, health care provider; PA, prior authorization; SP, specialty pharmacy.

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Getting Started (cont'd)

NEMLUVIO Network of Specialty Pharmacies (SPs)

To avoid delays in patient access, send the prescription to your office's chosen SP that is in NEMLUVIO's preferred network.

Please refer to the network of SPs for NEMLUVIO below. Our SP network provides enhanced service offerings so that you and your patients are supported throughout the entire NEMLUVIO access journey.

Specialty Pharmacy	Phone Number	Fax
AcariaHealth	800-511-5144	877-541-1503
Accredo Health Group, Inc.	866-839-2162	866-531-1025
Amber Specialty Pharmacy	888-370-1724	877-645-7514
BioPlus Specialty Pharmacy	800-292-0744	800-269-5493
Blue Sky Specialty Pharmacy	866-822-0103	833-898-3992
Centerwell Specialty Pharmacy	800-486-2668	877-405-7940
CVS Specialty	800-237-2767	800-323-2445
Kroger Specialty Pharmacy	888-355-4191	888-355-4192
Lumicera Health Services	855-847-3553	855-847-3558
Optum Specialty	855-427-4682	877-342-4596
Senderra	855-460-7928	888-777-5645
Walgreens Specialty Pharmacy	888-347-3416	877-231-8302

For more information on the specialty distribution network, please scan the code to the right or click here to access the *Distribution Fact Sheet* for NEMLUVIO

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Prior Authorization (PA)

PA is a tool used by payers that requires a prescriber to provide information that the medication requested is appropriate for the patient. Drugs that require a PA will not be approved for payment until the conditions for approval of the drug are met.[1]*

Examples of Common PA Criteria for Atopic Dermatitis (AD)

- Diagnosis of moderate-to-severe AD[2]
- Prescribed by or in consultation with a specialist, such as a dermatologist, allergist, or immunologist[2-5]
- Age within FDA label and indication[3]
- At least 10% body surface area involvement[5,6]
- History of failure, contraindication, or intolerance to previous AD treatment(s), such as topical corticosteroids, topical calcineurin inhibitors, or a topical PDE4 inhibitor[2,4,6,7]
- Patient is not receiving NEMLUVIO in combination with another biologic immunomodulator or JAK inhibitor[2]

Examples of Common PA Criteria for Prurigo Nodularis (PN)

- Diagnosis of PN[2]
- Prescribed by or in consultation with a specialist, such as a dermatologist, allergist, or immunologist[2-5]
- Age within FDA label and indication[3]
- ≥20 nodular lesions[2,5,6]
- Pruritus duration for ≥6 weeks[5,6]
- History of failure, contraindication, or intolerance to previous PN treatment(s), such as phototherapy, topical corticosteroids, topical calcineurin inhibitors, methotrexate, or cyclosporine[2,4,6,7]
- Patient is not receiving NEMLUVIO in combination with another biologic immunomodulator[2]

*PA does not guarantee reimbursement or payment.
FDA, United States Food and Drug Administration; JAK, Janus kinase; PDE4, phosphodiesterase 4.

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PA (cont'd)

PA Checklist

Payers often require certain information to process a PA request for drug coverage. This checklist will help you capture common necessary information from your patient to facilitate the processing of a PA request to the payer.

Atopic Dermatitis (AD) | **Prurigo Nodularis (PN)**

Step 1: Getting Started with GPS for NEMLUVIO

- ☐ Complete the NEMLUVIO Enrollment Form, available here

Step 2: Clinical Records

- ☐ ICD-10 Diagnosis Code. See codes for AD below
  Coding is a clinical decision; ensure you are coding to the highest level of specificity. The codes shown below are only suggestions and may vary by patient.
  - ○ L20.8: Other atopic dermatitis[8]
  - ○ L20.9: Atopic dermatitis, unspecified[8]
- ☐ Age of patient
- ☐ Chart notes/documentation of diagnosis
  - ○ Body location (i.e., head, hands, feet, face, and genital area)
  - ○ Body surface area involvement (<10% or ≥10%)
  - ○ Severity of disease (moderate or severe)
    - IGA score of 3 (moderate disease) or 4 (severe disease), if required by payer
  - ○ Quality of life impact
  - ○ For continuation of therapy or reauthorization, documentation of improvement may be requested

Checklist continued on page 7.

GPS, Galderma Patient Services; ICD-10, International Classification of Diseases, Tenth Revision; IGA, Investigator's Global Assessment; PA, prior authorization.

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PA (cont'd)

Atopic Dermatitis (AD) | **Prurigo Nodularis (PN)**

Step 3: Treatment History

Payers often require trial and failure of certain prescription or over-the-counter drugs prior to approving NEMLUVIO.

☐ List **all** products the patient has tried and failed. See examples below:

Examples of Previous Treatments	Required Information
☐ Phototherapy ☐ Topicals ○ Topical corticosteroids ○ Topical calcineurin inhibitors ○ Topical PDE4 inhibitors ○ Topical JAK inhibitors ☐ Oral immunomodulators ○ Methotrexate ○ Cyclosporine ○ Azathioprine ○ Mycophenolate mofetil ☐ Biologics ○ Dupilumab ○ Tralokinumab-ldrm ○ Lebrikizumab-lbkz ☐ JAK inhibitors ○ Abrocitinib ○ Upadacitinib	☐ Clinical documentation of the following: ○ Duration of therapy ○ Inadequate response ○ Adverse events experiences with treatment OR ○ Information regarding contraindication/intolerance ○ Discontinuation plan of current treatment(s) (i.e., if patient is currently being treated with a biologic or JAK inhibitor but you are seeking approval to switch to NEMLUVIO)

Step 4: Submission

☐ Ensure all information is accurate and complete

☐ Submit the PA form and all chart notes/documentation via the payer's preferred method

NOTE: Please reference the payer's specific policy for that patient in order to ensure all required information is included

Scan the QR code or click here to access the *AD Checklist for Atopic Dermatitis Patients*

JAK, Janus kinase; PA, prior authorization; PDE4, phosphodiesterase 4.

Please see Important Safety Information on page 1 and accompanying Prescribing Information or click here for full Prescribing Information including Patient Information.

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PA (cont'd)

PA Checklist

Payers often require certain information to process a PA request for drug coverage. This checklist will help you capture common necessary information from your patient to facilitate the processing of a PA request to the payer.

Atopic Dermatitis (AD) | **Prurigo Nodularis (PN)**

Step 1: Getting Started with GPS for NEMLUVIO

- ☐ Complete the NEMLUVIO Enrollment Form, available here

Step 2: Clinical Records

- ☐ ICD-10 Diagnosis Code. See code for PN below
  Coding is a clinical decision; ensure you are coding to the highest level of specificity. The code shown below is only a suggestion and may vary by patient.
  - ○ L28.1: Prurigo nodularis[8]
- ☐ Age of patient
- ☐ Weight of patient (when requesting a maintenance dose of 60 mg every 4 weeks for NEMLUVIO)
- ☐ Chart notes/documentation of diagnosis
  - ○ Body location (i.e., head, hands, feet, face, and genital area)
  - ○ Number of nodules (specify ≥20 nodules)
  - ○ Duration/intensity of symptoms (specify ≥6 weeks of pruritus)
  - ○ History/signs of repeated itch/scratch cycle
  - ○ Quality of life impact
  - ○ For continuation of therapy or reauthorization, documentation of improvement may be requested

Checklist continued on page 9.

GPS, Galderma Patient Services; ICD-10, International Classification of Diseases, Tenth Revision; IGA, Investigator's Global Assessment; PA, prior authorization.

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PA (cont'd)

Atopic Dermatitis (AD) | **Prurigo Nodularis (PN)**

Step 3: Treatment History

Payers often require trial and failure of certain prescription or over-the-counter drugs prior to approving NEMLUVIO.

☐ List **all** products the patient has tried and failed. See examples below:

Examples of Previous Treatments	Required Information

☐ Phototherapy
☐ Intralesional injections
☐ Topicals
  ○ Topical corticosteroids
  ○ Topical calcineurin inhibitors
  ○ Topical PDE4 inhibitors
☐ Oral immunomodulators
  ○ Methotrexate
  ○ Cyclosporine
☐ Biologics
  ○ Dupilumab
	☐ Clinical documentation of the following:
	  ○ Duration of therapy
	  ○ Inadequate response
	  ○ Adverse events experiences with treatment
	OR
	  ○ Information regarding contraindication/intolerance
	  ○ Discontinuation plan of current treatment(s) (i.e., if patient is currently being treated with a biologic but you are seeking approval to switch to NEMLUVIO)

Step 4: Submission

☐ Ensure all information is accurate and complete

☐ Submit the PA form and all chart notes/documentation via the payer's preferred method

NOTE: Please reference the payer's specific policy for that patient in order to ensure all required information is included

Scan the QR code or click here to access the *PA Checklist for Prurigo Nodularis Patients*

PA, prior authorization; PDE4, phosphodiesterase 4.

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PA (cont'd)

Reauthorization

A reauthorization may be required after a specified time period following initial PA approval. There are often plan-specific requirements to show evidence of clinical response, such as improvement from baseline measurements (ie, number of nodules, PP-NRS, and IGA for PN or BSA, EASI, PP-NRS, and IGA for AD) and supporting documentation to provide evidence of the therapy's efficacy. Payers may have specific forms for reauthorization.

Atopic Dermatitis (AD) | **Prurigo Nodularis (PN)**

Flexible Maintenance Dosing for AD[9]

	Required Information
Initial Dosing	60 mg (two 30 mg injections)
Maintenance Dosing	30 mg every 4 weeks
Maintenance Dosing With Extended Interval for Responders Is recommended after 16 weeks of treatment for patients who achieve clear or almost clear skin	30 mg every 8 weeks

Some payers may require the dosing interval of every 8 weeks be utilized for reauthorization or documentation as to why increasing the dosing interval is not appropriate for the patient.

Common Reasons for a PA Denial

- Patient does not meet clinical criteria for approval
- A need for additional information, such as missing or incorrect chart notes/documentation
- Original submission did not include prior treatments tried/failed, reasons for failure, or contraindications to alternative treatments
- Patient is currently using a contraindicated medication or another advanced therapy without a discontinuation plan
- Age outside of FDA-approved label
- For reauthorizations, denials may occur if demonstrated efficacy is not communicated

If a PA is denied, an appeal can be submitted.
Please refer to the Appeals section for more information.

BSA, body surface area; EASI, Eczema Area and Severity Index; FDA, United States Food and Drug Administration; IGA, Investigator's Global Assessment; PA, prior authorization; PP-NRS, Peak Pruritus Numeric Rating Scale.

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Navigating Access

Quantity Limits

A payer may limit drug coverage to quantities that are consistent with FDA-approved durations or dosing.[1]

- For loading doses, a drug and quantity PA may be required
- Most payers limit each fill to a 28-day supply while others may allow a 3-month supply

Best Practice

- The pharmacy may contact the physician to change the prescription, or the physician may choose to submit a quantity limit exception request if the prescription as written is medically necessary[12]

Atopic Dermatitis (AD) | **Prurigo Nodularis (PN)**

Weight-based Dosing for PN[9]

	Adults Weighing <90 kg	Adults Weighing ≥90 kg
Initial Dosing	60 mg (two 30 mg injections)	
Maintenance Dosing	30 mg every 4 weeks	60 mg every 4 weeks

In adults with PN weighing ≥90 kg, 2 subcutaneous injections of NEMLUVIO 30 mg is the approved dosing schedule.[9]

FDA, United States Food and Drug Administration; PA, prior authorization.

Please see Important Safety Information on page 1 and accompanying Prescribing Information or click here for full Prescribing Information including Patient Information.

Navigating Access (cont'd)

Step Therapy

Step therapy requires the use of a first-line drug before the approval of another medication.[1]

Best Practices

- Review the payer's criteria
- Provide documentation to support medical necessity
- Include medications patient has tried and failed, the duration of therapy, and reason(s) why those treatments are no longer an option for the patient

Formulary Exclusion

A formulary exclusion list includes drugs that an insurer, payer, or pharmacy benefits manager does not cover.[10]

Best Practices

- The HCP may request a formulary exception (also known as a medical exception) for an excluded drug[11]
- The HCP may need to provide which drugs on the payer's formulary the patient has tried and failed or has a contraindication to

HCP, health care provider.

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Appeals

If a request for a prior authorization (PA) or a formulary exception is denied, your office or patient may consider submitting an appeal. An appeal is a request to your patient's payer to consider additional information for approval.

Overview of Appeals Process

1

PA or formulary exception denied*

2

Review reason for denial

- Non-clinical denial due to incorrect or incomplete information
- Clinical denial due to patient not meeting payer's clinical criteria

3

- Attempt to resubmit PA or formulary exception as appropriate†
- Review the payer's criteria and reassess patient appropriateness

Submit an appeal

Typically, denials and appeals are processed within 7 days, but timing may vary based on the payer. Review individual payer documents for specific timing.

*Prior to appeal, check with payer to see if they offer a peer-to-peer review.
†Note: Most plans will not allow resubmission of PA within a certain time frame, especially managed Medicaid plans.

Please see Important Safety Information on page 1 and accompanying Prescribing Information or click here for full Prescribing Information including Patient Information.

Appeals (cont'd)

Appeals Checklist

Step 1: Confirm Appeal Process With the Payer

- ☐ Review the reason for denial; ensure you understand fully prior to continuing with the appeal
- ☐ Review the payer's appeal process to determine the following:
  - ○ Specific form required by the payer
  - ○ Required or preferred method of submission (over the phone, in writing, etc.)
  - ○ Information that must be included in the appeal
  - ○ Anticipated timeline for review and response
  - ○ How the plan will communicate the decision
- ☐ Notify the patient if your office may need their involvement
- ☐ Reach out to your Galderma Field Access Manager for assistance with understanding the appeal process and tools available, if needed

Step 2: Submission

- ☐ Complete and submit appeal request
  - ○ Complete the required documentation
  - ○ Review the appeal request for accuracy and completeness
  - ○ Submit the required documentation
- ☐ Follow up
  - ○ Provide any additional documentation as requested within the required time frame

Step 3: Document Decision

- ☐ If the appeal is approved, document the medical exception or PA number to include within the patient's chart
- ☐ If the appeal is denied, document the date the denial was received and the reason for denial. Determine if an additional appeal will be requested

PA, prior authorization.

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Letter of Medical Necessity

A **Letter of Medical Necessity** is a written explanation from the HCP that describes the summary of treatment and rationale for why NEMLUVIO is clinically necessary for the patient. These letters should be presented in a concise manner while also making as strong an argument as possible.

Considerations and Best Practices for Writing a Letter of Medical Necessity

- ☐ Review the payer's coverage policy and provide background on your patient's condition
- ☐ Be sure to clearly state your patient's individual situation and justify why the prescribed therapy is the most appropriate treatment
- ☐ Present all required information such as documentation of all criteria your patient meets and a clear rationale for any they do not meet
- ☐ Include clinical justification, copies of relevant clinical data, and impact on quality of life to support your decision
- ☐ Submit the letter (on your office letterhead) as requested by your patient's payer along with the PA or formulary exception request
- ☐ Monitor the status of your request and follow up as needed

Please see the following page for a sample Letter of Medical Necessity. This is for informational purposes only and to be used as an example of what may be required or helpful when submitting a request to a patient's payer. Use of this information does not constitute medical or legal advice and does not guarantee reimbursement for coverage. It is not intended to be a substitute for the independent clinical decision of the prescribing HCP.

HCP, health care provider; PA, prior authorization.

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Letter of Medical Necessity (cont'd)

Atopic Dermatitis (AD) | **Prurigo Nodularis (PN)**

[Date]

[Patient's name]
[Date of birth]
[Case identification]

SAMPLE LETTER

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

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

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.

US-NPN-2400099 (12/24)

Scan the QR code to the right or click here to download the sample letter to customize for your patient.

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Letter of Medical Necessity (cont'd)

Atopic Dermatitis (AD) | Prurigo Nodularis (PN)

[Date]

[Patient's name]
[Date of birth]
[Case identification]

SAMPLE LETTER

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 adults with prurigo nodularis (PN). In brief, treatment with NEMLUVIO is medically necessary based on the patient's confirmed diagnosis of PN, 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

Patient Demographics
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, i.e., school bus driver who is not getting enough sleep]

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].

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;] 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.

US-NPN-2400024 (11/24)

Scan the QR code to the right or click here to download the sample letter to customize for your patient.

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Letter of Appeal

A **Letter of Appeal** is a document that requests a payer to reconsider its initial decision to deny coverage for NEMLUVIO. These letters are tailored to the specific needs of the patient and describe why NEMLUVIO is the most appropriate treatment option for the patient. These letters should be presented in a concise manner while also making as strong an argument as possible.

Considerations and Best Practices for Writing a Letter of Appeal

- ☐ Review the payer's denial and clearly state your reason for disagreeing with the denial
  - ○ Provide background on your patient's condition
  - ○ Be sure to clearly state your patient's individual situation and justify why the prescribed therapy is the most appropriate therapy option
  - ○ Present all required information such as documentation of all criteria your patient meets and a clear rationale for any they do not meet
- ☐ Include clinical justification and copies of relevant clinical data to support your decision
- ☐ Including information on the role of IL-31 in the pathophysiology of the disease may help support the decision to use NEMLUVIO vs other treatment options
- ☐ Submit the letter (on your office letterhead) as requested by your patient's payer
- ☐ Monitor the status of your appeal and follow up as needed

Please see the following page for a sample Letter of Appeal. This is for informational purposes only and to be used as an example of what may be required or helpful when responding to a request from a patient's payer. Use of this information does not constitute medical or legal advice and does not guarantee reimbursement for coverage. It is not intended to be a substitute for the independent clinical decision of the prescribing health care provider.

AD, atopic dermatitis; IL, interleukin; PN, prurigo nodularis.

Please see Important Safety Information on page 1 and accompanying Prescribing Information or click here for full Prescribing Information including Patient Information.

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Letter of Appeal (cont'd)

Atopic Dermatitis (AD) | **Prurigo Nodularis (PN)**

[Date]

[Patient's name]
[Date of birth]
[Case identification]

SAMPLE LETTER

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.

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]

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 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].

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.

US-NAD-2400052 (12/24)

Scan the QR code to the right or click here to download the sample letter to customize for your patient.

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GPS for nemluvio™
GALDERMA PATIENT SERVICES

Letter of Appeal (cont'd)

Atopic Dermatitis (AD) | **Prurigo Nodularis (PN)**

[Date]

[Patient's name]
[Date of birth]
[Case identification]

SAMPLE LETTER

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.

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.

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.

US-NPN-2400023 (11/24)

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Patient Letter

A **Patient Letter** is a document written by the patient to the payer that requests a payer to reconsider its initial decision to deny coverage for NEMLUVIO. These letters describe the impact of disease on life. These letters should be presented in a concise manner while also making as strong an argument as possible.

Please see the following page for a template for a patient letter. This is for informational purposes only and to be used as an example of what may be required or helpful when responding to a request from a patient's payer. Use of this information does not constitute medical or legal advice and does not guarantee reimbursement for coverage. It is not intended to be a substitute for the patient's actual experience or the independent clinical decision of the prescribing health care provider.

Please see Important Safety Information on page 1 and accompanying Prescribing Information or click here for full Prescribing Information including Patient Information.

Patient Letter (cont'd)

Atopic Dermatitis (AD) | **Prurigo Nodularis (PN)**

[Date]

SAMPLE LETTER

[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 to request reconsideration of the denial of coverage of NEMLUVIO, as prescribed by [health care professional name & credentials]. I am [a patient/a caregiver of patient] diagnosed with moderate-to-severe atopic dermatitis (AD). Your reason(s) for the denial were [list reason(s) for the denial from the health insurance plan denial letter].

After reviewing the denial letter, I maintain that NEMLUVIO is appropriate as prescribed by [healthcare professional name] based upon clinical criteria. Listed below is a summary of my relevant clinical history and personal experience with the disease.

As a [patient with AD/caregiver of a patient with AD], here is information about how AD has personally impacted [my/the patient's] life and why I am requesting coverage for the claim to address ongoing clinical needs of living with the disease:

[Include relevant personal experience with the disease and medical information to support the appeal for coverage of NEMLUVIO. May include the following information:

- Supporting information as requested by the payer in its denial letter
- Diagnostic results confirming the disease
- Treatment history, including name of medications, dates of use, and reason(s) for discontinuation
- Summary of how the disease has impacted the patient's quality of life over time; social dynamics; employment dynamics; personal experience living with the disease, etc.
- Clinical attributes of NEMLUVIO and why the patient needs the medical intervention or medication now]

Based upon [my/the patient's] condition and medical history, I believe coverage for NEMLUVIO is appropriate and medically necessary and the claim should be covered and reimbursed.

If you have any further questions about this matter, please feel free to contact me or my HCP at [patient/caregiver phone number; physician phone number] or via email at [patient/caregiver email address; healthcare provider's email address]. Thank you for your time and consideration. I look forward to your timely approval of my request.

Sincerely,
[Patient or caregiver's name and signature]
[Patient or caregiver's contact information]

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

US-NAD-2400053 (12/24)

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Patient Letter (cont'd)

Atopic Dermatitis (AD) | **Prurigo Nodularis (PN)**

[Date]

SAMPLE LETTER

[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 to request reconsideration of the denial of coverage of NEMLUVIO, as prescribed by [health care professional name & credentials]. I am [an adult patient/a caregiver of an adult patient] diagnosed with prurigo nodularis (PN). Your reason(s) for the denial were [list reason(s) for the denial from the health insurance plan denial letter].

After reviewing the denial letter, I maintain that NEMLUVIO is appropriate as prescribed by [healthcare professional name] based upon clinical criteria. Listed below is a summary of the relevant clinical history and personal experience with the disease.

As a [patient with PN/caregiver of a patient with PN], here is information about how PN has personally impacted [my/the patient's] life and why I am requesting coverage for the claim to address ongoing clinical needs of living with the disease:

[Include relevant personal experience with the disease and medical information to support the appeal for coverage of NEMLUVIO. May include the following information:

- Supporting information as requested by the payer in its denial letter
- Diagnostic results confirming the disease
- Treatment history, including name of medications, dates of use, and reason(s) for discontinuation
- Summary of how the disease has impacted the patient's quality of life over time; social dynamics; employment dynamics; personal experience living with the disease, etc.
- Clinical attributes of NEMLUVIO and why the patient needs the medical intervention or medication now]

Based upon [my/the patient's] condition and medical history, I believe coverage for NEMLUVIO is appropriate and medically necessary, and the claim should be covered and reimbursed.

If you have any further questions about this matter, please feel free to contact me or my HCP at [patient/caregiver phone number; physician phone number] or via email at [patient/caregiver email address; healthcare provider's email address]. Thank you for your time and consideration. I look forward to your timely approval of my request.

Sincerely,
[Patient or caregiver's name and signature]
[Patient or caregiver's contact information]

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

US-NPN-2400025 (10/24)

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GPS for nemluvio™
GALDERMA PATIENT SERVICES

Summary of Support Programs

The Patient Support Program Services will be managed by Galderma Patient Services (GPS) for patients needing to determine coverage for NEMLUVIO and in need of certain support. When patients enroll in GPS for NEMLUVIO, they will have access to support programs including Nurse Navigators, which help to initiate therapy and stay on treatment. On behalf of enrolled patients, the Field Access Manager team will be able to communicate with offices to support patient access.

Support Program	Description
Quick Start	Treatment-naive patients will receive their first/loading dose while awaiting PA decision. Available to eligible, commercially insured patients. Patients can receive 2 additional refills. If there are further delays in the PA approval process, patients may move to the Bridge Program.
Bridge Program	Provides access to eligible patients who have been on NEMLUVIO and are experiencing a gap in treatment due to a new insurance obstacle. Patients participating in the Bridge Program may receive free product for up to 2 years while their HCP works with their insurance to obtain a coverage determination, as long as the US prescriber continues to advocate for the patient.
Copay Support	Qualified, commercially insured patients may pay as little as $0 for their treatment. Patients will be automatically re-enrolled for the following year, if they are still on the same treatment. Reduces or eliminates copays for eligible, commercially insured patients, up to $15,000 annually.
Patient Assistance Program	Provides access to eligible uninsured patients or patients whose insurance does not provide adequate coverage when no other programs are available to help the patient.
Injection Training	Educates patients on recommended preparation and administration techniques. May be done virtually or telephonically.
Nurse Navigator Support	Nurses are available 8:00 AM-8:00 PM EST (Monday-Friday) to help educate patients about NEMLUVIO. This service is not intended to take the place of your medical guidance and advice—it is for educational purposes only. Patients seeking medical advice will be referred back to their prescriber.

HCP, health care provider; PA, prior authorization.

To access these programs, please click the link below:
https://www.nemluviohcp.com/access-support

Terms and Conditions

Please see Important Safety Information on page 1 and accompanying Prescribing Information or click here for full Prescribing Information including Patient Information.

References

1. Academy of Managed Care Pharmacy. Prior authorization. Accessed September 5, 2024. https://www.amcp.org/about/managed-care-pharmacy-101/concepts-managed-care-pharmacy/prior-authorization
2. UnitedHealthcare. Dupixent pharmacy prior authorization request form. Accessed September 5, 2024. https://www.uhcprovider.com/content/dam/provider/docs/public/prior-auth/drugs-pharmacy/commercial/a-g/PA-Med-Nec-Dupixent.pdf
3. West Virginia Department of Health and Human Resources. Prior authorization request form. Accessed September 5, 2024. https://dhhr.wv.gov/bms/BMS%20Pharmacy/Documents/Drug%20PA%20Criteria/Dupixent%20Criteria%201.1.23.pdf
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7. CVS/Caremark. Dupixent. Accessed September 23, 2024. https://www.caremark.com/portal/asset/HMSAFaxForm_Dupixent.pdf
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9. NEMLUVIO. Prescribing Information. Galderma Laboratories, L.P.
10. Patient Engagement HIT. Drug formulary exclusion lists reduce patient access to treatment. Accessed September 5, 2024. https://patientengagementhit.com/news/drug-formulary-exclusion-lists-reduce-patient-access-to-treatment
11. Security Health. Pharmacy utilization management guidelines. Accessed September 5, 2024. https://www.securityhealth.org/prescription-tools/exception-process
12. Serve You Rx. Understanding quantity limits. Accessed September 5, 2024. https://serveyourx.com/wp-content/uploads/2022/01/Understanding-Quantity-Limits-CS0022.pdf

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