Last review: 9.2026

Nemluvio (nemolizumab-ilto) – ARBCBS Custom Criteria

FDA approved Indications

- 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
- Treatment of adults with prurigo nodularis (PN)

All other indications are considered experimental/investigational and not medically necessary

DOCUMENTATION

1. Atopic dermatitis
    a. *Initial requests:*
        i. Chart notes or medical record documentation showing affected area(s) and body surface area (where applicable).
        ii. Chart notes, medical record documentation, or claims history of prerequisite therapies including response to therapy. If prerequisite therapies are not advisable, documentation of why therapies are not advisable for the member.
    b. *Continuation requests:*
        i. Chart notes or medical record documentation that the member has experienced a positive clinical response to therapy as evidenced by low disease activity or improvement in signs or symptoms of atopic dermatitis.
2. Prurigo Nodularis (PN)
    a. *Initial requests:*
        i. Chart notes or medical record documentation of symptoms (e.g., pruritus, nodular lesions).
        ii. Chart notes, medical record documentation, or claims history of prerequisite therapies including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
    b. *Continuation requests:*
        i. Chart notes or medical record documentation supporting positive clinical response.

PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with one of the following:

- Atopic dermatitis: dermatologist or allergist/immunologist
- Prurigo nodularis: dermatologist or allergist/immunologist

Policy/Coverage:

For all indications: Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

ATOPIC DERMATITIS

INITIAL APPROVAL STANDARD REVIEW for up to 6 months:

1. Individual has a confirmed diagnosis of moderate to severe atopic dermatitis supported by the submitted medical records; **AND**
2. Individual is ≥ 12 years of age; **AND**
3. Individual has chronic or relapsing history that has been present for at least 6 months **AND**
4. Individual has a history of pruritus associated with atopic dermatitis (Boguniewicz, 2018); **AND**
5. Individual has at least one of the following (Boguniewicz, 2018):
    a. Early age of onset (≤ 5 years of age) (Lyons, 2015); **OR**
    b. Atopy; **OR**
    c. Family history; **OR**
    d. Xerosis; **AND**

6. Individual has one of the following:
    - Involvement of >10% of body surface area; **OR**
    - Involvement of critical areas (e.g., palms, face, etc) (FDA, 2021); **OR**
    - Individual has an Investigator's Global Assessment (IGA) score ≥ 3 (FDA, 2021; **OR**
    - Eczema Area and Severity Index (EASI) score ≥ 21 (Simpson, 2016; Simpson 2020); **OR** Weekly-average baseline worst itch score (Peak, Pruritus Numerical Rating Scale [NRS]) ≥ 4 (Efficacy, 2022) **AND**

7. Individual has a skin biopsy consistent with the diagnosis of atopic dermatitis OR documentation is provided that other skin conditions have been excluded or adequately treated (such as scabies, seborrheic dermatitis, contact dermatitis (irritant or allergic), ichthyoses, cutaneous T-cell lymphoma, psoriasis, photosensitivity dermatoses, immune deficiency disease, and erythroderma of other causes) (Boguniewicz, 2018) **AND**

8. The drug is prescribed by or in consultation with a physician with expertise in the treatment of atopic dermatitis (e.g., allergist/immunologist or dermatologist) **AND**

9. Topical therapy failure (FDA, 2021). The patient has either failed a trial, proved intolerant of a medication, or has contraindications to both below topical treatments (in accordance with AAD Guidelines (Eichenfield, 2014) (Howe, 2022):
    a. A topical calcineurin inhibitor [i.e., pimecrolimus (Elidel) or tacrolimus (Protopic)] with an inadequate response to maintenance therapy that includes intermittent use (at least 2 days per week) for at least 12 weeks; **AND**
    b. A topical corticosteroid with an inadequate response to maintenance therapy that includes intermittent use (at least 2 days per week) for at least 12 weeks of a

moderate-to-high-potency topical corticosteroid, unless involvement is limited to the face and intertriginous areas in which a lower-potency corticosteroid may be used; **AND**

10. The drug will NOT be used in combination with a Janus kinase (JAK) inhibitor or another biologic agent for the treatment of atopic dermatitis [e.g., dupilumab (e.g., Dupixent), mepolizumab (e.g., Nucala), reslizumab (e.g., Cinqair), tralokinumab (e.g., Adbry) and rituximab (e.g., Rituxan)] or another atopic condition; **AND**
11. Individual is prescribed the requested medication in combination with a topical corticosteroid or topical calcineurin inhibitor, unless the use of a topical corticosteroid and topical calcineurin inhibitor are not advisable for the member (e.g., due to contraindications, prior intolerances). **AND**
12. Must be dosed in accordance with the FDA label.

CONTINUED APPROVAL for up to 1 year:
Requirement of documentation in the medical records that the member has achieved and maintains a clinically meaningful benefit as defined below:

1. Reduction in disease severity (e.g., erythema, dryness, edema/papulation, excoriations, lichenification, oozing/crusting); **AND**
2. Reduction in the frequency or intensity of pruritus associated with atopic dermatitis; **AND**
3. Reduction in the frequency of disease exacerbations/flairs; **AND**
4. Reduction in the amount of Body Surface Area involvement relative to pretreatment baseline; **AND**
5. Improvement in overall patient quality of life (e.g., improved sleep, less depression or anxiety, etc.); **AND**
6. The drug will NOT be used in combination with a Janus kinase (JAK) inhibitor or another biologic agent for the treatment of atopic dermatitis [e.g., omalizumab (e.g., Xolair), mepolizumab (e.g., Nucala), reslizumab (e.g., Cinqair), tralokinumab (e.g., Adbry) and rituximab (e.g., Rituxan)] or another atopic condition **AND**
7. Individual is prescribed the requested medication in combination with a topical corticosteroid or topical calcineurin inhibitor, unless the use of a topical corticosteroid and topical calcineurin inhibitor are not advisable for the member (e.g., due to contraindications, prior intolerances). **AND**
8. Must be dosed in accordance with the FDA label.

PRURIGO NODULARIS (PN)

INITIAL APPROVAL STANDARD REVIEW for up to 6 months:

1. Individual must have documentation of confirmed diagnosis of PN by a dermatologist (PRIME2, 2022); **AND**

2. Individual has been diagnosed with PN a least 3 months prior to initiation of dupilumab (PRIME2, 2022); **AND**
3. Individual is ≥ 18 years of age (PRIME2, 2022); **AND**
4. Individual has presence of chronic pruritus lasting longer than 6 weeks as documented by both of the following (Stander, 2020):
   a. An average worst itch numeric rating scale (WI-NRS) score ≥ 7, (PRIME2, 2022); **AND**
   b. History and/or signs of repeated scratching (e.g., excoriations and scars) (Stander, 2020); **AND**

5. Individual has at least 20 PN lesions in total located on at least two of the following (PRIME2, 2022):
   a. Both legs (bilaterally symmetric lesions); **OR**
   b. Both arms (bilaterally symmetric lesions); **OR**
   c. Trunk; **AND**

6. Individual has failed at least a 2-week course (or for the maximum duration recommended by the product prescribing information, whichever is shorter) or has a contraindication to a medium- to super high-potency topical corticosteroid (PRIME2, 2022); **AND**
7. Individual has failed at least one systemic therapy (e.g. UV phototherapy, gabapentin, cyclosporine, methotrexate, etc); **AND**
8. Medication is ordered by or in consultation with a dermatologist; **AND**
9. Member is not treated concurrently with any other biologic drug or targeted synthetic drug for the same indication **AND**
10. Must be dosed in accordance with the FDA label.

CONTINUED APPROVAL for up to 1 year:
1. Individual has confirmed diagnosis of PN by a dermatologist; **AND**
2. Individual is ≥ 18 years of age; **AND**
3. Individual has documented clinical improvement as demonstrated by a decrease from baseline in the number of lesions and their WI-NRS score; **AND**
4. Medication is ordered by or in consultation with a dermatologist; **AND**
5. Member is not treated concurrently with any other biologic drug or targeted synthetic drug for the same indication **AND**
6. Must be dosed in accordance with the FDA label.

References

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10. Davis DMR, Drucker AM, Alikhan A, et al. Guidelines of care for the management of atopic dermatitis in adults with phototherapy and systemic therapies. J Am Acad Dermatol. 2024 Feb;90(2):e43-e56.
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