Nemluvio® (nemolizumab-ilto)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy. For this program, Dupixent, Ebglyss and Rinvoq are the preferred products and will apply to members requesting treatment for an indication that is FDA-approved for the preferred product. The criteria will require the use of two of the health plan's preferred products before the use of non-preferred products unless there are clinical circumstances that exclude the use of all the preferred products, the patient is currently receiving treatment with the non-preferred drug and experience a positive therapeutic outcome, or there is only one preferred product for an indication

FDA-Approved Indications

1. Nemluvio is indicated for the treatment of adult patients with prurigo nodularis (PN).
2. Nemluvio is 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.

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

1. Prurigo Nodularis
    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: Chart notes or medical record documentation supporting positive clinical response.

2. Atopic Dermatitis
   A. Initial requests:
      i. Member's chart notes or medical records showing affected area(s) and body surface area (where applicable).
      ii. Member's chart notes or medical record documentation and claims history of prerequisite therapies (see Criteria for Initial Approval A.2) including dosage, duration, and response to therapy. If prerequisite therapies are not advisable, documentation of why therapies are not advisable for the member.
   B. Continuation requests: Documentation (e.g., chart notes) 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.

Must meet BOTH the Preferred Drug Plan Design and Criteria for Initial Approval when applicable.

Preferred Drug Plan Design

Prurigo Nodularis

Criteria for initial approval for Nemluvio (nemolizumab) for prurigo nodularis will only apply when one of the following criteria are met:

1. The patient has had an inadequate response to treatment, intolerable adverse event, or has a contraindication to therapy with the preferred product, Dupixent (dupilumab).

Atopic Dermatitis

Criteria for initial approval for Nemluvio (nemolizumab) for atopic dermatitis will only apply when one of the following criteria are met:

1. The patient has had an inadequate response to treatment, intolerable adverse event, or has a contraindication to therapy with at least two of the preferred products, Dupixent, Ebglyss, and Rinvoq

Prescriber Specialties

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

1. Dermatologist
2. Allergist/Immunologist

Criteria for Initial Approval

Prurigo Nodularis (PN)

Authorization of 6 months may be granted for treatment of prurigo nodularis in members 18 years of age or older when all of the following criteria are met:

1. Member has pruritus lasting at least 6 weeks.
2. Member has history or signs of repeated itch-scratch cycle (e.g., scratching, picking, or rubbing).
3. Member has a minimum of 20 nodular lesions.
4. Member meets either of the following:
   A. Member has had an inadequate response to one of the following:
      i. A medium to super-high potency topical corticosteroid (see Appendix A)
      ii. A topical calcineurin inhibitor
      iii. Phototherapy (e.g., UVB, PUVA)

iv. Pharmacologic treatment with methotrexate or cyclosporine

B. Member has had an intolerance or a clinical reason to avoid either of the following:
   i. Medium to super-high potency topical corticosteroid (see Appendix A) and topical calcineurin inhibitor
   ii. Pharmacologic treatment with methotrexate and cyclosporine (see Appendix B)

Moderate-to-severe atopic dermatitis

1. Authorization of **4 months** may be granted for members 12 years of age or older who have previously received a biologic (e.g., Dupixent) or targeted synthetic drug (e.g., Cibinqo, Rinvoq) indicated for moderate-to-severe atopic dermatitis in the past year.
2. Authorization of **4 months** may be granted for treatment of moderate-to-severe atopic dermatitis in members 12 years of age or older when all of the following criteria are met:
   A. Affected body surface area is greater than or equal to 10% OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
   B. Member meets either of the following:
      i. Member has had an inadequate treatment response to one of the following in the past 180 days:
         1. A medium potency to super-high potency topical corticosteroid (see Appendix A)
         2. A topical calcineurin inhibitor
         3.
      ii. The use of medium potency to super-high potency topical corticosteroid, topical calcineurin inhibitor, topical JAK inhibitor, and topical PDE-4 inhibitor are not advisable for the member (e.g., due to contraindications, prior intolerances).
   C. Member will not exceed the maximum FDA-approved dose for this indication.
   D. Member will not use Nemluvio concomitantly with other biologics or JAK inhibitors indicated for atopic dermatitis.

<u>Continuation of Therapy</u>

Prurigo Nodularis (PN)

Authorization of **12 months** may be granted for members 18 years of age or older for continued treatment of prurigo nodularis when the member has achieved or maintained a positive clinical response as evidenced by one of the following:

1. Low disease activity (i.e., clear or almost clear skin)
2. Reduction in pruritic intensity and improvement in extent and severity of nodular lesions

Moderate-to-severe atopic dermatitis

Authorization of **12 months** may be granted for members 12 years of age or older when all of the following criteria is met:

1. Member has achieved or maintained a positive clinical response with Nemluvio therapy for moderate-to-severe atopic dermatitis as evidenced by low disease activity (i.e., clear or almost clear skin) or improvement in signs and symptoms of atopic dermatitis (e.g., redness, itching, oozing/crusting).
2. Member will not exceed the maximum FDA-approved dose for this indication
3. Member will not use Nemluvio concomitantly with other biologics or JAK inhibitors indicated for atopic dermatitis.

<u>Other</u>

Member cannot use Nemluvio concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Nemluvio (nemolizumab) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Members currently receiving the requested medication as samples or via the manufacturer's patient assistance program will be required to meet the criteria for initial approval. This ensures that members are treated equally regardless of their provider's ability to access medication samples.

Non-Formulary Exception Criteria

Non-Formulary Exception criteria applies to formularies which do not include the requested product(s) on the formulary drug list. Meeting the criteria above may satisfy some, or all, portions of the Non-Formulary Exception Criteria. A medication that is non-formulary may be covered when the Criteria for Approval AND the following criteria are met:

1. The requested drug must be used for an FDA-approved indication, or an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines). Diagnostic testing/lab results required when applicable.
2. The prescribed dose/quantity must fall within the FDA-approved labeling or dosing guidelines found in the compendia of current literature.
3. All covered formulary alternative drugs on any tier will be ineffective, have been ineffective, would not be as effective as the non-formulary drug, or would have adverse effects. Documentation is required and must include chart note(s) or other documentation indicating prior treatment failure, severity of the adverse event (if any), and dosage and duration of the prior treatment, or contraindication to formulary alternatives.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits Apply

Medication	Standard Limit	FDA Recommended Dosing
Nemluvio (nemolizumab-ilto) 30 mg/0.49 mL pre-filled pen	Initiation of therapy: 2 pens per first 28 days Maintenance: 2 pens per 28 days	**Prurigo nodularis** Adult Patients Weighing Less Than 90 kg: Initial dose of 60 mg (two 30 mg injections), followed by 30 mg every 4 weeks Adult Patients Weighing 90 kg or More: Initial dose of 60 mg (two 30 mg injections), followed by 60 mg (two 30 mg injections) every 4 weeks **Atopic Dermatitis** Initial dose of 60 mg (two 30 mg injections), followed by 30 mg every 4 weeks After 16 weeks of treatment, for patients who achieve clear or almost clear skin, a subcutaneous dosage of 30 mg every 8 weeks is recommended

Appendices

Appendix A: Relative potency of select topical corticosteroid products

Potency	Drug	Dosage form	Strength
I. Super-high potency (group 1)	Augmented betamethasone dipropionate	Ointment, Lotion, Gel	0.05%
	Clobetasol propionate	Cream, Gel, Ointment, Solution, Cream (emollient), Lotion, Shampoo, Foam, Spray	0.05%
	Fluocinonide	Cream	0.1%
	Flurandrenolide	Tape	4 mcg/cm^2
	Halobetasol propionate	Cream, Lotion, Ointment, Foam	0.05%
II. High potency (group 2)	Amcinonide	Ointment	0.1%
	Augmented betamethasone dipropionate	Cream	0.05%
	Betamethasone dipropionate	Ointment	0.05%
	Clobetasol propionate	Cream	0.025%
	Desoximetasone	Cream, Ointment, Spray	0.25%
		Gel	0.05%
	Diflorasone diacetate	Ointment, Cream (emollient)	0.05%
	Fluocinonide	Cream, Ointment, Gel, Solution	0.05%
	Halcinonide	Cream, Ointment	0.1%
	Halobetasol propionate	Lotion	0.01%
III. High potency (group 3)	Amcinonide	Cream, Lotion	0.1%
	Betamethasone dipropionate	Cream, hydrophilic emollient	0.05%
	Betamethasone valerate	Ointment	0.1%
		Foam	0.12%
	Desoximetasone	Cream, Ointment	0.05%
	Diflorasone diacetate	Cream	0.05%
	Fluocinonide	Cream, aqueous emollient	0.05%
	Fluticasone propionate	Ointment	0.005%
	Mometasone furoate	Ointment	0.1%
	Triamcinolone acetonide	Cream, Ointment	0.5%
IV. Medium potency (group 4)	Betamethasone dipropionate	Spray	0.05%
	Clocortolone pivalate	Cream	0.1%
	Fluocinolone acetonide	Ointment	0.025%
	Flurandrenolide	Ointment	0.05%
	Hydrocortisone valerate	Ointment	0.2%
	Mometasone furoate	Cream, Lotion, Solution	0.1%
	Triamcinolone acetonide	Cream	0.1%
		Ointment	0.05% and 0.1%
		Aerosol Spray	0.2 mg per 2-second spray
	Betamethasone dipropionate	Lotion	0.05%

Potency	Drug	Dosage form	Strength
V. Lower-mid potency (group 5)	Betamethasone valerate	Cream	0.1%
	Desonide	Ointment, Gel	0.05%
	Fluocinolone acetonide	Cream	0.025%
	Flurandrenolide	Cream, Lotion	0.05%
	Fluticasone propionate	Cream, Lotion	0.05%
	Hydrocortisone butyrate	Cream, Lotion, Ointment, Solution	0.1%
	Hydrocortisone probutate	Cream	0.1%
	Hydrocortisone valerate	Cream	0.2%
	Prednicarbate	Cream (emollient), Ointment	0.1%
	Triamcinolone acetonide	Lotion	0.1%
		Ointment	0.025%
VI. Low potency (group 6)	Alclometasone dipropionate	Cream, Ointment	0.05%
	Betamethasone valerate	Lotion	0.1%
	Desonide	Cream, Lotion, Foam	0.05%
	Fluocinolone acetonide	Cream, Solution, Shampoo, Oil	0.01%
	Triamcinolone acetonide	Cream, lotion	0.025%
VII. Least potent (group 7)	Hydrocortisone (base, greater than or equal to 2%)	Cream, Ointment, Solution	2.5%
		Lotion	2%
	Hydrocortisone (base, less than 2%)	Cream, Ointment, Gel, Lotion, Spray, Solution	1%
		Cream, Ointment	0.5%
	Hydrocortisone acetate	Cream	2.5%
		Lotion	2%
		Cream	1%

Appendix B: Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate or Cyclosporine

1. Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease
2. Drug interaction
3. Risk of treatment-related toxicity
4. Pregnancy or currently planning pregnancy
5. Breastfeeding
6. Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
7. Hypersensitivity
8. History of intolerance or adverse event

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

REFERENCES

Nemluvio [package insert]. Dallas, TX: Galderma Laboratories; December 2024.

Topical Corticosteroids. *Drug Facts and Comparisons.* Facts & Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health Inc; July 18, 2024. Accessed August 25, 2024.

Ständer HF, Elmariah S, Zeidler C, et al. Diagnostic and treatment algorithm for chronic nodular prurigo. *J Am Acad Dermatol*. 2020;82(2):460-468.

Elmariah S, Kim B, Berger T, et al. Practical approaches for diagnosis and management of prurigo nodularis: United States expert panel consensus. *J Am Acad Dermatol*. 2021;84(3):747-760.

Cyclosporine. *Drug Facts and Comparisons.* Facts & Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health Inc; August 15, 2024. Accessed August 25, 2024.

Methotrexate. *Drug Facts and Comparisons.* Facts & Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health Inc; July 30, 2024. Accessed August 25, 2024.

POLICY HISTORY

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