

# Specialty Guideline Management

## Nemluvio

### Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over the counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name     |
|------------|------------------|
| Nemluvio   | nemolizumab-ilto |

### Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

#### FDA-approved Indications<sup>1</sup>

- Treatment of adults with prurigo nodularis (PN).
- 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.

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

### Documentation

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

## Atopic Dermatitis

### Initial requests

- Chart notes or medical record documentation showing affected area(s) and body surface area (where applicable).
- Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

### Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

## Prurigo Nodularis (PN)

### Initial requests

- Chart notes or medical record documentation of symptoms (e.g., pruritus, nodular lesions).
- Chart notes, medical record documentation, or claims history supporting previous therapies tried, including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

### Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

## Prescriber Specialties

This medication must be prescribed by or in consultation with a dermatologist or allergist/immunologist.

## Coverage Criteria

### Atopic Dermatitis<sup>1,2,8-11</sup>

Authorization of 4 months may be granted for members 12 years of age or older who have previously received a biologic (e.g., Adbry, Dupixent, Ebglyss) or systemic targeted synthetic drug (e.g., Cibinqo, Rinvoq) indicated for moderate-to-severe atopic dermatitis in the past 12 months. The requested medication must be prescribed 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).

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:

- Affected body surface is greater than or equal to 10% body surface area OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
- Member meets either of the following:
  - Member has had an inadequate treatment response with one of the following in the past 12 months:
    - A medium potency to super-high potency topical corticosteroid (see Appendix A)
    - A topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus)
    - A topical Janus kinase (JAK) inhibitor (e.g., Opzelura)
    - A topical phosphodiesterase-4 (PDE-4) inhibitor (e.g., Eucrisa, Zoryve)
    - A topical aryl hydrocarbon receptor agonist (e.g., Vtama)
  - The use of medium potency to super-high potency topical corticosteroid, topical calcineurin inhibitor, topical JAK inhibitor, topical PDE-4 inhibitor, and topical aryl hydrocarbon receptor agonist are not advisable for the member (e.g., due to contraindications, prior intolerances)
- Member 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).

## Prurigo Nodularis (PN)<sup>1,3-5</sup>

Authorization of 6 months may be granted for members 18 years of age or older who have previously received a biologic drug (e.g., Dupixent) indicated for prurigo nodularis in the past 12 months.

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:

- Member has pruritus lasting at least 6 weeks.
- Member has history or signs of repeated itch-scratch cycle (e.g., scratching, picking, or rubbing).
- Member has a minimum of 20 nodular lesions.
- Member meets either of the following:
  - Member has had an inadequate response to one of the following:
    - A medium to super-high potency topical corticosteroid (see Appendix A)
    - A topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus)
    - Phototherapy (e.g., UVB, PUVA)
    - Pharmacologic treatment with methotrexate or cyclosporine
  - Member has had an intolerance or a clinical reason to avoid all of the following:
    - Medium to super-high potency topical corticosteroids (see Appendix A)
    - Topical calcineurin inhibitors
    - Phototherapy
    - Pharmacologic treatment with methotrexate and cyclosporine (see Appendix B)

# Continuation of Therapy

## Atopic Dermatitis<sup>1,8</sup>

Authorization of 12 months may be granted for members 12 years of age or older (including new members) who are using the requested medication for moderate-to-severe atopic dermatitis and who achieve or maintain a positive clinical response 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).

## Prurigo Nodularis (PN)<sup>3-5</sup>

Authorization of 12 months may be granted for members 18 years of age or older (including new members) who are using the requested medication for prurigo nodularis and who achieve or maintain a positive clinical response as evidenced by either of the following:

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

## Other

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

# Appendix

## Appendix A: Table. Relative Potency of Select Topical Corticosteroid Products<sup>2</sup>

| Potency                         | Drug                                 | Dosage form                                                                                                       | Strength |
|---------------------------------|--------------------------------------|-------------------------------------------------------------------------------------------------------------------|----------|
| I. Super-high potency (group 1) | Augmented betamethasone dipropionate | Ointment, Lotion, Gel                                                                                             | 0.05%    |
| I. Super-high potency (group 1) | Clobetasol propionate                | Cream, Gel, Ointment, Solution, Cream (emollient), Lotion, Shampoo, Foam Aerosol, Spray Aerosol, Solution (scalp) | 0.05%    |
| I. Super-high potency (group 1) | Fluocinonide                         | Cream                                                                                                             | 0.1%     |

|                     |
|---------------------|
| Reference number(s) |
| 6592-A              |

| Potency                         | Drug                                 | Dosage form                    | Strength              |
|---------------------------------|--------------------------------------|--------------------------------|-----------------------|
| I. Super-high potency (group 1) | Flurandrenolide                      | Tape                           | 4 mcg/cm <sup>2</sup> |
| I. Super-high potency (group 1) | Halobetasol propionate               | Cream, Lotion, Ointment, Foam  | 0.05%                 |
| II. High potency (group 2)      | Amcinonide                           | Ointment                       | 0.1%                  |
| II. High potency (group 2)      | Augmented betamethasone dipropionate | Cream                          | 0.05%                 |
| II. High potency (group 2)      | Betamethasone dipropionate           | Ointment                       | 0.05%                 |
| II. High potency (group 2)      | Clobetasol propionate                | Cream                          | 0.025%                |
| II. High potency (group 2)      | Desoximetasone                       | Cream, Ointment, Spray         | 0.25%                 |
| II. High potency (group 2)      | Desoximetasone                       | Gel                            | 0.05%                 |
| II. High potency (group 2)      | Diflorasone diacetate                | Ointment, Cream (emollient)    | 0.05%                 |
| II. High potency (group 2)      | Fluocinonide                         | Cream, Ointment, Gel, Solution | 0.05%                 |
| II. High potency (group 2)      | Halcinonide                          | Cream, Ointment, Solution      | 0.1%                  |
| II. High potency (group 2)      | Halobetasol propionate               | Lotion                         | 0.01%                 |
| III. High potency (group 3)     | Amcinonide                           | Cream                          | 0.1%                  |
| III. High potency (group 3)     | Betamethasone dipropionate           | Cream                          | 0.05%                 |
| III. High potency (group 3)     | Betamethasone valerate               | Ointment                       | 0.1%                  |
| III. High potency (group 3)     | Betamethasone valerate               | Foam                           | 0.12%                 |
| III. High potency (group 3)     | Desoximetasone                       | Cream, Ointment                | 0.05%                 |
| III. High potency (group 3)     | Diflorasone diacetate                | Cream                          | 0.05%                 |
| III. High potency (group 3)     | Fluocinonide                         | Cream (aqueous emollient)      | 0.05%                 |
| III. High potency (group 3)     | Fluticasone propionate               | Ointment                       | 0.005%                |

| Potency                        | Drug                       | Dosage form                           | Strength                  |
|--------------------------------|----------------------------|---------------------------------------|---------------------------|
| III. High potency (group 3)    | Mometasone furoate         | Ointment                              | 0.1%                      |
| III. High potency (group 3)    | Triamcinolone acetonide    | Cream, Ointment                       | 0.5%                      |
| IV. Medium potency (group 4)   | Betamethasone dipropionate | Spray                                 | 0.05%                     |
| IV. Medium potency (group 4)   | Clocortolone pivalate      | Cream                                 | 0.1%                      |
| IV. Medium potency (group 4)   | Fluocinolone acetonide     | Ointment                              | 0.025%                    |
| IV. Medium potency (group 4)   | Flurandrenolide            | Ointment                              | 0.05%                     |
| IV. Medium potency (group 4)   | Fluticasone propionate     | Cream                                 | 0.05%                     |
| IV. Medium potency (group 4)   | Hydrocortisone valerate    | Ointment                              | 0.2%                      |
| IV. Medium potency (group 4)   | Mometasone furoate         | Cream, Lotion, Solution               | 0.1%                      |
| IV. Medium potency (group 4)   | Triamcinolone acetonide    | Cream, Paste (mouth/throat), Ointment | 0.1%                      |
| IV. Medium potency (group 4)   | Triamcinolone acetonide    | Ointment                              | 0.05%                     |
| IV. Medium potency (group 4)   | Triamcinolone acetonide    | Aerosol Spray                         | 0.2 mg per 2-second spray |
| V. Lower-mid potency (group 5) | Betamethasone dipropionate | Lotion                                | 0.05%                     |
| V. Lower-mid potency (group 5) | Betamethasone valerate     | Cream                                 | 0.1%                      |
| V. Lower-mid potency (group 5) | Desonide                   | Ointment, Gel                         | 0.05%                     |
| V. Lower-mid potency (group 5) | Fluocinolone acetonide     | Cream                                 | 0.025%                    |
| V. Lower-mid potency (group 5) | Flurandrenolide            | Cream, Lotion                         | 0.05%                     |
| V. Lower-mid potency (group 5) | Fluticasone propionate     | Lotion                                | 0.05%                     |
| V. Lower-mid potency (group 5) | Hydrocortisone butyrate    | Cream, Lotion, Ointment, Solution     | 0.1%                      |
| V. Lower-mid potency (group 5) | Hydrocortisone probutate   | Cream                                 | 0.1%                      |

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

## Appendix B: Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate or Cyclosporine<sup>5,6</sup>

- Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease
- Drug interaction
- Risk of treatment-related toxicity
- Pregnancy or currently planning pregnancy

- Breastfeeding
- Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
- Hypersensitivity
- History of intolerance or adverse event

## References

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