## Louisiana Medicaid Atopic Dermatitis Immunomodulators

The Louisiana Uniform Prescription Drug Prior Authorization Form should be utilized to request:

- Prior authorization for non-preferred atopic dermatitis immunomodulators; OR
- Clinical authorization for dupilumab (Dupixent®), lebrikizumab-lbkz (Ebglyss<sup>TM</sup>), nemolizumab-ilto (Nemluvio®), or tralokinumab-ldrm (Adbry®).

Additional Point-of-Sale edits may apply.

By submitting the authorization request, the prescriber attests to the conditions available HERE.

When currently posted criteria are not met, a clinical reviewer will consider the most current FDA-approved prescribing information for the requested agent when evaluating the request.

# Non-Preferred Atopic Dermatitis Immunomodulators (Except Dupixent®, Ebglyss<sup>TM</sup>, Nemluvio® and Adbry®)

#### **Approval Criteria for Initiation and Continuation of Therapy**

- There is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- Previous use of a preferred product **ONE** of the following is required:
  - o The recipient has had a treatment failure with at least one preferred product; **OR**
  - o The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
  - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate to use for the condition being treated; **OR**
  - o There is no preferred product that is appropriate to use for the condition being treated.

#### Duration of approval for initiation and continuation of therapy: 2 weeks to 6 months

An appropriate duration of initial authorization and reauthorization approval (if needed) will be determined based upon patient-specific factors and the condition being treated.

## Dupilumab (Dupixent®)

## Approval Criteria for Initiation of Therapy for Atopic Dermatitis

- The recipient is 6 months of age or older on the date of the request; AND
- The recipient has a diagnosis of moderate to severe atopic dermatitis (AD); AND
- There has been a treatment failure or intolerable side effect with or contraindication to a preferred topical corticosteroid agent (see Dermatology Steroids, Topical Low, Medium, High and Very High Potency); **AND**
- The medication is prescribed by, or the request states that this medication is being prescribed in consultation with, a dermatologist, immunologist or allergist; **AND**
- If request is for a non-preferred agent **ONE** of the following is required:
  - o The recipient has had a treatment failure with at least one preferred product; **OR**

- o The recipient has had an intolerable side effect to at least one preferred product; **OR**
- The recipient has documented contraindication(s) to all of the preferred products that are appropriate to use for the condition being treated; **OR**
- There is no preferred product that is appropriate to use for the condition being treated;
   AND
- The requested dose and dosing frequency are appropriate for the recipient's age, weight and diagnosis based on the prescribing information.

### Approval Criteria for Continuation of Therapy for Atopic Dermatitis

• The prescriber **states on the request** that there is evidence of a positive response to therapy including a significant reduction in areas affected and/or severity of AD.

# Approval Criteria for Initiation of Therapy for Moderate to Severe Asthma with an Eosinophilic Phenotype

- The recipient is 6 years of age or older on the date of the request; **AND**
- The recipient has a diagnosis of moderate to severe asthma with an eosinophilic phenotype; **AND**
- The recipient has a baseline blood eosinophil count of ≥150 cells/μL within the previous 3 months (Date and results must be **stated on the request**); **AND**
- The prescriber **states on the request** that the recipient is using Dupixent® (dupilumab) as an add-on maintenance treatment in combination with other controller medications (e.g., inhaled corticosteroids (ICS), long-acting beta-agonists (LABA), combination ICS/LABA; leukotriene modifiers); **AND**
- The medication is prescribed by, or the request states that this medication is being prescribed in consultation with, a pulmonologist, immunologist or allergist; **AND**
- If request is for a non-preferred agent **ONE** of the following is required:
  - o The recipient has had a treatment failure with at least one preferred product; **OR**
  - The recipient has had an intolerable side effect to at least one preferred product; **OR**
  - The recipient has documented contraindication(s) to all of the preferred products that are appropriate to use for the condition being treated; **OR**
  - There is no preferred product that is appropriate to use for the condition being treated;
     AND
- The requested dose and dosing frequency are appropriate for the recipient's age, weight and diagnosis based on the prescribing information.

# Approval Criteria for Continuation of Therapy for Moderate to Severe Asthma with an Eosinophilic Phenotype

- The prescriber **states on the request** that there is evidence of a positive response to therapy by one of the following:
  - o Decrease in the frequency of asthma exacerbations; **OR**
  - O Decrease in the use of rescue medications; **OR**
  - o Reduction in asthma-related symptoms; **OR**
  - o Increase in FEV1 percent predicted; AND

• The prescriber **states on the request** that the recipient is using Dupixent® (dupilumab) as an add-on maintenance treatment in combination with other controller medications (e.g., inhaled corticosteroids (ICS), long-acting beta-agonists (LABA), combination ICS/LABA; leukotriene modifiers).

## Approval Criteria for Initiation of Therapy for Corticosteroid-Dependent Asthma

- The recipient is 6 years of age or older on the date of the request; AND
- The recipient has a diagnosis of corticosteroid-dependent asthma; AND
- The recipient requires daily oral corticosteroid treatment for at least three months (Medication name and date range of therapy are **stated on the request**); **AND**
- The prescriber **states on the request** that the recipient is using Dupixent® (dupilumab) as an add-on maintenance treatment in combination with other controller medications (e.g., inhaled corticosteroids (ICS), long-acting beta-agonists (LABA), combination ICS/LABA; leukotriene modifiers); **AND**
- The medication is prescribed by, or the request states that this medication is being prescribed in consultation with, a pulmonologist, immunologist or allergist; **AND**
- If request is for a non-preferred agent **ONE** of the following is required:
  - o The recipient has had a treatment failure with at least one preferred product; **OR**
  - The recipient has had an intolerable side effect to at least one preferred product; **OR**
  - The recipient has documented contraindication(s) to all of the preferred products that are appropriate to use for the condition being treated; **OR**
  - There is no preferred product that is appropriate to use for the condition being treated;
     AND
- The requested dose and dosing frequency are appropriate for the recipient's age, weight and diagnosis based on the prescribing information.

#### Approval Criteria for Continuation of Therapy for Corticosteroid-Dependent Asthma

- The prescriber states on the request that the recipient has been able to maintain asthma control while taking a lower dose of daily oral corticosteroid compared to baseline dose; **AND**
- The prescriber **states on the request** that there is evidence of a positive response to therapy by one of the following:
  - o Decrease in the frequency of asthma exacerbations; **OR**
  - O Decrease in the use of rescue medications; **OR**
  - o Reduction in asthma-related symptoms; **OR**
  - o Increase in FEV1 percent predicted; AND
- The prescriber **states on the request** that the recipient is using Dupixent® (dupilumab) as an add-on maintenance treatment in combination with other controller medications (e.g., inhaled corticosteroids (ICS), long-acting beta-agonists (LABA), combination ICS/LABA; leukotriene modifiers).

#### Approval Criteria for Initiation of Therapy for Chronic Rhinosinusitis with Nasal Polyposis

- The recipient is 12 years of age or older on the date of the request; AND
- The recipient has a diagnosis of chronic rhinosinusitis with nasal polyposis; AND

- The prescriber **states on the request** that the recipient is using Dupixent<sup>®</sup> (dupilumab) as an add-on maintenance treatment in combination with other controller medications (e.g., intranasal corticosteroids); **AND**
- The medication is prescribed by, or the request states that this medication is being prescribed in consultation with, an allergist or otolaryngologist; **AND**
- If request is for a non-preferred agent **ONE** of the following is required:
  - o The recipient has had a treatment failure with at least one preferred product; **OR**
  - o The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
  - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate to use for the condition being treated; **OR**
  - There is no preferred product that is appropriate to use for the condition being treated;
     AND
- The requested dose and dosing frequency are appropriate for the recipient's age, weight and diagnosis based on the prescribing information.

# Approval Criteria for Continuation of Therapy for Chronic Rhinosinusitis with Nasal Polyposis

- The prescriber **states on the request** that there is evidence of a positive response to therapy by reduction in nasal polyp size or severity of congestion compared to the recipient's baseline prior to initiation of Dupixent®; **AND**
- The prescriber **states on the request** that the recipient is using Dupixent® (dupilumab) as an add-on maintenance treatment in combination with other controller medications (e.g., intranasal corticosteroids).

## Approval Criteria for Initiation of Therapy for Eosinophilic Esophagitis

- The recipient is 1 year of age or older on the date of the request; AND
- The recipient weighs at least 15 kg (33 lbs) [weight of recipient must be **stated on the request**]; **AND**
- The recipient has a diagnosis of eosinophilic esophagitis; AND
- The medication is prescribed by, or the request states that this medication is being prescribed in consultation with, an allergist or gastroenterologist; **AND**
- If request is for a non-preferred agent **ONE** of the following is required:
  - o The recipient has had a treatment failure with at least one preferred product; **OR**
  - o The recipient has had an intolerable side effect to at least one preferred product; **OR**
  - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate to use for the condition being treated; **OR**
  - There is no preferred product that is appropriate to use for the condition being treated;
     AND
- The requested dose and dosing frequency are appropriate for the recipient's age, weight and diagnosis based on the prescribing information.

## Approval Criteria for Continuation of Therapy for Eosinophilic Esophagitis

• The prescriber **states on the request** that there is evidence of a positive response to therapy.

## Approval Criteria for Initiation of Therapy for Prurigo Nodularis

- The recipient is 18 years of age or older on the date of the request; **AND**
- The recipient has a diagnosis of prurigo nodularis (PN); AND
- The medication is prescribed by, or the request states that this medication is being prescribed in consultation with, a dermatologist, immunologist, or allergist; **AND**
- There has been a treatment failure or intolerable side effect with or contraindication to a preferred super-potent topical corticosteroid agent (see Dermatology Steroids, Topical High and Very High Potency); **AND**
- If request is for a non-preferred agent **ONE** of the following is required:
  - o The recipient has had a treatment failure with at least one preferred product; **OR**
  - o The recipient has had an intolerable side effect to at least one preferred product; **OR**
  - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate to use for the condition being treated; **OR**
  - There is no preferred product that is appropriate to use for the condition being treated;
     AND
- The requested dose and dosing frequency are appropriate for the recipient's age, weight and diagnosis based on the prescribing information.

# Approval Criteria for Continuation of Therapy for Prurigo Nodularis

• The prescriber **states on the request** that there is evidence of a positive response to therapy including a significant reduction in areas affected and/or severity of PN.

# Approval Criteria for Initiation of Therapy for Chronic Obstructive Pulmonary Disease (COPD) with an Eosinophilic Phenotype

- The recipient is 18 years of age or older on the date of the request; AND
- The recipient has a diagnosis of COPD with an eosinophilic phenotype; AND
- The recipient has a baseline blood eosinophil count of ≥300 cells/μL within the previous 3 months (Date and results must be **stated on the request**); **AND**
- The prescriber **states on the request** that the recipient is using Dupixent® (dupilumab) as an add-on maintenance treatment in combination with maintenance triple therapy consisting of a long-acting muscarinic antagonist (LAMA), long-acting beta agonist (LABA), and inhaled corticosteroid (ICS) [unless contraindicated]; **AND**
- The recipient has been compliant for at least 3 consecutive months with optimized pharmacotherapy for the treatment of COPD, which is **stated on the request**; **AND**
- Even with compliant use of optimized pharmacotherapy for at least 3 consecutive months, the recipient's COPD continues to be uncontrolled as defined by **ONE** of the following which is **stated on the request**:
  - o The recipient required treatment with systemic corticosteroids and/or antibiotics; **OR**

- o The recipient was hospitalized or in observation for over 24 hours in an emergency department or urgent care facility; **AND**
- The medication is prescribed by, or the request states that this medication is being prescribed in consultation with, a pulmonologist, immunologist or allergist; **AND**
- If request is for a non-preferred agent **ONE** of the following is required:
  - o The recipient has had a treatment failure with at least one preferred product; OR
  - o The recipient has had an intolerable side effect to at least one preferred product; **OR**
  - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate to use for the condition being treated; **OR**
  - There is no preferred product that is appropriate to use for the condition being treated;
     AND
- The requested dose and dosing frequency are appropriate for the recipient's age, weight and diagnosis based on the prescribing information.

# Approval Criteria for Continuation of Therapy for Chronic Obstructive Pulmonary Disease (COPD) with an Eosinophilic Phenotype

- The prescriber **states on the request** that there is evidence of a positive response to therapy including a reduction in COPD exacerbations; **AND**
- The prescriber **states on the request** that the recipient is using Dupixent® (dupilumab) as an add-on maintenance treatment in combination with maintenance triple therapy consisting of a long-acting muscarinic antagonist (LAMA), long-acting beta agonist (LABA), and inhaled corticosteroid (ICS) [unless contraindicated].

#### **Approval Criteria for Initiation of Therapy for Chronic Spontaneous Urticaria**

- The recipient is 12 years of age or older on the date of the request; AND
- The recipient has a diagnosis of chronic spontaneous urticaria; AND
- The medication is prescribed by, or the request states that this medication is being prescribed in consultation with, a dermatologist, immunologist, or allergist; **AND**
- The recipient has been adherent to H1 antihistamine therapy for a minimum of 4 weeks but is still symptomatic. [Each medication and date range of treatment must be **stated on the request**. Adherence to drug therapy will be validated through claims data review]; **AND**
- If request is for a non-preferred agent **ONE** of the following is required:
  - o The recipient has had a treatment failure with at least one preferred product; **OR**
  - o The recipient has had an intolerable side effect to at least one preferred product; OR
  - The recipient has documented contraindication(s) to all of the preferred products that are appropriate to use for the condition being treated; OR
  - There is no preferred product that is appropriate to use for the condition being treated; AND
- The requested dose and dosing frequency are appropriate for the recipient's age, weight and diagnosis based on the prescribing information.

#### Approval Criteria for Continuation of Therapy for Chronic Spontaneous Urticaria

• The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

#### Approval Criteria for Initiation of Therapy for Bullous Pemphigoid

- The recipient is 18 years of age or older on the date of the request; **AND**
- The recipient has a confirmed diagnosis of bullous pemphigoid (BP) based on objective clinical evidence consistent with the diagnosis and positive findings using **ONE** of the following modalities:
  - o Direct immunofluorescence microscopy (DIF); **OR**
  - o Indirect immunofluorescence (IIF) microscopy; **OR**
  - o Enzyme-linked immunosorbent assay (ELISA); AND
- The disease state is moderate to severe confirmed by a Bullous Pemphigoid Disease Area Index (BPDAI) activity score ≥20; AND
- The medication is prescribed by, or the request states that this medication is being prescribed in consultation with, a dermatologist, immunologist, or allergist; **AND**
- If request is for a non-preferred agent ONE of the following is required:
  - o The recipient has had a treatment failure with at least one preferred product; **OR**
  - o The recipient has had an intolerable side effect to at least one preferred product; OR
  - The recipient has documented contraindication(s) to all of the preferred products that are appropriate to use for the condition being treated; OR
  - There is no preferred product that is appropriate to use for the condition being treated; AND
- The requested dose and dosing frequency are appropriate for the recipient's age, weight and diagnosis based on the prescribing information.

#### Approval Criteria for Continuation of Therapy for Bullous Pemphigoid

• The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

Duration of approval for initiation of therapy: 6 months Duration of approval for continuation of therapy: 12 months

# Lebrikizumab-lbkz (Ebglyss<sup>TM</sup>)

#### **Approval Criteria for Initiation of Therapy**

- The recipient is 12 years of age or older on the date of the request; **AND**
- The recipient weighs at least 40 kg (88 lbs) [weight of recipient must be **stated on the request**]; **AND**
- The recipient has a diagnosis of moderate to severe atopic dermatitis (AD); AND
- **ONE** of the following:

- There has been a treatment failure or intolerable side effect with a preferred topical corticosteroid agent (see Dermatology Steroids, Topical Low, Medium, High and Very High Potency) (names and dates of medications must be stated on the request); OR
- The recipient has a contraindication to ALL preferred topical corticosteroid agents; AND
- The medication is prescribed by, or the request states that this medication is being prescribed in consultation with, a dermatologist, immunologist or allergist; **AND**
- The prescriber **states on the request** that the medication requested is not prescribed concurrently with another biologic immunomodulator or JAK inhibitor; **AND**
- If request is for a non-preferred agent **ONE** of the following is required: (see Dermatology Atopic Dermatitis Immunomodulators on the PDL/NPDL for a list of preferred agents)
  - The recipient has had a treatment failure with at least one preferred product;
     OR
  - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
  - The recipient has documented contraindication(s) to all of the preferred products that are appropriate to use for the condition being treated; OR
  - There is *no preferred product that is appropriate* to use for the condition being treated.

# **Approval Criteria for Continuation of Therapy**

- The prescriber **states on the request** that there is evidence of a positive response to therapy including a significant reduction in areas affected and/or severity of AD; **AND**
- The prescriber **states on the request** that the medication requested is not prescribed concurrently with another biologic immunomodulator or JAK inhibitor.

**Duration of approval for initiation of therapy: 6 months Duration of approval for continuation of therapy: 12 months** 

#### Nemolizumab-ilto (Nemluvio®)

# Approval Criteria for Initiation of Therapy for Prurigo Nodularis

- The recipient is 18 years of age or older on the date of the request; AND
- The recipient has a diagnosis of prurigo nodularis (PN); AND
- The medication is prescribed by, or the request states that this medication is being prescribed in consultation with, a dermatologist, immunologist, or allergist; **AND**
- **ONE** of the following:
  - There has been a treatment failure or intolerable side effect with a preferred super-potent topical corticosteroid agent (see Dermatology Steroids, Topical High and Very High Potency); OR

- The recipient has a contraindication to ALL preferred super-potent topical corticosteroid agents (see Dermatology – Steroids, Topical – High and Very High Potency); AND
- The prescriber **states on the request** that the medication requested is not prescribed concurrently with another biologic immunomodulator or JAK inhibitor; **AND**
- If request is for a non-preferred agent **ONE** of the following is required: (see Dermatology Atopic Dermatitis Immunomodulators on the PDL/NPDL for a list of preferred agents)
  - The recipient has had a *treatment failure* with at least one preferred product; **OR**
  - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
  - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate to use for the condition being treated; **OR**
  - There is *no preferred product that is appropriate* to use for the condition being treated.

## Approval Criteria for Continuation of Therapy for Prurigo Nodularis

- The prescriber states on the request that there is evidence of a positive response to therapy including a significant reduction in areas affected and/or severity of PN;
   AND
- The prescriber **states on the request** that the medication requested is not prescribed concurrently with another biologic immunomodulator or JAK inhibitor.

#### Approval Criteria for Initiation of Therapy for Atopic Dermatitis

- The recipient is 12 years of age or older on the date of the request; **AND**
- The recipient has a diagnosis of moderate to severe atopic dermatitis (AD); AND
- The medication is prescribed by, or the request states that this medication is being prescribed in consultation with, a dermatologist, immunologist, or allergist; **AND**
- **ONE** of the following:
  - There has been a treatment failure or intolerable side effect with a preferred topical corticosteroid agent (see Dermatology Steroids, Topical High and Very High Potency) or a preferred topical calcineurin inhibitor (see Dermatology Atopic Dermatitis Immunomodulators); OR
  - The recipient has a contraindication to ALL topical corticosteroid agents (see Dermatology – Steroids, Topical – High and Very High Potency) and topical calcineurin inhibitors (see Dermatology – Atopic Dermatitis Immunomodulators); AND
- The requested medication is prescribed concurrently with a topical corticosteroid and/or topical
  calcineurin inhibitor, unless contraindicated or clinically significant adverse effects are
  experienced; AND
  - The prescriber **states on the request** that the medication requested is not prescribed concurrently with another biologic immunomodulator or JAK inhibitor; **AND**

- If request is for a non-preferred agent **ONE** of the following is required: (see Dermatology Atopic Dermatitis Immunomodulators on the PDL/NPDL for a list of preferred agents)
  - The recipient has had a treatment failure with at least one preferred product;
     OR
  - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
  - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate to use for the condition being treated; **OR**
  - There is *no preferred product that is appropriate* to use for the condition being treated.

### Approval Criteria for Continuation of Therapy for Atopic Dermatitis

- The prescriber states on the request that there is evidence of a positive response to therapy including a significant reduction in areas affected and/or severity of AD;
   AND
- The prescriber **states on the request** that the medication requested is not prescribed concurrently with another biologic immunomodulator or JAK inhibitor.

Duration of approval for initiation of therapy: 6 months Duration of approval for continuation of therapy: 12 months

# Tralokinumab-ldrm (Adbry®)

### **Approval Criteria for Initiation of Therapy**

- The recipient is 12 years of age or older on the date of the request; AND
- The recipient has a diagnosis of moderate to severe atopic dermatitis (AD); AND
- There has been a treatment failure or intolerable side effect with or contraindication to a preferred topical corticosteroid agent (see Dermatology Steroids, Topical Low, Medium, High and Very High Potency) (names and dates of medications must be stated on the request); AND
- The medication is prescribed by, or the request states that this medication is being prescribed in consultation with, a dermatologist, immunologist or allergist; **AND**
- If request is for a non-preferred agent **ONE** of the following is required:
  - The recipient has had a treatment failure with at least one preferred product;
     OR
  - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
  - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate to use for the condition being treated; **OR**
  - There is no preferred product that is appropriate to use for the condition being treated.

## **Approval Criteria for Continuation of Therapy**

The prescriber states on the request that there is evidence of a positive response to therapy including a significant reduction in areas affected and/or severity of atopic dermatitis.

### Duration of approval for initiation and continuation of therapy: 6 months

#### References

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Revision / Date	Implementation Date
Single PDL Implementation	May 2019
Separated "Select Therapeutic Classes Not Established" into individual therapeutic class documents / November 2019	January 2020
Added reference to Dupixent® criteria document / December 2019	January 2020
Added revision table, removed footer, combined atopic dermatitis immunomodulators criteria and Dupixent® criteria into one document / January 2020	January 2020
Added topical corticosteroid treatment failure and modified age for Dupixent® for atopic dermatitis, formatting changes, updated references / June 2020	October 2020
Added preferred brand Elidel® wording, formatting changes, updated references / November 2020	January 2021
Updated Dupixent® criteria to include prescriber specialty, modified reauthorization criteria, added eosinophilic requirements for asthma, modified authorization duration, formatting changes / July 2021	January 2022
Decreased Dupixent® age for asthma to 6 years of age / October 2021	January 2022
Combined Adbry™ with current criteria, updated references / May 2022	July 2022
Added indication of eosinophilic esophagitis for Dupixent®, modified age of atopic dermatitis for Dupixent®, updated references / May 2022	October 2022
Formatting change to Elidel® wording, modified duration of therapy for Dupixent® / November 2022	January 2023
Added indication of prurigo nodularis for Dupixent®, previous use policy clarification, updated references / October 2022	April 2023
Modified age for atopic dermatitis for Adbry <sup>®</sup> , modified age and weight for eosinophilic esophagitis for Dupixent®, removed specific wording for the use of Elidel®, updated references, formatting changes / February 2024	July 2024
Added statement for clinical review of most recent prescribing information when currently posted criteria are not met / October 2024	November 2024
Added indication of COPD for Dupixent®, modified age of chronic rhinosinusitis for Dupixent®, updated references / November 2024	March 2025
Combined Ebglyss® <sup>TM</sup> and Nemluvio® with current criteria document / May 2025	July 2025
Added indications of chronic spontaneous urticaria and bullous pemphigoid for Dupixent®, updated references / June 2025	January 2026