

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®); **OR**
- Clinical authorization for 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® 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:
 - 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.

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:
 - 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 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/ μ L 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:
 - 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:
 - Decrease in the frequency of asthma exacerbations; **OR**
 - Decrease in the use of rescue medications; **OR**
 - Reduction in asthma-related symptoms; **OR**
 - 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:
 - 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:
 - Decrease in the frequency of asthma exacerbations; **OR**
 - Decrease in the use of rescue medications; **OR**
 - Reduction in asthma-related symptoms; **OR**
 - 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~~8~~ 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® (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:
 - 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 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:
 - 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 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:
 - 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 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/ μ L 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**:

- The recipient required treatment with systemic corticosteroids and/or antibiotics; **OR**
- 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:
 - 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 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].

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

Adbry (tralokinumab-ldrm) [package insert]. Madison, NJ: LEO Pharma Inc; December 2023.
<https://www.leo-pharma.us/Files/Billeder/US%20Website%20Product%20PIs/AdbryPI.pdf>

Boguniewicz M, Alexis AF, Beck LA, Block J, Eichenfield LF, Fonacier L, Guttman-Yassky E, Paller AS, Pariser D, Silverberg JI, Lebwohl M. Expert Perspectives on Management of Moderate-to-Severe Atopic Dermatitis: A Multidisciplinary Consensus Addressing Current and Emerging Therapies. *J Allergy Clin Immunol Pract*. 2017 Nov-Dec;5(6):1519-1531. doi: 10.1016/j.jaip.2017.08.005. Epub 2017 Sep 29. PMID: 28970084.

Chu, Derek K. et al. Atopic dermatitis (eczema) guidelines: 2023 American Academy of Allergy, Asthma and Immunology/American College of Allergy, Asthma and Immunology Joint Task Force on Practice Parameters GRADE– and Institute of Medicine–based recommendations. *Annals of Allergy, Asthma & Immunology*. 2023;(132)3:274 – 312.

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.;
<https://www.clinicalkey.com/pharmacology/>

DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey L. eds. Pharmacotherapy: A Pathophysiologic Approach, 10e New York, NY: McGraw-Hill;
<https://accesspharmacy.mhmedical.com/book.aspx?bookid=1861>

Dupixent (dupilumab) [package insert]. Bridgewater, NJ: sanofi-aventis U.S. LLC;
~~September~~January 2024. https://www.regeneron.com/sites/default/files/Dupixent_FPI.pdf

~~Eichenfield LF, Tom WL, Berger TG, et al. Guidelines of care for the management of atopic dermatitis: section 2. Management and treatment of atopic dermatitis with topical therapies. *J Am Acad Dermatol*. 2014;71(1):116-132. doi:10.1016/j.jaad.2014.03.023~~

Satoh T, Yokozeki H, Murota H, et al. 2020 guidelines for the diagnosis and treatment of prurigo. *J Dermatol*. 2021;48(9):e414-e431. doi:10.1111/1346-8138.16067

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®, 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
<u>Added indication of COPD for Dupixent®, modified age of chronic rhinosinusitis for Dupixent®, updated references / November 2024</u>	<u>March 2024</u>