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.

*These agents may have **Black Box Warnings**, and/or may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations. Please refer to individual prescribing information for details.*

Non-Preferred Atopic Dermatitis Immunomodulators (Except Dupixent® and Adbry™)

Approval Criteria for Initial and Reauthorization Requests

- For pimecrolimus (generic for Elidel®), there has been a treatment failure or intolerable side effect with or contraindication to brand Elidel®; **OR**
- 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; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.

Duration of initial and reauthorization approval: 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®)

Initial Approval Criteria for Atopic Dermatitis

- The recipient is 6 months~~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); **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**
- 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; **AND**
- The requested dose and dosing frequency are appropriate for the recipient's age, weight and diagnosis based on the prescribing information; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.

Reauthorization Criteria for Atopic Dermatitis

- The recipient continues to meet initial criteria; **AND**
- 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.

Initial Approval Criteria 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/mcL 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**
- 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; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The recipient has been adherent to controller medication therapy, using proper inhaler technique (if applicable) and has had an inadequate response; **AND**
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.

Reauthorization Criteria for Moderate to Severe Asthma with an Eosinophilic Phenotype

- The recipient continues to meet initial criteria; **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).

Initial Approval Criteria 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**
- 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; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The recipient has been adherent to controller medication therapy, using proper inhaler technique (if applicable) and has had an inadequate response; **AND**
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.

Reauthorization Criteria for Corticosteroid-Dependent Asthma

- The recipient continues to meet initial criteria; **AND**
- 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).

Initial Approval Criteria for Chronic Rhinosinusitis with Nasal Polyposis

- The recipient is 18 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**
- 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; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The recipient has been adherent to controller medication therapy, using proper technique (if applicable) and has had an inadequate response; **AND**
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.

Reauthorization Criteria for Chronic Rhinosinusitis with Nasal Polyposis

- The recipient continues to meet initial criteria; **AND**
- 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).

Initial Approval Criteria for Eosinophilic Esophagitis

- 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 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**
- 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; **AND**
- By submitting the authorization request, the prescriber attests to the following:
  - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
  - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
  - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.

Reauthorization Criteria for Eosinophilic Esophagitis

- The recipient continues to meet initial criteria; **AND**
- The prescriber **states on the request** that there is evidence of a positive response to therapy.

Duration of initial and reauthorization approval: 6 months

Tralokinumab-ldrm (Adbry™)

Approval Criteria

- The recipient is 18 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**
- 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; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.

Reauthorization Criteria

- The recipient continues to meet initial criteria; **AND**
- 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 initial and reauthorization approval: 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