

## 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®).

Additional Point-of-Sale edits may apply.

~~Some of these~~ *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.*

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### Non-Preferred Atopic Dermatitis Immunomodulators (Except Dupixent®)

#### 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 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.*

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## Dupilumab (Dupixent®)

### Initial Approval Criteria for ~~F~~or Atopic Dermatitis

- 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 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 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.
  - ~~The recipient has no concomitant drug therapies or disease states that limit the use of dupilumab.~~

### 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 Authorization ~~F~~for Moderate to Severe Asthma with an Eosinophilic Phenotype

- The recipient is 6+2 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  $\geq 150$  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<sup>®</sup> (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 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 request, the prescriber attests that the recipient has been adherent to controller medication therapy, using proper inhaler technique (if applicable) and has had an inadequate response; 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.

~~The recipient has no concomitant drug therapies or disease states that limit the use of dupilumab.~~

### 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<sup>®</sup> (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 Authorization for Corticosteroid--Dependent Asthma

- The recipient is ~~64~~ 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 with and and dates range of therapy are **stated on the request**); **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., 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**
- 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 request, the prescriber attests that the recipient has been adherent to controller medication therapy, using proper inhaler technique (if applicable) and has had an inadequate response; **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 prior to initiation of dupilumab does not require daily oral corticosteroid treatment; 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 Authorization 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 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 request, the prescriber attests that the recipient has been adherent to controller medication therapy, using proper technique (if applicable) and has had an inadequate response; 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.
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- ~~The recipient has no concomitant drug therapies or disease states that limit the use of dupilumab.~~

### **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).

**Duration of initial and reauthorization approval: 612 months**

### **References**

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<b><u>Revision / Date</u></b>	<b><u>Date Implementation Date</u></b>
Single PDL Implementation	May 2019
Separated “Select Therapeutic Classes Not Established” into individual therapeutic class documents / <del>November 2019</del>	<del>January 2020</del> <a href="#">November 2019</a>
Added reference to Dupixent <sup>®</sup> criteria document / <del>December 2019</del>	<del>December 2019</del> <a href="#">January 2020</a>
Added revision table, removed footer, combined atopic dermatitis immunomodulators criteria and Dupixent <sup>®</sup> criteria into one document / <del>January 2020</del>	<del>January 2020</del> <a href="#">January 2020</a>
Added topical corticosteroid treatment failure and modified age for Dupixent <sup>®</sup> for atopic dermatitis, formatting changes, updated references / <del>June 2020</del>	<del>June 2020</del> <a href="#">October 2020</a>
Added preferred brand Elidel <sup>®</sup> wording, formatting changes, updated references / <del>November 2020</del>	<del>November 2020</del> <a href="#">January 2021</a>
<del>Updated criteria for Dupixent<sup>®</sup> / July 2021</del>	
<del>Decreased Dupixent age for asthma to 6 years of age / October 2021</del>	