

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 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®)

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.

Dupilumab (Dupixent®)

For 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; **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**
- 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 dupilumab.

For Moderate to Severe Asthma with an Eosinophilic Phenotype

- 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 asthma with an eosinophilic phenotype; **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**
- 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 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 dupilumab.

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**
- 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 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 dupilumab.

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.

Duration of initial and reauthorization approval: 12 months

References

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; <https://www.clinicalkey.com/pharmacology/>" <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; June 2020. 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

Elidel (pimecrolimus) [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals International, Inc.; June 2017. <https://www.bauschhealth.com/Portals/25/Pdf/PI/Elidel-PI.pdf>

Revision	Date
Single PDL Implementation	May 2019
Separated “Select Therapeutic Classes Not Established” into individual therapeutic class documents.	November 2019
Added reference to Dupixent® criteria document	December 2019
Added revision table, removed footer, combined atopic dermatitis immunomodulators criteria and Dupixent® criteria into one document	January 2020
Added topical corticosteroid treatment failure and modified age for Dupixent® for atopic dermatitis, formatting changes, updated references	June 2020
Added preferred brand Elidel® wording , formatting changes, updated references	November 2020