



# Louisiana

## dupilumab (Dupixent<sup>®</sup>)

Policy # 00567

Original Effective Date: 06/21/2017

Current Effective Date: 06/20/2018

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

### When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member's contract/certificate, and
- Medical necessity criteria and guidelines are met.

Based on review of available data, the Company may consider dupilumab (Dupixent<sup>®</sup>)<sup>†</sup> for the treatment of atopic dermatitis to be **eligible for coverage**.

### Patient Selection Criteria

Coverage eligibility for dupilumab (Dupixent) will be considered when ALL of the following criteria are met:

#### Initial (6 months)

- Patient has moderate to severe atopic dermatitis; AND
- Patient is 18 years of age or older; AND
- Patient has had chronic atopic dermatitis for at least 3 years; AND  
*(Note: This criterion is an additional Company requirement, based on clinical trials, for coverage eligibility and will be denied as not medically necessary\*\* if not met.*
- Patient has atopic dermatitis involvement estimated to be  $\geq 10\%$  of the body surface area (BSA) according to the prescribing physician; AND  
*(Note: This criterion is an additional Company requirement, based on clinical trials, for coverage eligibility and will be denied as not medically necessary\*\* if not met.*
- Patient has tried and failed at least ONE prescription generic topical corticosteroid, unless there is clinical evidence or patient history that suggests the use of ONE prescription generic topical corticosteroid will be ineffective or cause an adverse reaction to the patient; AND
- Patient has tried and failed generic tacrolimus ointment, unless there is clinical evidence or patient history that suggests the use of generic tacrolimus ointment will be ineffective or cause an adverse reaction to the patient; AND
- Patient has tried and failed one of the following generic systemic agents for the treatment of atopic dermatitis: oral corticosteroid, intramuscular corticosteroid, oral cyclosporine, oral azathioprine, oral methotrexate, or oral mycophenolate mofetil, unless there is clinical evidence or patient history that suggests the use of the generic systemic agents listed above will be ineffective or cause an adverse reaction to the patient.  
*(Note: This criterion is an additional Company requirement, based on national guidelines, for coverage eligibility and will be denied as not medically necessary\*\* if not met.*

#### Continuation (1 year)

- Patient has received an initial authorization; AND

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- Patient has had an improvement in atopic dermatitis symptoms per the prescribing physician  
*(Note: This criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary\*\* if not met.*

## **When Services Are Considered Not Medically Necessary**

Based on review of available data, the Company considers the use of dupilumab (Dupixent) when any of the following criteria are NOT met to be **not medically necessary\*\***:

- Patient has had chronic atopic dermatitis for at least 3 years; OR
- Patient has atopic dermatitis involvement estimated to be  $\geq 10\%$  of the BSA according to the prescribing physician; OR
- Patient has tried and failed one of the following generic systemic agents for the treatment of atopic dermatitis: oral corticosteroid, intramuscular corticosteroid, oral cyclosporine, oral azathioprine, oral methotrexate, or oral mycophenolate mofetil; OR
- Patient has had an improvement in atopic dermatitis symptoms per the prescribing physician.

## **When Services Are Considered Investigational**

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

Based on review of available data, the Company considers the use of dupilumab (Dupixent) when the patient selection criteria are not met (EXCEPT those denoted as **not medically necessary\*\***) to be **investigational**.\*

## **Background/Overview**

Dupixent is an interleukin-4 receptor alpha antagonist indicated for the treatment of adult patients with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable Dupixent can be used with or without topical corticosteroids. The recommended dose of Dupixent is 600 mg injected subcutaneously initially (two injections in different sites), then 300 mg given subcutaneously every other week. Dupixent is supplied as 300 mg prefilled syringes.

## **Atopic Dermatitis**

There are various treatment options for atopic dermatitis, including first line agents such as topical corticosteroids (many of which are in generic form), and topical immunomodulatory agents, such as generic tacrolimus. For those that are refractory to topical therapies, systemic immunomodulatory agents are indicated (e.g. cyclosporine, azathioprine, and methotrexate) via guidelines from the American Academy of Dermatology. Dupixent has not yet been integrated into the guidelines at the time of this publication. The availability of generic products in this treatment category lends itself to be a more economical option for the treatment of atopic dermatitis versus the branded products available on the market. However, if these products have been tried and failed, then Dupixent is a reasonable approach to therapy based on the current standard of care.

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## **FDA or Other Governmental Regulatory Approval**

### **U.S. Food and Drug Administration (FDA)**

Dupilumab is indicated for the treatment of adult patients with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Dupilumab can be used with or without topical corticosteroids.

## **Rationale/Source**

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. FDA approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, Blue Cross and Blue Shield Association technology assessment program (TEC) and other non-affiliated technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

The safety and efficacy of Dupilumab was established in three randomized, double-blind, placebo controlled pivotal studies. The populations in these trials included adults that had atopic dermatitis for at least 3 years and had involvement  $\geq 10\%$  of the BSA. The study entrants were also previously uncontrolled by topical therapies. SOLO-1 (n=671) and SOLO-2 (n=708) evaluated Dupilumab as monotherapy, while CHRONOS (n=740) evaluated Dupilumab as combination therapy. In all studies, the primary endpoint was a score of 0 (clear) or 1 (almost clear) on the Investigator's Global Assessment (IGA) and a reduction of  $\geq 2$  points from baseline to week 16. In SOLO-1, the primary endpoint was met in 38% of subjects in the Dupilumab group versus 10% of subjects in the placebo group (P<0.001). In SOLO-2, the primary endpoint was achieved in 36% of subjects in the Dupilumab group versus 18% in the placebo group (P<0.001). In week 16 of the CHRONOS trial, 38.7% of Dupilumab subjects met the primary endpoint versus 10% of those treated with placebo (P<0.001). At week 52, similar results were reported for the CHRONOS trial.

## **References**

1. Dupilumab [package insert]. Regeneron Pharmaceuticals, Inc. Tarrytown, New York. Updated March 2017.
2. Dupilumab Drug Evaluation. Express Scripts. Updated March 2017.
3. Dupilumab Prior Authorization Policy. Express Scripts. Updated March 2017.
4. Sidbury R, et al. Guidelines of care for the management of atopic dermatitis Section 3. Management and treatment with phototherapy and systemic agents. J Am Acad Dermatol. 2014;71(2): 327-349.
5. 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.

## **Policy History**

Original Effective Date: 06/21/2017

Current Effective Date: 06/20/2018

06/01/2017 Medical Policy Committee review

06/21/2017 Medical Policy Implementation Committee approval. New policy.

06/07/2018 Medical Policy Committee review

06/20/2018 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 06/2019

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\*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
  1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
  2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
  3. Reference to federal regulations.

\*\*Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

**NOTICE:** Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

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