

Drug Therapy Guidelines

Dupixent® (dupilumab)

Applicable

Medical Benefit		Effective: 11/1/18
Pharmacy- Formulary 1	X	Next Review: 9/19
Pharmacy- Formulary 2	X	Date of Origin: 7/17
Pharmacy- Formulary 3/Exclusive	X	Review Dates: 7/17, 9/17, 9/18
Pharmacy- Formulary 4/AON	X	

I. Medication Description

Dupilumab is a human monoclonal IgG4 antibody that inhibits interleukin-4 (IL-4) and interleukin-13 (IL-13) signaling by binding specifically to the IL-4R alpha subunit shared by the IL-4 and IL-13 receptor complexes. By blocking IL-4R alpha, dupilumab inhibits IL-4 and IL-13 cytokine-induced inflammatory response, including the release of proinflammatory cytokines, chemokines, and IgE, which plays a role in the development of atopic dermatitis. Consistent with receptor blockade, serum levels of IL-4 and IL-13 are increased following dupilumab treatment.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage of Dupixent is available when the following criteria have been met:

- Member is at least 18 years of age **AND**
- The medication is prescribed by an allergist, immunologist, or dermatologist **AND**
- Member has been diagnosed with moderate-to-severe atopic dermatitis **AND**
- Member has atopic dermatitis involvement estimated to be $\geq 10\%$ of the body surface area (BSA) according to the prescribing physician **AND**
- Member has tried at least one of the following systemic medications: oral corticosteroid, intramuscular corticosteroid, oral cyclosporine, oral azathioprine, oral methotrexate, or oral mycophenolate mofetil **AND**
- Member has used at least one medium-, medium-high, high-, and/or super-high-potency prescription topical corticosteroid (or use is shown to be contraindicated) **AND**
- Member has tried a topical calcineurin inhibitor (unless use is contraindicated).

IV. Quantity Limitations

- Coverage is available as follows:
 - Up to 8 ml (4 syringes) are covered in the first month to accommodate induction dosing
 - Up to 4 ml (2 syringes) are covered in subsequent months to accommodate maintenance dosing

- Coverage of loading dose must be specifically requested and approved for the required quantity to be covered.

V. Coverage Duration

Coverage is available for 12 months and may be renewed.

VI. Coverage Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Stabilization of disease or in absence of disease progression **AND**
- Absence of unacceptable toxicity from the drug

VII. Billing/Coding Information

- Available in cartons containing 2 prefilled syringes.
- Each syringe delivers 300mg of Dupixent in a 2ml solution.

VIII. Summary of Policy Changes

- 7/19/17: new policy
- 10/11/17: removed time frame for trials of systemic medications and topical calcineurin inhibitor; quantity limitations updated
- 11/1/18: no policy changes

IX. References

1. Dupixent[™] subcutaneous injection [prescribing information]. Bridgewater, NJ: sanofi aventis; April 2018.
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3. Data on file. Formulary Submission Dossier for Dupixent[®] (dupilumab) injection. Regeneron Pharmaceuticals and Sanofi Genzyme; January 2017.
4. Schneider L, Tilles S, Lio P, et al. Atopic dermatitis: a practice parameter update 2012. *J Allergy Clin Immunol*. 2013;131:295-299.
5. 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.
6. 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.
7. Wenzel S, Ford L, Pearlman D, et al. Dupilumab in persistent asthma with elevated eosinophil levels. *N Engl J Med*. 2013;368(26):2455-2466.

8. Wenzel S, Castro M, Corren J, et al. Dupilumab efficacy and safety in adults with uncontrolled persistent asthma despite use of medium-to-high-dose inhaled corticosteroids plus a long-acting beta-2 agonist: a randomized double-blind placebo-controlled pivotal phase 2b dose-ranging trial. *Lancet*. 2016;388:31-44.
9. US National Institutes of Health. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000- [cited 2016 Nov 16]. Available from: <https://www.clinicaltrials.gov/ct2/results?term=dupilumab&Search=Search>. Search term: dupilumab.
10. Bachert C, Mannent L, Naclerio RM, et al. Effect of subcutaneous dupilumab on nasal polyp burden in patients with chronic sinusitis and nasal polyposis: a randomized clinical trial. *JAMA*. 2016;315(5):469-479.
11. Lexi-Comp Online: Dupixent. Hudson, Ohio. Accessed Aug 2017.

The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.