Humana. CareSource™

# PHARMACY POLICY STATEMENT
## Kentucky Medicaid

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| DRUG NAME | Dupixent (dupilumab) |
| BILLING CODE | Must use valid NDC code |
| BENEFIT TYPE | Pharmacy |
| SITE OF SERVICE ALLOWED | Home |
| COVERAGE REQUIREMENTS | Prior Authorization Required (Non-Preferred Product)<br>QUANTITY LIMIT— 600 mg per month after loading dose |
| LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY | Click Here |

Dupixent (dupilumab) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

## MODERATE-TO-SEVERE ATOPIC DERMATITIS

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by a dermatologist, allergist or immunologist; AND
3. Member's atopic dermatitis involving 10% or more of the body surface area (BSA); AND
4. Documented member's Eczema Area and Severity Index (EASI) score is ≥16 (on a scale of 0-72) submitted with chart notes; AND
5. Member has documented trial and failure of or contraindication to at least **two** medium potency to very-high potency topical corticosteroids (e.g. Elocon (mometasone furoate), Synalar (fluocinolone acetonide), Lidex (fluocinonide)); AND
6. Member has tried and failed to respond to phototherapy treatment (i.e. UV-A, UV-B, a combination of both, psoralen plus UV-A (PUVA), or UV-B1 (narrow-band UV-B)) for at least 30 days; AND
7. Member has documented trial and failure of or contraindication to at least **one** oral immunomodulatory agent (cyclosporine, methotrexate, azathioprine, or mycophenolate mofetil); AND
8. Member has documented trial and failure of or contraindication to both topical calcineurin inhibitors: Elidel (pimecrolimus) and Protopic (tacrolimus)); AND
9. Member is not receiving Dupixent in combination with another biologic medication for the treatment of atopic dermatitis (e.g. Xolair (omalizumab), Rituxan (rituximab), Enbrel (etanercept), Remicade/Inflectra (infliximab)).
10. **Dosage allowed:** Initial dose of 600 mg (two 300 mg injections in different injection sites), followed by 300 mg given every other week.

***If member meets all the requirements listed above, the medication will be approved for 6 months.***

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Documented member's EASI score improvement; AND
3. Member is not receiving Dupixent in combination with another biologic medication for the treatment of atopic dermatitis (e.g. Xolair (omalizumab), Rituxan (rituximab), Enbrel (etanercept), Remicade/Inflectra (infliximab)).

***If member meets all the reauthorization requirements above, the medication will be approved for an additional 6 months.***

## CareSource considers Dupixent (dupilumab) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Scabies
- Seborrheic dermatitis
- Contact dermatitis (irritant or allergic)
- Ichthyoses
- Cutaneous T-cell lymphoma
- Psoriasis
- Photosensitivity dermatosis
- Immune deficiency diseases
- Erythroderma of other causes

| DATE | ACTION/DESCRIPTION |
|---|---|
| **06/12/2017** | New policy for Dupixent created. |

References:

1. Dupixent [package insert]. Tarrytown, NY; Regeneron Pharmaceuticals, Inc.: March, 2017. Accessed on April 5, 2017.
2. Atopic dermatitis clinical guideline (2017). In American Academy of Dermatology. Retrieved from https://www.aad.org/practicecenter/quality/clinical-guidelines/atopic-dermatitis.
3. Eichenfield LF, Tom WL, Chamlin SL et al. Guidelines of care for the management of atopic dermatitis: section 1. Diagnosis and assessment of atopic dermatitis. J Am Acad Dermatol. 2014; 70(1):338-51.
4. Sidbury R, Davis DM, Cohen DE, 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 Aug;71(2):327-49.
5. Montes-Torres A, Llamas-Velasco M, Pérez-Plaza A et al. Biological Treatments in Atopic Dermatitis. J. Clin. Med. 2015, 4, 593-613.

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