

PHARMACY POLICY STATEMENT

Indiana Medicaid

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) 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 12 weeks; 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.

Effective date: 01/01/2018

Revised date: 06/12/2017