Humana.

CareSource™

PHARMACY POLICY STATEMENT
Kentucky 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— up to 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 12 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)) for at least 3 months; 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 (*Note*: *tanning beds or outdoor exposure are not true and appropriate substitutes for true UVB or PUVA therapy and therefore would not meet this criteria*).*
   *If member does not have access to light therapy two oral immunomodulatory agents should be used as alternative treatment option (that includes one agent from criterion 7); 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 **one** of the following:
   a) Eucrisa and/or Elidel (pimecrolimus);
   b) 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/Erelzi (etanercept), Remicade/Inflectra/Renflexis (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.

Humana. CareSource™

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/Erelzi (etanercept), Remicade/Inflectra/Renflexis (infliximab)).

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

MODERATE-TO-SEVERE PERSISTENT ASTHMA

For **initial** authorization:
1. Member must be 12 years of age or older; AND
2. Member has diagnosis of moderate-to-severe persistent asthma with an eosinophilic phenotype (baseline peripheral blood eosinophil level ≥ 150 cells/μL within the past 6 weeks or history of blood eosinophils greater than or equal to 300 cells/μL) OR with oral corticosteroid dependent asthma; AND
3. Medication must be prescribed by a pulmonologist, immunologist or allergist for the diagnosis of asthma; AND
4. Member has at least two documented severe asthma exacerbation within last year; AND
5. Member's asthma has been inadequately controlled after 3 month of conventional treatment including **one** of the following:
   a) Medium to high doses of inhaled corticosteroids and long acting beta 2-agonists;
   b) High dose inhaled corticosteroid and a Leukotriene Receptor Antagonists; OR
6. Member is requiring any of the following despite adherent use of conventional therapy:
   a) Oral/systemic corticosteroid treatment (or increase in dose if already on oral corticosteroid);
   b) Urgent care visit or hospital admission;
   c) Intubation; AND
7. Medication is being used as the add-on maintenance treatment to conventional therapies for asthma (i.e., ICS, LABA, etc.); AND
8. Medication is not used in combination with Nucala (mepolizumab), Cinqair (reslizumab), Xolair (omalizumab) or Fasenra (benralizumab).
9. **Dosage allowed:** Initial dose of 400 mg (two 200 mg injections) followed by 200 mg given every other week, or an initial dose of 600 mg (two 300 mg injections) followed by 300 mg given every other week. For members requiring concomitant oral corticosteroids start with an initial dose of 600 mg followed by 300 mg given every other week.

If member meets all the requirements listed above, the medication will be approved for 16 weeks.

For **reauthorization**:
1. Medication is not being used as monotherapy for asthma; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has demonstrated improvement during 16 weeks of medication therapy:
   a) Decreased frequency of emergency department visits; OR
   b) Decreased frequency of hospitalizations due to asthma symptoms; OR
   c) Increase in percent predicted FEV1 from pretreatment baseline; OR
   d) Improved functional ability (i.e., decreased effect of asthma on ability to exercise, function in school or at work, or quality of sleep); OR
   e) Decreased utilization of rescue medications; OR
   f) Reduction in exacerbations or corticosteroid dose.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 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:

- Allergic broncho-pulmonary aspergillosis
- Allergic conditions without asthma
- Allergic rhinitis
- Bullous pemphigoid
- Cholinergic urticaria and urticaria of other known causes
- Chronic idiopathic urticaria (CIU)
- Contact dermatitis (irritant or allergic)
- Cutaneous T-cell lymphoma
- Eosinophilic esophagitis
- Eosinophilic gastroenteritis
- Eosinophilic granulomatosis with polyangiitis (EGPA/Churg-Strauss Syndrome)
- Eosinophilic pneumonia
- Erythroderma of other causes
- Food allergy (e.g., peanut allergy)
- Ichthyoses
- Immune deficiency diseases
- Initial therapy for allergic asthma
- Insulin allergy
- Latex allergy
- Nasal polyposis
- Non-allergic (non-atopic) asthma
- Photosensitivity dermatosis
- Psoriasis
- Scabies
- Seborrheic dermatitis
- Subcutaneous immunotherapy, adjunct
- Vibratory angioedema

DATE	ACTION/DESCRIPTION
06/12/2017	New policy for Dupixent created.
05/22/2019	New indication of Moderate-to-Severe Persistent Asthma added. For Atopic Dermatitis: age requirements expanded (covered for 12 years old members and older); topical corticosteroids use required for at least 3 months; clarification on

	tanning beds for UV exposure entered; step therapy for topical calcineurin inhibitors revised.

References:

1. Dupixent [package insert]. Tarrytown, NY; Regeneron Pharmaceuticals, Inc.: March, 2019.
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.
6. Chung KF, Wenzel SE, Brozek JL, et al. International ERS/ATS guidelines on definition, evaluation and treatment of severe asthma. The European respiratory journal. 2014;43(2):343-373.
7. Kuehn BM. Fevipiprant shows promise for severe, refractory asthma. Medscape. 2016 Aug 11. http://www.medscape.com/viewarticle/867344.
8. Mayer Knutsen R. Novartis aims to bring first oral asthma drug to market in two decades. Medical Marketing & Media. 2017 Mar 22. http://www. mmm-online.com/pipeline/novartis-nvs-first-to-market-oral-asthma-respiratory-drug-in-two-decades/article/645364.
9. IPD Analytics. New Drug Approval. Dupixent (dupilumab). Available at: http://www.ipdanalytics.com/.

Effective date: 07/01/2019
Revised date: 05/22/2019