CareSource

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— 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.

CHRONIC RHINOSINUSITIS WITH NASAL POLYPOSIS (CRSwNP)

For **initial** authorization:

1. Member is 18 years old or older with diagnosis of bilateral CRSwNP. *Note:* chart notes required with documentation of severity and amount of bilateral sinonasal polyposis. Documentation must include: Evidence of nasal polyposis by direct examination OR endoscopy OR sinus CT scan; AND
2. Member has bilateral CRSwNP and symptoms of chronic rhinosinusitis despite intranasal corticosteroid therapy with history of ONE or more of the following:
   a) Prior sinonasal surgery;
   b) Systemic corticosteroids use in the past 2 years (unless were ineligible to or were intolerant to systemic corticosteroids); AND
3. Medication must be prescribed by or in consultation with allergist, immunologist, or otorhinolaryngologist (ENT); AND
4. Medication is used as an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP); AND
5. Member has bilateral CRSwNP for ≥ 12 weeks with 2 or more of the following:
   a) Facial pressure or pain;
   b) Decreased or absent sense of smell (and/or taste);
   c) Moderate to severe nasal congestion/blockage/obstruction;
   d) Intranasal steroid use;
   e) Rhinorrhea or post-nasal drip; AND
6. Member does **not** have ANY of the following:
   a) Hepatitis B or Hepatitis C (member must be treated prior to initiating Dupixent);
   b) Conditions/concomitant diseases such as:
      i) Antrochoanal polyps;
      ii) Acute sinusitis, nasal infection or upper respiratory infection;
      iii) Ongoing rhinitis medicamentosa;
      iv) Radiologic suspicion or confirmed invasive or expansive fungal rhinosinusitis.
7. **Dosage allowed:** 300 mg every other week.

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

For **reauthorization**:

1. Medication is not being used as monotherapy for CRSwNP; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

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

MODERATE-TO-SEVERE ATOPIC DERMATITIS

For **initial** authorization:

8. Member must be 12 years of age or older; AND
9. Medication must be prescribed by a dermatologist, allergist or immunologist; AND
10. Member's atopic dermatitis involving 10% or more of the body surface area (BSA); AND
11. Documented member's Eczema Area and Severity Index (EASI) score is ≥ 16 (on a scale of 0-72) submitted with chart notes; AND
12. 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
13. 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
14. Member has documented trial and failure of or contraindication to at least **one** oral immunomodulatory agent (cyclosporine, methotrexate, azathioprine, or mycophenolate mofetil); AND
15. Member has documented trial and failure of or contraindication to **one** of the following:
    a) Eucrisa and/or Elidel (pimecrolimus);
    b) Protopic (tacrolimus); AND
16. 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)).
17. **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**:

4. Member must be in compliance with all other initial criteria; AND
5. Documented member's EASI score improvement; AND
6. 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)
- Chronic rhinosinusitis without nasal polyps
- 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.
10/14/2019	New diagnosis of Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP) was added.

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