CareSource

PHARMACY POLICY STATEMENT
Georgia 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; AND**
2. **Medication must be prescribed by or in consultation with allergist, immunologist, or otorhinolaryngologist (ENT); AND**
3. **Member has a diagnosis of bilateral CRSwNP for more than 12 weeks; AND**
4. **Chart notes must show documentation of bilateral nasal polyps by direct examination, endoscopy, or sinus CT scan; AND**
5. **Member has symptoms of chronic rhinosinusitis after at least a 4-week trial with an intranasal corticosteroid (e.g., mometasone, fluticasone) in combination with nasal saline irrigation AND one of the following:**
   a) **Prior sinonasal surgery;**
   b) **Systemic corticosteroids (unless not tolerated or contraindicated); AND**
6. **Medication is used as an add-on maintenance treatment in combination with intranasal corticosteroid, unless not tolerated or contraindicated; AND**
7. **Member does not have allergic fungal rhinosinusitis (AFRS).**
8. **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. **Member must be in compliance with all other initial criteria; AND**
2. **Medication is to be used as add-on maintenance therapy in combination with intranasal corticosteroids, unless not tolerated or contraindicated; AND**
3. **Chart notes have been provided showing improvement of nasal congestion/obstruction symptoms, and/or reduced nasal polyp size.**

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:

1. **Member must be 6 years of age or older; AND**
2. **Medication must be prescribed by a dermatologist, allergist, or immunologist; AND**
3. **Member has a documented diagnosis of moderate-to-severe atopic dermatitis; AND**
4. Member's atopic dermatitis involves 10% or more of the body surface area (BSA) OR involves highly **visible or functional areas (e.g., neck, face, genitals, palms) and is significantly impairing quality of life; AND**
5. **Member has a documented trial and failure of, intolerance, or contraindication to at least one medium to high potency topical corticosteroid for at least 4 weeks. Note: a topical calcineurin inhibitor (e.g., tacrolimus, pimecrolimus) or Eucrisa may also be acceptable.**
6. **Member has documented trial and failure of, intolerance, or contraindication to one of the following:**
   a) **At least 8 weeks of phototherapy treatment (i.e., UV-A, UV-B, a combination of both, psoralen plus UV-A (PUVA), or UV-B1 (narrow-band UV-B));**
   b) **At least 12 weeks of one oral immunomodulatory agent (e.g., cyclosporine, methotrexate, azathioprine).**
7. **Dosage allowed:**
   Adults: Initial dose of 600 mg (two 300 mg injections), followed by 300 mg given every other week.
   Pediatrics:

Body Weight	Initial Dose	Subsequent Doses
15 to less than 30 kg	600 mg (two 300 mg injections)	300 mg every 4 weeks (Q4W)
30 to less than 60 kg	400 mg (two 200 mg injections)	200 mg every other week (Q2W)
60 kg or more	600 mg (two 300 mg injections)	300 mg every other week (Q2W)

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

For reauthorization:

1. **Chart notes demonstrate improvement of signs and symptoms such as fewer flares, less itching/erythema, improved quality of life, etc.**

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

MODERATE TO SEVERE PERSISTENT ASTHMA

For initial authorization:

1. **Member must be 12 years of age or older; AND**
2. **Medication must be prescribed by or in consultation with a pulmonologist, immunologist or allergist; AND**
3. **Member has one of the following:**
   a) **Severe eosinophilic asthma including:**
      i) **Blood eosinophil count of at least 150 cells/µL; AND**
      ii) **At least two documented severe asthma exacerbations requiring oral corticosteroids (OCS), or at least one requiring hospitalization, within last year; OR**
   b) **Oral corticosteroid (OCS) dependent asthma; AND**
4. Member's asthma has been inadequately controlled after 3 month**s of conventional treatment on medium to high doses of inhaled corticosteroids (ICS) and long acting beta 2-agonists (LABA); AND**

5. Medication is being used as the add-on maintenance treatment to conventional therapies for asthma (i.e., ICS, LABA, etc.); AND
6. Medication is not used in conjunction with any other biologic therapy for asthma.
7. 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 hospitalizations due to asthma exacerbations; OR
   b) Increase in percent predicted FEV1 from pretreatment baseline; OR
   c) Improved functional ability (i.e., decreased effect of asthma on ability to exercise, function in school or at work, or quality of sleep); OR
   d) Decreased utilization of rescue medications or oral corticosteroids.

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 diseases that are not listed in this document.

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.
06/05/2020	Age lowered to 6 years old for atopic dermatitis and pediatric dosing table added.
01/12/2021	Persistent Asthma: eosinophil count was updated to be consistent with guidelines; exacerbation number was updated to be consistent with guidelines (2 requiring OCS or 1 requiring hospitalization in the last year); ICS + LTRA treatment removed; requirements despite adherence to therapy removed (i.e. intubation, urgent care visit or hospital admin); changed from not to be used with Nucala, Cinqair, or Fasenra to not to be used with any other asthma biologic. CRSwNP: removed documentation of severity/amount of polyposis; removed "use in the past 2 years" for systemic steroid. Specified 4 weeks of trial for intranasal steroid and added that it must be used with nasal saline. Specified that Dupixent must be used as add-on treatment with intranasal steroid for initial and reauth. Removed list of symptoms of sinusitis. Removed Hep B & C requirement. Specified what improvement looks like for reauth. Reduced the list of exclusion to only ask that member does not have AFRS. Atopic Dermatitis: removed EASI score requirement. Added diagnosis of AD. Added that AD involvement that significantly affects QoL also qualifies for moderate to severe. Reduced topical trials to just one trial of steroid for 4 weeks. Made Eucrisa and TCI optional if member cannot use steroid. Reduced phototherapy trial to 8 weeks. Changed from phototherapy and immunosuppressant to phototherapy OR immunosuppressant.

	Removed requirement of combination with another biologic. Updated reauth to require specific signs and symptoms of AD improvements. Increased reauth length to 12 months. Updated references.

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