CareSource Rx Innovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Dupixent (dupilumab)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Dupixent was originally approved by the FDA in 2017 for the treatment of moderate to severe atopic dermatitis. Since then, it has also been granted approvals for the treatment of moderate to severe asthma, chronic rhinosinusitis with nasal polyposis, eosinophilic esophagitis, prurigo nodularis, chronic obstructive pulmonary disease (COPD) and chronic spontaneous urticaria (CSU). It is administered by subcutaneous injection.
Dupixent is an interleukin (IL) - 4 receptor alpha antagonist monoclonal antibody. It inhibits the signaling of IL-4 and IL-13 to help combat cytokine-induced inflammatory responses.

Dupixent (dupilumab) will be considered for coverage when the following criteria are met:

Atopic Dermatitis

For **initial** authorization:

1. Member is at least 6 months of age; 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 ONE of the following:
   a) Medium to very high potency topical corticosteroids for 2 weeks; OR
   b) Topical calcineurin inhibitor *(e.g., tacrolimus, pimecrolimus)* for 6 weeks.
   Note: Eucrisa for 4 weeks or Opzelura for 8 weeks may also be acceptable.
6. **Dosage allowed/Quantity limit:**
   Adults: Initial dose of 600 mg (two 300 mg injections), followed by 300 mg given every other week.
   Pediatric patients 6 to 17 years of age:

Body Weight	Initial Loading Dose	Subsequent Dosage[a]
15 to less than 30 kg	600 mg (two 300 mg injections)	300 mg Q4W
30 to less than 60 kg	400 mg (two 200 mg injections)	200 mg Q2W
60 kg or more	600 mg (two 300 mg injections)	300 mg Q2W

[a] Q2W – every other week; Q4W – every 4 weeks

Pediatric patients 6 months to 5 years of age:

Body Weight	Initial and Subsequent Dosage
5 to less than 15 kg	200 mg (one 200 mg injection) every 4 weeks (Q4W)
15 to less than 30 kg	300 mg (one 300 mg injection) every 4 weeks (Q4W)

If all the above requirements are met, 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 all the above requirements are met, the medication will be approved for an additional 12 months.

Moderate-to-Severe Asthma

For **initial** authorization:
1. Member is at least 6 years of age; 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 months of conventional treatment on medium to high doses of inhaled corticosteroids (ICS) and additional maintenance therapy (i.e, LABA, LAMA etc.); 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/Quantity limit**:
   Adults and adolescents 12 years of age and older:

Initial Loading Dose	Subsequent Dosage
400 mg (two 200 mg injections)	200 mg every 2 weeks (Q2W)
or	
600 mg (two 300 mg injections)	300 mg every 2 weeks (Q2W)
Dosage for patients with oral corticosteroid-dependent asthma or with co-morbid moderate-to-severe atopic dermatitis or adults with co-morbid chronic rhinosinusitis with nasal polyposis	
600 mg (two 300 mg injections)	300 mg every 2 weeks (Q2W)

Pediatric patients age 6 to 11 years of age:

Body Weight	Initial Dose and Subsequent Dosage
15 to less than 30 kg	300 mg every four weeks (Q4W)
≥30 kg	200 mg every other week (Q2W)

*No loading dose for this age group

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Medication is **NOT** being used as monotherapy for asthma; AND
2. Chart notes have been provided that show the member has demonstrated improvement (i.e. increased FEV1, decreased rate of exacerbations or decreased utilization of oral corticosteroids, etc.).

If all the above requirements are met, the medication will be approved for an additional 12 months.

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

For **initial** authorization:
1. Member is at least 12 years of age; AND
2. Medication must be prescribed by or in consultation with an allergist, immunologist, or otorhinolaryngologist (ENT); AND
3. Member has a diagnosis of severe CRSwNP with at least **TWO** of the following symptoms for 12 weeks or more:
   a) Nasal blockage/obstruction/congestion
   b) Nasal discharge
   c) Facial pain/pressure
   d) Reduction in smell; AND
4. Chart notes must show documentation of bilateral nasal polyps by direct examination, endoscopy, or sinus CT scan; AND
5. Member has failed a 4-week trial with an intranasal corticosteroid (e.g., mometasone, fluticasone) in combination with nasal saline irrigation; AND
6. Member has tried and failed systemic corticosteroids; AND
7. Medication is used as an add-on maintenance treatment in combination with intranasal corticosteroid; AND
8. Medication is NOT used in combination with other biologic therapies for CRSwNP.
9. **Dosage allowed/Quantity limit:** 300 mg every other week.
   Quantity limit: 2 pens/syringes per 28 days.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Medication is being used as add-on maintenance therapy in combination with intranasal corticosteroids; AND
2. Chart notes have been provided showing improvement of nasal congestion/obstruction symptoms, and/or reduced nasal polyp size.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Eosinophilic Esophagitis (EoE)

For **initial** authorization:
1. Member is at least 1 year of age AND weighs at least 15 kg; AND
2. Medication is prescribed by or in consultation with an allergist, immunologist, otorhinolaryngologist (ENT), or gastroenterologist; AND
3. Member has a diagnosis of EoE confirmed by endoscopy with esophageal biopsy showing ≥15 intraepithelial eosinophils per high-power field (eos/hpf); AND
4. Member has symptoms of dysphagia; AND
5. Member has had a trial and failure of **TWO** of the following:
   a) High dose proton pump inhibitor (PPI) for 8 weeks;
   b) Topical (swallowed) corticosteroid therapy (i.e., budesonide or fluticasone) for 12 weeks;
   c) Dietary modifications; AND
6. Member's weight is provided for dose calculation.

7. **Dosage allowed/Quantity limit:** Administer subcutaneously per table below.. Quantity limit: 4 pens/syringes per 28 days.

Body Weight	Recommended Dosage
15 to less than 30 kg	200 mg every other week
30 to less than 40 kg	300 mg every other week
40 kg or more	300 mg every week

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes have been provided documenting at least **ONE** of the following:
   a) Histological remission (peak esophageal intraepithelial eosinophil count ≤6 eos/hpf);
   b) Improvement in frequency or severity of dysphagia symptoms.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Prurigo Nodularis (PN)

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication is prescribed by or in consultation with a dermatologist; AND
3. Member has a documented diagnosis of prurigo nodularis with **ALL** of the following:
   a) Chronic pruritis lasting more than 6 weeks;
   b) Severe itch with repeated scratching;
   c) At least 20 total lesions present; AND
4. Member has had a trial and failure of a medium to super high potency topical corticosteroid for at least 2 weeks.
   a) NOTE: If topical corticosteroids are contraindicated, must alternatively try and fail **ONE** of the following: topical emollient, capsaicin, calcipotriol, calcineurin inhibitor, phototherapy, or oral antihistamine.
5. **Dosage allowed/Quantity limit**: Initial dose of 600 mg (two 300 mg injections), followed by 300 mg given every other week. Quantity limit: 2 pens/syringes per 28 days after loading dose.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes have been provided documenting clinically significant reduction of itch intensity and/or nodule clearance compared to baseline.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Chronic obstructive pulmonary disease (COPD)

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication is prescribed by or in consultation with a pulmonologist or allergist/immunologist; AND
3. Member has a documented diagnosis of moderate to severe COPD; AND
4. Member has type 2 inflammation with baseline blood eosinophil count of at least 300 cells/µL; AND
5. Member has tried and failed triple therapy with LABA, LAMA, and ICS for at least 3 months (or LABA + LAMA only if ICS is contraindicated); AND
6. Member is inadequately controlled, defined as at least 1 severe or 2 moderate exacerbations in the past 12 months; AND

7. Dupixent is prescribed as add-on to standard maintenance therapy.
8. **Dosage allowed/Quantity limit**: 300 mg every other week by subcutaneous injection.
   QL: 2 pens/syringes per 28 days

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes have been provided with documentation of positive clinical response such as fewer exacerbations, improved lung function, improved respiratory symptoms.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Chronic Spontaneous Urticaria (CSU)

For **initial** authorization:
1. Member is at least 12 years of age or older; AND
2. Medication must be prescribed by or under the recommendation of an allergist, dermatologist, or immunologist; AND
3. Member has a diagnosis of moderate to severe chronic spontaneous urticaria, with the presence of itch and hives, that has been present for more than 6 weeks; AND
4. Member has trialed and failed a second generation H1 antihistamine (i.e. loratadine, cetirizine, fexofenadine) at 2-4 times the FDA-approved dosage for 14 days; AND
5. Member is omalizumab naive; AND
6. Member will continue to use a second generation H1 antihistamine with Dupixent.
7. **Dosage allowed/Quantity limit**: quantity limit: 2 syringes or pens per 28 days.
   a. 18 years or older: initial dose of 600 mg (two 300 mg injections), followed by 300 mg given every 2 weeks
   b. 12 to 17 years of age: see table below.

Body Weight	Initial Loading Dose	Subsequent Dosage
30 to less than 60 kg	400 mg (two 200 mg injections)	200 mg every two weeks
60 kg or more	600 mg (two 300 mg injections)	300 mg every two weeks

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes have been provided with documentation of positive clinical response such as reduction in itch severity and/or hive count.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Dupixent (dupilumab) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

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.
11/16/2021	Transferred to new template. For asthma, amended minimum age from 12 years to 6 years per recent label update and added dosing information for the new age group.
06/14/2022	Updated min age for atopic dermatitis from 6 years to 6 months and added dosing. Added new indication for diagnosis of EOE.
10/19/2022	Added new indication for prurigo nodularis.
11/13/2023	Added/removed/updated references. Asthma: Updated dosing chart for pediatric patients 6 to 11 years of age, increased initial authorization length to 6 months, simplified reauthorization criteria to allow for improvement in signs and symptoms with specific examples. AD: changed trials to two topicals, one topical and phototherapy or one immunomodulator and one topical; changed duration of steroid topicals to 2 weeks, added duration of 6 weeks for TCI, 4 weeks for Eucrisa; added option of Opzelura for 8 weeks duration; changed steroid requirement from high to very high. CRSwNP: removed contraindication of AFRS and nasal polyp surgery in the past 6 months
01/30/2024	Updated references. EoE: Lowered age limit to 1 year of age and greater than 15 kg; added submission of weight for dosing; updated dosing.
07/19/2024	Nasal polyps: updated references; removed requirement for surgery.
10/25/2024	AD: Updated trial and failure criteria to single step topical corticosteroid or calcilneurin inhibitor Asthma: Updated diagnosis to "moderate-to-severe." Updated requirement for ICS + LABA to ICS + another asthma controller medication (i.e., LABA, LAMA, etc)
11/05/2024	CRSwNP: Lowered age limit from 18 to 12 years (label update). Added section for new COPD indication.
05/02/2025	Updated references; added CSU diagnosis criteria.

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