Dupilumab (Dupixent®)	Place of Service Office Administration Infusion Center Administration Home Infusion Self-Administration *(May be requested from the pharmacy benefit)* HCPCS: J3590 NDCs: Pre-filled syringe with needle shield: • 300 mg (NDC 0024-5914-00) • 200 mg (NDC 0024-5918-00) • 100 mg (NDC 0024-5911-00) Pre-filled pen: • 300 mg (NDC 0024-5915-00) • 200 mg (NDC 0024-5919-00) Pre-filled syringes with needle shield, Pack of 2: • 300 mg: NDC 0024-5914-01 • 200 mg: NDC 0024-5918-01 • 100 mg: NDC 0024-5911-02 Pre-filled Pen: Pack of 2 300 mg: NDC 0024-5915-02 200 mg: NDC 0024-5919-02

Condition listed in policy *(see criteria for details)*

- Atopic dermatitis - moderate to severe
- Chronic rhinosinusitis with nasal polyps (CRSwNP)
- Eosinophilic asthma - moderate to severe
- Eosinophilic esophagitis
- Oral corticosteroid-dependent asthma
- Prurigo nodularis (PN)

AHFS therapeutic class: Skin and mucous membrane agent

Mechanism of action: Interleukin-4 receptor alpha antagonist

(1) Special Instructions and Pertinent Information

This drug is managed under the outpatient Pharmacy Benefit for self-administration. Please contact the member's Pharmacy Benefit for information on how to obtain this drug.

To submit a request to the Medical Benefit, please submit clinical information for prior authorization review and include medical rationale why the patient cannot self-administer this drug in the home.

For plans with self-injectables only covered under the Medical Benefit, please submit clinical information for prior authorization review.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Dupixent® (dupilumab) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Atopic dermatitis, moderate to severe

1. Prescribed by or in consultation with a dermatologist, allergist, or immunologist, **AND**
2. Patient is at least 6 months old, **AND**
3. Diagnosis of moderate to severe atopic dermatitis with at least one of the following:
    a. Investigator's Global Assessment (IGA) score of 3-4, or
    b. Eczema Area and Severity Index (EASI) score of at least 16, or
    c. Body surface area of at least 10%, or
    d. Severity Scoring of Atopic Dermatitis Index (SCORAD) score of at least 25

    AND
4. Inadequate response or intolerable side effect to two of the following, or contraindication to all of the following:
    a. Medium, high, or very high potency topical corticosteroid, or
    b. Topical calcineurin inhibitor (e.g., tacrolimus, pimecrolimus), or
    c. Systemic immunomodulating agents (e.g., methotrexate, azathioprine, mycophenolate, cyclosporine) or
    d. Phototherapy

    AND
5. Not used in combination with JAK inhibitors, biologic immunomodulators, or other immunosuppressants (e.g., Opzelura)

*Inadequate response defined as failure to achieve and maintain remission or a low disease activity state (IGA score of 0 to 2) despite treatment with topical agent applied for at least one month or for the maximum duration recommended by the product prescribing information (e.g., 14 days for super-potent topical corticosteroids), whichever is shorter.

Covered Dose

Adults (18 years old and above)

Up to 600 mg given SC as a one-time loading dose, followed by 300 mg given SC every 2 weeks

Pediatric (6-17 years of age): Weight-based

Body Weight	Initial Loading Dose	Subsequent Doses
15 to less than 30 kg	600 mg (two 300 mg SC injections)	300 mg SC every 4 weeks
30 to less than 60 kg	400 mg (two 200 mg SC injections)	200 mg SC every 2 weeks
60 kg or more	600 mg (two 300 mg SC injections)	300 mg SC every 2 weeks

Coverage Period

Initial coverage period: 16 weeks

Subsequent reauthorization: Indefinite if all the below are met

1. Provider attestation of clinical response, **AND**

2. Not used in combination with JAK inhibitors, biologic immunomodulators, or other immunosuppressants (e.g., Opzelura)

ICD-10:
L20.0, L20.81- L20.84, L20.89, L20.9

Chronic rhinosinusitis with nasal polyps (CRSwNP)

1. Prescribed or recommended by an allergist, immunologist, or otolaryngologist, **AND**
2. Provider attestation that patient has nasal polyps, **AND**
3. Patient is ≥ 18 years of age, **AND**
4. Inadequate response, intolerable side effect, or contraindication to an intranasal glucocorticoid

Covered Dose
Up to 300 mg SC every other week

Coverage Period
Indefinite

ICD-10:
J32.9

Eosinophilic asthma, moderate to severe

1. Prescribed by or in consultation with a pulmonologist, allergist, or immunologist, **AND**
2. Patient is ≥ 6 years of age, **AND**
3. Eosinophil blood count of ≥ 150 cells/µL within last 6 weeks or ≥ 300 cells/µL within the last 12 months, **AND**
4. Asthma symptoms remain uncontrolled despite 3 months of treatment with a high-dose inhaled corticosteroid to a high-dose inhaled corticosteroid in combination with long-acting beta agonist (LABA) or leukotriene receptor antagonists (LTRA), **AND**
5. Will not be used in combination with another monoclonal antibody for asthma (e.g., Cinqair, Fasenra, Nucala and Xolair), **AND**
6. Meets one of the following within the past year:
    a. One or more acute asthma attacks requiring emergency care (hospital emergency dept visit), or
    b. One or more acute inpatient visits where asthma was the principal diagnosis, or
    c. Use of chronic systemic steroids due to severe asthma OR two or more acute asthma exacerbations requiring oral systemic steroids

Covered Doses

Dosage in Adults and Adolescents (12 Years and Older)

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

600 mg (two 300 mg SC injections)	300 mg SC every 2 weeks

Dosage in Pediatric Patients (6 to 11 Years of Age)

Body Weight	Initial Dose and Subsequent Doses
15 to less than 30 kg	100 mg SC every other week or 300 mg every four weeks
≥ 30 kg	200 mg SC every other week

For pediatric patients (6 to 11 years old) with asthma and co-morbid moderate-to-severe atopic dermatitis, follow the recommended dosage in the previous table which includes an initial loading dose.

Coverage Period
Initial: 6 months
Reauthorization: Indefinite if the following criteria is met:
1. Patient is not receiving this medication in combination with another biologic medication indicated for asthma treatment, **AND**
2. Provider attestation that asthma symptoms have improved and/or controlled while on Dupixent

ICD-10:
J45.20-J45.998

Eosinophilic esophagitis
1. Prescribed by or in consultation with an allergist, immunologist, or gastroenterologist, **AND**
2. Age ≥ 12 years of age, **AND**
3. One of the following:
    a. Inadequate response or intolerable side effect with a proton pump inhibitor (PPI), or contraindication to all PPIs, OR
    b. Inadequate response or intolerable side effect with a guideline-supported glucocorticoid (e.g., inhaled fluticasone, inhaled budesonide), or contraindication to all glucocorticoids

Covered dose
300 mg SC every week

Coverage period
Initial: 6 months
Reauthorization: Indefinite if provider attest that eosinophilic esophagitis symptoms have improved while on Dupixent (e.g., histologic remission, dysphagia symptoms)

ICD-10:
K20.0

Oral corticosteroid-dependent asthma
1. Prescribed by or in consultation with a pulmonologist or immunologist, **AND**
2. Age ≥ 6 years of age, **AND**
3. Asthma symptoms remain uncontrolled despite 3 months of treatment with a high-dose inhaled corticosteroid to a high-dose inhaled corticosteroid in combination with long-acting beta agonist (LABA) or leukotriene receptor antagonists (LTRA), **AND**
4. Currently on maximally tolerated oral corticosteroid, **AND**

5. Will not be used in combination with another biologic medication indicated for asthma treatment (e.g., Cinqair, Fasenra, Nucala and Xolair), **AND**
6. Meets one of the following within the past year:
    a. One or more acute asthma-related ED visit(s), or
    b. One or more acute inpatient visits where asthma was the principal diagnosis, or
    c. Two or more acute asthma exacerbations requiring dose increases in oral systemic steroids

Covered dose

Dosage in Adults and Adolescents (12 Years and Older)

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

Dosage in Pediatric Patients (6 to 11 Years of Age)

Body Weight	**Initial Dose and Subsequent Doses**
15 to less than 30 kg	100 mg SC every other week or 300 mg every four weeks
≥ 30 kg	200 mg SC every other week

For pediatric patients (6 to 11 years old) with asthma and co-morbid moderate-to-severe atopic dermatitis, follow the recommended dosage in the previous table which includes an initial loading dose.

Coverage period

Initial: 6 months

Reauthorization: Indefinite if the following criteria is met:

1. Patient is not receiving this medication in combination with another biologic medication indicated for asthma treatment, **AND**
2. Provider attestation that asthma symptoms have improved and/or controlled while on Dupixent

ICD-10:

J45.20-J45.998

Prurigo nodularis (PN)

1. Prescribed by or in consultation with a dermatologist, AND
2. Age ≥ 18 years of age, AND
3. Inadequate response or intolerable side effects to two of the following, or contraindication to all of the following:
    a. Medium, high, or very high potency topical or intralesional corticosteroids, or
    b. Non-steroidal topical therapies [e.g., tacrolimus (Protopic), pimecrolimus (Elidel), capsaicin], or
    c. Phototherapy, or
    d. Systemic immunomodulating agents (e.g., methotrexate, cyclosporine, azathioprine, cyclophosphamide, thalidomide)

Covered dose
Up to 600 mg SC for the initial dose, followed by 300 mg every other week

Coverage Period
Initial: 6 months
Reauthorization: Indefinite if meets criteria below
1. Provider attestation that prurigo nodularis symptoms have improved while on Dupixent (e.g., itch, lesions)

ICD-10:
L28.1

(3) The following condition(s) DO NOT require Prior Authorization/Preservice
All requests for Dupixent® (dupilumab) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)
Blue Shield's research indicates there is inadequate clinical evidence to support off-label use of this drug for the following conditions (Health and Safety Code 1367.21)

- Combination use with another biologic medication for asthma (e.g., Cinqair, Fasenra, Nucala, and Xolair)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information
How Supplied:
- Single-Dose Pre-Filled Syringe with Needle Shield
    - Injection: 300 mg/2 mL
    - Injection: 200 mg/1.14 mL
    - Injection: 100 mg/0.67 mL
- Single-Dose Pre-Filled Pen
    - Injection: 300 mg/2 mL
    - Injection: 200 mg/1.14 mL

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Dupixent® (dupilumab) [Prescribing information]. Tarrytown, NY: Regeneron. 12/2021.
- Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention, 2021. Available at: www.ginasthma.org.
- Peters AT, Spector S, Hsu J, et al. Diagnosis and management of rhinosinusitis: a practice parameter update. Ann Allergy Asthma Immunol. 2014;113(4):347-85.
- Rosenfeld RM, Piccirillo JF, Chandrasekhar SS, et al. Clinical Practice Guideline (Update): Adult Sinusitis. Otolaryngol Head Neck Surg 2015;152(1 Suppl):S1-S39.
- Sidbury R, Davis DM, Cohen DE, Cordoro KM, Berger TG, Bergman JN, 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;71(2):327-49.

(7) Policy Update

Date of last review: 4Q2022

Date of next review: 2Q2023

Changes from previous policy version:

- New indication in Section (2): Added coverage for Prurigo nodularis (PN)

  Rationale: In October 2022, FDA approved Dupixent for treatment of adult patients with prurigo nodularis.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee