Dupilumab (Dupixent®)	**Place of Service** **Office Administration** **Infusion Center Administration** **Home Infusion** **Self-Administration** **HCPCS**: **J3590** **NDCs:** • 0024-5914-01: 300 mg/2 mL single-dose prefilled syringe with needle shield • 0024-5918-00: 200 mg/1.14 mL single-dose prefilled syringe with needle shield

Condition listed in policy *(see criteria for details)*
- Atopic dermatitis, moderate to severe
- Eosinophilic asthma, moderate to severe
- Oral corticosteroid-dependent asthma

AHFS therapeutic class: Skin and mucous membrane agent

Mechanism of action: Interleukin-4 receptor alpha antagonist

(1) Special Instructions and Pertinent Information

If member has a Prescription Benefit, please refer cases to Pharmacy Services for prior authorization**.**

If covered under the Medical Benefit, please submit clinical information for prior authorization review via fax. **Please include medical rationale why medication cannot be home self-administered.**

(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
- Prescribed by dermatologist, allergist, or immunologist, **AND**
- Patient is ≥12 years of age, **AND**
- One of the following:
  - Inadequate response to a medium, high, or very high potency topical corticosteroid [see section (5)], OR if unable to use topical corticosteroids only, require an inadequate response, intolerable side-effect, or contraindication to use of topical tacrolimus
    OR
  - Inadequate* response intolerable side-effect, or contraindication to a medium, high, or very high potency topical corticosteroid, AND Inadequate* response, intolerable side-effect, or contraindication to use of topical calcineurin

  AND
- Inadequate response/intolerance/contraindication to one of the following: phototherapy, methotrexate, azathioprine, intermittent/pulse therapy with oral steroids, mycophenolate mofetil, or cyclosporine
  AND

- Diagnosis of moderate to severe atopic dermatitis with at least one of the following:
    a) Investigator's Global Assessment (IGA) score of 3-4,
    b) Eczema Area and Severity Index (EASI) score of at least 16
    c) Body surface area of at least 10%
    d) Severity Scoring of Atopic Dermatitis Index (SCORAD) score of at least 25

*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 subcutaneously as a one-time loading dose, followed by 300 mg given subcutaneously every 2 weeks

Adolescents (12-17 years old): Weight-based

<60kg	400 mg subcutaneously as a one-time loading dose, followed by 200 mg subcutaneously every other week
≥60kg	600 mg subcutaneously as a one-time loading dose, followed by 300 mg subcutaneously every other week

Coverage Period

Initial coverage period: 16 weeks

Subsequent reauthorization period:

- First reauthorization after the initial 16 weeks:
    - If there is response to therapy: Approve indefinitely
    - If there is no response to therapy: Approve for an additional 36 weeks

- Second reauthorization after 52 weeks *(when first reauthorization was only approved for an addition 36 weeks)*:
    - If there is response to therapy: Approve indefinitely
    - If there is no response after 52 weeks of therapy: Dupixent is not covered

ICD-10:

L20.0, L20.81- L20.84, L20.89, L20.9

Eosinophilic asthma, moderate to severe

- Prescribed by a pulmonologist or immunologist, **AND**
- Patient is at least 12 years of age, **AND**
- Eosinophil blood count of ≥ 150 cells/µL within last 6 weeks or ≥ 300 cells/µL within the last 12 months, **AND**
- Patient had inadequate response to a high-dose inhaled corticosteroid in combination with long-acting beta agonist [LABA] **and** has been compliant with therapy for the last 3 months, **AND**
- Will not be used in combination with another monoclonal antibody for asthma (e.g., Cinqair, Fasenra, Nucala and Xolair), **AND**
- Patient is not a current smoker, **AND**
- Meets ONE of the following within the past year:
    - One or more acute asthma attacks requiring emergency care (Hospital Emergency Dept visit), OR
    - One or more acute inpatient visits where asthma was the principal diagnosis, OR
    - Use of chronic systemic steroids due to severe asthma OR two or more acute asthma exacerbations requiring oral systemic steroids

Covered Dose

Up to 400 mg subcutaneously initially (administered as two 200 mg injections), followed by 200 mg subcutaneously every other week,

OR

Up to 600 mg subcutaneously initially (administered as two 300 mg injections), followed by 300 mg subcutaneously every other week

Coverage Period

Initial Authorization: 6 months

Re-Authorization:

- **First re-authorization**: 1 year, if all of the following are met:
    1. Prescribed by a pulmonologist or immunologist, **AND**
    2. Patient is continually compliant on an inhaled corticosteroid (ICS) and a second
    3. controller asthma medication, **AND**
    4. Response to treatment with Dupixent, as evidenced by at least one of the following:
        a. Reduction in asthma symptoms (e.g., decreased number of sick days, improvement in physical activity, reduction in PRN use of short acting beta agonists), or
        b. Reduction in dose and frequency of inhaled steroids compared to baseline, or
        c. Reduction in acute asthma exacerbations requiring oral systemic steroids

- **Subsequent re-authorization**: Yearly, if all of the following are met:
    1. Prescribed by a pulmonologist or immunologist, **AND**
    2. Patient is continually compliant on an inhaled corticosteroid (ICS) and a second controller asthma medication, **AND**
    3. Continued response to treatment with Dupixent, as evidenced by at least one of the following:
        a. Stable or reduced asthma symptoms (e.g., no increase in number of sick days, decrease in physical activity, increase in PRN use of SABA) or
        b. Stable or reduced (but not discontinued) dose and frequency of inhaled steroids compared to baseline or
        c. Stable or reduced acute asthma exacerbations requiring oral systemic steroids.

ICD-10: J45.20-J45.998

Oral corticosteroid-dependent asthma

- Prescribed by a pulmonologist or immunologist, **AND**
- Age ≥ 12 years of age, **AND**
- Patient had inadequate response to a high-dose inhaled corticosteroid in combination with long-acting beta agonist [LABA] and has been compliant with therapy for the last least 3 months, **AND**
- Currently on maximally tolerated oral corticosteroid, **AND**
- Patient is not a current smoker, **AND**
- Will not be used in combination with another monoclonal antibody for asthma (e.g., Cinqair, Fasenra, Nucala and Xolair), **AND**
- Meets one of the following within the past year:
    - One or more acute asthma-related ED visit(s)
    - One or more acute inpatient visits where asthma was the principal diagnosis
    - Two or more acute asthma exacerbations requiring dose increases in oral systemic steroids

Covered dose:
Up to 600 mg given subcutaneously initially (administered as two 300 mg injections), followed by 300 mg given subcutaneously every other week

Coverage period:
Initial: 6 months

First reauthorization: One year, if all of the following are met:
1. Prescribed by a pulmonologist or immunologist, **AND**
2. Patient is continually complaint on an inhaled corticosteroid (ICS) and a second controller asthma medication, **AND**
3. Response to treatment with Dupixent, as evidenced by at least one of the following:
    a. Reduction in asthma symptoms (e.g., decreased number of sick days, improvement in physical activity, reduction in PRN use of short acting beta agonists), or
    b. Reduction in dose and frequency of inhaled steroids compared to baseline, or
    c. Reduction in acute asthma exacerbations requiring oral systemic steroids

Subsequent reauthorization: Yearly, if all of the following are met:
1. Prescribed by a pulmonologist or immunologist, **AND**
2. Patient is continually complaint on an inhaled corticosteroid (ICS) and a second controller asthma medication, **AND**
3. Response to treatment with Dupixent, as evidenced by at least one of the following:
    a. Stable or reduced in asthma symptoms (e.g., decreased number of sick days, improvement in physical activity, reduction in PRN use of short acting beta agonists), or
    b. Stable or reduced in dose and frequency of inhaled steroids compared to baseline, or
    c. Stable or reduced in acute asthma exacerbations requiring oral systemic steroids

ICD-10: J45.20-J45.998

(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 monoclonal antibody 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:

- 200 mg/1.14 mL (single-dose prefilled syringe with needle shield)
- 300 mg/2 mL (single-dose prefilled syringe with needle shield)

Topical corticosteroid potency

Low Potency	• alclometasone 0.05% cream, ointment (Aclovate) • betamethasone valerate 0.1% lotion (Valisone) • fluocinolone 0.01% oil (Derma-Smoothe-FS) • fluocinolone acetonide 0.01% solution (Synalar) • hydrocortisone 1%/iodoquinol (Vytone) • hydrocortisone 2.5% cream, ointment, lotion (Hytone) • triamcinolone acetonide 0.025% cream, lotion, ointment (Kenalog) • hydrocortisone 2% lotion (Ala-Scalp) • desonide 0.05% cream, lotion, ointment (Desowen) • hydrocortisone 2% lotion (Scalacort) • desonide 0.05% foam (Verdeso)
Medium Potency	• betamethasone dipropionate 0.05% lotion (Maxivate, Diprosone) • betamethasone valerate 0.1% cream (Betatrex, Valisone) • desoximetasone 0.05% cream (Topicort LP) • hydrocortisone valerate 0.2% cream, ointment (Westcort) • mometasone furoate 0.1% cream, ointment, lotion (Elocon) • prednicarbate 0.1% cream, ointment (Dermatop) • triamcinolone acetonide 0.1% cream, ointment, lotion (Kenalog) • fluocinolone acetonide 0.01% shampoo (Capex) • clocortolone pivalate 0.1% cream (Cloderm) • flurandrenolide tape (Cordran) • flurandrenolide 0.05% ointment (Cordran) • fluticasone 0.05% lotion (Cutivate) • triamcinolone 0.147 mg/gm (Kenalog Spray) • hydrocortisone butyrate 0.1% cream (Locoid) • hydrocortisone butyrate 0.1% cream (Locoid Lipocream) • betamethasone valerate 0.12% foam (Luxiq) • fluocinolone 0.01% solution (Synalar) • triamcinolone acetonide 0.05% ointment (Trianex)

High Potency	• augmented betamethasone dipropionate 0.05% cream (Diprolene AF) • betamethasone dipropionate 0.05% cream, ointment (Maxivate, Diprosone) • betamethasone valerate 0.1% ointment (Betatrex, Valisone) • fluocinonide 0.05% cream (Lidex E) • fluocinonide 0.05% cream, gel, ointment, solution (Lidex) • triamcinolone acetonide 0.5% cream (Kenalog) • triamcinolone acetonide 0.5% ointment (Aristocort HP) • amcinonide 0.1% cream, lotion, ointment (Cyclocort) • diflorasone 0.05% cream (Psorcon) • desoximetasone 0.25% cream, 0.25% ointment, 0.25% spray, 0.05% cream, 0.05% gel, 0.05% ointment (Topicort)
Very High Potency	• augmented betamethasone dipropionate 0.05% gel, ointment, lotion (Diprolene) • clobetasol 0.05% cream, ointment, solution, gel, cream emollient (Temovate) • clobetasol 0.05% foam, emollient foam (Olux, Olux-E) • halobetasol 0.05% cream, ointment (Ultravate) • clobetasol 0.05% lotion, shampoo (Clobex) • clobetasol 0.05% shampoo (Clodan) • diflorasone acetate/emollient 0.05% cream (ApexiCon E) • diflorasone 0.05% ointment (Psorcon) • fluocinonide 0.1% cream (Vanos)

(6) References

- Dupixent® prescribing information. Sanofi-Aventis U.S. LLC (Bridgewater, NJ) and Regeneron Pharmaceuticals, Inc. (Tarrytown, NY). 2019.
- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch

1. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention, 2018. Available at: www.ginasthma.org. Accessed 11/5/2018.
2. 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 revision: 2Q2019
Date of next review: 2Q2020
Changes from previous policy version:

- Section (2): Atopic dermatitis –
  - Expanded age requirement to include 12 years of age or older for the treatment of moderate-to-severe atopic dermatitis. Previously allowed for 18 years of age and older.
    Rationale: Coverage based on expanded FDA-approved indication
  - Expanded atopic dermatitis diagnosis to include Severity Scoring of Atopic Dermatitis Index (SCORAD) score
    Rationale: Coverage based on assessment use in clinical trials and advisor opinion support as standard of practice