Clinical Guideline

Oscar Clinical Guideline: Dupixent (dupilumab) (PG026, Ver. 14)

Dupixent (dupilumab)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Dupixent (dupilumab), a monoclonal antibody that inhibits interleukin-4 (IL-4) and interleukin-13 (IL-13) signaling, is FDA-approved for the following conditions:

1. Atopic Dermatitis, *indicated for the treatment of adult and pediatric patients aged 6 months and older with moderate-to-severe atopic dermatitis (AD) whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.*
2. Asthma, *indicated as an add-on maintenance treatment of adult and pediatric patients aged 6 years and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma.*
3. Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP), *indicated as an add-on maintenance treatment in adult and pediatric patients aged 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP).*
4. Eosinophilic Esophagitis, *indicated for the treatment of adult and pediatric patients aged 1 year and older, weighing at least 15 kg, with eosinophilic esophagitis (EoE).*
5. Prurigo Nodularis, *indicated for the treatment of adult patients with prurigo nodularis (PN).*
6. Chronic Obstructive Pulmonary Disease, *indicated as an add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype.*
7. Chronic Spontaneous Urticaria, *indicated for the treatment of adult and pediatric patients aged 12 years and older with chronic spontaneous urticaria (CSU) who remain symptomatic despite H1 antihistamine treatment.*

Definitions

"Asthma" is defined by the The National Asthma Education and Prevention Program (NAEPP) guidelines as "a chronic inflammatory disease of the airways in which many cells and cellular elements play a role: in particular mast cells, neutrophils, eosinophils, T lymphocytes, macrophages, and epithelial cells. In susceptible individuals, this inflammation causes recurrent episodes of coughing (particularly at night or early in the morning), wheezing, breathlessness, and chest tightness. The episodes are usually associated with widespread but variable airflow obstruction that is reversible either spontaneously or as a result of treatment." Depending on symptoms and pulmonary function testing, asthma can be further classified into different severity such as mild intermittent, mild persistent, moderate persistent, and severe persistent.

"Chronic rhinosinusitis with nasal polyposis (CRSwNP)" is chronic inflammation of the nose and paranasal sinuses with the presence of bilateral nasal polyps, often inadequately controlled with intranasal corticosteroids.

"COPD" refers to chronic obstructive pulmonary disease, a lung disease characterized by chronic obstruction of lung airflow that interferes with normal breathing

"COPD exacerbation" is defined as an acute worsening of respiratory symptoms that results in additional therapy.

"Chronic Spontaneous Urticaria (CSU)" or "Chronic Idiopathic Urticaria" are used interchangeably. CSU is not triggered by identifiable factors, and specifically excludes physical urticaria or other inducible forms of urticaria. CSU is defined by the presence of recurrent urticaria (hives or wheals), angioedema, or both, for a period of 6 weeks or longer. If the standard therapeutic dose of a non-sedating second-generation H1 antihistamine does not relieve symptoms, guidelines recommend up-dosing to four times the standard dose.

"Dysphagia" is trouble swallowing.

"Eczema" is a condition that can cause skin on different parts of the body to be itchy, inflamed and rough. It is also commonly referred to as "atopic dermatitis."

"Eosinophilic Asthma" refers to asthma characterized by elevated levels of eosinophils, measured in the blood (≥150 cells/mcL), sputum, or lung tissue.

"Eosinophilic Esophagitis" is a chronic immune-mediated disease characterized by eosinophilic infiltration of the esophagus (≥15 eosinophils per high-power field) and symptoms like dysphagia.

"Exacerbations" is trouble breathing. In asthma, this is sometimes called an asthma attack or acute bronchospasm. This is usually because the air passages have become tighter and narrower than normal, causing coughing, shortness of breath, and wheezing.

"FEV1" is forced expiratory volume in 1 second, a measure of lung function

"ICS" is inhaled corticosteroid, an anti-inflammatory medication

"LABA" is long-acting beta2-agonist, a bronchodilator medication

"LAMA" is long-acting muscarinic antagonist, an anticholinergic bronchodilator medication

"Nasal polyps" are growths that form in the nose or the sinuses. They can be large or small, are usually found in both sides of the nose, and can make it hard to breathe through the nose.

"Oral Corticosteroid Dependent Asthma" is asthma that requires daily or near-daily systemic corticosteroids to maintain control.

"Phenotype" is a recognizable pathophysiologic characteristic. Asthma has phenotypes such as allergic asthma or eosinophilic asthma.

"Prurigo Nodularis" refers to a skin disease characterized by intensely pruritic, hyperkeratotic papules and nodules.

"Worst-Itch Numeric Rating Scale (WI-NRS)" is a useful, quick, and validated tool to reliably measure itch severity, rated on a scale from 0 ("no itch") to 10 ("worst imaginable itch").

Clinical Indications

Medical Necessity Criteria for Initial Clinical Review

General Medical Necessity Criteria

The Plan considers Dupixent (dupilumab) medically necessary when ALL of the following criteria are met:

1. Prescribed by or in consultation with a specialist experienced in the diagnosis and treatment of the relevant condition:
    a. Moderate-to-severe atopic dermatitis - dermatologist or allergist/immunologist*; or*
    b. Moderate-to-severe asthma - allergist/immunologist or pulmonologist*; or*
    c. Chronic rhinosinusitis with nasal polyps (CRSwNP) - allergist/immunologist or ENT specialist*; or*
    d. Chronic obstructive pulmonary disease (COPD) - allergist/immunologist or pulmonologist*; or*
    e. Chronic spontaneous urticaria - allergist/immunologist or dermatologist*; or*
    f. Eosinophilic esophagitis (EoE) - gastroenterologist or allergist/immunologist*; or*
    g. Immune Checkpoint Inhibitor-Related Toxicities - dermatologist, hematologist or oncologist*; or*
    h. Prurigo nodularis (PN) - dermatologist or allergist/immunologist*; AND*
2. Prescribed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in a compendia of current literature*; AND*

3. Clinical documentation is provided showing the member meets ALL of the following indication-specific criteria:

Initial Indication-Specific Criteria

Atopic dermatitis, moderate to severe

4. The member is 6 months of age or older*; AND*
5. The member has a diagnosis of moderate-to-severe atopic dermatitis*; AND*
6. The member's affected body surface area (BSA) before treatment meets ONE of the following:
    a. is equal to or greater than 10%*; or*
    b. is less than 10% but sensitive body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected*; AND*
7. The member is unable to use, or has adequately tried and failed ONE of the following topical therapies for at least 8 weeks each in the past 365 days:
    a. A topical corticosteroid (TCS) from medium potency (group III to IV) classes to higher potencies (groups I to II) classes (see Appendix A, Table 4)*; and/or*
    b. Tacrolimus ointment*; and/or*
    c. Eucrisa (crisaborole) [PA may be required, please check the member's Plan-specific Formulary]*; AND*
8. Dupixent (dupilumab) will not be used concomitantly with other biologics (e.g., Adbry, Cibinqo, or Rinvoq) in the treatment of atopic dermatitis.

If the above prior authorization criteria are met, Dupixent (dupilumab) will be approved for 4-months.

Asthma, moderate to severe:

- with an eosinophilic phenotype*; or*
- oral corticosteroid (OCS)-dependent (regardless of phenotype)

4. The member is 6 years of age or older; *AND*
5. The member has a diagnosis of moderate-to-severe asthma; *AND*
6. The member meets ONE of the following criteria:
    a. The member has experienced two or more (≥2) exacerbations (e.g., requiring urgent, unscheduled care, hospitalization, or ICU admission) within the last 12 months AND the member is unable to use or has tried and failed ALL of the following at optimized[#] doses:
        i. high-dose inhaled corticosteroids (ICS)*; and*
        ii. adjunctive therapy (in combination with inhaled corticosteroid), such as ONE of the following:
            1. Long-Acting Beta-2 Agonists (LABA), such as formoterol or salmeterol*; or*
            2. Leukotriene Receptor Antagonist (LTRA), such as montelukast (Singulair) or zafirlukast (Accolate)*; or*
            3. extended-release theophylline*; and*

iii. oral/systemic corticosteroids (at least 5 mg per day of prednisone/prednisolone or equivalent)*; or*

[#]*member should be receiving treatment with inhaled corticosteroid and additional controller (adjunctive therapy) for at least the previous 3 months, and oral/systemic corticosteroids for most days during the previous 6 months [e.g. 50% of days, 3 steroid bursts in the previous 6 months]*

b. The member has documented evidence of BOTH of the following:
   i. baseline blood eosinophil count of at least 150 cells per microliter*; and*
   ii. inadequate asthma control (e.g., requiring urgent, unscheduled care, hospitalization, or ICU admission) within the last 12 months AND the member is unable to use or has tried and failed BOTH of the following at optimized doses for at least three (3) months:
      1. high-dose inhaled corticosteroids (ICS)*; and*
      2. adjunctive therapy (in combination with inhaled corticosteroid), such as ONE of the following:
         a. Long-Acting Beta-2 Agonists (LABA), such as formoterol or salmeterol*; or*
         b. Leukotriene Receptor Antagonist (LTRA), such as montelukast (Singulair) or zafirlukast (Accolate)*; or*
         c. extended-release theophylline*; AND*

7. Documentation indicates BOTH of the following:
   a. Dupixent (dupilumab) will not be used as monotherapy; *and*
   b. Dupixent (dupilumab) will not be used concomitantly with other biologics (e.g., Cinqair, Fasenra, Nucala or Xolair) in the treatment of asthma.

<u>If the above prior authorization criteria are met, Dupixent (dupilumab) will be approved for 6-months.</u>

<u>Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)</u>

4. The member is 12 years of age or older*; AND*
5. The member has a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP)*; AND*
6. Documentation of bilateral nasal endoscopy or anterior rhinoscopy showing polyps reaching below the lower border of the middle turbinate or beyond in each nostril*; AND*
7. The member has nasal obstruction AND ONE of the following additional symptoms:
   a. Rhinorrhea (anterior/posterior); *or*
   b. Reduction or loss of smell*; AND*
8. The member has CRSwNP despite ONE of the following:
   a. Prior sino-nasal surgery; *or*
   b. Tried and failed treatment with systemic corticosteroids within the last two years, unless the member is unable to use systemic corticosteroids*; AND*
9. The member has bilateral nasal polyposis and chronic symptoms of sinusitis AND the member is unable to use or has tried and failed intranasal corticosteroid treatment for at least two (2) months*; AND*
10. Dupixent (dupilumab) will be used together with a daily intranasal corticosteroid as part of the member's treatment plan, unless the member is unable to use intranasal corticosteroid.

If the above prior authorization criteria are met, Dupixent (dupilumab) will be approved for 6-months.

Chronic Obstructive Pulmonary Disease (COPD), refractory (prevention of exacerbation)

4. The member is 18 years of age or older; *AND*
5. The member has a diagnosis of chronic obstructive pulmonary disease (COPD)*; AND*
6. Inadequate control of COPD as evidenced by ONE of the following:
    a. History of ≥2 moderate exacerbations in the past 12 months despite adherence to a 3-month trial of triple therapy with ALL of the following:
        i. Long-acting beta-2 agonist (LABA)*; and*
        ii. Long-acting muscarinic antagonist (LAMA)*; and*
        iii. Inhaled corticosteroid (ICS)*; or*
    b. History of ≥1 severe exacerbation in the past 12 months requiring hospitalization or observation for over 24 hours in an emergency department or urgent care facility despite adherence to a 3-month trial of triple therapy as described above*; or*
    c. Inadequate response to a 3-month trial of LABA + LAMA combination therapy if ICS is contraindicated*; AND*
7. Eosinophilic phenotype, as evidenced by baseline blood eosinophil count ≥300 cells/mcL*; AND*
8. Will be used in combination with continued maintenance therapy.

If the above prior authorization criteria are met, Dupixent (dupilumab) will be approved for 12-months.

Chronic Spontaneous Urticaria (CSU)

4. The member is 12 years of age or older*; AND*
5. The member has a diagnosis of chronic spontaneous urticaria (CSU)*; AND*
6. The member remains symptomatic despite maximal up-dosing (4 times the standard therapeutic dose) of a second-generation H1 antihistamine (e.g., cetirizine, levocetirizine, desloratadine) for at least 2 weeks (see Appendix A, Table 5)*; AND*
7. The member has experienced a spontaneous onset of wheals (hives), angioedema, or both, for at least 6 weeks*; AND*
8. The member has been evaluated for other causes of urticaria, including bradykinin-related angioedema and interleukin-1-associated urticarial syndromes (auto-inflammatory disorders, urticarial vasculitis).

If the above prior authorization criteria are met, Dupixent (dupilumab) will be approved for 6-months.

Eosinophilic Esophagitis

4. The member is 1 year of age or older*; AND*
5. The member weighs at least 15 kg (33 lbs)*; AND*
6. Clinical chart documentation is provided showing ALL of the following:

a. The member has a documented diagnosis of eosinophilic esophagitis (EoE)*; and*
b. The member has eosinophil-predominant inflammation on esophageal biopsy, showing 15 or more eosinophils per high-power field (or approximately 60 eosinophils per mm^2)*; and*
c. Secondary (other) causes or contributors of esophageal eosinophilia has been excluded*; and*
d. The member has symptoms related to esophageal dysfunction (e.g, abdominal pain, chest pain, food impaction, heartburn, solid food dysphagia, weight loss, vomiting, food refusal, failure to thrive)*; and*
e. ONE of the following based on member age:
    i. For members 1 to 11 years of age - documented history of EoE signs and symptoms; or
    ii. For members 12 years of age and older - documented history of at least 2 episodes of dysphagia per week on average*; AND*

7. The member is unable to use, or has tried and failed BOTH of the following for at least two (2) months:
    a. proton pump inhibitor therapy, such as omeprazole or esomeprazole*; and*
    b. swallowed inhaled respiratory corticosteroid therapy, such as fluticasone or budesonide suspension.

<u>If the above prior authorization criteria are met, Dupixent (dupilumab) will be approved for 6-months.</u>

<u>Immune Checkpoint Inhibitor-Related Toxicities</u>

4. The member is receiving an immune checkpoint inhibitor [e.g., CTLA-4 inhibitor (ipilimumab), PD-1 inhibitor (pembrolizumab, nivolumab, cemiplimab), or PD-L1 inhibitor (atezolizumab, avelumab, durvalumab)*; AND*
5. The member has documentation of ONE of the following:
    a. Severe (Grade 3) pruritus refractory to ≥1 month trial of gabapentinoids (e.g., gabapentin, pregabalin)*; or*
    b. Moderate (Grade 2) or severe (Grade 3) bullous dermatitis inadequately controlled with topical/systemic corticosteroids (e.g., prednisone, IV methylprednisolone).

<u>If the above prior authorization criteria are met, Dupixent (dupilumab) will be approved for 6-months.</u>

<u>Prurigo Nodularis (PN)</u>

4. The member is 18 years of age or older; *AND*
5. The member has a documented diagnosis of prurigo nodularis (PN) AND BOTH of the following:
    a. Severe or very severe pruritis intensity (e.g., an average worst itch score of greater than or equal to (≥) 7 on the Worst Itch Numeric Rating Scale (WI-NRS) ranging from 0 to 10)*; and*
    b. A minimum of 20 PN lesions in total on both legs, and/or both arms and/or trunk*; AND*
6. The member is unable to use, or has tried and failed a 2-week course of ONE topical corticosteroid (TCS) from medium potency (group III to IV) classes to higher potencies (groups I to II) classes (see Appendix A, Table 4).

<u>If the above prior authorization criteria are met, Dupixent (dupilumab) will be approved for 6-months.</u>

Continued Care

Medical Necessity Criteria for Subsequent Clinical Review

All prior authorization renewals are subject to review. Current chart documentation must be provided to substantiate ongoing medical necessity. Reauthorization may be provided based on the diagnosis, response to therapy, and documented medical records and/or pharmacy claims.

Subsequent Indication-Specific Criteria

Atopic dermatitis, moderate to severe

Authorization of 12 months may be provided for members 6 months of age or older when recent chart documentation (within the past 4-months) is provided showing ALL of the following criteria are met:

1. The member's condition has improved on Dupixent (dupilumab) treatment based upon the prescriber's assessment as demonstrated by at least ONE of the following:
    a. decreased disease activity (e.g., a reduction in BSA%)*; or*
    b. symptomatic improvement (e.g., redness, itching, oozing/crusting)*; AND*
2. Dupixent (dupilumab) will not be used concomitantly with other biologics (e.g., Adbry, Cibinqo, or Rinvoq) for atopic dermatitis*; AND*
3. Dupixent (dupilumab) is being prescribed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in a compendia of current literature.

Asthma, moderate to severe:

- with an eosinophilic phenotype*; or*
- oral corticosteroid (OCS)-dependent (regardless of phenotype)

Authorization of 12 months may be provided for members 6 years of age or older when recent chart documentation (within the past 6-months) is provided showing ALL of the following criteria are met:

1. The member's condition has improved on dupilumab treatment based upon the prescriber's assessment as demonstrated by at least ONE of the following:
    a. A reduction in the frequency and/or severity of symptoms and exacerbations*; or*
    b. A reduction in the daily maintenance oral corticosteroid dose*; AND*
2. Dupixent (dupilumab) will be used with concomitant asthma controller medications (e.g. ICS, ICS/LABA) and not as monotherapy*; AND*
3. Dupixent (dupilumab) will not be used concomitantly with other biologics (e.g., Cinqair, Fasenra, Nucala or Xolair) for asthma*; AND*
4. Dupixent (dupilumab) is being prescribed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in a compendia of current literature.

Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)

Authorization of 12 months may be provided for members 12 years of age or older when recent chart documentation (within the past 6-months) is provided showing ALL of the following criteria are met:

1. The member's condition has improved on Dupixent (dupilumab) treatment based upon the prescriber's assessment as demonstrated by symptomatic improvement of CRSwNP (e.g., improvement in nasal congestion, nasal polyp size, loss of smell, anterior or posterior rhinorrhea, sinonasal inflammation, hyposmia and/or facial pressure or pain or reduction in corticosteroid use)*; AND*
2. The member will continue consistent use of intranasal corticosteroids while on Dupixent (dupilumab) therapy, unless the member is unable to use intranasal corticosteroid*; AND*
3. Dupixent (dupilumab) is being prescribed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in a compendia of current literature.

Chronic Obstructive Pulmonary Disease (COPD), refractory (prevention of exacerbation)

Authorization of 12 months may be granted for continued treatment of chronic obstructive pulmonary disease (COPD) when ALL of the following criteria are met:

1. The member's condition has improved or stabilized while on Dupixent as demonstrated by at least ONE of the following:
    a. Reduction in the frequency and/or severity of COPD exacerbations*; or*
    b. Improvement in respiratory symptoms and functional capacity (e.g., reduced dyspnea, increased exercise tolerance, improved ability to perform daily activities)*; or*
    c. Reduction in COPD-related healthcare utilization (e.g., fewer emergency department visits, hospitalizations, or unscheduled healthcare provider visits)*; or*
    d. Improvement in lung function parameters (e.g., increased FEV1, improved FEV1/FVC ratio)*; AND*
2. Dupixent will be used in combination with continued maintenance therapy*; AND*
3. Dupixent is being prescribed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in compendia of current literature.

Chronic Spontaneous Urticaria (CSU)

Authorization of 12 months may be provided for members 12 year of age or older with CSU when the following criterion is met:

1. The member has experienced a positive response (e.g., improved symptoms, decrease in weekly urticaria activity score [UAS7]) since initiation of therapy.

Eosinophilic Esophagitis

Authorization of 12 months may be provided for members 1 year of age or older weighing at least 15 kg (33 lbs) when recent chart documentation (within the past 6-months) is provided showing BOTH of the following criteria are met:

1. The member has experienced ONE of the following:

a. Complete regression of disease*; or*
b. Improvement in clinical symptoms (e.g, abdominal pain, chest pain, food impaction, heartburn, solid food dysphagia, weight loss, vomiting, food refusal, failure to thrive)*; or*
c. Reduction in eosinophilic infiltration of the esophagus*; or*
d. Reduced incidence or recurrence of food impaction*; AND*

2. Dupixent (dupilumab) is being prescribed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in a compendia of current literature.

Immune checkpoint inhibitor toxicities

Authorization of 12 months may be provided when recent chart documentation (within the past 6-months) shows ALL of the following criteria are met:

1. The member continues to receive an immune checkpoint inhibitor [e.g., CTLA-4 inhibitor (ipilimumab), PD-1 inhibitor (pembrolizumab, nivolumab, cemiplimab), or PD-L1 inhibitor (atezolizumab, avelumab, durvalumab)]*; AND*
2. The member has documented improvement in immune-related adverse events attributed to checkpoint inhibitor therapy supported by ONE of the following:
    a. Clinically meaningful reduction in pruritus or rash severity*; or*
    b. Improvement in other dermatologic toxicities (e.g. bullous dermatitis)*; or*
    c. Resolution or improvement of other immune-related adverse events that necessitated Dupixent (dupilumab) use*; or*
    d. Other meaningful improvement; *AND*
3. Dupixent (dupilumab) is being prescribed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in a compendia of current literature.

Prurigo Nodularis (PN)

Authorization of 12 months may be provided for members 18 years of age or older when recent chart documentation (within the past 6-months) is provided showing ALL of the following criteria are met:

1. The member's condition has improved on Dupixent (dupilumab) treatment based upon the prescriber's assessment as demonstrated by ONE of the following:
    a. a clinically meaningful reduction in itch from baseline*; or*
    b. achieved clear or almost clear skin*; or*
    c. improvements in measures of overall health-related quality of life, skin pain, and symptoms of anxiety and depression*; AND*
2. Dupixent (dupilumab) is being prescribed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in a compendia of current literature.

Experimental or Investigational / Not Medically Necessary

Dupixent (dupilumab) for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. Additionally, the safety and efficacy of this medication in patients younger than the approved age for each indication has not been established. Non-covered indications include, but are not limited to, the following:

- Asthma in patients under 6 years of age.
- Mild atopic dermatitis or atopic dermatitis adequately controlled with topical therapies.
- Atopic dermatitis in patients under 6 months of age.
- Chronic idiopathic urticaria under 12 years of age.
- Chronic spontaneous urticaria under 12 years of age.
- Eosinophilic gastritis, gastroenteritis, or colitis.
- Eosinophilic granulomatosis with polyangiitis (EGPA).
- Food allergy, including peanut allergy.
- Hypereosinophilic syndromes.
- Immune checkpoint inhibitor-related toxicities for:
    - Mild (Grade 1) or moderate (Grade 2) pruritus.
    - Mild (Grade 1) bullous dermatitis.
    - Any other immune-related adverse events.
- Prurigo nodularis in patients under 18 years of age.
- Severe allergic conjunctivitis.
- Severe chronic rhinosinusitis without nasal polyposis.

Applicable Billing Codes

Table 1	
CPT/HCPCS Codes for Applicable Medication - Dupixent (dupilumab)	
Code	*Description*
C9399 (NOC)	Unclassified drugs or biologicals
J3590 (NOC)	Unclassified biologics

Table 2	
ICD-10-CM Codes for Clinical Indications	
Code	*Description*
J32.9	Chronic sinusitis, unspecified
J33.0	Polyp of nasal cavity

J33.1	Polypoid sinus degeneration
J33.8	Other polyp of sinus
J33.9	Nasal polyp, unspecified
J42	Unspecified chronic bronchitis
J43.0	Unilateral pulmonary emphysema
J43.1	Panlobular emphysema
J43.2	Centrilobular emphysema
J43.8	Other emphysema
J43.9	Emphysema, unspecified
J44.9	Chronic obstructive pulmonary disease, unspecified
J45.40	Moderate persistent asthma, uncomplicated
J45.41	Moderate persistent asthma with (acute) exacerbation
J45.50	Severe persistent asthma, uncomplicated
J45.51	Severe persistent asthma with (acute) exacerbation
J45.901	Unspecified asthma with (acute) exacerbation
J45.902	Unspecified asthma with status asthmaticus
J45.909	Unspecified asthma, uncomplicated
J45.991	Cough variant asthma
J45.998	Other asthma
J82.83	Eosinophilic asthma
K20.0	Eosinophilic esophagitis
L20.0	Besnier's prurigo
L20.81	Atopic neurodermatitis
L20.82	Flexural eczema
L20.83	Infantile (acute) (chronic) eczema
L20.84	Intrinsic (allergic) eczema
L20.89	Other atopic dermatitis
L20.9	Atopic dermatitis, unspecified
L28.1	Prurigo nodularis
L50.1	Idiopathic urticaria

References

1. Albert D, Heifert TA, Min SB, et al. Comparisons of fluticasone to budesonide in the treatment of eosinophilic esophagitis. Dig Dis Sci. 2016;61(7):1996-2001.[PubMed 27093866]

2. Andreae DA, Hanna MG, Magid MS, et al. Swallowed fluticasone propionate is an effective long-term maintenance therapy for children with eosinophilic esophagitis. Am J Gastroenterol. 2016;111(8):1187-1197.[PubMed 27325220]
3. Arnold MJ, Buelt A. Treatment of Chronic Obstructive Pulmonary Disease: Guidelines from the VA/DoD. Am Fam Physician. 2021 Jul 1;104(1):98-99. PMID: 34264617.
4. Arnold MJ. Treatment of Chronic Obstructive Pulmonary Disease: Guidelines from the American Thoracic Society. Am Fam Physician. 2021 Jul 1;104(1):102-103. PMID: 34264596.
5. Bachert C, Han JK, Desrosiers M, et al. Efficacy and safety of dupilumab in patients with severe chronic rhinosinusitis with nasal polyps (LIBERTY NP SINUS-24 and LIBERTY NP SINUS-52): results from two multicentre, randomised, double-blind, placebo-controlled, parallel-group phase 3 trials. Lancet. 2019;394(10209):1638.
6. Bhatt SP, Rabe KF, Hanania NA, Vogelmeier CF, Cole J, Bafadhel M, Christenson SA, Papi A, Singh D, Laws E, Mannent LP, Patel N, Staudinger HW, Yancopoulos GD, Mortensen ER, Akinlade B, Maloney J, Lu X, Bauer D, Bansal A, Robinson LB, Abdulai RM; BOREAS Investigators. Dupilumab for COPD with Type 2 Inflammation Indicated by Eosinophil Counts. N Engl J Med. 2023 Jul 20;389(3):205-214. doi: 10.1056/NEJMoa2303951. Epub 2023 May 21. PMID: 37272521.
7. Bonis P, Gupta SK. Treatment of eosinophilic esophagitis. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. https://www-uptodate-com. Accessed June 9, 2022.
8. Castro M, Corren J, Pavord ID, et al. Dupilumab efficacy and safety in moderate-to-severe uncontrolled Asthma. N Engl J Med. 2018;378(26):2486-2496.
9. Chuang MY, Chinnaratha MA, Hancock DG, et al. Topical steroid therapy for the treatment of eosinophilic esophagitis (EoE): A systematic review and meta-analysis. Clin Transl Gastroenterol. 2015;6:e82. doi:10.1038/ctg.2015.9[PubMed 25809314]
10. Criner GJ, Bourbeau J, Diekemper RL, Ouellette DR, Goodridge D, Hernandez P, Curren K, Balter MS, Bhutani M, Camp PG, Celli BR, Dechman G, Dransfield MT, Fiel SB, Foreman MG, Hanania NA, Ireland BK, Marchetti N, Marciniuk DD, Mularski RA, Ornelas J, Road JD, Stickland MK. Prevention of acute exacerbations of COPD: American College of Chest Physicians and Canadian Thoracic Society Guideline. Chest. 2015 Apr;147(4):894-942. doi: 10.1378/chest.14-1676. PMID: 25321320; PMCID: PMC4388124.
11. Dellon ES, Gonsalves N, Hirano I, Furuta GT, Liacouras CA, Katzka DA; American College of Gastroenterology. ACG clinical guideline: evidence based approach to the diagnosis and management of esophageal eosinophilia and eosinophilic esophagitis (EoE). Am J Gastroenterol. 2013;108(5):679-692. doi:10.1038/ajg.2013.71[PubMed 23567357]
12. Dellon ES, Katzka DA, Collins MH, Hamdani M, Gupta SK, Hirano I; MP-101-06 Investigators. Budesonide oral suspension improves symptomatic, endoscopic, and histologic parameters compared with placebo in patients with eosinophilic esophagitis. Gastroenterology. 2017;152(4):776-786.e5. doi: 10.1053/j.gastro.2016.11.021[PubMed 27889574]
13. Dellon ES, Liacouras CA, Molina-Infante J, et al. Updated International Consensus Diagnostic Criteria for Eosinophilic Esophagitis: Proceedings of the AGREE Conference. Gastroenterology 2018; 155:1022.
14. Dellon ES, Liacouras CA. Advances in clinical management of eosinophilic esophagitis. Gastroenterology. 2014;147(6):1238-1254. doi: 10.1053/j.gastro.2014.07.055[PubMed 25109885]
15. Dupixent (dupilumab) [prescribing information]. Tarrytown, NY: Regeneron Pharmaceuticals Inc; April 2025.
16. Dupixent. Micromedex. www.micromedexsolutions.com. Greenwood Village, CO: Truven Health Analytics. Last updated Feb 2022. Accessed February 23, 2022.
17. Eichenfield LF, Tom WL, Berger TG, et al. Guidelines of care for the management of atopic dermatitis: Section 2. Management and treatment of atopic dermatitis with topical therapies. J Am Acad Dermatol. 2014;71:116-32. (Including potencies of topical corticosteroids).
18. Eichenfield LF, Tom WL, Berger TG, et al. Guidelines of care for the management of atopic dermatitis. J Am Acad Dermatol. 2014;71:116-32.
19. Fable JM, Fernandez M, Goodine S, Lerer T, Sayej WN. Retrospective comparison of fluticasone propionate and oral viscous budesonide in children with eosinophilic esophagitis. J Pediatr Gastroenterol Nutr. 2018;66(1):26-32.[PubMed 28489670]
20. Global Initiative for Asthma (GINA). Global strategy for asthma management and prevention. https://ginasthma.org/2023-gina-main-report/. Updated 2023.

21. Global Initiative for Asthma (GINA). Global strategy for asthma management and prevention. https://ginasthma.org/wp-content/uploads/2021/05/GINA-Main-Report-2021-V2-WMS.pdf. Updated 2021. Accessed June 9, 2021.
22. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global Strategy for the Diagnosis, Management, and Prevention of COPD. 2024 Report.
23. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global Strategy for the Diagnosis, Management, and Prevention of COPD. 2025 Report. Available at: https://goldcopd.org/2025-gold-report/. Accessed May 16, 2025.
24. Halling AS, Loft N, Silverberg JI, Guttman-Yassky E, Thyssen JP. Real-world evidence of dupilumab efficacy and risk of adverse events: a systematic review and meta-analysis. J Am Acad Dermatol. 2021;84(1):139-147. doi:10.1016/j.jaad.2020.08.051[PubMed 32822798]
25. Hirano I, Chan ES, Rank MA, et al; AGA Institute Clinical Guidelines Committee; Joint Task Force on Allergy-Immunology Practice Parameters. AGA Institute and the Joint Task Force on Allergy-Immunology Practice Parameters clinical guidelines for the management of eosinophilic esophagitis. Gastroenterology. 2020;158(6):1776-1786. doi:10.1053/j.gastro.2020.02.038[PubMed 32359562]
26. Murali AR, Gupta A, Attar BM, Ravi V, Koduru P. Topical steroids in eosinophilic esophagitis: systematic review and meta-analysis of placebo controlled randomized clinical trials. J Gastroenterol Hepatol. 2016;31(6):1111-1119. doi:10.1111/jgh.13281[PubMed 26699695]
27. National Psoriasis Foundation. Topical Steroids Potency Chart. Retrieved June 9, 2022. Available on the World Wide Web at https://www.psoriasis.org/potency-chart/.
28. Rabe KF, Nair P, Brusselle G, et al. Efficacy and safety of dupilumab in glucocorticoid-dependent severe asthma. N Engl J Med. 2018;378(26):2475-2485.
29. Rank MA, Sharaf RN, Furuta GT, et al. Technical review on the management of eosinophilic esophagitis: a report from the AGA institute and the joint task force on allergy-immunology practice parameters. Ann Allergy Asthma Immunol. 2020;124(5):424-440.e17.[PubMed 32336463]
30. Rubinstein E, Lee JJ, Fried A, et al. Comparison of 2 delivery vehicles for viscous budesonide to treat eosinophilic esophagitis in children. J Pediatr Gastroenterol Nutr. 2014;59(3):317-320.[PubMed 24821535]
31. Simpson EL., Bieber T, Guttman-Yassky E, et al. Two phase 3 trials of dupilumab versus placebo in atopic dermatitis. N Engl J Med. 2016;375:2335-2348.
32. Tadicherla S, Ross K, Shenefelt PD, et al. Topical corticosteroids in dermatology. J Drugs Dermatol 2009;8:1093.
33. Zuberbier T, Abdul Latiff AH, Abuzakouk M, et al. The international EAACI/GA2LEN/EuroGuiDerm/APAACI guideline for the definition, classification, diagnosis, and management of urticaria. Allergy. 2022;73:734-766.

Appendix A

Table 3: Dupixent (dupilumab) Dosage and Retreatment Information

Indication	Body weight	Initial dose	Subsequent dose
Atopic Dermatitis			
Atopic Dermatitis (pediatric: age 6 months to 5 years)	5 to less than 15 kg	200 mg (one 200 mg injection) every 4 weeks	
Atopic Dermatitis (pediatric: age 6 months to 5 years)	15 to less than 30 kg	300 mg (one 300 mg injection) every 4 weeks	
Atopic Dermatitis (pediatric: age 6 to 17 years)	15 to less than 30 kg	600 mg (two 300 mg injections)	300 mg every 4 weeks

Indication	Body weight	Initial dose	Subsequent dose
Atopic Dermatitis (pediatric: age 6 to 17 years)	30 to less than 60 kg	400 mg (two 200 mg injections)	200 mg every 2 weeks
Atopic Dermatitis (pediatric: age 6 to 17 years)	60 kg or more	600 mg (two 300 mg injections)	300 mg every 2 weeks
Atopic Dermatitis (adult)		600 mg (two 300 mg injections)	300 mg every 2 weeks
Asthma			
Asthma (pediatric: age 6 to 11years)	15 to less than 30 kg	100 mg	100 mg every 2 weeks
		300 mg	300 mg every 4 weeks
Asthma (pediatric: age 6 to 11 years)	≥30 kg	200 mg	200 mg every 2 weeks
Asthma (age 12 years or greater)		400 mg (two 200 mg injections)	200mg every 2 weeks
		600 mg (two 300 mg injections)	300mg every 2 weeks
Asthma (oral corticosteroid-dependent, 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)	300mg every 2 weeks
Chronic rhinosinusitis with nasal polyposis (CRSwNP)			
Chronic rhinosinusitis with nasal polyposis (CRSwNP)		300mg	300 mg every 2 weeks
Chronic Obstructive Pulmonary Disease (COPD)			
Chronic Obstructive Pulmonary Disease (COPD)		300mg	300 mg every 2 weeks
Chronic Spontaneous Urticaria (CSU)			
Chronic Spontaneous Urticaria (CSU) (pediatric: age 12 to 17 years)	30 to less than 60 kg	400 mg (two 200 mg injections)	200 mg every 2 weeks
Chronic Spontaneous Urticaria (CSU)	≥60 kg	600 mg (two 300 mg injections)	300 mg every 2 weeks

Indication	Body weight	Initial dose	Subsequent dose
(pediatric: age 12 to 17 years)			
Chronic Spontaneous Urticaria (CSU) (18 years or greater)		600 mg (two 300 mg injections)	300 mg given every 2 weeks
Eosinophilic esophagitis			
Eosinophilic esophagitis	15 kg to <30 kg	200 mg	200 mg every other week
Eosinophilic esophagitis	30 kg to <40 kg	300 mg	300 mg every other week
Eosinophilic esophagitis	≥40 kg	300 mg	300 mg once weekly
Prurigo Nodularis			
Prurigo Nodularis		600 mg (two 300 mg injections)	300 mg every 2 weeks

Table 4: Topical Corticosteroid Potency

NOTE: The following chart is only for approximate comparative purposes. Please check product-specific information to best assess product potency, which can also be affected by a multitude of factors (e.g., formulation, site of application, member and disease-specific factors)

Group	Potency	Steroid	Strength	Dosage Form
I	Very High	Betamethasone dipropionate (augmented)	0.05%	Gel, Lotion, and Ointment
		Clobetasol propionate	0.05%	Cream, Emollient Cream, Foam, Gel, Lotion, Ointment, Spray, and Solution
		Desoximetasone	0.25%	Spray
		Diflorasone diacetate	0.05%	Ointment
		Fluocinonide	0.1%	Cream
		Flurandrenolide	0.05%	Tape
		Halobetasol propionate	0.05% and 0.01%	Cream, Foam, Lotion and Ointment
II	High	Amcinonide	0.1%	Ointment
		Betamethasone dipropionate (augmented)	0.05%	Cream
		Betamethasone dipropionate	0.05%	Ointment
		Desoximetasone	0.25%	Cream and Ointment
		Desoximetasone	0.05%	Gel
		Diflorasone diacetate	0.05%	Cream, and Emollient Cream
		Fluocinonide	0.05%	Cream, Gel, Ointment, and Solution
		Halcinonide	0.1%	Cream, Ointment, and Solution
		Triamcinolone acetonide	0.5%	Ointment
III	Upper Medium	Amcinonide	0.1%	Cream and Lotion
		Betamethasone dipropionate	0.05%	Cream
		Betamethasone valerate	0.12%	Foam
		Betamethasone valerate	0.1%	Ointment
		Fluocinonide	0.05%	Emollient Cream

Group	Potency	Steroid	Strength	Dosage Form
		Fluticasone propionate	0.005%	Ointment
		Mometasone furoate	0.1%	Ointment
		Triamcinolone acetonide	0.5%	Cream
		Triamcinolone acetonide	0.1%	Ointment
IV	Medium	Betamethasone dipropionate	0.05%	Spray
		Clocortolone pivalate	0.1%	Cream
		Desoximetasone	0.05%	Cream and Ointment
		Fluocinolone acetonide	0.025%	Ointment
		Flurandrenolide	0.05%	Ointment
		Hydrocortisone valerate	0.2%	Ointment
		Mometasone furoate	0.1%	Cream, Lotion, and Solution
		Triamcinolone acetonide	0.1%	Cream and Spray
V	Lower Medium	Betamethasone dipropionate	0.05%	Lotion
		Betamethasone valerate	0.1%	Cream and Lotion
		Desonide	0.05%	Gel and Ointment
		Fluocinolone acetonide	0.025%	Cream
		Fluocinolone acetonide	0.01%	Shampoo
		Flurandrenolide	0.05%	Cream and Lotion
		Fluticasone propionate	0.05%	Cream and Lotion
		Hydrocortisone butyrate	0.1%	Cream, Lotion, Ointment, and Solution
		Hydrocortisone probutate	0.1%	Cream
		Hydrocortisone valerate	0.2%	Cream
		Prenicarbate	0.1%	Emollient Cream and Ointment
		Triamcinolone acetonide	0.1%	Lotion
		Triamcinolone acetonide	0.025%	Ointment

Group	Potency	Steroid	Strength	Dosage Form
VI	Low	Alclometasone dipropionate	0.05%	Cream and Ointment
		Desonide	0.05%	Cream, Lotion, and Foam
		Fluocinolone acetonide	0.01%	Cream, Oil, and Solution
		Triamcinolone acetonide	0.025%	Cream and Lotion
VII	Lowest	Hydrocortisone acetate	0.5% and 1%	Cream and Ointment
		Hydrocortisone base	0.5% to 2.5%	Cream, Lotion, Ointment, Solution, and Spray

Table 5: Nonsedating Second Generation H1 Antihistamines and Standard Therapeutic Dose

Drug	Standard Therapeutic Dose
cetirizine	10 mg once daily
levocetirizine	5 mg once daily
fexofenadine	180 mg once daily
loratadine	10 mg once daily
desloratadine	5 mg once daily

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