Oscar Clinical Guideline: Dupixent (dupilumab) (PG026, Ver. 16)

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. Allergic Fungal Rhinosinusitis
2. Atopic Dermatitis
3. Asthma
4. Bullous Pemphigoid
5. Chronic Obstructive Pulmonary Disease
6. Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)
7. Chronic Spontaneous Urticaria
8. Eosinophilic Esophagitis
9. Prurigo Nodularis

If an individual is a current smoker or vaper, they should be counseled on the harmful effects of smoking and vaping on pulmonary conditions and available smoking and vaping cessation options.

Definitions

"Allergic Fungal Rhinosinusitis (AFRS)" is a distinct type of chronic rhinosinusitis (CRS). AFRS is believed to result from chronic, intense allergic inflammation directed against colonizing fungi.

"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.

"Bullous pemphigoid" is an autoimmune subepidermal blistering disorder and generally presents with tense bullae and intense generalized pruritus.

"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.

"Documentation" refers to written information, including but not limited to:

- Up-to-date chart notes, relevant test results, and/or relevant imaging reports to support diagnoses; or
- Prescription claims records, and/or prescription receipts to support prior trials of formulary alternatives.

"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").

"[s]" indicates state mandates may apply.

Clinical Indications

Medical Necessity Criteria for Clinical Review

General Medical Necessity Criteria for Initial Clinical Review

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. Allergic Fungal Rhinosinusitis - allergist/immunologist or otolaryngologist; *or*
    b. Moderate-to-severe atopic dermatitis - dermatologist or allergist/immunologist*; or*

c. Moderate-to-severe asthma - allergist/immunologist or pulmonologist*; or*
d. Bullous Pemphigoid (BP) - dermatologist, hematologist, or oncologist*; or*
e. Chronic rhinosinusitis with nasal polyps (CRSwNP) - allergist/immunologist or otolaryngologist*; or*
f. Chronic obstructive pulmonary disease (COPD) - allergist/immunologist or pulmonologist*; or*
g. Chronic spontaneous urticaria - allergist/immunologist or dermatologist*; or*
h. Eosinophilic esophagitis (EoE) - gastroenterologist or allergist/immunologist*; or*
i. Immune Checkpoint Inhibitor-Related Toxicities - dermatologist, hematologist or oncologist*; or*
j. Prurigo nodularis (PN) - dermatologist or allergist/immunologist*; AND*

2. Dupixent (dupilumab) is being prescribed at a dose and frequency that is within FDA approved labeling (see Appendix A) OR is supported by compendia or evidence-based published dosing guidelines for the requested indication*; AND*
3. For all indications, the member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication*; AND*
4. Documentation is provided showing the member meets ALL of the following indication-specific criteria below (see Initial Indication-Specific Criteria):

Initial Indication-Specific Criteria

Allergic Fungal Rhinosinusitis (AFRS)

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

5. The member meets the above General Medical Necessity Criteria for Initial Clinical Review; *AND*
6. The member is 6 years of age or older weighing at least 15 kg (33 lbs); *AND*
7. The member has a diagnosis of allergic fungal rhinosinusitis (AFRS) that is confirmed with ALL of the following:
    a. The member has had IgE mediated inflammatory response to fungal hyphae (specific IgE serology or skin test), evidence of sensitization to fungus by skin testing, or positive fungal-specific IgE in serum*; and*
    b. The member has had nasal polyposis confirmed by nasal endoscopy*; and*
    c. The member has an endoscopic nasal polyp score (NPS) of greater than or equal (≥) to 2 out of 4 for unilateral polyps OR greater than or equal to 3 (≥) out of 8 for bilateral polyps*; and*
    d. The member has had a characteristic CT scan which includes ONE of the following:
        i. Hyperdensities*; or*
        ii. Bony demineralization*; or*
        iii. Bone erosion of sinus*; and*
    e. The member has evidence of sinus opacification with a Lund Mackay (LMK) score of greater than or equal (≥) to 9 for members with unilateral polyps and greater than (≥) 12 for members with bilateral polyps*; and*
    f. The member has a presence of eosinophilic mucin without invasion*; and*
8. The member has a history of sino-nasal surgery[s]; *AND*

9. The member had a positive fungal stain of sinus contents removed at the time of surgery.

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

Atopic Dermatitis, moderate to severe

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

5. The member meets the above General Medical Necessity Criteria for Initial Clinical Review; *AND*
6. The member is 6 months of age or older*; AND*
7. The member has a diagnosis of moderate-to-severe atopic dermatitis*; AND*
8. The member's affected body surface area (BSA) before treatment meets ONE (1) of the following:
    a. Involvement of is equal to or greater (≥) than 10% of BSA*; or*
    b. Involvement is less than 10% but sensitive body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected*; AND*
9. The member is unable to use, or has tried and failed ONE (1) of the following topical therapies for at least 8 weeks each in the past 365 days[s]:
    a. A topical corticosteroid (TCS) from medium potency (group III to IV) classes to higher potencies (groups I to II) classes (see Appendix B, Table 4)*; and/or*
    b. Tacrolimus ointment*; and/or*
    c. Eucrisa (crisaborole) [PA may be required, please check the member's Plan-specific Formulary].

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

Asthma, moderate to severe:

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

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

5. The member meets the above General Medical Necessity Criteria for Initial Clinical Review; *AND*
6. The member is 6 years of age or older; *AND*
7. The member has a diagnosis of moderate-to-severe asthma; *AND*
8. The member meets ONE (1) of the following criteria:
    a. The member has a history of ALL of the following within the last 12 months:
        i. The member meets ONE of the following:
            1. Two or more (≥2) exacerbations requiring oral or systemic corticosteroids treatment*; or*
            2. One or more (≥1) exacerbation resulting in hospitalization or intensive care unit (ICU) admission*; and*

ii. The member has tried and failed, or is unable to use, ALL of the following for at least 3 months[s]:
1. High-dose inhaled corticosteroids (ICS)*; and*
2. Adjunctive therapy (in combination with inhaled corticosteroid), such as ONE (1) 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. Long-Acting Muscarinic Antagonists (LAMA), such as tiotropium; *or*
d. Extended-release theophylline*; or*

b. The member has documented evidence of ALL 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 for at least three (3) months[s]:
1. High-dose inhaled corticosteroids (ICS)*; and*
2. Adjunctive therapy (in combination with inhaled corticosteroid), such as ONE (1) 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*
e. Long-Acting Muscarinic Antagonists (LAMA), such as tiotropium; *or*
c. Extended-release theophylline*; AND*

9. Dupixent (dupilumab) will NOT be used as monotherapy as the member will continue to use with maintenance asthma treatments (i.e., inhaled corticosteroid and additional controller).

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

<u>Bullous Pemphigoid (BP)</u>

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

5. The member meets the above General Medical Necessity Criteria for Initial Clinical Review; *AND*
6. The member is 18 years or older*; AND*
7. The member has a diagnosis of moderate-to-severe bullous pemphigoid*; AND*
8. The member's diagnosis has been confirmed by ONE of the following:
a. Direct immunofluorescence (DIF) study*; or*
b. Immune serological test(s) (e.g., Indirect immunofluorescence microscopy [IIF], ELISA)*; AND*

9. The member demonstrates characteristic clinical features of bullous pemphigoid (e.g., urticarial or eczematous or erythematous plaques, bullae, pruritus)*; AND*
10. The member is unable to use or has tried and failed ONE (1) oral systemic corticosteroid (e.g., prednisone or prednisolone)[s].

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

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

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

5. The member meets the above General Medical Necessity Criteria for Initial Clinical Review; *AND*
6. The member is 18 years of age or older; *AND*
7. The member has a diagnosis of chronic obstructive pulmonary disease (COPD)*; AND*
8. Inadequate control of COPD as evidenced by ONE (1) of the following[s]:
    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*
9. Eosinophilic phenotype, as evidenced by baseline blood eosinophil count ≥300 cells/mcL*; AND*
10. Dupixent (dupilumab) will be used in combination with continued COPD maintenance therapy (e.g., ICS with LAMA and LABA, LAMA and LABA).

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

Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)

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

5. The member meets the above General Medical Necessity Criteria for Initial Clinical Review; *AND*
6. The member is 12 years of age or older*; AND*
7. The member has a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP)*; AND*
8. The member has documentation of ONE (1) of the following:
    a. Bilateral nasal endoscopy, anterior rhinoscopy, or computed tomography (CT) showing polyps reaching below the lower border of the middle turbinate or beyond in each nostril*; or*

b. Meltzer Clinical Score of 2 or higher in both nostrils; or
c. A total endoscopic nasal polyp score (NPS) of at least 5 with a minimum score of 2 for each nostril; AND

9. The member has nasal blockage, congestion, or obstruction AND ONE (1) of the following additional symptoms:
    a. Rhinorrhea (anterior/posterior); *or*
    b. Reduction or loss of smell*; or*
    c. Facial pain or pressure; *AND*
10. The member has CRSwNP despite ONE (1) of the following:
    a. Prior sino-nasal surgery; *or*
    b. The member is unable to use, or has tried and failed treatment with systemic corticosteroids within the last two years[s];*AND*
11. 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 4 weeks[s] *; AND*
12. 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 an intranasal corticosteroid.

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

Chronic Spontaneous Urticaria (CSU)

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

5. The member meets the above General Medical Necessity Criteria for Initial Clinical Review; *AND*
6. The member is 2 years of age or older*; AND*
7. The member has a diagnosis of chronic spontaneous urticaria (CSU)*; AND*
8. The member has experienced a spontaneous onset of wheals (hives), angioedema, or both, for at least 6 weeks*; AND*
9. The member remains symptomatic despite maximal up-dosing of a second-generation H1 antihistamine as appropriate (e.g., cetirizine, levocetirizine, desloratadine) for at least 2 weeks (see Appendix C, Table 5)[s]*; AND*
10. The member has been evaluated for other causes of wheals (hives) and/or angioedema, including bradykinin-related angioedema (e.g., angiotensin-converting-enzyme (ACE)-inhibitor induced angioedema, hereditary angioedema) and interleukin-1-associated urticarial syndromes (e.g., auto-inflammatory disorders, urticarial vasculitis).

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

Eosinophilic Esophagitis

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

5. The member meets the above General Medical Necessity Criteria for Initial Clinical Review; *AND*
6. The member is 1 year of age or older*; AND*
7. The member weighs at least 15 kg (33 lbs)*; AND*
8. 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. The member meets ONE (1) 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*
9. The member is unable to use, or has tried and failed BOTH of the following for at least two (2) months[s]:
    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 up to 6-months.</u>[s]

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

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

5. The member meets the above General Medical Necessity Criteria for Initial Clinical Review; *AND*
6. The member is receiving an immune checkpoint inhibitor (e.g., CTLA-4 inhibitor [ipilimumab], PD-1 inhibitor [pembrolizumab, nivolumab, cemiplimab], or PD-L1 inhibitor [atezlizumab, avelumab, durvalumab])*; AND*
7. The member has documentation of ONE (1) of the following:
    a. Moderate (Grade 2) or severe (Grade 3) pruritus refractory (no response) to ≥1 month trial of gabapentinoids (e.g., gabapentin, pregabalin)*; or*
    b. Moderate (Grade 2) bullous dermatitis if diagnosis of bullous pemphigoid is confirmed by biopsy or serology; *or*

c. Severe (Grade 3) or life-threatening (Grade 4) bullous dermatitis as a steroid-sparing measure if bullous pemphigoid is confirmed; *or*
d. Moderate (Grade 2) or severe (Grade 3) bullous dermatitis inadequately controlled with topical/systemic corticosteroids (e.g., prednisone, IV methylprednisolone); or
e. Severe (>30%) body surface area lichen planus and lichenoid diseases).

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

Prurigo Nodularis (PN)

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

5. The member meets the above General Medical Necessity Criteria for Initial Clinical Review; *AND*
6. The member is 18 years of age or older; *AND*
7. The member has a documented diagnosis of prurigo nodularis (PN) AND BOTH of the following:
   a. Severe or very severe pruritus 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*
8. The member is unable to use, or has tried and failed ONE (1) of the following[s]:
   a. Topical corticosteroid (TCS) from medium potency (group III to IV) classes to higher potencies (groups I to II) classes (see Appendix B, Table 4)*; o*r
   b. Topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus)*; or*
   c. Phototherapy (e.g., UVB, PUVA)*; or*
   d. Pharmacologic treatment with methotrexate or cyclosporine (see Appendix D).

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

Continued Care

Medical Necessity Criteria for Subsequent Clinical Review

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

Subsequent General Medical Necessity Criteria

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

1. Dupixent (dupilumab) is being prescribed at a dose and frequency that is within FDA approved labeling (see Appendix A) OR is supported by compendia or evidence-based published dosing guidelines for the requested indication; *AND*
2. For all indications, the member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication*; AND*

3. Documentation is provided showing the member meets ALL of the following applicable indication-specific criteria (see Subsequent Indication-Specific Criteria):

Subsequent Indication-Specific Criteria

Allergic Fungal Rhinosinusitis

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

4. The member meets the above Subsequent General Medical Necessity Criteria; *AND*
5. The member is 6 years of age or older weighing at least 15 kg (33lb)*; AND*
6. The member's condition has improved on Dupixent (dupilumab) treatment based upon the prescriber's assessment as demonstrated by ONE (1) of the following:
    a. Improvement of symptoms of allergic fungal rhinosinusitis (e.g., improvement in sense of smell, improvement in SNOT-22 scores); *or*
    b. Lower Lund-Mackay score; *or*
    c. Minimal or no eosinophilic mucin; *or*
    d. Reduction in nasal congestion or blockage; *or*
    e. Reduction of nasal polyps or formation or new polyps.*; or*
    f. Reduction in sinus opacification; *or*
    g. Reduction in the need for rescue treatment.

If the above reauthorization criteria are met, the requested product will be authorized for up to 12-months.[s]

Atopic dermatitis, moderate to severe

The Plan considers Dupixent (dupilumab) medically necessary when recent chart documentation (within the past 6 months) is provided showing ALL of the following criteria are met:

4. The member meets the above Subsequent General Medical Necessity Criteria; *AND*
5. The member is 6 months of age or older*; AND*
6. The member's condition has improved on Dupixent (dupilumab) treatment based upon the prescriber's assessment as demonstrated by at least ONE (1) of the following:
    a. Decreased disease activity (e.g., a reduction in BSA%)*; or*
    b. Symptomatic improvement (e.g., redness, itching, oozing/crusting).

If the above reauthorization criteria are met, the requested product will be authorized for up to 12-months.[s]

Asthma, moderate to severe:

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

4. The Plan considers Dupixent (dupilumab) medically necessary when recent chart documentation (within the past 6 months) is provided showing ALL of the following criteria are met:The member meets the above Subsequent General Medical Necessity Criteria; *AND*
5. The member is 6 years of age or older*; AND*
6. The member's condition has improved on Dupixent (dupilumab) treatment based upon the prescriber's assessment as demonstrated by at least ONE (1) 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*
7. Dupixent (dupilumab) will NOT be used as monotherapy as the member will continue to use with maintenance asthma treatments (i.e., inhaled corticosteroid and additional controller).

If the above reauthorization criteria are met, the requested product will be authorized for up to 12-months.[s]

Bullous Pemphigoid (BP)

The Plan considers Dupixent (dupilumab) medically necessary when recent chart documentation (within the past 6 months) is provided showing ALL of the following criteria are met:

4. The member meets the above Subsequent General Medical Necessity Criteria; *AND*
5. The member is 18 years of age or older*; AND*
6. The member has experienced a positive response as demonstrated by ONE (1) of the following:
    a. Low disease activity (e.g., absence of new or established lesions)*; or*
    b. Reduction in pruritus intensity and improvement in extent and severity of lesions.

If the above reauthorization criteria are met, the requested product will be authorized for up to 12-months.[s]

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

The Plan considers Dupixent (dupilumab) medically necessary when recent chart documentation (within the past 6 months) is provided showing ALL of the following criteria are met:

4. The member meets the above Subsequent General Medical Necessity Criteria; *AND*
5. The member is 18 years of age or older; *AND*
6. The member's condition has improved or stabilized while on Dupixent as demonstrated by at least ONE (1) 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)*; or*

e. Disease stability since starting the requested medication; *AND*

7. Dupixent (dupilumab) will be used in combination with continued COPD maintenance therapy (e.g., ICS with LAMA and LABA, LAMA and LABA).

If the above reauthorization criteria are met, the requested product will be authorized for up to 12-months.[s]

Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)

The Plan considers Dupixent (dupilumab) medically necessary when recent chart documentation (within the past 6 months) is provided showing ALL of the following criteria are met:

4. The member meets the above Subsequent General Medical Necessity Criteria; *AND*
5. The member is 12 years of age or older*; AND*
6. 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*
7. The member will continue consistent use of intranasal corticosteroids while on Dupixent (dupilumab) therapy, unless the member is unable to use intranasal corticosteroid.

If the above reauthorization criteria are met, the requested product will be authorized for up to 12-months.[s]

Chronic Spontaneous Urticaria (CSU)

The Plan considers Dupixent (dupilumab) medically necessary when recent chart documentation (within the past 6 months) is provided showing ALL of the following criteria are met:

4. The member meets the above Subsequent General Medical Necessity Criteria; *AND*
5. The member is 2 years of age or older*; AND*
6. The member has experienced a positive response (e.g., improved symptoms, decrease in weekly urticaria activity score [UAS7]) since initiation of therapy).

If the above reauthorization criteria are met, the requested product will be authorized for up to 12-months.[s]

Eosinophilic Esophagitis

The Plan considers Dupixent (dupilumab) medically necessary when recent chart documentation (within the past 6 months) is provided showing ALL of the following criteria are met:

4. The member meets the above Subsequent General Medical Necessity Criteria; *AND*
5. The member is 1 year of age or older weighing at least 15 kg (33 lbs)*; AND*
6. The member has experienced ONE (1) 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.

If the above reauthorization criteria are met, the requested product will be authorized for up to 12-months.[s]

Immune checkpoint inhibitor toxicities

4. The Plan considers Dupixent (dupilumab) medically necessary when recent chart documentation (within the past 6 months) is provided showing ALL of the following criteria are met:The member meets the above Subsequent General Medical Necessity Criteria; *AND*
5. 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)] as applicable to the member and as documented as appropriate by the provider*; AND*
6. The member has documented improvement in immune-related adverse events attributed to checkpoint inhibitor therapy supported by ONE (1) 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 improvements.

If the above reauthorization criteria are met, the requested product will be authorized for up to 12-months.[s]

Prurigo Nodularis (PN)

The Plan considers Dupixent (dupilumab) medically necessary when recent chart documentation (within the past 6 months) is provided showing ALL of the following criteria are met:

4. The member meets the above Subsequent General Medical Necessity Criteria; *AND*
5. The member is 18 years of age or older*; AND*
6. The member's condition has improved on Dupixent (dupilumab) treatment based upon the prescriber's assessment as demonstrated by ONE (1) of the following:
    a. A clinically meaningful reduction in itch from baseline*; or*
    b. Achieved clear or almost clear skin (e.g., reduction in number or severity of lesions)*; or*
    c. Improvements in measures of overall health-related quality of life, skin pain, and symptoms of anxiety and depression.

If the above reauthorization criteria are met, the requested product will be authorized for up to 12-months.[s]

Experimental / Investigational, or unproven[s]

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

- Allergic fungal rhinosinusitis in members under 6 years of age.
- Asthma in members under 6 years of age.
- Mild atopic dermatitis or atopic dermatitis adequately controlled with topical therapies.
- Atopic dermatitis in members under 6 months of age.
- Bullous pemphigoid in members under 18 years of age.
- Chronic rhinosinusitis with nasal polyps in members under 12 years of age.
- Chronic spontaneous urticaria under 2 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 (without failure of gabapentinoid for at least 1 month, or without confirmed diagnosis of bullous pemphigoid)
    - Mild (Grade 1) bullous dermatitis.
- Prurigo nodularis in members under 18 years of age.
- Severe allergic conjunctivitis.
- Severe chronic rhinosinusitis without nasal polyposis.

Applicable Billing Codes

Table 1	
CPT/HCPCS codes considered medically necessary if criteria are met:	
Code	*Description*
C9399	Dupixent Unclassified drugs or biologicals
J3590	Dupixent Unclassified biologics

Table 2	
ICD-10 diagnosis codes considered medically necessary with Table 1 (CPT/HCPCS) codes if criteria are met:	
Code	*Description*
B49	Unspecified mycosis
J30.89	Other allergic rhinitis
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
J44.1	Chronic obstructive pulmonary disease with (acute) exacerbation
J44.9	Chronic obstructive pulmonary disease, unspecified
J45.20	Mild intermittent asthma, uncomplicated
J45.30	Mild persistent asthma, uncomplicated
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

Table 2	
ICD-10 diagnosis codes considered medically necessary with Table 1 (CPT/HCPCS) codes if criteria are met:	
Code	*Description*
J45.909	Unspecified asthma, uncomplicated
J45.990	Exercise induced bronchospasms
J45.991	Cough variant asthma
J45.998	Other asthma
J82.83	Eosinophilic asthma
K20.0	Eosinophilic esophagitis
L12.0	Bullous Pemphigoid
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
L50.8	Other urticaria

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Appendix A

Table 3: Dupixent (dupilumab) Dosage and Retreatment Information

Indication	Body Weight or Age Group	Initial Dose	Subsequent Dose
Allergic Fungal Rhinosinusitis			
Allergic Fungal Rhinosinusitis (pediatrics: age 6 to 17 years)	15 to less than 30 kg	300 mg (one 300 mg injection) every 4 weeks	
Allergic Fungal Rhinosinusitis (pediatrics: age 6 to 17 years)	30 to less than 60 kg	200 mg (one 200 mg injection) every 2 weeks	
Allergic Fungal Rhinosinusitis (pediatrics: age 6 to 17 years)	60 kg or more	300 mg (one 300 mg injection) every 2 weeks	
Allergic Fungal Rhinosinusitis (adult)	N/A	300 mg (one 300 mg injection) every 2 weeks	
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
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)	N/A	600 mg (two 300 mg injections)	300 mg every 2 weeks
Asthma			

Indication	Body Weight or Age Group	Initial Dose	Subsequent Dose
Asthma (pediatric: age 6 to 11years)	15 to less than 30 kg		
		300 mg (one 300 mg injection) every 4 weeks	
Asthma (pediatric: age 6 to 11 years)	≥30 kg	200 mg (one 200 mg injection) every 2 weeks	
Asthma (age 12 years or greater)	N/A	400 mg (two 200 mg injections)	200 mg every 2 weeks
		600 mg (two 300 mg injections)	300 mg 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)	Ages 12 years and older Ages 6 to 11 years weighing ≥ 60 kg	600 mg (two 300 mg injections)	300 mg every 2 weeks
	Ages 6 to 11 years weighing 30 to less than 60 kg	400 mg (two 200 mg injections)	200 mg every 2 weeks
	Ages 6 to 11 years weighing 15 to less than 30 kg	600 mg (two 300 mg injections)	300 mg every 4 weeks
Bullous Pemphigoid			
Bullous pemphigoid	N/A	600 mg (two 300 mg injections)	300 mg every 2 weeks
Chronic rhinosinusitis with nasal polyposis (CRSwNP)			
Chronic rhinosinusitis with nasal polyposis (CRSwNP)	N/A	300 mg (one 300 mg injection) every 2 weeks	
Chronic Obstructive Pulmonary Disease (COPD)			

Indication	Body Weight or Age Group	Initial Dose	Subsequent Dose
Chronic Obstructive Pulmonary Disease (COPD)	N/A	300 mg (one 300 mg injection) 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) (pediatric: age 12 to 17 years)	≥60 kg	600 mg (two 300 mg injections)	300 mg every 2 weeks
Chronic Spontaneous Urticaria (CSU) (18 years or greater)	N/A	600 mg (two 300 mg injections)	300 mg given every 2 weeks
Eosinophilic Esophagitis			
Eosinophilic esophagitis	15 to less than 30 kg	200 mg (one 200 mg injection) every 2 weeks	
Eosinophilic esophagitis	30 to less than40 kg	300 mg (one 300 mg injection) every 2 weeks	
Eosinophilic esophagitis	≥40 kg	300 mg (one 300 mg injection) every week	
Prurigo Nodularis			
Prurigo Nodularis	N/A	600 mg (two 300 mg injections)	300 mg every 2 weeks

Appendix B

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, Shampoo, Spray, and Solution
		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
		Clobetasol propionate	0.025%	Cream
		Desoximetasone	0.25%	Cream, Ointment, and Spray
		Desoximetasone	0.05%	Gel
		Diflorasone diacetate	0.05%	Cream, Emollient Cream, and Ointment
		Fluocinonide	0.05%	Cream, Gel, Ointment, and Solution
		Halcinonide	0.1%	Cream, Ointment, and Solution

Group	Potency	Steroid	Strength	Dosage Form
		Halobetasol propionate	0.01%	Lotion
III	Upper Medium	Amcinonide	0.1%	Cream and Lotion
		Betamethasone dipropionate	0.05%	Cream
		Betamethasone valerate	0.12%	Foam
		Betamethasone valerate	0.1%	Ointment
		Desoximetasone	0.05%	Cream and Ointment
		Fluocinonide	0.05%	Emollient Cream
		Fluticasone propionate	0.005%	Ointment
		Mometasone furoate	0.1%	Ointment
		Triamcinolone acetonide	0.5%	Cream and Ointment
IV	Medium	Betamethasone dipropionate	0.05%	Spray
		Clocortolone pivalate	0.1%	Cream
		Desoximetasone	0.05%	Cream and Ointment
		Fluocinolone acetonide	0.025%	Cream and Ointment
		Flurandrenolide	0.05%	Ointment
		Fluticasone propionate	0.05%	Cream
		Hydrocortisone valerate	0.2%	Ointment
		Mometasone furoate	0.1%	Cream, Lotion, and Solution

Group	Potency	Steroid	Strength	Dosage Form
		Triamcinolone acetonide	0.1%	Cream, Dental Paste, Ointment, and Spray
V	Lower Medium	Betamethasone dipropionate	0.05%	Lotion
		Betamethasone valerate	0.1%	Cream
		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%	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
VI	Low	Alclometasone dipropionate	0.05%	Cream and Ointment
		Betamethasone valerate	0.1%	Lotion
		Desonide	0.05%	Cream, Lotion, and Foam
		Fluocinolone acetonide	0.01%	Cream, Oil, Shampoo and Solution
		Triamcinolone acetonide	0.025%	Cream and Lotion

Group	Potency	Steroid	Strength	Dosage Form
VII	Lowest	Hydrocortisone acetate	1% to 2.5%	Cream, Lotion, and Ointment
		Hydrocortisone base	0.5% to 2.5%	Cream, Gel, Liquid, Lotion, Ointment, Solution, and Spray

Appendix C

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

Appendix D

Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate or Cyclosporine

- Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
- Drug interaction
- Risk of treatment-related toxicity
- Pregnancy or currently planning pregnancy
- Breastfeeding
- Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
- Hypersensitivity
- History of intolerance or adverse event

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