oscar

Clinical Guideline

Oscar Clinical Guideline: Dupixent (dupilumab) (PG026, Ver. 9)

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) is a human monoclonal antibody that is approved for use in the treatment of eczema, eosinophilic esophagitis, sinus inflammation with nasal polyps, and to prevent the symptoms of asthma. This biologic agent works by decreasing inflammation. Dupixent (dupilumab) is indicated:

1. for the treatment of adult and pediatric patients aged 6 months and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Dupixent can be used with or without topical corticosteroids.
2. 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 (Limitations of Use - Dupixent is not indicated for the relief of acute bronchospasm or status asthmaticus).
3. as an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP).
4. for the treatment of adult and pediatric patients aged 12 years and older, weighing at least 40 kg, with eosinophilic esophagitis (EoE).
5. for the treatment of adult patients with prurigo nodularis (PN).

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.

"**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 esophagitis**" is a condition caused by allergy cells called 'eosinophils' infiltrating into the esophagus, leading to esophageal dysfunction.

"**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 more tight and narrow than normal, causing coughing, shortness of breath, and wheezing.

"**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.

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

"**Prurigo nodularis (PN)**" is an uncommon skin disease that causes itchy hard lumps (called nodules) to form on the skin. Its cause is unknown, and the associated itching (pruritus) can become so severe that people may scratch to the point of bleeding or pain.

"**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

The Plan considers **Dupixent (dupilumab)** medically necessary when **ALL** of the following criteria are met for the applicable indication listed below:

Medical Necessity Criteria for Initial Authorization

Atopic dermatitis, moderate to severe

1. Dupixent (dupilumab) is being prescribed by or in consultation with a specialist in dermatology, allergy or immunology***; AND***
2. The member is 6 months of age or older***; AND***
3. 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***
4. 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 **Table 2**)***; and/or***
    b. Tacrolimus ointment***; and/or***
    c. Eucrisa (crisaborole) [PA may be required, please check the member's Plan-specific Formulary]***; AND***
5. Dupixent (dupilumab) will not be used concomitantly with other biologics (e.g., Adbry, Cibinqo, or Rinvoq) in the treatment of atopic dermatitis***; AND***
6. Dupixent (dupilumab) is being prescribed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in a compendia of current literature***; AND***
7. Clinical chart documentation is provided for review to substantiate the above-listed requirements.

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

Asthma, moderate to severe:

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

1. The member is 6 years of age or older; ***AND***
2. 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. Clinical chart documentation is provided showing **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***

3. Clinical chart documentation is provided showing **ALL** of the following:
    a. the member's pre-treatment FEV_1 and Asthma Control Questionnaire (ACQ); ***and***
    b. documentation or attestation that the member is currently smoke-free; ***and***
    c. Dupixent (dupilumab) will not be used as monotherapy; ***and***
    d. Dupixent (dupilumab) will not be used concomitantly with other biologics (e.g., Cinqair, Fasenra, Nucala or Xolair) in the treatment of 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***; AND***
5. Clinical chart documentation is provided for review to substantiate the above listed requirements.

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

Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)

1. The member is 18 years of age or older***; AND***
2. The member has a bilateral nasal endoscopy or anterior rhinoscopy showing polyps reaching below the lower border of the middle turbinate or beyond in each nostril***; AND***
3. The member has nasal obstruction **AND ONE** of the following additional symptom(s):
    a. Rhinorrhea (anterior/posterior); ***or***
    b. Reduction or loss of smell***; AND***
4. 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***
5. 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***
6. 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***; AND***
7. Dupixent (dupilumab) is being prescribed within within the manufacturer's published dosing guidelines or falls within dosing guidelines found in a compendia of current literature***; AND***
8. Clinical chart documentation is provided for review to substantiate the above listed requirements.

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

Eosinophilic Esophagitis

1. Dupixent (dupilumab) is being prescribed by or in consultation with a specialist in gastroenterology, allergy or immunology***; AND***
2. The member is 12 years of age or older***; AND***
3. The member weighs at least 40 kg (88 lbs)***; AND***
4. Clinical chart documentation is provided showing **ALL** of the following:
    a. The member has a documented diagnosis of eosinophilic esophagitis (EoE) by endoscopy***; 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)***; and***
e. The member has on average at least 2 episodes of dysphagia per week***; AND***

5. 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***; AND***
6. Dupixent (dupilumab) is being prescribed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in a compendia of current literature***; AND***
7. Clinical chart documentation is provided for review to substantiate the above listed requirements.

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

Prurigo Nodularis (PN)

1. Dupixent (dupilumab) is being prescribed by or in consultation with a specialist in dermatology; ***AND***
2. The member is 18 years of age or older; ***AND***
3. 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***
4. 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 **Table 2**).

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

Medical Necessity Criteria for Reauthorization

All prior authorization renewals will be reviewed for the following indications to determine if continuation of therapy is medically necessary. Chart documentation and supporting labwork should be provided with any reauthorization requests to substantiate medical necessity. Prior Authorization may be extended based on the diagnosis, documentation of the response to therapy, and pharmacy claims record.

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) in the treatment of 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.

<u>Asthma, moderate to severe:</u>

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

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. The member's most current FEV1 and Asthma Control Questionnaire (ACQ)***; AND***
3. Dupixent (dupilumab) will not be used as monotherapy***; AND***
4. Dupixent (dupilumab) will not be used concomitantly with other biologics (e.g., Cinqair, Fasenra, Nucala or Xolair) in the treatment of asthma***; AND***
5. Dupixent (dupilumab) is being prescribed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in a compendia of current literature.

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

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 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.

Eosinophilic Esophagitis

Authorization of 12 months may be provided for members 12 years of age or older weighing at least 40 kg when recent chart documentation (within the past 6 months) is provided showing **ONE** of the following criteria are met:

1. The member has experienced complete regression of disease***; OR***
2. The member has documented improvement in clinical symptoms (e.g, abdominal pain, chest pain, food impaction, heartburn, solid food dysphagia, weight loss, vomiting)***; OR***
3. Documentation of lessened eosinophilic infiltration in esophagus***; OR***
4. The member has experienced reduced incidence or recurrence of food impaction

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 3 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.

Table 1: Dupixent (dupilumab) dosage and retreatment information

Indication	Body weight	Initial dose	Subsequent dose
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)		600 mg (two 300 mg injections)	300 mg every 2 weeks
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)		300mg	300 mg every 2 weeks
Eosinophilic esophagitis		300 mg	300 mg once weekly
Prurigo Nodularis		600 mg (two 300 mg injections)	300 mg every 2 weeks

Table 2: 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
		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
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

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.

Applicable Billing Codes

CPT/HCPCS Codes for Applicable Medication - Dupixent (dupilumab)	
Code	***Description***
C9399 (NOC)	Unclassified drugs or biologicals
J3590 (NOC)	Unclassified biologics
ICD-10-CM Codes for Clinical Indications	
Code	***Description***
J31.0	Chronic rhinitis
J33.0	Polyp of nasal cavity
J33.1	Polypoid sinus degeneration
J33.8	Other polyp of sinus
J33.9	Nasal polyp, unspecified
J45.20	Mild intermittent asthma, uncomplicated
J45.21	Mild intermittent asthma with (acute) exacerbation
J45.22	Mild intermittent asthma with status asthmaticus
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
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

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Clinical Guideline Revision / History Information

Original Date: 08/06/2020

Reviewed/Revised: 06/24/2021, 12/01/2021, 03/17/2022, 06/23/2022, 12/08/2022, 6/29/2023, 9/21/2023, 10/27/2023