Dupixent (dupilumab)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

1) Dupixent is indicated for the treatment of patients aged 6 years 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) Dupixient is indicated as an add-on maintenance treatment in patients with moderate-to-severe asthma aged 12 years and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma.
3) Dupixent is indicated as an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP).

Limitation of use:

- Dupixent is **not** indicated for the relief of acute bronchospasm or status asthmaticus.

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

A. Atopic dermatitis (for initial requests): Member's chart or medical record to support inadequate treatment response to prerequisite therapies and affected area(s) and body surface area.

B. Asthma (for initial requests): Member's chart or medical record showing pretreatment blood eosinophil count and prerequisite therapies. For oral glucocorticoid use history, the documentation must also include drug, dose, frequency and duration.
C. Chronic rhinosinusitis with nasal polyposis (for initial requests): Member's chart or medical record showing nasal endoscopy or anterior rhinoscopy details (e.g., location, size).

Prescriber Specialties

This medication must be prescribed by or in consultation with one of the following:

A. Atopic dermatitis: dermatologist or allergist/immunologist
B. Asthma: allergist/immunologist or pulmonologist
C. Chronic rhinosinusitis with nasal polyposis: allergist/immunologist or otolaryngologist

Criteria for Initial Approval

A. Moderate-to-severe atopic dermatitis

Authorization of **4 months** may be granted for treatment of moderate-to-severe atopic dermatitis when all of the following criteria are met:

1. Member is 6 years of age or older
2. Affected body surface area is greater than or equal to 10% OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected..
3. Member has had an inadequate treatment response to ALL of the following in the past 180 days unless the member has a clinical reason to avoid:
    a. At least one medium or high potency topical corticosteroid (see Appendix) or topical calcineurin inhibitor (e.g., tacrolimus, pimecrolimus)
    b. Phototherapy (e.g., UVB, PUVA) or systemic treatment (e.g., immunosuppressants)

B. Moderate-to-severe asthma

Authorization of **6 months** may be granted for treatment of moderate-to-severe when all of the following criteria are met:

1. Member is 12 years of age or older
2. Member meets one of the following criteria:
    a. Member has inadequate asthma control (e.g. hospitalization or emergency medical care visit within the past year) despite current treatment with all of the following medications at optimized doses*:
        i. High-dose inhaled corticosteroid
        ii. Additional controller (long-acting beta-2 agonist, leukotriene modifier, or sustained-release theophylline)
        iii. Oral glucocorticoids at maintenance dosing

        * Members should be receiving treatment with inhaled corticosteroid and additional controller for at least the previous 3 months, and oral glucocorticoids for most days during the previous 6 months (e.g. 50% of days, 3 steroid bursts in the previous 6 months).
    b. Member has a baseline blood eosinophil count of at least 150 cells per microliter and asthma is inadequately controlled despite treatment for at least 3 months with both of the following at optimized doses:
        i. Medium-to-high-dose inhaled corticosteroid
        ii. Additional controller (long acting beta2-agonist, leukotriene modifier, or sustained-release theophylline)
3. Member will not use Dupixent as monotherapy
4. Member will not use Dupixent concomitantly with other biologics (e.g., Cinqair, Fasenra, Nucala or Xolair).

C. Chronic rhinosinusitis with nasal polyposis (CRSwNP)

Authorization of **6 months** may be granted for treatment of CRSwNP in members 18 years of age or older when all of the following criteria are met:

1. Member has bilateral nasal polyposis and chronic symptoms of sinusitis despite intranasal corticosteroid treatment for at least 2 months unless contraindicated or not tolerated; and
2. The member has CRSwNP despite one of the following:
   a. Prior sino-nasal surgery; or
   b. Prior treatment with systemic corticosteroids within the last two years was ineffective, unless contraindicated or not tolerated; and
3. 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
4. Member has nasal obstruction plus one additional symptom:
   a. Rhinorrhea (anterior/posterior); or
   b. Reduction or loss of smell; and
5. Member will be using a daily intranasal corticosteroid while being treated with Dupixent, unless contraindicated or not tolerated.

Continuation of Therapy

A. Moderate-to-severe atopic dermatitis

Authorization of **6 months** may be granted for continuation of treatment for members 6 years of age or older who achieve or maintain positive clinical response for **moderate-to-severe atopic dermatitis** as evidenced by low disease activity (i.e., clear or almost clear skin) or improvement in signs and symptoms of atopic dermatitis (e.g., redness, itching, oozing/crusting).

B. Moderate-to-severe asthma

Authorization of **12 months** may be granted for continuation of treatment for members 12 years of age or older when all of the following criteria are met:

1. Member has achieved and maintained positive clinical response with Dupixent therapy for asthma as evidenced by at least one of the following:
   a. A reduction in the frequency or severity of symptoms and exacerbations
   b. A reduction in the daily maintenance oral corticosteroid dose
2. Member will not use Dupixent as monotherapy
3. Member will not use Dupixent concomitantly with other biologics (e.g., Cinqair, Fasenra, Nucala or Xolair)

C. Chronic rhinosinusitis with nasal polyposis (CRSwNP)

Authorization of 12 months may be granted for members 18 years of age or older who achieve or maintain positive clinical response to Dupixent therapy as evidenced by improvement in signs and symptoms 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).

*Note: If the member 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 cessastion options.

Dupixent is considered **not medically necessary** for members who do not meet the criteria set forth above.

Quantity Limits Apply

Medication	Standard Limit	FDA-recommended dosing
Dupixent 200 mg/ 1.14 mL pre-filled syringe	Initiation of therapy: 4 syringes per first 28 days Maintenance: 2 syringes per 28 days	Atopic Dermatitis • Adults and adolescents weighing ≥ 60 kg: Initial dose of 600 mg (two 300 mg injections), followed by 300 mg every other week. • Pediatric patients weighing 30 to < 60 kg: Initial dose of 400 mg (two 400 mg injections), followed by 200 mg every other week • Pediatric patients weighing 15 to < 30 kg: Initial dose of 600 mg (two 300 mg injections), followed by 300 mg every 4 weeks. Asthma • Initial dose of 400 mg (two 200 mg injections), followed by 200 mg every other week, or • Initial dose of 600 mg (two 300 mg injections), followed by 300 mg every other week • Patients with oral corticosteroid-dependent asthma, or with co-morbid moderate-to-severe atopic dermatitis for which Dupixent is indicated: initial dose of 600 mg followed by 300 mg every other week Chronic rhinosinusitis with nasal polyposis (CRSwNP) • 300 mg every other week
Dupixent 300 mg/ 2 mL pre-filled syringe	Initiation of therapy: 4 syringes per first 28 days Maintenance: 2 syringes per 28 days	

Appendix

Relative potency of select topical corticosteroid products			
Potency	**Drug**	**Dosage form**	**Strength**
I. Very high potency	Augmented betamethasone dipropionate	Ointment, Gel	0.05%
	Clobetasol propionate	Cream, Ointment	0.05%
	Diflorasone diacetate	Ointment	0.05%
	Halobetasol propionate	Cream, Ointment	0.05%
II. High potency	Amcinonide	Cream, Lotion, Ointment	0.1%
	Augmented betamethasone dipropionate	Cream, Lotion	0.05%
	Betamethasone dipropionate	Cream, Ointment	0.05%
	Betamethasone valerate	Ointment	0.1%
	Desoximetasone	Cream, Ointment	0.25%
		Gel	0.05%
	Diflorasone diacetate	Cream, Ointment (emollient base)	0.05%
	Fluocinonide	Cream, Ointment, Gel	0.05%
	Halcinonide	Cream, Ointment	0.1%
	Triamcinolone acetonide	Cream, Ointment	0.5%
III. Medium potency	Betamethasone dipropionate	Lotion	0.05%
	Betamethasone valerate	Cream	0.1%
	Clocortolone pivalate	Cream	0.1%
	Desoximetasone	Cream	0.05%
	Fluocinolone acetonide	Cream, Ointment	0.025%

Relative potency of select topical corticosteroid products			
Potency	**Drug**	**Dosage form**	**Strength**
	Flurandrenolide	Cream, Ointment, Lotion	0.05%
		Tape	4 mcg/cm^2
	Fluticasone propionate	Cream	0.05%
		Ointment	0.005%
	Hydrocortisone butyrate	Ointment, Solution	0.1%
	Hydrocortisone valerate	Cream, Ointment	0.2%
	Mometasone furoate	Cream, Ointment, Lotion	0.1%
	Prednicarbate	Cream, Ointment	0.1%
	Triamcinolone acetonide	Cream, Ointment, Lotion	0.025%, 0.1%
IV. Low potency	Alclometasone dipropionate	Cream, Ointment	0.05%
	Desonide	Cream	0.05%
	Fluocinolone acetonide	Cream, Solution	0.01%
	Hydrocortisone	Lotion	0.25%
		Cream, Ointment, Lotion, Aerosol	0.5%
		Cream, Ointment, Lotion, Solution	1%
		Cream, Ointment, Lotion	2.5%
	Hydrocortisone acetate	Cream, Ointment	0.5%, 1%

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

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POLICY HISTORY

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