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 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) Dupixent is indicated as an add-on maintenance treatment in patients with moderate-to-severe asthma aged 6 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).
4) Dupixent is indicated for the treatment of adult and pediatric patients aged 12 years and older, weighing at least 40 kg, with eosinophilic esophagitis (EoE).

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

1. Initial requests: Member's chart notes or medical record documentation and claims history of prerequisite therapies (see Criteria for Initial Approval A.2) including dosage, duration, and response to therapy.
2. Continuation requests: Documentation (e.g., chart notes) that the member has experienced a positive clinical response to therapy as evidenced by low disease activity or improvement in signs or symptoms of atopic dermatitis.

B. Asthma

1. Initial requests:
   i. Member's chart or medical record showing pretreatment blood eosinophil count (where applicable).
   ii. Chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency, and duration.
2. Continuation requests: Chart notes or medical record documentation of positive clinical response.

C. Chronic rhinosinusitis with nasal polyposis

1. Initial requests:
   i. Member's chart or medical record showing nasal endoscopy, anterior rhinoscopy details, or computed tomography (CT) (e.g., location, size), or Meltzer Clinical Score or endoscopic nasal polyps score (NPS) (where applicable).
   ii. Chart notes, medical record documentation, or claims history supporting previous medications tried. If therapy is not advisable, documentation of clinical reason to avoid therapy.
2. Continuation requests: Chart notes or medical record documentation of positive clinical response.

D. **Eosinophilic esophagitis**

1. For initial requests:
   i. Member's chart or medical record showing endoscopic biopsy details including intraepithelial esophageal eosinophil count.
   ii. Chart notes, medical record documentation, or claims history supporting previous medications tried. If therapy is not advisable, documentation of clinical reason to avoid therapy.
2. For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

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
D. Eosinophilic esophagitis: gastroenterologist or allergist/immunologist

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 in members 6 months of age or older when all of the following criteria are met:

1. 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.
2. Member meets one of the following:

i. Member has had an inadequate treatment response to one of the following in the past 180 days:
   a) A high potency or super-high potency topical corticosteroid (see Appendix)
   b) A topical calcineurin inhibitor
ii. The use of high potency or super-high potency topical corticosteroids and topical calcineurin inhibitors are not advisable for the member (e.g., due to contraindications, prior intolerances, potency not appropriate for member's age)

3. Member's dose will not exceed the following:
   i. Adult members: Initial 600 mg dose followed by 300 mg every other week
   ii. Pediatric members (6 months to 5 years of age) 5 kg to less than 15 kg: 200 mg every 4 weeks
   iii. Pediatric members (6 months to 5 years of age) 15 kg to less than 30 kg: 300 mg every 4 weeks
   iv. Pediatric members (6 to 17 years of age) 15 kg to less than 30 kg: Initial 600 mg dose followed by 300 mg every 4 weeks
   v. Pediatric members (6 to 17 years of age) 30 kg to less than 60 kg: Initial 400 mg dose followed by 200 mg every other week
   vi. Pediatric members (6 to 17 years of age) 60 kg or more: Initial 600 mg dose followed by 300 mg every other week
4. Member will not use Dupixent concomitantly with other biologics or JAK inhibitors indicated for atopic dermatitis.

B. Moderate-to-severe asthma

Authorization of **6 months** may be granted for treatment of moderate-to-severe asthma in members 6 years of age or older when all of the following criteria are met:

1. Member has uncontrolled asthma as demonstrated by experiencing at least one of the following within the past year:
   i. Two or more asthma exacerbations requiring oral or injectable corticosteroid treatment.
   ii. One or more asthma exacerbation resulting in hospitalization or emergency medical care visit.
   iii. Poor symptom control (frequent symptoms or reliever use, activity limited by asthma, night waking due to asthma).
2. Member meets one of the following criteria:
   i. 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:
      a. Medium-to-high-dose inhaled corticosteroid
         1. Adult and adolescent members (12 years age and older): greater than 250 microgram total daily dose of fluticasone propionate or equivalent
         2. Pediatric members (6 to 11 years of age): greater than 100 microgram total daily dose of fluticasone propionate or equivalent
      b. Additional controller (long acting beta-2agonist, long acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline)
   ii. Member has inadequate asthma control despite current treatment with all of the following medications at optimized doses*:
      a. High-dose inhaled corticosteroid
         1. Adult and adolescent members (12 years of age and older): greater than 500 microgram total daily dose of fluticasone propionate or equivalent)
         2. Pediatric members (6 to 11 years of age): greater than 200 microgram total daily dose of fluticasone propionate or equivalent

b. Additional controller (long-acting beta-2 agonist, long acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline)
c. Oral glucocorticoids (at least 5 mg per day of prednisone/prednisolone or equivalent)

* 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).

3. Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with Dupixent.
4. Member will not use Dupixent concomitantly with other biologics indicated for asthma (e.g., Cinqair, Fasenra, Nucala, Tezspire or Xolair).
5. Member's dose will not exceed the following:
   i. Adult and adolescent members (12 years of age and older): Initial dose 600 mg followed by 300 mg every other week or initial dose 400 mg followed by 200 mg every other week
   ii. Adult and adolescent members (12 years of age and older) with co-morbid moderate-to-severe atopic dermatitis: initial dose 600 mg followed by 300 mg every other week
   iii. Pediatric members (6 to 11 years of age) 15 to less than 30 kg: 100 mg every other week or 300 mg every four weeks
   iv. Pediatric members (6 to 11 years of age) ≥ 30 kg: 200 mg every other week
   v. Pediatric members (6 to 11 years of age) with co-morbid moderate-to-severe atopic dermatitis:
      a. 15 kg to less than 30 kg: Initial 600 mg dose followed by 300 mg every 4 weeks
      b. 30 kg to less than 60 kg: Initial 400 mg dose followed by 200 mg every other week
      c. 60 kg or more: Initial 600 mg dose followed by 300 mg every other week

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:
   i. Prior sino-nasal surgery; or
   ii. Prior treatment with systemic corticosteroids within the last two years was ineffective, unless contraindicated or not tolerated; and
3. Member has one of the following:
   i. 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
   ii. Meltzer Clinical Score of 2 or higher in both nostrils
   iii. A total endoscopic nasal polyp score (NPS) of at least 5 with a minimum score of 2 for each nostril
4. Member has nasal blockage plus one additional symptom:
   i. Rhinorrhea (anterior/posterior); or
   ii. Reduction or loss of smell; or
   iii. Facial pain or pressure
5. Member will continue to use a daily intranasal corticosteroid while being treated with Dupixent, unless contraindicated or not tolerated.
6. Member's dose will not exceed the following:
   i. 300 mg every other week
   ii. Members with co-morbid moderate-to-severe asthma: initial dose of 600 mg followed by 300 mg every other week
7. Member will not use Dupixent concomitantly with other biologics indicated for nasal polyps (e.g., Nucala, Xolair)

D. Eosinophilic esophagitis (EoE)

Authorization of 6 months may be granted for treatment of EoE in members 12 years of age or older, weighing at least 40 kg, when all of the following criteria are met:

1. Member has history of an average of at least 2 episodes of dysphagia (with intake of solids) per week
2. Diagnosis has been confirmed by esophageal biopsy as characterized by 15 or more intraepithelial esophageal eosinophils per high power field
3. Member has had an inadequate treatment response to both of the following:
    i. Proton pump inhibitor
    ii. Systemic corticosteroid or local therapies (e.g., budesonide, fluticasone [powder or suspension for inhalation] swallowed), unless contraindicated or not tolerated.
4. Member's dose will not exceed 300 mg every week

Continuation of Therapy

A. Moderate-to-severe atopic dermatitis

Authorization of **6 months** may be granted for members 6 months of age or older when all of the following criteria is met:

1. Member has achieved or maintained a positive clinical response with Dupixent therapy 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).
2. Member's dose will not exceed the following:
    i. Adult members: Initial 600 mg dose followed by 300 mg every other week
    ii. Pediatric members (6 months to 5 years of age) 5 kg to less than 15 kg: 200 mg every 4 weeks
    iii. Pediatric members (6 months to 5 years of age) 15 kg to less than 30 kg: 300 mg every 4 weeks
    iv. Pediatric members (6 to 17 years of age) 15 kg to less than 30 kg: Initial 600 mg dose followed by 300 mg every 4 weeks
    v. Pediatric members (6 to 17 years of age) 30 kg to less than 60 kg: Initial 400 mg dose followed by 200 mg every other week
    vi. Pediatric members (6 to 17 years of age) 60 kg or more: Initial 600 mg dose followed by 300 mg every other week
3. Member will not use Dupixent concomitantly with other biologics or JAK inhibitors indicated for atopic dermatitis.

B. Moderate-to-severe asthma

Authorization of **12 months** may be granted for continuation of treatment of moderate-to-severe asthma in members 6 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:
    i. A reduction in the frequency and/or severity of symptoms and exacerbations
    ii. A reduction in the daily maintenance oral corticosteroid dose
2. Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with Dupixent.
3. Member will not use Dupixent concomitantly with other biologics indicated for asthma (e.g., Cinqair, Fasenra, Nucala, Tezspire or Xolair)
4. Member's dose will not exceed Member's dose will not exceed the following:
    i. Adult and adolescent members (12 years of age and older): Initial dose 600 mg followed by 300 mg every other week or initial dose 400 mg followed by 200 mg every other week

ii. Adult and adolescent members (12 years of age and older) with co-morbid moderate-to-severe atopic dermatitis: initial dose 600 mg followed by 300 mg every other week
iii. Pediatric members (6 to 11 years of age) 15 to less than 30 kg: 100 mg every other week or 300 mg every four weeks
iv. Pediatric members (6 to 11 years of age) ≥ 30 kg: 200 mg every other week
v. Pediatric members (6 to 11 years of age) with co-morbid moderate-to-severe atopic dermatitis:
    a. 15 kg to less than 30 kg: Initial 600 mg dose followed by 300 mg every 4 weeks
    b. 30 kg to less than 60 kg: Initial 400 mg dose followed by 200 mg every other week
    c. 60 kg or more: Initial 600 mg dose followed by 300 mg every other week

C. Chronic rhinosinusitis with nasal polyposis (CRSwNP)

Authorization of 12 months may be granted for continuation of treatment of chronic rhinosinusitis with nasal polyposis in members 18 years of age or older when all of the following are met:

1. Member has achieved or maintained 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)
2. Member's dose will not exceed 300 mg every other week
3. Member will not use Dupixent concomitantly with other biologics indicated for nasal polyps (e.g., Nucala, Xolair)

D. Eosinophilic Esophagitis

Authorization of 12 months may be granted for continuation of treatment of eosinophilic esophagitis in members 12 years of age or older, weighing at least 40 kg, when all of the following are met:

1. Member has achieved or maintained positive clinical response with Dupixent therapy as evidenced by improvement in signs and symptoms of eosinophilic esophagitis (e.g., dysphagia, heartburn, chest pain, emesis).
2. Member's dose will not exceed 300 mg every week

For all indications: Member cannot use Dupixent concomitantly with any other biologic drug or targeted synthetic drug.

*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 cessation options.

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

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits

<table>
<tr><th>Medication</th><th>Standard Limit</th><th>FDA-recommended dosing</th></tr>
<tr><td>Dupixent 100 mg/ 0.67 mL pre-filled syringe</td><td>Maintenance:
2 syringes per 28 days</td><td rowspan="3">Atopic dermatitis
• Adults and adolescents weighing ≥ 60 kg: Initial dose of 600 mg (two 300 mg injections), followed by 300 mg every other week.
<u>Age 6 months to 5 years:</u>
• Body weight 5 to < 15 kg: 200 mg every four weeks
• Body weight 15 to < 30 kg: 300 mg every four weeks
<u>Age 6 to 17 years:</u>
• Body weight 15 to < 30 kg: Initial dose of 600 mg (two 300 mg injections), followed by 300 mg every 4 weeks.
• Body weight 30 to < 60 kg: Initial dose of 400 mg (two 200 mg injections), followed by 200 mg every other week
Asthma (patients 12 years of age and older)
• 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
Asthma (patients 6-11 years of age)
• Body weight 15 to less than 30 kg: 100 mg every other week OR 300 mg every 4 weeks
• Body weight ≥ 30 kg: 200 mg every other week
Chronic rhinosinusitis with nasal polyposis (CRSwNP)
• 300 mg every other week
Eosinophilic esophagitis
• 300 mg every week</td></tr>
<tr><td>Dupixent 200 mg/ 1.14 mL pre-filled syringe or pen-injector</td><td>Initiation of therapy*:
4 syringes/pens per first 28 days

Maintenance:
2 syringes/pens per 28 days</td></tr>
<tr><td>Dupixent 300 mg/ 2 mL pre-filled syringe or pen-injector</td><td>Initiation of therapy*:
4 syringes/pens per first 28 days

Maintenance:
2 syringes/pens per 28 days

Maintenance (EoE):
4 syringes/pens per 28 days</td></tr>
</table>

*Loading doses do not apply to patients 6 months to 5 years of age with atopic dermatitis, patients 6-11 years of age with asthma, eosinophilic esophagitis, and chronic rhinosinusitis with nasal polyposis.

<u>Appendix</u>

Relative potency of select topical corticosteroid products			
Potency	**Drug**	**Dosage form**	**Strength**
I. Super-high potency (group 1)	Augmented betamethasone dipropionate	Ointment, Lotion, Gel	0.05%
	Clobetasol propionate	Cream, Gel, Ointment, Solution, Cream (emollient), Lotion, Shampoo, Foam, Spray	0.05%

Relative potency of select topical corticosteroid products			
Potency	**Drug**	**Dosage form**	**Strength**
	Fluocinonide	Cream	0.1%
	Flurandrenolide	Tape	4 mcg/cm^2
	Halobetasol propionate	Cream, Lotion, Ointment, Foam	0.05%
II. High potency (group 2)	Amcinonide	Ointment	0.1%
	Augmented betamethasone dipropionate	Cream	0.05%
	Betamethasone dipropionate	Ointment	0.05%
	Clobetasol propionate	Cream	0.025%
	Desoximetasone	Cream, Ointment, Spray	0.25%
		Gel	0.05%
	Diflorasone diacetate	Ointment, Cream (emollient)	0.05%
	Fluocinonide	Cream, Ointment, Gel, Solution	0.05%
	Halcinonide	Cream, Ointment	0.1%
	Halobetasol propionate	Lotion	0.01%
III. High potency (group 3)	Amcinonide	Cream, Lotion	0.1%
	Betamethasone dipropionate	Cream, hydrophilic emollient	0.05%
	Betamethasone valerate	Ointment	0.1%
		Foam	0.12%
	Desoximetasone	Cream, Ointment	0.05%
	Diflorasone diacetate	Cream	0.05%
	Fluocinonide	Cream, aqueous emollient	0.05%
	Fluticasone propionate	Ointment	0.005%
	Mometasone furoate	Ointment	0.1%
	Triamcinolone acetonide	Cream, Ointment	0.5%
IV. Medium potency (group 4)	Betamethasone dipropionate	Spray	0.05%
	Clocortolone pivalate	Cream	0.1%
	Fluocinolone acetonide	Ointment	0.025%
	Flurandrenolide	Ointment	0.05%
	Hydrocortisone valerate	Ointment	0.2%
	Mometasone furoate	Cream, Lotion, Solution	0.1%
	Triamcinolone acetonide	Cream	0.1%
		Ointment	0.05% and 0.1%
		Aerosol Spray	0.2 mg per 2-second spray
V. Lower-mid potency (group 5)	Betamethasone dipropionate	Lotion	0.05%
	Betamethasone valerate	Cream	0.1%
	Desonide	Ointment, Gel	0.05%
	Fluocinolone acetonide	Cream	0.025%
	Flurandrenolide	Cream, Lotion	0.05%
	Fluticasone propionate	Cream, Lotion	0.05%
	Hydrocortisone butyrate	Cream, Lotion, Ointment, Solution	0.1%
	Hydrocortisone probutate	Cream	0.1%

Relative potency of select topical corticosteroid products			
Potency	**Drug**	**Dosage form**	**Strength**
	Hydrocortisone valerate	Cream	0.2%
	Prednicarbate	Cream (emollient), Ointment	0.1%
	Triamcinolone acetonide	Lotion	0.1%
		Ointment	0.025%
VI. Low potency (group 6)	Alclometasone dipropionate	Cream, Ointment	0.05%
	Betamethasone valerate	Lotion	0.1%
	Desonide	Cream, Lotion, Foam	0.05%
	Fluocinolone acetonide	Cream, Solution, Shampoo, Oil	0.01%
	Triamcinolone acetonide	Cream, Lotion	0.025%
VII. Least potent (group 7)	Hydrocortisone (base, less than 2%)	Cream, Ointment, Solution	2.5%
		Lotion	2%
		Cream, Ointment, Gel, Lotion, Spray, Solution	1%
		Cream, Ointment	0.5%
	Hydrocortisone acetate	Cream	2.5%
		Lotion	2%
		Cream	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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