

Reference number(s)
1690-A

SPECIALTY GUIDELINE MANAGEMENT

DUPIXENT (dupilumab)

POLICY

I. INDICATIONS

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

FDA-Approved Indications

- A. 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.
- B. 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.
- C. 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

All other indications are considered experimental/investigational and not medically necessary.

II. 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 showing prerequisite therapies (see section III.A.2).
- B. **Asthma**
 1. For 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. For continuation requests: Chart notes or medical record documentation supporting improvement in asthma control.
- C. **Chronic rhinosinusitis with nasal polyposis**
 1. For initial requests:
 - i. Member's chart or medical record showing nasal endoscopy or anterior rhinoscopy details (e.g., location, size).
 - 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.

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III. 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 years of age or older when all of the following criteria is met:

1. Affected body surface is greater than or equal to 10% body surface area OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
2. Member has had an inadequate treatment response to a high potency or super-high potency topical corticosteroid (see Appendix) or a topical calcineurin inhibitor in the past 180 days, or the use of topical corticosteroids and topical calcineurin inhibitors is not advisable for the member (e.g., due to contraindications or prior intolerances).

B. Asthma

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

1. Member meets one of the following criteria:
 - i. 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*:
 - a. High-dose inhaled corticosteroid
 - b. Additional controller (long acting beta2-agonist, 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).⁶
 - ii. Member has a baseline blood eosinophil count of at least 150 cells per microliter and inadequate asthma control (e.g. hospitalization or emergency medical care visit within the past year) despite current treatment with both of the following medications at optimized doses:
 - a. Inhaled corticosteroid
 - b. Additional controller (long acting beta2-agonist, leukotriene modifier, or sustained-release theophylline)
2. Member will not use Dupixent as monotherapy
3. Member will not use Dupixent concomitantly with other biologics indicated for asthma (e.g., Cinqair, Fasentra, 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:
 - 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 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 blockage plus one additional symptom:
 - i. Rhinorrhea (anterior/posterior); or
 - ii. Reduction or loss of smell; and

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- Member will be using a daily intranasal corticosteroid while being treated with Dupixent, unless contraindicated or not tolerated.

IV. CONTINUATION OF THERAPY

A. Moderate-to-severe atopic dermatitis

Authorization of 12 months may be granted for members 6 years of age or older who achieve or maintain 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).

B. Asthma

Authorization of 12 months may be granted for continuation of treatment of asthma in members 6 years of age or older when all of the following criteria are met:

- Asthma control has improved on Dupixent treatment as demonstrated by at least one of the following:
 - A reduction in the frequency and/or severity of symptoms and exacerbations
 - A reduction in the daily maintenance oral corticosteroid dose
- Member will not use Dupixent as monotherapy
- Member will not use Dupixent concomitantly with other biologics indicated for asthma (e.g., Cinqair, Fasena, Nucala, or Xolair)

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 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).

V. OTHER

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.

VI. APPENDIX

Table. 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%
	Fluocinonide	Cream	0.1%
	Flurandrenolide	Tape	4 mcg/cm ²
	Halobetasol propionate	Cream, Lotion, Ointment	0.05%
II. High potency (group 2)	Amcinonide	Ointment	0.1%
	Augmented betamethasone dipropionate	Cream	0.05%
	Betamethasone dipropionate	Ointment	0.05%

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Potency	Drug	Dosage form	Strength
	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%
Potency	Drug	Dosage form	Strength
III. High potency (group 3)	Amcinonide	Cream Lotion	0.1%
	Betamethasone dipropionate	Cream, hydrophilic emollient	0.05%
		Ointment	0.1%
		Foam	0.12%
	Desoximetasone	Cream	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%
	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%

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Potency	Drug	Dosage form	Strength
	Fluocinolone acetonide	Cream, Solution, Shampoo, Oil	0.01%
	Triamcinolone acetonide	Cream, lotion	0.025%
VII. Least potent (group 7)	Hydrocortisone	Cream, Ointment, Solution	2.5%
		Lotion	2%
		Cream, Ointment, Gel, Lotion, Spray, Solution	1%
	Hydrocortisone acetate	Cream, Ointment	0.5%
		Cream	2.5%
		Lotion	2%

VII. REFERENCES

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9. ClinicalTrials.gov. National Library of Medicine (US). Identifier NCT02898454, A Controlled Clinical Study of Dupilumab in Patients with Nasal Polyps (SINUS-52) 2016 Sep 13. Available from: <https://clinicaltrials.gov/ct2/show/NCT02898454>.