

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.

A. 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.

Limitation of Use: Dupixent is not indicated for the relief of acute bronchospasm or status asthmaticus

3. Dupixent is indicated as an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyps (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).
5. Dupixent is indicated for the treatment of adult patients with prurigo nodularis (PN).

B. Compendial Uses

Immune checkpoint inhibitor-related toxicities

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**

1. For initial requests:
 - i. Member's chart notes or medical records showing affected area(s) and body surface area (where applicable).
 - ii. Member's chart notes, medical record documentation, or claims history of prerequisite therapies including response to therapy. If prerequisite therapies are not advisable, documentation of why therapies are not advisable for the member.
2. For 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.

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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, anterior rhinoscopy, or computed tomography (CT) details (e.g., location, size), or Meltzer Clinical Score or endoscopic nasal polyp 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. For continuation requests: Chart notes or medical record documentation supporting 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.

E. Prurigo Nodularis

1. For initial requests:
 - i. Member's chart or medical record of symptoms (e.g., pruritus, nodular lesions).
 - ii. Member's chart, medical record, or claims history of prerequisite therapies including response to therapy. 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.

III. 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
- E. Prurigo nodularis: dermatologist or allergist/immunologist

IV. CRITERIA FOR INITIAL APPROVAL

A. Atopic dermatitis

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

B. Asthma

1. Authorization of 6 months may be granted for members 6 years of age or older who have previously received a biologic drug (e.g., Nucala, Cinqair) indicated for asthma.
2. 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:
 - i. Member has uncontrolled asthma as demonstrated by experiencing at least one of the following within the past year:
 - a. Two or more asthma exacerbations requiring oral or injectable corticosteroid treatment.
 - b. One or more asthma exacerbation resulting in hospitalization or emergency medical care visit.
 - c. Poor symptom control (frequent symptoms or reliever use, activity limited by asthma, night waking due to asthma).
 - ii. Member meets either of the following criteria:
 - a. Member has a baseline blood eosinophil count of at least 150 cells per microliter and inadequate asthma control despite current treatment with both of the following medications at optimized doses:
 1. Medium-to-high-dose inhaled corticosteroid
 2. Additional controller (i.e., long acting beta2-agonist, long acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline)
 - b. Member has inadequate asthma control despite current treatment with all of the following medications at optimized doses*:
 1. High-dose inhaled corticosteroid
 2. Additional controller (i.e., long acting beta2-agonist, long acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline)
 3. Oral glucocorticoids (at least 5 mg per day of prednisone/prednisolone or equivalent)
 - iii. Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with the requested medication.

C. Chronic rhinosinusitis with nasal polyposis (CRSwNP)

1. Authorization of 6 months may be granted for adult members who have previously received a biologic drug (e.g., Nucala, Xolair) indicated for CRSwNP.
2. 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:
 - i. Member has bilateral nasal polyposis and chronic symptoms of sinusitis despite intranasal corticosteroid treatment for at least 2 months unless contraindicated or not tolerated

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- ii. The member has CRSwNP despite one of the following:
 - a. Prior sino-nasal surgery
 - b. Prior treatment with systemic corticosteroids within the last two years was ineffective, unless contraindicated or not tolerated
- iii. Member has one of the following:
 - a. 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
 - b. Meltzer Clinical Score of 2 or higher in both nostrils
 - c. A total endoscopic nasal polyp score (NPS) of at least 5 with a minimum score of 2 for each nostril
- iv. Member has symptoms of nasal blockage, congestion, or obstruction plus one of the following additional symptoms:
 - a. Rhinorrhea (anterior/posterior)
 - b. Reduction or loss of smell
 - c. Facial pain or pressure
- v. Member will continue to use a daily intranasal corticosteroid while being treated with the requested medication, unless contraindicated or not tolerated.

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 oral topical corticosteroid therapies (e.g., budesonide, fluticasone [powder or suspension for inhalation] swallowed), unless contraindicated or not tolerated.

E. Prurigo Nodularis

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

- 1. Member must have pruritus lasting at least 6 weeks.
- 2. Member has history or signs of repeated itch-scratch cycle (e.g., scratching, picking, or rubbing).
- 3. Member must have a minimum of 20 nodular lesions.
- 4. Member meets one of the following:
 - i. Member has had an inadequate response to one of the following:
 - a. A medium to super-high potency topical corticosteroid (see Appendix A)
 - b. A topical calcineurin inhibitor
 - c. Phototherapy (e.g., UVB, PUVA)
 - d. Pharmacologic treatment with methotrexate or cyclosporine
 - ii. Member has had an intolerance or a clinical reason to avoid any of the following:
 - a. Medium to super-high potency topical corticosteroid (see Appendix A) and topical calcineurin inhibitor
 - b. Pharmacologic treatment with methotrexate and cyclosporine (see Appendix B)

F. Immune checkpoint inhibitor-related toxicity

Authorization of 1 month may be granted for treatment of immune checkpoint inhibitor-related toxicity when member has a refractory case of immune-therapy related severe (G3) pruritus.

V. CONTINUATION OF THERAPY

A. Atopic dermatitis

Authorization of 12 months may be granted for members 6 months of age or older (including new members) who are using the requested medication for moderate-to-severe atopic dermatitis when the member has achieved or maintained a positive clinical response 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 moderate-to-severe asthma in members 6 years of age or older when all of the following criteria are met:

1. Asthma control has improved on the requested medication as demonstrated 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 the requested medication.

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 with the requested medication 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 will continue to use a daily intranasal corticosteroid while being treated with the requested medication, unless contraindicated or not tolerated.

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 member has achieved or maintained a positive clinical response with the requested medication as evidenced by improvement in signs and symptoms of eosinophilic esophagitis (e.g., dysphagia, heartburn, chest pain, emesis).

E. Prurigo Nodularis

Authorization of 12 months may be granted for members 18 years of age or older (including new members) who are using the requested medication for prurigo nodularis when the member has achieved or maintained a positive clinical response as evidenced by one of the following:

1. Low disease activity (i.e., clear or almost clear skin).
2. Reduction in pruritis intensity and improvement in extent and severity of nodular lesions.

F. Immune checkpoint inhibitor-related toxicities

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

VI. OTHER

For all indications: Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

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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.

VII. APPENDICES

Appendix A: Table. Relative potency of select topical corticosteroid products⁹

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, 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%
Potency	Drug	Dosage form	Strength
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%
IV. Medium potency (group 4)	Triamcinolone acetonide	Cream, Ointment	0.5%
	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%

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Potency	Drug	Dosage form	Strength
		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%
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, greater than or equal to 2%)	Cream, Ointment, Solution	2.5%
		Lotion	2%
	Hydrocortisone (base, less than 2%)	Cream, Ointment, Gel, Lotion, Spray, Solution	1%
		Cream, Ointment	0.5%
	Hydrocortisone acetate	Cream	2.5%
		Lotion	2%
		Cream	1%

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

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

VIII. REFERENCES

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