Effective Date: 3/2018
Revised: 9/2019 Reviewed: 3/2018, 9/2019 Scope: Medicaid, Exchange SHOP 2018-2019

ENHANCED 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 12 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 12 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 are not a covered benefit.

II. DOCUMENTATION

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

A. Atopic dermatitis (initial requests): Member's chart or medical record showing prerequisite therapies and affected area(s) and body surface area (see section IV.A.1).
B. Asthma (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 CT, nasal endoscopy or anterior rhinoscopy details (e.g., location, size).

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, otolaryngologist or pulmonologist

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IV. 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 12 years 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 has had an inadequate treatment response to a topical calcineurin inhibitor and at least one medium or higher potency topical corticosteroids in the past 180 days, OR topical corticosteroids or topical calcineurin inhibitors are not advisable for the member.

B. Moderate-to-severe asthma

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

1. Member meets one of the following criteria (a OR b):
    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 beta2-agonist + Tiotropium +/- leukotriene modifier), unless contraindicated or not tolerated)
        iii. Oral glucocorticoids (at least 5 mg per day of prednisone/prednisolone or equivalent or 3 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 + Tiotropium +/- leukotriene modifier), unless contraindicated or not tolerated
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 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, anterior rhinoscopy, or CT showing polyps; 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.

V. CONTINUATION OF THERAPY

A. Moderate-to-severe atopic dermatitis

Authorization of 12 months may be granted for members 12 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. Moderate-to-severe asthma

Authorization of 12 months may be granted 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 and/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).

VI. 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%
II. High potency	Augmented betamethasone dipropionate	Cream, Lotion	0.05%
	Betamethasone dipropionate	Cream	0.05%
	Betamethasone valerate	Ointment	0.1%
	Fluocinonide	Ointment, Gel	0.05%
	Triamcinolone acetonide	Cream, Ointment	0.5%
III. Medium potency	Betamethasone dipropionate	Lotion	0.05%
	Betamethasone valerate	Cream	0.1%
	Fluocinolone acetonide	Cream, Ointment	0.025%
	Fluticasone propionate	Cream	0.05%
		Ointment	0.005%
	Mometasone furoate	Ointment	0.1%
	Triamcinolone acetonide	Cream, Ointment, Lotion	0.025%, 0.1%

Potency	Drug	Dosage form	Strength
IV. Low potency	Desonide	Cream	0.05%
	Fluocinolone acetonide	Cream, Solution	0.01%
	Hydrocortisone	Cream, Ointment	0.5%
		Cream, Ointment	1%
		Cream, Ointment	2.5%

VII. REFERENCES

1. Dupixent [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; June 2019.
2. Eichenfield LF, Tom WL, et. al. Guidelines of care for the management of atopic dermatitis: Section 2. Management and treatment of atopic dermatitis with topical therapies. *J Am Acad Dermatol.* 2014;71:116-32.
3. Simpson E.L., et al. Two phase 3 trials of dupilumab versus placebo in atopic dermatitis. *N Engl J Med.* 2016 [Epub ahead of print].
4. Topical Corticosteroids. *Drug Facts and Comparisons.* Facts & Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health Inc; March 18, 2019. Accessed March 27, 2019.
5. Castro M, Corren J, Pavord ID, et al. Dupilumab Efficacy and Safety in Moderate-to-Severe Uncontrolled Asthma. The New England Journal Of Medicine. 2018;378(26):2486-2496.
6. Rabe KF, Nair P, Brusselle G, et al. Efficacy and Safety of Dupilumab in Glucocorticoid-Dependent Severe Asthma. The New England Journal Of Medicine. 2018;378(26):2475-2485.
7. ClinicalTrials.gov. National Library of Medicine (US). Identifier NCT02912468, A Controlled Clinical Study of Dupilumab in Patients with Nasal Polyps (SINUS-24) 2016 Sep 23. Available from: https://clinicaltrials.gov/ct2/show/NCT02912468.
8. 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.