Effective Date: 3/2018
Revised: 9/2019, 6/2020, 11/2020, 3/2021 Reviewed: 3/2018, 9/2019, 6/2020, 11/2020, 3/2021, 12/2021, 9/2022, 1/2023, 3/2024 Scope: Medicaid

ENHANCED SPECIALTY GUIDELINE MANAGEMENT

DUPIXENT (dupilumab)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendia 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 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.
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).
D. Dupixent is indicated for the treatment of adult and pediatric patients aged 1 year and older, weighing at least 15 kg, with eosinophilic esophagitis (EoE).
E. Dupixent is indicated for the treatment of adult patients with prurigo nodularis (PN).

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
    a. 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.
    b. Continuation requests: Member's Chart notes or medical record documentation supporting improvement in asthma control.
C. Chronic rhinosinusitis with nasal polyposis
    a. Initial requests: Member's chart or medical record showing CT, nasal endoscopy or anterior rhinoscopy details (e.g., location, size).
    b. Continuation requests: members Chart notes or medical record documentation supporting positive clinical response.

D. Eosinophilic esophagitis
   a. Initial requests: Member's chart or medical record showing endoscopic biopsy details including intraepithelial esophageal eosinophil count and chart notes, medical record documentation, or claims history supporting previous medications tried.
   b. Continuation requests: Member's chart or medial record documentation supporting positive clinical response.

E. Prurigo Nodularis
   a. 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.
   b. 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, otolaryngologist or pulmonologist
D. Eosinophilic esophagitis: gastroenterologist or allergist/immunologist
E. Prurigo Nodularis: dermatologist or allergist/immunologist

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

Adults:

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 will not use Dupixent concomitantly with other biologics (e.g., Xolair, Remicade, Enbrel, Nucala, Adbry, etc.) or JAK inhibitors (e.g., Cibinqo, Rinvoq, etc.)
3. Member has tried and failed or had an inadequate response for at least 2-3 months to at least one medium-high to very high potency topical corticosteroid; AND
4. Member has tried and failed or had an inadequate response for at least 2-3 months to pimecrolimus, tacrolimus ointment or crisaborole (Eucrisa); AND
5. Member has tried and failed or had an inadequate response for at least 6 months to cyclosporine, azathioprine, methotrexate, or mycophenolate mofetil.

Pediatrics (6 months of age or older):

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 will not use Dupixent concomitantly with other biologics (e.g., Xolair, Remicade, Enbrel, Nucala, Adbry etc.) or JAK inhibitors (e.g., Cibinqo, Rinvoq, etc.)
3. Member has tried and failed or had an inadequate response for at least 2-3 months to at least one medium-high very high potency topical corticosteroid; AND
4. Member has tried and failed or had an inadequate response for at least 2-3 months to pimecrolimus, tacrolimus ointment or crisaborole (Eucrisa)

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 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 for at least 3 months at optimized doses:
      i. High-dose inhaled corticosteroid
      ii. Additional controller (long acting beta2-agonist, long-acting muscarinic antagonists 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 μL 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.

D. Eosinophilic esophagitis (EoE)

Authorization of 6 months may be granted for treatment of EoE in members 1 year of age or older, weighing at least 15 kg, when all of the following criteria are met:

1. Member meets one of the following:
    a. Member is 1 year of age to less than 11 years of age and has clinical manifestations of disease (e.g., vomiting, heartburn, abdominal pain, food refusal, failure to thrive).
    b. Member is 11 years of age or older and 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 for at least 8 weeks
    ii. Systemic corticosteroid or local therapies (e.g., budesonide or fluticasone swallowed), unless contraindicated or not tolerated.

E. Prurigo Nodularis(PN)

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 very high potency topical corticosteroid (see Appendix VIII)
        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 VIII) and topical calcineurin inhibitor
        b. Member has one of the following clinical reasons to avoid pharmacologic treatment with methotrexate or cyclosporine:
            iii. Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease
            iv. Breastfeeding
            v. Drug interaction
            vi. Cannot be used due to risk of treatment-related toxicity
            vii. Pregnancy or currently planning pregnancy
            viii. Significant comorbidity prohibits use of systemic agents (examples include liver or kidney disease, blood dyscrasias, uncontrolled hypertension)

V. CONTINUATION OF THERAPY

A. **Moderate-to-severe atopic dermatitis**
Authorization of 12 months may be granted for members 6 months 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 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:
   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).

D. **Eosinophilic esophagitis (EoE)**
Authorization of 12 months may be granted for continuation of treatment of eosinophilic esophagitis in members 1 year of age or older, weighing at least 15 kg, when 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)

E. **Prurigo Nodularis**
Authorization of 12 months may be granted for members 18 years of age or older who are using Dupixent for prurigo nodularis when the member has achieved or maintained positive clinical response with Dupixent therapy 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.

VI. QUANTITY LIMIT

a. Dupixent 100mg: 2 syringes per 28 days or daily dose of 0.048
b. Dupixent 200mg 2 syringes/pens per 28 days or daily dose of 0.09
c. Dupixent 300mg 2 syringes/pens per 28 days or daily dose of 0.15 for all indications other than EoE, with post-limit exception of 4 syringes/pens per 28 days or daily dose of 0.29 for EoE and loading doses for AD, PN, and CRSwNP with co-morbid asthma

VII. DOSING

Indication	Dosing
Atopic dermatitis	*Adults:* 600mg SQ initially, followed by 300mg every other week *6 months to 5 years (5kg to less than 15kg):* 200mg SQ every 4 weeks *6 months to 5 years (15kg to less than 30kg):* 300mg SQ every 4 weeks *6 years or older (15kg to less than 60kg):* 600mg SQ initially followed by 300mg every other week *6 years or older (30kg to less than 60kg):* 400mg SQ initially followed by 200mg every other week *6 years or older (60kg or more):* 600mg SQ initially followed by 300mg every other week
Asthma	*Adults:* 400mg SQ initially, followed by 200mg every other week OR 600mg SQ initially followed by 300mg every other week *6-11 years old(15kg to less than 30kg):* 100mg SQ every other week or 300mg every 4 weeks *6-11 years old(30kg or greater):* 200mg SQ every other week *12 years and older:* 400mg SQ initially, followed by 200mg every other week OR 600mg SQ initially followed by 300mg every other week
Chronic rhinosinusitis with nasal polyposis	*Adults:* 300mg SQ every other week
Eosinophilic esophagitis	*1 year and older (and weighing 15kg):* *15kg to less than 30kg*: 200mg SQ every other week *30kg to less than 40kg:* 300mg SQ every other week *40kg or more:* 300mg SQ every week

VIII. APPENDIX: Relative potency of select topical corticosteroid products

Potency	Drug	Dosage form	Strength
Very high potency	Augmented betamethasone dipropionate	Ointment, Gel	0.05%
High potency	Clobetasol propionate	Cream, Ointment	0.05%
	Augmented betamethasone dipropionate	Cream, Lotion	0.05%
	Betamethasone dipropionate	Cream	0.05%
	Betamethasone valerate	Ointment	0.1%
	Fluocinonide	Ointment, Gel	0.05%
Very high potency Medium potency	Triamcinolone acetonide	Cream, Ointment	0.5%
	Betamethasone dipropionate	Lotion	0.05%
High potency	Betamethasone valerate	Cream	0.1%

Potency	Drug	Dosage form	Strength
	Fluocinolone acetonide	Cream, Ointment	0.025%
	Fluticasone propionate	Cream	0.05%
	Fluocinonide	Ointment	0.005%
	Mometasone furoate	Ointment	0.1%
Medium potency	Triamcinolone acetonide	Cream, Ointment, Lotion	0.025%, 0.1%
Low potency	Desonide	Cream	0.05%
	Fluocinolone acetonide	Cream, Solution	0.01%
	Hydrocortisone	Cream, Ointment	0.5%
		Cream, Ointment	1%
	Mometasone furoate	Cream, Ointment	2.5%

IX. REFERENCES

1. Dupixent [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; February 2024.
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.