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, 10/2024, 2/2025, 2/2026, 5/2026 Scope: Medicaid

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 and pediatric patients aged 12 years and older 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).
F. Dupixent is indicated as add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype
G. Dupixent is indicated for the treatment of adult and pediatric patients aged 12 years and older with chronic spontaneous urticaria (CSU) who remain symptomatic despite H1 antihistamine treatment
H. Dupixent is indicated for the treatment of adult patients with bullous pemphigoid (BP)

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

All other indications are considered experimental/investigational and are not a covered benefit.

II. 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
F. Chronic obstructive pulmonary disease: pulmonologist or allergist/immunologist
G. Chronic Spontaneous Urticaria: allergist/immunologist or dermatologist
H. Bullous Pemphigoid: dermatologist, hematologist, or oncologist

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, 10/2024, 2/2025, 2/2026, 5/2026 Scope: Medicaid

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

Adults:

1. Documentation of 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. Documentation that the member has had an inadequate treatment response to at least one medium to super-high potency topical corticosteroid for ≥ 2 consecutive weeks (see Appendix), or pimecrolimus cream or tacrolimus ointment for ≥ 6 consecutive weeks

Pediatrics (6 months of age or older):

1. Documentation of 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.)
4. Documentation that the member has had an inadequate treatment response to at least one medium to super-high potency topical corticosteroid for ≥ 2 consecutive weeks (see Appendix) or pimecrolimus cream, tacrolimus ointment or Eucrisa (crisaborole) ointment for ≥ 4-6 consecutive weeks

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. Documentation that the 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. Documentation that the 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).
4. Documentation of baseline measurements of at least one of the following for assessment of clinical status:

i. Use of systemic corticosteroids
ii. Use of inhaled corticosteroids
iii. Number of hospitalizations, ER visits, or unscheduled visits to healthcare provider due to condition
iv. Forced expiratory volume in 1 second (FEV_1)

C. Chronic rhinosinusitis with nasal polyposis (CRSwNP)

Authorization of 6 months may be granted for treatment of CRSwNP in adult and pediatric members aged 12 years and older when ALL of the following criteria are met:

1. Documentation that the member has bilateral nasal polyposis and chronic symptoms of sinusitis despite intranasal corticosteroid treatment for at least 2 months unless contraindicated or not tolerated
2. Documentation that the member has CRSwNP despite ONE of the following:
    i. Prior sino-nasal surgery
    ii. Prior treatment with systemic corticosteroids within the last two years was ineffective, unless contraindicated or not tolerated
3. Documentation that the member has a bilateral nasal endoscopy, anterior rhinoscopy, or CT showing polyps
4. Documentation that the member has nasal obstruction plus ONE additional symptom:
    i. Rhinorrhea (anterior/posterior)
    ii. Reduction or loss of smell; AND
5. Documentation that the 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. Documentation that the member meets one of the following:
    i. 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).
    ii. 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. Documentation that the diagnosis has been confirmed by esophageal biopsy as characterized by 15 or more intraepithelial esophageal eosinophils per high power field
3. Documentation that the 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 adult members 18 years of age and older when all of the following criteria are met:

1. Documentation that the member has pruritus lasting at least 6 weeks, with a severity level of severe to very severe (WI-NRS score ≥7) reported on ≥2 separate days.

2. Documentation that the member has history or signs of repeated itch-scratch cycle (e.g., scratching, picking, or rubbing).
3. Documentation that the member has a minimum of 20 nodular lesions.
4. Documentation that the member meets either of the following (i or ii):
    i. Member has had an inadequate response to one of the following:
        a. A medium to super-high potency topical corticosteroid (see Appendix) for ≥ 2 weeks
        b. A topical calcineurin inhibitor for ≥ 2 weeks
        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 a medium to super-high potency topical corticosteroid (see Appendix) and topical calcineurin inhibitor
5. Member will not use Dupixent concomitantly with any other biologic drug or targeted synthetic drug.

F. Chronic Obstructive Pulmonary Disease (COPD)

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

1. Documentation that the member has a confirmed diagnosis of inadequately controlled COPD
2. Documentation that the member has history of ≥ 2 moderate or ≥ 1 severe exacerbations within the past 12 months
3. Documentation that the member has an eosinophilic phenotype, EOS ≥ 300 cells/μL
4. Documentation that the member has had an inadequate response, intolerance or contraindications to ≥ 3-month trial of ALL of the following treatments:
    b. Long-acting beta 2 agonist (LABA)
    c. Long-acting muscarinic antagonist/anticholinergic (LAMA)
    d. Inhaled corticosteroid (ICS); OR ≥ 3-month trial of double therapy (LABA + LAMA) permitted if ICS is contraindicated
5. Member will continue to receive maintenance therapy concomitantly with Dupixent

G. Chronic Spontaneous Urticaria

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

1. Member has been evaluated for other causes of urticaria, including bradykinin-related angioedema and interleukin-1-associated urticarial syndromes (auto-inflammatory disorders, urticarial vasculitis), and is not considered to have any other form(s) of urticaria
2. Member's baseline documentation score from an objective clinical evaluation tool, such as urticaria activity score (UAS7), angioedema activity score (AAS), Dermatology Life Quality Index (DLQI), Angioedema Quality of Life (AE-QoL), urticaria control test (UCT), angioedema control test (AECT), or Chronic Urticaria Quality of Life Questionnaire (CU-QoL), is provided
3. Documentation that the member has experienced a spontaneous onset of wheals (hives), angioedema, or both for at least 6 weeks
4. Documentation that the member remains symptomatic despite treatment with up-dosing up to fourfold (in accordance with EAACI/GA2LEN/EuroGuiDerm/APAACI guidelines) of second-generation H1 antihistamine (e.g., cetirizine, fexofenadine, levocetirizine, loratadine) for at least 2 weeks.
5. The requested drug will NOT be used in combination with any other biologic or targeted synthetic drug for the same indication (e.g., Rhapsido, Xolair).

H. Bullous Pemphigoid

Authorization of 12 months may be granted for treatment of bullous pemphigoid in members 18 years of age or older when all of the following criteria are met:

1. Diagnosis has been confirmed by either of the following:
   a. Direct immunofluorescence (DIF) study
   b. Immune serological test(s) (e.g., Indirect immunofluorescence microscopy [IIF], ELISA)
2. Member demonstrates characteristic clinical features of bullous pemphigoid (e.g., urticarial or eczematous or erythematous plaques, bullae, pruritis).
3. Member has moderate to severe disease.
4. Member has had an inadequate treatment response to a super-high potency topical corticosteroid (see appendix A) or an oral corticosteroid, OR the use of super-high potency topical corticosteroid or oral corticosteroid is not advisable for the member (e.g., contraindications, prior intolerances).

IV. CONTINUATION OF THERAPY

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

A. Moderate-to-severe atopic dermatitis

Authorization of 12 months may be granted for members 6 months of age or older with documentation showing members 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. The member has had clinical benefit with the requested agent as evidenced by a decrease in one of the following:
   a. Use of systemic corticosteroids
   b. Hospitalizations
   c. ER visits
   d. Unscheduled visits to healthcare provider; OR
   e. Improvement from baseline in forced expiratory volume in 1 second (FEV1)
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 adult and pediatric members aged 12 years and older with documentation showing memberswho 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 documentation showing they have 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 either low disease activity (i.e., clear or almost clear skin) or a reduction in pruritis intensity and improvement in extent and severity of nodular lesions

F. Chronic Obstructive Pulmonary Disease (COPD)

Authorization of 12 months may be granted for members 18 years of age or older who are using Dupixent for COPD with documentation that the member has achieved or maintained positive clinical response with Dupixent as evidenced by a reduction in the frequency and/or severity of symptoms & exacerbations and the member will continue to receive maintenance therapy concomitantly with Dupixent.

G. Chronic Spontaneous Urticaria

Authorization of 12 months may be granted for continuation of treatment of chronic spontaneous urticaria in members 12 years of age or older, when the member has experienced a positive clinical response (e.g., improved symptoms, decrease in weekly urticaria activity score [UAS7]) since initiation of therapy).

H. Bullous Pemphigoid

Authorization of 12 months may be granted for continuation of treatment of bullous pemphigoid in members 18 years of age or older, when the member has achieved or maintained a positive clinical response as evidenced by either of the following:

- Low disease activity (e.g., absence of new or established lesions)
- Reduction in pruritic intensity and improvement in extent and severity of lesions

V. 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

VI. DOSING

Indication	Dosing
Atopic dermatitis	*Adults:* 600mg SC initially, followed by 300mg every other week *6 months to 5 years (5kg to less than 15kg):* 200mg SC every 4 weeks *6 months to 5 years (15kg to less than 30kg):* 300mg SC every 4 weeks *6 years or older (15kg to less than 60kg):* 600mg SC initially followed by 300mg every other week *6 years or older (30kg to less than 60kg):* 400mg SC initially followed by 200mg every other week *6 years or older (60kg or more):* 600mg SC initially followed by 300mg every other week
Asthma	*Adults:* 400mg SC initially, followed by 200mg every other week OR 600mg SC initially followed by 300mg every other week *6-11 years old (15kg to less than 30kg):* 100mg SC every other week or 300mg every 4 weeks *6-11 years old (30kg or greater):* 200mg SC every other week *12 years and older:* 400mg SC initially, followed by 200mg every other week OR 600mg SC initially followed by 300mg every other week
Chronic rhinosinusitis with nasal polyposis	*Pediatric members aged 12 years and older and Adults:* 300mg SC every other week
Eosinophilic esophagitis	*1 year and older (and weighing 15kg):* *15kg to less than 30kg*: 200mg SC every other week *30kg to less than 40kg:* 300mg SC every other week *40kg or more:* 300mg SC every week
Chronic Obstructive Pulmonary Disease	*Adults:* 300mg SC every other week
Prurigo Nodularis	*Adults:* 600mg SC initially, followed by 300mg every other week
Chronic Spontaneous Urticaria	*Adults:* 600mg SC initially, followed by 300mg every other week *Pediatric members 12 and older:* *30 to less than 60 kg:* 400 mg initially, followed by 200 mg every 2 weeks *60 kg or more:* 600 mg initially, followed by 300 mg every 2 weeks
Bullous Pemphigoid	*Adults:* 600 mg SC initially, followed by 300 mg every other week

VII. APPENDIX: Relative potency of select topical corticosteroid products

Potency	Drug	Dosage form	Strength
I. Super-high potency (group 1)	Augmented betamethasone dipropionate	Ointment, Gel	0.05%
	Clobetasol propionate	Cream, Ointment, Solution, Cream (emollient)	0.05%
	Fluocinonide	Cream	0.1%
II. High potency (group 2)	Augmented betamethasone dipropionate	Cream	0.05%
	Betamethasone dipropionate	Ointment	0.05%
	Fluocinonide	Cream, Ointment, Gel, Solution	0.05%
III. High potency (group 3)	Betamethasone dipropionate	Cream	0.05%
	Betamethasone valerate	Ointment	0.1%
	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)	Fluocinolone acetonide	Ointment	0.025%
	Mometasone furoate	Cream	0.1%
	Triamcinolone acetonide	Cream	0.1%
		Ointment	0.05% and 0.1%

VIII. REFERENCES

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