BlueCross BlueShield Federal Employee Program.

DUPIXENT (dupilumab)

Pre - PA Allowance

None

Prior-Approval Requirements

Age 6 months of age or older

Diagnosis

Patient must have the following:

Moderate-to-severe atopic dermatitis (AD) (eczema)

AND submission of medical records (e.g., chart notes, laboratory values) documenting the following:

1. Inadequate treatment response, intolerance, or contraindication to **ONE** medication in **EACH** of the following categories:
    a. 18 years of age or older:
        a. Topical calcineurin inhibitor (see Appendix 1)
        b. **High** potency topical corticosteroid (see Appendix 2)
    b. 2 to 17 years of age:
        a. Topical calcineurin inhibitor (see Appendix 1)
        b. Topical corticosteroid (see Appendix 2)
    c. 6 months to less than 2 years of age:
        a. Topical corticosteroid (see Appendix 2)
2. Baseline evaluation of the condition using **ONE** of the following scoring tools:
    a. Investigator's Static Global Assessment [ISGA] with a score $\geq$ 3 (e.g., *https://www.eczemacouncil.org/assets/docs/Validated-Investigator-Global-Assessment-Scale_vIGA-AD_2017.pdf*)
    b. Eczema Area and Severity Index (EASI) with a score ≥ 16 (e.g., *https://dermnetnz.org/topics/easi-score/*)
    c. Patient-Oriented Eczema Measure (POEM) with a score ≥ 8 (e.g., *https://jamanetwork.com/data/Journals/DERM/11776/dea40003f1.png*)
    d. Scoring Atopic Dermatitis (SCORAD) index with a score ≥ 15 (e.g., *https://dermnetnz.org/topics/scorad/*)
3. **NOT** used in combination with another non-topical Prior Authorization (PA) medication for atopic dermatitis (see Appendix 3)
4. **NOT** given concurrently with live vaccines

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current

utilization, including samples, does not guarantee approval of coverage.

Age 6 years of age or older

Diagnosis

Patient must have the following:

Moderate-to-severe asthma

AND submission of medical records (e.g., chart notes, laboratory values) and use of claims history documenting the following:

1. Patient has **ONE** of the following:
    a. Asthma with eosinophilic phenotype with eosinophil count greater than or equal to 150 cells/mcL in the past 90 days **OR** 300 cells/mcL in the past 12 months
    b. Oral corticosteroid dependent asthma with **ONE** of the following:
        i. 1 month of daily oral corticosteroid use within the last 3 months
        ii. Patient currently requires oral corticosteroids
2. Exacerbation history in the past year of **ONE** of the following:
    a. ≥ 2 moderate asthma exacerbations
    b. ≥ 1 severe asthma exacerbation leading to hospitalization
3. Inadequate control of asthma symptoms after a minimum of 3 months of compliant use with greater than or equal to 50% adherence with **ONE** of the following within the past 6 months:
    a. Inhaled corticosteroids & long acting $beta_2$ agonist
    b. Inhaled corticosteroids & long acting muscarinic antagonist
4. **NOT** used for the emergency relief of acute bronchospasm or status asthmaticus
5. **NO** dual therapy with another monoclonal antibody for the treatment of asthma or COPD (see Appendix 4)
6. **NOT** given concurrently with live vaccines

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Age 1 year of age or older

Diagnosis

Patient must have the following:

Eosinophilic esophagitis (EoE)

AND submission of medical records (e.g., chart notes, laboratory values) documenting the following:

1. Patient has ≥15 intraepithelial eosinophils per high-power field (eos/hpf)
2. Symptoms of dysphagia (e.g., pain while swallowing, drooling, sensation of food getting stuck in the throat or chest)
3. Inadequate treatment response, intolerance, or contraindication to a proton pump inhibitor (PPI)
4. Patient weight ≥ 15 kg
5. **NOT** given concurrently with live vaccines

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Age 12 years of age or older

Diagnosis

Patient must have the following:

Chronic rhinosinusitis with nasal polyps (CRSwNP)

AND submission of medical records (e.g., chart notes, laboratory values) documenting the following:

1. Inadequate treatment response, intolerance, or contraindication to a 3-month trial of **EACH** of the following:
    a. **TWO** nasal corticosteroid sprays
    b. **ONE** oral corticosteroid
2. Prescribed by or recommended by an otolaryngologist (ENT)
3. **NO** dual therapy with another monoclonal antibody for the treatment of CRSwNP (see Appendix 5)
4. **NOT** given concurrently with live vaccines

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Age 18 years of age or older

Diagnosis

Patient must have the following:

Prurigo nodularis (PN)

AND submission of medical records (e.g., chart notes, laboratory values) documenting the following:

1. Inadequate treatment response, intolerance, or contraindication to a **high** potency topical steroid (see Appendix 2)
2. Inadequate treatment response, intolerance, or contraindication to either conventional systemic therapy (i.e., cyclosporine, methotrexate) or phototherapy
    ii. If the patient is intolerant or contraindicated to one therapy then the patient must have an inadequate treatment response, intolerance, or contraindication to the other treatment option
3. Baseline evaluation of the condition using the Investigator's Global Assessment (IGA) for prurigo nodularis with a score ≥ 3
   (e.g., *https://www.medicaljournals.se/acta/html-editor/table-pdf/big/5947/5947_30402.png*)
4. **NOT** given concurrently with live vaccines

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Age 18 years of age or older

Diagnosis

Patient must have the following:

Chronic obstructive pulmonary disease (COPD)

AND submission of medical records (e.g., chart notes, laboratory values) documenting the following:

1. Patient has **ONE** of the following
    a. Eosinophil count greater than or equal to 150 cells/mcL in the past 90 days **OR** 300 cells/mcL in the past 12 months

   b. Oral corticosteroid dependent COPD with **ONE** of the following:
      i. 1 month of daily oral corticosteroid use within the last 3 months
      ii. Patient currently requires oral corticosteroids
2. Exacerbation history in the past year of **ONE** of the following:
   a. ≥ 2 moderate COPD exacerbations
   b. ≥ 1 severe COPD exacerbation leading to hospitalization
3. Inadequate control of COPD symptoms after a minimum of 3 months of compliant use with greater than or equal to 50% adherence with **ONE** of the following within the past 6 months:
   a. Long acting beta$_2$ agonist & long acting muscarinic antagonist & inhaled corticosteroid
   b. Long acting beta$_2$ agonist & long acting muscarinic antagonist if inhaled corticosteroids are contraindicated
4. **NOT** used for the emergency relief of acute bronchospasm
5. **NO** dual therapy with another monoclonal antibody for the treatment of asthma or COPD (see Appendix 4)
6. **NOT** given concurrently with live vaccines

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Age 12 years of age or older

Diagnosis

Patient must have the following:

Chronic spontaneous urticaria (CSU)

AND submission of medical records (e.g., chart notes, laboratory values) documenting the following:

1. Symptomatic after at least **TWO** previous trials of H1-antihistamines
2. Inadequate treatment response, intolerance, or contraindication to Xolair (omalizumab)/biosimilar
3. Baseline urticaria activity score (UAS) (e.g., *https://www.mdcalc.com/urticaria-activity-score-uas*)
4. **NO** dual therapy with another monoclonal antibody for the treatment of CSU (see Appendix 6)
5. **NOT** given concurrently with live vaccines

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Prior - Approval Limits

Quantity

Strength	Diagnosis	Quantity
100 mg	Asthma	8 injections per 112 days **OR**
	Atopic dermatitis	N/A
	Chronic rhinosinusitis with nasal polyps	N/A
	Eosinophilic esophagitis	N/A
	Prurigo nodularis	N/A
	Chronic obstructive pulmonary disease	N/A
	Chronic spontaneous urticaria	N/A
200 mg	Asthma	10 injections per 112 days **OR**
	Atopic dermatitis	
	Chronic rhinosinusitis with nasal polyps	N/A
	Eosinophilic esophagitis	8 injections per 112 days **OR**
	Prurigo nodularis	N/A
	Chronic obstructive pulmonary disease	N/A
	Chronic spontaneous urticaria	10 injections per 112 days **OR**
300 mg	Asthma	10 injections per 112 days **OR**
	Atopic dermatitis	
	Chronic rhinosinusitis with nasal polyps	8 injections per 112 days **OR**
	Eosinophilic esophagitis	16 injections per 112 days **OR**
	Prurigo nodularis	10 injections per 112 days **OR**
	Chronic obstructive pulmonary disease	8 injections per 112 days **OR**
	Chronic spontaneous urticaria	10 injections per 112 days

Duration 16 weeks

Prior – Approval *Renewal* Requirements

Age 6 months of age or older

BlueCross BlueShield Federal Employee Program.

DUPIXENT (dupilumab)

Diagnosis

Patient must have the following:

Atopic dermatitis (AD) (eczema)

AND submission of medical records (e.g., chart notes, laboratory values) documenting the following:

1. Documented improvement of the condition using **ONE** of the following scoring tools:
    a. ISGA – decrease from baseline by at least 2 points (e.g., *https://www.eczemacouncil.org/assets/docs/Validated-Investigator-Global-Assessment-Scale_vIGA-AD_2017.pdf*)
    b. EASI – decrease from baseline by at least 75% (e.g., *https://dermnetnz.org/topics/easi-score/*)
    c. POEM – decrease from baseline by at least 3 points (e.g., *https://jamanetwork.com/data/Journals/DERM/11776/dea40003f1.png*)
    d. SCORAD – decrease from baseline by at least 50% (e.g., *https://dermnetnz.org/topics/scorad/*)
2. Patient has been adherent to Dupixent therapy
3. **NOT** used in combination with another non-topical Prior Authorization (PA) medication for atopic dermatitis (see Appendix 3)
4. **NOT** given concurrently with live vaccines

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Age 6 years of age or older

Diagnosis

Patient must have the following:

Asthma

AND submission of medical records (e.g., chart notes, laboratory values) and use of claims history documenting the following:

1. Decreased exacerbations **OR** improvement in symptoms
2. Patient has been adherent to Dupixent therapy
3. **NOT** used for the emergency relief of acute bronchospasm or status asthmaticus
4. **NO** dual therapy with another monoclonal antibody for the treatment of asthma or COPD (see Appendix 4)
5. **NOT** given concurrently with live vaccines

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Age 1 year of age or older

Diagnosis

Patient must have the following:

Eosinophilic esophagitis (EoE)

AND submission of medical records (e.g., chart notes, laboratory values) and use of claims history documenting the following:

1. Decrease in intraepithelial eosinophils per high-power field (eos/hpf) from baseline
2. Improvement in symptoms of dysphagia
3. Patient weight ≥ 15 kg
4. Patient has been adherent to Dupixent therapy
5. **NOT** given concurrently with live vaccines

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Age 12 years of age or older

Diagnosis

Patient must have the following:

Chronic rhinosinusitis with nasal polyps (CRSwNP)

AND submission of medical records (e.g., chart notes, laboratory values) and use of claims history documenting the following:

1. Improvement in sino-nasal symptoms
2. Decreased utilization of oral corticosteroids
3. **NO** dual therapy with another monoclonal antibody for the treatment of CRSwNP (see Appendix 5)
4. Patient has been adherent to Dupixent therapy
5. **NOT** given concurrently with live vaccines

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Age 18 years of age or older

Diagnosis

Patient must have the following:

Prurigo nodularis (PN)

AND submission of medical records (e.g., chart notes, laboratory values) and use of claims history documenting the following:

1. Documented improvement of the condition using IGA for prurigo nodularis with a decrease from baseline by at least 2 points (e.g., *https://www.medicaljournals.se/acta/html-editor/table-pdf/big/5947/5947_30402.png*)
2. Patient has been adherent to Dupixent therapy
3. **NOT** given concurrently with live vaccines

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Age 18 years of age or older

Diagnosis

Patient must have the following:

Chronic obstructive pulmonary disease (COPD)

AND submission of medical records (e.g., chart notes, laboratory values) and use of claims history documenting the following:

1. Decreased exacerbations **OR** improvement in symptoms
2. Patient has been adherent to Dupixent therapy
3. **NOT** used for the emergency relief of acute bronchospasm
4. **NO** dual therapy with another monoclonal antibody for the treatment of asthma or COPD (see Appendix 4)
5. **NOT** given concurrently with live vaccines

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Age 12 years of age or older

Diagnosis

Patient must have the following:

Chronic spontaneous urticaria (CSU)

AND submission of medical records (e.g., chart notes, laboratory values) and use of claims history documenting the following:

1. Decrease in urticaria activity score (UAS), such as improvement in pruritic wheals, hives, and itching (e.g., *https://www.mdcalc.com/urticaria-activity-score-uas*)
2. Patient has been adherent to Dupixent therapy
3. **NO** dual therapy with another monoclonal antibody for the treatment of CSU (see Appendix 6)
4. **NOT** given concurrently with live vaccines

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Prior - Approval *Renewal* Limits

Quantity

Strength	Diagnosis	Quantity
100 mg	Asthma	6 injections per 84 days **OR**
	Atopic dermatitis	N/A
	Chronic rhinosinusitis with nasal polyps	N/A
	Eosinophilic esophagitis	N/A
	Prurigo nodularis	N/A
	Chronic obstructive pulmonary disease	N/A
	Chronic spontaneous urticaria	N/A
200 mg	Asthma	6 injections per 84 days **OR**
	Atopic dermatitis	
	Chronic rhinosinusitis with nasal polyps	N/A
	Eosinophilic esophagitis	6 injections per 84 days **OR**
	Prurigo nodularis	N/A
	Chronic obstructive pulmonary disease	N/A
	Chronic spontaneous urticaria	6 injections per 84 days **OR**
300 mg	Asthma	6 injections per 84 days **OR**
	Atopic dermatitis	
	Chronic rhinosinusitis with nasal polyps	6 injections per 84 days **OR**
	Eosinophilic esophagitis	12 injections per 84 days **OR**
	Prurigo nodularis	6 injections per 84 days **OR**
	Chronic obstructive pulmonary disease	6 injections per 84 days **OR**
	Chronic spontaneous urticaria	6 injections per 84 days

Duration 12 months

Appendix 1

Relative Potency of Topical Calcineurin Inhibitors		
Drug	**Dosage Form**	**Strength**
Medium Potency		
Tacrolimus	Ointment	0.1%

Low Potency		
Tacrolimus	Ointment	0.03%
Pimecrolimus	Cream	1%

Appendix 2

Relative Potency of Selected Topical Corticosteroids		
Drug	**Dosage Form**	**Strength**
Very high Potency		
Augmented betamethasone dipropionate	Ointment, Gel	0.05%
Clobetasol propionate	Cream, Ointment	0.05%
Diflorasone diacetate	Ointment	0.05%
Flurandrenolide	Tape	4 mcg/cm2
Halobetasol propionate	Cream, Ointment	0.05%
High Potency		
Amcinonide	Cream, Lotion,	0.1%
Augmented betamethasone dipropionate	Cream, Lotion	0.05%
Betamethasone dipropionate	Cream, Ointment	0.05%
Betamethasone valerate	Ointment	0.1%
Desoximetasone	Cream, Ointment	0.25%
	Gel	0.05%
Diflorasone diacetate	Cream, Ointment (emollient base)	0.05%
Fluocinonide	Cream, Ointment,	0.05%
Halcinonide	Cream, Ointment	0.1%
Triamcinolone acetonide	Cream, Ointment	0.5%
Medium Potency		
Betamethasone dipropionate	Lotion	0.05%
Betamethasone valerate	Cream	0.1%
Clocortolone pivalate	Cream	0.1%
Desoximetasone	Cream	0.05%
Fluocinolone acetonide	Cream, Ointment	0.025%
Flurandrenolide	Cream, Ointment,	0.05%
Fluticasone propionate	Cream	0.05%
	Ointment	0.005%
Hydrocortisone butyrate	Ointment, Solution	0.1%
Hydrocortisone valerate	Cream, Ointment	0.2%
Mometasone furoate	Cream, Ointment,	0.1%
Prednicarbate	Cream, Ointment	0.1%
Triamcinolone acetonide	Cream, Ointment, Lotion	0.025% 0.1%

Low Potency		
Alclometasone dipropionate	Cream, Ointment	0.05%
Desonide	Cream	0.05%
Fluocinolone acetonide	Cream, Solution	0.01%
Hydrocortisone	Lotion	0.25%
	Cream, Ointment, Lotion,	0.5%
	Cream, Ointment, Lotion,	1%
	Cream, Ointment,	2.5%
Hydrocortisone acetate	Cream, Ointment	0.5%
	Cream, Ointment	1%

Appendix 3 - List of Non-Topical PA Medications for Atopic Dermatitis

Generic Name	Brand Name
abrocitinib	Cibinqo
dupilumab	Dupixent
tralokinumab-ldrm	Adbry
upadactinib	Rinvoq

Appendix 4 - List of Monoclonal Antibodies for Asthma or COPD

Generic Name	Brand Name
benralizumab	Fasenra
dupilumab	Dupixent
mepolizumab	Nucala
omalizumab	Xolair
reslizumab	Cinqair
tezepelumab-ekko	Tezspire

Appendix 5 - List of Monoclonal Antibodies for CRSwNP

Generic Name	Brand Name
dupilumab	Dupixent
mepolizumab	Nucala
omalizumab	Xolair

Appendix 6 - List of Monoclonal Antibodies for CSU

Generic Name	Brand Name
dupilumab	Dupixent
omalizumab	Xolair