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Section:	Prescription Drugs	**Effective Date:**	October 1, 2024
Subsection:	Topical Products	**Original Policy Date:**	April 7, 2017
Subject:	Dupixent	**Page:**	1 of 15

Last Review Date: September 6, 2024

Dupixent

Description

Dupixent (dupilumab)

Background
Dupixent (dupilumab) is a human monoclonal IgG4 antibody that inhibits interleukin-4 (IL-4) and interleukin-13 (IL-13) signaling by specifically binding to the IL-4Rα subunit shared by the IL-4 and IL-13 receptor complexes. This blocks the IL-4 and IL-13 cytokine-induced inflammatory responses, including the release of proinflammatory cytokines, chemokines, nitric oxide, and IgE; however, the mechanism of action for Dupixent has not been definitively established (1).

Regulatory Status
FDA-approved indications: Dupixent is an interleukin-4 receptor alpha antagonist indicated: (1)

1. Atopic Dermatitis
    a. For the treatment of adult and pediatric patients aged 6 months and older with moderate-to-severe atopic dermatitis (AD) 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. Asthma
    a. As an add-on maintenance treatment of patients aged 6 years and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma.
        i. Limitations of Use: Not for the relief of acute bronchospasm or status asthmaticus.
3. Chronic Rhinosinusitis with Nasal Polyposis
    a. As an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP).

4. Eosinophilic Esophagitis
    a. For the treatment of adult and pediatric patients aged 1 year and older, weighing at least 15 kg, with eosinophilic esophagitis (EoE).
5. Prurigo Nodularis
    a. For the treatment of adult patients with prurigo nodularis (PN).

Dupixent has warnings for hypersensitivity reactions, conjunctivitis and keratitis, and parasitic infections. Patients should be monitored and Dupixent treatment should be discontinued if appropriate (1).

Patients should not discontinue systemic, topical, or inhaled corticosteroids abruptly upon initiation of Dupixent therapy. Steroids should be reduced gradually, if appropriate (1).

FEP adherence is defined as ≥50% utilization within the last 180 days.

The safety and effectiveness of Dupixent in pediatric patients less than 6 months of age with atopic dermatitis have not been established. The safety and effectiveness of Dupixent in pediatric patients less than 6 years of age with asthma have not been established. The safety and effectiveness of Dupixent in pediatric patients less than 1 year of age with eosinophilic esophagitis have not been established. The safety and effectiveness of Dupixent in pediatric patients less than 18 years of age with CRSwNP or PN have not been established (1).

Related policies
Adbry, Cibinqo, Cinqair, Doxepin cream 5%, Eohilia, Eucrisa, IL-5 Antagonists, Rinvoq, Tezspire, Xolair

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Dupixent may be considered **medically necessary** if the conditions indicated below are met.

Dupixent may be considered **investigational** for all other indications.

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 ≥ 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
        i. Patient has had prior acute exacerbation(s)
    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. 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
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
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) 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 18 years of age or older

Diagnosis

Patient must have the following:

Chronic rhinosinusitis with nasal polyposis (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. **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. 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*)
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.

Prior – Approval *Renewal* Requirements

Age 6 months of age or older

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. **NOT** used in combination with another non-topical Prior Authorization (PA) medication for atopic dermatitis (see Appendix 3)
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 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. Decreased utilization of rescue medications
3. Patient has been compliant on Dupixent therapy
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
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) 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. **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 rhinosinusitis with nasal polyposis (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. Patient has been compliant on Dupixent therapy
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) 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 compliant on 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.

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

Strength	Diagnosis	Quantity
100 mg	Asthma	8 syringes per 112 days **OR**
	Atopic dermatitis	N/A

	Chronic rhinosinusitis with nasal polyposis	N/A
	Eosinophilic esophagitis	N/A
	Prurigo nodularis	N/A
200 mg	Asthma	10 syringes per 112 days **OR**
	Atopic dermatitis	
	Chronic rhinosinusitis with nasal polyposis	N/A
	Eosinophilic esophagitis	8 syringes per 112 days **OR**
	Prurigo nodularis	N/A
300 mg	Asthma	10 syringes per 112 days **OR**
	Atopic dermatitis	
	Chronic rhinosinusitis with nasal polyposis	8 syringes per 112 days **OR**
	Eosinophilic esophagitis	16 syringes per 112 days **OR**
	Prurigo nodularis	10 syringes per 112 days

Duration 16 weeks

Prior – Approval *Renewal* Limits

Quantity

Strength	Diagnosis	Quantity
100 mg	Asthma	6 syringes per 84 days **OR**
	Atopic dermatitis	N/A
	Chronic rhinosinusitis with nasal polyposis	N/A
	Eosinophilic esophagitis	N/A
	Prurigo nodularis	N/A
200 mg	Asthma	6 syringes per 84 days **OR**
	Atopic dermatitis	
	Chronic rhinosinusitis with nasal polyposis	N/A
	Eosinophilic esophagitis	6 syringes per 84 days **OR**
	Prurigo nodularis	N/A
300 mg	Asthma	6 syringes per 84 days **OR**
	Atopic dermatitis	

	Chronic rhinosinusitis with nasal polyposis	6 syringes per 84 days **OR**
	Eosinophilic esophagitis	12 syringes per 84 days **OR**
	Prurigo nodularis	6 syringes per 84 days

Duration 12 months

Rationale

Summary

Dupixent (dupilumab) is an interleukin-4 receptor alpha antagonist indicated for the treatment of atopic dermatitis (AD), asthma, eosinophilic esophagitis (EoE), chronic rhinosinusitis with nasal polyposis (CRSwNP), and prurigo nodularis (PN). Dupixent has warnings for hypersensitivity reactions, conjunctivitis and keratitis, and parasitic infections. Patients should be monitored and Dupixent treatment should be discontinued if appropriate. The safety and effectiveness of Dupixent in pediatric patients less than 6 months of age with atopic dermatitis have not been established. The safety and effectiveness of Dupixent in pediatric patients less than 6 years of age with asthma have not been established. The safety and effectiveness of Dupixent in pediatric patients less than 1 year of age with eosinophilic esophagitis have not been established. The safety and effectiveness of Dupixent in pediatric patients less than 18 years of age with CRSwNP or PN have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Dupixent while maintaining optimal therapeutic outcomes.

References

1. Dupixent [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals Inc.; April 2024.
2. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2019. Available from www.ginasthma.org.

Policy History

Date	Action
April 2017	Addition to PA Addition of EASI, POEM and SCORAD scoring tools to criteria for evaluation

June 2017	Annual review Addition of Dupixent into the Managed PA program Adjustment of the Baseline POEM and SCORAD values
May 2018	Addition of url links for scoring tools
June 2018	Annual editorial review
November 2018	Annual editorial review and reference update. Addition of asthma indication
March 2019	Decreased age requirement for atopic dermatitis from 18 and older to 12 and older and added 200 mg syringes for atopic dermatitis. Added no live vaccines requirement to asthma indication
June 2019	Annual review. Addition of the 50% adherence requirement to the asthma diagnosis
July 2019	Addition of indication: chronic rhinosinusitis with nasal polyposis (CRSwNP)
September 2019	Annual review
June 2020	Decreased age requirement for atopic dermatitis from 12 and older to 6 and older. Revised t/f steroid requirement for pediatric patients. Scoring tool links updated
September 2020	Annual review and reference update
March 2021	Annual editorial review. Investigator's Static Global Assessment link updated
May 2021	Revised the asthma eosinophil count to include ≥150 cells/mcL in the past 90 days. Updated Appendix 1 and 2
June 2021	Annual review
November 2021	Changed age requirement for asthma to 6 years and older per newest package insert. Added Dupixent 100mg to dosing chart. Revised initiation days supply and duration to accommodate new strength
December 2021	Annual review
January 2022	Changed requirement to t/f of TWO nasal corticosteroids sprays and ONE oral corticosteroid per FEP
March 2022	Annual review and reference update. Per SME: Changed asthma renewal requirement to "decreased exacerbations and/or improvement in symptoms"; Added asthma initiation requirement that patients with eosinophilic asthma must have prior acute exacerbation(s); Added asthma initiation option that patients with corticosteroid dependent asthma may be currently requiring oral corticosteroids.
April 2022	Addition of requirement for atopic dermatitis: "not used in combination with another non-topical PA medication for atopic dermatitis" and added Appendix 3. Added "emergency" to the requirement "not used for the emergency relief of acute bronchospasm or status asthmaticus"
June 2022	Annual review. Addition of indication per PI update: eosinophilic esophagitis. Per PI update, reduced atopic dermatitis age requirement to 6 months and older
September 2022	Annual review
October 2022	Per PI update, addition of indication prurigo nodularis (PN)

November 2022	Per FEP: addition of initiation requirement for CRSwNP, must be prescribed by or recommended by an ENT
December 2022	Annual review
January 2023	Changed Appendix 2 and moved fluradrenolide tape to very high potency
March 2023	Annual review and reference update
February 2024	Per PI update, decreased age requirement for EoE to 1 year and older and weight at least 15 kg. Added 200 mg to quantity chart for EoE
March 2024	Annual review
April 2024	Per FEP, revised CRSwNP initiation requirement to a 3-month trial of two nasal steroids and one oral steroid. Also added t/f of a PPI to EoE diagnosis initiation criteria
June 2024	Annual review and reference update
September 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 6, 2024 and is effective on October 1, 2024.

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, Ointment	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, Gel	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, Lotion	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, Lotion	0.1%
Prednicarbate	Cream, Ointment	0.1%
Triamcinolone acetonide	Cream, Ointment, Lotion	0.025%
	Cream, Ointment, Lotion	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, Aerosol	0.5%
	Cream, Ointment, Lotion, Solution	1%
	Cream, Ointment, Lotion	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