

5.90.30

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Subsection:	Topical Products	Original Policy Date:	April 7, 2017
Subject:	Dupilumab	Page:	1 of 11

Last Review Date: June 16, 2022

Dupilumab

Description

Dupilumab (dupilumab)

Background

Dupilumab (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-4R α 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 Dupilumab action in asthma has not been definitively established (1).

Regulatory Status

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

1. For the treatment of patients aged 6 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. Dupilumab can be used with or without topical corticosteroids.
2. 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.
 - a. Limitations of use: Not for the relief of acute bronchospasm or status asthmaticus.
3. As an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP).

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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 $\geq 50\%$ utilization within the last 180 days.

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

Related policies

Adbry, Cibinqo, Cinqair, Doxepin cream 5%, Eucrisa, IL-5 Antagonists, Rinvoq, 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** in patients with moderate-to-severe atopic dermatitis, asthma, or chronic rhinosinusitis with nasal polyposis and if the conditions indicated below are met.

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

Prior-Approval Requirements

Age 6 years of age or older

Diagnosis

Patient must have the following:

Moderate-to-severe atopic dermatitis (eczema)

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

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1. Inadequate response, intolerance, or contraindication to **ONE** medication in **EACH** of the following categories:
 - a. Topical calcineurin inhibitor (see Appendix 1)
 - b. 18 years of age or older: **High** potency topical corticosteroid (see Appendix II)
 - c. 6 to 17 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:

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- 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 beta₂ 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

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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 response, intolerance, or contraindication to the following:
 - a. **TWO** nasal corticosteroid sprays
 - b. **ONE** oral corticosteroid
2. **NOT** given concurrently with live vaccines

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Prior – Approval *Renewal*/Requirements

Age 6 years of age or older

Diagnosis

Patient must have the following:

Atopic dermatitis (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

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Age 6 years of age or older

Diagnosis

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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 and/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 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

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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
200 mg	Asthma	10 syringes per 112 days OR
	Atopic dermatitis	
	Chronic rhinosinusitis with nasal polyposis	N/A
300 mg	Asthma	10 syringes per 112 days OR
	Atopic dermatitis	
	Chronic rhinosinusitis with nasal polyposis	8 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
200 mg	Asthma	6 syringes per 84 days OR
	Atopic dermatitis	

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	Chronic rhinosinusitis with nasal polyposis	N/A
300 mg	Asthma	6 syringes per 84 days OR
	Atopic dermatitis	
	Chronic rhinosinusitis with nasal polyposis	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 (eczema), asthma, and chronic rhinosinusitis with nasal polyposis. 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 years of age with atopic dermatitis or asthma have not been established. The safety and effectiveness of Dupixent in pediatric patients less than 18 years of age with CRSwNP 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.; December 2021.
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

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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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 16, 2022 and is effective on July 1, 2022.

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Relative Potency of Topical Calcineurin Inhibitors		
Drug	Dosage Form	Strength
<i>Medium Potency</i>		
Tacrolimus	Ointment	0.1%
<i>Low Potency</i>		
Tacrolimus	Ointment	0.03%
Pimecrolimus	Cream	1%

Appendix 2

Relative Potency of Selected Topical Corticosteroids		
Drug	Dosage Form	Strength
<i>Very high Potency</i>		
Augmented betamethasone dipropionate	Ointment, Gel	0.05%
Clobetasol propionate	Cream, Ointment	0.05%
Diflorasone diacetate	Ointment	0.05%
Halobetasol propionate	Cream, Ointment	0.05%
<i>High Potency</i>		
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	0.05%
	(emollient base)	
Fluocinonide	Cream, Ointment, Gel	0.05%
Halcinonide	Cream, Ointment	0.1%
Triamcinolone acetonide	Cream, Ointment	0.5%
<i>Medium Potency</i>		
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%

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Flurandrenolide	Cream, Ointment, Lotion	0.05%
	Tape	4 mcg/cm ²
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 ²	Cream, Ointment	0.1%
Triamcinolone acetonide	Cream, Ointment, Lotion	0.025%
	Cream, Ointment, Lotion	0.1%
<i>Low Potency</i>		
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%
	Aerosol	
	Cream, Ointment, Lotion,	1%
	Solution	
	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