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Section:	Prescription Drugs	**Effective Date:**	April 1, 2021
Subsection:	Topical Products	**Original Policy Date:**	April 7, 2017
Subject:	Dupixent	**Page:**	1 of 10

Last Review Date: March 12, 2021

Dupixent

Description

Dupixent (dupilumab)

Background
Dupixent (dupilumab) is a medication used for the treatment of atopic dermatitis (eczema). Atopic dermatitis, a chronic inflammatory skin disease, is often referred to as “eczema,” which is a general term for several types of inflammation of the skin. In atopic dermatitis, the skin develops red, scaly and crusted bumps, which are extremely itchy. Scratching leads to swelling, cracking, “weeping” clear fluid, and finally, coarsening and thickening of the skin. Dupixent is an antibody that binds to a protein that causes inflammation. By binding to this protein, Dupixent is able to inhibit the inflammatory response that plays a role in the development of atopic dermatitis (1-6).

Dupixent is a human monoclonal IgG4 antibody that inhibits interleukin-4 (IL-4) and interleukin-13 (IL-13) signaling by specifically binding to the IL-4Ra 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 Dupixent action in asthma has not been definitively established (1).

Regulatory Status
FDA-approved indications: Dupixent 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. Dupixent can be used with or without topical corticosteroids.

2. As an add-on maintenance treatment in patients with moderate-to-severe asthma aged 12 years and older with 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).

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 years of age with atopic dermatitis have not been established. The safety and effectiveness of Dupixent in pediatric patients less than 12 years of age with 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
Cinqair, Doxepin cream 5%, Eucrisa, IL-5 Antagonists, 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:

1. Inadequate response, intolerance or contraindication to **ONE** medication in **EACH** of the following categories:
    a. Topical calcineurin inhibitor (see Appendix I)
    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 II)

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** given concurrently with live vaccines

Age 12 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 300 cells/mcL in the past 12 months
    b. Oral corticosteroid dependent asthma with at least 1 month of daily oral corticosteroid use within the last 3 months
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 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

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 **ONE** medication in **EACH** of the following categories:
    a. Nasal corticosteroid spray
    b. Oral corticosteroid

2. **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 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** given concurrently with live vaccines

Age 12 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 and improvement in symptoms
2. Decreased utilization of rescue medications
3. Patient has been compliant on Dupixent therapy
4. **NOT** used for the 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

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.

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

Strength	Quantity
200 mg*	10 syringes per 120 days **OR**
300 mg for atopic dermatitis or asthma	10 syringes per 120 days **OR**

300 mg for chronic rhinosinusitis with nasal polyposis	8 syringes per 120 days

*200 mg syringes are **NOT** approved for chronic rhinosinusitis with nasal polyposis

Duration 4 months

Prior – Approval *Renewal* Limits

Quantity

Strength	Quantity
200 mg*	6 syringes per 84 days **OR**
300 mg	6 syringes per 84 days

*200 mg syringes are **NOT** approved for chronic rhinosinusitis with nasal polyposis

Duration 12 months

Rationale

Summary
Dupixent (dupilumab) is a medication used for treatment of atopic dermatitis (eczema), asthma, and chronic rhinosinusitis with nasal polyposis. Dupixent is an antibody that binds to a protein that causes inflammation. By binding to this protein, Dupixent is able to inhibit the inflammatory responses that play a role in the development of atopic dermatitis and asthma. The safety and effectiveness of Dupixent in pediatric patients less than 6 years of age with atopic dermatitis have not been established. The safety and effectiveness of Dupixent in pediatric patients less than 12 years of age with 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.; June 2020.
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3. A.P. Oranje, E.J. Glazenburg, et al. Practical issues on interpretation of scoring atopic dermatitis: the SCORAD index, objective SCORAD and the three-item severity score. British Journal of Dermatology (2007) 157, pp645–648.
4. C.R. Charman, A.J. Venn, et al. Translating Patient-Oriented Eczema Measure (POEM) scores into clinical practice by suggesting severity strata derived using anchor-based methods. British Journal of Dermatology (2013) 169, pp1326–1332.
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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.

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.

APPENDIX I

Relative Potency of Topical Calcineurin Inhibitors			
	Drug	**Dosage Form**	**Strength**
I.	***Medium potency***		
	Tacrolimus	Ointment	0.1%
II.	***Low potency***		
	Tacrolimus	Ointment	0.03%
	Pimecrolimus	Cream	1%

APPENDIX II

Relative Potency of Selected Topical Corticosteroid			
	Drug	**Dosage Form**	**Strength**
I.	***Very high potency***		
	Augmented betamethasone dipropionate	Ointment, Gel	0.05%
	Clobetasol propionate	Cream, Ointment	0.05%
	Diflorasone diacetate	Ointment	0.05%
	Halobetasol propionate	Cream, Ointment	0.05%
II.	***High potency***		
	Amcinonide	Cream, Lotion,	0.1%
	Augmented betamethasone dipropionate	Cream, Lotion	0.05%
	Betamethasone	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%
III.	***Medium potency***		
	Betamethasone	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%
		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,	0.1%
	Prednicarbate[2]	Cream, Ointment	0.1%
III.	Triamcinolone acetonide	Cream, Ointment, Lotion	0.025%
		Cream, Ointment, Lotion	0.1%
IV.	***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%