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# 5.90.030

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2026
<b>Subsection:</b>	Topical Products	<b>Original Policy Date:</b>	April 7, 2017
<b>Subject:</b>	Dupilumab	<b>Page:</b>	1 of 23

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**Last Review Date:** March 6, 2026

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## 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 interleukin-4 receptor alpha (IL-4R $\alpha$ ) 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 Dupilumab has not been definitively established (1).

#### Regulatory Status

FDA-approved indications: Dupilumab 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. Dupilumab can be used with or without topical corticosteroids.
2. Asthma
  - a. As an add-on maintenance treatment of adult and pediatric 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 Polyps

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2026
<b>Subsection:</b>	Topical Products	<b>Original Policy Date:</b>	April 7, 2017
<b>Subject:</b>	Dupixent	<b>Page:</b>	2 of 23

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- a. As an add-on maintenance treatment in adult and pediatric patients aged 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyps (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).
- 6. Chronic Obstructive Pulmonary Disease (COPD)
  - a. As an add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype.
    - i. Limitations of Use: Not for the relief of acute bronchospasm.
- 7. Chronic Spontaneous Urticaria (CSU)
  - a. 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.
    - i. Limitations of Use: Not indicated for other forms of urticaria.
- 8. Bullous Pemphigoid
  - a. For the treatment of adult patients with bullous pemphigoid (BP).

Dupixent has warnings for hypersensitivity reactions, conjunctivitis and keratitis, eosinophilic conditions, psoriasis, arthralgia and psoriatic arthritis, 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.

Dupixent is approved to treat both asthma and COPD. Patients with features of both these conditions should follow treatment for asthma, per the Global Initiative for Asthma (GINA) report (2).

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

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2026
<b>Subsection:</b>	Topical Products	<b>Original Policy Date:</b>	April 7, 2017
<b>Subject:</b>	Dupixent	<b>Page:</b>	3 of 23

---

patients less than 12 years of age with CRSwNP and CSU have not been established. The safety and effectiveness of Dupixent in pediatric patients less than 18 years of age with PN, COPD, and BP have not been established (1).

### Related policies

Adbry, Cibinqo, Cinqair, Doxepin cream 5%, Eohilia, Eucrisa, IL-5 Antagonists, Nemluvio, 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 ALL** of the following with provided documentation (e.g., medical records, laboratory reports):

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)

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2026
<b>Subsection:</b>	Topical Products	<b>Original Policy Date:</b>	April 7, 2017
<b>Subject:</b>	Dupixent	<b>Page:</b>	4 of 23

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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](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  $\geq 16$  (e.g., <https://dermnetnz.org/topics/easi-score/>)
  - c. Patient-Oriented Eczema Measure (POEM) with a score  $\geq 8$  (e.g., <https://jamanetwork.com/data/Journals/DERM/11776/dea40003f1.png>)
  - d. Scoring Atopic Dermatitis (SCORAD) index with a score  $\geq 15$  (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
5. 12 years of age and older **ONLY**: Patient **MUST** have tried the preferred product(s) (see Appendix 7) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

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 ALL** of the following with provided documentation (e.g., medical records, laboratory values):

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:

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2026
<b>Subsection:</b>	Topical Products	<b>Original Policy Date:</b>	April 7, 2017
<b>Subject:</b>	Dupixent	<b>Page:</b>	5 of 23

---

- 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.  $\geq 2$  moderate asthma exacerbations
  - b.  $\geq 1$  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<sub>2</sub> 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
7. Patient **MUST** have tried the preferred product(s) (see Appendix 7) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

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**Age** 1 year of age or older

## Diagnosis

Patient must have the following:

Eosinophilic esophagitis (EoE)

**AND ALL** of the following with provided documentation (e.g., medical records, laboratory values):

1. Patient has  $\geq 15$  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)

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2026
<b>Subsection:</b>	Topical Products	<b>Original Policy Date:</b>	April 7, 2017
<b>Subject:</b>	Dupixent	<b>Page:</b>	6 of 23

---

3. Inadequate treatment response, intolerance, or contraindication to a proton pump inhibitor (PPI)
4. Patient weight  $\geq$  15 kg
5. **NOT** given concurrently with live vaccines
6. 11 years of age and older **ONLY**: Patient **MUST** have tried the preferred product(s) (see Appendix 7) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

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**Age** 12 years of age or older

## Diagnosis

Patient must have the following:

Chronic rhinosinusitis with nasal polyps (CRSwNP)

**AND ALL** of the following with provided documentation (e.g., medical records, laboratory values):

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
5. 18 years of age and older **ONLY** Patient **MUST** have tried the preferred product(s) (see Appendix 7) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

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---

<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2026
<b>Subsection:</b>	Topical Products	<b>Original Policy Date:</b>	April 7, 2017
<b>Subject:</b>	Dupixent	<b>Page:</b>	7 of 23

---

**Age** 18 years of age or older

## Diagnosis

Patient must have the following:

Prurigo nodularis (PN)

**AND ALL** of the following with provided documentation (e.g., medical records, laboratory values):

1. Inadequate treatment response, intolerance, or contraindication to a **high** potency topical steroid (see Appendix 2)
2. Inadequate treatment response, intolerance, or contraindication to phototherapy **OR** a topical calcineurin inhibitor (see Appendix 1)
3. Baseline evaluation of the condition using the Investigator's Global Assessment (IGA) for prurigo nodularis with a score  $\geq 3$  (e.g., [https://www.medicaljournals.se/acta/html-editor/table-pdf/big/5947/5947\\_30402.png](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.

**Age** 18 years of age or older

## Diagnosis

Patient must have the following:

Chronic obstructive pulmonary disease (COPD)

**AND ALL** of the following with provided documentation (e.g., medical records, laboratory values):

1. Patient has **ONE** of the following

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2026
<b>Subsection:</b>	Topical Products	<b>Original Policy Date:</b>	April 7, 2017
<b>Subject:</b>	Dupixent	<b>Page:</b>	8 of 23

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- 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.  $\geq 2$  moderate COPD exacerbations
  - b.  $\geq 1$  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<sub>2</sub> agonist & long acting muscarinic antagonist & inhaled corticosteroid
  - b. Long acting beta<sub>2</sub> 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
7. Patient **MUST** have tried the preferred product(s) (see Appendix 7) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

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 ALL** of the following with provided documentation (e.g., medical records, laboratory values):

1. Symptomatic after at least **TWO** previous trials of H1-antihistamines

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2026
<b>Subsection:</b>	Topical Products	<b>Original Policy Date:</b>	April 7, 2017
<b>Subject:</b>	Dupixent	<b>Page:</b>	9 of 23

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2. Baseline urticaria activity score (UAS)  
(e.g., <https://www.mdcalc.com/urticaria-activity-score-uas>)
3. **NO** dual therapy with another monoclonal antibody for the treatment of CSU (see Appendix 6)
4. **NOT** given concurrently with live vaccines
5. Patient **MUST** have tried the preferred product(s) (see Appendix 7) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

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:

Bullous pemphigoid (BP)

**AND ALL** of the following with provided documentation (e.g., medical records, laboratory values):

1. Inadequate treatment response, intolerance, or contraindication to a 3-month trial of **TWO** of the following:
  - a. **High** potency topical corticosteroid (see Appendix 2)
  - b. Oral corticosteroid
  - c. Tetracycline antibiotic or dapsone
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 months of age or older

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2026
<b>Subsection:</b>	Topical Products	<b>Original Policy Date:</b>	April 7, 2017
<b>Subject:</b>	Dupixent	<b>Page:</b>	10 of 23

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## Diagnosis

Patient must have the following:

Atopic dermatitis (AD) (eczema)

**AND ALL** of the following with provided documentation (e.g., medical records, laboratory values):

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](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
5. 12 years of age and older **ONLY**: Patient **MUST** have tried the preferred product(s) (see Appendix 7) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

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

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2026
<b>Subsection:</b>	Topical Products	<b>Original Policy Date:</b>	April 7, 2017
<b>Subject:</b>	Dupixent	<b>Page:</b>	11 of 23

---

**AND ALL** of the following with provided documentation (e.g., medical records, laboratory values):

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
6. Patient **MUST** have tried the preferred product(s) (see Appendix 7) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

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 ALL** of the following with provided documentation (e.g., medical records, laboratory values):

1. 11 years of age and older **ONLY**: Decrease in intraepithelial eosinophils per high-power field (eos/hpf) from baseline
2. Improvement in symptoms of dysphagia
3. Patient weight  $\geq$  15 kg
4. Patient has been adherent to Dupixent therapy
5. **NOT** given concurrently with live vaccines
6. 11 years of age and older **ONLY**: Patient **MUST** have tried the preferred product(s) (see Appendix 7) if adjudicated through the pharmacy benefit

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2026
<b>Subsection:</b>	Topical Products	<b>Original Policy Date:</b>	April 7, 2017
<b>Subject:</b>	Dupixent	<b>Page:</b>	12 of 23

---

unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

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 ALL** of the following with provided documentation (e.g., medical records, laboratory values):

1. Improvement in sino-nasal symptoms
2. Decreased utilization of oral corticosteroids
3. Patient has been adherent to Dupixent therapy
4. **NO** dual therapy with another monoclonal antibody for the treatment of CRSwNP (see Appendix 5)
5. **NOT** given concurrently with live vaccines
6. 18 years of age and older **ONLY**: Patient **MUST** have tried the preferred product(s) (see Appendix 7) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

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:

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2026
<b>Subsection:</b>	Topical Products	<b>Original Policy Date:</b>	April 7, 2017
<b>Subject:</b>	Dupixent	<b>Page:</b>	13 of 23

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## Prurigo nodularis (PN)

**AND ALL** of the following with provided documentation (e.g., medical records, laboratory values):

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](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 ALL** of the following with provided documentation (e.g., medical records, laboratory values):

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
6. Patient **MUST** have tried the preferred product(s) (see Appendix 7) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2026
<b>Subsection:</b>	Topical Products	<b>Original Policy Date:</b>	April 7, 2017
<b>Subject:</b>	Dupixent	<b>Page:</b>	14 of 23

---

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 ALL** of the following with provided documentation (e.g., medical records, laboratory values):

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
5. Patient **MUST** have tried the preferred product(s) (see Appendix 7) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

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:

Bullous pemphigoid (BP)

<b>Section:</b> Prescription Drugs	<b>Effective Date:</b> April 1, 2026
<b>Subsection:</b> Topical Products	<b>Original Policy Date:</b> April 7, 2017
<b>Subject:</b> Dupixent	<b>Page:</b> 15 of 23

**AND ALL** of the following with provided documentation (e.g., medical records, laboratory values):

1. Improvement in symptoms
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.

## Policy Guidelines

### Pre - PA Allowance

None

### Prior - Approval Limits

#### Quantity

Strength	Diagnosis	Quantity
100 mg	Asthma	12 injections per 168 days <b>OR</b>
	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
	Bullous pemphigoid	N/A
200 mg	Asthma	14 injections per 168 days <b>OR</b>
	Atopic dermatitis	
	Chronic rhinosinusitis with nasal polyps	N/A
	Eosinophilic esophagitis	12 injections per 168 days <b>OR</b>
	Prurigo nodularis	N/A

**Section:** Prescription Drugs

**Effective Date:** April 1, 2026

**Subsection:** Topical Products

**Original Policy Date:** April 7, 2017

**Subject:** Dupixent

**Page:** 16 of 23

	Chronic obstructive pulmonary disease	N/A
	Chronic spontaneous urticaria	14 injections per 168 days <b>OR</b>
	Bullous pemphigoid	N/A
300 mg	Asthma	14 injections per 168 days <b>OR</b>
	Atopic dermatitis	
	Chronic rhinosinusitis with nasal polyps	12 injections per 168 days <b>OR</b>
	Eosinophilic esophagitis	24 injections per 168 days <b>OR</b>
	Prurigo nodularis	14 injections per 168 days <b>OR</b>
	Chronic obstructive pulmonary disease	12 injections per 168 days <b>OR</b>
	Chronic spontaneous urticaria	14 injections per 168 days <b>OR</b>
	Bullous pemphigoid	14 injections per 168 days

**Duration** 24 weeks

## Prior – Approval *Renewal* Limits

### Quantity

Strength	Diagnosis	Quantity
100 mg	Asthma	6 injections per 84 days <b>OR</b>
	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
	Bullous pemphigoid	N/A
	200 mg	Asthma
Atopic dermatitis		
Chronic rhinosinusitis with nasal polyps		N/A
Eosinophilic esophagitis		6 injections per 84 days <b>OR</b>
Prurigo nodularis		N/A

<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2026
<b>Subsection:</b>	Topical Products	<b>Original Policy Date:</b>	April 7, 2017
<b>Subject:</b>	Dupixent	<b>Page:</b>	17 of 23

	Chronic obstructive pulmonary disease	N/A
	Chronic spontaneous urticaria	6 injections per 84 days <b>OR</b>
	Bullous pemphigoid	N/A
300 mg	Asthma	6 injections per 84 days <b>OR</b>
	Atopic dermatitis	
	Chronic rhinosinusitis with nasal polyps	6 injections per 84 days <b>OR</b>
	Eosinophilic esophagitis	12 injections per 84 days <b>OR</b>
	Prurigo nodularis	6 injections per 84 days <b>OR</b>
	Chronic obstructive pulmonary disease	6 injections per 84 days <b>OR</b>
	Chronic spontaneous urticaria	6 injections per 84 days <b>OR</b>
	Bullous pemphigoid	6 injections 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 polyps (CRSwNP), prurigo nodularis (PN), chronic obstructive pulmonary disease (COPD), chronic spontaneous urticaria (CSU), and bullous pemphigoid (PG). 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 12 years of age with CRSwNP and CSU have not been established. The safety and effectiveness of Dupixent in pediatric patients less than 18 years of age with PN, COPD, and BP have not been established (1).

<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2026
<b>Subsection:</b>	Topical Products	<b>Original Policy Date:</b>	April 7, 2017
<b>Subject:</b>	Dupixent	<b>Page:</b>	18 of 23

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 2025.
2. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2024. Available from [www.ginasthma.org](http://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 $\geq 150$ 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

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2026
<b>Subsection:</b>	Topical Products	<b>Original Policy Date:</b>	April 7, 2017
<b>Subject:</b>	Dupixent	<b>Page:</b>	19 of 23

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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
October 2024	Per PI update, changed indication to chronic rhinosinusitis with nasal polyps and decreased age to 12 and older. Also added COPD indication. Adjusted dual therapy for Asthma indication to prohibit use with another monoclonal antibody for asthma/COPD. Added Appendix 4 noting monoclonal antibodies for the treatment of Asthma or COPD. Per FEP, added requirement to t/f phototherapy or conventional treatment for prurigo nodularis. Added renewal requirement for patient to be adherent to Dupixent therapy to each indication in renewal criteria.
December 2024	Annual editorial review. Added Appendix 5 and no dual therapy requirement for CRSwNP
March 2025	Annual review
May 2025	Per PI update, added indication of CSU. Added Appendix 6
August 2025	Per PI update, added indication of BP
September 2025	Annual review
December 2025	Annual review. Moved Dupixent to non-preferred. Added documentation requirement for all indications. Added Appendix 7

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2026
<b>Subsection:</b>	Topical Products	<b>Original Policy Date:</b>	April 7, 2017
<b>Subject:</b>	Dupixent	<b>Page:</b>	20 of 23

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March 2026      Annual review. Per FEP, for EoE continuation, added that only patients 11 and older need a decrease in intraepithelial eosinophils from baseline and per FEP, increased initiation duration to 24 weeks. Per SME, changed PN requirement from t/f conventional systemic therapy to t/f a topical calcineurin inhibitor and removed BP requirement to t/f conventional systemic therapy

## Keywords

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 6, 2026 and is effective on April 1, 2026.**

**Section:** Prescription Drugs**Effective Date:** April 1, 2026**Subsection:** Topical Products**Original Policy Date:** April 7, 2017**Subject:** Dupixent**Page:** 21 of 23**Appendix 1**

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

**Appendix 2**

<b>Relative Potency of Selected Topical Corticosteroids</b>		
<b>Drug</b>	<b>Dosage Form</b>	<b>Strength</b>
<b>Very high Potency</b>		
Augmented betamethasone dipropionate	Ointment, Gel	0.05%
Clobetasol propionate	Cream, Ointment	0.05%
Diflorasone diacetate	Ointment	0.05%
Flurandrenolide	Tape	4 mcg/cm <sup>2</sup>
Halobetasol propionate	Cream, Ointment	0.05%
<b>High Potency</b>		
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%
<b>Medium Potency</b>		
Betamethasone dipropionate	Lotion	0.05%
Betamethasone valerate	Cream	0.1%
Clocortolone pivalate	Cream	0.1%
Desoximetasone	Cream	0.05%

**Section:** Prescription Drugs**Effective Date:** April 1, 2026**Subsection:** Topical Products**Original Policy Date:** April 7, 2017**Subject:** Dupixent**Page:** 22 of 23

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%
<b><i>Low Potency</i></b>		
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
lebrikizumab-lbkz	Ebglyss
nemolizumab-ilto	Nemludio
tralokinumab-ldrm	Adbry
upadactinib	Rinvoq

**Appendix 4 - List of Monoclonal Antibodies for Asthma or COPD**

Generic Name	Brand Name
benralizumab	Fasenra

<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2026
<b>Subsection:</b>	Topical Products	<b>Original Policy Date:</b>	April 7, 2017
<b>Subject:</b>	Dupixent	<b>Page:</b>	23 of 23

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
tezepelumab-ekko	Tezspire

#### Appendix 6 - List of Monoclonal Antibodies for CSU

Generic Name	Brand Name
dupilumab	Dupixent
omalizumab	Xolair

#### Appendix 7 - List of Preferred Products

List of preferred products:

[https://info.caremark.com/content/dam/enterprise/caremark/microsites/dig/pdfs/pa-fep/fep-misc/FEP\\_IndicationMedChx.pdf](https://info.caremark.com/content/dam/enterprise/caremark/microsites/dig/pdfs/pa-fep/fep-misc/FEP_IndicationMedChx.pdf)

Refer to formulary documents for confirmation of coverage:

<https://www.fepblue.org/pharmacy/prescriptions#drug-lists>