

Request for Prior Authorization for Dupixent (dupilumab)

Website Form – www.highmarkhealthoptions.com

Submit request via: Fax - 1-855-476-4158

All requests for Dupixent (dupilumab) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Dupixent (dupilumab) Prior Authorization Criteria:

Coverage may be provided with a diagnosis of Moderate to Severe Asthma and the following criteria is met:

- Member is 12 years of age or older
- The medication must be prescribed by or in association with an pulmonologist, allergist, or immunologist
- If the member has eosinophilic phenotype moderate to severe asthma, member must have a blood eosinophil count > 300 cells/microliter within 4 weeks of treatment initiation
- Member must have failure to controller medications defined as symptoms that have been uncontrolled despite adherence with at least a three month trial of controller medications, which includes at least a high-dosed inhaled corticosteroid plus another agent.
- Dupixent will be used in conjunction with ONE of the following (which can be verified via pharmacy claims):
 - A maximally-dosed combination inhaled corticosteroid/long-acting-beta2-agonist product
 - Combination therapy consisting of BOTH of the following:
 - A high-dose inhaled corticosteroid
 - An additional standard asthma controller medication (e.g., long-acting beta agonist, leukotriene receptor antagonist, etc.)
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- **Initial Duration of Approval:** 6 months
- **Reauthorization criteria**
 - Documentation the member had a positive clinical response or stabilization as demonstrated by one of the following:
 - An increase in the member's FEV₁
 - A decreased need for systemic corticosteroids
 - A decrease in the number of asthma related hospitalizations
 - A reduction in reported asthma-related symptoms
 - Adjunctive therapies (inhaled corticosteroids, long-acting beta-2 agonist, leukotriene receptor antagonist, theophylline) must be consistently filled per pharmacy claims history
 - If pharmacy claims do not confirm fills within the previous 3 months, the request will be denied
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided with a diagnosis of Moderate to Severe Atopic dermatitis and the following criteria is met:

- Member is 6 years of age or older
- The medication must be prescribed by or in association with a dermatologist, allergist, or immunologist
- In addition to pruritic skin, member must have three or more of the following:
 - History of skin creases being involved. These include: antecubital fossae, popliteal fossae, neck, areas around eyes, fronts of ankles.
 - History of asthma or hay fever
 - The presence of generally dry skin within the past year.
 - Symptoms beginning before the age of two years.
 - Visible dermatitis involving flexural surfaces.
- Must provide documentation of involvement of at least 10% of body surface area.
- Must provide documentation showing the member has tried and failed (which will be verified via pharmacy claims if available) or had an intolerance or contraindication to ALL of the following:
 - Two-week trial of at least one medium to high potency topical corticosteroid
 - Six-week trial of tacrolimus* or Elidel*
 - A four week trial of Eucrisa*
 - Eight week trial of at least one systemic immunosuppressive therapy (e.g., cyclosporine, azathioprine, methotrexate)
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- **Initial Duration of Approval:** 4 months
- **Reauthorization criteria**
 - Body Surface Area involvement at baseline
 - Member has experienced and maintained a reduction in body surface area involvement relative to baseline
- **Reauthorization Duration of Approval:** 12 months

*Elidel, tacrolimus ointment, and Eucrisa may require a prior authorization.

Coverage may be provided with a diagnosis of Chronic Rhinosinusitis with Nasal Polyposis and the following criteria is met:

- Member is 18 years of age or older
- The medication must be prescribed by or in association with allergist, ear/nose/throat specialist or immunologist
- Medication must be used for add-on maintenance therapy
- Must provide documentation showing the member has tried and failed (which will be verified via pharmacy claims if available) or had an intolerance or contraindication to ALL of the following:
 - 12 week trial of intranasal or oral corticosteroid
 - 1 week trial of nasal saline irrigations
 - 3 week course of antibiotics
- Member has relapsed from sinus surgery or has a contraindication from sinus surgery
- Member must have presence of at least two of the following symptoms prior to taking medication:

- Nasal blockade/obstruction/congestion or nasal discharge (anterior/posterior nasal drip)
 - Facial pain/pressure
 - Reduction or loss of smell.
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- **Initial Duration of Approval:** 6 months
- **Reauthorization criteria**
 - Reauthorization benefit will be approved if there is evidence of positive clinical response involving the following clinical/laboratory parameters:
 - Nasal blockade/obstruction/congestion or nasal discharge (anterior/posterior nasal drip)
 - Facial pain/pressure
 - Reduction or loss of smell.
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

Drugs are authorized in generic form unless the branded product is on the preferred drug list or the prescriber has indicated in writing that the branded product is medically necessary. If only the branded product is on the preferred drug list, the generic form will be considered non-preferred and shall not require the prescriber to indicate in writing that the branded product is medically necessary.

**DUPIXENT (DUPILUMAB)
PRIOR AUTHORIZATION FORM**

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Health Options Pharmacy Services. **FAX:** (855) 476-4158

If needed, you may call to speak to a Pharmacy Services Representative.

PHONE: (844) 325-6251 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:
Health Options ID:	Member weight: _____ pounds or _____ kg

REQUESTED DRUG INFORMATION

Medication:	Strength:
Frequency:	Duration:
Is the member currently receiving requested medication? <input type="checkbox"/> Yes <input type="checkbox"/> No	
Date Medication Initiated:	
Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? <input type="checkbox"/> Yes <input type="checkbox"/> No	

BILLING INFORMATION

This medication will be billed: <input type="checkbox"/> at a pharmacy OR <input type="checkbox"/> medically (if medically please provide a JCODE: _____)	
Place of Service: <input type="checkbox"/> Hospital <input type="checkbox"/> Provider's office <input type="checkbox"/> Member's home <input type="checkbox"/> Other	

PLACE OF SERVICE INFORMATION

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

1) Which of the following diagnoses will the medication be used for:

a. Moderate to Severe Asthma. ☐ Yes ☐ No

If yes, please answer the following questions:

i. Is the member 12 year of age or older?
☐ Yes ☐ No

ii. Will the medication be prescribed by or in consultation with a pulmonologist, allergist or immunologist?
☐ Yes ☐ No

iii. Is the Blood eosinophil count ≥ 300 cells/microliter within 4 weeks of treatment initiation?
☐ Yes ☐ No

iv. Does the member have failure to controller medications defined as symptoms that have been uncontrolled despite adherence with at least a three month trial of controller medications, which includes at least a high-dosed inhaled corticosteroid plus another agent?
☐ Yes ☐ No

v. Will Dupixent be used in conjunction with ONE of the following:

1. A maximally-dosed combination inhaled corticosteroid/long-acting-beta2-agonist product.
☐ Yes ☐ No

2. Combination therapy consisting of BOTH of the following:

- a. A high-dose inhaled corticosteroid
- b. An additional standard asthma controller medication (e.g., long-acting beta agonist, leukotriene receptor antagonist, etc.)

☐ Yes ☐ No

b. Moderate to Severe Atopic Dermatitis ☐ Yes ☐ No

If yes, please answer the following questions:

i. Is member 6 years of age or older?

☐ Yes ☐ No

ii. Will the medication be prescribed by or in association with a dermatologist, allergist, or immunologist?

☐ Yes ☐ No

iii. Does the member have any of the following? (Check ALL that apply):

- 1. History of skin creases being involved. These include: antecubital fossae, popliteal fossae, neck, areas around eyes, fronts of ankles. ☐ Yes ☐ No
- 2. History of asthma or hay fever. ☐ Yes ☐ No
- 3. The presence of generally dry skin within the past year. ☐ Yes ☐ No
- 4. Symptoms beginning in a child before the age of two years. ☐ Yes ☐ No
- 5. Visible dermatitis involving flexural surfaces. ☐ Yes ☐ No

iv. Provide percentage of body surface area involved: _____

v. Is there documentation showing the member has tried and failed or had an intolerance or contraindication to any of the following? (Please check ALL that apply)

- 1. At least one medium to high potency topical corticosteroid
☐ Yes ☐ No
- 2. 6 week trial of tacrolimus* or Elidel
☐ Yes ☐ No
- 3. Eight week trial of at least one systemic immunosuppressive therapy (e.g., cyclosporine, azathioprine, methotrexate)
☐ Yes ☐ No

c. Chronic Rhinosinusitis with Nasal Polyposis

i. Is member 12 years of age or older?

☐ Yes ☐ No

ii. Will the medication be prescribed by or in association with an allergist, ear/nose/throat specialist, or immunologist?

☐ Yes ☐ No

iii. Is there documentation showing the member has tried and failed or had an intolerance or contraindication to ANY of the following:

- 1. 12 week trial of intranasal or oral corticosteroid
☐ Yes ☐ No
- 2. 1 week trial of nasal saline irrigations
☐ Yes ☐ No

3. 3 to 4 week courses of antibiotics
☐ Yes ☐ No
- iv. Has the member relapsed from sinus surgery or has a contraindication from sinus surgery?
☐ Yes ☐ No
- v. Will the medication be used as add-on maintenance therapy?
(If yes, please also document in section below)
☐ Yes ☐ No
- vi. Does the member have presence of at any of the following symptoms prior to taking medication:
1. Nasal blockade/obstruction/congestion or nasal discharge (anterior/posterior nasal drip)
☐ Yes ☐ No
 2. Facial pain/pressure
☐ Yes ☐ No
 3. Reduction or loss of smell
☐ Yes ☐ No
- d. Other Diagnosis: _____

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

REAUTHORIZATION

1. If using medication for atopic dermatitis, please provide percentage of body surface area involved: _____
Please describe:
2. If using medications for asthma, please answer the following questions:
- a. Is there documentation that the member had a positive clinical response or stabilization as demonstrated by one of the following:
 - i. An increase in the member's FEV₁
☐ Yes ☐ No
 - ii. A decreased need for systemic corticosteroids
☐ Yes ☐ No
 - iii. A decrease in the number of asthma related hospitalizations
☐ Yes ☐ No
 - iv. A reduction in reported asthma-related symptoms
☐ Yes ☐ No
 - b. Are adjunctive therapies (inhaled corticosteroids, long-acting beta-2 agonist, leukotriene receptor antagonist, theophylline) being consistently filled?
☐ Yes ☐ No

- c. If member is using medication for Chronic Rhinosinusitis with Nasal Polyposis, is there evidence of positive clinical response involving the following clinical/laboratory parameters:
- i. Nasal blockade/obstruction/congestion or nasal discharge (anterior/posterior nasal drip)
 - ii. Facial pain/pressure
 - iii. Reduction or loss of smell.
- ☐ Yes ☐ No

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature

Date