Updated: 05/2019
PARP Approved: 07/2019

Prior Authorization Criteria

Dupixent (dupilumab)

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

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
- Documentation of bronchodilator reversibility demonstrated either by an increase in FEV1 of ≥ 12 percent from baseline or an increase of ≥ 10 percent of predicted FEV1
- If the member has eosinophilic phenotype moderate to severe asthma, member must have a blood eosinophil count ≥150 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:
    - 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 FEV_1
        - A decreased need for systemic corticosteroids
        - A decrease in the number of asthma related hospitalizations
        - A reduction in reported asthma-related symptoms
    - Documentation the prescribed dose and dosing frequency of Dupixent remain appropriate for the current weight of the member
    - 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 12 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.
    - Pruritus, eczema (acute, subacute, chronic)
    - Facial, neck, and extensor involvement in infants and children
    - Current or previous flexural lesions in any age group
    - Sparing of the groin and axillary regions
    - Early age of onset
    - Atopy
    - Personal and/or family history
    - Immunoglobulin E reactivity
    - Xerosis
- Must provide documentation of involvement of at least 10% of body surface area and/or based on factors of prescriber assessment.
- 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 ALL of the following:
    - Two-week trial of at least one medium to high potency topical corticosteroid
    - Six-week trial of tacrolimus* or Elidel*
    - 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, or any clinical documentation that provides evidence of clinical improvement.
- **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.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

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

Gateway Health

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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 Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 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:
Gateway ID:	Member weight: _____pounds or _____kg

REQUESTED DRUG INFORMATION

Medication:	Strength:
Frequency:	Duration:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:

Billing Information

This medication will be billed: ☐ at a pharmacy **OR**
☐ medically (if medically please provide a JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ 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 there documentation of bronchodilator reversibility demonstrated either by an increase in FEV1 of ≥ 12 percent from baseline or an increase of ≥ 10 percent of predicted FEV1?
      ☐ Yes ☐ No

      iv. If the member has eosinophilic phenotype moderate to severe asthma, is the Blood eosinophil count ≥ 150 cells/microliter within 4 weeks of treatment initiation?
      ☐ Yes ☐ No

      v. 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

vi. 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 18 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. Prurititis, eczema (acute, subacute, chronic) ☐ Yes ☐ No

2. History of skin creases being involved. These include: antecubital fossae, popliteal fossae, neck, areas around eyes, fronts of ankles. ☐ Yes ☐ No

3. History of asthma or hay fever. ☐ Yes ☐ No

4. The presence of generally dry skin within the past year. ☐ Yes ☐ No

5. Symptoms beginning in a child before the age of two years. ☐ Yes ☐ No

6. Visible dermatitis involving flexural surfaces. ☐ Yes ☐ No

7. Facial, neck, and extensor involvement in infants and children. ☐ Yes ☐ No

8. Current or previous flexural lesions in any age group ☐ Yes ☐ No

9. Sparing of the groin and axillary regions ☐ Yes ☐ No

10. Early age of onset ☐ Yes ☐ No

11. Atopy ☐ Yes ☐ No

12. Personal and/or family history ☐ Yes ☐ No

13. Immunoglobulin E reactivity ☐ Yes ☐ No

14. Xerosis ☐ 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. 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:
   - Is there documentation that the member had a positive clinical response or stabilization as demonstrated by one of the following:
     - An increase in the member's FEV_1
       ☐ Yes ☐ No
     - A decreased need for systemic corticosteroids
       ☐ Yes ☐ No
     - A decrease in the number of asthma related hospitalizations
       ☐ Yes ☐ No
     - A reduction in reported asthma-related symptoms
       ☐ Yes ☐ No
   - Is there documentation that the prescribed dose and dosing frequency of Xolair remain appropriate for the current weight of the member?
     ☐ Yes ☐ No
   - Are adjunctive therapies (inhaled corticosteroids, long-acting beta-2 agonist, leukotriene receptor antagonist, theophylline) being consistently filled?
     ☐ Yes ☐ No

SUPPORTING INFORMATION or CLINICAL RATIONALE	
Prescribing Provider Signature	Date