Gateway Health Plan
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

Gateway Health It's Wholecare.

Requirements for Prior Authorization of Dupixent (dupilumab)

A. Prescriptions That Require Prior Authorization

All prescriptions for Dupixent (dupilumab) must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for Dupixent (dupilumab), the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is being treated for a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**

2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. If currently using a different Monoclonal Antibody (MAB) – Anti-IL, Anti-IgE, will discontinue the other MAB – Anti-IL, Anti-IgE prior to starting Dupixent (dupilumab); **AND**

4. For treatment of moderate to severe chronic atopic dermatitis, has a history of therapeutic failure of at least **two** of the following OR a contraindication or an intolerance to **all** of the following:

    a. **One** of the following:
        i. For treatment of the face, skin folds, or other critical areas, a low-potency topical corticosteroid
        ii. For treatment of other areas, a medium-potency or higher topical corticosteroid,
    b. A topical calcineurin inhibitor,
    c. Phototherapy in accordance with current consensus guidelines,
    d. Systemic immunosuppressives in accordance with current consensus guidelines (e.g., cyclosporine, azathioprine, methotrexate, mycophenolate mofetil);

    AND

2. For a diagnosis of asthma, **all** of the following:

    a. Is prescribed Dupixent (dupilumab) by or in consultation with an appropriate specialist (e.g., allergist, immunologist, pulmonologist),
    b. Has asthma severity consistent with the FDA-approved indication for Dupixent (dupilumab) despite maximal therapeutic doses of or intolerance or contraindication to asthma controller medications based on current national treatment guidelines for the diagnosis and management of asthma,
    c. **One** of the following:
        i. Has absolute blood eosinophil count ≥150 cells/microL
        ii. Is dependent on oral corticosteroids,
    d. Will use Dupixent (dupilumab) in addition to standard asthma controller medications as recommended by current national treatment guidelines;

Gateway Health Plan
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR DUPIXENT (DUPILUMAB): The determination of medical necessity of a request for renewal of a prior authorization for Dupixent (dupilumab) that was previously approved will take into account whether the beneficiary:

1. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

2. For a diagnosis of atopic dermatitis or chronic rhinosinusitis with nasal polyposis, has documented evidence of improvement in disease severity; **AND**

3. For a diagnosis of asthma, **all** of the following:

    a. Is prescribed Dupixent (dupilumab) by or in consultation with an appropriate specialist (e.g., allergist, immunologist, pulmonologist),

    b. **One** of the following:
        i. Has documented measurable evidence of improvement in the severity of the asthma condition
        ii. Has reduction of oral corticosteroid dose while maintaining asthma control,

    c. Continues to use Dupixent (dupilumab) in addition to standard asthma controller medications as recommended by current national treatment guidelines;

    NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for Dupixent (dupilumab). If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

Gateway Health
It's Wholecare.

Gateway Health Plan
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

DUPIXENT (dupilumab) PRIOR AUTHORIZATION FORM

☐New request ☐Renewal request	# of pages: _____	Prescriber name:	
Name of office contact:		Specialty:	
Contact's phone number:		NPI:	State license #:
LTC facility contact/phone:		Street address:	
Beneficiary name:		Suite #:	City/state/zip:
Beneficiary ID#:	DOB:	Phone:	Fax:

CLINICAL INFORMATION

Drug requested: Dupixent	Strength/formulation:	Weight: _____ lbs / kg	
Directions:		Quantity:	Refills:
Diagnosis (*submit documentation*):		Diagnosis code (*required*):	
For a diagnosis of asthma, is Dupixent being prescribed by or in consultation with a specialist?		☐Yes ☐No	*Submit documentation of consultation if applicable.*

INITIAL requests

☐ ***For the treatment of atopic dermatitis:*** Which of the following treatments have been tried (or cannot be tried due to intolerance or contraindication) by the beneficiary? *Check all that apply. SUBMIT DOCUMENTATION for each.*

- ☐For the face or skin folds, low-potency (or higher) topical corticosteroids
- ☐For other body areas, a topical corticosteroid with a potency appropriate for the beneficiary's age and affected area(s) of the body
- ☐Elidel (pimecrolimus) or Protopic (tacrolimus)
- ☐Phototherapy / photochemotherapy (e.g., PUVA, UVB light)
- ☐Systemic immunosuppressives (e.g., azathioprine, cyclosporine, methotrexate, mycophenolate)

☐ ***For the treatment of asthma:*** Indicate which of the following apply to the beneficiary. *Check all that apply. SUBMIT DOCUMENTATION for each.*

- ☐Has a diagnosis of asthma with an eosinophilic phenotype with an absolute blood eosinophil count ≥ 150 cells/microliter
- ☐Has a diagnosis of oral corticosteroid-dependent asthma
- ☐Has asthma that is moderate-to-severe
- ☐Has tried or cannot use standard asthma controller medications (e.g., inhaled corticosteroids, inhaled long-acting beta agonists (LABAs), etc.)
- ☐Will use Dupixent in addition to tolerated standard asthma controller medications (e.g., inhaled corticosteroids, inhaled LABAs, etc.)

☐ ***For treatment of chronic rhinosinusitis with nasal polyposis:*** *Check all that apply. SUBMIT DOCUMENTATION for each.*

- ☐Will use Dupixent as an add-on maintenance treatment for inadequately controlled chronic rhinosinusitis with nasal polyposis

RENEWAL requests

Since starting Dupixent, did the beneficiary experience a positive clinical response and/or improvement in disease severity?	☐Yes ☐No *Submit documentation of clinical response.*

PLEASE FAX COMPLETED FORM TO GATEWAY – PHARMACY DIVISION

Prescriber Signature:	Date: