Highmark Wholecare
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

I. 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 age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

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

4. Is prescribed Dupixent (dupilumab) by or in consultation with an appropriate specialist (e.g., pulmonologist, allergist, immunologist, dermatologist, hematologist/oncologist, rheumatologist, etc.); **AND**

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

6. If currently using a different targeted systemic Immunomodulator, Atopic Dermatitis (e.g., Adbry [tralokinumab], Cibinqo [abrocitinib], Rinvoq [upadacitinib]), will discontinue the other targeted systemic Immunomodulator, Atopic Dermatitis prior to starting Dupixent (dupilumab); **AND**

7. For a diagnosis of moderate to severe chronic atopic dermatitis, has a history of therapeutic failure of or a contraindication or an intolerance to **both** of the following:

   a. **One** of the following:

      i. For treatment of the face, skin folds, or other critical areas, a 4-week trial of a low-potency topical corticosteroid
      ii. For treatment of other areas, a 4-week trial of a medium-potency or higher topical corticosteroid

   b. An 8-week trial of a topical calcineurin inhibitor;

   AND

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

    a. Has asthma severity consistent with the FDA-approved indication for Dupixent (dupilumab) despite maximal therapeutic doses of or a contraindication or an intolerance to asthma controller medications based on current national treatment guidelines for the diagnosis and management of asthma,

    b. **One** of the following:

        i. Has absolute blood eosinophil count ≥150 cells/microL
        ii. Is dependent on oral corticosteroids,

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

    AND

9. For a diagnosis of eosinophilic esophagitis, has a history of therapeutic failure of or a contraindication or an intolerance to a proton pump inhibitor; **AND**

10. For a diagnosis of prurigo nodularis, **both** of the following:

    a. Has a history of pruritis lasting at least 6 weeks

    b. Has prurigo nodularis associated with at least **one** of the following:

        i. ≥20 nodular lesions
        ii. Significant disability or impairment of physical, mental, or psychosocial functioning;

    AND

11. For all other diagnoses, has a history of therapeutic failure of or a contraindication or an intolerance to first line therapy(ies) if applicable according to consensus 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.

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. Is prescribed Dupixent (dupilumab) by or in consultation with an appropriate specialist (e.g., pulmonologist, allergist, immunologist, dermatologist, hematologist/oncologist, rheumatologist, etc.); **AND**

3. Has documented evidence of improvement in disease severity; **AND**

4. For a diagnosis of asthma, **both** of the following:

   a. **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

   b. 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.

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DUPIXENT (dupilumab) PRIOR AUTHORIZATION FORM *(form effective 1/8/2024)*

☐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:		City/state/zip:	
Beneficiary ID#:	DOB:	Phone:	Fax:

CLINICAL INFORMATION

Drug requested: Dupixent	Strength:	Formulation (pen, syringe, etc):	Weight: _____ lbs / kg	
Directions:			Quantity:	Refills:
Diagnosis (*submit documentation*):			Diagnosis code (*required*):	
Is Dupixent prescribed by or in consultation with a specialist (eg, allergist, dermatologist, hematologist/oncologist, immunologist, pulmonologist, rheumatologist, etc)?			☐Yes ☐No	*Submit documentation of consultation, if applicable.*

Complete the section(s) below applicable to the beneficiary and this request and SUBMIT DOCUMENTATION for each item.

INITIAL requests

1. **For 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.*
   - ☐At least ONE of the of the following:
     - ☐For the face, skin folds, or other critical areas, a 4-week trial of a low-potency (or higher) topical corticosteroid
     - ☐For other body areas, a 4-week trial of a medium potency or higher topical corticosteroid
   - ☐An 8-week trial of a topical calcineurin inhibitor (eg, pimecrolimus, tacrolimus)

2. **For treatment of asthma:** Indicate which of the following apply to the beneficiary. *Check all that apply.*
   - ☐At least ONE of the following:
     - ☐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.)

3. **For treatment of chronic rhinosinusitis with nasal polyposis:**
   - ☐Will use Dupixent as an add-on maintenance treatment for inadequately controlled chronic rhinosinusitis with nasal polyposis

4. **For treatment of eosinophilic esophagitis:**
   - ☐Has tried and failed or cannot try (due to intolerance or contraindication) a proton pump inhibitor (eg, omeprazole, lansoprazole, etc)

5. **For treatment of prurigo nodularis:**
   - ☐Has a history of pruritis for at least 6 weeks
   - ☐Has prurigo nodularis associated with at least ONE of the following:
     - ☐≥20 nodular lesions
     - ☐Significant disability or impairment of physical, mental, or psychosocial functioning

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6. **Other diagnosis – specify:** _____

List other treatments tried (including start/stop dates, dose, outcomes, etc.): _____

_____

RENEWAL requests

1. **For the treatment of <u>asthma</u>:**

☐ Has documented measurable evidence of improvement in the beneficiary's asthma
☐ Maintained asthma control while decreasing the oral corticosteroid dose
☐ Continues to use Dupixent in addition to tolerated standard asthma controller medications (e.g., inhaled corticosteroids, inhaled LABAs, etc.)

2. **For the treatment of <u>all other diagnoses</u>:**

☐ Has documented evidence of improvement in disease severity

PLEASE <u>FAX</u> COMPLETED FORM TO HIGHMARK WHOLECARE – PHARMACY DIVISION

Prescriber Signature:	**Date**: