Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	January 8, 2018 November 27, 2018, March 13, 2019, July 2, 2019, September 4, 2019, June 12, 2020, November 2, 2021, March 11, 2022, July 7, 2022, July 11, 2022, October 20, 2022, November 15, 2022, January 24, 2024, February 8, 2024, July 1, 2024, August 19, 2024, November 13, 2024

DUPIXENT® (dupilumab)

LENGTH OF AUTHORIZATION: One year

REVIEW CRITERIA:

- Dupixent will not be used in combination with other biologics (e.g. Xolair, Remicade, Enbrel, Humira, etc.).

Atopic Dermatitis

- Patient must be ≥ 6 months of age; **AND**
- Patient has documented diagnosis of atopic dermatitis; **AND**
- Patient has had a trial of at least one preferred medium to very-high potency topical steroid and experienced inadequate response or intolerance; **AND**
- Patient has had a trial of at least one preferred topical calcineurin inhibitor and experienced inadequate response or intolerance.

Asthma

- Patient must be ≥ 6 years of age; **AND**
- Must have diagnosis of moderate to severe asthma, eosinophilic phenotype **OR** oral corticosteroid-dependent **(**OCS) dependent; **AND**
- Prescribed by or in consultation with an allergist, pulmonologist, or immunologist; **AND**
- If eosinophilic phenotype, must have a blood eosinophil count of ≥ 150 cells/mcL (documentation required); **AND**
- Patient has ongoing symptoms of asthma with a minimum three-month trial of an inhaled corticosteroid plus a long-acting beta 2 agonist (LABA) combination therapy.

Chronic Obstructive Pulmonary Disease (COPD)

- Patient must be ≥ 18 years of age; **AND**
- Must have diagnosis of COPD and an eosinophilic phenotype; **AND**
- Patient has a baseline blood eosinophil count ≥ 300 cells/mcL (documentation required); **AND**
- Patient has moderate to severe airflow limitation confirmed by pulmonary function tests (e.g., FEV_1/FVC ratio, FEV_1) performed within the past 30 days; **AND**
- Patient has a history of moderate to severe COPD exacerbations and symptoms of chronic productive cough for at least 3 months, both within the past year while on maintenance triple therapy with an inhaled corticosteroid (ICS), a long-acting beta agonist (LABA), and a long-acting muscarinic antagonist (LAMA).

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Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)

- Patient must be ≥ 18 years of age; **AND**
- Must have a diagnosis of chronic rhinosinusitis with nasal polyposis (progress notes or diagnosis codes); **AND**
- Patient is inadequately controlled with first line therapy (inflammation of the paranasal sinuses lasting more than 12 weeks); **AND**
- Dupixent is add on therapy to first line treatment: intranasal or oral corticosteroids, nasal saline irrigations, and 3-4 week courses of antibiotics (submission of current therapy required).

Eosinophilic Esophagitis (EoE)

- Patient must be ≥ 1 year of age and ≥ 15 kg; **AND**
- Must have a diagnosis of Eosinophilic Esophagitis; **AND**
- Prescribed or in consultation with an allergist, pulmonologist, immunologist, or gastroenterologist; **AND**
- Patient has an eosinophilic count ≥15 eosinophils per high-power microscopy field (eos/hpf); Must have a diagnosis of Eosinophilic Esophagitis; **AND**
- Symptoms of dysphagia or prior history of esophageal dilation.

Prurigo Nodularis

- Patient must be ≥ 18 years of age; **AND**
- Patient has documented diagnosis of prurigo nodularis with ≥ 20 nodular lesions; **AND**
- Patient has had a trial with phototherapy; **AND**
- Patient has had a trial of at least one preferred medium to very-high potency topical steroid and experienced inadequate response or intolerance; **AND**
- Patient has had a trial of at least one preferred immunosuppressive agent (cyclosporine, methotrexate, azathioprine, cyclophosphamide, tacrolimus).

CONTINUATION OF THERAPY:

- Initial approval criteria for therapy has been met at the time of initiation of therapy.
- Dupixent will not be used in combination with other biologics (e.g. Xolair, Remicade, Enbrel, Humira, etc.).
- Dosing is appropriate as per labeling or is supported by compendia.

Atopic Dermatitis

- Treatment with Dupixent has resulted in clinical improvement documented in the progress notes (e.g. clinical reduction in pruritus and flares).

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Asthma

- Treatment with Dupixent has resulted in clinical improvement as documented in progress notes by:
  - One or more of the following:
    - Decreased utilization of rescue medications; **OR**
    - Decreased frequency of exacerbations (defined as worsening of asthma that requires increase in inhaled corticosteroid dose or treatment with systemic corticosteroids); **OR**
    - Reduction in reported asthma-related symptoms, such as, but not limited to, wheezing, shortness of breath, coughing, fatigue, sleep disturbance, or asthmatic symptoms upon awakening.
- Continued use of inhaled corticosteroid plus LABA combination while on Dupixent therapy for asthma is documented; **AND**
- Patients should periodically be reassessed for the need to continue therapy based on the disease severity and/or the level of asthma control.

Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)

- Treatment with Dupixent has resulted in clinical improvement documented in the progress notes.

Eosinophilic Esophagitis (EoE)

- Treatment with Dupixent has resulted in clinical improvement documented in the progress notes.

Prurigo Nodularis

- Treatment with Dupixent has resulted in clinical improvement documented in the progress notes by:
  - Reduction in itch intensity; **OR**
  - Reduction in number of nodules

Chronic Obstructive Pulmonary Disease (COPD)

- Improved lung function as demonstrated by a reduction in COPD exacerbations and significant improvement in pulmonary function tests compared to baseline.
- Documented continuation of maintenance triple therapy (e.g., an inhaled corticosteroid, long-acting beta agonist and long-acting muscarinic antagonist) while on Dupixent.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as 300 mg/2 mL solution in a single-dose pre-filled pen, 300 mg/2 mL solution in a single-dose pre-filled syringe with needle shield, 200 mg/1.14 mL solution in a single-dose pre-filled pen, 200 mg/1.14

mL solution in a single-dose pre-filled syringe with needle shield and 100 mg/0.67 mL solution in a single-dose pre-filled syringe with needle shield.