Division: Pharmacy Policy	Subject: State of Florida's Agency for Health Care Administration's 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, June 16, 2022

DUPIXENT® (dupilumab)

LENGTH OF AUTHORIZATION: SIX MONTHS

CLINICAL NOTES: Dupixent® is an interleukin-4 receptor alpha antagonist indicated for the treatment of patients aged 6 years of age and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Dupixent® can be used with or without topical corticosteroids. It is indicated as an add-on maintenance treatment in patients with moderate-to-severe asthma aged 6 years of age and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma. It is indicated as an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis. It is also indicated for the treatment of eosinophilic esophagitis in patients 12 years of age and older.

REVIEW CRITERIA:

Atopic Dermatitis

1. Patient must be 6 years of age or older.
2. Patient has documented diagnosis of atopic dermatitis.
3. Patient has had a trial of at least one preferred medium to very-high potency topical steroid and experienced inadequate response or intolerance; **AND**
4. Patient has had a trial of at least one preferred topical calcineurin inhibitor and experienced inadequate response or intolerance.
5. Dupixent will not be used in combination with other biologics (e.g. Xolair, Remicade, Enbrel, Humira, etc).
6. Patient does not have a parasitic infection.

Asthma (moderate to severe), adjunct, eosinophilic phenotype or oral corticosteroid-dependent (OCS)

1. Patient must be 6 years of age or older
2. Prescribed or in consultation with an allergist, pulmonologist, or immunologist.
3. If eosinophilic phenotype, must have a blood eosinophil count of ≥ 150 cells/mcL within the past six weeks or ≥ 300 cells/mcL within the past year (submit documentation), or FeNO > 20 ppb (parts per billion).
4. Must have diagnosis of asthma, eosinophilic phenotype **OR** OCS dependent.
5. 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 Rhinosinusitis with Nasal Polyposis

1. Patient must be 18 years of age or older.
2. Must have a diagnosis of chronic rhinosinusitis with nasal polyposis inadequately controlled with first line therapy (inflammation of the paranasal sinuses lasting more than 12 weeks).

3. 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)

1. Patient must be 12 years of age or older.
2. Prescribed or in consultation with an allergist, pulmonologist, or immunologist.
3. Must have a diagnosis of Eosinophilic Esophagitis.
4. Patient has an eosinophilic count ≥15 eosinophils per high-power microscopy field (eos/hpf).
5. Symptoms of dysphagia or prior history of esophageal dilation.

CONTINUATION OF THERAPY:

Atopic Dermatitis

1. Patient must be 6 years of age or older.
2. Patient has documented diagnosis of atopic dermatitis.
3. Documentation of positive clinical response: clinical reduction in pruritus and flares.
4. Dupixent will not be used in combination with other biologics (e.g. Xolair, Remicade, Enbrel, Humira, etc).
5. Member does not have a parasitic infection.

Asthma (moderate to severe), adjunct, eosinophilic phenotype or oral corticosteroid-dependent

1. Initial approval criteria for therapy has been met at the time of initiation of therapy.
2. Treatment with Dupixent has resulted in clinical improvement as documented by:
    - One or more of the following:
        a. Decreased utilization of rescue medications; **OR**
        b. Decreased frequency of exacerbations (defined as worsening of asthma that requires increase in inhaled corticosteroid dose or treatment with systemic corticosteroids); **OR**
        c. 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.
3. Continued use of inhaled corticosteroid plus LABA combination while on Dupixent therapy for asthma is documented; **AND**
4. 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

1. Initial approval criteria for therapy has been met at the time of initiation of therapy.
2. Patient must be 18 years of age or older.
3. Treatment with Dupixent has resulted in clinical improvement documented in the progress notes.

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Eosinophilic Esophagitis (EoE)

1. Initial approval criteria for therapy has been met at the time of initiation of therapy.
2. Documentation of improved clinical response.
3. Dosing is appropriate as per labeling or is supported by compendia.

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.