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 also indicated as an add-on maintenance treatment in patients with moderate-to-severe asthma aged 12 years of age and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma. It is also indicated as an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis.

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
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 blood eosinophil count of ≥ 150 cells/mcL within the past six weeks while on oral corticosteroid or ≥ 300 cells/mcL within the past year (submit documentation).
4. Must have diagnosis of asthma, eosinophilic phenotype OR
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).
CONTINUATION OF THERAPY:

**Atopic Dermatitis**
1. Patient must be 6 years of age or older.
2. Patient has documented diagnosis of atopic dermatitis.
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 Polypsis**
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.

**DOSING:**

**Atopic Dermatitis:**

**Adults (18 years and older):**
- Inject 600 mg subcutaneously (in two 300mg injections in different injection sites) for initial dose, then 300mg subcutaneously every other week. Use this dosing regimen for patients with co-morbid moderate to severe atopic dermatitis. **OR**
- An initial dose of 400mg (in two 200mg injections) followed by 200mg every other week.
Pediatric Patients (ages 6-17):

- 15kg to < 30 kg, 600mg (two 300mg injections) initially, followed by 300mg every 4 weeks.
- 30kg to < 60 kg, 400 mg (two 200 mg injections) initially, followed by 200mg every 2 weeks.
- 60kg or more, 600mg (two 300mg injections) initially, followed by 300mg every 2 weeks.

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

- 400 mg subcutaneously (in two 200mg injections) for initial dose, followed by 200mg every other week.
  OR
- 600 mg (in two 300mg injections) followed by 300mg every other week. Use this dosing regimen in patients requiring concomitant oral corticosteroids.

Chronic Rhinosinusitis with Nasal Polyposis

The recommended dose of Dupixent® for adult patients is 300 mg given every other week.