Prior Authorization Criteria

Dupixent® (dupilumab) Criteria FOR ASTHMA:

Dupixent® (dupilumab) is an interleukin-4 receptor alpha antagonist FDA approved for add-on maintenance treatment in patients with moderate-to-severe asthma with an eosinophilic phenotype or with oral corticosteroid-dependent asthma.

ICD-10 code(s): ____________________________________________________________

Initial Authorization: Submission of medical records or prescription claims history documenting the following requirements for the indications below is required.

Dupixent will be approved based on ALL of the following criteria:

☐ Yes  ☐ No  Age of patient is within the age range as recommended by the FDA label
-AND-

☐ Yes  ☐ No  Prescribed by or in consultation with an allergist, immunologist or pulmonologist
-AND-

☐ Yes  ☐ No  Diagnosis of moderate-to-severe asthma and one of the following:
   a. Asthma is an eosinophilic phenotype
   -OR-
   b. Currently receiving maintenance treatment with systemic glucocorticoids and has received treatment for at least 4 weeks
-AND-

☐ Yes  ☐ No  All of the following:
   ☐ Yes  ☐ No  ☐ Not Applicable. If asthma is an eosinophilic phenotype, there should be a documented eosinophil level > 150 cells/mcL within the past 12 weeks as evidenced by submission of medical records (e.g., chart notes, laboratory values, etc.) Please check "Not Applicable" if the diagnosis was based on "b" above.
   AND
   ☐ Yes  ☐ No  Patient has experienced ≥ 2 exacerbations within the last 12 months, requiring at least one of the following despite adherent use (defined as consistent timely fills over 90 days) of controller therapy (i.e., moderate to high dose inhaled corticosteroid (ICS) plus either a long-acting beta-2 agonist (LABA) or leukotriene modifier (LTRA) if LABA contraindication/intolerance)
      a. Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 months
      b. Asthma-related emergency treatment (e.g., emergency department visit, hospital admission, or unscheduled physician’s office visit for nebulizer or other urgent treatment)
      c. Airflow limitation (e.g., after appropriate bronchodilator withheld, forced expiratory volume in 1 second [FEV1] less than 80% predicted [in the face of reduced FEV1/forced vital capacity [FVC] defined as less than the lower limit of normal])
- AND -
☐ Yes ☐ No  Dupixent will be used in combination with one of the following:
a. One preferred high dose combination ICS/LABA
- OR -
b. Combination therapy including both of the following:
   i. One preferred high-dose ICS medication
- AND -
   ii. One additional preferred asthma controller medication [e.g., LABA or LTRA]
- OR -
☐ Yes ☐ No  Patient is currently on Dupixent therapy
- AND -
☐ Yes ☐ No  Patient is not receiving Dupixent in combination with any of the following:
a. Anti-interleukin-5 therapy [e.g. Nucala (mepolizumab), Cinqair (reslizumab), Fasenra (benralizumab)]
b. Anti-IgE therapy [e.g. Xolair (omalizumab)]
- AND -
☐ Yes ☐ No  Dose does not exceed the following:
a. Initial (one time) dose: 600 mg
b. Maintenance dose 300 mg every other week

Authorization will be issued for 6 months.

Reauthorization

Dupixent will be approved based on all of the following criteria:

☐ Yes ☐ No  Patient continues to meet initial authorization criteria
- AND -
☐ Yes ☐ No  Documentation of positive clinical response to Dupixent therapy as demonstrated by at least one of the following:
   (a) Reduction in the frequency of exacerbations
   (b) Decreased utilization of rescue medications
   (c) Increase in percent predicted FEV1 from pretreatment baseline
   (d) Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)
   (e) Reduction in systemic corticosteroid requirements
- AND -
☐ Yes ☐ No  Demonstrated adherence to asthma controller therapy that includes either of the following:
a) ICS medication
   OR
b) ICS + LABA or LTRA medication

Reauthorization will be issued for 12 months.