Prior Authorization Criteria

MISSISSIPPI DIVISION OF MEDICAID

DUPIXENT® (dupilumab) PA Criteria FOR CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD):

DUPIXENT® (dupilumab) is an interleukin-4 receptor alpha antagonist indicated as an add-on maintenance treatment of adults with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype. It is not for the relief of acute bronchospasm.

Prior authorization is required for DUPIXENT® (dupilumab) for COPD. Prior authorization approval will be considered when the following criteria are met. Along with the Universal PA Form, please submit any supporting clinical documentation.

INITIAL AUTHORIZATION: (will be issued for 6 months)

1. Age of patient is within the age range as recommended by the FDA label; **AND**

2. Diagnosis of COPD confirmed by postbronchodilator forced expiratory volume in 1 second (FEV_1) / forced vital capacity (FVC) ratio less than 0.7 on spirometry; **AND**

3. Documentation of an eosinophilic phenotype with a blood eosinophil count greater than or equal to 300 cells/µL within the past 3 months; **AND**

4. Chronic bronchitis symptoms (e.g., productive cough) for 3 months or more in the past year; **AND**

5. Patient had ≥ 2 moderate or ≥ 1 severe exacerbation within the past 12 months despite the adherent use of inhaled long-acting $beta_2$-agonist + long-acting muscarinic antagonist + inhaled corticosteroid (LABA + LAMA + ICS) triple therapy [or LABA + LAMA dual therapy if ICS is contraindicated] for a minimum of 3 months
    a. Moderate exacerbation requires treatment with systemic corticosteroids and/or antibiotics
    b. Severe exacerbation requires hospitalization or observation for over 24 hours in an emergency department or urgent care facility; **AND**

6. Prescribed by or in consultation with an allergist, immunologist, or pulmonologist; **AND**

7. Prescriber attests that DUPIXENT® will be used as an add-on maintenance agent to LABA + LAMA + ICS triple therapy (or LABA + LAMA dual therapy if ICS is contraindicated); **AND**

8. Patient is not receiving DUPIXENT® in combination with another biologic medication [e.g., Adbry (tralokinumab-ldrm), Xolair (omalizumab), Nucala (mepolizumab), Cinqair (reslizumab), Fasenra (benralizumab)] or Ohtuvayre (ensifentrine); **AND**

9. Prescribed dose does not exceed 300 mg every other week.

<u>REAUTHORIZATION</u>: (will be issued for 12 months)

1. Positive clinical response to DUPIXENT® therapy (e.g., reduction in COPD exacerbations, reduction in the severity or frequency of COPD-related symptoms); **AND**

2. Patient is using DUPIXENT® as an add-on maintenance agent to LABA + LAMA + ICS triple therapy (or LABA + LAMA dual therapy if ICS is contraindicated); **AND**

3. Patient is not receiving DUPIXENT® in combination with another biologic medication [e.g., Adbry (tralokinumab-ldrm), Xolair (omalizumab), Nucala (mepolizumab), Cinqair (reslizumab), Fasenra (benralizumab)] or Ohtuvayre (ensifentrine); **AND**

4. Prescribed dose does not exceed 300 mg every other week.