Prior Authorization Criteria

MISSISSIPPI DIVISION OF MEDICAID

Xolair® (omalizumab) Criteria FOR ASTHMA:

Xolair® (omalizumab) is an anti-IgE antibody FDA approved for add-on maintenance treatment of moderate to severe asthma with a positive skin test or *in vitro* reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids. NOTE: Xolair is not indicated for acute bronchospasm or status asthmaticus.

ICD-10 code(s):_____

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

Xolair 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-

☐ Yes ☐ No **All** of the following:

☐ 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])
d. Currently dependent on oral corticosteroids for the treatment of asthma

-AND-

☐ Yes ☐ No **One** of the following:

a. Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting a baseline (pre-omalizumab treatment) serum total IgE level greater than or equal to 30 IU/mL and less than or equal to 1300 IU/mL

-OR-

b. Patient is currently dependent on maintenance therapy with oral corticosteroids for the treatment of asthma

-AND-

☐ Yes ☐ No Xolair 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:

One preferred high-dose ICS medication

-AND-

One additional preferred asthma controller medication (LABA or LTRA)

-AND-

☐ Yes ☐ No Positive skin test or in vitro reactivity to a perennial aeroallergen

-AND-

☐ Yes ☐ No Patient is NOT receiving Xolair in combination with any of the following: Cinqair, Dupixent, Fasenra, Nucala, Tezspire.

Authorization will be issued for 6 months.

Reauthorization

Xolair 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 Xolair 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

-AND-

☐ Yes ☐ No Patient is NOT receiving Xolair in combination with any of the following: Cinqair, Dupixent, Fasenra, Nucala, Tezspire.

Reauthorization will be issued for 12 months.