Prior Authorization Criteria

MISSISSIPPI DIVISION OF MEDICAID

XOLAIR® (omalizumab) Criteria FOR Chronic Spontaneous Urticaria:

XOLAIR® (omalizumab) is an anti-IgE antibody indicated for chronic spontaneous urticaria (CSU) in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment. NOTE: Xolair is not indicated for other forms of urticaria.

Prior authorization is required for Xolair® (omalizumab) for CSU. 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 the patient is within the age range as recommended by the FDA label

   -AND-

2. Diagnosis of chronic spontaneous urticaria

   -AND-

3. Patient meets ONE of the following scenarios:

   a. Patient remains symptomatic despite at least a 2-week trial of, or history of contraindication or intolerance to, two H1 antihistamines (e.g., cetirizine, loratadine, desloratadine, levocetirizine, diphenhydramine)

      -OR-

   b. Patient remains symptomatic despite at least a 2-week trial of, or history of contraindication or intolerance to, BOTH of the following taken in combination:
      i. A second-generation H1 antihistamine (e.g., cetirizine, loratadine, desloratadine, levocetirizine)

         -AND-

      ii. One of the following:
         1. A different second-generation H1 antihistamine
         2. A first-generation H1 antihistamine (e.g., chlorpheniramine, diphenhydramine, hydroxyzine)
         3. An H2 antihistamine (e.g., famotidine, cimetidine, nizatidine)
         4. A leukotriene modifier (e.g., montelukast)

   -AND-

4. Prescribed by or in consultation with an allergist, immunologist, or dermatologist

   -AND-

5. Patient is not receiving XOLAIR ® in combination with another biologic medication [e.g., Adbry (tralokinumab-ldrm), Dupixent (dupilumab), Nucala (mepolizumab), Cinqair (reslizumab), Fasenra (benralizumab)]

   -AND-

6. Prescribed dose does not exceed 300 mg every four weeks.

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

1. Positive clinical response to XOLAIR ® therapy (e.g., reduction in exacerbation, itching severity, or hives)

   -AND-

2. Patient is not receiving XOLAIR ® in combination with another biologic medication [e.g., Adbry (tralokinumab-ldrm), Dupixent (dupilumab), Nucala (mepolizumab), Cinqair (reslizumab), Fasenra (benralizumab)]

   -AND-

3. Prescribed dose does not exceed 300 mg every four weeks.