



Prior Authorization Criteria

Xolair® (omalizumab) Criteria FOR Chronic Spontaneous Urticaria:

Xolair® (omalizumab) is an anti-IgE antibody FDA approved for add-on maintenance treatment of 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 allergic conditions or other forms of urticaria.

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, dermatologist, or immunologist
-AND-
- Yes No Diagnosis of chronic urticaria
-AND-
- Yes No Patient continues to experience symptoms despite at least a 2 week trial of, or history of contraindication or documented intolerance to:
 - a. A first generation H1 antihistamines (e.g. chlorpheniramine, diphenhydramine, hydroxyzine)
-OR-
 - b. A second generation H1 antihistamine (e.g. cetirizine, fexofenadine, loratadine)
-AND-

One of the following:

- a. A H2 antihistamine (e.g. cimetidine, famotidine)
-OR-
- b. A leukotriene modifier (e.g. montelukast)

-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) Reduction of severity of itch and/or hives

-AND-

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

Reauthorization will be issued for 12 months.