Field Name	Field Description
Prior Authorization Group Description	**Xolair for Asthma and Urticaria**
Drugs	Xolair (omalizumab)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, the Drug Package Insert, and/or per the standard of care guidelines
Exclusion Criteria	Use of Xolair concomitantly with another pulmonary biologic (e.g. Fasenra, Nucala, Cinqair, Dupixent, Tezspire)
Required Medical Information	See "Other Criteria"
Age Restrictions	Asthma: ≥ 6 years Chronic idiopathic urticaria: ≥ 12 years
Prescriber Restrictions	Prescribed by, or in consultation with, an allergist/immunologist, pulmonologist, or dermatologist
Coverage Duration	If all of the conditions are met, the request will be approved for up to a 4 month duration for initial requests and up to a 6 month duration for renewal requests.
Other Criteria	****For nasal polyposis, please refer to the "Biologic Agents for Nasal Polyposis" policy**** **Initial Authorization:** Asthma: • Member has at least a 6 month history of moderate to severe asthma • The drug is being prescribed at an approved dose according to member's weight and IgE level • Member is taking maximally tolerated ICS/LABA combination in addition to a LAMA (e.g. tiotropium) for at least 3 months, or there is a documented medical reason why the member is unable to take these medications • Member's asthma is uncontrolled as defined by having one of the following: o Frequent severe exacerbations requiring two or more bursts of systemic glucocorticoids (more than three days each) in the previous year o History of serious exacerbation: at least one hospitalization, intensive care unit stay, or mechanical ventilation in the previous year o Airflow limitation defined as a forced expiratory volume in 1 second (FEV1) less than 80% of predicted o Poor symptom control including at least THREE of the following: ▪ Asthma Control Questionnaire (ACQ) consistently > 1.5 or Asthma Control Test (ACT)

	< 20 ▪ Daytime asthma symptoms more than twice per week ▪ Use of an inhaled short acting B-2 agonist to relieve asthma symptoms more than twice per week (not including use prior to exercise) ▪ Limited physical activity due to asthma symptoms ▪ Nighttime awakening due to asthma symptoms • Member has a positive immediate response on RAST test and/or skin prick test to at least 1 common allergen (e.g. dermatophagoides farinae, dermatop hagoides pteronyssinus, dog, cat, or cockroach) that is an asthma trigger (copy of results required). • Pre-treatment serum IgE levels must be greater than or equal to 30 IU/mL <u>Chronic Idiopathic Urticaria:</u> • The drug is prescribed at an approved dose • Member has at least a 6 week history of urticaria • Member requires oral corticosteroids to control symptoms • The patient remains symptomatic despite a minimum two week trial (or has medical reason for not utilizing) of two preferred second generation H1 antihistamines at the maximum tolerated dose **<u>Re-Authorization:</u>** • The drug is being prescribed at an approved dose • The member has experienced a clinical benefit from medication (e.g. decrease exacerbations, reduction in use of oral steroids) **If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.**
Review/Revision Date: 10/2023	