STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES

Office of Pharmacy Service
Prior Authorization Criteria

Xolair® (Omalizumab)

Prior Authorization Request Form

Prior authorization requests for Xolair will be approved for the following conditions

1) Asthma, **OR**
2) Chronic Idiopathic Urticaria

If the following criteria are met:

For moderate to severe persistent asthma

1) Patient is six (6) years of age or older; **AND**
2) Current body weight is between 20kg and 150kg; **AND**
3) Patient is symptomatic despite receiving recommended first line treatments (inhaled corticosteroids) and exhibiting compliance with the treatments; **AND**
4) Patient has reacted positively to a perennial aeroallergen skin or blood test; **AND**
5) Patient must have an IgE level not less than 30 IU/ml or more than the Manufacturer's recommendation, based on weight. (The patient's weight and pretreatment serum IgE must be presented to review dosing); **AND**
6) Must be prescribed by a board certified pulmonologist or board certified allergist.

If all criteria have been met, prior authorization requests will be for twelve (12) months.

For moderate to severe Chronic Idiopathic Urticaria:

1) Current diagnosis must be Chronic Idiopathic Urticaria, (documentation supporting diagnosis must be provided with PA request); **AND**
2) Patient is twelve (12) years of age or older; **AND**
3) Prescribed by a board certified Allergist, Immunologist, or Dermatologist; **AND**
4) Contraindication to, or documented failure of, scheduled H-1 antihistamine at maximum tolerable dosing***** and leukotriene inhibitor therapy; **AND**
5) Evidence of an evaluation that excludes other medical diagnoses associated with chronic urticaria (supporting documentation must be provided with PA request).

Prior authorization requests will be initially granted for three (3) months. Prior authorization will be granted for an additional twelve (12) months after receipt of documentation supporting clinical improvement from prior to initiating omalizumab.

Chronic Idiopathic Urticaria (CIU): Omalizumab 150 or 300mg SC every four (4) weeks. Dosing in CIU is not dependent on serum IgE level or body weight. (Package Insert)

* Intolerance or contraindication of maximum dosing of H-1 Antihistamine must be clearly documented and justified on the prior authorization request. Medication purchase history will be reviewed as part of the process for prior authorization review. As-needed or "burst" therapies will not be considered as adequate therapy attempts.

References:

1) Xolair® (package insert) Genentech Inc. South San Francisco, CA. July, 2016
2) Lexi-Comp™ Xolair monograph and Clinical Consult™ application 2014.

Reviewed and Approved
Drug Utilization Review Board
September 17th, 2014

Edited by DUR coordinator
7/18/2016

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