

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

I. Requirements for Prior Authorization of Xolair

A. Prescriptions That Require Prior Authorization

All prescriptions for Xolair must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for Xolair, the determination of whether the requested prescription is medically necessary will take into account whether:

1. The recipient is 12 years of age or older.

AND

2. Xolair (omalizumab) is being prescribed by, or in consultation with, a pulmonologist, allergist, immunologist or dermatologist

AND

3. The dose of Xolair (omalizumab) is consistent with Food and Drug Administration (FDA) approved package labeling for the diagnosis

AND

4. For a diagnosis of asthma:

- a. The diagnosis is confirmed by all of the following:

- i. Medical history and physical exam findings that are consistent with asthma according to the most current NHLBI guidelines on the diagnosis and management of asthma

AND

- ii. Spirometry that demonstrates obstruction

AND

- iii. Reversibility demonstrated either by an increase in FEV1 of ≥ 12 percent from baseline or by an increase ≥ 10 percent of predicted FEV1

AND

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- b. The recipient's asthma is graded as moderate to severe persistent, despite maximal therapeutic doses of, intolerance, or contraindication to asthma controller medications, confirmed by one or more of the following:
 - i. Daily asthma symptoms such as coughing, wheezing, and dyspnea
 - ii. Daily use of a rescue inhaler such as a short acting beta2-agonist
 - iii. Two or more exacerbations per year requiring oral systemic corticosteroids
 - iv. One or more nights per week of nocturnal asthma causing awakening
 - v. $FEV1 \leq 80\%$

AND

- c. The recipient has a diagnosis of allergen-induced asthma (allergic asthma confirmed by either a positive skin test or Radioallergosorbent Test (RAST) to an unavoidable perennial aeroallergen (such as pollen, mold, dust mite, etc.)

AND

- d. The serum total IgE measurement is between 30 International Units/mL and 700 International Units/mL.

AND

- 5. For a diagnosis of chronic idiopathic urticaria, the recipient:
 - a. Has a documented history of urticaria for a period of at least 3 months

AND

- b. Requires steroids to control urticarial symptoms

OR

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- c. Has a documented history of therapeutic failure, contraindication, or intolerance to all of the following at maximum tolerated doses:
 - i. H1 antihistamine
 - ii. H2 antihistamine
 - iii. Leukotriene modifier
 - iv. Dapsone, sulfasalazine or hydroxychloroquine

OR

- 6. The recipient does not meet the clinical review guidelines listed above, but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

NOTE FOR RENEWALS OF PRESCRIPTIONS FOR XOLAIR (omalizumab): Requests for prior authorization of renewals of prescriptions for Xolair (omalizumab) that were previously approved will take into account whether the recipient:

- 1. For a diagnosis of asthma, has shown measurable evidence of improvement in the severity of the asthma condition.
- 2. For a diagnosis of chronic idiopathic urticarial, has documented:

- a. Improvement of symptoms

AND

- b. Rationale for continued use

C . Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above, to assess the medical necessity of the request for a prescription for Xolair. If the guidelines in Section B are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

D. Dose and Duration of Therapy

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Requests for prior authorization of Xolair (omalizumab) will be approved as follows:

1. For a diagnosis of asthma:
 - a. The initial prescription will be approved for a period of up to 6 months.
 - b. Renewals of prescriptions that were previously approved will be approved for a period of up to 12 months.
2. For a diagnosis of chronic idiopathic urticaria, both initial prescriptions and renewals of prescriptions that were previously approved will be approved for a period of up to 6 months.

E. References

1. Xolair package insert. Genentech, Inc. March 2014
2. Chronic urticaria: Standard management and patient education. UpToDate. Accessed June 30, 2014
3. New onset urticaria. UpToDate. Accessed June 30, 2014
4. Chronic urticaria: Clinical manifestations, diagnosis, pathogenesis, and natural history. UpToDate. Accessed June 30, 2014