1. Requirements for Prior Authorization of Anti-Allergens, Oral

A. Prescriptions That Require Prior Authorization

All prescriptions for Anti-Allergens, Oral must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Anti-Allergen, Oral the determination of whether the requested prescription is medically necessary will take into account whether:

1. The prescribed Anti-Allergen, Oral is for the treatment of a condition that is U.S. Food and Drug Administration (FDA) approved, or a medically accepted, indication

AND

2. The recipient is being prescribed a dose of the requested medication that is appropriate for the recipient's age according to package labeling

AND

3. The Anti-Allergen, Oral is being prescribed by, or in consultation with, an allergist, immunologist or otolaryngologist with expertise in allergy treatment

AND

4. The first dose of the Anti-Allergen, Oral will be administered under the supervision of a physician with experience in the diagnosis and treatment of severe allergic reactions, and in a setting equipped for monitoring and treatment of such reactions.

AND

5. The recipient will be observed in the office for at least 30 minutes following the initial dose

AND

6. The recipient does not have any contraindications to the prescribed Anti-Allergen, Oral

AND

7. The recipient does not have moderate to severe asthma

AND

8. The recipient does not have active oral inflammation or oral wounds

AND

9. The recipient does not have medical conditions (i.e. unstable angina, recent myocardial infarction, significant arrhythmia, uncontrolled hypertension, etc.) that may reduce the ability to survive a serious allergic reaction or increase the risk of adverse reactions after epinephrine administration

AND

10. The recipient is not taking beta-adrenergic blockers, alpha-adrenergic blockers or ergot alkaloids

AND

11. The recipient will not be receiving concomitant allergen immunotherapy

AND

12. The recipient has documented therapeutic failure, contraindication or intolerance to all of the following:

    a. Intranasal glucocorticoids
    b. Intranasal or oral antihistamines
    c. Montelukast
    d. Cromolyn sodium
    e. Antihistamine eye drops (if the recipient also has conjunctivitis)
    f. Subcutaneous immunotherapy

AND

13. Treatment with the prescribed Anti-Allergen, Oral will be initiated at least 12 weeks prior to the onset of the specific allergy inducing pollen season

AND

14. The recipient is also prescribed auto-injectable epinephrine

OR

15. The request 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.

FOR RENEWALS OF PRESCRIPTIONS FOR AN ANTI-ALLERGAN, ORAL - The determination of medical necessity of requests for prior authorization of renewals of prescriptions for Anti-Allergens, Oral, that were previously approved, will take into account whether:

1. The request meets the guidelines for initial approval

AND

2. The request is being made during the specific allergy inducing pollen season

AND

3. The recipient has documented improvement in allergy symptoms and reduced use of symptomatic treatments

AND

4. Since taking the prescribed Anti-allergen, Oral, the recipient does not have a history of the following:

    a. Persistent escalating adverse reactions of the mouth or throat
    b. Severe or persistent gastro-esophageal symptoms
    c. Recurrent or new onset asthma exacerbations

OR

5. The request 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.

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 an Anti-Allergen, Oral. 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

The Department will limit authorization of prescriptions for Anti-Allergens, Oral as follows:

1. Up to four (4) months of therapy for an initial request

2. Up to three (3) months for a renewal of a previously approved request

E. References

1. Grastek prescribing information, Merck & Co. June 2014
2. Oralair prescribing information, Stallergenes S.A. April 2014
3. Ragwitek prescribing information, Merck & Co. June 2014
4. Pharmacotherapy of allergic rhinitis. UpToDate, accessed July 17, 2014.
5. Overview of immunologic treatments for allergic rhinitis. UpToDate, accessed July 17, 2014.