IMPORTANT REMINDER: All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMISe to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at: https://www.dhs.pa.gov/providers/Providers/Pages/PROMISe-Enrollment.aspx.

PURPOSE:

The purpose of this bulletin is to issue updated handbook pages that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Anti-Allergens, Oral submitted for prior authorization.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program and providing services in the fee-for-service delivery system. Providers rendering services in the MA managed care delivery system should address any questions related to Anti-Allergens, Oral to the appropriate managed care organization.

BACKGROUND/DISCUSSION:

The Department of Human Services (Department) is updating the medical necessity guidelines for Anti-Allergens, Oral to include the addition of guidelines for age-appropriate and dose consistent with the U.S. Food and Drug Administration-approved package labeling,

<table>
<thead>
<tr>
<th>Number</th>
<th>Issue Date</th>
<th>Expiration Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>*01-19-100</td>
<td>01-19-96</td>
<td>27-19-95</td>
</tr>
<tr>
<td>02-19-94</td>
<td>02-19-93</td>
<td>30-19-92</td>
</tr>
<tr>
<td>03-19-93</td>
<td>03-19-92</td>
<td>31-19-100</td>
</tr>
<tr>
<td>08-19-103</td>
<td>08-19-95</td>
<td>32-19-92</td>
</tr>
</tbody>
</table>

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

The appropriate toll-free number for your provider type

Visit the Office of Medical Assistance Programs Web site at https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx.
nationally recognized compendia, or peer-reviewed medical literature and to allow for approval of renewal requests for prior authorization for up to four months.

The revisions to the guidelines to determine medical necessity of Anti-Allergens, Oral were subject to public review and comment and subsequently approved for implementation by the Department.

PROCEDURE:

The procedures for prescribers to request prior authorization of Anti-Allergens, Oral are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. The Department will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages in the SECTION II chapter related to Anti-Allergens, Oral) when reviewing the prior authorization request to determine medical necessity.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for drugs that require prior authorization.

ATTACHMENTS:

Prior Authorization of Pharmaceutical Services Handbook - Updated pages
I. 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 the beneficiary:

1. Is prescribed the Anti-Allergen, Oral for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; AND

2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

3. Is prescribed a dose, duration, and timing of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

4. Is prescribed the Anti-Allergen, Oral by or in consultation with an allergist, immunologist, or otolaryngologist with expertise in allergy treatment; AND

5. Does not have a history of a contraindication to the prescribed medication; AND

6. Does not have moderate to severe asthma; AND

7. Will not be receiving concomitant allergen immunotherapy; AND

8. Has documented therapeutic failure, contraindication, or intolerance of all of the following:
   a. Intranasal glucocorticoids,
   b. Intranasal or oral antihistamines,
   c. Montelukast,
   d. Intranasal or ophthalmic cromolyn sodium,
   e. Antihistamine eye drops (if the beneficiary also has conjunctivitis),
   f. Subcutaneous immunotherapy;

   AND

9. Is also prescribed auto-injectable epinephrine.
NOTE: If the beneficiary 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 beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR ANTI-ALLERGENS, ORAL: The determination of medical necessity of a request for renewal of a prior authorization for an Anti-Allergen, Oral that was previously approved will take into account whether the beneficiary:

1. Meets the guidelines for initial approval; **AND**
2. Has documented improvement in allergy symptoms and reduced use of symptomatic treatments while taking the requested Anti-Allergen, Oral; **AND**
3. Has documentation of tolerability of the medication.

NOTE: If the beneficiary 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 beneficiary, the request for prior authorization will be approved.

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 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 beneficiary.

D. Dose and Duration of Therapy

Initial and renewal requests for prior authorization of an Anti-Allergen, Oral will be approved for up to 4 months.

E. References