Updated: 12/2018
PARP Approved: 02/2019

Prior Authorization Criteria

Sublingual Allergy Immunotherapy: Oralair®, Odactra®

All requests for Sublingual Allergy Immunotherapy: Oralair®, and Odacra® require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Products requested that correspond to appropriate FDA-approved indications are noted below:

Indication	**Product**
Immunotherapy for the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for any of the five grass species contained in this product.	Oralair ® (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens Allergen Extract)
Immunotherapy for house dust mite (HDM)-induced allergic rhinitis, with or without conjunctivitis, confirmed by *in vitro* testing for IgE antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites, or skin testing to licensed house dust mite allergen extracts**.**	Odactra® House Dust Mite (*Dermatphagoides Farinae* and *Dermatophaoides pteronyssinus)* Allergen Extract

For all requests for Sublingual Allergy Immunotherapy all of the following criteria must be met:

- Medication must be prescribed by or in association with an allergist/immunologist or an otolaryngologist
- Member must have a history of trial and failure, contraindication, or intolerance of at least 1 month to at least two of the following:
    - Intranasal corticosteroid (e.g. fluticasone)
    - Oral non-sedating antihistamine, intranasal antihistamine (loratadine, levocetirizine, cetirizine)
    - Oral leukotriene receptor antagonist (montelukast)
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines

Coverage may be provided with a diagnosis of immunotherapy for the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis and the following criteria is met:

- Medication is Oralair®
- The diagnosis is confirmed by ONE of the following within the past 2 years:
    - Positive skin test to any of the following allergens: Sweet vernal, orchard, perennial rye, Timothy or Kentucky grass
    - IgE specific antibodies to any of the following allergens: Sweet vernal, orchard, perennial rye, Timothy or Kentucky grass

- Member is between the age of 5 and 65 years old.
- Treatment should be initiated 16 weeks prior to grass season typically occurring during the summer months, starting in May. Treatment should NOT be initiated mid-season.
- **Initial Duration of Approval:** January 1st through September 30th.
- **Reauthorization criteria**
    - Reauthorization benefit will be approved if there is documented, significant improvement with prior courses of treatment

Coverage may be provided with a diagnosis of immunotherapy for house dust mite (HDM)-induced allergic rhinitis, with or without conjunctivitis, and the following criteria is met:

- Medication is Odactra
- The diagnosis confirmed by ONE of the following within the past 2 years:
    - Positive skin test to licensed house dust mite allergen extracts.
    - IgE specific antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites
- Member is between the age of 18 and 65 years old.
- **Initial Duration of Approval:** 12 months
- **Reauthorization criteria**
    - Reauthorization benefit will be approved if there is documented, significant improvement with prior courses of treatment

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

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Sublingual Allergy Immunotherapy- Oralair, Odactra
PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg

REQUESTED DRUG INFORMATION

Medication:	Strength:
Frequency:	Duration:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:

Billing Information

This medication will be billed: ☐ at a pharmacy **OR**
☐ medically (if medically please provide a JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

1. Will the medication must be prescribed by or in association with an allergist/immunologist or an otolaryngologist? ☐ Yes ☐ No

2. Does the member have a history of trial and failure, contraindication, or intolerance of at least 1 month to any of the following:
   Please check all that applies:

   i. Intranasal corticosteroid (e.g. fluticasone) ☐ Yes ☐ No

   ii. Oral non-sedating antihistamine, intranasal antihistamine (loratadine, levocetirizine, cetirizine) ☐ Yes ☐ No

   iii. Oral leukotriene receptor antagonist (montelukast) ☐ Yes ☐ No

3. If member is being prescribed Oralair®, answer the following questions?

   i. Was the diagnosis confirmed by any of the following within the past 2 years:
   Please check all that applies
      i. Positive skin test to any of the following allergens: Sweet vernal, orchard, perennial rye, Timothy or Kentucky grass
      ☐ Yes ☐ No

      ii. IgE specific antibodies to any of the following allergens: Sweet vernal, orchard, perennial rye, Timothy or Kentucky grass

☐ Yes ☐ No

ii. Is member between the age of 5 and 65 years old?
☐ Yes ☐ No

iii. Will treatment be initiated 16 weeks prior to grass season typically occurring during the summer months, starting in May?
☐ Yes ☐ No

4. If member is being prescribed Odactra®, answer the following questions?
   i. Was the diagnosis confirmed by ONE of the following within the past 2 years:
      i. Positive skin test to licensed house dust mite allergen extracts.
      ☐ Yes ☐ No

      ii. IgE specific antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites
      ☐ Yes ☐ No
   ii. Is member between the age of 18 and 65 years old?
   ☐ Yes ☐ No

CURRENT or PREVIOUS THERAPY			
Medication Name	**Strength/ Frequency**	**Dates of Therapy**	**Status (Discontinued & Why/Current)**

REAUTHORIZATION

Has the member experienced a significant improvement with treatment? ☐ Yes ☐ No
Please describe:

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date