Louisiana Medicaid
Allergen Extract Agents

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for the following allergen extract agents:

- *Dermatophagoides farinae* and *Dermatophagoides pteronyssinus* Allergen Extract (Odactra™ House Dust Mite)
- Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens Allergen Extract (Oralair®)
- Peanut (*Arachis hypogaea*) Allergen Powder-dnfp (Palforzia®)

Additional Point-of-Sale edits may apply.

*These agents may have **Black Box Warnings**. and may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations. Please refer to individual prescribing information for details.*

Odactra™ House Dust Mite (HDM)

Approval Criteria

- The recipient is at least 18 years of age but not older than 65 years of age on the date of the request; **AND**
- The recipient has the diagnosis of HDM-induced allergic rhinitis with or without conjunctivitis confirmed by **ONE** of the following and is **stated on the request**:
    - positive skin test for licensed house dust mite allergen extracts; **OR**
    - in vitro testing for pollen-specific IgE antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites; **AND**
- The medication is prescribed by, or the request states that this medication is being prescribed in consultation with, **ONE** of the following specialties:
    - Allergy; **OR**
    - Otology/Laryngology/Rhinology; **OR**
    - Ophthalmology/Otology/Laryngology/Rhinology; **AND**
- The prescriber **states on the request** that the recipient has been given a prescription for an auto-injectable epinephrine product within the previous 12 months; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The first dose of Odactra™ HDM will be administered in a healthcare setting under the supervision of a physician with experience in the diagnosis and treatment of severe allergic reactions and the patient will be observed for at least 30 minutes; **AND**
    - The recipient does not have any of the following conditions:
        - Severe, unstable or uncontrolled asthma; **OR**
        - History of any severe systemic allergic reaction; **OR**
        - History of any severe local reaction to sublingual allergen immunotherapy; **OR**

        - A history of eosinophilic esophagitis; **AND**
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.

Reauthorization Criteria

- The recipient continues to meet initial approval criteria; **AND**
- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

Duration of initial and reauthorization approval: 12 months

Oralair®

Approval Criteria

- The recipient is at least 10 years of age but not older than 65 years of age on the date of the request; **AND**
- The recipient has the diagnosis of grass pollen-induced allergic rhinitis with or without conjunctivitis confirmed by **ONE** of the following and is **stated on the request**:
    - positive skin test for any of the five grass species contained in this product; **OR**
    - in vitro testing for pollen-specific IgE antibodies for any of the five grass species contained in this product; **AND**
- The medication is prescribed by, or the request states that this medication is being prescribed in consultation with, **ONE** of the following specialties:
    - Allergy; **OR**
    - Otology/Laryngology/Rhinology; **OR**
    - Ophthalmology/Otology/Laryngology/Rhinology; **AND**
- The prescriber **states on the request** that the recipient has been given a prescription for an auto-injectable epinephrine product within the previous 12 months; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The first dose of Oralair® will be administered in a healthcare setting under the supervision of a physician with experience in the diagnosis and treatment of severe allergic reactions and the patient will be observed for at least 30 minutes; **AND**
    - The recipient does not have any of the following conditions:

        - Severe, unstable or uncontrolled asthma; **OR**
        - History of any severe systemic allergic reaction; **OR**
        - History of any severe local reaction to sublingual allergen immunotherapy; **OR**
        - A history of eosinophilic esophagitis; **AND**
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.

Reauthorization Criteria

- The recipient continues to meet initial approval criteria; **AND**
- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

Duration of initial and reauthorization approval: 12 months

Palforzia®

Approval Criteria

- The recipient is at least 4 years of age on the date of the request; **AND**
- The recipient has a confirmed diagnosis of peanut allergy and this is **stated on the request**; **AND**
- The medication is prescribed by, or the request states that this medication is being prescribed in consultation with, **ONE** of the following specialties:
    - Allergy; **OR**
    - Otology/Laryngology/Rhinology; **OR**
    - Ophthalmology/Otology/Laryngology/Rhinology; **AND**
- The prescriber **states on the request** that the recipient has been given a prescription for an auto-injectable epinephrine product within the previous 12 months; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The initial dose escalation and first dose of each up-dosing level of Palforzia® will be administered in a healthcare setting under the supervision of a physician with experience in the diagnosis and treatment of severe allergic reactions and the patient will be observed for at least 60 minutes; **AND**
    - The recipient does not have any of the following conditions:
        - Uncontrolled asthma; **OR**

        - A history of eosinophilic esophagitis or other eosinophilic gastrointestinal disease; **AND**
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.

Reauthorization Criteria

- The recipient continues to meet initial approval criteria; **AND**
- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

Duration of initial and reauthorization approval: 12 months

References

Odactra (*Dermatophagoides farinae* and *Dermatophagoides pteronyssinus* allergen extract) [package insert]. Hørsholm, Denmark: ALK-Abelló A/S; April 2017. https://www.odactrahcp.com/assets/pdf/odactra-full-pi.pdf

Oralair (sweet vernal, orchard, perennial rye, timothy, and Kentucky blue grass mixed pollens allergen extract) [package insert] Lenoir, NC: GREER Laboratories, Inc; October 2014. https://oralair.com/assets/pdf/ORALAIR%20Prescribing%20Information-Med%20Guide.pdf

Palforzia [peanut (*Arachis hypogaea*) allergen powder-dnfp] [package insert]. Brisbane, CA: Aimmune Therapeutics, Inc; January 2020. https://www.palforzia.com/static/pi_palforzia.pdf

Revision	Date
Policy created	September 2020