Oscar Clinical Guideline: Allergy (Allergen) Immunotherapy (CG059, Ver. 6)

Allergy (Allergen) Immunotherapy

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

The Plan members who have severe allergies may be eligible for treatment with allergen immunotherapy to alleviate their symptoms. Allergies are often the result of a hypersensitive immune response to specific substances causing an exaggerated reaction. These allergies can develop in response to various antigens including insect bites/stings, seasonal pollen, or certain foods like peanuts. Symptoms include runny nose or congestion, watery or itchy eyes, asthma symptoms, skin rashes, and in severe cases, anaphylaxis. Most allergy cases are successfully treated with over-the-counter medications, although some may require prescriptions in the form of nasal sprays, inhalers, or oral medications to prevent and/or address symptoms. When symptoms are severe or unresponsive to prescription medication, a specialized type of treatment called allergen immunotherapy may be indicated.

Allergen immunotherapy works by slowly introducing very small amounts of the allergic substance over a prolonged period of time in a controlled environment to train a person's immune system to adapt to the allergic substance. It can be performed with subcutaneous injections (SCIT), sublingual administration

(SLIT), or in the case of peanut allergy, oral immunotherapy (OIT) with products like Palforzia. The administration requirements vary by type:

- SCIT - All doses must be administered in a medically supervised setting equipped to manage adverse reactions.
- SLIT - The first dose must be administered under medical supervision, but subsequent doses can be administered at home, following practice parameters from the American Academy of Allergy, Asthma & Immunology.
- Peanut OIT (Palforzia) - The initial dose escalation and first dose of each up-dosing level must be administered in a certified healthcare setting, while subsequent doses are taken daily at home.

NOTE: This policy addresses subcutaneous allergen immunotherapy (SCIT) for certain indications (e.g., respiratory allergies and Hymenoptera venom allergy. Coverage criteria[ɳ] for sublingual immunotherapy (SLIT) and food oral immunotherapy (e.g., Palforzia for peanut allergy) are addressed in separate dedicated policies:

- Oscar Clinical Guideline: Allergen Sublingual Immunotherapy (SLIT) (PG093).
- Oscar Clinical Guideline: Palforzia [Peanut (Arachis hypogaea) Allergen Powder-dnfp] (PG245)

[ɳ]*Please refer to these policies for specific coverage criteria for SLIT and Palforzia. The Plan reserves the right to modify these policies and/or create additional policies as the evidence and treatment landscape for these modalities evolve. Providers should consult all relevant policies and the member's benefit plan to determine coverage.*

Definitions

"Allergen immunotherapy" is a treatment where very small amounts of an allergic substance are introduced via injection or sublingual administration to a patient with that specific allergy in order to desensitize the immune system.

"Allergy" refers to having both allergen-specific IgE and developing symptoms upon exposure to substances containing that allergen.

"Anaphylaxis" is a severe, systemic immune response (e.g., affecting more than 1 organ system) which may be characterized by flushing, trouble breathing, vomiting/diarrhea, swelling in the mouth/throat, rash, etc. It can be rapidly fatal without immediate treatment.

"Antigen" (or Allergen) refers to an offending substance that causes the allergic reaction through the immune system hypersensitivity. An antigen can be anything from a certain type of pollen to the venom of a bee sting.

"Rapid Desensitization" is an allergen immunotherapy technique where the protocol is performed on a shorter time scale, where standard allergen immunotherapy is performed over longer periods of time (e.g., 3-5 years).

"Sensitization" is when individuals may produce IgE to allergens verified through blood or positive skin tests but do not develop symptoms upon exposure to that substance.

"Subcutaneous" refers to the delivery of medication via injection just under the skin.

"Sublingual" refers to the delivery of medication under a patient's tongue.

Clinical Indications

Medical Necessity Criteria for Initial Authorization

Subcutaneous immunotherapy (SCIT)

SCIT should be administered under medical supervision (e.g., MD/PA/NP) with a minimum of 30 minutes of monitoring to promptly recognize and manage adverse reactions (e.g., anaphylaxis).

The Plan considers **subcutaneous immunotherapy (SCIT)** medically necessary for members diagnosed with allergies when **ALL** the following criteria are met:

1. The member has **ONE** of the following conditions and meets the condition-specific criteria as below:
    a. Allergic rhinitis or conjunctivitis, when **ALL** the following criteria are met:
        i. **ONE** or more of the following:
            1. Asthma exacerbation directly linked to allergic rhinitis; *or*
            2. A minimum of 2 consecutive seasons of related allergy symptoms; *or*
            3. Chronic (perennial) allergies; *and*
        ii. Documented inadequate response after an appropriate trial of **ALL** of the following, unless specifically contraindicated or poorly tolerated:
            1. Avoidance of environmental or situational antigen exposure; *and*
            2. One of the following nasal sprays:
                a. Nasal antihistamine (e.g., azelastine); *or*

b. Nasal cromolyn (sodium cromoglycate); *or*
c. Nasal ipratropium; *and*

3. Nasal steroids (e.g., fluticasone); *and*
4. One of the following oral medications:
   a. Oral antihistamine (e.g., cetirizine); *or*
   b. Oral antihistamine-decongestant (e.g., cetirizine-pseudoephedrine); *or*
   c. Oral leukotriene receptor antagonist (e.g., montelukast); *and*

iii. There is documented positive skin prick test or serologic IgE test to the allergen being used for immunotherapy; *and*

iv. The condition and allergen are such that there is expected to be a therapeutic benefit to the treatment for that specific allergen; *OR*

b. Allergic (extrinsic) asthma, when **ALL** the following criteria are met:

i. Forced Expiratory Volume in 1 second (FEV1) is >70% of the predicted age-specific value; *and*

ii. At least **ONE** of the following situations is present:
   1. Severity of symptoms, when present, prevents normal daily functioning; *or*
   2. Symptoms have persisted for 2 or more consecutive seasons or are perennial; *and*

iii. Documented inadequate response after an appropriate trial of **ONE** of the following, unless specifically contraindicated or poorly tolerated:
   1. Increasing use of short-acting beta2-agonist (e.g., albuterol) or use >2 days/week for symptom relief (not related to incidents of exercise-induced bronchospasm); *or*
   2. Diagnosed with persistent asthma needing daily medication within levels Step 2, Step 3, or Step 4 as defined by National Asthma Education and Prevention Program or National Heart, Lung, and Blood Institute (e.g., low-medium dose inhaled corticosteroids, long-acting beta2-agonist, cromolyn, leukotriene receptor antagonist, or theophylline); *and*

iv. There is documented positive skin prick test or serologic IgE test to the specific allergen being used for immunotherapy; *and*

v. Avoidance of environmental or situational allergen exposure (e.g, tobacco smoke); *and*

vi. The condition and allergen are such that there is expected to be a therapeutic benefit to the treatment for that specific allergen; *OR*

c. Hymenoptera (e.g., bees, ants, hornets, etc.) sting/bite allergy, when **ALL** the following criteria are met:
    i. Documented history of anaphylactic or systemic reaction to the suspected offending venom; *and*
    ii. There is documented serologic or skin allergen-specific IgE test evidence to the venom being used for immunotherapy; *and*
    iii. Baseline serum tryptase level assessed; *and*
    iv. The venom immunotherapy (VIT) used is appropriate for the allergen(s) positive on the skin test and is a single preparation (e.g., not mixed); *and*
    v. The protocol should be as appropriate per manufacturer guidelines (e.g., 1-3 injections per week during the initial treatment phase and then once per 4-12 weeks for maintenance); *and*
    vi. The total duration of injections should be 3 years, unless member has any of the following circumstances necessitating longer durations:
        1. History of severe, life threatening reaction; *or*
        2. Honey bee venom allergy; *or*
        3. Systemic reactions to VIT; *or*
        4. Elevated tryptase from baseline (>11.4 ng/ml)
    vii. The condition and allergen are such that there is expected to be a therapeutic benefit to the treatment for that specific allergen; *AND*

2. The member has no contraindications to treatment, including but not limited to any of the following:
    a. Current pregnancy or breastfeeding (*note; if treatment is started prior to pregnancy or breastfeeding, treatment may be continued in the absence of adverse effects)*; *or*
    b. Concurrent use of beta blockers; *or*
    c. Moderate to severe asthma or any uncontrolled asthma; *or*
    d. History of severe reaction to any form of immunotherapy; *or*
    e. Comorbidities that may reduce ability to survive a severe reaction to the immunotherapy or reduce the effectiveness of epinephrine, including but not limited to:
        i. Acute or chronic compromised lung function; *or*
        ii. Significant cardiovascular diseases (e.g., unstable angina, recent myocardial infarction, significant arrhythmia, and uncontrolled hypertension).

Accelerated Schedules for SCIT (Rapid Desensitization, Rush/Cluster Schedules)

The Plan considers SCIT with a rapid **desensitization** protocol medically necessary when **ONE** or more of the following situations are present:

1. The member has a specific medication allergy and **ALL** the following criteria are met:
    a. The medication is essential for a condition that cannot be effectively treated with alternatives; *and*
    b. The allergic side effects are severe enough to warrant discontinuation; *and*
    c. Member would be at risk of serious complications or health outcomes without the medication; *or*
2. Member meets above general allergen immunotherapy criteria for hymenoptera allergy above **AND** is at a reasonable risk of another bite/sting in the near future; *or*
3. Member has allergic conjunctivitis/rhinitis meeting **ALL** the following criteria:
    a. The above general allergen immunotherapy criteria are met; *and*
    b. Symptoms are moderate to severe in intensity; *and*
    c. Treatment is needed during or immediately before the allergy season; *or*
4. Member is contemplating pregnancy and meets **ONE** or more of the following criteria:
    a. The general allergen immunotherapy criteria above are met*; and*
    b. **ONE** of the following situations is present:
        i. The current allergy medications would increase risk to the fetus if the member becomes pregnant; *or*
        ii. Allergen immunotherapy is already being initiated but member plans to get pregnant within the next 3 years.

Preparation for SCIT

1. The preparation of allergen extracts should follow these guidelines:
    a. Fungal (mold) or cockroach allergen extracts must be prepared and administered individually, not mixed with any other extracts.
    b. House dust mite, animal dander, and pollen allergens can be mixed together for members sensitized with those specific allergens.

Medical Necessity Criteria for Reauthorization

The initial therapy duration is expected to last at least three years. After three years, therapy may be extended only if there is a documented clinical response meeting **ONE** of the following criteria:

1. Decreased medication usage**; *OR***
2. Improvement in clinical symptoms and sustained benefit from treatment.

Experimental or Investigational / Not Medically Necessary

Allergen immunotherapy for any indication or by any method other than those outlined in this policy or in the Plan's related immunotherapy policies [*Oscar Clinical Guideline: Allergen Sublingual Immunotherapy (SLIT) (PG093), Palforzia [Peanut (Arachis hypogaea) Allergen Powder-dnfp] (PG245)*] is considered experimental, investigational, or unproven. Non-covered indications and methods include, but are not limited to, the following:

- Home administration of SCIT.
- Allergen immunotherapy in the presence of the following contraindications, or any other contraindication listed above:
    - Severe or very labile asthma, as members with unstable asthma are at risk for severe bronchospasm during systemic reactions;
    - Significant cardiovascular disease (e.g., unstable angina, recent myocardial infarction, significant arrhythmia, and uncontrolled hypertension);
    - Pregnancy.
- Allergen immunotherapy for any of the following indications:
    - Bradykinin-induced, idiopathic, or isolated (standalone) angioedema;
    - Atopic dermatitis not related to dust mites;
    - Chronic urticaria;
    - Latex allergy;
    - Medication allergy except as specifically documented above in criteria;
    - Food allergies;
    - Intrinsic (non-allergic) asthma;
    - Migraine headaches;
    - Non-allergic vasomotor rhinitis.
- Oral immunotherapy for food allergies other than FDA-approved products for peanut allergy (refer to Oscar Clinical Guideline: Palforzia [Peanut (Arachis hypogaea) Allergen Powder-dnfp] (PG245) for Palforzia coverage criteria).
- SLIT for any condition other than allergic rhinitis or conjunctivitis (refer to Oscar Clinical Guideline: Allergen Sublingual Immunotherapy (SLIT) (PG093) for SLIT coverage criteria).
- The following treatments:
    - Urine auto injections;
    - Repository emulsion treatment;
    - Low-dose Rinkel technique;
    - Acupuncture;
    - Rhinophototherapy;
    - Oral mucosal/Allerdent.

- Venom immunotherapy for severe cutaneous reactions, defined as a generalized rash, swelling, or other skin manifestation of the venom reaction not meeting criteria for anaphylaxis (e.g., no involvement of other organ systems, no swelling of the mouth or throat, etc.).
- Venom immunotherapy for severe local reactions, defined as a reaction localized to the sting/bite site but that does not spread elsewhere in the body and does not meet criteria for anaphylaxis.
- Repeat skin or serum IgE testing for response to treatment.

Applicable Billing Codes (HCPCS/CPT Codes)

Allergen Immunotherapy	
CPT/HCPCS Codes considered medically necessary if criteria are met:	
Code	*Description*
95115	Professional services for allergen immunotherapy not including provision of allergenic extracts; single injection
95117	Professional services for allergen immunotherapy not including provision of allergenic extracts; 2 or more injections
95120	Professional services for allergen immunotherapy in the office or institution of the prescribing physician or other qualified healthcare professional, including provision of allergenic extract; single injection
95125	Professional services for allergen immunotherapy in the office or institution of the prescribing physician or other qualified healthcare professional, including provision of allergenic extract; 2 or more injections
95130	Professional services for allergen immunotherapy in the office or institution of the prescribing physician or other qualified healthcare professional, including provision of allergenic extract; single stinging insect venom
95131	Professional services for allergen immunotherapy in the office or institution of the prescribing physician or other qualified healthcare professional, including provision of allergenic extract; 2 stinging insect venoms
95132	Professional services for allergen immunotherapy in the office or institution of the prescribing physician or other qualified healthcare professional, including provision of allergenic extract; 3 stinging insect venoms

95133	Professional services for allergen immunotherapy in the office or institution of the prescribing physician or other qualified healthcare professional, including provision of allergenic extract; 4 stinging insect venoms
95134	Professional services for allergen immunotherapy in the office or institution of the prescribing physician or other qualified healthcare professional, including provision of allergenic extract; 5 stinging insect venoms
95144	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy, single dose vial(s) (specify number of vials)
95145	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); single stinging insect venom
95146	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); 2 single stinging insect venoms
95147	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); 3 single stinging insect venoms
95148	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); 4 single stinging insect venoms
95149	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); 5 single stinging insect venoms
95165	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy; single or multiple antigens (specify number of doses)
95170	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy; whole body extract of biting insect or other arthropod (specify number of doses)
95180	Rapid desensitization procedure, each hour (eg, insulin, penicillin, equine serum) [Rapid/rush/cluster schedules]
ICD-10 codes considered medically necessary if criteria are met:	
Code	*Description*
H10.10	Acute atopic conjunctivitis, unspecified eye
H10.11	Acute atopic conjunctivitis, right eye

H10.12	Acute atopic conjunctivitis, left eye
H10.13	Acute atopic conjunctivitis, bilateral
H10.44	Vernal conjunctivitis
H10.45	Other chronic allergic conjunctivitis
J30.1	Allergic rhinitis due to pollen
J30.2	Other seasonal allergic rhinitis
J30.5	Allergic rhinitis due to food
J30.8	Other allergic rhinitis
J30.81	Allergic rhinitis due to animal (cat) (dog) hair and dander
J30.89	Other allergic rhinitis
J30.9	Allergic rhinitis, unspecified
J45.2	Mild intermittent asthma
J45.20	Mild intermittent asthma, uncomplicated
J45.21	Mild intermittent asthma with (acute) exacerbation
J45.22	Mild intermittent asthma with status asthmaticus
J45.3	Mild persistent asthma
J45.30	Mild persistent asthma, uncomplicated
J45.31	Mild persistent asthma with (acute) exacerbation
J45.32	Mild persistent asthma with status asthmaticus
J45.4	Moderate persistent asthma
J45.40	Moderate persistent asthma, uncomplicated
J45.41	Moderate persistent asthma with (acute) exacerbation
J45.42	Moderate persistent asthma with status asthmaticus
J45.5	Severe persistent asthma
J45.50	Severe persistent asthma, uncomplicated
J45.51	Severe persistent asthma with (acute) exacerbation
J45.52	Severe persistent asthma with status asthmaticus
J45.9	Other and unspecified asthma
J45.90	Unspecified asthma

J45.901	Unspecified asthma with (acute) exacerbation
J45.902	Unspecified asthma with status asthmaticus
J45.909	Unspecified asthma, uncomplicated
J45.99	Other asthma
J45.990	Exercise induced bronchospasm
J45.991	Cough variant asthma
J45.998	Other asthma
J67.0	Farmer's lung
J67.1	Bagassosis
J67.2	Bird fancier's lung
J67.3	Suberosis
J67.4	Maltworker's lung
J67.5	Mushroom-worker's lung
J67.6	Maple-bark-stripper's lung
J67.7	Air conditioner and humidifier lung
J67.8	Hypersensitivity pneumonitis due to other organic dusts
J67.9	Hypersensitivity pneumonitis due to unspecified organic dust
J82.83	Eosinophilic asthma
T63.42	Toxic effect of venom of ants
T63.421	Toxic effect of venom of ants, accidental (unintentional)
T63.422	Toxic effect of venom of ants, intentional self-harm
T63.423	Toxic effect of venom of ants, assault
T63.424	Toxic effect of venom of ants, undetermined
T63.44	Toxic effect of venom of bees
T63.441	Toxic effect of venom of bees, accidental (unintentional)
T63.442	Toxic effect of venom of bees, intentional self-harm
T63.443	Toxic effect of venom of bees, assault
T63.444	Toxic effect of venom of bees, undetermined
T63.45	Toxic effect of venom of hornets

T63.451	Toxic effect of venom of hornets, accidental (unintentional)
T63.452	Toxic effect of venom of hornets, intentional self-harm
T63.453	Toxic effect of venom of hornets, assault
T63.454	Toxic effect of venom of hornets, undetermined
T63.46	Toxic effect of venom of wasps
T63.461	Toxic effect of venom of wasps, accidental (unintentional)
T63.462	Toxic effect of venom of wasps, intentional self-harm
T63.463	Toxic effect of venom of wasps, assault
T63.464	Toxic effect of venom of wasps, undetermined
Z91.03	Insect allergy status
Z91.030	Bee allergy status
Z91.038	Other insect allergy status

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