Allergy Immunotherapy - Limits

Policy Number: **M20230314017**

Effective Date: **5/1/2023**

Sponsoring Department: **Health Care Services**

Impacted Department(s):

Type of Policy: ☒ Internal ☒ External

Data Classification: ☐Confidential ☐Restricted ☒Public

Applies to (Line of Business):

☐ Corporate (All)
☒ State Products, if yes which plan(s): ☒MediSource; ☒MediSource Connect; ☒Child Health Plus; ☒Essential Plan
☒ Medicare, if yes, which plan(s): ☒MAPD; ☐PDP; ☒ISNP; ☒CSNP
☒ Commercial, if yes, which type: ☒Large Group; ☒Small Group; ☒Individual
☒ Self-Funded Services *(Refer to specific Summary Plan Descriptions (SPDs) to determine any pre-authorization or pre-certification requirements and coverage limitations. In the event of any conflict between this policy and the SPD of a Self-Funded Plan, the SPD shall supersede the policy.)*

Excluded Products within the Selected Lines of Business (LOB)

N/A

Applicable to Vendors? Yes ☐ No☒

Purpose and Applicability:

To set forth Independent Health's policy for **allergy immunotherapy (AIT)** treatment limits.

Policy:

Commercial, Self-Funded and Medicare Advantage:

1. Supervision (including preparation) and provision of 150 allergen/antigen preparations or less per 12 months of subcutaneous allergy immunotherapy is considered medically necessary for the first year, including the build-up phase.

2. Supervision (including preparation) and provision of 120 allergen/antigen preparations or less per 12 months of subcutaneous allergy immunotherapy is considered medically necessary after the first year as maintenance therapy.

3. The duration of all forms of immunotherapy must be individualized. A presumption of failure can be made when, after 12 months of therapy, a person does not experience a noticeable decrease of symptoms, does not demonstrate an increase in tolerance to the offending allergen and there is not a reduction in medication usage. Treatment will not be reimbursed long term when there is no apparent clinical benefit.

Documentation Requirements:
The patient's medical record must document the medical necessity of services performed for each date of service submitted on a claim, and documentation must be available upon request.

MediSource, MediSource Connect, Child Health Plus and Essential Plan
MediSource, MediSource Connect, Child Health Plus and Essential Plan utilizes the criteria above.

Background
An allergy is an abnormal reaction or increased sensitivity to certain substances in the environment. Substances that cause this sensitivity or reaction are called allergens and may vary from naturally occurring materials, such as pollen and grass, to man-made materials, such as soaps or chemicals. First-line treatment includes avoidance and minimization of exposure when possible. Medication, including antihistamines, bronchodilators, leucotriene inhibitors, and steroids (cortisone), may be used to reverse some of the symptoms of allergic reactions.

Allergy Immunotherapy alters the immune system's reaction to causative allergens and induces long-lasting tolerance to these allergens. **Subcutaneous immunotherapy (SCIT)** is the best studied form of AIT and is effective for allergic rhinitis and rhinoconjunctivitis, and allergic asthma. **Sublingual immunotherapy (SLIT)** is an alternate approach of administering allergens orally, offering specific advantages over injection immunotherapy including self-administration by patients or caregivers, is not an injection, and carries a much lower risk of serious systemic allergic reactions compared with SCIT. SLIT-drops (liquid extract) are used in other parts of the world but are not approved by the US Food and Drug Administration (FDA).

Based on the practice parameter from the Joint Task Force on Practice Parameters, representing the American Academy of Allergy, Asthma & Immunology (AAAAI); the American College of Allergy, Asthma & Immunology (ACAAI); and the Joint Council of Allergy, Asthma & Immunology, allergen immunotherapy prescribing information, the clinical need to separate certain allergens into individual injections, and specialty input, the administration of a maximum of 150 allergen/antigen preparations per 12 months of subcutaneous allergy immunotherapy for the first year in the build-up phase and a maximum of 120 allergen/antigen preparations per 12 months of maintenance therapy is considered an appropriate course of treatment for the majority of individuals.

An evaluation of the peer-reviewed scientific literature, including but not limited to subscription materials, has provided Independent Health the basis for its medical necessity coverage outlined above.

Pre-Authorization Required? Yes ☐ No ☒

Pre-authorization is not required for this service. Criteria will be utilized upon retro-review.

Definitions

Allergy immunotherapy (AIT) is the administration of allergen to which a patient is sensitive, for the purpose of modulating the untoward immune response to that allergen and alleviating allergic symptoms. AIT represents the only therapy capable of inducing a state of immune tolerance and, through its inherent disease-modifying properties, provides the potential to affect a sustained clinical benefit with long-lasting clinical remission of the allergic condition.

Subcutaneous immunotherapy (SCIT) involves the repeated subcutaneous injection of increasing amounts of allergen beginning with very small doses of allergen and gradually increasing to higher doses.

Sublingual immunotherapy (SLIT) is an alternate approach of administering allergens orally, in which the allergen is given as either a dissolvable tablet under the tongue or as an aqueous or liquid extract.

References

Related Policies, Processes and Other Documents

Allergy Immunotherapy Reimbursement Guidelines; Policy No. M900701009

Non-Regulatory references

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Jutel M, Agache I, Bonini S, et al. International consensus on allergy immunotherapy. J Allergy Clin Immunol. 2015; 136(3):556-568.

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Regulatory References

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New York State Medicaid Update [web site]; Volume 32; Number 5; May 2016: p. 7 -9. Available at: https://www.health.ny.gov/health_care/medicaid/program/update/2016/may16_mu.pdf. Accessed February 14, 2024.

U.S. Food and Drug Administration (FDA). Vaccines, blood & biologics. Allergen Extracts – Injectable. Available at: http://www.fda.gov/BiologicsBloodVaccines/Allergenics/ucm391303.htm Accessed February 14, 2024.

Version Control

Signature / Approval on File? Yes ☒ No☐

Revision Date	Owner	Notes
4/1/2024	Health Care Services	Reviewed
1/1/2024	Health Care Services	Revised