Clinical Policy: Timothy Grass Pollen Allergen Extract (Grastek)
Reference Number: CP.PMN.XX
Effective Date: 08/17
Last Review Date: 08/17
Line of Business: Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Timothy grass pollen allergen extract (Grastek®) is an allergen extract.

FDA approved indication
Grastek is indicated as 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 Timothy grass or cross-reactive grass pollens. Grastek is approved for use in persons 5 through 65 years of age.

Grastek is not indicated for the immediate relief of allergic symptoms.

Policy/Criteria
Provider must submit documentation (which may include~~including~~ office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Centene Corporation® that Grastek is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Allergic Rhinitis (must meet all)**:**

1. Diagnosis of grass pollen-induced allergic rhinitis;
2. Confirmation of a positive skin test or in vitro testing for pollen-specific IgE antibodies for Timothy grass pollen or cross-reactive grass pollens (e.g., Sweet Vernal, Orchard, Perennial Rye, Kentucky Blue/June Grass, Meadow Fescue, or Redtop);
3. Prescribed by or in consultation with an allergist or immunologist;
4. Failure of one intranasal corticosteroid, unless all are contraindicated or clinically significant adverse effects are experienced;
5. Failure of one oral antihistamine at up to maximally indicated doses unless all are contraindicated or clinically significant adverse effects are experienced:
6. Dose does not exceed 1 tablet daily.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Allergic Rhinitis (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Documentation of positive response to therapy [e.g., improvement in nasal symptoms (e.g., congestion, itching, and rhinorrhea), reduction in medication use];
3. If request is for a dose increase, new dose does not exceed 1 tablet daily.

Approval duration: Duration of request or 12 months (whichever is less)

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.PMN.53 or evidence of coverage documents;

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
BAUs: Bioequivalent Allergy Units (BAUs)
FDA: Food and Drug Administration

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Grass pollen-induced allergic rhinitis	One tablet sublingually daily Treatment should be initiated at least 12 weeks before the expected onset of each grass pollen season and continue treatment throughout the season. For sustained effectiveness for one grass pollen season after cessation of treatment, Grastek may be taken daily for three consecutive years.	1 tablet per day

VI. Product Availability

Tablet: 2800 Bioequivalent Allergy Units (BAUs)

VII. Workflow Document

N/A

VIII. References

1. Grastek Prescribing Information. Whitehouse Station, NJ: Merck Sharp & Dohme Corp.; September 2016. Available at: https://www.grastek.com/. Accessed April 5, 2017.
2. Seidman MD, Gurgel RK, Lin SY, et al. Clinical practice guideline: Allergic rhinitis. Otolaryngol Head Neck Surg. 2015 Feb;152(1 Suppl):S1-43. doi: 10.1177/0194599814561600.
3. Wallace DV, Dykewicz MS, Bernstein DI, Blessing-Moore J, Cox L, Khan DA, Lang DM, Nicklas RA, Oppenheimer J, Portnoy JM, Randolph CC, Schuller D, Spector SL, Tilles SA, Joint Task Force on Practice, American Academy of Allergy, Asthma&Immunology, American College of Allergy, Asthma and Immunology, Joint Council of Allergy, Asthma and Immunology. The diagnosis and management of rhinitis: an updated practice parameter. J Allergy Clin Immunol. 2008;122(2 Suppl):S1-84.
4. Cox L, Nelson H, Lockey R, et al. Allergen immunotherapy: a practice parameter third update. J Allergy Clin Immunol. 2011 Jan;127(1 Suppl):S1-55.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	04/17	08/17

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.