



Allergen Extracts Clinical Edit Criteria

Drug/Drug Class:

Allergen Extracts

Superior HealthPlan follows the guidance of the Texas Vendor Drug Program (VDP) for all clinical edit criteria. This clinical edit criteria applies to all Superior HealthPlan Medicaid (STAR, STAR Health, STAR Kids, STAR+PLUS) and CHIP members. Superior has adjusted the clinical criteria to ease the prior authorization process regarding this clinical edit by removing step 7 as a requirement for Grastek and Ragwitek and step 8 as a requirement for Oralair clinical edits. Adjusted criteria steps are outlined/highlighted in yellow.

The original clinical edit can be referenced at the Texas Vendor Drug Program website located at: https://paxpress.txpa.hidinc.com/allergen_extractpdg.pdf.

Clinical Edit Information Included in this Document:

Grastek (Timothy Grass Pollen Allergen Extract)

- **Drugs requiring prior authorization:** the list of drugs requiring prior authorization for this clinical criteria.
- **Prior authorization criteria logic:** a description of how the prior authorization request will be evaluated against the clinical criteria rules.
- **Logic diagram:** a visual depiction of the clinical edit criteria logic.
- **Supporting tables:** a collection of information associated with the steps within the criteria (diagnosis codes, procedure codes, and therapy codes); provided when applicable.
- **Clinical edit references:** clinical edit references as provided by Texas VDP
- **Publication history:** record of when the eased criteria was put into production and any updates since this time.

Please note: All tables are provided by original Texas Vendor Drug Program Allergen Extracts Edit.

Oralair (Mixed Grass Pollens Allergen Extract)

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Palforzia (Peanut Allergen Powder)

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Ragwitek (Short Ragweed Pollen Allergen Extract)

- **Drugs requiring prior authorization:** the list of drugs requiring prior authorization for this clinical criteria.
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- **Supporting tables:** a collection of information associated with the steps within the criteria (diagnosis codes, procedure codes, and therapy codes); provided when applicable
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Please note: All tables are provided by original Texas Vendor Drug Program Allergen Extracts Edit.

Drugs Requiring Prior Authorization Grastek (Timothy Grass Pollen Allergen Extract):

The listed GCNs may not be an indication of TX Medicaid Formulary coverage.

To learn the current formulary coverage, visit

TxVendorDrug.com/formulary/formulary-search.

Drugs Requiring Prior Authorization	
Label Name	GCN
GRASTEK 2800 BAU SUBLINGUAL TABLET	35777

Superior HealthPlan Clinical Criteria Logic Grastek (Timothy Grass Pollen Allergen Extract):

1. Is the client greater than or equal to (\geq) 5 years of age?

Yes – Go to #2

No – Deny

2. Is the client less than or equal to (\leq) 65 years of age?

Yes – Go to #3

No – Deny

3. Does the client have a diagnosis of allergic rhinitis in the last 730 days?

Yes – Go to #4

No – Deny

4. Has the client had hypersensitivity testing in the last 5 years?

Yes – Go to #5

No – Deny

5. Does the client have 1 claim for auto-injectable epinephrine in the last 365 days or is the patient receiving auto-injectable epinephrine concurrently?

Yes – Go to #6

No – Deny

6. Does the client have a history of severe, unstable or uncontrolled asthma OR a history of eosinophilic esophagitis in the last 365 days?

Yes – Deny

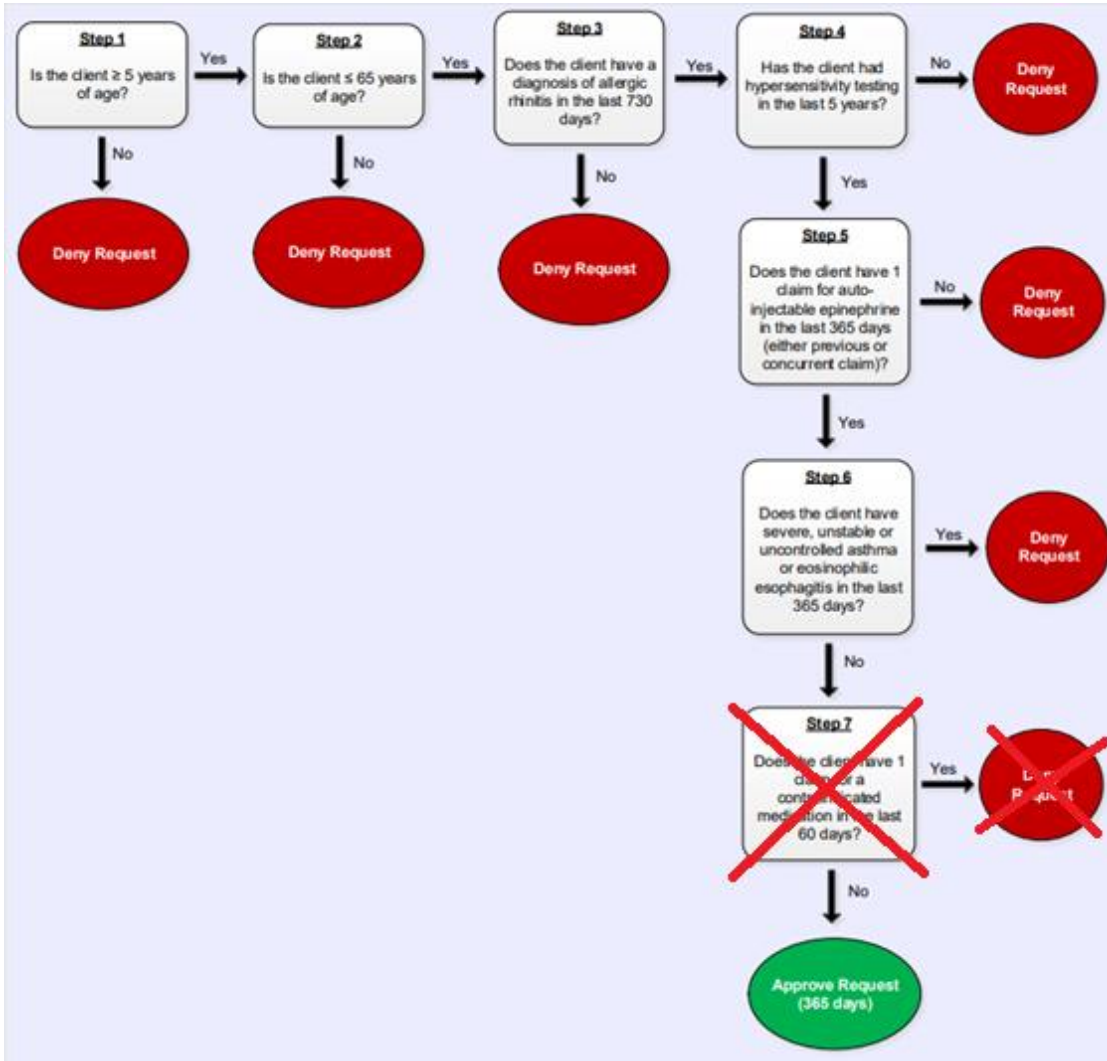
No – ~~Go to #7~~ Approve (365 days)

~~7. Does the client have 1 claim for a medication not recommended to be taken in conjunction with Grastek in the last 60 days?~~

~~Yes – Deny~~

~~No – Approve (365 days)~~

Superior HealthPlan Clinical Edit Logic Diagram Grastek (Timothy Grass Pollen Allergen Extract):



Drugs Requiring Prior Authorization Oralair (Mixed Grass Pollen Allergen Extract):

The listed GCNs may not be an indication of TX Medicaid Formulary coverage.

To learn the current formulary coverage, visit

TxVendorDrug.com/formulary/formulary-search.

Drugs Requiring Prior Authorization	
Label Name	GCN
ORALAIR 300 IR SUBLINGUAL TABLET	33970

Superior HealthPlan Clinical Criteria Logic Oralair (Mixed Grass Pollen Allergen Extract):

1. Is the client greater than or equal to (\geq) 5 years of age?

Yes – Go to #2

No – Deny

2. Is the client less than or equal to (\leq) 65 years of age?

Yes – Go to #3

No – Deny

3. Does the client have a diagnosis of allergic rhinitis in the last 730 days?

Yes – Go to #4

No – Deny

4. Has the client had hypersensitivity testing in the last 5 years?

Yes – Go to #5

No – Deny

5. Does the client have 1 claim for auto-injectable epinephrine in the last 730 days or is the patient receiving auto-injectable epinephrine concurrently?

Yes – Go to #6

No – Deny

6. Has the client had therapy with an intranasal corticosteroid AND an intranasal antihistamine OR one combination intranasal corticosteroid and intranasal antihistamine product in the last 730 days?

Yes – Go to #7

No – Deny

7. Does the client have a history of severe, unstable or uncontrolled asthma OR a history of eosinophilic esophagitis in the last 365 days?

Yes – Deny

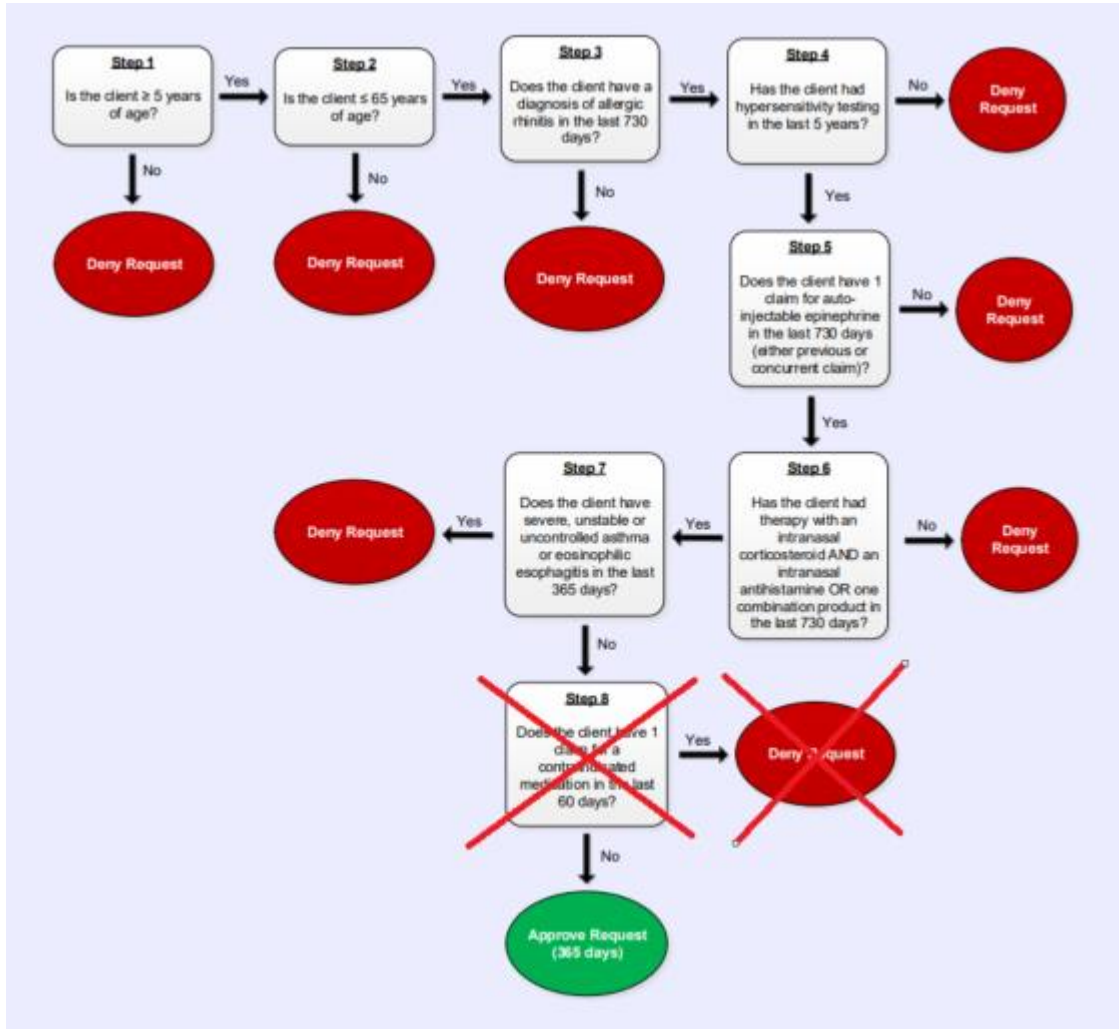
No – Go to #8 Approve (365 days)

8. Does the client have 1 claim for a medication not recommended to be taken in conjunction with Oralair in the last 60 days?

Yes – Deny

No – Approve (365 days)

Superior HealthPlan Clinical Edit Logic Diagram Oralair (Mixed Grass Pollen Allergen Extract):



Drugs Requiring Prior Authorization Palforzia (Peanut Allergen Powder):

The listed GCNs may not be an indication of TX Medicaid Formulary coverage.

To learn the current formulary coverage, visit

TxVendorDrug.com/formulary/formulary-search.

Drugs Requiring Prior Authorization	
Label Name	GCN
PALFORZIA INITIAL DOSE PACK	47639
PALFORZIA 12 MG (LEVEL 3)	47654
PALFORZIA 120 MG (LEVEL 7)	47659
PALFORZIA 160 MG (LEVEL 8)	47664
PALFORZIA 20 MG (LEVEL 4)	47655
PALFORZIA 200 MG (LEVEL 9)	47649
PALFORZIA 240 MG (LEVEL 10)	47652
PALFORZIA 3 MG (LEVEL 1)	47647
PALFORZIA 300 MG (MAINTENANCE)	47653
PALFORZIA 300 MG (LEVEL 11)	47653
PALFORZIA 40 MG (LEVEL 5)	47656
PALFORZIA 6 MG (LEVEL 2)	47648
PALFORZIA 80 MG (LEVEL 6)	47658

Superior HealthPlan Clinical Criteria Logic Palforzia (Peanut Allergen Powder):

1. Is the client greater than or equal to (\geq) 4 years of age?

Yes – Go to #2

No – Deny

2. Does the client had at least 1 paid claim for the requested agent in the last 60 days?

Yes – Go to #4

No, and the client is 4 – 17 years of age – Go to #3

No, and the client is \geq 18 years of age - Deny

3. Does the client have a diagnosis of peanut allergy in the last 730 days?

Yes – Go to #4

No – Deny

4. Does the client have 1 claim for auto-injectable epinephrine in the last 365 days or is the patient receiving auto-injectable epinephrine concurrently?

Yes – Go to #5

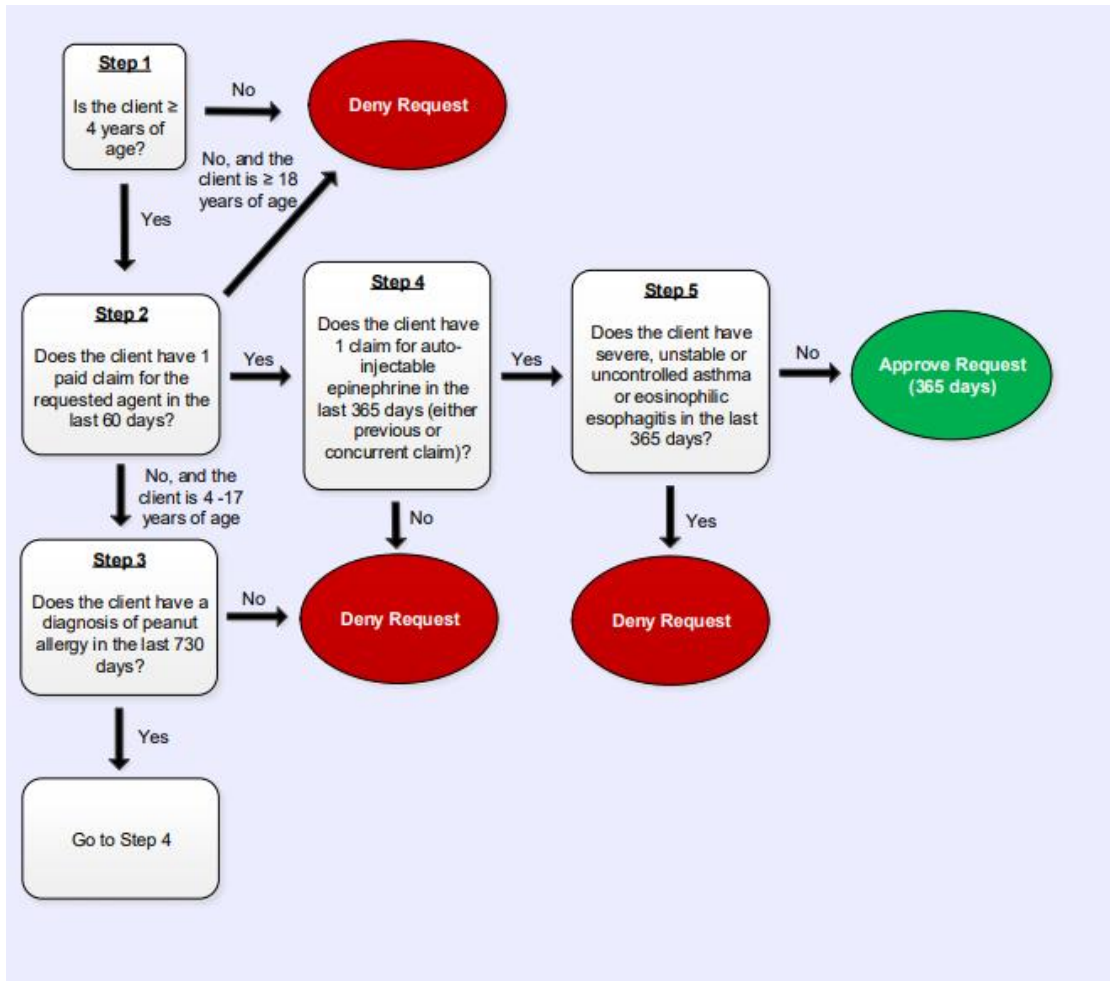
No – Deny

5. Does the client have a history of severe, unstable or uncontrolled asthma OR a history of eosinophilic esophagitis in the last 365 days?

Yes – Deny

No – Approve (365 days)

Superior HealthPlan Clinical Edit Logic Diagram Palforzia (Peanut Allergen Powder):



Drugs Requiring Prior Authorization Ragwitek (Short Ragweed Pollen Allergen Extract):

The listed GCNs may not be an indication of TX Medicaid Formulary coverage.

To learn the current formulary coverage, visit

TxVendorDrug.com/formulary/formulary-search.

Drugs Requiring Prior Authorization	
Label Name	GCN
RAGWITEK SUBLINGUAL TABLET	36402

Superior HealthPlan Clinical Criteria Logic Ragwitek (Short Ragweed Pollen Allergen Extract):

1. Is the client greater than or equal to (\geq) 18 years of age?

Yes – Go to #2

No – Deny

2. Is the client less than or equal to (\leq) 65 years of age?

Yes – Go to #3

No – Deny

3. Does the client have a diagnosis of allergic rhinitis in the last 730 days?

Yes – Go to #4

No – Deny

4. Has the client had hypersensitivity testing in the last 5 years?

Yes – Go to #5

No – Deny

5. Does the client have 1 claim for auto-injectable epinephrine in the last 365 days or is the patient receiving auto-injectable epinephrine concurrently?

Yes – Go to #6

No – Deny

6. Does the client have a history of severe, unstable or uncontrolled asthma OR a history of eosinophilic esophagitis in the last 365 days?

Yes – Deny

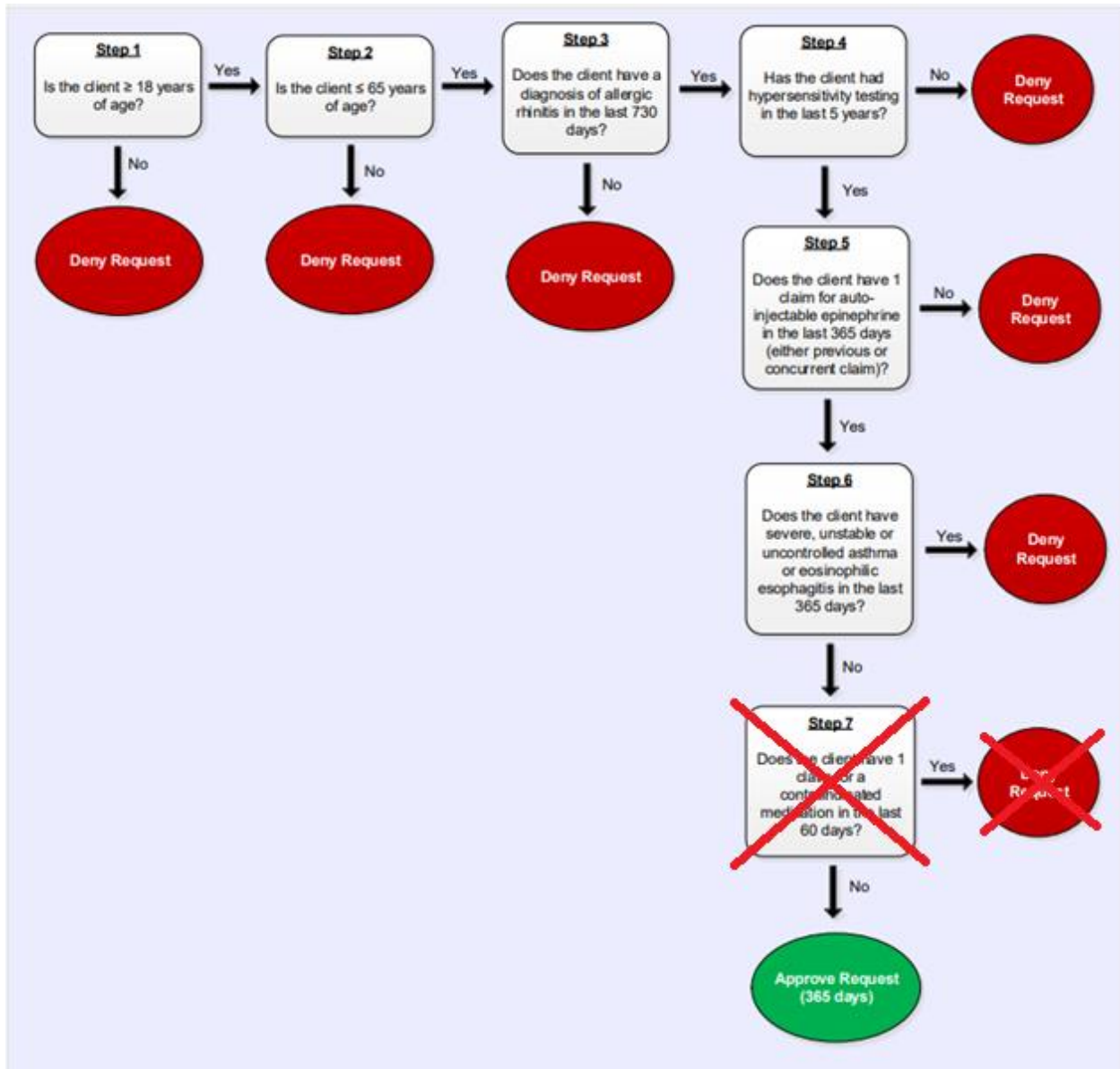
No – **Go to #7** Approve (365 days)

7. Does the client have 1 claim for a medication not recommended to be taken in conjunction with Ragwitek in the last 60 days?

Yes – Deny

No – Approve (365 days)

Superior HealthPlan Clinical Edit Logic Diagram Ragwitek (Short Ragweed Pollen Allergen Extract):



Clinical Criteria Supporting Tables:

Step 3 (diagnosis of allergic rhinitis) Required quantity: 1 Look back timeframe: 730 days	
ICD-10 Code	Description
J301	ALLERGIC RHINITIS DUE TO POLLEN

Peanut Allergy	
ICD-10 Code	Description
T7801XA	ANAPHYLACTIC REACTION DUE TO PEANUTS INITIAL ENCOUNTER
T7801XD	ANAPHYLACTIC REACTION DUE TO PEANUTS SUBSEQUENT ENCOUNTER
T7801XS	ANAPHYLACTIC REACTION DUE TO PEANUTS SEQUELA
Z91010	ALLERGY TO PEANUTS

Step 4 (hypersensitivity testing) Required quantity: 1 Look back timeframe: 5 years	
CPT/ICD-10 Code	Description
86003	ALLERGEN SPECIFIC IGE; QUANTITATIVE OR SEMIQUANTITATIVE, EACH ALLERGEN
86005	ALLERGEN SPECIFIC IGE; QUALITATIVE, MULTIALLERGEN SCREEN
82785	TOTAL QUANTITATIVE IGE
83518	TOTAL QUALITATIVE IGE
95004	PERCUTANEOUS TESTS WITH ALLERGENIC EXTRACTS, IMMEDIATE TYPE REACTION, INCLUDING TEST INTERPRETATION AND REPORT
95024	INTRACUTANEOUS (INTRADERMAL) TESTS WITH ALLERGENIC EXTRACTS, IMMEDIATE TYPE REACTION, INCLUDING TEST INTERPRETATION AND REPORT
95027	INTRACUTANEOUS (INTRADERMAL) TESTS, SEQUENTIAL AND INCREMENTAL, WITH ALLERGENIC EXTRACTS FOR AIRBORNE ALLERGENS, IMMEDIATE TYPE REACTION, INCLUDING TEST INTERPRETATION AND REPORT
95028	INTRACUTANEOUS (INTRADERMAL) TESTS WITH ALLERGENIC EXTRACTS, DELAYED TYPE REACTION, INCLUDING READING
Z0182	ENCOUNTER FOR ALLERGY TESTING

Step 5 (history of auto-injectable epinephrine) Required quantity: 1 Look back timeframe: 365/730 days	
GCN	Description
28038	EPINEPHRINE 0.15MG AUTO-INJECTOR
19861	EPINEPHRINE 0.15MG AUTO-INJECT
19862	EPINEPHRINE 0.3MG AUTO-INJECTOR
19862	EPIPEN 0.3MG AUTO-INJECTOR
19861	EPIPEN JR 0.15MG AUTO-INJECTOR
46623	SYMJEPI 0.15MG/0.3ML SYRINGE
22547	SYMJEPI 0.3MG/0.3ML SYRINGE

Step 6a (history of an intranasal corticosteroid)	
Required quantity: 1	
Look back timeframe: 730 days	
GCN	Description
47100	BECONASE AQ 0.042% SPRAY
92231	BUDESONIDE 32MCG NASAL SPRAY
40708	BUDESONIDE 32MCG NASAL SPRAY
34280	FLUNISOLIDE 0.025% SPRAY
62263	FLUTICASONE PROP 50MCG SPRAY
37683	FLUTICASONE PROP 50MCG SPRAY
71431	MOMETASONE FUROATE 50MGCG SPRY
71431	NASONEX 50MCG NASAL SPRAY
97453	OMNARIS 50 MCG NASAL SPRAY
31769	QNASL 80MCG NASAL SPRAY
37654	QNASL CHILDRENS 40MCG SPRAY
36145	TRIAMCINOLONE 55MCG NASAL SPRAY
43878	XHANCE 93MCG NASAL SPRAY

Step 6b (history of intranasal antihistamine)	
Required quantity: 1	
Look back timeframe: 730 days	
GCN	Description
60544	AZELASTINE 0.1% (137 MCG) SPRY
27584	AZELASTINE 0.15% NASAL SPRAY
99602	OLOPATADINE 665 MCG NASAL SPRY
99602	PATANASE 665 MCG NASAL SPRAY

Step 6c (history of an intranasal corticosteroid/intranasal antihistamine combination product)	
Required quantity: 1	
Look back timeframe: 730 days	
GCN	Description
32099	AZELASTIN-FLUTIC 137-50 MCG SPR
32099	DYMISTA NASAL SPRAY

Step 7 (diagnosis of asthma or eosinophilic esophagitis)	
Required quantity: 1	
Look back timeframe: 365 days	
ICD-10 Code	Description
J4550	SEVERE PERSISTENT ASTHMA, UNCOMPLICATED
J4551	SEVERE PERSISTENT ASTHMA, WITH (ACUTE) EXACERBATION
J4552	SEVERE PERSISTENT ASTHMA, WITH STATUS ASTHMATICUS
J45901	UNSPECIFIED ASTHMA, WITH (ACUTE) EXACERBATION
J45902	UNSPECIFIED ASTHMA, WITH STATUS ASTHMATICUS
K200	EOSINOPHILIC ESOPHAGITIS

Step 8 (claim for a non-recommended medication)**Required quantity: 1****Look back timeframe: 365 days**

ICD-10 Code	Description
26460	ACEBUTOLOL 200MG CAPSULE
26461	ACEBUTOLOL 400MG CAPSULE
20660	ATENOLOL 100MG TABLET
20662	ATENOLOL 25MG TABLET
20664	ATENOLOL 50MG TABLET
66994	ATENOLOL-CHLORTHAL 100-25MG TAB
66990	ATENOLOL-CHLORTHAL 50-25MG TAB
92024	ALFUZOSIN HCL ER 10MG TABLET
12791	BETAXOLOL 10MG TABLET
12792	BETAXOLOL 20MG TABLET
63820	BISOPROLOL FUMARATE 10MG TABLET
63821	BISOPROLOL FUMARATE 5MG TABLET
45063	BISOPROLOL-HCTZ 10-6.25MG TABLET
45064	BISOPROLOL-HCTZ 2.5-6.25MG TABLET
45062	BISOPROLOL-HCTZ 5-6.25MG TABLET
99236	BYSTOLIC 10MG TABLET
99235	BYSTOLIC 2.5MG TABLET
18703	BYSTOLIC 20MG TABLET
07055	BYSTOLIC 5MG TABLET
33431	CARDURA 1MG TABLET
33432	CARDURA 2MG TABLET
33433	CARDURA 4MG TABLET
33434	CARDURA 8MG TABLET
01552	CARVEDILOL 12.5MG TABLET
01551	CARVEDILOL 25MG TABLET
01553	CARVEDILOL 3.125MG TABLET
01554	CARVEDILOL 6.25MG TABLET
97596	CARVEDILOL ER 10MG CAPSULE
97597	CARVEDILOL ER 20MG CAPSULE
97598	CARVEDILOL ER 40MG CAPSULE
97599	CARVEDILOL ER 80MG CAPSULE
01552	COREG 12.5MG TABLET
01551	COREG 25MG TABLET
01553	COREG 3.125MG TABLET
01554	COREG 6.25MG TABLET
97596	COREG CR 10MG CAPSULE
97597	COREG CR 20MG CAPSULE
97598	COREG CR 40MG CAPSULE
97599	COREG CR 80MG CAPSULE
52060	CORZIDE 40-5 TABLET
52061	CORZIDE 80-5 TABLET
01590	D.H.E. 45 1MG/ML AMPULE
01590	DIHYDROERGOTAMINE 1MG/ML AMPULE
33431	DOXAZOSIN MESYLATE 1MG TABLET
33432	DOXAZOSIN MESYLATE 2MG TABLET
33433	DOXAZOSIN MESYLATE 4MG TABLET
33434	DOXAZOSIN MESYLATE 8MG TABLET
28596	DUTASTERIDE-TAMSULOSIN 0.5-0.4
02213	ERGOLOID MESYLATES 1MG TABLET

48191	FLOMAX 0.4MG CAPSULE
36526	HEMANGEOL 4.28MG/ML ORAL SOLN
03231	INDERAL LA 120MG CAPSULE
03232	INDERAL LA 160MG CAPSULE
03233	INDERAL LA 60MG CAPSULE
03230	INDERAL LA 80MG CAPSULE
19359	INNOPRAN XL 120MG CAPSULE
20621	INNOPRAN XL 80MG CAPSULE
28596	JALYN 0.5 0.4MG CAPSULE
10342	LABETALOL HCL 100MG TABLET
10341	LABETALOL HCL 200MG TABLET
10340	LABETALOL HCL 300MG TABLET
11340	METHERGINE 0.2MG/ML AMPULE
11350	METHYLERGONOVINE 0.2MG TABLET
20742	METOPROLOL SUCC ER 100MG TABLET
20743	METOPROLOL SUCC ER 200MG TABLET
12947	METOPROLOL SUCC ER 25MG TABLET
20741	METOPROLOL SUCC ER 50MG TABLET
20641	METOPROLOL TARTRATE 100MG TABLET
17734	METOPROLOL TARTRATE 25MG TABLET
37653	METOPROLOL TARTRATE 37.5MG TABLET
20642	METOPROLOL TARTRATE 50MG TABLET
37656	METOPROLOL TARTRATE 75MG TABLET
51551	METOPROLOL-HCTZ 100-25MG TAB
51552	METOPROLOL-HCTZ 100-50MG TAB
51550	METOPROLOL-HCTZ 50-25MG TAB
01250	MINIPRESS 1MG CAPSULE
01251	MINIPRESS 2MG CAPSULE
01252	MINIPRESS 5MG CAPSULE
20654	NADOLOL 20MG TABLET
20652	NADOLOL 40MG TABLET
20653	NADOLOL 80MG TABLET
52060	NADOLOL-BENDROFLU 40-5MG TABLET
52061	NADOLOL-BENDROFLU 80-5MG TABLET
99236	NEBIVOLOL 10 MG TABLET
18703	NEBIVOLOL 20 MG TABLET
99235	NEBIVOLOL 2.5 MG TABLET
07055	NEBIVOLOL 5 MG TABLET
20680	PINDOLOL 10MG TABLET
20681	PINDOLOL 5MG TABLET
01250	PRAZOSIN 1MG CAPSULE
01251	PRAZOSIN 2MG CAPSULE
01252	PRAZOSIN 5MG CAPSULE
20630	PROPRANOLOL 10MG TABLET
20631	PROPRANOLOL 20MG TABLET
45260	PROPRANOLOL 20MG/5ML SOLUTION
45261	PROPRANOLOL 40MG/5ML SOLUTION
20632	PROPRANOLOL 40MG TABLET
20633	PROPRANOLOL 60MG TABLET
20634	PROPRANOLOL 80MG TABLET
03231	PROPRANOLOL ER 120MG CAPSULE
03232	PROPRANOLOL ER 160MG CAPSULE
03233	PROPRANOLOL ER 60MG CAPSULE

03230	PROPRANOLOL ER 80MG CAPSULE
52030	PROPRANOLOL-HCTZ 40-25MG TABLET
52034	PROPRANOLOL-HCTZ 80-25MG TABLET
16857	RAPAFLO 4MG CAPSULE
16858	RAPAFLO 8MG CAPSULE
16857	SILODOSIN 4MG CAPSULE
16858	SILODOSIN 8MG CAPSULE
39516	SORINE 120MG TABLET
39514	SORINE 160MG TABLET
39513	SORINE 240MG TABLET
39512	SORINE 80MG TABLET
39516	SOTALOL 120MG TABLET
39514	SOTALOL 160MG TABLET
39513	SOTALOL 240MG TABLET
39512	SOTALOL 80MG TABLET
37877	SOTYLIZE 5MG/ML ORAL SOLUTION
48194	TAMSULOSIN HCL 0.4MG CAPSULE
66994	TENORETIC 100 TABLET
66990	TENORETIC 50 TABLET
20660	TENORMIN 100MG TABLET
20662	TENORMIN 25MG TABLET
20664	TENORMIN 50MG TABLET
47127	TERAZOSIN 10MG CAPSULE
47124	TERAZOSIN 1MG CAPSULE
47125	TERAZOSIN 2MG CAPSULE
47126	TERAZOSIN 5MG CAPSULE
20670	TIMOLOL MALEATE 10MG TABLET
20674	TIMOLOL MALEATE 20MG TABLET
20672	TIMOLOL MALEATE 5MG TABLET
20742	TOPROL XL 100MG TABLET
20743	TOPROL XL 200MG TABLET
12947	TOPROL XL 25MG TABLET
20744	TOPROL XL 50MG TABLET
45063	ZIAC 10-6.25MG TABLET
45064	ZIAC 2.5-6.25MG TABLET
45062	ZIAC 5-6.25MG TABLET

Clinical Criteria References:

1. 2022 ICD-10-CM Diagnosis Codes, Volume 1. 2022. Available at <http://www.icd10data.com/>. Accessed on January 20, 2023.
2. 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: A practice parameter third update. JACI 2011;127(1):S1-S55. Available at www.jacionline.org. Accessed January 2, 2015.
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4. Clinical Pharmacology [online database]. Tampa, FL: Elsevier/Gold Standard, Inc.; 2022. Available at www.clinicalpharmacology.com. Accessed on July 22, 2022.
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7. Seidman MD, Gurgel RK, Lin SY, et al. Clinical Practice Guideline: Allergic Rhinitis. Otolaryngology – Head and Neck Surgery February 2015;152:S1-S43.
8. Greenhawt M, Oppenheimer J, Nelson M, et al. Sublingual immunotherapy: A focused allergen immunotherapy practice parameter update. Ann Allergy Asthma Immunol 118(2017);276-282.
9. Dykewicz MS, Wallace DV, Baroody F, et al. Treatment of seasonal allergic rhinitis. An evidence-based focused 2017 guideline update. Ann Allergy Asthma Immunol 2017;1-23.
10. Grastek Prescribing Information. Horsholm, Denmark. ALK-Abello Inc. December 2019.
11. Palforzia Prescribing Information. Brisbane, CA. Aimmune Therapeutics. July 2022.
12. Ragwitek Prescribing Information. Horsholm, Denmark. ALK-Abello Inc. April 2021.

Publication History:

Publication	Notes
01/22/2020	Criteria created and cross referenced to VDP criteria.
03/30/2020	Removed step 7 from Clinical Criteria Logic. Adjusted step 6 response: No to Approve 365 days.
04/10/2020	Updated URL link to VDP criteria
11/16/2022	Revised diagnoses to include only allergic rhinitis due to pollen (J301) Updated criteria to require trial of an intranasal corticosteroid and an intranasal antihistamine Added GCNs for metoprolol (37653, 37656) and nebivolol (99236, 18703, 99235, 07055) Updated lookback for epinephrine and prior therapy to 730 days as requested by the DUR Board Updated prior therapy to include approval if a trial of a combination intranasal corticosteroid/intranasal antihistamine agent is found
2/22/2023	Added GCNs for budesonide (40708) and fluticasone (37683) Updated references
08/17/2023	Updated Allergen Extracts description to reference removal of step 8 vs step 7 as a requirement for Oralair clinical edit Updated URL link to VDP criteria Added Palforzia criteria to Allergen Extracts guide Added additional ICD-10 codes for peanut allergy (T7801XA, T7801XD, T7801XS) to Peanut Allergies table Added Symjepi/GCN to step 5 table Added CPT to step 4 table Changed ICD-10 to GCN in step 5 table
9/7/2023	Added criteria for Grastek and Ragwitek (previously approved by the DUR Board) Removed step 7 from Clinical Criteria Logic for both Grastek and Ragwitek. Adjusted step 6 response: No to Approve 365 days. Updated Allergen Extracts description to reference removal of step 7 as a requirement for Grastek and Ragwitek clinical edits Updated Clinical Criteria References to include #10-12