

**Texas Prior Authorization Program
Clinical Criteria**

Drug/Drug Class

Allergen Extracts

Clinical Information Included in this Document

Oralair (Mixed Grass Pollens 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 criteria logic
- **Supporting tables:** a collection of information associated with the steps within the criteria (diagnosis codes, procedure codes, and therapy codes)
- **References:** clinical publications and sources relevant to this clinical criteria

Note: Click the hyperlink to navigate directly to that section.

Revision Notes

Updated age to 5 years for Oralair on criteria logic and diagram, pages 3 and 4

Updated Table 6, page 6



Oralair (Grass Pollen Allergen Extract)

Drugs Requiring Prior Authorization

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.

Oralair	
Label Name	GCN
ORALAIR 300 IR SUBLINGUAL TABLET	33970



Oralair (Grass Pollen Allergen Extract)

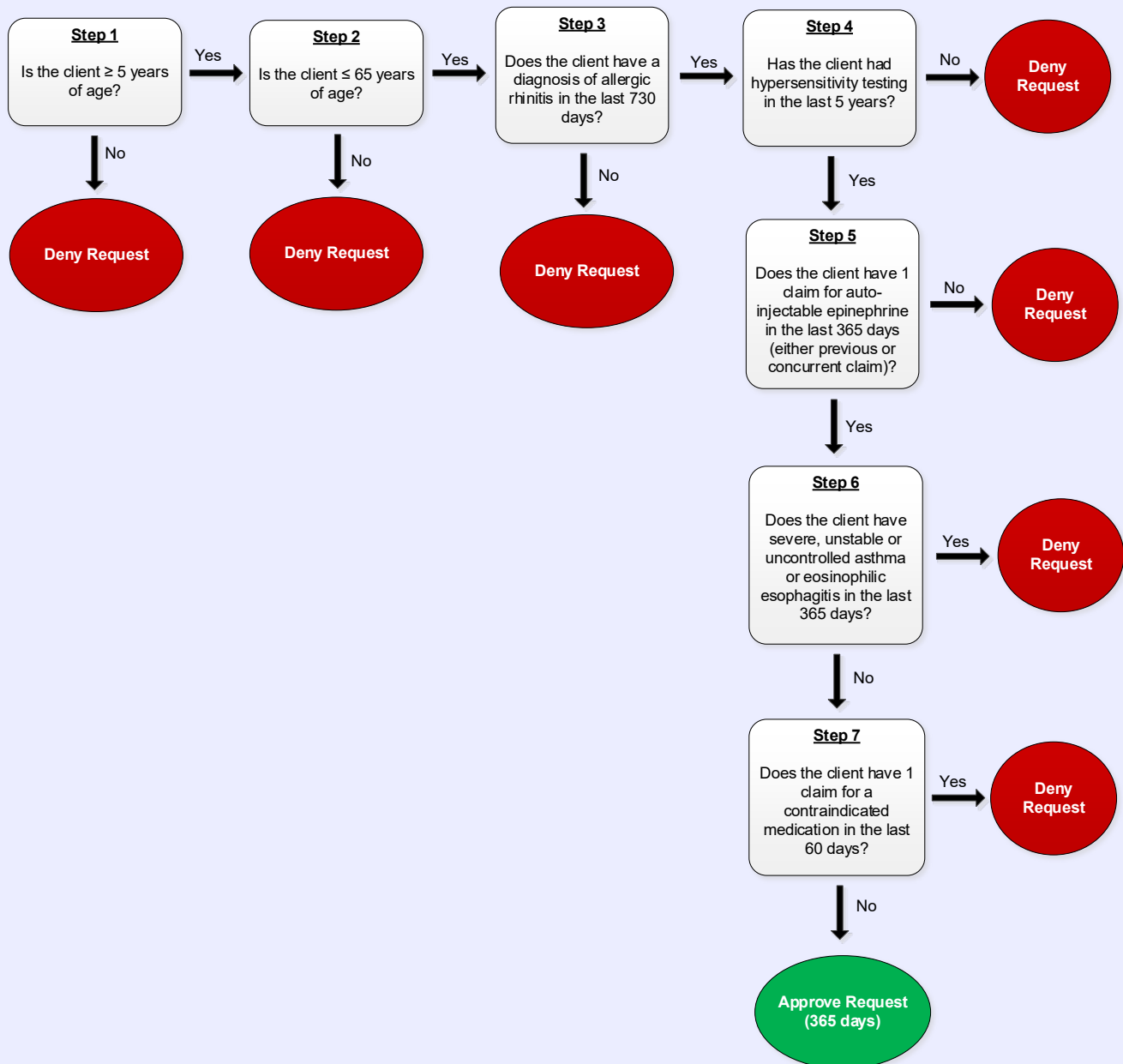
Clinical Criteria Logic

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
7. 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)



Oralair (Grass Pollen Allergen Extract)

Clinical Criteria Logic Diagram





Oralair (Grass 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
J300	VASOMOTOR RHINITIS
J301	ALLERGIC RHINITIS DUE TO POLLEN
J302	OTHER SEASONAL ALLERGIC RHINITIS
J3089	OTHER ALLERGIC RHINITIS
J309	ALLERGIC RHINITIS, UNSPECIFIED

Step 4 (hypersensitivity testing) Required quantity: 1 Look back timeframe: 5 years	
CPT 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

Step 5 (history of auto-injectable epinephrine)	
Required quantity: 1	
Look back timeframe: 365 days	
GCN	Description
28038	EPINEPHRINE 0.15MG AUTO-INJECTOR
19861	EPINEPHRINE 0.15MG AUTO-INJCT
19862	EPINEPHRINE 0.3MG AUTO-INJECTOR
19862	EIPEN 0.3MG AUTO-INJECTOR
19861	EIPEN JR 0.15MG AUTO-INJECTOR

Step 6 (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 7 (claim for a non-recommended medication)	
Required quantity: 1	
Look back timeframe: 60 days	
GCN	Description
26460	ACEBUTOLOL 200MG CAPSULE
26461	ACEBUTOLOL 400MG CAPSULE
20660	ATENOLOL 100MG TABLET
20662	ATENOLOL 25MG TABLET
20661	ATENOLOL 50MG TABLET
66991	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

Step 7 (claim for a non-recommended medication)	
Required quantity: 1	
Look back timeframe: 60 days	
GCN	Description
45061	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

Step 7 (claim for a non-recommended medication)	
Required quantity: 1	
Look back timeframe: 60 days	
GCN	Description
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
20642	METOPROLOL TARTRATE 50MG 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
20680	PINDOLOL 10MG TABLET
20681	PINDOLOL 5MG TABLET
01250	PRAZOSIN 1MG CAPSULE
01251	PRAZOSIN 2MG CAPSULE
01252	PRAZOSIN 5MG CAPSULE
20630	PROPRANOLOL 10MG TABLET

Step 7 (claim for a non-recommended medication)	
Required quantity: 1	
Look back timeframe: 60 days	
GCN	Description
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
52031	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
39511	SORINE 160MG TABLET
39513	SORINE 240MG TABLET
39512	SORINE 80MG TABLET
39516	SOTALOL 120MG TABLET
39511	SOTALOL 160MG TABLET
39513	SOTALOL 240MG TABLET
39512	SOTALOL 80MG TABLET
37877	SOTYLIZE 5MG/ML ORAL SOLUTION
48191	TAMSULOSIN HCL 0.4MG CAPSULE
66991	TENORETIC 100 TABLET
66990	TENORETIC 50 TABLET
20660	TENORMIN 100MG TABLET
20662	TENORMIN 25MG TABLET
20661	TENORMIN 50MG TABLET
47127	TERAZOSIN 10MG CAPSULE
47124	TERAZOSIN 1MG CAPSULE
47125	TERAZOSIN 2MG CAPSULE
47126	TERAZOSIN 5MG CAPSULE
20670	TIMOLOL MALEATE 10MG TABLET
20671	TIMOLOL MALEATE 20MG TABLET

Step 7 (claim for a non-recommended medication)	
Required quantity: 1	
Look back timeframe: 60 days	
GCN	Description
20672	TIMOLOL MALEATE 5MG TABLET
20742	TOPROL XL 100MG TABLET
20743	TOPROL XL 200MG TABLET
12947	TOPROL XL 25MG TABLET
20741	TOPROL XL 50MG TABLET
45063	ZIAC 10-6.25MG TABLET
45061	ZIAC 2.5-6.25MG TABLET
45062	ZIAC 5-6.25MG TABLET



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Clinical Criteria References

1. 2014 ICD-9-CM Diagnosis Codes, Volume 1. 2014. Available at <http://www.icd9data.com/>. Accessed on July 31, 2015.
2. 2014 ICD-10-CM Diagnosis Codes, Volume 1. 2014. Available at <http://www.icd10data.com/>. Accessed on July 31, 2015.
3. 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.
4. Wallace DV, Dykewicz MS, et al. The diagnosis and management of rhinitis: and updated practice parameter. JACI 2008;122:S1-84. Available at www.aaaai.org. Accessed January 2, 2015.
5. Clinical Pharmacology [online database]. Tampa, FL: Elsevier/Gold Standard, Inc.; 2019. Available at www.clinicalpharmacology.com. Accessed on May 10, 2019.
6. Micromedex [online database]. Available at www.micromedexsolutions.com. Accessed on May 10, 2019.
7. Grastek Prescribing Information. ALK-Abello A/S. Horsholm, Denmark. April 2017.
8. Oralair Prescribing Information. Greer Laboratories. Lenoir, NC.
9. Ragwitek Prescribing Information. ALK-Abello A/S. Horsholm, Denmark. April 2017.
10. Seidman MD, Gurgel RK, Lin SY, et al. Clinical Practice Guideline: Allergic Rhinitis. Otolaryngology – Head and Neck Surgery February 2015;152:S1-S43.
11. 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.

Publication History

The Publication History records the publication iterations and revisions to this document. Notes for the *most current revision* are also provided in the **Revision Notes** on the first page of this document.

Publication Date	Notes
01/29/2015	Presented to the DUR Board
02/27/2015	Initial publication and posting to website
07/31/2015	Review of ICD-9 and ICD-10 codes
08/01/2018	Annual review by staff Removed ICD-9 codes Updated Table 7, pages 8-11 Added GCN for Odactra, page 17 Updated references, page 22
11/09/2018	Removed criteria for Grastek – drug is not currently on formulary Removed GCN for Odactra, page 12
03/21/2019	Updated to include formulary statement (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 .) on each 'Drug Requiring PA' table
07/15/2019	Annual review by staff Removed criteria for Ragwitek – drug is no longer on formulary Updated Table 5, page 6 Updated Table 7, pages 7-10 Updated references, page 11
12/10/2019	Updated age to 5 years for Oralair on criteria logic and diagram, pages 3 and 4 Updated Table 6, page 6