

Nonsedating Antihistamines Step Therapy Criteria

FDA APPROVED INDICATIONS AND DOSAGE¹⁻⁶

Drug	Seasonal Allergic Rhinitis	Perennial Allergic Rhinitis	Chronic Idiopathic Urticaria
Allegra[®] (fexofenadine) tablets, ODT (orally disintegrating) tablets, oral suspension	≥ 12 years of age: 60 mg twice daily or 180 mg once daily 6-11 years of age: 30 mg twice daily 2-5 years of age: 30 mg twice daily 6 mo-<2 years: 15 mg twice daily		≥ 12 years of age: 60 mg twice daily or 180 mg once daily 6-11 years of age: 30 mg twice daily 2-5 years of age: 30 mg twice daily 6 mo-<2 years: 15 mg twice daily
Clarinet[®] (desloratadine) tablets, redi-tabs, syrup	≥ 12 years of age: 5 mg once daily 6-11 years of age: 2.5 mg once daily 12 mo-6 years of age: 1.25 mg once daily	≥ 12 years of age: 5 mg once daily 6-11 years of age: 2.5 mg once daily 12 mo-6 years of age: 1.25 mg once daily	≥ 12 years of age: 5 mg once daily 6-11 years of age: 2.5 mg once daily 12 mo-6 years of age: 1.25 mg once daily
Clarinet[®] D 12 Hour (desloratadine 2.5 mg/ pseudoephedrine 120 mg) tablets	≥ 12 years of age: 1 tablet twice daily		
Clarinet[®] D 24 Hour (desloratadine 5 mg/ pseudoephedrine 240 mg) tablets	≥ 12 years of age: 1 tablet once daily		
Semprex[®] D (acrivastine 8 mg/ pseudoephedrine 60 mg) capsules	≥ 12 years of age: 1 capsule up to 4 times daily; efficacy beyond 14 days not established		
Xyzal[®] (levocetirizine) tablets, oral solution	≥ 12 years of age: 5 mg once daily 6-11 years of age: 2.5 mg once daily 12 mo-5 years of age: 1.25 mg once daily	≥ 12 years of age: 5 mg once daily 6-11 years of age: 2.5 mg once daily 12 mo-5 years of age: 1.25 mg once daily	≥ 12 years of age: 5 mg once daily 6-11 years of age: 2.5 mg once daily 12 mo-5 years of age: 1.25 mg once daily

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CLINICAL RATIONALE

The practice parameter for rhinitis developed by the Joint Task Force on Practice Parameters, representing the American Academy of Allergy, Asthma & Immunology; the American College of Allergy, Asthma and Immunology; and the Joint Council of Allergy, Asthma and Immunology have found intranasal corticosteroids to be the most effective medication class for controlling symptoms of allergic rhinitis.⁷ No single nonsedating antihistamine (NSAH) agent has been conclusively shown to have superior efficacy to any other agent.⁷

Nonsedating antihistamines are preferred over sedating antihistamines for the treatment of allergic rhinitis. Sedating antihistamines have significant potential to cause sedation, performance impairment, and anticholinergic effects. Nonsedating antihistamines have fewer tendencies to cause these effects.⁷

The British Association of Dermatologists Therapy Guidelines for the evaluation and management of urticaria in adults and children note that antihistamines are the mainstay of therapy. Patients should be offered the choice of at least 2 nonsedating histamines because responses and tolerance vary between individuals. The use of sedating antihistamines as monotherapy is less common because of concerns about reduced concentration and performance.⁸

For additional clinical information see Prime Therapeutics Formulary Chapter 6.1B: Nonsedating Antihistamines and Chapter 6.3B: Cough-Cold-Allergy, Decongestant and Nonsedating Combinations.

REFERENCES

1. Allegra prescribing information. Sanofi-Aventis US LLC. June 2008.
2. Clarinex prescribing information. Schering Corporation. February 2007.
3. Clarinex-D 12 Hour prescribing information. Schering Corporation. December 2009.
4. Clarinex-D 24 Hour prescribing information. Schering Corporation. December 2009.
5. Xyzal prescribing information. Sanofi-Aventis US LLC/UCB Inc. August 2009.
6. Semprex-D (acrivastine and pseudoephedrine) capsules. Customized Monograph. Clinical Pharmacology, online version. February 2010.
7. Wallace DV, Dykewicz MS, Bernstein DI, et al. The Joint Task Force on Practice Parameters, representing the American Academy of Allergy, Asthma & Immunology. The diagnosis and management of rhinitis: an updated practice parameter. *J Allergy Clin Immunol* 2008; 122 (2): S1-S84.
8. Grattan CE, Humphreys F, British Association of Dermatologists Therapy Guidelines and Audit Subcommittee. Guidelines for evaluation and management of urticaria in adults and children. *Br J Dermatol* 2007; 157(6): 1116-23.

Document History

Original Prime Standard criteria approved by P&T UM Committee 05/2009
Initial Client Review Client Specific criteria approved by HCSC Corporate Clinical Committee 04/2010
Client Specific Mid-Year Review (clarification of auto-grandfathering) 06/2010

Nonsedating Antihistamines Step Therapy

OBJECTIVE

The intent of the Nonsedating Antihistamines Step Therapy (ST) program for brand name nonsedating antihistamines (NSAHs) is to encourage the use of generic fexofenadine or the generic fexofenadine/pseudoephedrine combination (as available) prior to the brand name products in patients 6 years of age or older. Patients stabilized on therapy with one of these agents will be allowed to continue on that agent. Because young children may be unable to swallow tablet dosage forms available generically, children younger than 6 years of age will be exempt from the step therapy requirements. This program will accommodate use of brand NSAHs when there is history of use of a generic fexofenadine product not detected electronically or if generic fexofenadine products cannot be administered due to allergy, intolerance, or contraindication. All strengths and dosage forms of the targets listed below are included in this program.

TARGET DRUGS

Allegra[®] (fexofenadine)

Clarinet[®] (desloratadine)

Xyzal[®] (levocetirizine)

Clarinet D 12 Hour (desloratadine /pseudoephedrine)

Clarinet D 24 Hour (desloratadine /pseudoephedrine)

Semprex-D[®] (acrivastine/pseudoephedrine)

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Brand Nonsedating Antihistamines will be approved when ANY ONE of the following is met:

1. The patient is currently receiving the requested brand agent
OR
2. The patient has tried and failed previously prescribed generic fexofenadine or the generic fexofenadine/pseudoephedrine combination
OR
3. The patient has an allergy, contraindication, or intolerance to generic fexofenadine or fexofenadine/pseudoephedrine combination

Length of Approval: 12 months.

Nonsedating Antihistamines Step Therapy

ELECTRONIC EDIT

For the nonsedating antihistamines step therapy edit, the 90-day search period was chosen to capture the most recent or current therapy for one preferred agent.

SUMMARY OF NONSEDATING ANTIHISTAMINES STEP THERAPY

Targeted Agent(s)	Allegra, Clarinex, Xyzal; Clarinex-D, Semprex-D
Is auto-grandfathering implemented? (with look-back time frame)	Y (90 days ^a)
Prerequisite Agent(s)	fexofenadine, fexofenadine/pseudoephedrine (as available)
Number of prerequisites required	1
Prerequisite look-back time frame	90 days ^a
Age-related edit?	Edit does not apply to children <6 years of age
Additional Comments	Any nonsedating antihistamine or nonsedating antihistamine combination product will auto-grandfather another product with the same nonsedating antihistamine

a - The system searches for a claim with a days supply that begins or ends in the past 90 days. For claims with a 30 day supply the system would be able to identify a claim processed for payment between 1 and 120 days prior to the new claim. For claims that are dispensed as an extended days supply (90 days), the system would identify a claim processed between 1 and 180 days.

DETAILS OF NONSEDATING ANTIHISTAMINES STEP THERAPY

Targeted Agents	GPIs (multisource code)	Prior Agents	GPIs (multisource code)	Look-back Time frames
ANY ONE of: Allegra, Clarinex, Xyzal; Clarinex-D, Semprex-D	415500***** 4399300203**** 4399300262**** (M, N, or O)	For Prerequisites, ANY ONE of: fexofenadine, fexofenadine/ pseudoephedrine	41550024***** 4399300268**** (Y)	90 days ^a
		For auto-grandfathering, ANY ONE of: Allegra, Clarinex, Xyzal; Clarinex-D, Semprex-D	415500***** 4399300203**** 4399300262**** (M, N, or O) Set up at a drug or GPI 10 level **single entity and combination with the same nonsedating antihistamine will auto-grandfather each other	90 days ^a

a - The system searches for a claim with a days supply that begins or ends in the past 90 days. For claims with a 30 day supply the system would be able to identify a claim processed for payment between 1 and 120 days prior to the new claim. For claims that are dispensed as an extended days supply (90 days), the system would identify a claim processed between 1 and 180 days.

PRIOR AUTHORIZATION CRITERIA QUESTION SET

Initial and Renewal Evaluation

1. Is the patient less than 6 years of age?
If yes, review is not applicable. If no, continue to 2.

2. Is the patient currently receiving therapy with the requested brand agent?
If yes, approve for 12 months. If no, continue to 3.

3. Has the patient tried and failed previously prescribed generic fexofenadine or generic fexofenadine/pseudoephedrine combination?
If yes, approve for 12 months. If no, continue to 4.

4. Does the patient have an allergy, contraindication, or intolerance to generic fexofenadine or fexofenadine/pseudoephedrine combination?
If yes, approve for 12 months. If no, deny.