Clinical Policy Title: **Desloratadine (Clarinex), Desloratadine/Pseudoephedrine (Clarinex-D)**

Policy Number: **RxA.72**

Drug(s) Applied: **desloratadine (Clarinex®) and desloratadine/ pseudoephedrine (Clarinex-D® 12 Hour)**

Last Review Date: **05/08/2020**

Line of Business: **Commercial**

Background

The following are H1-antagonists that are antihistamines aloneor in combination with a decongestant requiring prior authorization: desloratadine (Clarinex®) and desloratadine/ pseudoephedrine (Clarinex-D® 12 Hour).

Clarinex is indicated for the treatment of:

- Seasonal allergic rhinitis: relief of nasal and non-nasal symptoms in patients 2 years ofage and older
- Perennial allergic rhinitis: relief of nasal and non-nasal symptoms in patients 6 months ofage and older
- Chronic idiopathic urticaria: symptomatic relief of pruritus, reduction in the number ofhives, and size of hives in patients 6 months of age and older

Drug Name	Indication	Dosing Regimen	Maximum Dose
Desloratadine (Clarinex)	Seasonal and perennial allergic rhinitis and chronic idiopathic urticaria	≥ 12 years: 5 mg tab PO QD or 2 tsp oral solution PO QD 6-11 years: 2.5 mg tab or 1 tsp oral solution PO QD 1-5 years: ½ tsp oral solution PO QD 6-11 months: 2 mL oral solution PO QD	≥ 12 years: 5 mg/day 6-11 years: 2.5 mg/day 1-5 years: 1.25 mg/day 6-11 months: 1 mg/day
Desloratadine/ pseudoephedrine (Clarinex-D 12 Hour)	Seasonal allergic rhinitis	≥ 12 years: 1 tab PO BID	5 mg/day

Drug Name	Availability
Desloratadine (Clarinex)	Tablet: 5 mg Oral solution: 0.5 mg/1 ml (16oz)
Desloratadine/pseudoephedrine (Clarinex-D 12 Hour)	Tablet: 2.5 mg/120 mg

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Allergic Rhinitis, Chronic Idiopathic Urticaria (must meet all)**:**

1. Diagnosis of allergic rhinitis or chronic idiopathic urticaria;
2. Age is one of the following:
   a. Clarinex tablets/oral solution: ≥ 6 months;
   b. Clarinex-D 12 Hour: ≥ 12 years;
3. Failure of two oral antihistamines (e.g., cetirizine, loratadine, or fexofenadine) at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed:
   a. Clarinex: 5 mg per day;
   b. Clarinex-D 12 Hour: 5 mg-240 mg per day.

Approval duration:
Medicaid – 12 months
Commercial – Length of Benefit

II. Continued Therapy

A. Allergic Rhinitis, Chronic Idiopathic Urticaria (must meet all)**:**

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed:
   a. Clarinex: 5 mg per day
   b. Clarinex-D 12 Hour: 5 mg-240 mg per day.

Approval duration:
Medicaid – 12 months
Commercial – Length of Benefit

III. Appendices

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
cetirizine (Zyrtec®)	≥ 6 years: 5 mg to 10 mg QD 1-5 years: 2.5 to 5 mg QD	≥ 6 years: 10 mg/day 1-5 years: 5 mg/day
loratadine (Claritin®)	≥ 6 years: 10 mg QD 2-5 years: 5 mg QD	≥ 6 years: 10 mg/day 2-5 years: 5 mg/day
fexofenadine (Allegra®)	≥ 12 years: 60 mg BID or 180 mg QD 6-11 years: 30 mg BID	≥ 12 years: 180 mg/day 2-11 years: 60 mg/day 6 months to < 2 years: 30 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications / Boxed Warnings

Clarinex-D 12 Hour

- Contraindication(s):
  - Narrow-angle glaucoma
  - Urinary retention
  - Monoamine oxidase (MAO) inhibitor therapy or within 14 days of stopping such treatment
- Boxed Warning(s): none reported

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Review/Revision History	Review/Revised Date	P&T Approval Date
Policy was established	01/2020	02/07/2020
Updates: • Grammar • Specifics to dosage forms • Added "seasonal" allergic rhinitis to indications • References	05/08/2020	05/21/2020