Clinical Policy Title:	desloratadine and desloratadine/ pseudoephedrine
Policy Number:	RxA.72
Drug(s) Applied:	Clarinex®, Clarinex-D® 12 Hour
Original Policy Date:	02/07/2020
Last Review Date:	03/09/2021
Line of Business Policy Applies to:	All lines of business

Background

The following are H1-antagonists that are antihistamines alone or 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 of age and older
- Perennial allergic rhinitis: relief of nasal and non-nasal symptoms in patients 6 months of age and older
- Chronic idiopathic urticaria: symptomatic relief of pruritus, reduction in the number of hives, and size of hives in patients 6 months of age and older.

Clarinex-D® 12 Hour is indicated for the treatment of:

- Relief of nasal and non-nasal symptoms of seasonal allergic rhinitis, including nasal congestion, in adults and adolescents 12 years of age and older.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
desloratadine (Clarinex®)	Seasonal and perennial allergic rhinitis and chronic idiopathic urticaria	≥ 12 years: 5 mg tab PO once daily or 2 tsp oral solution PO once daily 6-11 years: 2.5 mg tab or 1 tsp oral solution PO once daily 12 months-5 years: ½ tsp oral solution PO once daily 6-11 months: 2 mL oral solution PO once daily	≥ 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

Dosage Forms

- desloratadine (Clarinex®) Tablet: 5 mg
- 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
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

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

1. Member is 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
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
MAO: Monoamine Oxidase

APPENDIX B: Therapeutic Alternatives

Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

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

- Contraindication(s):
  Clarinex®:
  - Hypersensitivity.

  Clarinex-D® 12 Hour:
  - Narrow-angle glaucoma
  - Hypersensitivity
  - Urinary retention
  - Severe hypertension or severe coronary artery disease
  - Monoamine oxidase (MAO) inhibitor therapy or within 14 days of stopping such treatment.

- Boxed Warning(s):
  - None reported.

APPENDIX D: General Information

- Desloratadine is a long-acting tricyclic histamine antagonist with selective H1-receptor histamine antagonist activity. Receptor binding data indicates that at a concentration of 2-3 ng/mL (7 nanomolar), desloratadine shows significant interaction with the human histamine H1-receptor. Desloratadine inhibited histamine release from human mast cells in vitro.
- Clarinex-D® 12 Hour ER tablet should be avoided in patients with renal and hepatic impairment.

References

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Review/Revision History	Review/Revision Date	P&T Approval Date

Policy established.	01/2020	02/07/2020
Updates: 1. Grammar 2. Specifics to dosage forms 3. Added “seasonal” allergic rhinitis to indications. 4. References	05/08/2020	05/20/2020
Policy was reviewed: 1. Clinical policy title was updated. 2. Line of Business Policy Applies to was updated to “All lines of business”. 3. Commercial approval duration was updated for initial and Continued approval criteria. 4. Continued therapy criteria II.A.1 was rephrased to “Member is currently receiving medication that has been authorized by RxAdvance…”. 5. Contraindications were updated. 6. Appendix D was updated. 7. References were reviewed and updated.	02/09/2021	03/09/2021