Clinical Policy Title:	desloratadine
Policy Number:	RxA.072
Drug(s) Applied:	Clarinex®
Original Policy Date:	02/07/2020
Last Review Date:	01/17/2022
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®)

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.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
desloratadine (Clarinex®)	Seasonal and perennial allergic rhinitis and chronic idiopathic urticaria	≥ 12 years: 5 mg tablet orally once daily ≤5 years: 1.25 mg once daily. 6-11 years: 2.5 mg tab once daily 6-11 months:1 mg once daily Hepatic Impairment Dosing: Adults- a starting dose of 5 mg orally every other day Renal Impairment Dosing: Adults- CrCl 50 mL/minute or less: 5 mg orally every other day	≥ 12 years: 5 mg/day ≤5 years: 1.25 mg/day 6-11 years: 2.5 mg/day 5 years: 1.25 mg/day 6-11 months: 1 mg/day

Dosage Forms

- desloratadine (Clarinex®) Tablet: 5 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. The provision of provider samples does not guarantee coverage under the

terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

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

1. Diagnosis of allergic rhinitis or chronic idiopathic urticaria;
2. Prescribed by or in consultation with an otolaryngologist or dermatologist;
3. Age is one of the following:
   a. Clarinex® tablets: ≥ 6 months;
4. 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;
5. Dose does not exceed 5 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 5 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.

Drug Name	Dosing Regimen	Maximum Dose
levocetirizine dihydrochloride (Xyzal®)	5 mg orally once daily in the evening	5 mg/day

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

APPENDIX C: Contraindications/Boxed Warnings

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

- Boxed Warning(s):
  - None reported.

*Contraindications listed reflect direct statements made in manufacturer's package insert; for additional uses, warnings, and precautions, please refer to clinical guidelines.

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.

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:	02/09/2021	03/09/2021

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.		
Policy was reviewed: 1. Clinical policy title updated to remove desloratadine/pseudoephedrine. 2. Drug(s) applied updated to remove Clarinex-D® 12 Hour as it does nor require prior authorization. 3. Background, Dosing information, Dosage forms, Clinical policy , Appendix C and Appendix D updated to remove information about Clarinex-D® 12 Hour as it does not require prior authorization. 4. Dosing Information, Updated: a. Dosing Regimen, Clarinex®: Updated dosing information to remove ,12 months-5 years: ½ tsp oral solution orally once daily 6-11 months: 2 mL oral solution once daily indication Seasonal and perennial allergic rhinitis and chronic idiopathic urticaria. b. Dosing Regimen, Clarinex®: Updated dosing information from 6-11 months: 2 mL oral solution orally once daily to 6-11 months: 2.5 mg once daily for indication Seasonal and perennial allergic rhinitis and chronic idiopathic urticaria. c. Dosing Regimen, Clarinex®: Updated to include hepatic impairment dosing information for indication Seasonal and perennial allergic rhinitis and chronic idiopathic urticaria. d. Dosing Information, Dosing Regimen, Clarinex®: Updated to include renal impairment dosing information for indication Seasonal and perennial allergic rhinitis and chronic idiopathic urticaria. 5. Statement about provider sample ‘‘The provision of provider samples does not	12/07/2021	01/17/2022

guarantee coverage…" was added to Clinical Policy. 6. Initial Approval Criteria, I.A.2: Updated to include new prescriber criteria Prescribed by or in consultation with an otolaryngologist or dermatologist. 7. Appendix B, Drug Name: Updated to include new therapeutic alternative levocetirizine dihydrochloride (Xyzal®). 8. Therapeutic Alternatives was rephrased to "Below are suggested therapeutic alternatives based on clinical guidance.". 9. Disclaimer about contraindications," Contraindications listed reflect statements made in the manufacturer's package insert.." was added to Appendix C. 10. References were reviewed and updated.		