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

Reference Number: CP.CPA.123
Effective Date: 08.01.18
Last Review Date: 08.23
Line of Business: Commercial

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

The following are antihistamines that contain a histamine-1 (H1) receptor antagonist requiring prior authorization: desloratadine (Clarinex®) and desloratadine/pseudoephedrine (Clarinex-D® 12 Hour). Clarinex-D 12 Hour also contains a decongestant.

FDA Approved Indication(s)

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

Policy/Criteria

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

It is the policy of health plans affiliated with Centene Corporation® that Clarinex and Clarinex-D 12 Hour are **medically necessary** when the following criteria are met:

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

Approval duration: 12 months or duration of request, whichever is less

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial; or
   b. For drugs NOT on the formulary (commercial), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial.

II. Continued Therapy

A. Allergic Rhinitis, Chronic Idiopathic Urticaria (must meet all)**:**
1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed one of the following (a or b):
   a. Clarinex: 5 mg per day;
   b. Clarinex-D 12 Hour: 5 mg/240 mg per day.

Approval duration: 12 months or duration of request, whichever is less

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial; or
   b. For drugs NOT on the formulary (commercial), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial or evidence of coverage documents.

IV. Appendices/General Information

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 PO QD 1-5 years: 2.5 to 5 mg PO QD 6 months to < 1 year: 2.5 mg PO QD	≥ 6 years: 10 mg/day 1-5 years: 5 mg/day 6 months to < 1 year: 2.5 mg/day
loratadine (Claritin®)	≥ 6 years: 10 mg PO QD 2-5 years: 5 mg PO QD	≥ 6 years: 10 mg/day 2-5 years: 5 mg/day
fexofenadine (Allegra®)	≥ 12 years: 60 mg PO BID or 180 mg PO QD 2-11 years: 30 mg PO BID 6-months to 2 years: 15 mg PO 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

- Contraindication(s):
  - Hypersensitivity
  - Clarinex-D 12 Hour only: narrow-angle glaucoma, urinary retention, monoamine oxidase (MAO) inhibitor therapy or within 14 days of stopping such treatment, severe hypertension or severe coronary artery disease
- Boxed warning(s): none reported

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Desloratadine (Clarinex)	Allergic rhinitis, chronic idiopathic urticaria	≥ 12 years: 5 mg tab PO QD or 2 tsp PO QD 6-11 years: 2.5 mg or 1 tsp PO QD 1-5 years: ½ tsp PO QD 6-11 months: 2 mL 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	Allergic rhinitis	≥ 12 years: 1 tablet PO BID	5 mg/day

Drug Name	Indication	Dosing Regimen	Maximum Dose
(Clarinex-D 12 Hour)			

VI. Product Availability

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

**Although the oral solution and the orally disintegrating tablet formulation of desloratadine may be available in the marketplace, branded versions of Clarinex oral solution and Clarinex RediTabs tablets are no longer marketed.*

VII. References

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4. Clarinex-D 12 Hour Prescribing Information. Whitehouse Station, NJ: Merck & Co., Inc.; June 2021. Available at: https://www.merck.com/product/usa/pi_circulars/c/clarinex_d_12/clarinex_d_12_pi.pdf. Accessed April 18, 2023.
5. Dykewicz et al. Diagnosis and management of rhinitis: Complete guidelines of the Joint Task Force on Practice Parameters in allergy, asthma and immunology. Ann Allergy Asthma Immunol 1998;81:478-518.Allergic rhinitis and its impact on asthma. J Allergy Clin Immunol 2001 Nov;108(5):S147-334.
6. Institute for Clinical Systems Improvement (ICSI). Rhinitis. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2003.
7. Clarinex. American Hospital Formulary Service Drug Information. AHFS Web site. Available at: http://www.medicinescomplete.com/mc/ahfs/current/. Accessed April 6, 2020.
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9. Dykewicz MS, Wallace DV, Amrol DJ, et al. Rhinitis 2020: A practice parameter update. J Allergy Clin Immunol. 2020; 136(4): 721-767.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q 2019 annual review: no significant changes; organized contraindications to reflect association to pseudoephedrine; references reviewed and updated.	05.31.19	08.19
3Q 2020 annual review: no significant changes; removed all references to Medicaid; references reviewed and updated.	04.06.20	08.20

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q 2021 annual review: no significant changes; references reviewed and updated.	03.22.21	08.21
Revised approval duration for Commercial line of business from length of benefit to 12 months or duration of request, whichever is less	09.27.21	02.22
3Q 2022 annual review: no significant changes; references reviewed and updated.	03.24.22	08.22
Template changes applied to other diagnoses/indications and continued therapy section.	09.22.22	
3Q 2023 annual review: no significant changes; references reviewed and updated.	04.18.23	08.23

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise

professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.