Clinical Policy: Levocetirizine Oral Solution (Xyzal)

Reference Number: CP.CPA.08
Effective Date: 08.01.18
Last Review Date: 08.24
Line of Business: Commercial

Revision Log

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

Description

Levocetirizine oral solution (Xyzal®) is a histamine-1 (H1) receptor antagonist.

FDA Approved Indication(s)

Xyzal is indicated in adults and children 6 months of age and older for the treatment of:

- Relief of symptoms associated with seasonal and perennial allergic rhinitis.
- Uncomplicated skin manifestations of chronic idiopathic urticaria.

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 levocetirizine and Xyzal 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 ≥ 6 months;
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 5 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 5 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
H1: histamine-1

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 years: 10 mg/day 1-5 years: 5 mg/day 6 months to < 1 year: 2.5 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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 6-11 years: 30 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):
  - Known hypersensitivity to levocetirizine or any of the ingredients of Xyzal, or to cetirizine
  - Children 6 months to 11 years of age with impaired renal function
  - End-stage renal disease at less than 10 mL/min creatinine clearance or patients undergoing hemodialysis
- Boxed warning(s): none reported

V. Dosage and Administration

Drug Name	Dosing Regimen	Maximum Dose
Levocetirizine (Xyzal)	≥ 12 years: 5 mg PO QD 6-11 years: 2.5 mg PO QD 6 months-5 years: 1.25 mg PO QD	≥ 12 years: 5 mg/day 6-11 years: 2.5 mg/day 6 months-5 years: 1.25 mg/day

VI. Product Availability

Oral solution: 2.5 mg/5 mL (0.5 mg/mL)

VII. References

1. Xyzal Prescribing Information. Bridgewater, NJ: Sanofi-Aventis U.S. LLC; April 2019. Available at https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=a6ca9f62-c065-4eda-bf95-97165cdd5fec. Accessed May 7, 2024.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2024. Available at: http://www.clinicalpharmacology-ip.com. Accessed May 9, 2024.
3. Wallace DV, Dykewicz MS, Bernstein DI, et al. The diagnosis and management of rhinitis: an updated practice parameter. J Allegy Clin Immunol. 2008. 122(2 Suppl): S1-S84.
4. Wallace DV, Dykewicz MS, Oppenheimer J et al. Pharmacologic treatment of seasonal allergic rhinitis: synopsis of guidance from the 2017 Joint Task Force on Practice Parameters. Ann Intern Med. 2017 Dec 19;167(12):876-881. doi: 10.7326/M17-2203.
5. Dykewicz MS, Wallace DV, Baroody F, et al. Treatment of seasonal allergic rhinitis: An evidence-based focused 2017 guideline update. Ann Allergy Immunol. 2017; 119: 489-511.
6. 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 2020 annual review: no significant changes; references reviewed and updated.	04.06.20	08.20
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; revised policy name to include "oral solution" as only this formulation requires PA; references reviewed and updated.	04.18.23	08.23
3Q 2024 annual review: no significant changes; revised policy/ criteria section to also include generic levocetirizine; references reviewed and updated.	05.09.24	08.24

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.