RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	levocetirizine
Policy Number:	RxA.404
Drug(s) Applied:	Xyzal®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of business

Background

Levocetirizine (Xyzal®) is a histamine H1-receptor antagonist.
Xyzal is indicated in adults and children 6 months of age and older for the treatment of:

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

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
levocetirizine (Xyzal®)	Relief of symptoms associated with seasonal and perennial allergic rhinitis. Uncomplicated skin manifestations of chronic idiopathic urticaria	≥ 12 years: 5 mg PO once daily 6-11 years: 2.5 mg PO once daily 6 months-5 years: 1.25 mg PO once daily	≥ 12 years: 5 mg/day 6-11 years: 2.5 mg/day 6 months-5 years: 1.25 mg/day

Dosage Forms

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

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 ≥ 6 months;

3. Failure of two oral antihistamines (e.g., cetirizine, loratadine, fexofenadine) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
4. 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. 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

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	Maximum Dose
cetirizine (Zyrtec®)	≥ 6 years: 5 mg to 10 mg once daily 1-5 years: 2.5 to 5 mg once daily	≥ 6 years: 10 mg/day 1-5 years: 5 mg/day 6 months and older: 2.5 mg/day
loratadine (Claritin®)	≥ 6 years: 10 mg once daily 2-5 years: 5 mg once daily	≥ 6 years: 10 mg/day 2-5 years: 5 mg/day
fexofenadine (Allegra®)	≥ 12 years: 60 mg BID or 180 mg once daily 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

- 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

APPENDIX D: General Information

- Not Applicable

References

1. Xyzal Prescribing Information. Bridgewater, NJ: Sanofi-Aventis U.S. LLC; April 2019. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/022064s038,022157s020lbl.pdf. Accessed July 15, 2020.
2. Xyzal Allergy 24HR Prescribing Information. Chattanooga, TN: Chattem, Inc.; March 2017. Available at https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=8be45c2a-1eca- 4a00-81b9-f7babdbdcd41. Accessed July 15, 2020.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2019. Available at: http://www.clinicalpharmacology-ip.com. Accessed July 15, 2020.
4. 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.
5. 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

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established	01/2020	03/06/2020
Policy was reviewed: 1. Policy title table was updated. 2. Dosing information was updated to include specific dosing regimen. 3. Continued therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by RxAdvance…”. 4. Approval duration was updated in initial as well as in continued therapy to include commercial as well as Medicaid plan. 5. QD was updated to "once daily" in document. 6. References were updated.	07/15/2020	09/14/2020