Clinical Policy: Respiratory Agents: Antihistamines – Second Generation

Reference Number: OH.PHAR.PPA.80
Effective Date: 01/01/2020
Last Review Date: 01/2022
Line of Business: Medicaid

Coding Implications
Revision Log

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

Description:

RESPIRATORY AGENTS: ANTIHISTAMINES: SECOND GENERATION

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
CETIRIZINE syrup (generic of Zyrtec®) CETIRIZINE tablets (generic of Zyrtec®) LORATADINE rapid dissolve (generic of Claritin® RediTabs) LORATADINE syrup (generic of Claritin® Syrup) LORATADINE tablets (generic of Claritin®)	CETIRIZINE chewable (generic of Zyrtec®) DESLORATADINE ODT (generic of Clarinex®) DESLORATADINE tablets (generic of Clarinex®) FEXOFENADINE tablets, suspension (generic of Allegra®) LEVOCETIRIZINE (generic of Xyzal®)

RESPIRATORY AGENTS: ANTIHISTAMINE/DECONGESTANT COMBO: SECOND GENERATION

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
CETIRIZINE/PSEUDOEPHEDRINE (generic of Zyrtec- D®) LORATADINE/PSEUDOEPHEDRINE (generic of Claritin-D®)	CLARINEX-D 12, 24 HOUR® (desloratadine/ pseudoephedrine)

FDA Approved Indication(s):
Second Generation Antihistamines and Second Generation Antihistamine/Decongestant Combinations are indicated for the treatment of:

- allergic rhinitis
- chronic idiopathic urticaria
- nasal congestion
- perennial allergies
- pruritus
- seasonal allergies

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 Buckeye Health Plan, an affiliate of Centene Corporation®, that Zyrtec Chewable Tablets, Clarinex, Allegra, Xyzal, and Clarinex-D are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. PA Required Agents (must meet all)**:**

1. FDA-approved or supported by standard pharmacopeias;
2. Age ≥ 6 months for Cetirizine, Levocetirizine, and Desloratadine;
3. Age ≥ 2 years for Loratadine;
4. Age ≥ 6 years for Fexofenadine;
5. Age ≥ 12 years for Zyrtec-D, Claritin-D, Allegra-D, and Clarinex-D;
6. Documentation that there have been therapeutic failures after courses of treatment (e.g., 30 days for allergic rhinitis) with a medication not requiring prior approval UNLESS there is a reason the member cannot be changed to a preferred medication. Acceptable reasons include:
   - Allergies to all medications not requiring prior approval.
   - Contraindication to or drug-to-drug interaction with medications not requiring prior approval.
   - History of unacceptable/toxic side effects to meds not requiring prior approval.

Approval duration: 12 months.

B. Other diagnoses/indications:

1. There are no pharmacy and therapeutic committee approved off-label use criteria for the diagnosis;
2. Use is supported by one of the following (a, b, or c):
   a. The National Comprehensive Cancer Network (NCCN) Drug Information and Biologics Compendium level of evidence 1 or 2A;
   b. Evidence from at least two high-quality, published studies in reputable peer-reviewed journals or evidence-based clinical practice guidelines that provide all of the following (i – iv):
      i. Adequate representation of the member's clinical characteristics, age, and diagnosis;
      ii. Adequate representation of the prescribed drug regimen;
      iii. Clinically meaningful outcomes as a result of the drug therapy in question;
      iv. Appropriate experimental design and method to address research questions;
   c. Micromedex DrugDex® with strength of recommendation Class I, IIa, or IIb;
3. Prescribed by or in consultation with an appropriate specialist for the diagnosis;
4. Failure of an adequate trial of at least two FDA-approved drugs for the indication and/or drugs that are considered the standard of care, when such agents exist for the same indication at maximum indicated doses, unless no such drugs exist, at maximum indicated doses, unless contraindicated or clinically significant adverse effect are experienced;
5. Dosing regimen and duration are within dosing guidelines recommended by clinical practice guidelines and/or medical literature.

Approval duration: 12 months.

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

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.PMN.53 for Medicaid or evidence of coverage documents.

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
ER: Extended Release
FDA: Food and Drug Administration
ODT: Orally disintegrating tablet
PA: Prior Authorization

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 syrup (generic of Zyrtec®)	5 to 10 mg once daily, depending on severity of symptoms	10mg/day
Cetirizine tablets (generic of Zyrtec®)	5 to 10 mg once daily, depending on severity of symptoms	10mg/day
LORATADINE rapid dissolve (generic of Claritin® RediTabs)	10 mg once daily	10mg/day
LORATADINE syrup (generic of Claritin® Syrup)	10 mg once daily	10mg/day
LORATADINE tablets (generic of Claritin®)	10 mg once daily	10mg/day
Cetirizine/Pseudoephedrine (generic of Zyrtec- D®)	1 tablet up to twice a day as needed	10 mg/day cetirizine; 240 mg/day pseudoephedrine
LORATADINE-D (generic of Claritin-D®)	12-Hour: 1 tablet every 12 hours as needed	10 mg/day loratadine; 240 mg/day pseudoephedrine
LORATADINE-D (generic of Claritin-D®)	24-Hour: 1 tablet once daily	10 mg/day loratadine; 240 mg/day pseudoephedrine

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):
  - Acute Myocardial Infarction
  - Angina
  - Closed-Angle Glaucoma
  - Coronary Artery Disease
  - Dialysis
  - Hydroxyzine Hypersensitivity

- Hypertension
- MAOI Therapy
- Neonates
- Renal failure
- Renal impairment
- Urinary Retention

IV. Dosage and Administration

- Varies by drug product. See FDA approved dosing and administration AND Appendix B.

V. Product Availability

Drug Name	Availability
Allegra	Orally disintegrating tablets: 30 mg
Cetirizine	Capsules: 10 mg
Cetirizine	Chewable tablets: 5 mg, 10 mg
Cetirizine	Oral solution: 1 mg/mL
Cetirizine	Orally disintegrating tablets: 10 mg
Cetirizine	Tablets: 5 mg, 10 mg
Desloratadine	Orally disintegrating tablets: 2.5 mg, 5 mg
Desloratadine	Tablets: 5 mg
Fexofenadine	Oral suspension: 30 mg/5 mL
Fexofenadine	Tablets: 30 mg, 60 mg, 180 mg
Levocetirizine	Oral solution: 2.5 mg/5 mL
Levocetirizine	Tablets: 5 mg
Loratadine	Capsules: 10 mg
Loratadine	Chewable tablets: 5 mg
Loratadine	Oral solution: 5 mg/5 mL
Loratadine	Orally disintegrating tablets: 5 mg, 10 mg
Loratadine	Tablets: 10 mg
Cetirizine/Pseudoephedrine	Tablets: 5 mg-120 mg
Clarinex-D	Tablets: 2.5 mg-120 mg
Fexofenadine/Pseudoephedrine	Tablets: 60 mg-120 mg; 180 mg-240 mg
Loratadine/Pseudoephedrine	Tablets: 5 mg-120 mg; 10 mg-240 mg

VI. References

- Cetirizine Clinical Pharmacology. Elsevier. Tampa, FL. Available at https://www.clinicalpharmacology-ip.com. Accessed November 11, 2019.
- Desloratadine. Clinical Pharmacology. Elsevier. Tampa, FL. Available at https://www.clinicalpharmacology-ip.com. Accessed November 11, 2019.
- Fexofenadine. Clinical Pharmacology. Elsevier. Tampa, FL. Available at https://www.clinicalpharmacology-ip.com. Accessed November 11, 2019.
- Levocetirizine. Clinical Pharmacology. Elsevier. Tampa, FL. Available at https://www.clinicalpharmacology-ip.com. Accessed November 11, 2019.

- Loratadine. Clinical Pharmacology. Elsevier. Tampa, FL. Available at https://www.clinicalpharmacology-ip.com. Accessed November 11, 2019.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New policy created.	10.19	N/A
Annual review. Removed Clarinex Syrup from list of available medications since it is no longer on the market. Removed Claritin RediTabs from non-preferred list since Claritin RediTabs was listed under both preferred and non-preferred list (preferred med).	10.21	N/A
ODM Q4 P&T update. Removed age restriction from Cetirizine Syrup. Added Cetirizine Chewable to list of non-preferred medications.	01.22	N/A

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.

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Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.