Clinical Policy: Levofloxacin in Pediatric Community Acquired Pneumonia

Reference Number: GA.PMN.05
Effective Date: 03/01/16
Last Review Date: 1/2024
Line of Business: Medicaid

Revision Log

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

Description

The intent of the criteria is to ensure that patients follow selection elements established by Centene® medical policy for the use of Levofloxacin (Levaquin®) in pediatric patients older than 3 months of age for community acquired pneumonia.

FDA Approved Indication(s)

Levaquin is indicated for the treatment of:

- Pneumonia: nosocomial and community acquired
- Acute bacterial sinusitis
- Acute bacterial exacerbation of chronic bronchitis
- Skin and skin structure infections: complicated and uncomplicated
- Chronic bacterial prostatitis
- Urinary tract infections: complicated and uncomplicated
- Acute pyelonephritis

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 Levaquin is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Community Acquired Pneumonia (must meet all)**:**

1. Diagnosis of community acquired pneumonia;
2. Prescribed by or in consultation with a physician;
3. Member meets one of the following (a or b):
   a. Documentation of Georgia Registry of Immunization Transactions and Services (GRITS) status if not fully immunized to *H. Influenzae* and/or *S. Pneumoniae*;
   b. Member is in a community with a high rate of pneumococcal resistance to penicillin
4. If *Typical Bacteria*, then failure of ≥ 5 days trial of Amoxicillin or Amoxicillin/Clavulanate unless contraindicated or clinically significant adverse effects are experienced;
5. If *Atypical Bacteria* (i.e., *M. Pneumonia, C. Pneumonia*), then trial and failure of a Macrolide antibiotic (Erythromycin or Clarithromycin for ≥5 days, Azithromycin for

5 days) or doxycycline for ≥5days unless contraindicated or clinically significant adverse effects are experienced;

6. Levofloxacin dose does not exceed:
   a. Age 6 months to 5 years old: 16-20 mg/kg/day divided in 2 doses. Max: 750mg/day;
   b. Age 5-16 years old: 8-10 mg/kg/day once daily. Max: 750mg/day.

Approval duration: up to 10 days

B. Other diagnoses/indications:
Not applicable

II. Continued Therapy

A. Community Acquired Pneumonia

1. Authorization for additional days must be reviewed by the plan on a case by case basis.

Approval duration: Not applicable

B. Other diagnoses/indications:
Not applicable

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

Not applicable

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
GRITS: Georgia Registry of Immunization Transactions and Services

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
Amoxicillin (Amoxil®)	Lower respiratory tract 45 mg/kg/day in divided doses every 12 hours or 40 mg/kg/day in divided doses every 8 hours	90 mg/kg/day
Amoxicillin/ Clavulanate potassium (Augmentin®)	Lower respiratory tract 45 mg/kg/day in divided doses every 12 hours or 40 mg/kg/day in divided doses every 8 hours	90 mg/kg/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: General Information

Pneumonia is a lower respiratory tract infection. It is the single greatest cause of death in children worldwide. Community Acquired Pneumonia (CAP) in children is defined as the presence of signs and symptoms in a previously healthy child caused by an infection that has been acquired outside of the hospital. Viruses and bacteria can be responsible for CAP in children. Before the widespread use of *H. Influenzae* and *S. Pneumoniae* vaccines, *S. Pneumoniae* was documented as the most common bacterial pathogen. Usual atypical pathogens include *M. pneumoniae* commonly in older children and C. pneumonia in infants. Since viral pathogens are common in pre-school aged children with CAP, antimicrobial therapy is not usually warranted for this population. High-dose Amoxicillin (90mg/kg/day) or Augmentin is recommended as first-line treatment for pre-school and school aged children and adolescents who are previously healthy and appropriately immunized with mild to moderate CAP since it provides coverage for *S. Pneumoniae*. When atypical pathogens are suspected then macrolides or doxycycline can be tried or added to penicillin therapy. In penicillin allergic patients' clindamycin, levofloxacin, linezolid, or macrolides (resistance may be high) may be appropriate. For mild allergic reactions, then another trial of amoxicillin or a cephalosporin (i.e., Cefpodoxime, Cefprozil, cefuroxime) with activity against S. Pneumonia under medical supervision might be beneficial. No oral cephalosporin at doses studied in children provides activity at the site of infection that equals high-dose amoxicillin. Second and third generation cephalosporins generally only provide activity against 60%-70% of current isolates of pneumococcus. Alternatively clindamycin provides activity against 60%-85% pneumococcal strains and Levofloxacin and Linezolid provide activity against >95% of strains. Careful selection with patient variability and infection characteristics is prudent

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Community acquired pneumonia	• Age 6 months to 5 years old: 16-20 mg/kg/day divided in 2 doses • Age 5-16 years old: 8-10 mg/kg/day once daily	750 mg/day

VI. Product Availability

Tablets: 250mg, 500mg, 750mg
Oral Solution: 25 mg/ml

VII. References

1. Bradley et al. The Management of Community-Acquired Pneumonia in Infants and Children Older than 3 months of Age: Clinical Practice Guidelines by the Pediatric Infectious Diseases Society and the Infectious Diseases Society of America. *Clin Infect Dis 2011*
2. McIntosh K. Community-acquired pneumonia in children. N Engl J Med 2002; 346:429.
3. American Academy of Pediatrics. Tables of antibacterial drug dosages. In: Red Book: 2018 Report of the Committee on Infectious Diseases, 31st ed, Kimberlin DW, Brady MT, Jackson MA, Long SS (Eds), American Academy of Pediatrics, Itasca, IL 2018. p.914.

4. Barson WJ. (2022) Community-acquired pneumonia in children: Outpatient treatment. *UpToDate*. Retrieved January 9, 2023, from https://www.uptodate.com/contents/community-acquired-pneumonia-in-children-outpatient-treatment

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	03.01.16	03.16
1Q 2017 annual review: no significant changes	01.01.17	01.17
1Q 2018 annual review: no significant changes	01.01/18	01.18
Changed current Georgia policy templates to corporate standard templates for drug coverage criteria to meet corporate compliance. Changes/revisions included; new formatting, font size, use of standard policy language for each section of policy, and rearranged order of certain steps in criteria and sections.	2/21/19	2/2019
Annual review. Added "high risk pneumococcal resistance" as approval criteria for levofloxacin use. Added separate approval criteria for antibiotic treatment failures based on "typical" vs "atypical" bacteria. Updated references.	1/2020	1/2020
Annual review. Formatting changes made to initial criteria	1/2021	1/2021
1Q 2022 annual review. No changes made. References reviewed and updated.	1/2022	1/2022
1Q 2023 annual review. Changed required duration of therapy from 7-10 days to ≥5 days for trial and failure treatments of amoxicillin, amoxicillin/clavulanate, erythromycin, and clarithromycin for initial approval criteria. References reviewed and updated.	1/2023	1/2023
1Q 2024 annual review.	1/2024	1/2024

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.

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.