Clinical Policy: Long-term Antibiotic Treatment for Tick-borne Diseases

Reference Number: CP.PMN.279
Effective Date: 06.01.22
Last Review Date: 08.23
Line of Business: Medicaid – Illinois, HIM – Illinois Revision Log

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

Description

This policy applies to antibiotic therapy that requires prior authorization or has quantity limits on the formulary.

Long-term antibiotic therapy describes the administration of oral, intramuscular, or intravenous antibiotics singly or in combination for periods of time in excess of 4 weeks. Examples of drugs for this purpose are, but are not limited to, doxycycline, cefuroxime axetil, and amoxicillin.

Tick-borne disease is a disease caused when an infected tick bites a person, and the tick's saliva transmits an infectious agent (bacteria, viruses, or parasites) that can cause illness, including, but not limited to, the following:

1) a severe infection with borrelia burgdorferi;
2) a late stage, persistent, or chronic infection or complications related to such an infection;
3) an infection with other strains of borrelia or a tick-borne disease that is recognized by the United States Centers for Disease Control and Prevention; and
4) the presence of signs or symptoms compatible with acute infection of borrelia or other tick-borne diseases.

FDA Approved Indication(s)

Varies by agent. Refer to the individual prescribing information.

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 long-term antibiotic treatment for tick-borne diseases may be **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Tick-borne Disease (must meet all)**:**

1. Diagnosis of a tick-borne disease (*see Appendix D*);
2. If request is for a branded agent, member must use the generic formulation, when available, unless contraindicated or clinically significant adverse effects are experienced;
3. If request is for a non-formulary agent, member must use a formulary agent within the same therapeutic class that is recognized as standard of care for the treatment of

the relevant diagnosis, unless contraindicated, clinically significant adverse effects are experienced, or no such agent exists;
4. Request meets one of the following (a or b):
   a. New dose does not exceed FDA-approved maximum dose;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 3 months or duration of request, whichever is less

II. Continued Therapy

A. Tick-borne Disease (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 continues to have signs or symptoms consistent with a tick-borne disease;
3. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed FDA-approved maximum dose;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months or duration of request, whichever is less

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 – HIM.PA.154 for health insurance marketplace and CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings
Varies. Refer to individual prescribing information.

Appendix D: Examples of Tick-borne Diseases

- Anaplasmosis
- Babesiosis
- Borrelia Miyamotoi disease
- Colorado tick fever
- Ehrlichiosis
- Heartland and bourbon virus diseases

- Lyme disease
- Powassan virus disease
- Rocky Mountain spotted fever
- *Rickettsia Parkeri* rickettsiosis
- Tickborne relapsing fever
- Tularemia

V. Dosage and Administration

Varies. Refer to individual prescribing information.

VI. Product Availability

Varies. Refer to individual prescribing information.

VII. References

1. Centers for Disease Control and Prevention, National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Vector-Borne Diseases (DVBD). Tickborne Diseases of the United States. U.S. Department of Health & Human Services. Page last reviewed: august 5, 2022. Available at: https://www.cdc.gov/ticks/tickbornediseases/index.html. Accessed May 30, 2023.
2. Cameron DJ, Johnson LB, and Maloney EL. Evidence assessments and guideline recommendations in Lyme disease: the clinical management of known tick bites, erythema migrans rashes and persistent disease. Expert Review of Anti-infective Therapy. 2014; 12(9):1103-1135. DOI: 10.1586/14787210.2014.940900.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	04.25.22	05.22 (ad hoc)
Template changes applied to continued therapy section.	10.07.22	
3Q 2023 annual review: no significant changes; references reviewed and updated.	05.30.23	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.

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.