



Drug Coverage Policy

Effective Date.....4/1/2024

Coverage Policy Number IP0352

LymePak

- LymePak™ (doxycycline hyclate tablets)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer’s particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer’s benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer’s benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Medical Necessity Criteria

LymePak is considered medically necessary when the following criteria is/are met:

1. **Early Lyme Disease as evidenced by erythema migrans due to *Borrelia burgdorferi*.** Individual meets **BOTH** of the following criteria:
 - A. Age 8 years and older
 - B. Weight 45 kg (99 lb) and above
 - C. Preferred product criteria are met for the products listed in the below table(s)

Employer Plans:

Product	Criteria
LymePak (doxycycline hyclate tablets)	Documentation of an inability to obtain BOTH doxycycline hyclate capsules <u>and</u> tablets (not supplied as a dose pack).

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Reauthorization Criteria

Not applicable for continuation beyond initial approval duration.

Authorization Duration

Initial approval duration: once cycle of therapy
 Reauthorization approval duration: not applicable

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven.

Background

OVERVIEW

Doxycycline is a broad-spectrum oral antibiotic agent available generically in the hyclate salt as capsules, tablets, delayed-release tablets, and injection.

Lyme disease is an infection caused by *Borrelia burgdorferi* from the bite of *Ixodes* ticks. Clinical trials support the use of doxycycline to prevent Lyme disease when given within 72 hours of a tick bite.¹⁻² Clinical practice guidelines published by the Infectious Diseases Society of America (IDSA), American Academy of Neurology (AAN), and American College of Rheumatology (ACR) also support the use of doxycycline for prevention of Lyme disease and recommend it for this use.³

There are some doxycycline products with unique indications. LymePak is indicated for the treatment of early Lyme disease (as evidenced by erythema migrans) due to *Borrelia burgdorferi* in adults and pediatric individuals 8 years of age and older weighing 45 kg and above.⁴

References

1. Nadelman RB, Nowakowski J, Fish D, et al; Tick Bite Study Group. Prophylaxis with single-dose doxycycline for the prevention of Lyme disease after an *Ixodes scapularis* tick bite. *N Engl J Med*. 2001;345(2):79-84.
2. Stupica D, Lusa L, Ruzić-Sabljić E, Cerar T, Strle F. Treatment of erythema migrans with doxycycline for 10 days versus 15 days. *Clin Infect Dis*. 2012;55(3):343-350.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	No criteria change.	4/1/2024

The policy effective date is in force until updated or retired.

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