

Quantity Limit; Post Limit Prior Authorization Tetracycline Capsules

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form
tetracycline (all brands)	tetracycline	capsules

Indications

FDA-Approved Indications

To reduce the development of drug-resistant bacteria and maintain the effectiveness of tetracycline hydrochloride and other antibacterial drugs, tetracycline hydrochloride should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

Tetracycline is indicated in the treatment of infections caused by susceptible strains of the designated organisms in the conditions listed below:

- Upper respiratory tract infections caused by *Streptococcus pyogenes*, *Streptococcus pneumoniae* and *Hemophilus influenzae*. Note: Tetracycline should not be used for streptococcal disease unless the organism has been demonstrated to be susceptible.

- Lower respiratory tract infections caused by *Streptococcus pyogenes*, *Streptococcus pneumoniae*, *Mycoplasma pneumoniae* (Eaton agent, and *Klebsiella* sp.)
- Skin and soft tissue infections caused by *Streptococcus pyogenes*, *Staphylococcus aureus*. (Tetracyclines are not the drugs of choice in the treatment of any type of staphylococcal infections.)
- Infections caused by rickettsia including Rocky Mountain spotted fever, typhus group infections, Q fever, rickettsialpox.
- Psittacosis caused by *Chlamydophila psittaci*.
- Infections caused by *Chlamydia trachomatis* such as uncomplicated urethral, endocervical or rectal infections, inclusion conjunctivitis, trachoma, and lymphogranuloma venereum.
- Granuloma inguinale caused by *Klebsiella granulomatis*.
- Relapsing fever caused by *Borrelia* sp.
- Bartonellosis caused by *Bartonella bacilliformis*.
- Chancroid caused by *Hemophilus ducreyi*.
- Tularemia caused by *Francisella tularensis*.
- Plague caused by *Yersinia pestis*.
- Cholera caused by *Vibrio cholerae*.
- Brucellosis caused by *Brucella* species (tetracycline may be used in conjunction with an aminoglycoside).
- Infections due to *Campylobacter fetus*.
- As adjunctive therapy in intestinal amebiasis caused by *Entamoeba histolytica*.
- Urinary tract infections caused by susceptible strains of *Escherichia coli*, *Klebsiella*, etc.
- Other infections caused by susceptible gram-negative organisms such as *E. coli*, *Enterobacter aerogenes*, *Shigella* sp., *Acinetobacter* sp., *Klebsiella* sp., and *Bacteroides* sp.
- In severe acne, adjunctive therapy with tetracycline may be useful.

When penicillin is contraindicated, tetracyclines are alternative drugs in the treatment of the following infections:

- Syphilis and yaws caused by *Treponema pallidum* and *pertenue*, respectively,
- Vincent's infection caused by *Fusobacterium fusiforme*,
- Infections caused by *Neisseria gonorrhoeae*,
- Anthrax caused by *Bacillus anthracis*,
- Infections due to *Listeria monocytogenes*,
- Actinomycosis caused by *Actinomyces* species,
- Infections due to *Clostridium* species.

Compendial Uses:

Melioidosis caused by *Burkholderia pseudomallei*³

Balantidiasis caused by *Balantidium coli*²

Dientamoeba fragilis Infections²

Diverticulitis³

Necrotizing ulcerative gingivitis, acute³

Leptospirosis²

Lyme Disease²

Malaria^{2,3}

Pinta²

Rosacea³

Initial Quantity Limit

Limit Criteria

Limits do not accumulate together; patient is allowed the maximum limit for each drug and strength

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

If the patient is requesting more than the initial quantity limit, the claim will reject with a message indicating that a prior authorization is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

Drug	1 Month Limit	3 Month Limit
Tetracycline Capsules	120 caps / 25 days	360 caps / 75 days

Coverage Criteria

Melioidosis

Authorization may be granted when the requested drug is being prescribed for the treatment of melioidosis caused by *Burkholderia pseudomallei* when the following criteria is met:

- The requested drug is NOT being used in a footbath

Plague Caused by *Yersinia Pestis*

Authorization may be granted when the requested drug is being prescribed for the treatment of Plague caused by *Yersinia pestis* when the following criteria is met:

- The requested drug is NOT being used in a footbath

Quantity Limits Apply

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Plague caused by *Yersinia pestis*

Drug	1 Month Limit	3 Month Limit
Tetracycline Capsules	240 capsules / 25 days	720 capsules / 75 days

Melioidosis caused by *Burkholderia pseudomallei*

Drug	1 Month Limit	3 Month Limit
Tetracycline Capsules	180 capsules / 25 days	540 capsules / 75 days

Duration of Approval (DOA)

- 4326-HJ:
 - Plague caused by *Yersinia pestis*: DOA: 3 months
 - Melioidosis caused by *Burkholderia pseudomallei*: DOA: 6 months

References

1. Tetracycline Capsules [package insert]. Congers, NY: Chartwell Pharmaceuticals, LLC.; February 2021.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2025. <https://online.lexi.com>. Accessed January 27, 2025.
3. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 01/27/2025).
4. Centers for Disease Control and Prevention – Melioidosis. Available at: <https://www.cdc.gov/melioidosis/hcp/clinical-overview/>. Accessed February 19, 2025.
5. Centers for Disease Control and Prevention – Plague. Available at: <https://www.cdc.gov/plague/hcp/clinical-care/>. Accessed February 19, 2025.