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5.01.015

Section:	Prescription Drugs	**Effective Date:**	July 1, 2024
Subsection:	Anti-Infective Agents	**Original Policy Date:**	December 7, 2011
Subject:	Injectable Antibiotics	**Page:**	1 of 5

Last Review Date: June 13, 2024

Injectable Antibiotics

Description

IV Antibiotics include: Ceftriaxone, Cefotaxime sodium, Colistimethate, Daptomycin, Doxycycline, Gentamicin, Penicillin G potassium, Streptomycin, Tobramycin, Vancomycin (this list is not all inclusive)

*Injectable Antibiotics that have separate criteria do not apply to this policy

Background
The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Injectable antibiotic products have the potential for misuse, which can lead to increased antibiotic resistance. It is very important to inform people about the possible complications of these drugs and the extent of the problem because of irrational use of these drugs. This criteria is also intended to help prevent use of injectable antibiotics in topical foot baths.

Regulatory Status
FDA-approved indications:

Injectable antibiotics are used for bacterial infections. Choice of antibiotic is based on their spectrum of antibiotic activity.

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Injectable antibiotics may be considered **medically necessary** if the conditions indicated below are met.

Injectable antibiotics may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnoses

Patient must have **ONE** of the following:

ALL diagnoses and **ANY** route of administration (e.g., IV, injectable, infusion, nebulization, bladder instillation) are covered **EXCEPT** for the following:

1. Topical use, including foot baths and nasal rinses

Ceftriaxone, Cefotaxime sodium, Doxycycline, Penicillin G potassium **only:**

2. Diagnosis of Lyme disease

AND ALL of the following:

a. Positive or indeterminate ELISA for Lyme Disease
b. Positive immunoblot as defined by CDC criteria, also known as a Western blot

AND ONE of the following

a. Neuroborreliosis with objective neurologic complications
    I. Neurological complications include:
        i. Lymphocytic meningitis with documented cerebrospinal fluid (CSF) abnormalities
        ii. Cranial neuropathy, other than uncomplicated cranial nerve palsy, with documented CSF abnormalities

iii. Encephalitis or encephalomyelitis with documented CSF abnormalities
iv. Radiculopathy
v. Polyneuropathy

b. Documented Lyme carditis
   I. Documentation of Lyme carditis may include PCR-based direct detection of *B. burgdorferi* in the blood when results of serologic studies are equivocal
c. Documented Lyme arthritis that has not responded to a 4-week course of oral antibiotics

Prior – Approval *Renewal* Requirements

Patient must have **ONE** of the following:

ALL diagnoses and **ANY** route of administration (e.g., IV, injectable, infusion, nebulization, bladder instillation) are covered **EXCEPT** for the following:

1. Topical use, including foot bath and nasal rinses

NO renewal for Lyme disease

Policy Guidelines

Pre - PA Allowance

Duration 2 weeks

Prior - Approval Limits

Duration 2 weeks for Lyme disease
12 months for all diagnoses other than Lyme disease

Prior – Approval *Renewal* Limits

Duration 12 months for all diagnoses other than Lyme disease
No renewal for Lyme disease

Rationale

Summary
The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Injectable antibiotic products have the potential for misuse, which can lead to increased antibiotic resistance. It is very important to inform people about the possible complications of these drugs and the extent of the problem because of irrational use of these drugs. This criteria is also intended to help prevent use of injectable antibiotics in topical foot baths.

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of injectable antibiotics while maintaining optimal therapeutic outcomes.

Policy History

Date	Action
December 2011	New policy
December 2012	Annual review and update
June 2014	Annual editorial review and reference update
March 2016	Annual review and reference update Policy number changed from 5.03.15 to 5.01.15
December 2017	Annual editorial review and reference update
November 2018	Annual review and reference update
December 2019	Annual review. Renamed policy Injectable Antibiotics and added requirements for IV, injectable, or infusion administration and no topical use for all diagnoses other than Lyme disease
February 2020	Revised indication to ALL diagnoses and routes of administration are covered except for topical use, including foot baths and nasal rinses. Addition of renewal for diagnoses other than Lyme disease
March 2020	Annual review
June 2021	Annual review
March 2022	Annual review
June 2023	Annual review. Changed policy number to 5.01.015
June 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 13, 2024 and is effective on July 1, 2024.