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**
Section: Prescription Drugs  Effective Date: January 1, 2020
Subsection: Anti-Infective Agents  Original Policy Date: December 7, 2011
Subject: Injectable Antibiotics  Page: 2 of 4

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

Ceftriaxone, cefotaxime sodium, doxycycline for injection and penicillin G potassium may be considered medically necessary for the treatment of Lyme disease if the conditions indicated below are met.

Injectable antibiotics may be considered medically necessary for the treatment of infections and if the conditions indicated below are met.

Injectable antibiotics may be considered investigational for all non FDA approved indications.

Prior-Approval Requirements

Diagnoses

Patient must have ONE of the following:

1. An approved FDA indication
   a. Used as IV, injectable, or infusion
   b. NOT for topical use

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
None

**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**
None

**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.

References

Policy History

<table>
<thead>
<tr>
<th>Date</th>
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<tbody>
<tr>
<td>December 2011</td>
<td>New Policy</td>
</tr>
<tr>
<td>December 2012</td>
<td>Annual review and update</td>
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<tr>
<td>June 2014</td>
<td>Annual editorial review and reference update</td>
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<tr>
<td>March 2016</td>
<td>Annual review and reference update</td>
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<td>Policy number changed from 5.03.15 to 5.01.15</td>
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<td>December 2017</td>
<td>Annual editorial review and reference update</td>
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<tr>
<td>November 2018</td>
<td>Annual review and reference update</td>
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<tr>
<td>December 2019</td>
<td>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</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective on January 1, 2020.