Clinical Policy: Ceftriaxone Sodium Injection

Reference Number: CP.HNMC.05
Effective Date: 07.01.17
Last Review Date: 02.18 Revision Log
Line of Business: Medicaid - HNMC

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

Description
Ceftriaxone sodium injection is a sterile, semisynthetic, broad-spectrum cephalosporin antibiotic for intravenous or intramuscular administration.

FDA approved indication
Ceftriaxone sodium injection is indicated:

- For the treatment of lower respiratory tract infections caused by *Streptococcus pneumoniae, Staphylococcus aureus, Haemophilus influenzae, Haemophiluspara influenzae, Klebsiella pneumoniae, Escherichia coli, Enterobacteraerogenes, Proteus mirabilis,* or *Serratia marcescens*
- For the treatment of acute bacterial otitis media caused by *Streptococcus pneumoniae, Haemophilus influenzae* (including beta-lactamase producing strains), or *Moraxella catarrhalis* (including beta-lactamase producing strains)
- For the treatment of skin and skin structure infections caused by *Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus pyogenes, Viridans* group streptococci, *Escherichia coli, Enterobacter cloacae, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Morganella morganii, Pseudomonas aeruginosa, Serratia marcescens, Acinetobacter calcoaceticus, Bacteroides fragilis,* or *Peptostreptococcus* species
- For the treatment of urinary tract infections (complicated and uncomplicated) caused by *Escherichia coli, Proteus mirabilis, Proteus vulgaris, Morganella morganii,* or *Klebsiella pneumoniae*
- For the treatment of uncomplicated gonorrhea (cervical/urethral and rectal) caused by *Neisseria gonorrhoeae,* including both penicillinase- and nonpenicillinase-producing strains, and pharyngeal gonorrhea caused by nonpenicillinase-producing strains of *Neisseria gonorrhoeae*
- For the treatment of pelvic inflammatory disease caused by *Neisseria gonorrhoeae*
- For the treatment of bacterial septicemia caused by *Staphylococcus aureus, Streptococcus pneumoniae, Escherichia coli, Haemophilus influenza,* or *Klebsiella pneumoniae*
- For the treatment of bone and joint infections caused by *Staphylococcus aureus, Streptococcus pneumoniae, Escherichia coli, Proteus mirabilis, Klebsiella pneumoniae,* or *Enterobacter* species
- For the treatment of intra-abdominal infections caused by *Escherichia coli, Klebsiella pneumoniae, Bacteroides fragilis, Clostridium* species (note: most strains of Clostridium difficile are resistant), or *Peptostreptococcus* species
- For the treatment of meningitis caused by *Haemophilus influenzae, Neisseria meningitides,* or *Streptococcus pneumoniae*

- For the prophylaxis of postoperative infections in patients undergoing surgical procedures classified as contaminated or potentially contaminated (e.g., vaginal or abdominal hysterectomy or cholecystectomy for chronic calculous cholecystitis in high-risk patients, such as those over 70 years of age, with acute cholecystitis not requiring therapeutic antimicrobials, obstructive jaundice or common duct bile stones) and in surgical patients for whom infection at the operative site would present serious risk (e.g., during coronary artery bypass surgery): as a single dose

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Centene Corporation® that Ceftriaxone sodium injection is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Lower Respiratory Tract Infection (must meet all)**:**
1. Diagnosis of lower respiratory tract infection caused by *Streptococcus pneumoniae*, *Staphylococcus aureus*, *Haemophilus influenzae*, *Haemophiluspara influenzae*, *Klebsiella pneumoniae*, *Escherichia coli*, *Enterobacteraerogenes*, *Proteus mirabilis*, or *Serratia marcescens*;
2. Member was discharged from an acute care hospital;
3. Intravenous therapy with ceftriaxone sodium was started prior to discharge.

Approval duration: Length of benefit

B. Acute Bacterial Otitis Media (must meet all)**:**
1. Diagnosis of acute bacterial otitis media caused by *Streptococcus pneumoniae*, *Haemophilus influenzae* (including beta-lactamase producing strains), or *Moraxella catarrhalis* (including beta-lactamase producing strains);
2. Member was discharged from an acute care hospital;
3. Intravenous therapy with ceftriaxone sodium was started prior to discharge.

Approval duration: Length of benefit

C. Skin and Skin Structure Infection (must meet all)**:**
1. Diagnosis of skin and skin structure infection caused by *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Streptococcus pyogenes*, *Viridans* group streptococci, *Escherichia coli*, *Enterobacter cloacae*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Proteus mirabilis*, *Morganella morganii*, *Pseudomonas aeruginosa*, *Serratia marcescens*, *Acinetobacter calcoaceticus*, *Bacteroides fragilis*, or *Peptostreptococcus* species;
2. Member was discharged from an acute care hospital;
3. Intravenous therapy with ceftriaxone sodium was started prior to discharge.

Approval duration: Length of benefit

D. Urinary Tract Infection (must meet all)**:**

1. Diagnosis of urinary tract infection (complicated or uncomplicated) caused by *Escherichia coli, Proteus mirabilis, Proteus vulgaris, Morganella morganii,* or *Klebsiella pneumoniae*;
2. Member was discharged from an acute care hospital;
3. Intravenous therapy with ceftriaxone sodium was started prior to discharge.

Approval duration: Length of benefit

E. Uncomplicated Gonorrhea (must meet all)**:**

1. Diagnosis of uncomplicated gonorrhea (cervical/urethral or rectal) caused by *Neisseria gonorrhoeae,* including both penicillinase- and nonpenicillinase-producing strains, and pharyngeal gonorrhea caused by nonpenicillinase-producing strains of *Neisseria gonorrhoeae*;
2. Member was discharged from an acute care hospital;
3. Intravenous therapy with ceftriaxone sodium was started prior to discharge.

Approval duration: Length of benefit

F. Pelvic Inflammatory Disease (must meet all)**:**

1. Diagnosis of pelvic inflammatory disease caused by *Neisseria gonorrhoeae*;
2. Member was discharged from an acute care hospital;
3. Intravenous therapy with ceftriaxone sodium was started prior to discharge.

Approval duration: Length of benefit

G. Bacterial Septicemia (must meet all)**:**

1. Diagnosis of bacterial septicemia caused by *Staphylococcus aureus, Streptococcus pneumoniae, Escherichia coli, Haemophilus influenza,* or *Klebsiella pneumoniae*;
2. Member was discharged from an acute care hospital;
3. Intravenous therapy with ceftriaxone sodium was started prior to discharge.

Approval duration: Length of benefit

H. Bone and Joint Infection (must meet all)**:**

1. Diagnosis of bone and joint infection caused by *Staphylococcus aureus, Streptococcus pneumoniae, Escherichia coli, Proteus mirabilis, Klebsiella pneumoniae,* or *Enterobacter* species;
2. Member was discharged from an acute care hospital;
3. Intravenous therapy with ceftriaxone sodium was started prior to discharge.

Approval duration: Length of benefit

I. Intra-Abdominal Infection (must meet all)**:**

1. Diagnosis of intra-abdominal infection caused by *Escherichia coli, Klebsiella pneumoniae, Bacteroides fragilis, Clostridium* species, or *Peptostreptococcus* species;
2. Member was discharged from an acute care hospital;
3. Intravenous therapy with ceftriaxone sodium was started prior to discharge.

Approval duration: Length of benefit

J. Meningitis (must meet all)**:**

1. Diagnosis of meningitis caused by *Haemophilus influenzae*, *Neisseria meningitides*, or *Streptococcus pneumonia*;
2. Member was discharged from an acute care hospital;
3. Intravenous therapy with ceftriaxone sodium was started prior to discharge.

Approval duration: Length of benefit

K. Prevention Of Postoperative Infections (must meet all)**:**

1. Request is for prevention of postoperative infections: as a single dose in members undergoing surgical procedures classified as contaminated or potentially contaminated (e.g., vaginal or abdominal hysterectomy or cholecystectomy for chronic calculous cholecystitis in high-risk members, such as those over 70 years of age, with acute cholecystitis not requiring therapeutic antimicrobials, obstructive jaundice or common duct bile stones) and in surgical members for whom infection at the operative site would present serious risk (e.g., during coronary artery bypass surgery);
2. Member was discharged from an acute care hospital;
3. Intravenous therapy with ceftriaxone sodium was started prior to discharge.

Approval duration: Length of benefit

L. Other diagnoses/indications

1. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy [examples: labs, sign/symptom reduction, no disease progression, no significant toxicity, etc].

Approval duration: Length of benefit

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

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

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Lower respiratory tract infection	1 to 2 g/day IV/IM, given once daily or in divided doses twice daily	4 g
Acute otitis media	1 to 2 g IV every 24 hours or in divided doses twice a day	4 g
Infection of skin and/or subcutaneous tissue	1 to 2 g/day IV/IM, given once daily or in divided doses twice daily	4 g
Urinary tract infectious disease	1 to 2 g/day IV/IM, given once daily or in divided doses twice daily	4 g
Uncomplicated Gonococcal Infection of the Cervix, Urethra, and Rectum	250 mg IM as a single dose plus a single dose of azithromycin 1 g orally	250 mg
Pelvic inflammatory disease	1 to 2 g IM every 24 hours or in divided doses twice a day	4 g
Bacterial Septicemia	1 to 2 g/day IV/IM, given once a day or twice daily in divided doses	4 g
Intra-Abdominal Infection	1 to 2 g/day IV/IM, given once daily or in divided doses twice daily	4 g
Meningitis	4 g/day IV divided every 12 to 24 hours	4 g
Prevention Of Postoperative Infections	2 g IV 60 minutes prior to surgery	2 g (total treatment duration should not exceed 24 hours)

VI. Product Availability

Injection Powder for Solution: 1 GM, 2 GM, 250 MG, 500 MG
Intravenous Powder for Solution: 10 GM
Intravenous Solution: 1 GM/50 ML, 2 GM/50 ML

VII. Workflow Document

N/A

VIII. References

1. Ceftriaxone Prescribing Information. Lake Forest, IL: G.D. Searle & Co.; July 2015. Available at: www.accessdata.fda.gov. Accessed July 21, 2017.
2. DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed July 27, 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	07.01.17	02.18

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.

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.