Clinical Policy: Infectious Disease Agents: Antibiotics - Quinolones

Reference Number: OH.PHAR.PPA.67
Effective Date: 01/01/2020
Last Review Date: N/A
Line of Business: Medicaid

Coding Implications
Revision Log

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

Description:

INFECTIOUS DISEASE AGENTS: QUINOLONES, SECOND GENERATION - ORAL

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
CIPROFLOXACIN (generic of Cipro®) CIPRO® suspension (no PA required for age 12 or under) (ciprofloxacin)	CIPROFLOXACIN suspension (PA required for age over 12) (generic of Cipro®) CIPROFLOXACIN ER (generic of Cipro®XR)

INFECTIOUS DISEASE AGENTS: QUINOLONES, THIRD GENERATION - ORAL

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
LEVOFLOXACIN (generic of Levaquin®)	MOXIFLOXACIN (generic of Avelox®)

INFECTIOUS DISEASE AGENTS: QUINOLONES, OTHER - ORAL

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	BAXDELA™ (delafloxacin)

FDA Approved Indication(s):
Macrolides are indicated for the treatment of:

- anthrax prophylaxis
- bacterial conjunctivitis
- bone and joint infections
- bronchitis
- campylobacteriosis
- cervicitis
- community-acquired pneumonia
- corneal ulcer
- cystitis
- diabetic foot ulcer
- febrile neutropenia
- gastroenteritis
- gonorrhea
- infectious arthritis
- infectious diarrhea
- intraabdominal infections
- lower respiratory tract infections

- nosocomial pneumonia
- osteomyelitis
- otitis externa
- otitis media
- plague
- plague prophylaxis
- pneumonia
- prostatitis
- pyelonephritis
- shigellosis
- sinusitis
- skin and skin structure infections
- typhoid fever
- urethritis
- urinary tract infection (UTI)

Baxdela is indicated in adults for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of the following:

- Gram-positive organisms: *Staphylococcus aureus* (including methicillin-resistant [MRSA] and methicillin-susceptible [MSSA] isolates), *Staphylococcus haemolyticus*, *Staphylococcus lugdunensis*, *Streptococcus agalactiae*, *Streptococcus anginosus* Group (including *Streptococcus anginosus*, *Streptococcus intermedius*, and *Streptococcus constellatus*), *Streptococcus pyogenes*, and *Enterococcus faecalis*.
- Gram-negative organisms: *Escherichia coli*, *Enterobacter cloacae*, *Klebsiella pneumoniae*, and *Pseudomonas aeruginosa*.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health Buckeye Health Plan, an affiliate of Centene Corporation®, that Cipro Suspension (age over 12), Cipro XR, Avelox, and Baxdela are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. For Cipro Suspension (age over 12), Cipro XR, and Avelox requests (must meet all)**:**

1. FDA-approved or supported by standard pharmacopeias;
2. Member must meet labeled age requirements for the medication;
3. The member meets one of the following (a, b, or c):
   a. Documentation that the infection is caused by an organism resistant to medications not requiring prior approval (note diagnosis and any culture and sensitivity reports);
   b. Documentation that there have been therapeutic failures to no less than a 3 day trial of at least one medication not requiring prior approval UNLESS there is a reason the member cannot be changed to a preferred medication. Acceptable reasons include:

- Allergies to all medications not requiring prior approval.
- Contraindication to or drug-to-drug interaction with medications not requiring prior approval.
- History of unacceptable/toxic side effects to medications not requiring prior approval.

c. Documentation that the member is completing a course of therapy with a medication requiring prior approval, which was initiated in the hospital;

4. For Ciprofloxacin Suspension requests: PA required for age over 12.

NOTE: A non-preferred agent may be approved if the prescriber expresses concern over safety issues of a preferred agent.

Approval duration: 60 days; no refills**.**

B. For Baxdela Requests (must meet all)**:**

1. Diagnosis of Acute Bacterial Skin and Skin Structure Infection (ABSSSI);
2. Age ≥ 18 years;
3. The member meets one of the following (a, b, or c):
   a. Documentation that the infection is caused by an organism resistant to medications not requiring prior approval (note diagnosis and any culture and sensitivity reports);
   b. Documentation that there have been therapeutic failures to no less than a 3 day trial of at least one medication not requiring prior approval UNLESS there is a reason the member cannot be changed to a preferred medication. Acceptable reasons include:
      - Allergies to all medications not requiring prior approval.
      - Contraindication to or drug-to-drug interaction with medications not requiring prior approval.
      - History of unacceptable/toxic side effects to medications not requiring prior approval.
   c. Documentation that the member is completing a course of therapy with a medication requiring prior approval, which was initiated in the hospital;
4. Dose does not exceed one of the following (a or b):
   a. IV: 600 mg (2 vials) per day;
   b. PO: 900 mg (2 tablets) per day.

NOTE: A non-preferred agent may be approved if the prescriber expresses concern over safety issues of a preferred agent.

Approval duration: 14 days; no refills**.**

C. Other diagnoses/indications:

1. There are no pharmacy and therapeutic committee approved off-label use criteria for the diagnosis;
2. Use is supported by one of the following (a, b, or c):
   a. The National Comprehensive Cancer Network (NCCN) Drug Information and Biologics Compendium level of evidence 1 or 2A;
   b. Evidence from at least two high-quality, published studies in reputable peer-reviewed journals or evidence-based clinical practice guidelines that provide all of the following (i – iv):

i. Adequate representation of the member's clinical characteristics, age, and diagnosis;
ii. Adequate representation of the prescribed drug regimen;
iii. Clinically meaningful outcomes as a result of the drug therapy in question;
iv. Appropriate experimental design and method to address research questions;

c. Micromedex DrugDex® with strength of recommendation Class I, IIa, or IIb;

3. Prescribed by or in consultation with an appropriate specialist for the diagnosis;
4. Failure of an adequate trial of at least two FDA-approved drugs for the indication and/or drugs that are considered the standard of care, when such agents exist for the same indication at maximum indicated doses, unless no such drugs exist, at maximum indicated doses, unless contraindicated or clinically significant adverse effect are experienced;
5. Dosing regimen and duration are within dosing guidelines recommended by clinical practice guidelines and/or medical literature.

Approval duration: 60 days; no refills**.**

II. Diagnoses/Indications for which coverage is NOT authorized:

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 for Medicaid or evidence of coverage documents.

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ABSSSI: Acute Bacterial Skin and Skin Structure Infections
ER: Extended Release
FDA: Food and Drug Administration
MRSA: Methicillin-resistant Staphylococcus aureus
MSSA: Methicillin-susceptible Staphylococcus aureus
PA: Prior Authorization
UTI: Urinary Tract Infection

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Ciprofloxacin tablets (Cipro), Ciprofloxacin (Cipro) suspension (12 or under)	**Acute, uncomplicated UTI** 250 mg every 12 hours for 3 days. **Mild to moderate UTIs and for the treatment of severe and/or complicated UTIs, including pyelonephritis** 250 to 500 mg every 12 hours for 7 to 14 days.	1.5 g/day regular release products

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Ciprofloxacin tablets (Cipro), Ciprofloxacin (Cipro) suspension (12 or under) - continued	**Lower respiratory tract infections** 500 to 750 mg every 12 hours for 7 to 14 days. **Skin and skin structure infections** 500 to 750 mg every 12 hours for 7 to 14 days. **Mild to moderate acute sinusitis** 500 mg every 12 hours for 10 days. **Cutaneous anthrax** 500 mg every 12 hours. Treat for 7 to 10 days for naturally acquired infection. For a bioterrorism event, treat for 60 days. **Anthrax prophylaxis after exposure to Bacillus anthracis** 500 mg every 12 hours for 60 days after exposure. **Bone and joint infections** 500 to 750 mg every 12 hours for 4 to 8 weeks.	1.5 g/day regular release products
levofloxacin (Levaquin)	**Acute bacterial sinusitis** 500 mg every 24 hours for 10 to 14 days or 750 mg every 24 hours for 5 days. **Mild to moderate complicated UTI or acute pyelonephritis** 750 mg every 24 hours for 5 days or 250 mg every 24 hours for 10 days. **Mild to moderate uncomplicated UTI** 250 mg every 24 hours for 3 days. **Acute bacterial exacerbation of chronic bronchitis** 500 mg every 24 hours for 7 days. **Community-acquired pneumonia (CAP)** 750 mg every 24 hours for at least 5 days. Alternatively, 500 mg every 24 hours for 7 to 14 days.	750 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
levofloxacin (Levaquin) - continued	**Nosocomial pneumonia** 750 mg every 24 hours for 7 to 14 days. **Mild to moderate skin and skin structure infections** 500 mg every 24 hours for 7 to 10 days for uncomplicated infections and 750 mg every 24 hours for 7 to 14 days for complicated infections. **Anthrax prophylaxis after exposure to Bacillus anthracis** 750 mg every 24 hours for 60 days after exposure. Alternately, 500 mg every 24 hours.	750 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Quinolone Hypersensitivity
- Boxed warning(s):
  - Myasthenia Gravis
  - Neurotoxicity
  - Peripheral Neuropathy
  - Psychiatric Event
  - Tendinitis
  - Tendon Rupture

IV. Dosage and Administration

- Varies by drug product. See FDA approved dosing and administration AND Appendix B.

V. Product Availability

Drug Name	Availability
Baxdela	Tablets: 450 mg
Ciprofloxacin	Oral suspension: 250 mg/5 mL, 500 mg/5 mL
Ciprofloxacin	Tablets: 100 mg, 250 mg, 500 mg, 750 mg
Ciprofloxacin	Extended-Release Tablets: 500 mg, 1000 mg
Factive	Tablets: 320 mg
Levofloxacin	Oral solution: 25 mg/mL
Levofloxacin	Tablets: 250 mg, 500 mg, 750 mg
Moxifloxacin	Tablets: 400 mg
Ofloxacin	Tablets: 200 mg, 300 mg, 400 mg

VI. References

- Baxdela (delafloxacin) [package insert]. Lincolnshire, IL; Melinta Therapeutics Inc.; Revised 2019.
- Ciprofloxacin. Clinical Pharmacology. Elsevier. Tampa, FL. Available at https://www.clinicalpharmacology-ip.com. Accessed November 18, 2019.
- Levofloxacin. Clinical Pharmacology. Elsevier. Tampa, FL. Available at https://www.clinicalpharmacology-ip.com. Accessed November 18, 2019.
- Moxifloxacin. Clinical Pharmacology. Elsevier. Tampa, FL. Available at https://www.clinicalpharmacology-ip.com. Accessed November 18, 2019.
- Ofloxacin. Clinical Pharmacology. Elsevier. Tampa, FL. Available at https://www.clinicalpharmacology-ip.com. Accessed November 18, 2019.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New policy created.	10.19	N/A

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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. 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.