Clinical Policy: Injectable Antibiotics Not on the Statewide Preferred Drug List

Reference Number: PA.CP.PHAR.15
Effective Date: 09/2022
Last Review Date: 05/2023 Revision Log

Description
This policy is to be used to determine medical necessity of existing or newly approved intravenous antibiotics where no custom coverage criteria are available.

Policy/Criteria
It is the policy of PA Health & Wellness that an Injectable Antibiotic is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Infections Caused by Susceptible Bacteria (must meet all)**:**

1. Request is for an IV antibiotic not covered on the Statewide PDL (penicillins, fluoroquinolones, macrolides, tetracyclines[1]) or for an IV antibiotic without custom criteria;
2. The drug is prescribed for an FDA (Food and Drug Administration) approved indication, or by or in consultation with an infectious disease specialist;
3. Culture and sensitivity (C&S) report shows isolated pathogen is susceptible to the antibiotic being requested or organism has been identified and C&S is not needed, unless provider submits documentation that obtaining a C&S is not feasible;
4. Member meets one of the following (a, b, c, d, e or f):
   a. Culture and sensitivity report or noted isolated organism shows resistance of the isolated pathogen to ALL Preferred Drug List (PDL) antibiotics that are FDA-approved for members diagnosis;
   b. Member has failed treatment with PDL antibiotics to which the isolated pathogen is susceptible, unless contraindicated, intolerant, or agents are not indicated for member's diagnosis;
   c. Provider documents that obtaining a C&S report is not feasible and member has tried and failed 2* preferred Statewide PDL antibiotics indicated for member's diagnosis, unless all are contraindicated or clinically significant adverse effects are experienced;
   d. Oral antibiotic is not indicated or recommended by guideline or compendia for the member's diagnosis;
   e. Member is not able to tolerate oral antibiotics;
   f. Member has been discharged from the hospital on requested antibiotic;
5. Prescribed doses do not exceed product labeling maximum recommended dosing.

Approval duration: up to 6 week duration

*Provided 2 antibiotics on the Statewide Preferred Drug List exist to which the pathogen is susceptible and/or are indicated for member's diagnosis
[1]For IV Vancomycin and IV Cephalosporins, please use PA.CP.PMN.16

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

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53

II. Continued Approval

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

1. Currently receiving medication via PA Health & Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Documentation supports positive response to therapy (examples: sign/symptom reduction, no disease progression, no significant toxicity);
3. If request is for a dose increase, new dose does not exceed dosing guidelines recommended by clinical practice guidelines and/or medical literature.
   Approval duration: 30 days

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

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53.

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
PDL: Preferred Drug List
C&S: Culture and Sensitivity

Appendix B: General Information

- The U.S. FDA approves drugs for specific indications included in the drug's product information label. The approval by the FDA means that the company can include the information in their package insert. Omission of uses for a specific age group or a specific disorder from the approved label means that the evidence required by law to allow their inclusion in the label has not been submitted to the FDA. Off-label, or "unlabeled," drug use is the utilization of an FDA-approved drug for indications, treatment regimens, or populations other than those listed in the FDA-approved labeling. Many off-label uses are effective and well-documented in the peer-reviewed literature, and they are widely used even though the manufacturer has not pursued the additional indications. Refer to the drug's FDA approved indication(s) and labeling (varies among drug products).

IV. Dosage and Administration

A. Refer to prescribing information

V. Product Availability

A. Refer to prescribing information

VI. References

Food and Drug Administration. Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices. January 2009. Available at: https://www.govinfo.gov/content/pkg/FR-2009-01-13/pdf/E9-452.pdf. Accessed August 18, 2022.

Reviews, Revisions, and Approvals	Date	Approval Date
3Q 2022 Policy created	08/2022	
3Q 2023 annual review: For IV Vancomycin and IV Cephalosporins, please use PA.CP.PMN.16; add for drug without custom criteria; added if use of oral antibiotics indicated	05/2023	