Clinical Policy: Non-Formulary Injectable Antibiotics

Reference Number: IL.ERX.PHAR.15
Effective Date: 06.01.21
Last Review Date: 05.21
Line of Business: Illinois Medicaid

Revision Log

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

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

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that non-formulary injectable antibiotics are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. The drug is prescribed for an FDA (Food and Drug Administration)-approved indication by or in consultation with an infectious disease specialist;
2. Culture and sensitivity (C&S) report (dated within the past 7 days) shows isolated pathogen is susceptible to the antibiotic being requested, unless provider submits documentation that obtaining a C&S is not feasible;
3. Member meets one of the following (a, b, c, or d):
   a. Culture and sensitivity report 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 members diagnosis;
   c. Provider documents that obtaining a C&S report is not feasible, and member has tried and failed 2* formulary antibiotics indicated for member's diagnosis, unless all are contraindicated or clinically significant adverse effects are experienced;
      **Provided 2 formulary antibiotics exist to which the pathogen is susceptible and/or are indicated for member's diagnosis*
   d. Member has been discharged from the hospital on requested antibiotic;
4. Prescribed doses do not exceed product labeling maximum recommended dosing.

Approval duration: Up to a 6 week duration

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All requests (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met all initial approval criteria;
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

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 – ERX.PA.01 or evidence of coverage documents;

B. Indications or diagnoses in which the drug has been shown to be unsafe or ineffective.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

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

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).

V. Dosage and Administration

Refer to prescribing information

VI. Product Availability

Refer to prescribing information

VII. References

1. 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: http://www.fda.gov/RegulatoryInformation/Guidances/ucm125126.htm. Accessed June 29, 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	04.15.21	05.21

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute

a contract or guarantee regarding payment or results. 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.