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RETIRED
Effective Date: 10/08/2020

Xerava™ (eravacycline)

FDA approval: 8/27/2018

HPCS: J0122

Benefit: Medical

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

- A. Coverage of the requested drug is provided when all the following are met:
 - a. Must be diagnosed with complicated intra-abdominal infection
 - b. Organism must be susceptible to Xerava
 - c. Member must be 18 years or older
- B. Quantity Limitations, Authorization Period and Renewal Criteria
 - a. Quantity Limit: FDA approved dosing
 - b. Initial Authorization Period: 14 days
 - c. Renewal Criteria: N/A
- C. Xerava is considered investigational when used for all other conditions, including but not limited to:
 - a. Complicated urinary tract infections (cUTI)

***Note: Coverage may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at <http://www.cms.hhs.gov/>. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Therapeutic considerations:

- A. **FDA approved indication / Diagnosis**
 - a. Xerava is indicated for the treatment of complicated intra-abdominal infections (cIAs) caused by susceptible microorganisms such as: Escherichia coli, Klebsiella pneumoniae, Citrobacter freundii, Enterobacter cloacae, Klebsiella oxytoca, Enterococcus faecalis, Enterococcus faecium, Staphylococcus aureus, Streptococcus anginosus group, Clostridium perfringens, Bacteroides species, and Parabacteroides distasonis in patients ≥ 18 years of age

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- b. Limitations of use: Xerava is not indicated for the treatment of complicated urinary tract infections (cUTI)

**Please refer to most recent prescribing information.*

<https://www.xerava.com/assets/pdf/prescribinginformation.pdf>

B. Background Information

- a. Complicated intra-abdominal infection extends beyond the hollow viscus of origin into the peritoneal space and is associated with either abscess formation or peritonitis
- b. Complicated intra-abdominal infection is a common problem, with appendicitis alone affecting ~300,000 patients/year and consuming 11 million hospital days. Intra-abdominal infection is the second most common cause of infectious mortality in the intensive care unit
- c. The Surgical Infection Society and Infectious Diseases Society of America (IDSA) recommend selection of empiric therapy based on microorganism susceptibility. Antimicrobial regimens with broad-spectrum activity against gram negative organisms, such as meropenem, imipenem-cilastatin, doripenem, and piperacillin-tazobactam are recommended for high risk community acquired cAIs in adults. Single-agent therapies such as tigecycline, Cefoxitin, ertapenem, moxifloxacin and ticarcillin-clavulanic acid are recommended for mild to moderate community acquired cAIs in adults
- d. Xerava is a tetracycline antibiotic that disrupts bacterial protein synthesis by binding to the 30S ribosomal subunit thus preventing the incorporation of amino acid residues into elongating peptide chains
- e. Dose of Xerava don't need to be adjusted in patients whose kidneys are impaired. Renal function can be highly changeable in critically ill patients. Xerava may be given safely to patients with penicillin allergy, which may be significant as other options for empiric therapy are penicillin-class drugs

C. Efficacy

**Please refer to most recent prescribing information.*

D. Medication Safety Considerations

Black Box Warning: No

**Please refer to most recent prescribing information.*

E. Dosing and administration

- a. Dosing: 1 mg/kg by IV infusion over approximately 60 minutes every 12 hours for a total duration of 4 to 14 days

**Please refer to most recent prescribing information.*

F. How supplied

- a. 50 mg lyophilized powder in a single-dose vial

**Please refer to most recent prescribing information.*

References:

1. Xerava [prescribing information] Watertown, MA: Tetraphase Pharmaceuticals, Inc. 2018.
2. Manufacturer press release. Available at: <https://ir.tphase.com/news-releases/news-release-details/tetraphase-pharmaceuticals-announces-fda-approval-xeravatm>.
3. JS Solomkin, JE Mazuski, JS Bradley, et al; Diagnosis and Management of Complicated Intra-abdominal Infection in Adults and Children: Guidelines by the Surgical Infection Society and the Infectious Diseases Society of America. *Clinical Infectious Diseases*; 2010;50:133-64.
4. Lexicomp Online, Hudson, OH: Wolters Kluwer Health Clinical Drug Information, Inc.; 2018. Eravacycline. Accessed on October 16th, 2018.
5. Solomkin J, Evans D, Slepavicius A, et al. Assessing the Efficacy and Safety of Eravacycline vs Ertapenem in Complicated Intra-abdominal Infections in the Investigating Gram-Negative Infections Treated With Eravacycline (IGNITE 1) TrialA Randomized Clinical Trial. *JAMA Surg*. 2017;152(3):224–232. doi:10.1001/jamasurg.2016.4237

Policy History												
#	Date	Change Description										
1.2	Effective Date: 10/08/2020	Retiring policy as this drug is no longer managed with prior authorization										
1.1	Effective Date: 11/07/2019	Annual Review of Medical Policies										
1.0	Effective Date: 11/01/2018	New Policy<table><tr><th>Line of Business</th><th>PA Required (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>No</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table>	Line of Business	PA Required (Yes/No)	BCBS	No	BCN	No	MAPPO	No	BCNA	No
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* The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or <http://dailymed.nlm.nih.gov/dailymed/index.cfm>.