Medical Policy:

Fetroja® (cefiderocol) for injection

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.212	March 1, 2024	June 3, 2020

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Fetroja is indicated in patients 18 years of age or older who have limited or no alternative treatment options for the treatment of complicated urinary tract infections (cUTIs), including pyelonephritis caused by the following susceptible Gram-negative microorganisms: *Escherichia coli*, *Klebsiella pneumoniae*, *Proteus mirabilis*, *Pseudomonas aeruginosa*, and *Enterobacter cloacae* complex. In addition, Fetroja is indicated in patients 18 years of age or older for the treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP), caused by the following susceptible Gram-negative microorganisms: Acinetobacter baumannii complex, Escherichia coli, Enterobacter cloacae complex, Klebsiella pneumoniae, Pseudomonas aeruginosa, and Serratia marcescens. Approval of these indications is based on limited clinical safety and efficacy data for Fetroja.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Fetroja and other antibacterial drugs, Fetroja should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

Length of Authorization

Coverage will be provided for 6 months and may be renewed.

Dosing Limits [Medical Benefit]

Max Units (per dose and over time):
84 grams/treatment

Guideline

I. Initial Approval Criteria

Fetroja (cefiderocol) may be considered medically necessary when all of the below conditions are met:

1. **Complicated urinary tract infection (cUTI)**
    A. Patient is 18 years of age or older; **AND**
    B. Patient has a diagnosis of complicated urinary tract infection (cUTI); **AND**
    C. Patient has limited or no alternative treatment options for the treatment of cUTI caused by one of the following susceptible Gram-negative microorganisms per culture and susceptibility information: *Escherichia coli*, *Klebsiella pneumoniae*, *Proteus mirabilis*, *Pseudomonas aeruginosa*, and *Enterobacter cloacae* complex.

2. **Hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP)**
A. Patient is 18 years of age or older; **AND**
B. Fetroja will be used for the treatment caused by the following susceptible Gram-negative microorganisms: Acinetobacter baumannii complex, Escherichia coli, Enterobacter cloacae complex, Klebsiella pneumoniae, Pseudomonas aeruginosa, and Serratia marcescens.

Limitations/Exclusions

Fetroja (cefiderocol) is not considered medically necessary when any of the below conditions are met:

1. Patient has a known history of severe hypersensitivity to cefiderocol and other beta-lactam antibacterial drugs or other components of Fetroja.
2. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

Dosage/Administration

Indication	Dose
Hospital-acquired Bacterial Pneumonia and Ventilator-associated Bacterial Pneumonia (HABP/VABP)	2 g IV infusion over 3 hours every 8 hours for 7 to 14 days, depending on severity of infection
Pyelonephritis	2 g IV infusion over 3 hours every 8 hours for 7 to 14 days, depending on severity of infection
Urinary tract infectious disease, Complicated, with limited or no alternative treatment options	2 g IV infusion over 3 hours every 8 hours for 7 to 14 days, depending on severity of infection

Applicable Procedure Codes

Code	Description
J0699	Injection, cefiderocol; 1 billable unit = 5 mg

Applicable NDCs

Code	Description
59630-0266-XX	Fetroja 1 gm single-dose vial

ICD-10 Diagnoses

Code	Description
J15.0	Pneumonia due to Klebsiella pneumoniae
J15.1	Pneumonia due to Pseudomonas
J15.5	Pneumonia due to Escherichia coli
J15.6	Pneumonia due to other Gram-negative bacteria
J18.9	Pneumonia, unspecified organism
J95.851	Ventilator associated pneumonia
N10	Acute pyelonephritis
N11.0	Nonobstructive reflux-associated chronic pyelonephritis
N11.8	Other chronic tubulo-interstitial nephritis
N11.9	Chronic tubulo-interstitial nephritis, unspecified
N12	Tubulo-interstitial nephritis, not specified as acute or chronic
N13.6	Pyonephrosis
N16	Renal tubulo-interstitial disorders in diseases classified elsewhere
N30.00	Acute cystitis without hematuria
N30.01	Acute cystitis with hematuria
N30.20	Other chronic cystitis without hematuria
N30.21	Other chronic cystitis with hematuria
N30.80	Other cystitis without hematuria
N30.81	Other cystitis with hematuria
N30.90	Cystitis, unspecified without hematuria
N30.91	Cystitis, unspecified with hematuria
N34.1	Nonspecific urethritis
N34.2	Other urethritis
N39.0	Urinary tract infection, site not specified

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	3/1/2024	Annual Review: No criteria changes

EmblemHealth & ConnectiCare	6/30/2023	Annual review: no criteria changes
EmblemHealth & ConnectiCare	6/15/2022	Transferred policy to new template. Updated procedure code from J0693 to J0699.
EmblemHealth & ConnectiCare	1/1/2021	Updated J-code J0693
EmblemHealth & ConnectiCare	10/08/2020	Addition of covered use for the treatment of Hospital-acquired Bacterial Pneumonia and Ventilator-associated Bacterial Pneumonia (HABP/VABP) caused by select microorganisms; added the following ICD-10 codes: J15.0, J15.1, J15.5, J15.6, J18.9, J95.851
EmblemHealth & ConnectiCare	06/03/2020	New Medical Policy

References

1. Fetroja [package insert]. Florham Park, NJ; Shionogi Inc.; September 2020.
2. Clinicaltrials.gov. NCT02321800. A Study of Efficacy and Safety of Intravenous Cefiderocol (S-649266) Versus Imipenem/Cilastatin in Complicated Urinary Tract Infections (APEKS-cUTI). Available at: https://clinicaltrials.gov/ct2/show/NCT02321800. Accessed May 2020.
3. Portsmouth S, van Veenhuyzen D, Echols R, et al. Cefiderocol versus imipenem-cilastatin for the treatment of complicated urinary tract infections caused by Gram-negative uropathogens: a phase 2, randomised, double-blind, non-inferiority trial. *Lancet Infect Dis*. 2018;18(12):1319-1328.