Fetroja® – Use in the Outpatient/Home Infusion Setting

SHIONOGI

This medical response contains information in addition to that provided in the Fetroja® (cefiderocol) for injection, for intravenous use Full Prescribing Information approved by the US Food and Drug Administration (FDA). Shionogi does not recommend the use of Fetroja in any manner other than as described in the Full Prescribing Information. **Please read the attached Fetroja Full Prescribing Information.**

Summary

- The recommended dosage of cefiderocol in the outpatient setting or home infusion setting has not been evaluated in clinical trials
- Dosing in the outpatient/home infusion setting should follow the **Dosage and Administration** recommendations outlined in the **Fetroja Full Prescribing Information**[1]
- **Parra-Plaza et al (2025)** conducted a retrospective, multicenter real-world observational study describing the use of cefiderocol in a HaH/OPAT setting in 27 patients with CR Gram-negative infections in Spain[2]
  - ADRs occurred in 7.4% of patients
- **Babich et al (2025)** reported a patient with NDM-producing *Klebsiella pneumoniae* otomastoiditis who successfully received cefiderocol 6 g/day for 62 days administered as a 24 h continuous infusion using an elastomeric pump[3]
- **Schellong et al (2024)** reported a patient with NDM-producing *Pseudomonas aeruginosa* osteomyelitis who successfully received cefiderocol for a total of 169 days, including 63 days through OPAT from an elastomeric pump[4]
  - The patient experienced manifest iron deficiency anemia possibly due to the extended treatment duration of cefiderocol
- **Dagher et al (2020)** described a patient with polymicrobial osteomyelitis with XDR *Acinetobacter baumannii*, *Enterococcus faecalis*, and *Corynebacterium striatum*, who received cefiderocol on a compassionate use basis on hospital Day 7. The patient was discharged from the hospital on Day 26 with cefiderocol (2 g q8h) administered through a PICC[5]
- **Sigmon et al (2020)** described a patient who was admitted with MDR *P. aeruginosa* bacteremia. The patient was started on cefiderocol on Day 14 on a compassionate use basis. He was discharged home with 6 weeks of cefiderocol[6]

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Clinical Studies

The recommended dosage of cefiderocol in the outpatient or home infusion setting has not been evaluated in clinical trials.

- The **APEKS-cUTI** Phase 2 trial included adult patients admitted to the hospital with a diagnosis of cUTI with or without pyelonephritis, or patients with acute uncomplicated pyelonephritis[7]
- The **APEKS-NP** Phase 3 trial included adult patients admitted to the hospital with acute pneumonia in the form of HABP, VABP, or HCABP[8]
- The **CREDIBLE-CR** Phase 3 trial included hospitalized adult patients with a diagnosis of HABP, VABP, HCABP, BSI or sepsis (the primary source of infection was not pneumonia or cUTIs) or cUTIs with evidence of CR Gram-negative infection[9]

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Retrospective Study

Parra-Plaza et al (2025) conducted a retrospective, multicenter, real-world observational study describing the use of cefiderocol in a HaH/OPAT setting for CR Gram-negative infections across 6 centers in Spain between January 2023 and December 2024.[2]

Methods[2]

- Adult patients with documented CR Gram-negative infections treated with cefiderocol for ≥4 doses were included
- Clinical success was defined by resolution of infection that led to treatment with cefiderocol and attributable mortality was defined by death related directly to the underlying infectious process
- This was designed as a descriptive study with no statistical correlation or formal inferential analyses

Results[2]

- 27 patients were included with a median age of 69 years (IQR, 53–80.6 years). 70.4% of patients were male, 40.7% were immunosuppressed, and the median CCI was 3 (IQR, 2.5–7)
- A majority of infections were nosocomial (65.4%), with the most common infection sites being skin/soft tissue (37%), intra-abdominal (22.2%), urinary tract (18.5%), and respiratory tract (14.8%)
- The most frequent pathogens were *P. aeruginosa* (66.7%) and *K. pneumoniae* (14.8%)
- Among cases with available resistance data (n=20), the predominant resistance mechanism was VIM (50%), with additional mechanisms including OXA-48 (15%) and NDM (10%)
- Cefiderocol was administered using a standard daily dose of 6000 mg (consistent with 2 g q8h), with center-specific delivery either as extended infusions every 8–12 h or a continuous 24 h infusion
  - Infusions were administered via electronic infusion pumps (52%) or elastomeric devices (48%). 3 patients self-administered the full cefiderocol course after training and monitoring
  - Venous access included PICC (33.3%), peripheral venous catheter (29.6%), midline (22.2%), and central venous catheter (11.1%)
- In patients with renal impairment, cefiderocol dosing was reduced as follows:
  - 4500 mg/day (consistent with 1.5 g q8h) for eGFR 30–60 mL/min (n=2)
  - 3000 mg/day (1 g q8h) for eGFR 15–20 mL/min (n=3)
- The mean cefiderocol treatment duration was 21.7 days, and the mean treatment HaH duration was 16.37 days
- ADRs occurred in 2 patients (7.4%): renal failure and cutaneous mycosis, which resulted in treatment discontinuation in 1 case

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Published Case Reports

Babich et al (2025) described a 31-year-old male patient who developed right-sided otomastoiditis caused by NDM-producing *K. pneumoniae* and successfully received cefiderocol 6 g/day administered as a 24 h continuous infusion using an elastomeric pump for 62 days, in conjunction with TDM.[3]

- During a previous hospitalization, he developed purulent right otitis media caused by NDM-producing *K. pneumoniae* and was treated with IV ceftazidime–avibactam plus aztreonam for 10 days
- 11 months later, the patient developed a new episode of right-sided otitis complicated by mastoiditis. Middle ear pus cultures resulted in NDM-producing *K. pneumoniae*
  - Cefiderocol MIC=1 µg/mL and was resistant to ceftazidime–avibactam
- Cefiderocol was initiated at 6 g/day as a 24 h continuous infusion using an elastomeric pump (INFUSOR LV; product code 2C2063K, 10 mL/h; Baxter), diluted in 240 mL of NS

Schellong et al (2024) described a male patient who presented to a hospital in Germany with osteomyelitis due to NDM-producing *P. aeruginosa* that received cefiderocol for a total of 169 days, including 63 days through OPAT.[4]

- During a prior hospitalization, NDM-producing *P. aeruginosa* and *E. faecalis* was isolated from multiple bone cultures and was treated with ampicillin–sulbactam 3 g q8h for 28 days, and was subsequently treated with cefiderocol 2–3 g q6h for 14 days
- During the patient's current hospitalization, multiple cultures from the tibial medullary cavity revealed NDM-producing *P. aeruginosa* with a cefiderocol MIC of 0.5 mg/L as tested by the Etest method on Mueller-Hinton agar
- Cefiderocol 2 g q8h was started and after 23 days of therapy, the patient was discharged and switched to outpatient cefiderocol treatment via a PICC line for 63 days
- The OPAT service utilized an elastomeric pump (EASYPUMP II ST 400-4-S, B. Braun, Melsungen, Germany) to provide cefiderocol over the 3 h infusion duration
  - There were no reported complications during OPAT
- Planned readmission occurred after OPAT, where the patient underwent autogenous cancellous bone grafting with 4 g of cefiderocol followed by IV cefiderocol 3 g q8h for 83 days
  - Investigators utilized TDM to guide dosing
- Manifest iron deficiency anemia was observed 10 days after cefiderocol cessation which could possibly be related to the extended therapy duration
  - Hemoglobin was 5.1 mmol/L (normal range, 8.7–10.9 mmol/L), serum iron was 1.5 µmol/L (normal range, 6.3–30.1 µmol/L), transferrin saturation was 2% (normal range, 16–45%), and ferritin was 11.4 µg/L (normal range, 30–400 µg/L)

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Published Case Reports (Cont.)

Dagher et al (2020) described a 57-year-old male patient who developed a polymicrobial osteomyelitis with XDR *A. baumannii*, *E. faecalis*, and *C. striatum*, and received cefiderocol on a compassionate use basis. The patient underwent 5 surgical debridements and was started on cefiderocol on Day 7 in the hospital.[5]

- He underwent 1 final debridement and was discharged from the hospital on Day 26 with IV vancomycin (1.25 g q24h) and cefiderocol (2 g q8h) administered through a PICC
- Treatment with antibiotics was discontinued on Day 116 with the patient receiving a total of 109 days of treatment with cefiderocol, with no drug-related AEs or infusion site reactions reported
- Follow-up clinic visits 21, 65, and 128 days following the cessation of antibiotic treatment demonstrated no evidence of persistence or infection relapse

Sigmon et al (2020) reported a patient case of a 51-year-old male with a history of dilated cardiomyopathy, and who had a LVAD, as well as an ICD.[6]

- The patient was admitted with a recurrent *P. aeruginosa* bacteremia which was previously treated with meropenem, gentamicin, and suppressive ciprofloxacin
- After 4 months, the patient presented with MDR *P. aeruginosa* bacteremia and treatment was initiated with extended-infusion meropenem, high-dose, extended-interval gentamicin (which was switched to tobramycin due to susceptibility results)
- A LVAD explant took place on Day 7 with a placement of an extracorporeal LVAD followed by an ICD explant on Day 8
- On Day 14, cefiderocol was initiated on a compassionate use basis in addition to meropenem and tobramycin
- He was discharged home with 6 weeks of cefiderocol and meropenem which was well tolerated. The patient received a heart transplant 3 months later and had no evidence of infection relapse

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Relevant Prescribing Information

Fetroja® is indicated in patients 18 years of age or older for the treatment of:[1]

- Complicated urinary tract infections (cUTIs), including pyelonephritis caused by the following susceptible Gram-negative microorganisms:
  - *Escherichia coli*
  - *Klebsiella pneumoniae*
  - *Proteus mirabilis*
  - *Pseudomonas aeruginosa*
  - *Enterobacter cloacae* complex
- 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*
  - *Serratia marcescens*

Fetroja is contraindicated in:[1]

- Patients with a known history of severe hypersensitivity to cefiderocol or other beta-lactam antibacterial drugs, or any other component of **Fetroja**

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Literature Search

As of June 2026, a computerized search of the published medical literature using internal and external databases (ie, Medline®, Embase®, and PubMed®) has identified additional relevant references regarding the use of cefiderocol in the outpatient/home infusion setting. For your review, these references are listed below:

- Boettcher S, Kenney RM, Everson N, et al. Discharge delays and costs associated with outpatient parenteral antimicrobial therapy for multi-drug-resistant organisms: opportunities for improvement. Poster presented at IDWeek 2025; October 19-22, 2025; Atlanta, GA.
- Wolie ZT, Roberts JA, López-Cortés LE, et al. Current practices in outpatient parenteral antimicrobial therapy programmes: an international multi-centre survey. *JAC Antimicrob Resist*. 2025;7(3):dlaf075. [Web Link]
- Babich S, Di Bella S, De Rivo R, et al. Continuous infusion OPAT via elastomeric pumps: effectiveness, safety, and cost-saving potential in a real-world Italian cohort. *Infection*. 2026;54(1):365-375. [Web Link]
- Rose L, Lai L, Byrne D. Successful prolonged treatment of a carbapenem-resistant *Acinetobacter baumannii* hip infection with cefiderocol: a case report. *Pharmacotherapy*. 2022;42(3):268-271. [Web Link]

Please keep in mind that medical literature databases, while considered a major source of biomedical information, are selective in their sources, and the information derived from them should not be considered all-inclusive.

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Abbreviations

ADR	adverse drug reaction	L	liter
AE	adverse event	LVAD	left ventricular assist device
BSI	bloodstream infection	MDR	multidrug resistant
CCI	Charlson Comorbidity Index	MIC	minimum inhibitory concentration
CR	carbapenem-resistant	NDM	New Delhi metallo-β-lactamase
cUTI	complicated urinary tract infection	NS	normal saline
eGFR	estimated glomerular filtration rate	OPAT	outpatient parenteral antimicrobial therapy
FDA	US Food and Drug Administration	OXA	oxacillinase
g	grams	PICC	peripherally inserted central catheter
h	hours	q6h	every 6 hours
HABP	hospital-acquired bacterial pneumonia	q8h	every 8 hours
HaH	Hospital at Home	q24h	every 24 hours
HCABP	healthcare-associated bacterial pneumonia	TDM	therapeutic drug monitoring
ICD	implantable cardioverter-defibrillator	VABP	ventilator-associated bacterial pneumonia
IQR	interquartile range	VIM	Verona integron-encoded metallo-β-lactamase
IV	intravenous	XDR	extensively-drug resistant

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References

1. Fetroja® (cefiderocol) for injection, for intravenous use [Prescribing Information]. Shionogi Inc.
2. Parra-Plaza A, Ugarte A, Benavent E, et al. Use of cefiderocol for carbapenem-resistant Gram-negative infections in hospital at home: multicentric real-world experience. *Antibiotics (Basel)*. 2025;14(12):1216. [Web Link]
3. Babich S, Cojutti PG, Gatti M, Pea F, Di Bella S, Monticelli J. Feasibility of 24 h continuous-infusion cefiderocol administered by elastomeric pump in attaining an aggressive PK/PD target in the treatment of NDM-producing *Klebsiella pneumoniae* otomastoiditis. *JAC Antimicrob Resist*. 2025;7(3):dlaf066. [Web Link]
4. Schellong P, Wennek-Klose J, Spiegel C, Rödel J, Hagel S. Successful outpatient parenteral antibiotic therapy with cefiderocol for osteomyelitis caused by multi-drug resistant Gram-negative bacteria: a case report. *JAC Antimicrob Resist*. 2024;6(1):dlae015. [Web Link]
5. Dagher M, Ruffin F, Marshall S, et al. Case report: successful rescue therapy of extensively drug-resistant *Acinetobacter baumannii* osteomyelitis with cefiderocol. *Open Forum Infect Dis*. 2020;7(5):ofaa150. [Web Link]
6. Sigmon J, Kram S, Durham NC. Cefiderocol for *Pseudomonas* bacteremia with left ventricular assist device. *Crit Care Med*. 2020;48(1):281. [Web Link]
7. 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. [Web Link]
8. Wunderink RG, Matsunaga Y, Ariyasu M, et al. Cefiderocol versus high-dose, extended-infusion meropenem for the treatment of Gram-negative nosocomial pneumonia (APEKS-NP): a randomised, double-blind, phase 3, non-inferiority trial. *Lancet Infect Dis*. 2021;21(2):213-225. [Web Link]
9. Bassetti M, Echols R, Matsunaga Y, et al. Efficacy and safety of cefiderocol or best available therapy for the treatment of serious infections caused by carbapenem-resistant Gram-negative bacteria (CREDIBLE-CR): a randomised, open-label, multicentre, pathogen-focused, descriptive, phase 3 trial. *Lancet Infect Dis*. 2021;21(2):226-240. [Web Link]

Enclosure

Fetroja® (cefiderocol) for injection, for intravenous use [Prescribing Information]. Shionogi Inc.