FETROJA – POSTMARKETING DEVELOPMENT OF NON-SUSCEPTIBILITY IN PATIENTS

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 U.S. 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.**

1. SUMMARY

- **Falcone et al (2022)** described an observational retrospective cohort study in 124 patients with carbapenem-resistant *Acinetobacter baumannii* (CRAB) infections that received cefiderocol (n=47) or colistin-based regimens (n=77). Eight (17.4%) patients in the cefiderocol arm and 5 (6.8%) patients in the colistin group had microbiological failure. Of the 8 patients in the cefiderocol group with microbiological failure, 4 showed resistant minimum inhibitory concentrations (MIC). Two of these 4 patients developed resistance during treatment and the other 2 emerged after treatment when cefiderocol was discontinued[1]
- **Smoke et al (2022)** described 11 critically ill burn patients with CRAB infections who were treated with cefiderocol. Analyses performed on resistant isolates revealed *A. baumannii* ST2 and ST208 harboring $bla_{\text{OXA-23}}$, $bla_{\text{OXA-66}}$, and $bla_{\text{ADC-73}}$ and demonstrated disrupted *piuA* and *pirA* genes[2]
- **Klein et al (2021)** identified 5 cefiderocol-resistant isolates (MIC ≥256 µg/mL) of *Enterobacter cloacae* from a patient following 3 weeks of cefiderocol treatment. All strains possessed an OXA-48 and NDM β-lactamase. In addition, the resistant isolates had mutations in the *cirA* gene that encodes a siderophore receptor[3]
- **Kawai et al (2020)** described a patient with a multidrug-resistant (MDR) *E. cloacae* strain isolated from a patient who had not been treated with cephalosporins but had received meropenem and piperacillin-tazobactam. The strain exhibited resistance to cefiderocol with an MIC of >16 µg/mL. There was a mutation resulting in amino acid deletions at positions 294 and 295 of the R2 loop of the AmpC β-lactamase[4]
- **Shields et al (2020)** reported 2 patients with carbapenem-resistant (CR) strains of the *E. cloacae* complex who had been treated with cefepime, but not with cefiderocol or ceftazidime-avibactam. One *E. hormaechei* strain was resistant to cefiderocol with an MIC >16 µg/mL. The other *E. hormaechei* strain was susceptible to cefiderocol with an MIC of 4 µg/mL. Both strains had the same 2-amino acid deletion at positions 292 and 293 in the R2 loop of the AmpC β-lactamase[5]
- **Grande Perez et al (2021)** described a case report of a hospitalized patient who developed an extensively-drug resistant (XDR) *Pseudomonas aeruginosa* pancreatic infection that was susceptible to cefiderocol and colistin (MICs not reported). The patient received cefiderocol treatment for 6 weeks resulting in clinical improvement; however, they then developed an ischial eschar with detected XDR *P. aeruginosa* that was phenotypically identical to the previous XDR *P. aeruginosa* which was now resistant to cefiderocol (MIC of 8 µg/mL) and produced a GES β-lactamase[6]
- **Streling et al (2020)** identified a strain of *P. aeruginosa* from a patient with no prior cefiderocol treatment that was treated with meropenem and showed reduced susceptibility to cefiderocol (MIC of 8 µg/mL). The isolate had MICs against meropenem and ceftazidime-avibactam of >8 µg/mL and >16 µg/mL, respectively. Mutations in the *piuD* and *pirR* genes that encode iron transporters were revealed, resulting in premature stop codons and would be predicted to cause loss of cefiderocol transport into the bacterium, resulting in a higher MIC[7]
- **Tiseo et al (2021)** reported a case of a 68-year-old patient who developed bacteremia caused by KPC-producing *Klebsiella pneumoniae* which was initially resistant to meropenem and susceptible to

ceftazidime-avibactam and cefiderocol (MIC of 2 µg/mL). After treatment with ceftazidime-avibactam, another isolate of *K. pneumoniae* was obtained that was resistant to cefiderocol (MICs of 16 µg/mL and 8 µg/mL based on various broth microdilution methods). This isolate harbored a KPC-3 variant with a D179Y substitution that is known to confer resistance to ceftazidime-avibactam and restore susceptibility to carbapenems[8]

- **Coppi et al (2022)** described an outbreak of cefiderocol-resistant NDM-1-producing *K. pneumoniae* in a tertiary care center in Florence, Italy from August 2021 to June 2022. Cefiderocol susceptibility testing revealed 21 cases of cefiderocol resistance (MIC ranges from 4 to >64 mg/L), in patients with no previous exposure to cefiderocol. Alterations in the *cirA* siderophore receptor gene and missense mutations in *baeS* gene, or *envZ* gene, which are involved in the expression of *fiu* and *cirA* iron-uptake genes, were found[9]
- **Simner et al (2021)** reported a case of a 35-year-old female with intra-abdominal infection (IAI) caused by CR *Escherichia coli*, which was initially susceptible to cefiderocol. Following treatment for 19 days, cefiderocol-resistant *E. coli* was isolated with increased copy number of the gene encoding NDM-5 metallo-β-lactamase in addition to single nucleotide polymorphisms in genes related to iron transport, cell transportation and development of antibiotic resistance[10]
- **Price et al (2021)** identified a case of bacteremia in a 55-year-old patient being evaluated for liver transplant with 2 isolates of CR *E. coli* found to be resistant to cefiderocol (zone diameter, 7 mm and MIC >32 µg/mL) despite no prior exposure to cefiderocol. Whole genome sequencing confirmed the presence of a $bla_{\text{NDM-5}}$-producing *E. coli* in both isolates. Additional analysis showed a 4-amino-acid insertion (YRIN) in PBP3-encoding genes and a mutation of *cirA*[11]

2. RETROSPECTIVE STUDIES

Falcone et al (2022) completed an observational retrospective cohort study in 124 patients with CRAB infections who received cefiderocol (n=47) or colistin-based regimens (n=77). Patients included were consecutively hospitalized at the University Hospital of Pisa in Italy between June 2019 to August 2021.[1]

- Microbiological failure rates were calculated in patients that had available follow-up cultures (120/124). The difference in microbiological failure between the 2 groups was not statistically significant (*P*=0.079), with failure in 8/46 (17.4%) patients in the cefiderocol arm and 5/74 (6.8%) patients in the colistin group
- The 8 cefiderocol patients that experienced microbiological failure included 7 patients with burns
- Of the 8 patients that experienced microbiological failure in the cefiderocol group, there were 4 isolates (50%) with resistant MICs (based on European Committee on Antimicrobial Susceptibility Testing [EUCAST] breakpoints of 4 to ≥32 µg/mL)
    - Of the 4 cases with resistant MICs, 2 developed during treatment and the other 2 emerged after treatment when cefiderocol was discontinued

Smoke et al (2022) described 11 critically ill burn patients with CRAB infections who were treated with cefiderocol for >48 hours (h). The median duration for the initial course of cefiderocol treatment was 9 days (3-21). Susceptibility testing was performed on 34 isolates collected from 10 patients.[2]

- Baseline isolates collected prior to treatment were available for 6 patients, of which 4 (67%) were cefiderocol-resistant CRAB. There were 4 patients with only post-treatment isolates available for susceptibility testing, of which 2 (50%) were infected with isolates resistant to cefiderocol
    - Further analysis demonstrated that all 6 cefiderocol-resistant isolates harbored disrupted *piuA* (a TonB-dependent siderophore receptor gene) and *pirA* (a ferric enterobactin gene) genes, including in patients not previously treated with cefiderocol
- Analyses performed on 11 CRAB isolates from 9 patients revealed all isolates as *A. baumannii* ST2 and ST208 harboring $bla_{\text{OXA-23}}$, $bla_{\text{OXA-66}}$, and $bla_{\text{ADC-73}}$

- Paired cefiderocol-susceptible and cefiderocol-resistant isolates were collected from 1 patient following a 10-day course of cefiderocol treatment and demonstrated an MIC of 0.5 µg/mL. An additional 10 days of treatment (total of 20 days) resulted in an increase of MIC to >32 µg/mL

3. CASE REPORTS

<u>*Enterobacter cloacae* complex</u>

Klein et al (2021) identified 5 cefiderocol-resistant isolates of *E. cloacae* from a 58-year-old patient subsequent to 3 weeks of cefiderocol treatment.[3]

- The patient initially presented with a bloodstream infection and IAI following successful orthotopic liver re-transplantation. *K. pneumoniae* and a CR *E. cloacae* harboring NDM and OXA-48 β-lactamases were isolated
- Treatment was initiated with colistin and meropenem, however therapy was switched on Day 75 to cefiderocol (1-2 grams [g] every 8 h [q8h]) due to severe neurological side effects and colistin resistance
- After 3 weeks of cefiderocol treatment, 4 isolates had an MIC of 256 µg/mL and 1 had an MIC >256 µg/mL
    - All 5 isolates were also resistant to ceftazidime-avibactam with an MIC >16 µg/mL. Each strain possessed an OXA-48 β-lactamase and a NDM β-lactamase. In addition, the resistant isolates had mutations in the *cirA* gene that encodes a siderophore receptor
- The patient's clinical status worsened and expired on Day 107 due to consecutive necrosis of the bile duct, as well as intrahepatic abscesses and no curative surgical option due to the lack of arterial vascularization

Kawai et al (2020) described a MDR *E. cloacae* strain isolated from a patient who had not been administered either ceftazidime or cefiderocol (patient had not been treated with cephalosporins but had received meropenem and piperacillin-tazobactam).[4]

- The strain exhibited resistance to meropenem, ceftazidime-avibactam, and cefiderocol, with MICs of 16 µg/mL, 8 µg/mL, and >16 µg/mL, respectively
    - There was a mutation resulting in amino acid deletions at positions 294 and 295 of the R2 loop of the AmpC β-lactamase

Shields et al (2020) reported the isolation of CR strains of *E. cloacae* complex from 2 independent patients who had been treated with cefepime, but not with cefiderocol or ceftazidime-avibactam.[5]

- One *E. hormaechei* strain was resistant to cefepime (MIC >256 µg/mL), ceftazidime-avibactam (MIC of 64 µg/mL), cefiderocol (MIC >16 µg/mL) and meropenem (MIC of 8 µg/mL)
- The other *E. hormaechei* strain was also resistant to cefepime (MIC of 256 µg/mL) and ceftazidime-avibactam (MIC of 64 µg/mL) and was susceptible to cefiderocol with an MIC of 4 µg/mL
- The 2 strains had the same 2-amino acid deletion at positions 292 and 293 in the R2 loop of the AmpC β-lactamase

<u>*Pseudomonas aeruginosa*</u>

Grande Perez et al (2021) described a case report of a hospitalized patient who developed an XDR *P. aeruginosa* pancreatic infection that was susceptible to cefiderocol and colistin (MICs not reported).[6]

- After 6 weeks of colistin, cefiderocol (2 g q8h infused over 3 h), and metronidazole (500 mg three times daily), the patient showed clinical improvement and cefiderocol was discontinued

- The patient then developed an ischial eschar with detected XDR *P. aeruginosa* that was phenotypically identical to the previous XDR *P. aeruginosa*. This isolate was now resistant to cefiderocol (MIC of 8 µg/mL) and produced a GES β-lactamase
    - The patient also developed right ankle arthritis due to ESBL *Citrobacter koseri* that was resistant to cefiderocol (MIC of 16 µg/mL) that produced a CTX-M and OXA-1 β-lactamase
- The patient eventually expired due to an XDR *P. aeruginosa*-associated pneumonia

Streling et al (2020) identified a strain of *P. aeruginosa* from a patient that was treated with meropenem and showed reduced susceptibility to cefiderocol (MIC of 8 µg/mL), even though the patient had no prior exposure to cefiderocol.[7]

- The isolate was obtained as a colony in a zone of inhibition and had MICs against meropenem and ceftazidime-avibactam >8 µg/mL and >16 µg/mL, respectively
- A genetic analysis revealed mutations in the *piuD* and *pirR* genes that encode iron transporters. Both mutations resulted in premature stop codons and would be predicted to cause loss of cefiderocol transport into the bacterium, resulting in a higher MIC

<u>*Klebsiella pneumoniae*</u>

Tiseo et al (2021) reported a case of a 68-year-old patient who developed bacteremia caused by KPC-producing *K. pneumoniae* which was initially resistant to meropenem (MIC of 64 µg/mL) and susceptible to ceftazidime-avibactam (MIC of 1 µg/mL) and cefiderocol (MIC of 2 µg/mL).[8]

- After treatment with ceftazidime-avibactam, another isolate of *K. pneumoniae* was obtained that was resistant to cefiderocol (MIC of 16 µg/mL via iron-depleted cation-adjusted Mueller-Hinton broth microdilution [ID-CAMHB] and MIC of 8 µg/mL via Sensititre™ broth microdilution)
- Susceptibility to meropenem was restored in this isolate with an MIC of 2 µg/mL. This isolate harbored a KPC-3 variant with a D179Y substitution that is known to confer resistance to ceftazidime-avibactam and restore susceptibility to carbapenems

Coppi et al (2022) described an outbreak of cefiderocol-resistant NDM-1-producing *K. pneumoniae* in a tertiary care center in Florence, Italy from August 2021 to June 2022.[9]

- Cefiderocol susceptibility testing was retrospectively analyzed using reference broth microdilution with iron-depleted medium on 52 cases, revealing 21 cases of cefiderocol resistance (MIC ranges from 4 to >64 mg/L), all in patients with no previous exposure to cefiderocol
- Of these 21 cases, 17 isolates were found to carry an alteration in the *cirA* siderophore receptor gene, resulting in high-level resistance (MICs ≥ 32 mg/L)
    - Four isolates carried missense mutations in *baeS* gene, or *envZ* gene, which are involved in the expression of *fiu* and *cirA* iron-uptake genes, that was associated with low-level resistance (MICs of 4-8 mg/L)
- All cefiderocol-resistant isolates were also resistant to beta-lactams, including beta-lactam/beta-lactamase inhibitor antibiotics, fluoroquinolones, and aminoglycosides that were tested

<u>*Escherichia coli*</u>

Simner et al (2021) reported a case of a 35-year old patient with leukemia and IAI who was initially administered meropenem. Three days later, a CR *E. coli* expressing NDM-5 β-lactamase susceptible to cefiderocol was identified (MIC of 2 µg/mL, isolate 1).[10]

- On Day 3, just prior to cefiderocol treatment, a new isolate was collected from a drainage place into the pelvic abscess, which was susceptible to cefiderocol (MIC of 2 µg/mL, isolate 2). Meropenem treatment was switched to cefiderocol (2 g q8h infused over 3 h) and gentamicin
    - On Day 7, the patient switched to cefiderocol monotherapy (2 g q8h infused over 3 h) and on Day 17 tigecycline was added due to fevers
- After 19 days of cefiderocol treatment, 1 *E. coli* isolate, which was still susceptible to cefiderocol (MIC of 4 µg/mL, isolate 3), and a cefiderocol-resistant *E. coli* (MIC of 32 µg/mL, isolate 4) were collected from the urine
- After 24 days of treatment with cefiderocol, a new cefiderocol-resistant *E. coli* isolate was collected from the blood (MIC of 32 µg/mL, isolate 5). Cefiderocol treatment was switched to ceftazidime-avibactam plus aztreonam on Day 36 and continued until Day 65
- The 2 cefiderocol-resistant *E. coli* isolates (isolates 4 and 5) had increased copy number of the gene encoding NDM-5 enzyme (isolate 4: 5 copies, isolate 5: 10 copies). Single nucleotide polymorphisms in the *envZ, marR, and aroP* genes were also found in isolate 5, which are related to regulation of iron transport, multiple antibiotic resistance, and cell transportation, respectively

Price et al (2021) identified a case of bacteremia in a liver transplant candidate with two isolates of CR *E. coli* found to be resistant to cefiderocol (zone diameter, 7 mm and MIC >32 µg/mL) despite no prior exposure to cefiderocol.[11]

- Isolates were resistant to fluoroquinolones, aztreonam, carbapenems, tobramycin, cephalosporins, trimethoprim-sulfamethoxazole, and multiple β-lactam/β-lactamase combinations
- Whole genome sequencing confirmed the presence of $bla_{\text{NDM-5}}$ in both isolates. Additional analysis showed a 4-amino-acid insertion (YRIN) in PBP3-encoding genes (a target for beta-lactam antibiotics) and a mutation of *cirA*

4. PRESCRIBING INFORMATION

Fetroja® is indicated in patients 18 years of age or older for the treatment of:[12]

- 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

- 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*

Fetroja is contraindicated in:[12]

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

Please read the attached Fetroja **Full Prescribing Information**.

Back to the top

5. LITERATURE SEARCH

As of January 2025, a computerized search of the published medical literature using internal and external databases (ie, Medline® and Embase®) identified several references regarding patients with resistance to cefiderocol. For your review, these references are listed in the bibliography that follows:

Deroche L, Rozenholc A, Arrivé F, et al. Emergence of cefiderocol resistance during therapy in NDM-5-producing *Klebsiella pneumoniae* isolates harboring siderophore receptors mutations. *Int J Infect Dis*. 2025;151:107321. doi: 10.1016/j.ijid.2024.107321.

Teran N, Egge SL, Phe K, Baptista RP, Tam VH, Miller WR. The emergence of cefiderocol resistance in *Pseudomonas aeruginosa* from a heteroresistant isolate during prolonged therapy. *Antimicrob Agents Chemother*. 2024;68(1):e0100923. doi: 10.1128/aac.01009-23.

Findlay J, Bianco G, Boattini M, Nordmann P. *In vivo* development of cefiderocol resistance in carbapenem-resistant *Acinetobacter baumannii* associated with the downregulation of a TonB-dependent siderophore receptor, PiuA. *J Antimicrob Chemother*. 2024;79(4):928-930. doi: 10.1093/jac/dkae018.

Senchyna F, Murugesan K, Rotunno W, Nadimpalli SS, Deresinski S, Banaei N. Sequential treatment failure with aztreonam-ceftazidime-avibactam followed by cefiderocol due to preexisting and acquired mechanisms in a New Delhi Metallo-β-lactamase-producing *Escherichia coli* causing fatal bloodstream infection. *Clin Infect Dis*. 2024;78(6):1425-1428. doi: 10.1093/cid/ciad759.

Freiberg JA, Tao L, Manuel C, et al. A multi-species outbreak of VIM-producing carbapenem-resistant bacteria in a burn unit and subsequent investigation of rapid development of cefiderocol resistance. Antimicrob Agents Chemother. 2024;68(4):e0150723. doi: 10.1128/aac.01507-23.

Rodríguez-Aguirregabiria M, Lázaro-Perona F, Cacho-Calvo JB, et al. Challenges facing two outbreaks of carbapenem-resistant *Acinetobacter baumannii*: from cefiderocol susceptibility testing to the emergence of cefiderocol-resistant mutants. *Antibiotics (Basel)*. 2024;13(8):784. doi: 10.3390/antibiotics13080784.

Huang E, Thompson RN, Moon SE, et al. Treatment-emergent cefiderocol resistance in carbapenem-resistant *Acinetobacter baumannii* is associated with insertion sequence IS *Aba36* in the siderophore receptor *pirA*. *Antimicrob Agents Chemother*. 2024;68(7):e0029024. doi: 10.1128/aac.00290-24.

Alteri C, Teri A, Liporace MF, et al. Transmission cluster of cefiderocol-non-susceptible carbapenem-resistant *Acinetobacter baumannii* in cefiderocol-naïve individuals. *Ann Clin Microbiol Antimicrob*. 2024;23(1):104. doi: 10.1186/s12941-024-00763-7.

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McGann P, Geringer MR, Hall LR, et al. Pan-drug resistant *Providencia rettgeri* contributing to a fatal case of COVID-19. *J Med Microbiol*. 2021;70(8):001406. doi: 10.1099/jmm.0.001406

Lan P, Lu Y, Chen Z, et al. Emergence of high-level cefiderocol resistance in carbapenem-resistant *Klebsiella pneumoniae* from bloodstream infections in patients with hematologic malignancies in China. *Microbiol Spectr*. 2022;10(2): e0008422. doi: 10.1128/spectrum.00084-22

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 it should not be considered all-inclusive.

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

ENCLOSURE

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Back to the top