

A.7 - Cefiderocol

MSF supports the inclusion of cefiderocol in section 6.2.3 Reserve group antibiotics, in the WHO Model List of Essential Medicines (EML), for the treatment of confirmed or suspected infections due to multi-drug-resistant (MDR) organisms.

The Reserve group of the AWARe classification includes antibiotics that should be reserved for treatment of confirmed or suspected infections due to MDR organisms. Furthermore and according to the 2019 AWARe classification, antibiotics in Reserve group “should be treated as last resort options. These antibiotics should be accessible, but their use should be tailored to highly specific patients and settings, when all alternatives have failed or are not suitable”.

Antimicrobial resistance (AMR) is a major, and growing, threat to global public health with an estimated 700,000 related deaths every year globally. While AMR can affect many antibiotic groups and many organisms’ species, Gram-negative organisms are a growing source of concern due to their potential intrinsic resistance to antibacterials and the emergence of acquired resistance. Gram-negative organisms can cause infections in many sites including urinary tract, lungs, bloodstream, and gastro-intestinal tract, and are often involved in healthcare associated infections.

In particular, *Acinetobacter baumannii*, *Pseudomonas aeruginosa*, and *Enterobacteriaceae* are of major concern due to the increasing prevalence of Carbapenem resistance seriously limiting therapeutic options with the existing antibacterial agents.

Cefiderocol is a newly developed antimicrobial medicine that has not yet been included in many formal clinical guidelines. However, its efficacy in the treatment of serious infections in adult patients, hospital-acquired bacterial pneumonia (HABP), ventilator-associated bacterial pneumonia (VABP) or healthcare-associated pneumonia caused by Gram-negative pathogens has been shown in two clinical trials. Cefiderocol appears also to be well tolerated with a side effect profile that is comparable to other cephalosporin antimicrobials.

In 2019, cefiderocol has received the Food and Drug Administration (FDA) approval for the treatment of adult patients with complicated urinary tract infections (cUTI), including pyelonephritis, and hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia caused by Gram-negative bacteria including: *Escherichia coli*, *Klebsiella pneumoniae*, *Proteus mirabilis*, *Pseudomonas aeruginosa*, *Enterobacter cloacae* complex,

Acinetobacter baumannii complex, *Escherichia coli*, and *Serratia marcescens*. In 2020, the European Medicines Agency (EMA) has approved cefiderocol for the treatment of infections due to aerobic Gram-negative organisms in adults with limited treatment options.

Therefore it appears that cefiderocol is an interesting development that could help address the increasing number of infections caused by carbapenem-resistant and MDR Gram-negative bacilli, including extended-spectrum beta-lactamase- and carbapenemase-producing strains.


Cefiderocol is a new and expensive antibiotic, recently approved by FDA and EMA, available mostly in high-income countries. MSF highlights the issue of the availability and affordability of this very effective antibiotic in the low- and middle-income countries.

The inclusion of cefiderocol in the EML will serve as a basis for National Essential Medicines lists and therefore will attract additional manufacturers, facilitate importations, alert manufacturers about the need for local registrations, allow for better competition between manufacturers in order to reduce price and improve accessibility, particularly in low- and middle-income countries, and will give a strong signal to manufacturers, generic producers, country programs, international donors, and health regulatory authorities.

Improving use of antibiotics through antibiotic stewardship is a key intervention necessary to curb the further emergence and spread of AMR. MSF highlights the need to protect and prioritize stewardship programs involving monitoring and utilization reporting, to preserve effectiveness of Reserve group antibiotics with the aim of reducing antimicrobial resistance.

In light of these elements, MSF urges the 23rd Expert Committee on the Selection and Use of Essential Medicines to include cefiderocol in the section 6.2.3 Reserve group antibiotics in the WHO Model List of Essential Medicines, for the treatment of confirmed or suspected infections due to multi-drug-resistant organisms.

For Médecins Sans Frontières



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