Gemeinsamer Bundesausschuss

Resolution

of the Federal Joint Committee on an Amendment of the Pharmaceuticals Directive:
Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a SGB V
Cefiderocol (infections due to aerobic Gram-negative organisms)

of 5 May 2022

At its session on 5 May 2022, the Federal Joint Committee (G-BA) resolved to amend the Pharmaceuticals Directive (AM-RL) in the version dated 18 December 2008 / 22 January 2009 (Federal Gazette, BAnz. No. 49a of 31 March 2009), as last amended by the publication of the resolution of D Month YYYY (Federal Gazette, BAnz AT DD.MM.YYYY BX), as follows:

I. Annex XII shall be amended in alphabetical order to include the active ingredient Cefiderocol as follows:

Cefiderocol

Resolution of: 5 May 2022
Entry into force on: 5 May 2022
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 23 April 2020):

Fetcroja is indicated for the treatment of infections due to aerobic Gram-negative organisms in adults with limited treatment options.

Therapeutic indication of the resolution (resolution of 5 May 2022):

See therapeutic indication according to marketing authorisation.

1. Additional benefit of the medicinal product

For the medicinal product Fetcroja with the active ingredient cefiderocol, an exemption from the obligation to submit the evidence according to Section 35a, paragraph 1, sentence 3, numbers 2 and 3 SGB V was granted by resolution of 21 October 2021, as it is a reserve antibiotic within the meaning of Section 35a, paragraph 1c, sentence 1 SGB V. The additional benefit is deemed to be proven if the Federal Joint Committee has decided on an exemption for a reserve antibiotic in accordance with Section 35a, paragraph 1c, sentence 1 SGB V; the extent of the additional benefit and its therapeutic significance are not to be assessed by the Federal Joint Committee. By resolution pursuant to Section 35a, paragraph 3, sentence 1 SGB V, the Federal Joint Committee shall specify requirements for a quality-assured application of the reserve antibiotic, taking into account the effects on the resistance situation.

<u>Adults with infections due to aerobic Gram-negative organisms with limited treatment options</u>

Additional benefit of Cefiderocol:

The additional benefit is considered proven.

2. Number of patients or demarcation of patient groups eligible for treatment

<u>Adults with infections due to aerobic Gram-negative organisms with limited treatment options</u>

approx. 2,600 – 6,600 patients

3. Requirements for a quality-assured application

Notes on application

The requirements in the product information are to be taken into account.

The European Medicines Agency (EMA) provides the contents of the product information (summary of product characteristics, SmPC) for Fetcroja (active ingredient: cefiderocol) at the following publicly accessible link (last access: 3 December 2021):

https://www.ema.europa.eu/en/documents/product-information/fetcroja-epar-product-information_en.pdf

Cefiderocol may only be used in adults for the treatment of infections due to aerobic Gram-negative organisms with limited treatment options.

Before using cefiderocol, consult a specialist with an additional qualification in infectiology, a specialist in internal medicine and infectiology, or a specialist in microbiology, virology and epidemiology of infectious diseases. In case of unavailability of the above-mentioned groups of specialists at the time of use, a specialist with appropriate experience in the treatment of infectious diseases with multi-drug resistant pathogens must be consulted.

Additional antibiotics must be used if it is known or suspected that Gram-positive or anaerobic organisms are also involved in the infection.

Patients with a history of hypersensitivity to carbapenems, penicillins or other beta-lactam antibiotics may also be hypersensitive to cefiderocol. Before initiating cefiderocol therapy, it should be carefully clarified whether hypersensitivity reactions to betalactam antibiotics have occurred in the past. If a severe allergic reaction occurs, treatment with Fetcroja must be discontinued immediately and appropriate emergency treatment initiated.

Notes on pathogen detection

The reserve antibiotic may only be used as part of a targeted therapy. Before use, the causative pathogen and sensitivity to pathogen must always be proven by microbiological diagnostics of appropriate clinical material.

A calculated (empirical) use of cefiderocol without pathogen detection should only be carried out in exceptional cases. These include a known resistance problem in the treatment facility or in the case of a transfer from a facility with a known resistance problem, as well as in the case of a lack of therapeutic response to standard antibiotic therapy in the case of a serious infection and urgent suspicion that the infection is caused by multi-drug resistant aerobic Gram-negative pathogens. Samples for pathogen detection must be taken before the start of treatment. The calculated therapy must usually be adjusted after a maximum of 72 hours, if necessary, when an antibiogram is available.

Cefiderocol may not be used if the pathogen shows sensitivity to other antibiotics (without reserve status), unless other antibiotics cannot be used, for example because of contraindications or expected severe complications.

Notes on implementation

The current guidelines of the AWMF and medical and, if applicable, also international scientific-medical societies for the appropriate use of antibiotics must be taken into account. Furthermore, reference should be made to the listed requirements for a quality-assured application of cefiderocol in the locally available treatment guidelines and regulations of the measures for restrictive antibiotic use.

The aforementioned specifications are to be implemented within the framework of regulations of the hospital's Drug Commission. Implementation should take place in particular within the framework of the in-house Antibiotic Stewardship Programme (ABS)[1].

The treatment facility or clinic must have a local clearance policy for the use of cefiderocol in the respective treatment facility.

The restriction measures shall be drafted and explained in writing.

Consumption and resistance surveillance in accordance with Section 23 paragraph 4 Infection Protection Act must be implemented. This is to be done through participation in the AVS (Antibiotic Consumption Surveillance) and ARS (Antibiotic Resistance Surveillance) or ARVIA (ARS and AVS – Integrated Analysis) systems. In the absence of participation so far, the reporting of consumption and resistance data on cefiderocol to the said systems shall still be ensured within six months at the latest from the entry into force of this resolution. Until participation, consumption and resistance surveillance must be ensured via the existing systems.

The principles of antibiotic therapy of the Commission on Anti-infectives, Resistance and Therapy (ART) at the Robert Koch Institute must be observed (last accessed: 11.04.2022):

https://www.rki.de/DE/Content/Kommissionen/ART/Links/Grundsaetze-der-Therapie.html

4. Treatment costs

Annual treatment costs:

Adults with infections due to aerobic Gram-negative organisms with limited treatment options

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Cefiderocol	€ 5,355.00 - € 23,205.00

Cost of the clinic pack plus value added tax of 19% (LAUER-TAXE® last revised: 15 April 2022)

[1] See S3 guideline: strategies to ensure rational antibiotic use in hospitals, 2018 update: https://www.awmf.org/uploads/tx_szleitlinien/092-001l_S3_Strategien-zur-Sicherung-rationaler-Antibiotika-Anwendung-im-Krankenhaus_2020-02.pdf

Costs for additionally required SHI services: not applicable

Other SHI services:

Designation of the therapy	Type of service	Costs/ unit	Number/ treatment day	Number/ patient/ year	Costs/ patient/ year
Cefiderocol	Surcharge for the preparation of an infusion solution containing antibiotics and virustatics	€ 39	3	15 – 63	€ 585 – € 2,457

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 5 May 2022.

The justification to this resolution will be published on the website of the G-BA at www.g-ba.de.

Berlin, 5 May 2022

Federal Joint Committee (G-BA)
in accordance with Section 91 SGB V
The Chair

Prof. Hecken