Eravacycline (complicated intra-abdominal infections (cIAI))

Resolution of: 19 January 2023 valid until: unlimited
Entry into force on: 19 January 2023
Federal Gazette, BAnz AT 17 02 2023 B5

Therapeutic indication (according to the marketing authorisation of 20 September 2018):

Xerava is indicated for the treatment of complicated intra-abdominal infections (cIAI) in adults.

Consideration should be given to official guidelines on the appropriate use of antibacterial agents.

Therapeutic indication of the resolution (resolution of 19.01.2023):

See therapeutic indication according to marketing authorisation.

1. Extent of the additional benefit and significance of the evidence

For the medicinal product Xerava with the active ingredient eravacycline, an exemption from the obligation to submit the evidence according to Section 35a paragraph 1 sentence 3 number 2 and 3 SGB V was granted by resolution of 21 April 2022, 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.

Adults with complicated intra-abdominal infections (cIAI)

Additional benefits of eravacycline:

The additional benefit is considered proven.

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

Adults with complicated intra-abdominal infections (cIAI)

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 Xerava (active ingredient: eravacycline) at the following publicly accessible link (last access: 05.12.2022):

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

The requirements for a quality-assured application of eravacycline apply to the approved therapeutic indications as of July 2022.

Eravacycline may only be used for the treatment of complicated intra-abdominal infections (cIAI) in adults if there is evidence or, in exceptional cases, urgent suspicion that the infection is caused by multi-drug resistant pathogens on the RKI pathogen list and only limited treatment options are available (see also notes on pathogen detection).

Before using eravacycline, 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.

Serious and occasionally fatal hypersensitivity reactions are possible and have been reported with other antibiotics of the tetracycline class. In case of hypersensitivity reactions, treatment with eravacycline must be discontinued immediately and appropriate emergency measures must be 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 eravacycline 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 pathogens of the RKI pathogen list, as far as a sensitivity to eravacycline is to be expected. 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.

Eravacycline 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 eravacycline 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 eravacycline 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.

The reporting of consumption and resistance data on eravacycline to the above systems should be ensured by 1 January 2024 at the latest.

Until participation in the mentioned systems, consumption and resistance situation 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 access: 05.12.2022):

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

4. Treatment costs

Annual treatment costs:

Adults with complicated intra-abdominal infections (cIAI)

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Eravacycline	€ 1,487.50 - € 4,462.50

[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 after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 January 2023)

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
Eravacycline	Surcharge for the preparation of an infusion solution containing antibiotics and virustatics	€ 39	2	8 – 28	€ 312 - € 1,092

5. Medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V that can be used in a combination therapy with Eravacycline

Medicinal products with the following new active ingredients pursuant to Section 35a, paragraph 3, sentence 4 SGB V are medicinal products with the following new active ingredients that can be used in a combination therapy with eravacycline for the treatment of complicated intra-abdominal infections (cIAI) on the basis of the marketing authorisation granted under Medicinal Products Act:

Adults with complicated intra-abdominal infections (cIAI)

No active ingredient that can be used in a combination therapy that fulfils the requirements of Section 35a, paragraph 3, sentence 4 SGB V.