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
Eravacycline (new therapeutic indication: complicated intra-abdominal infections (cIAI), ≥ 12 to < 18 years, ≥ 50 kg)

From 16 July 2026

At their session on 16 July 2026, 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. In Annex XII, the following information shall be added after number 5 to the information on the benefit assessment of Eravacycline in accordance with the resolution of 19 January 2023:

Eravacycline

Resolution of: 16 July 2026
Entry into force on: 16 July 2026
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 24 December 2025):

Xerava is indicated in adolescents from the age of 12 years weighing at least 50 kg for the treatment of complicated intra-abdominal infections (cIAI).

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

Therapeutic indication of the resolution (resolution of 16 July 2026):

See new 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, numbers 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 have 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. In the resolution according 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>Adolescents aged 12 to < 18 years weighing ≥ 50 kg with complicated intra-abdominal infections (cIAI)</u>

Additional benefit of eravacycline:

The additional benefit is considered proven.

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

<u>Adolescents aged 12 to < 18 years weighing ≥ 50 kg with complicated intra-abdominal infections (cIAI)</u>

Approx. 175 – 440 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: 10 June 2026):

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 new therapeutic indications as of February 2026.

Eravacycline may only be used for the treatment of complicated intra-abdominal infections (cIAI) in adolescents from the age of 12 years weighing at least 50 kg 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 multidrug-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 must 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).

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 (IPA) 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-mentioned systems should be ensured within six months of the entry into force of this resolution. 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: 10 June 2026):

https://www.rki.de/DE/Themen/Infektionskrankheiten/Antibiotikaresistenz/Kommission-ART/Weitere-Dokumente/Grundsaetze-der-Therapie.html

4. Treatment costs

Annual treatment costs

Adolescents aged 12 to < 18 years weighing ≥ 50 kg with complicated intra-abdominal infections (cIAI)

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Eravacycline	€ 1,487.50 – € 2,975.00

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 15 May 2026)

Costs for additionally required SHI services: not applicable

5. Designation of 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 the assessed medicinal product

In the context of the designation of medicinal products with new active ingredients pursuant to Section 35a, paragraph 3, sentence 4 SGB V, the following findings are made:

Adolescents aged 12 to < 18 years weighing ≥ 50 kg with complicated intra-abdominal infections (cIAI)

– No designation of medicinal products with new active ingredients that can be used in combination therapy in accordance with Section 35a, paragraph 3, sentence 4 SGB V, as the G-BA have decided to exempt the assessed medicinal product as a reserve antibiotic in accordance with Section 35a, paragraph 1c, sentence 1 SGB V.

The designation of combinations exclusively serves the implementation of the combination discount according to Section 130e SGB V between health insurance funds and pharmaceutical companies. The findings made neither restrict the scope of treatment required to fulfil the medical treatment mandate, nor do they make statements about expediency or economic feasibility.

II. The resolution will enter into force on the day of its publication on the G-BA website on 16 July 2026.

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

Berlin, 16 July 2026

Federal Joint Committee
in accordance with Section 91 SGB V
The Chair

Dr Optendrenk