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
Imipenem/ cilastatin/ relebactam (new therapeutic indication: bacterial infections, multiple therapeutic indications, < 18 years)

From 6 August 2026

At their session on 6 August 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 No. 4 to the information on the benefit assessment of imipenem/ cilastatin/ relebactam in accordance with the resolution of 3 November 2022:

Imipenem/ cilastatin/ relebactam

Resolution of: 6 August 2026
Entry into force on: 6 August 2026
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 19 January 2026):

Recarbrio is indicated in paediatric patients from birth for:

- Treatment of hospital-acquired pneumonia (HAP), including ventilator-associated pneumonia (VAP).
- Treatment of bacteraemia that occurs in association with, or is suspected to be associated with HAP or VAP.
- Treatment of infections due to aerobic Gram-negative organisms with limited treatment options.

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

Therapeutic indication of the resolution (resolution of 6 August 2026):

See new therapeutic indication according to marketing authorisation.

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

For the medicinal product Recarbrio with the active ingredient imipenem/ cilastatin/ relebactam, 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 20 January 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.

a) <u>Paediatric patients aged < 18 years with hospital-acquired pneumonia (HAP), including ventilator-associated pneumonia (VAP)</u>

Additional benefit of imipenem/ cilastatin/ relebactam:

The additional benefit is considered proven.

b) <u>Paediatric patients aged < 18 years with bacteraemia that occurs in association with, or is suspected to be associated with HAP or VAP</u>

Additional benefit of imipenem/ cilastatin/ relebactam:

The additional benefit is considered proven.

c) Paediatric patients aged < 18 years with infections due to aerobic Gram-negative organisms with limited treatment options

Additional benefit of imipenem/ cilastatin/ relebactam:

The additional benefit is considered proven.

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

a) Paediatric patients aged < 18 years with hospital-acquired pneumonia (HAP), including ventilator-associated pneumonia (VAP)

and

b) Paediatric patients aged < 18 years with bacteraemia that occurs in association with, or is suspected to be associated with HAP or VAP

and

c) Paediatric patients aged < 18 years with infections due to aerobic Gram-negative organisms with limited treatment options

Approx. 520 – 1,300 patients

3. Requirements for a quality-assured 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 Recarbrio (active ingredient: imipenem/ cilastatin/ relebactam) at the following publicly accessible link (last access: 25 February 2026):

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

The following requirements for a quality-assured application of imipenem/ cilastatin/ relebactam apply to all new approved therapeutic indications as of January 2026.

Imipenem/ cilastatin/ relebactam may be used in paediatric patients from birth for:

- the treatment of hospital-acquired pneumonia (HAP), including ventilator-associated pneumonia (VAP),
- the treatment of bacteraemia that occurs in association with, or is suspected to be associated with HAP or VAP and
- the treatment of infections due to aerobic Gram-negative organisms with limited treatment options

only if there is evidence or, in exceptional cases, an urgent suspicion that the infection is caused by multi-drug resistant aerobic Gram-negative organisms and only limited treatment options are available (see also information on pathogen detection).

Before using imipenem/ cilastatin/ relebactam, 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 sometimes lethal (anaphylactic) hypersensitivity reactions have been reported in patients receiving beta-lactam antibiotics. These reactions are more likely to occur in subjects with a known history of hypersensitivity to multiple allergens. Before starting treatment with imipenem/ cilastatin/ relebactam, previous hypersensitivity reactions to carbapenems, penicillins, cephalosporins, other beta-lactam antibiotics and other allergens should be carefully queried. If an allergic reaction to imipenem/ cilastatin/ relebactam occurs, treatment with Recarbrio must be discontinued immediately. In case of severe anaphylactic reactions, appropriate emergency measures must be taken immediately.

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 imipenem/ cilastatin/ relebactam 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 organisms. 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.

Imipenem/ cilastatin/ relebactam 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 imipenem/ cilastatin/ relebactam 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 imipenem/ cilastatin/ relebactam 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 imipenem/ cilastatin/ relebactam 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: 25 February 2026):

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

4. Treatment costs

Annual treatment costs:

Treatment costs

a) Paediatric patients aged < 18 years with hospital-acquired pneumonia (HAP), including ventilator-associated pneumonia (VAP)

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Imipenem/ cilastatin/ relebactam	€ 7,065.63 – € 21,196.89

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 1 June 2026)

Costs for additionally required SHI services: not applicable

b) Paediatric patients aged < 18 years with bacteraemia that occurs in association with, or is suspected to be associated with HAP or VAP

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Imipenem/ cilastatin/ relebactam	€ 7,065.63 – € 21,196.89

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 1 June 2026)

Costs for additionally required SHI services: not applicable

c) Paediatric patients aged < 18 years 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:	
Imipenem/ cilastatin/ relebactam	€ 7,065.63 – € 21,196.89

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 1 June 2026)

Costs for additionally required SHI services: not applicable

II. The resolution will enter into force on the day of its publication on the G-BA website on 6 August 2026.

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

Berlin, 6 August 2026

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

Dr Optendrenk