Gemeinsamer Bundesausschuss

Justification

for the Resolution of the Federal Joint Committee (G-BA) 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

Contents

1. Legal basis

According to Section 35a paragraph 1 German Social Code, Book Five (SGB V), the Federal Joint Committee (G-BA) assess the benefit of all reimbursable medicinal products with new active ingredients.

Pursuant to Section 35a, paragraph 1c, sentence 1 SGB V, the Federal Joint Committee shall exempt the pharmaceutical company from the obligation to submit the evidence pursuant to Section 35a, paragraph 1, sentence 3, numbers 2 and 3 SGB V (medical benefit and additional medical benefit in relation to the appropriate comparator therapy) upon request, if it is an antibiotic that is effective against infections caused by multidrug-resistant bacterial pathogens with limited treatment options and the use of this antibiotic is subject to a strict medical assessment of the therapeutic indication (reserve antibiotic).

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 the requirements for a quality-assured application of the reserve antibiotic pursuant to Section 35a, paragraph 1c, sentence 8 SGB V, taking into account the effects on the resistance situation. Pursuant to Chapter 5, Section 20, paragraph 6, sentence 3 of the Rules of Procedure (VerfO) of the G-BA, the Federal Joint Committee may lay down restrictive requirements for the use of the antibiotic in order to ensure a strict medical assessment of the therapeutic indication, if this is necessary to maintain the reserve status of the medicinal product. With regard to these requirements for a quality-assured application of the reserve antibiotic, the Federal Joint Committee shall obtain a statement from the Robert Koch Institute (RKI), which shall be prepared in agreement with the Federal Institute for Drugs and Medical Devices (BfArM).

Pursuant to Section 35a, paragraph 3 SGB V, the G-BA pass a resolution on the benefit assessment, taking into account the requirements for a quality-assured application according to Section 35a, paragraph 1c, sentence 8 SGB V, within three months of publication of the resolution. The resolution is to be published on the internet and is part of the Pharmaceuticals Directive.

2. Key points of the resolution

By resolution of 20 January 2022, the Federal Joint Committee decided that the pharmaceutical company is exempted from the obligation to submit evidence in the benefit assessment procedure for the medicinal product Recarbrio with the combination of active ingredients imipenem/ cilastatin/ relebactam according to Section 35a, paragraph 1, sentence 3, numbers 2 and 3 SGB V, since the medicinal product Recarbrio with the combination of active ingredients imipenem/ cilastatin/ relebactam for the treatment of bacterial infections is a reserve antibiotic within the meaning of Section 35a, paragraph 1c, sentence 1 SGB V.

The combination of active ingredients imipenem/ cilastatin/ relebactam (Recarbrio) was listed for the first time on 15 June 2021 in the “LAUER-TAXE®”, the extensive German registry of available medicinal products and their prices.

On 19 January 2026, imipenem/ cilastatin/ relebactam received marketing authorisation for a new therapeutic indication to be classified as a major type 2 variation as defined according to

Annex 2, number 2, letter a to Regulation (EC) No. 1234/2008 of the Commission of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (OJ L 334 from 12.12.2008, sentence 7).

On 11 February 2026, i.e. at the latest within four weeks of informing the pharmaceutical company about the approval for a new therapeutic indication, the pharmaceutical company submitted the final dossier to the G-BA in due time in accordance with Section 4, paragraph 3, number 2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with Chapter 5, Section 8, paragraph 1, number 2 of the Rules of Procedure (VerfO) of the G-BA. In this, the pharmaceutical company submitted evidence pursuant to Section 35a, paragraph 1, sentence 3, numbers 1, 4 and 5 SGB V and evidence on the requirements for a quality-assured application of the reserve antibiotic, taking into account the effects on the resistance situation (Chapter 5 VerfO Annex II. 1 Section 1.4). The assessment procedure began on 15 February 2026.

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 draft of the requirements for a quality-assured application of the reserve antibiotic was made available to the RKI for drafting a statement in agreement with the BfArM in accordance with Section 35a, paragraph 1c SGB V.

The G-BA commissioned the IQWiG to assess the information provided by the pharmaceutical company in Module 3 of the dossier on treatment costs and patient numbers.

The draft of the requirements for a quality-assured application as well as the RKI statement drafted in agreement with the BfArM were published on the G-BA website (www.g-ba.de) together with IQWiG's assessment of treatment costs and patient numbers, thus initiating the written statement procedure. The oral hearing has been dispensed with since all assessment experts who submitted written statements waived their right to make an oral statement.

The G-BA have adopted their resolution on the basis of the dossier of the pharmaceutical company, the draft of the requirements for a quality-assured application prepared by the G-BA taking into account the joint statement of RKI/BfArM, the IQWiG's assessment of treatment costs and patient numbers (IQWiG 26-06) and the written statements.

2.1 Additional benefit of the medicinal product

2.1.1 Approved therapeutic indication of imipenem/ cilastatin/ relebactam (Recarbrio) in accordance with the product information

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 the approved therapeutic indication

2.1.2 Extent of the additional benefit and significance of the evidence

In summary, the additional benefit of imipenem/ cilastatin/ relebactam is assessed as follows:

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

The additional benefit is considered proven.

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

The additional benefit is considered proven.

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

The additional benefit is considered proven.

Justification:

For the medicinal product Recarbrio with the combination of active ingredients 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.

2.1.3 Summary of the assessment

Imipenem/ cilastatin/ relebactam 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.

3 patient groups were formed according to the individual therapeutic indications.

The additional benefit of imipenem/ cilastatin/ relebactam is considered proven for every patient group.

For the medicinal product Recarbrio with the combination of active ingredients 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 specified the requirements for a quality-assured application of the reserve antibiotic pursuant to Section 35a, paragraph 1c, sentence 8 SGB V, taking into account the effects on the resistance situation.

2.2 Number of patients or demarcation of patient groups eligible for treatment

The information on the number of patients is based on the target population in statutory health insurance (SHI). Since the requirements for a quality-assured application for imipenem/ cilastatin/ relebactam result in restrictive use, use is predominantly for infections with Gram-negative organisms.

This enables an approximately analogous calculation of adult patient numbers as in the resolution on cefiderocol (resolution of the G-BA of 5 May 2022) in the therapeutic indication "Infections caused by aerobic Gram-negative organisms for which only limited treatment options are available" (see resolution on imipenem/ cilastatin/ relebactam from 3 November 2022).

The paediatric patient numbers of 145 to 198 (with infections due to aerobic Gram-negative organisms) presented by the pharmaceutical company in the dossier for this resolution were assessed by the IQWiG as mathematically plausible but uncertain. On the one hand, the uncertainty stems from the choice of ICD-10 codes, which may have resulted in the inclusion of cases, where there was merely colonisation by the pathogen in question. On the other, the pharmaceutical company excludes pathogens, for which efficacy has not been demonstrated in clinical studies, but which, according to the product information, may show sensitivity. The restriction applied by the pharmaceutical company to pathogens producing KPC (Klebsiella

pneumoniae carbapenemase) 2 or 3, or to pathogens that do not produce carbapenemase, also gives rise to further uncertainty.

Due to these uncertainties, the information from the resolution on cefiderocol (approximately 2,600 – 6,600 adult patients) was used to present the number of patients (all patient groups) receiving imipenem/ cilastatin/ relebactam, as was already the case for the adult groups (resolution of 3 November 2022). The calculation was made using two different approaches based on data from the RKI and the HISS (Hospital Infection Surveillance System) pathogen surveillance, respectively, for 2019. These patient numbers are also to be assessed as uncertain overall.

According to the Federal Statistical Office[1], children and adolescents from birth to under 18 years of age account for 16.6 per cent of the total population. Based on the percentage of adults (83.4%) and the patient numbers from the resolution on imipenem/ cilastatin/ relebactam and/or cefiderocol, this results in approx. 520 – 1,300 paediatric patients. However, differences in incidence between children, adolescents and adults are not taken into account.

An overall lower number of patients in the SHI target population may result particularly against the background of the restrictive use of imipenem/ cilastatin/ relebactam within the framework of a quality-assured application as a reserve antibiotic.

2.3 Requirements for a quality-assured application

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. The requirements for a quality-assured application are based on the draft prepared by the Federal Joint Committee and the statement of the RKI, which was prepared in agreement with the BfArM. The written statements were taken into account.

About the notes on application

Reference is made to the marketing authorisation requirements.

The requirement that imipenem/ cilastatin/ relebactam may only be used for the treatment of the infections named in the therapeutic indication if only limited treatment options are available results directly from the approved therapeutic indication in the case of the partial therapeutic indication "Infections with Gram-negative organisms" (section 4.1 of the product information). For the other partial therapeutic indications, this requirement is specified within the framework of the requirements for a quality-assured application in the present resolution in order to ensure the strict medical assessment of all therapeutic indications in accordance with Section 35a, paragraph 1c SGB V.

According to the field of expertise, qualified consultation takes place with a specialist in the field of infectiology (internal medicine and infectiology, microbiology, virology and epidemiology of infectious diseases or additional qualification in infectiology) or, if not available, with a specialist from other disciplines who must have appropriate experience in the treatment of infectious diseases with multidrug-resistant pathogens.

[1] Statistisches Bundesamt (Federal Statistical Office). Statistical report: Population projections for 2025 based on the 2022 census (reference date: 31/12/2025). https://www-genesis.destatis.de/datenbank/online/statistic/12411/table/12411-0005

About the notes on pathogen detection

In principle, imipenem/ cilastatin/ relebactam should not be used as part of a calculated (empirical) therapy. The strict medical assessment of the therapeutic indication as a reserve antibiotic requires knowledge of the pathogen. Even in the exceptional cases mentioned, infection with a multi-drug resistant aerobic Gram-negative pathogen is at least probable. As a rule, pathogen detection can be expected after 72 hours at the latest. If the pathogen detection reveals that the pathogen is sensitive to other antibiotics (without reserve status), the therapy must be de-escalated accordingly to avoid unnecessary use of the reserve antibiotic. An empirical therapy with imipenem/ cilastatin/ relebactam should be as short as possible.

About the notes on implementation

In order to implement the requirements for a quality-assured application, it is necessary that they are taken into account in the hospital's internal regulations/ processes. The respective Drug Commission is responsible for integration into the processes. Evidence-based antibiotic stewardship teams are particularly suitable for implementation.

Pursuant to Section 23 paragraph 4 Infection Protection Act, the treatment facility is obliged to carry out consumption and resistance surveillance, whereby there is no specification of the systems to be used. The use of a uniform system is necessary for the future assessment of the resistance and consumption situation. The RKI's ARS, AVS and ARVIA systems aggregate Germany-wide data on antibiotic resistance and consumption. ARS also forms the basis for Germany's participation in international surveillance systems.[2]

For this reason, the participation of clinics using imipenem/ cilastatin/ relebactam in these systems should be sought.

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.

2.4 Treatment costs

The treatment costs are based on the contents of the product information and the information listed in the LAUER-TAXE® (last revised: 1 June 2026). The calculation of treatment costs is generally based on the last revised LAUER-TAXE® version following the publication of the benefit assessment.

The time unit "days" is used to calculate the "number of treatments/ patient/ year", time intervals between individual treatments and for the maximum treatment duration, if specified in the product information.

For dosages depending on body weight, the reference percentiles of the Robert Koch Institute from the "German Health Interview and Examination Survey for Children and Adolescents

[2] For further information, please visit https://ars.rki.de/.

(KiGGS)"[3] were used for the age group under consideration. The average body weights of boys and girls result in an average body weight of 3.46 kg for neonates and 5.22 kg for infants aged two months (as an approximation to < 3 months) as well as 5.87 kg for infants aged ≥ 3 months.

Furthermore, the adolescent dosage based on body weight (BW) was calculated using the average weight from the official representative statistics "2025 Microcensus – body measurements of the population"[4] (average body weight of under-18-year-olds: 67.9 kg).

Patient-individual dose adjustments (e.g. because of side effects or comorbidities) are not taken into account when calculating the annual treatment costs.

The (daily) doses recommended in the product information were used as the calculation basis.

The reconstituted, diluted antibacterial agent solution must be used immediately.

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

Treatment period:

According to the product information, treatment with imipenem/ cilastatin/ relebactam may be required for 7 to 14 days, depending on the type of infection.

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Medicinal product to be assessed				
Imipenem/ cilastatin/ relebactam	From birth to < 3 months 3 x daily	1	7 – 14	7 – 14
	≥ 3 months to < 18 years of age 4 x daily			

[3] Contributions to Federal Health Reporting. Reference percentiles for anthropometric statistics and blood pressure from the German Health Interview and Examination Survey for Children and Adolescents (KiGGS) (2013, both sexes, from birth), https://edoc.rki.de/handle/176904/3254

[4] Federal Health Reporting. Average body measurements of the population (2025, both sexes), www.gbe-bund.de

Consumption:

Designation of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
Medicinal product to be assessed					
Imipenem/ cilastatin/ relebactam	From birth to < 3 months 15 mg/kg imipenem/ 15 mg/kg cilastatin/ 7.5 mg/kg relebactam	3 x 52 mg imipenem/ 52 mg cilastatin/ 26 mg relebactam – 3 x 78 mg imipenem/ 78 mg cilastatin/ 39 mg relebactam	3 x 500 mg/ 500 mg/ 250 mg	7 – 14	21 x 500 mg/ 500 mg/ 250 mg – 42 x 500 mg/ 500 mg/ 250 mg
	≥ 3 months to < 18 years of age 15 mg/kg imipenem/ 15 mg/kg cilastatin/ 7.5 mg/kg relebactam – 500 mg imipenem/ 500 mg cilastatin/ 250 mg relebactam	4 x 88 mg imipenem/ 88 mg cilastatin/ 44 mg relebactam – 4 x 500 mg imipenem/ 500 mg cilastatin/ 250 mg relebactam	4 x 500 mg/ 500 mg/ 250 mg	7 – 14	28 x 500 mg/ 500 mg/ 250 mg – 56 x 500 mg/ 500 mg/ 250 mg

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

Treatment period:

According to the product information, treatment of infections due to Gram-negative organisms with imipenem/ cilastatin/ relebactam may be required for 5 to 14 days, depending on the site of infection.

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Medicinal product to be assessed				
Imipenem/ cilastatin/ relebactam	From birth to < 3 months 3 x daily	1	5 – 14	5 – 14
	≥ 3 months to < 18 years of age 4 x daily			

Consumption:

Designation of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
Medicinal product to be assessed					
Imipenem/ cilastatin/ relebactam	From birth to < 3 months 15 mg/kg imipenem/ 15 mg/kg cilastatin/ 7.5 mg/kg relebactam	3 x 52 mg imipenem/ 52 mg cilastatin/ 26 mg relebactam – 3 x 78 mg imipenem/ 78 mg cilastatin/ 39 mg relebactam	3 x 500 mg/ 500 mg/ 250 mg	5 – 14	15 x 500 mg/ 500 mg/ 250 mg – 42 x 500 mg/ 500 mg/ 250 mg
	≥ 3 months to < 18 years of age 15 mg/kg imipenem/ 15 mg/kg cilastatin/ 7.5 mg/kg relebactam – 500 mg imipenem/ 500 mg cilastatin/ 250 mg relebactam	4 x 88 mg imipenem/ 88 mg cilastatin/ 44 mg relebactam – 4 x 500 mg imipenem/ 500 mg cilastatin/ 250 mg relebactam	4 x 500 mg/ 500 mg/ 250 mg	5 – 14	20 x 500 mg/ 500 mg/ 250 mg – 56 x 500 mg/ 500 mg/ 250 mg

Patient population a-c)

Costs:

Imipenem/ cilastatin/ relebactam (Recarbrio) is listed in the LAUER-TAXE®, but is only dispensed as a clinic pack. Accordingly, the active ingredient is not subject to the Pharmaceutical Price Ordinance (Arzneimittelpreisverordnung) and no rebates according to Section 130 or Section 130a SGB V apply. The calculation is based on the purchase price of the clinic pack plus 19% value added tax, in deviation from the LAUER-TAXE® data usually taken into account. To calculate the annual treatment costs, the required number of packs of a particular potency was first determined on the basis of consumption. Having determined the number of packs of a particular potency, the costs of the medicinal products were then calculated on the basis of the costs per pack plus value added tax.

Costs of the medicinal products:

Designation of the therapy	Packaging size	Costs (clinic purchase registry)	Value added tax (19%)	Costs of the medicinal product
Imipenem/ cilastatin/ relebactam 500 mg/ 500 mg/ 250 mg	25 PIF	€ 5,937.50	€ 1,128.13	€ 7,065.63
Abbreviations: PIF = powder for the preparation of an infusion solution				

LAUER-TAXE® (last revised: 1 June 2026)

Costs for additionally required SHI services:

Only costs directly related to the use of the medicinal product are taken into account. If there are regular differences in the necessary use of medical treatment or in the prescription of other services in the use of the medicinal product to be evaluated and the appropriate comparator therapy in accordance with the product information, the costs incurred for this must be taken into account as costs for additionally required SHI services.

Medical treatment costs, medical fee services, and costs incurred for routine examinations (e.g. regular laboratory services such as blood count tests) that do not exceed the standard expenditure in the course of the treatment are not shown.

No additional SHI services required are taken into account for the cost representation.

3. Bureaucratic costs calculation

The proposed resolution does not create any new or amended information obligations for care providers within the meaning of Annex II to Chapter 1 VerfO and, accordingly, no bureaucratic costs.

4. Process sequence

On 11 February 2026, the pharmaceutical company submitted a dossier for the benefit assessment of imipenem/ cilastatin/ relebactam to the G-BA in due time.

The draft of the G-BA's requirements for a quality-assured application was published on the G-BA website (www.g-ba.de) on 15 May 2026 together with the IQWiG's assessment of treatment costs and patient numbers, thus initiating the written statement procedure. The deadline for submitting written statements was 5 June 2026.

The oral hearing has been dispensed with since all assessment experts who submitted written statements waived their right to make an oral statement.

In order to prepare a recommendation for a resolution, the Subcommittee on Medicinal Products commissioned a working group (Section 35a) consisting of the members nominated by the leading organisations of the care providers, the members nominated by the SHI umbrella organisation, and the representatives of the patient organisations. Representatives of the IQWiG also participate in the sessions.

The evaluation of the written statements received and the oral hearing were discussed at the Subcommittee's session on 28 July 2026, and the draft resolution was conclusively discussed.

At their session on 6 August 2026, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
Working group Section 35a	3 March 2026 5 May 2026	Consultation on the draft requirements for a quality-assured application
Subcommittee on Medicinal Products	10 March 2026	Draft requirements for a quality-assured application; notification of the RKI and BfArM
Subcommittee on Medicinal Products	12 May 2026	Draft requirements for a quality-assured application, taking into account RKI's statement
Working group Section 35a	16 June 2026	Information on statements received
Working group Section 35a	1 July 2026 15 July 2026	Consultation on the G-BA's draft requirements for a quality-assured application, the IQWiG's assessment of treatment costs and patient numbers, and the evaluation of the written statement procedure
Subcommittee on Medicinal Products	28 July 2026	Concluding discussion of the draft resolution
Plenum	6 August 2026	Adoption of the resolution on the amendment of the Pharmaceuticals Directive

Berlin, 6 August 2026

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

Dr Optendrenk