

# Justification

to 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  
Remdesivir (new therapeutic indication: COVID-19, not  
requiring supplemental oxygen,  $\geq 4$  weeks,  $\geq 3$  kg to  $< 40$  kg)

of 22 January 2026

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## **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. This includes in particular the assessment of the additional benefit and its therapeutic significance. The benefit assessment is carried out on the basis of evidence provided by the pharmaceutical company, which must be submitted to the G-BA electronically, including all clinical studies the pharmaceutical company have conducted or commissioned, at the latest at the time of the first placing on the market as well as the marketing authorisation of new therapeutic indications of the medicinal product, and which must contain the following information in particular:

1. approved therapeutic indications,
2. medical benefit,
3. additional medical benefit in relation to the appropriate comparator therapy,
4. number of patients and patient groups for whom there is a therapeutically significant additional benefit,
5. treatment costs for the statutory health insurance funds,
6. requirement for a quality-assured application.

The G-BA may commission the Institute for Quality and Efficiency in Health Care (IQWiG) to carry out the benefit assessment. According to Section 35a, paragraph 2 SGB V, the assessment must be completed within three months of the relevant date for submission of the evidence and published on the internet.

According to Section 35a paragraph 3 SGB V, the G-BA pass a resolution on the benefit assessment within three months of its publication. The resolution is to be published on the internet and is part of the Pharmaceuticals Directive.

## **2. Key points of the resolution**

The active ingredient remdesivir (Veklury) was listed for the first time on 1 June 2021 in the "LAUER-TAXE®", the extensive German registry of available drugs and their prices.

On 6 June 2025, remdesivir 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, 12.12.2008, sentence 7).

On 3 July 2025, i.e. at the latest within four weeks of informing the pharmaceutical company about the approval for a new therapeutic indication, the pharmaceutical company has submitted a dossier 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 on the active ingredient remdesivir with the new therapeutic indication

"Veklury is indicated for the treatment of coronavirus disease 2019 (COVID-19) in children and adolescents (at least 4 weeks of age and weighing  $\geq 3$  to  $< 40$  kg) who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19."

The G-BA commissioned the IQWiG to carry out the assessment of the dossier. The benefit assessment was published on 15 October 2025 on the G-BA website ([www.g-ba.de](http://www.g-ba.de)), 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 came to a resolution on whether an additional benefit of remdesivir compared to the appropriate comparator therapy could be determined on the basis of the dossier of the pharmaceutical company, the dossier assessment prepared by the IQWiG, and the statements submitted in the written statement procedure. In order to determine the extent of the additional benefit, the G-BA have evaluated the data justifying the finding of an additional benefit on the basis of their therapeutic relevance (qualitative), in accordance with the criteria laid down in Chapter 5 Section 5, paragraph 7 VerfO. The methodology proposed by the IQWiG in accordance with the General Methods <sup>1</sup> was not used in the benefit assessment of remdesivir.

In the light of the above, and taking into account the statements received, the G-BA has come to the following assessment:

## **2.1 Additional benefit of the medicinal product in relation to the appropriate comparator therapy**

### **2.1.1 Approved therapeutic indication of Remdesivir (Veklury) in accordance with the product information**

Veklury is indicated for the treatment of coronavirus disease 2019 (COVID-19) in adults and paediatric patients (aged at least 4 weeks and weighing at least 3 kg):

- with pneumonia requiring supplemental oxygen (low or high-flow oxygen therapy or other non-invasive ventilation at the start of treatment)
- who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19.

#### **Therapeutic indication of the resolution (resolution of 22.01.2026):**

Veklury is indicated for the treatment of coronavirus disease 2019 (COVID-19) in children and adolescents (at least 4 weeks of age and weighing  $\geq 3$  to  $< 40$  kg) who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19.

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<sup>1</sup> General Methods, version 7.0 from 19.09.2023. Institute for Quality and Efficiency in Health Care (IQWiG), Cologne.

### 2.1.2 Appropriate comparator therapy

The appropriate comparator therapy was determined as follows:

Children and adolescents at least 4 weeks of age and weighing  $\geq 3$  to  $< 40$  kg with a COVID-19 disease who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19

Appropriate comparator therapy for remdesivir:

- Best supportive care

Criteria according to Chapter 5 Section 6 of the Rules of Procedure of the G-BA and Section 6 paragraph 2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV):

The appropriate comparator therapy must be an appropriate therapy in the therapeutic indication in accordance with the generally recognised state of medical knowledge (Section 12 SGB V), preferably a therapy for which endpoint studies are available and which has proven its worth in practical application unless contradicted by the guidelines under Section 92, paragraph 1 SGB V or the principle of economic efficiency.

In determining the appropriate comparator therapy, the following criteria, in particular, must be taken into account as specified in Chapter 5 Section 6, paragraph 3 VerfO:

1. To be considered as a comparator therapy, the medicinal product must, principally, have a marketing authorisation for the therapeutic indication.
2. If a non-medicinal treatment is considered as a comparator therapy, this must be available within the framework of the SHI system.
3. As comparator therapy, medicinal products or non-medicinal treatments for which the patient-relevant benefit has already been determined by the G-BA shall be preferred.
4. According to the generally recognised state of medical knowledge, the comparator therapy should be part of the appropriate therapy in the therapeutic indication.

According to Section 6, paragraph 2, sentence 2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV), the determination of the appropriate comparator therapy must be based on the actual medical treatment situation as it would be without the medicinal product to be assessed. According to Section 6, paragraph 2, sentence 3 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV), the G-BA may exceptionally determine the off-label use of medicinal products as an appropriate comparator therapy or as part of the appropriate comparator therapy if they determine by resolution on the benefit assessment according to Section 7, paragraph 4 that, according to the generally recognised state of medical knowledge, this is considered a therapy standard in the therapeutic indication to be assessed or as part of the therapy standard in the medical treatment situation to be taken into account according to sentence 2, and

1. for the first time, a medicinal product approved in the therapeutic indication is available with the medicinal product to be assessed,

2. according to the generally recognised state of medical knowledge, the off-label use is generally preferable to the medicinal products previously approved in the therapeutic indication, or
3. according to the generally recognised state of medical knowledge, the off-label use for relevant patient groups or indication areas is generally preferable to the medicinal products previously approved in the therapeutic indication.

An appropriate comparator therapy may also be non-medicinal therapy, the best possible add-on therapy including symptomatic or palliative treatment, or monitoring wait-and-see approach.

Justification based on the criteria set out in Chapter 5 Section 6, paragraph 3 VerfO and Section 6, paragraph 2 AM-NutzenV:

- On 1. Apart from remdesivir, no other medicinal products are approved in the present therapeutic indication for the treatment of children and adolescents at least 4 weeks of age and weighing  $\geq 3$  to  $< 40$  kg with a COVID-19 disease who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19. For the symptomatic treatment of viral infections, medicinal treatment options such as analgesics or antipyretics are available.
- On 2. In the therapeutic indication of COVID-19 disease, without the need for supplemental oxygen and with an increased risk of progressing to severe COVID-19, no non-medicinal treatments are indicated.
- On 3. There are resolutions on the benefit assessment according to Section 35a SGB V in the COVID-19 therapeutic indication, but not for the patient group to be assessed (not requiring supplemental oxygen, age  $\geq 4$  weeks, body weight  $\geq 3$  kg to  $< 40$  kg).
- On 4. The generally recognised state of medical knowledge on which the resolution of the G-BA is based, was illustrated by a systematic search for guidelines as well as reviews of clinical studies in the present therapeutic indication.

The scientific-medical societies and the Drugs Commission of the German Medical Association (AkdÄ) were also involved in writing on questions relating to the comparator therapy in the present therapeutic indication according to Section 35a, paragraph 7 SGB V.

At present, the treatment of COVID-19 is based on the clinical manifestation (mild, severe) of the predominant symptoms.

Apart from remdesivir, no other medicinal products are approved in the present therapeutic indication for the treatment of children and adolescents at least 4 weeks of age and weighing  $\geq 3$  to  $< 40$  kg with a COVID-19 disease who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19. A majority of children and adolescents with mild to moderate, symptomatic COVID-19 disease can be treated as outpatients. Specific therapeutic measures are usually not required for mildly to moderately symptomatic COVID-19. Subjects in outpatient care may be given supportive measures, e.g. analgesics or antipyretics and, for previously ill subjects, thromboembolism prophylaxis if necessary.

In moderate and severe courses of COVID-19, hospitalisation may be indicated. In particular, severe organ involvement (lung, kidney) may also require intensive care

intervention. Supportive measures may be required for children and adolescents with more severe courses of the disease who require hospitalisation due to COVID-19. These include, among others, early oxygen administration or, in the case of severe respiratory impairment, even mechanical ventilation as well as thrombosis prophylaxis or therapeutic anticoagulation and balanced fluid therapy, depending on the previous and concomitant diseases. In addition, secondary infections should be prevented and sepsis therapy administered in line with the guidelines.

Therapy with dexamethasone is recommended for children and adolescents with low-flow/ high-flow oxygen therapy or non-invasive/ invasive ventilation due to COVID-19. However, this concerns later treatment settings that are not covered by the present therapeutic indication. Therapeutic measures that are used at a later (possibly more severe) stage of the disease are therefore not taken into account when determining the appropriate comparator therapy.

In the overall assessment, the G-BA therefore determined best supportive care as the appropriate comparator therapy for remdesivir in the treatment setting to be assessed. Best supportive care is defined as the therapy that provides the best possible, patient-individual, optimised supportive treatment to alleviate symptoms and improve quality of life. As part of best supportive care, primary symptomatic medicinal therapies (e.g. analgesics, antipyretics, thrombosis prophylaxis) should be taken into account, if indicated, depending on the severity of the disease. These therapies can also be used during treatment with remdesivir.

The marketing authorisation for the corresponding treatment options must be taken into account.

The findings in Annex XII do not restrict the scope of treatment required to fulfil the medical treatment mandate.

A change in the appropriate comparator therapy requires a resolution by the G-BA linked to the prior review of the criteria according to Chapter 5 Section 6, paragraph 3 Rules of Procedure.

### **2.1.3 Extent and probability of the additional benefit**

In summary, the additional benefit of remdesivir is assessed as follows:

Children and adolescents at least 4 weeks of age and weighing  $\geq 3$  to  $< 40$  kg with a COVID-19 disease who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19

An additional benefit is not proven.

Justification:

In their dossier, the pharmaceutical company did not present any data for the assessment of the additional benefit of remdesivir compared with the appropriate comparator therapy. No data are available to allow an assessment of the additional benefit of remdesivir for the treatment of coronavirus disease 2019 (COVID-19) in children and adolescents (at least 4 weeks of age and weighing  $\geq 3$  to  $< 40$  kg) who do not require supplemental oxygen and who

are at increased risk of progressing to severe COVID-19. An additional benefit is therefore not proven.

#### **2.1.4 Summary of the assessment**

The present assessment is the benefit assessment of a new therapeutic indication for the active ingredient remdesivir.

The therapeutic indication assessed here is as follows: "for the treatment of coronavirus disease 2019 (COVID-19) in children and adolescents (at least 4 weeks of age and weighing  $\geq 3$  to  $< 40$  kg) who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19".

Best supportive care was determined as the appropriate comparator therapy.

The pharmaceutical company did not present any data to prove the additional benefit of remdesivir compared to the appropriate comparator therapy. An additional benefit of remdesivir for the treatment of children and adolescents at least 4 weeks of age and weighing  $\geq 3$  to  $< 40$  kg with a COVID-19 disease who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19 is therefore not proven.

#### **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).

The G-BA take into account the patient number stated by the pharmaceutical company during the written statement procedure. The figure stated is a better estimate than the specification in the dossier, as the hospitalisation rate is applied to the entire population regardless of infection status.

The figure nevertheless tends to be underestimated, as the hospitalisation rate applied is only based on 7 days. Hospitalisations in the remaining weeks of the year under review are therefore not taken into account, although hospitalisation rates fluctuate throughout the year.

#### **2.3 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 Veklury (active ingredient: remdesivir) at the following publicly accessible link (last access: 19 November 2025):

[https://www.ema.europa.eu/en/documents/product-information/veklury-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/veklury-epar-product-information_en.pdf)

## 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: 01 November 2025). The calculation of treatment costs is generally based on the last revised LAUER-TAXE® version following the publication of the benefit assessment.

Remdesivir 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.

Children and adolescents at least 4 weeks of age and weighing  $\geq 3$  to  $< 40$  kg with a COVID-19 disease who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19

Treatment period:

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Medicinal product to be assessed				
Remdesivir	1 x daily	1	3	3
Best supportive care	Different from patient to patient			
Appropriate comparator therapy				
Best supportive care				
Best supportive care	Different from patient to patient			

Consumption:

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

For the cost representation, only the dosages of the general case are considered. Patient-individual dose adjustments (e.g. because of side effects or co-morbidities) are not taken into account when calculating the annual treatment costs.

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 (KiGGS)"<sup>2</sup> were used for the lower limit of the age group under consideration. Based on the average body weights of boys and girls, the average body weight of infants aged 4 weeks is 4.35 kg. The body weight of 39.9 kg was used as the upper weight limit.

<sup>2</sup> Contributions to Federal Health Reporting. Reference percentiles for anthropometric measures 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>

The diluted Remdesivir infusion solution can be stored for up to 24 hours at below 25°C or 48 hours in the refrigerator (2°C to 8°C).

Designation of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/	Treatment days/ patient/ year	Annual average consumption by potency
Medicinal product to be assessed					
Remdesivir	<u>Day 1:</u> 5 mg/kg	<u>Day 1:</u> 21.8 mg – 199.5 mg	<u>Day 1:</u> 1 x 100 mg – 2 x 100 mg	3	2 x 100 mg
	<u>Day 2 and 3</u> 2.5 mg/kg	<u>Day 2 and 3</u> 10.9 mg – 99.75 mg	<u>Day 2 and 3</u> 1 x 100 mg – 2 x 100 mg		– 4 x 100 mg
Best supportive care		Different from patient to patient			
Appropriate comparator therapy					
Best supportive care					
Best supportive care		Different from patient to patient			

### Costs:

#### **Costs of the medicinal products:**

Designation of the therapy	Packaging size	Costs (hospital purchase price)	Value added tax 19%	Costs plus value added tax
Remdesivir 100 mg	1 PIC	€ 345.00	€ 65.55	€ 410.55
Abbreviation: PIC = powder for the preparation of an infusion solution concentrate				

LAUER-TAXE® last revised: 1 November 2025

#### 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.

Because there are no 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, no costs for additionally required SHI services had to be taken into account.

## **2.5 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**

According to Section 35a, paragraph 3, sentence 4, the G-BA designate all medicinal products with new active ingredients that can be used in a combination therapy with the assessed medicinal product for the therapeutic indication to be assessed on the basis of the marketing authorisation under Medicinal Products Act.

### Basic principles of the assessed medicinal product

A designation in accordance with Section 35a, paragraph 3, sentence 4 SGB V requires that it is examined based on the product information for the assessed medicinal product whether it can be used in a combination therapy with other medicinal products in the assessed therapeutic indication. In the first step, the examination is carried out on the basis of all sections of the currently valid product information for the assessed medicinal product.

If the assessed medicinal product contains an active ingredient or a fixed combination of active ingredients in the therapeutic indication of the resolution (assessed therapeutic indication) and is approved exclusively for use in monotherapy, a combination therapy is not considered due to the marketing authorisation under Medicinal Products Act, which is why no designation is made.

A designation is also not considered if the G-BA have decided on an exemption as a reserve antibiotic for the assessed medicinal product in accordance with Section 35a, paragraph 1c, sentence 1 SGB V. The additional benefit is deemed to be proven if the G-BA 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 G-BA. Due to the lack of an assessment mandate by the G-BA following the resolution on an exemption according to Section 35a, paragraph 1c, sentence 1 SGB V with regard to the extent of the additional benefit and the therapeutic significance of the reserve antibiotic to be assessed, there is a limitation due to the procedural privileging of the pharmaceutical companies to the effect that neither the proof of an existing nor an expected at least considerable additional benefit is possible for exempted reserve antibiotics in the procedures according to Section 35a paragraph 1 or 6 SGB V and Section 35a paragraph 1d SGB V. The procedural privileging of the reserve antibiotics exempted according to Section 35a, paragraph 1c, sentence 1 SGB V must therefore also be taken into account at the level of designation according to Section 35a, paragraph 3, sentence 4 SGB V in order to avoid valuation contradictions.

With regard to the further examination steps, a differentiation is made between a "determined" or "undetermined" combination, which may also be the basis for a designation.

A "determined combination" exists if one or more individual active ingredients which can be used in combination with the assessed medicinal product in the assessed therapeutic indication are specifically named.

An "undetermined combination" exists if there is information on a combination therapy, but no specific active ingredients are named. An undetermined combination may be present if the information on a combination therapy:

- names a product class or group from which some active ingredients not specified in detail can be used in combination therapy with the assessed medicinal product, or
- does not name any active ingredients, product classes or groups, but the assessed medicinal product is used in addition to a therapeutic indication described in more detail in the relevant product information, which, however, does not include information on active ingredients within the scope of this therapeutic indication.

### Concomitant active ingredient

The concomitant active ingredient is a medicinal product with new active ingredients that can be used in combination therapy with the assessed medicinal product for the therapeutic indication to be assessed.

For a medicinal product to be considered as a concomitant active ingredient, it must be classified as a medicinal product with new active ingredients according to Section 2 paragraph 1 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with the corresponding regulations in Chapter 5 of the Rules of Procedure of the G-BA as of the date of the present resolution. In addition, the medicinal product must be approved in the assessed therapeutic indication, whereby a marketing authorisation is sufficient only for a sub-area of the assessed therapeutic indication.

Based on an "undetermined combination", the concomitant active ingredient must be attributable to the information on the product class or group or the therapeutic indication according to the product information of the assessed medicinal product in the assessed therapeutic indication, whereby the definition of a product class or group is based on the corresponding requirements in the product information of the assessed medicinal product.

In addition, there must be no reasons for exclusion of the concomitant active ingredient from a combination therapy with the assessed medicinal product, in particular no exclusive marketing authorisation as monotherapy.

In addition, all sections of the currently valid product information of the eligible concomitant active ingredient are checked to see whether there is any information that excludes its use in combination therapy with the assessed medicinal product in the assessed therapeutic indication under marketing authorisation regulations. Corresponding information can be, for example, dosage information or warnings. In the event that the medicinal product is used as part of a determined or undetermined combination which does not include the assessed medicinal product, a combination with the assessed medicinal product shall be excluded.

Furthermore, the product information of the assessed medicinal product must not contain any specific information that excludes its use in combination therapy with the eligible concomitant active ingredient in the assessed therapeutic indication under marketing authorisation regulations.

Medicinal products with new active ingredients for which the G-BA have decided on an exemption as a reserve antibiotic in accordance with Section 35a, paragraph 1c, sentence 1 SGB V are ineligible as concomitant active ingredients. The procedural privileging of the reserve antibiotics exempted according to Section 35a, paragraph 1c, sentence 1 SGB V also applies accordingly to the medicinal product eligible as a concomitant active ingredient.

### Designation

The medicinal products which have been determined as concomitant active ingredients in accordance with the above points of examination are named by indicating the relevant active ingredient and the invented name. The designation may include several active ingredients, provided that several medicinal products with new active ingredients may be used in the same combination therapy with the assessed medicinal product or different combinations with different medicinal products with new active ingredients form the basis of the designation.

If the present resolution on the assessed medicinal product in the assessed therapeutic indication contains several patient groups, the designation of concomitant active ingredients shall be made separately for each of the patient groups.

### Exception to the designation

The designation excludes combination therapies for which - patient group-related - a considerable or major additional benefit has been determined by resolution according to Section 35a, paragraph 3, sentence 1 SGB V or it has been determined according to Section 35a, paragraph 1d, sentence 1 SGB V that at least considerable additional benefit of the combination can be expected. In this context, the combination therapy that is excluded from the designation must, as a rule, be identical to the combination therapy on which the preceding findings were based.

In the case of designations based on undetermined combinations, only those concomitant active ingredients - based on a resolution according to Section 35a, paragraph 3, sentence 1 SGB V on the assessed medicinal product in which a considerable or major additional benefit had been determined - which were approved at the time of this resolution are excluded from the designation.

### Legal effects of the designation

The designation of combinations is carried out in accordance with the legal requirements according to Section 35a, paragraph 3, sentence 4 and is used exclusively to implement the combination discount according to Section 130e SGB V between health insurance funds and pharmaceutical companies. The designation is not associated with a statement as to the extent to which a therapy with the assessed medicinal products in combination with the designated medicinal products corresponds to the generally recognised state of medical knowledge. The examination was carried out exclusively on the basis of the possibility under Medicinal Products Act to use the medicinal products in combination therapy in the assessed therapeutic indication based on the product information; the generally recognised state of medical knowledge or the use of the medicinal products in the reality of care were not the subject of the examination due to the lack of an assessment mandate of the G-BA within the framework of Section 35a, paragraph 3, sentence 4 SGB V.

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.

Justification for the findings on designation in the present resolution:

Children and adolescents at least 4 weeks of age and weighing  $\geq 3$  to  $< 40$  kg with a COVID-19 disease who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19

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

References:

Product information for remdesivir (Veklury); Veklury® 100 mg powder for a concentrate for the preparation of an infusion solution; last revised: August 2025

### **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**

At their session on 24 June 2025, the Subcommittee on Medicinal Products determined the appropriate comparator therapy.

On 3 July 2025 the pharmaceutical company submitted a dossier for the benefit assessment of remdesivir to the G-BA in due time in accordance with Chapter 5 Section 8, paragraph 1, number 2 VerfO.

By letter dated 3 July 2025 in conjunction with the resolution of the G-BA of 1 August 2011 concerning the commissioning of the IQWiG to assess the benefits of medicinal products with new active ingredients in accordance with Section 35a SGB V, the G-BA commissioned the IQWiG to assess the dossier concerning the active ingredient remdesivir.

The dossier assessment by the IQWiG was submitted to the G-BA on 7 October 2025, and the written statement procedure was initiated with publication on the G-BA website on 15 October 2025. The deadline for submitting statements was 5 November 2025.

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 representatives of the patient organisations. Representatives of the IQWiG also participate in the sessions.

The evaluation of the written statements received was discussed at the session of the subcommittee on 13 January 2026, and the draft resolution was approved.

At their session on 22 January 2026, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

## Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee on Medicinal Products	24 June 2025	Determination of the appropriate comparator therapy
Working group Section 35a	18 November 2025	Information on statements received
Working group Section 35a	2 December 2025 16 December 2025	Consultation on the dossier evaluation by the IQWiG and evaluation of the written statement procedure
Subcommittee on Medicinal Products	13 January 2026	Concluding discussion of the draft resolution
Plenum	22 January 2026	Adoption of the resolution on the amendment of the Pharmaceuticals Directive

Berlin, 22 January 2026

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

Prof. Hecken