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

Nirmatrelvir/ ritonavir (new therapeutic indication: COVID-19, not requiring supplemental oxygen, ≥ 6 to < 18 years, ≥ 20 kg)

From 4 June 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. 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. requirements 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 decide 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 combination of active ingredients nirmatrelvir/ ritonavir (Paxlovid) was listed for the first time on 1 February 2022 in the "LAUER-TAXE®", the extensive German registry of available drugs and their prices.

On 26 November 2025, nirmatrelvir/ ritonavir 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 15 December 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 submitted a dossier 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 for the combination of active ingredients nirmatrelvir/ ritonavir with the new therapeutic indication: "Paxlovid is indicated for the treatment of coronavirus disease 2019 (COVID-19) in paediatric patients 6 to < 18 years of age weighing at least 20 kg who do not require supplemental oxygen and who are at increased risk for 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 16 March 2026 on the G-BA website (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 nirmatrelvir/ ritonavir compared with 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 and oral hearing 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 [1] was not used in the benefit assessment of nirmatrelvir/ ritonavir.

In the light of the above, and taking into account the statements received, the G-BA came 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 Nirmatrelvir/ ritonavir (Paxlovid) in accordance with the product information

Paxlovid is indicated for the treatment of coronavirus disease 2019 (COVID-19) in adults and paediatric patients 6 years of age and older weighing at least 20 kg who do not require supplemental oxygen and who are at increased risk for progressing to severe COVID-19.

Therapeutic indication of the resolution (resolution of 04.05.2026):

Paxlovid is indicated for the treatment of coronavirus disease 2019 (COVID-19) in paediatric patients 6 to < 8 years of age weighing at least 20 kg who do not require supplemental oxygen and who are at increased risk for progressing to severe COVID-19.

[1]General Methods, version 8.0 from 19.12.2025. Institute for Quality and Efficiency in Health Care (IQWiG), Cologne.

2.1.2 Appropriate comparator therapy

The appropriate comparator therapy was determined as follows:

Paediatric patients 6 to < 18 years of age weighing at least 20 kg who do not require supplemental oxygen and who are at increased risk for progressing to severe COVID-19

Appropriate comparator therapy for nirmatrelvir/ ritonavir

- Remdesivir

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 according to 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 for 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 for 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. In the present therapeutic indication for the treatment of paediatric patients 6 years of age and older weighing at least 20 kg who do not require supplemental oxygen and who are at increased risk for progressing to severe COVID-19, the active ingredient remdesivir is approved in addition to the combination of active ingredients nirmatrelvir/ ritonavir to be assessed.

In addition, medicinal therapy options such as analgesics or antipyretics are available for the symptomatic treatment of viral infections.

On 2. In the therapeutic indication of COVID-19 disease, not requiring supplemental oxygen and at an increased risk of progressing to severe disease, no non-medicinal treatments are indicated.

On 3. The following resolutions on the benefit assessment according to Section 35a SGB V in the therapeutic indication under assessment are available:

- Remdesivir (COVID-19, not requiring supplemental oxygen, ≥ 4 weeks, ≥ 3 kg to < 40 kg) – resolution of 22 January 2026
- Remdesivir (COVID-19, not requiring supplemental oxygen, < 18 years, ≥ 40 kg) – resolution of 6 April 2023

In addition, further resolutions on the benefit assessment according to Section 35a SGB V in the therapeutic indication of COVID-19 are available, although they do not address the patient group to be assessed.

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.

In the present case, it is assumed that antiviral medicinal therapy is generally indicated for patients who are eligible for treatment with the combination of active ingredients nirmatrelvir/ ritonavir.

In accordance with the S3 guideline "Therapy recommendations for COVID-19 patients"[2], patients who do not require supplemental oxygen and who are at increased risk for progressing to severe COVID-19 should receive antiviral therapy in addition to symptomatic therapy. In the therapeutic indication under assessment, remdesivir is the only active ingredient approved for antiviral therapy, apart from nirmatrelvir/ ritonavir.

In the overall assessment, antiviral therapy with the active ingredient remdesivir is therefore determined as the appropriate comparator therapy for paediatric patients 6 to < 18 years of age weighing at least 20 kg who do not require supplemental oxygen and who are at increased risk for progressing to severe COVID-19.

Change in the appropriate comparator therapy:

On 6 May 2025, the G-BA's Subcommittee on Medicinal Products determined best supportive care as the appropriate comparator therapy for nirmatrelvir/ ritonavir in the sub-population of "paediatric patients 6 to ≤ 17 years of age weighing 20 to 40 kg who do not require supplemental oxygen and who are at increased risk for progressing to severe COVID-19". At that time, the active ingredient remdesivir was only approved for the present indication in patients weighing at least 40 kg.

However, the active ingredient remdesivir was granted an extension of its therapeutic indication on 6 June 2025, and is now also approved for children weighing less than 40 kg in the present therapeutic indication. The active ingredient remdesivir has been approved for the treatment of COVID-19 since July 2020. The S3 guideline "Therapy recommendations for COVID-19 patients"[2] recommends the use of remdesivir as antiviral therapy for patients who do not require supplemental oxygen and who are at increased risk for progressing to severe COVID-19.

Determination of best supportive care as the appropriate comparator therapy therefore does not correspond to the current therapy standard, provided that antiviral therapy is generally indicated. Consequently, according to the current state of medical knowledge, the G-BA concluded that the active ingredient remdesivir is appropriate not only for paediatric patients weighing at least 40 kg, but also for children weighing between 20 and 40 kg. Remdesivir is therefore determined as the appropriate comparator therapy for nirmatrelvir/ ritonavir in the therapeutic indication "paediatric patients with COVID-19 6 to < 18 years of age weighing at least 20 kg who do not require supplemental oxygen and who are at increased risk for progressing to severe COVID-19". Division of the patients into two patient populations is therefore no longer required.

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

Any change to the appropriate comparator therapy requires a decision by the G-BA based on a prior review of the criteria set out in Chapter 5, Section 6, paragraph 3 VerfO.

2.1.3 Extent and probability of the additional benefit

In summary, the additional benefit of nirmatrelvir/ ritonavir is assessed as follows:

[2] S3 Guideline – Therapy recommendations for COVID-19 patients, version 11.0 (December 2024, last updated 28.02.2025, valid until 27.02.2026, currently under review).

Paediatric patients 6 to < 18 years of age weighing at least 20 kg who do not require supplemental oxygen and who are at increased risk for 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 nirmatrelvir/ ritonavir compared with the appropriate comparator therapy.

Overall, no data are therefore available to allow an assessment of the additional benefit of nirmatrelvir/ ritonavir for the treatment of coronavirus disease 2019 (COVID-19) in paediatric patients 6 to < 18 years of age weighing at least 20 kg who do not require supplemental oxygen and who are at increased risk for 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 combination of active ingredients nirmatrelvir/ ritonavir.

The therapeutic indication assessed here is: "for the treatment of coronavirus disease 2019 (COVID-19) in paediatric patients 6 to < 18 years of age weighing at least 20 kg who do not require supplemental oxygen and who are at increased risk for progressing to severe COVID-19".

Antiviral therapy with the active ingredient remdesivir was determined as the appropriate comparator therapy.

The pharmaceutical company did not submit any data to prove the additional benefit of nirmatrelvir/ ritonavir over remdesivir. An additional benefit of nirmatrelvir/ ritonavir in the treatment of paediatric patients 6 to < 18 years of age weighing at least 20 kg, who do not require supplemental oxygen and who are at increased risk for 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 bases its resolution on the information from the dossier of the pharmaceutical company.

The patient numbers indicated are underestimated overall due to the pharmaceutical company’s underestimation of the number of hospitalised patients.

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 Paxlovid (active ingredient: nirmatrelvir/ ritonavir) at the following publicly accessible link (last access: 13 January 2026):

https://www.ema.europa.eu/en/documents/product-information/paxlovid-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: 1 April 2026). The calculation of treatment costs is generally based on the last revised LAUER-TAXE® version following the publication of the benefit assessment.

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 comorbidities) are not taken into account when calculating the annual treatment costs.

For calculating the dosages depending on body weight, the average body measurements from the official representative statistics "Microcensus 2017 – body measurements of the population" [3] (average body weight of 6 to < 7-year-olds: 23.6 kg) and "Microcensus 2021 – body measurements of the population"[4] (average body weight of 17 to < 18-year-olds: 67.3 kg) were applied.

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

[3] Federal Health Reporting. Average body measurements of the population (2017, both sexes, 1 year and older), www.gbe-bund.de

[4] Federal Health Reporting. Average body measurements of the population (2021, both sexes, 15 years and older), www.gbe-bund.de

Paediatric patients 6 to < 18 years of age weighing at least 20 kg who do not require supplemental oxygen and who are at increased risk for 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:				
Nirmatrelvir/ ritonavir	2 x daily	1	5.0	5.0
Appropriate comparator therapy				
Remdesivir	1 x daily	1	3.0	3.0

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:					
Nirmatrelvir/ ritonavir	20 to < 40 kg BW 150 mg/100 mg	300 mg/ 200 mg	2 x 150 mg/ 2 x 100 mg	5.0	10 x 150 mg/ 10 x 100 mg
	≥ 40 kg BW 300 mg/100 mg	600 mg/ 200 mg	4 x 150 mg/ 2 x 100 mg	5.0	20 x 150 mg/ 10 x 100 mg
Appropriate comparator therapy					
Remdesivir	< 40 kg BW Day 1: 5 mg/kg BW: 118.0 mg	Day 1: 118.0 mg	Day 1: 118.0 mg	1.0	Day 1: 118.0 mg
	Day 2-3: 2.5 mg/kg BW 59.0 mg	Day 2-3: 59.0 mg	Day 2-3: 59.0 mg	2.0	Day 2-3: 59.0 mg
	≥ 40 kg BW Day 1: 200 mg Day 2-3: 100 mg	Day 1: 200 mg Day 2-3: 100 mg	Day 1: 2 x 100 mg Day 2-3: 1 x 100 mg	1.0 2.0	Day 1: 2 x 100 mg Day 2-3: 2 x 100 mg

Costs:

In order to improve comparability, the costs of the medicinal products were approximated both on the basis of the pharmacy sales price level and also deducting the statutory rebates

in accordance with Section 130 and Section 130a SGB V. 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 after deduction of the statutory rebates. Any reference prices shown in the cost representation may not represent the cheapest available alternative.

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.

Costs of the medicinal products:

Designation of the therapy	Packaging size	Costs (pharmacy sales price)	Rebate Section 130 SGB V	Rebate Section 130a SGB V	Costs after deduction of statutory rebates
Medicinal product to be assessed:					
Nirmatrelvir/ ritonavir 150 mg/100 mg	20/10 FCT	€ 1,149.19	€ 1.77	€ 63.00	€ 1,084.42

Designation of the therapy	Packaging size	Costs (clinic purchase registry)	Value added tax (19%)	Costs of the medicinal product
Appropriate comparator therapy				
Remdesivir 100 mg	1 PIC	€ 345.00	€ 65.55	€ 410.55
Abbreviations: FCT = film-coated tablets; PIC = powder for concentrate for solution for infusion				

LAUER-TAXE® last revised: 1 April 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.

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 data from the product 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 statutory 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:

Paediatric patients 6 to < 18 years of age weighing at least 20 kg who do not require supplemental oxygen and who are at increased risk for progressing to severe COVID-19

– No medicinal product with new active ingredients for use in combination therapy in compliance with the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

  Product information for nirmatrelvir/ ritonavir (Paxlovid); Paxlovid® 150 mg + 100 mg film-coated tablets; last revised: November 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 6 May 2025, the Subcommittee on Medicinal Products determined the appropriate comparator therapy.

On 15 December 2025, the pharmaceutical company submitted a dossier for the benefit assessment of nirmatrelvir/ ritonavir to the G-BA in due time in accordance with Chapter 5, Section 8, paragraph 1, number 2 VerfO.

By letter dated 16 December 2025 in conjunction with the resolution of the G-BA of 1 August 2011 concerning the commissioning of the IQWiG to assess the benefit 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 combination of active ingredients nirmatrelvir/ ritonavir.

The dossier assessment by the IQWiG was submitted to the G-BA on 11 March 2026, and the written statement procedure was initiated with publication on the G-BA website on 16 March 2026. The deadline for submitting written statements was 7 April 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 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 27 May 2026, and deliberation of the draft resolution was concluded.

At their session on 4 June 2026, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	**Date**	**Subject of consultation**
Subcommittee on Medicinal Products	6 May 2025	Determination of the appropriate comparator therapy
Working group Section 35a	14 April 2026	Information on written statements received; preparation of the oral hearing
Working group Section 35a	5 May 2026 19 May 2026	Consultation on the dossier assessment by the IQWiG and evaluation of the written statement procedure
Subcommittee on Medicinal Products	27 May 2026	Concluding discussion of the draft resolution
Plenum	4 June 2026	Adoption of the resolution on the amendment of the Pharmaceuticals Directive

Berlin, 4 June 2026

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

Prof. Hecken