Gemeinsamer Bundesausschuss

Resolution

of the Federal Joint Committee on an Amendment of the Pharmaceuticals Directive:
Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a SGB V
Nirmatrelvir/ ritonavir (new therapeutic indication: COVID-19, not requiring supplemental oxygen, ≥ 6 to < 18 years, ≥ 20 kg)

From 4 June 2026

At their session on 4 June 2026, the Federal Joint Committee (G-BA) resolved to amend the Pharmaceuticals Directive (AM-RL) in the version dated 18 December 2008 / 22 January 2009 (Federal Gazette, BAnz. No. 49a of 31 March 2009), as last amended by the publication of the resolution of D Month YYYY (Federal Gazette, BAnz AT DD.MM.YYYY BX), as follows:

I. In Annex XII, the following information shall be added after No. 5 to the information on the benefit assessment of Nirmatrelvir/ ritonavir in accordance with the resolution of 1 July 2022:

Nirmatrelvir/ ritonavir

Resolution of: 4 June 2026
Entry into force on: 4 June 2026
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 26 November 2025):

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 4 June 2026):

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.

1. Additional benefit of the medicinal product in relation to the appropriate comparator therapy

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:

- Remdesivir

Extent and probability of the additional benefit of nirmatrelvir/ ritonavir compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:[1]

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

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	∅	No data available.
Morbidity	∅	No data available.
Health-related quality of life	∅	No data available.
Side effects	∅	No data available.

[1] Data from the dossier assessment by the IQWiG (A25-158), unless otherwise indicated.

Explanations:
↑: statistically significant and relevant positive effect with low/unclear reliability of data
↓: statistically significant and relevant negative effect with low/unclear reliability of data
↑↑: statistically significant and relevant positive effect with high reliability of data
↓↓: statistically significant and relevant negative effect with high reliability of data
↔: no statistically significant or relevant difference
∅: No data available.
n.a.: not assessable

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

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

Approx. 40 – 230 patients

3. Requirements for a quality-assured application

The requirements in the product information are to be taken into account. The European Medicines Agency (EMA) provides the contents of the product information (summary of product characteristics, SmPC) for 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

4. Treatment costs

Annual treatment costs:

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

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Nirmatrelvir/ ritonavir	€ 1,084.42
Appropriate comparator therapy:	
Remdesivir	€ 1,231.65 – € 1,642.20

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

Costs for additionally required SHI services: not applicable

5. Designation of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V that can be used in a combination therapy with the assessed medicinal product

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

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.

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

II. The resolution will enter into force on the day of its publication on the G-BA website on 4 June 2026.

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

Berlin, 4 June 2026

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

Prof. Hecken