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)
Sipavibart (COVID-19, pre-exposure prophylaxis, ≥ 12 years)

of 7 August 2025

At their session on 7 August 2025, 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. Annex XII shall be amended in alphabetical order to include the active ingredient Sipavibart as follows:

Sipavibart

Resolution of: 7 August 2025
Entry into force on: 7 August 2025
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 20 January 2025):

KAVIGALE is indicated for the pre-exposure prophylaxis of COVID-19 in adults and adolescents 12 years of age and older weighing at least 40 kg and who are immunocompromised due to a medical condition or receipt of immunosuppressive treatments.

KAVIGALE should be used in accordance with official recommendations where available and based on information on the activity of sipavibart against presently circulating viral variants (see sections 4.4 and 5.1).

Therapeutic indication of the resolution (resolution of 7 August 2025):

Pre-exposure prophylaxis of COVID-19 in adults and adolescents 12 years of age and older weighing at least 40 kg, who are immunocompromised due to a medical condition or receipt of immunosuppressive treatments and are entitled to a supply of this medicinal product in accordance with Section 2 paragraph 1 of the COVID-19 Prevention Ordinance.

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

a) Adults, who are immunocompromised due to a medical condition or receipt of immunosuppressive treatments, with an indication for pre-exposure prophylaxis of COVID-19 disease

Appropriate comparator therapy:

Monitoring wait-and-see approach

Extent and probability of the additional benefit of sipavibart compared to monitoring wait-and-see approach:

An additional benefit is not proven.

b) Adolescents 12 years of age and older weighing at least 40 kg and who are immunocompromised due to a medical condition or receipt of immunosuppressive treatments, with an indication for pre-exposure prophylaxis of COVID-19 disease

Appropriate comparator therapy:

Monitoring wait-and-see approach

Extent and probability of the additional benefit of sipavibart compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:[1]

a) Adults, who are immunocompromised due to a medical condition or receipt of immunosuppressive treatments, with an indication for pre-exposure prophylaxis of COVID-19 disease

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	↔	No relevant differences for the benefit assessment.
Morbidity	↔	No relevant differences for the benefit assessment.
Health-related quality of life	∅	No data available.
Side effects	↔	No relevant differences for the benefit assessment.
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		

SUPERNOVA RCT: Sipavibart vs placebo or tixagevimab/ cilgavimab;

Relevant sub-population: Population for which reimbursement is possible according to Section 2 COVID-19 Prevention Ordinance, sipavibart vs placebo

[1] Data from the dossier assessment of the IQWiG (A25-28) and from the addendum (A25-84), unless otherwise indicated.

Mortality

Endpoint	Sipavibart		Placebo		Intervention vs control
	N	*Patients with event n (%)*	N	*Patients with event n (%)*	RR [95% CI] p value[a]
Overall mortality					
Overall mortality[b] until day 181	221	1 (0.5)	168	1 (0.6)	0.76 [0.05; 12.07]; 0.912

Morbidity

Endpoint	Sipavibart		Placebo		Intervention vs control
	N	*Patients with event n (%)*	N	*Patients with event n (%)*	RR [95% CI] p value
Confirmed symptomatic COVID-19 (any SARS-CoV-2 variant)					
until day 181	221	21 (9.5)	168	22 (13.1)	0.68 [0.37; 1.25]; 0.216
Severe COVID-19[c] (any SARS-CoV-2 variant)					
until day 181	221	0 (0)	168	0 (0)	-

Health-related quality of life

No data collected.

Side effects[d]

Endpoint	Sipavibart		Placebo		Intervention vs control
	N	*Patients with event n (%)*	N	*Patients with event n (%)*	RR [95% CI] p value
AEs until day 91[e] (presented additionally)	221	133 (60.2)	168	94 (56.0)	–
SAEs[f] until day 181[g]	221	25 (11.3)	168	17 (10.1)	1.12 [0.62; 2.00];

Endpoint	**Sipavibart**		**Placebo**		Intervention vs control
	N	*Patients with event n (%)*	N	*Patients with event n (%)*	RR [95% CI] p value
					0.725
Severe AEs[h, i] until day 91[e]	221	20 (9.0)	168	11 (6.5)	1.38 [0.68; 2.81]; 0.377
Therapy discontinuation due to AEs	No suitable data				

a. Endpoints on morbidity, RR, CI and p value: Poisson model with robust variance, with the stratification factors COVID-19 vaccination within six months before randomisation (yes vs no), administration of tixagevimab/ cilgavimab within twelve months before randomisation (yes vs no) and SARS-CoV-2 infection within six months before randomisation (yes vs no) as covariates and the logarithmised follow-up time as offset; endpoints on mortality and side effects: Estimate is unstratified, CI calculation asymptotic, p value from own calculation (unconditional exact test [CSZ method according to Martín Andrés, Silva Mato 1994)

b. The results on overall mortality are based on the data on fatal AEs.

c. Severe COVID-19 was defined as a combination of a score ≥ 5 on the WHO Clinical Progression Scale for COVID-19 and the presence of at least one of the following two events: Pneumonia (fever ≥ 38°C, cough, tachypnoea or dyspnoea and pulmonary infiltrates), hypoxaemia (SpO_2 < 90% in room air and/or severe dyspnoea).

d. Excluding events categorised by the pharmaceutical company as secondary complications of COVID-19

e. According to the pharmaceutical company, events that occurred within a follow-up period of 90 days after administration of the study medication plus a tolerance range of 13 days were taken into account.

f. SAEs including events categorised by the pharmaceutical company as secondary complications of COVID-19, n (%) sipavibart vs placebo: 25 (11.3%) vs 21 (12.5%), RR [95% CI]; p value (unconditional exact test [CSZ method according to Martín Andrés, Silva Mato 1994): 0.90 [0.53; 1.56]; 0.730

g. or until day 188 if no 2nd dose of the study medication was administered

h. Operationalised as CTCAE grade ≥ 3

i. Severe AEs including events categorised by the pharmaceutical company as secondary complications of COVID-19, n (%) sipavibart vs placebo: 20 (9.0%) vs 14 (8.3%), RR [95% CI]; p value (unconditional exact test [CSZ method according to Martín Andrés, Silva Mato 1994): 1.09 [0.57; 2.09]; 0.844

Abbreviations used:
RR: relative risk; COVID-19: coronavirus disease CI = confidence interval; CIo: upper limit of the confidence interval; N = number of patients evaluated; n = number of patients with (at least one) event, PC = pharmaceutical company, RR = relative risk, SARS-CoV-2 = severe acute respiratory syndrome coronavirus type 2, SAE = serious adverse event, AE = adverse event, vs = versus

b) Adolescents 12 years of age and older weighing at least 40 kg and who are immunocompromised due to a medical condition or receipt of immunosuppressive treatments, with an indication for pre-exposure prophylaxis of COVID-19 disease

No data available.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	∅	No data available.
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Side effects	∅	No data available.

Explanations:
↑: statistically significant and relevant positive effect with low/unclear reliability of data
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↔: 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

a) Adults, who are immunocompromised due to a medical condition or receipt of immunosuppressive treatments, with an indication for pre-exposure prophylaxis of COVID-19 disease

and

b) Adolescents 12 years of age and older weighing at least 40 kg and who are immunocompromised due to a medical condition or receipt of immunosuppressive treatments, with an indication for pre-exposure prophylaxis of COVID-19 disease

Approx. 0[2] patients

[2] At the time of adoption of the resolution, the efficacy of sipavibart against the currently predominantly circulating viral variants with F456L mutations in the spike protein is not available. Pre-exposure prophylaxis with sipavibart may nevertheless be considered in individual cases based on medical assessment.

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 Kavigale (active ingredient: sipavibart) at the following publicly accessible link (last access: 23 June 2025):

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

The viral variants predominantly circulating in Germany at the time of adoption of the resolution show F456L mutations in the spike protein.

Due to the lack of in vitro neutralisation activity, it cannot be assumed that sipavibart offers protection against symptomatic COVID-19 in viral variants with F456L mutations in the spike protein.

4. Treatment costs

Annual treatment costs:

a) Adults, who are immunocompromised due to a medical condition or receipt of immunosuppressive treatments, with an indication for pre-exposure prophylaxis of COVID-19 disease

and

b) Adolescents 12 years of age and older weighing at least 40 kg and who are immunocompromised due to a medical condition or receipt of immunosuppressive treatments, with an indication for pre-exposure prophylaxis of COVID-19 disease

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Sipavibart	€ 2,253.88[3]
Appropriate comparator therapy:	
Monitoring wait-and-see approach	Not calculable

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 July 2025)

Costs for additionally required SHI services: not applicable

[3] Repeated use within one year may be indicated.

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:

a) Adults, who are immunocompromised due to a medical condition or receipt of immunosuppressive treatments, with an indication for pre-exposure prophylaxis of COVID-19 disease

– 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.

b) Adolescents 12 years of age and older weighing at least 40 kg and who are immunocompromised due to a medical condition or receipt of immunosuppressive treatments, with an indication for pre-exposure prophylaxis of COVID-19 disease

– 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.

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.

6. Percentage of study participants at study sites within the scope of SGB V in accordance with Section 35a, paragraph 3, sentence 5 SGB V

The medicinal product Kavigale is a medicinal product placed on the market from 1 January 2025.

The percentage of study participants in the clinical studies of the medicinal product conducted or commissioned by the pharmaceutical company in the therapeutic indication to be assessed who participated at study sites within the scope of SGB V (German Social Security Code) is < 5 per cent of the total number of study participants.

The clinical studies of the medicinal product in the therapeutic indication to be assessed were therefore not conducted to a relevant extent within the scope of SGB V.

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 7 August 2025.

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

Berlin, 7 August 2025

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

Prof. Hecken