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
Sotatercept (new therapeutic indication: pulmonary arterial hypertension, WHO Functional Class IV)

From 6 August 2026

At their session on 6 August 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 number 5 to the information on the benefit assessment of sotatercept in accordance with the resolution of 6 March 2025 (pulomonary arterial hypertension):

Sotatercept

Resolution of: 6 August 2026
Entry into force on: 6 August 2026
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 19 January 2026):

Winrevair, in combination with other pulmonary arterial hypertension (PAH) therapies, is indicated for the treatment of PAH in adult patients with WHO Functional Class (FC) II, III, and IV.

Therapeutic indication of the resolution (resolution of 6 August 2026):

Winrevair, in combination with other pulmonary arterial hypertension (PAH) therapies, is indicated for the treatment of PAH in adult patients with WHO Functional Class (FC) IV.

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

Adults with pulmonary arterial hypertension (PAH) of WHO Functional Class (WHO FC) IV

Appropriate comparator therapy for sotatercept in combination with other PAH therapies:

Individualised therapy with selection of the following triple therapies:

- Parenteral PCA[1] (epoprostenol, treprostinil) + ERA[2] (ambrisentan, bosentan, macitentan) + PDE5 inhibitor[3] (sildenafil, tadalafil)
- Parenteral PCA[1] (epoprostenol, treprostinil) + ERA[2] (ambrisentan, bosentan, macitentan) + sGC stimulator[4] (riociguat)

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

Hint of non-quantifiable additional benefit.

[1] Prostacyclin analogue (PCA)
[2] Endothelin receptor antagonist (ERA)
[3] Phosphodiesterase type 5 inhibitor
[4] Soluble guanylate cyclase (sGC) stimulator

Study results according to endpoints:[5]

Adults with pulmonary arterial hypertension (PAH) of WHO Functional Class (WHO FC) IV

Summary of results for relevant clinical endpoints

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

ZENITH study: RCT, sotatercept versus placebo (each in addition to PAH background therapy), 2nd data cut-off from 6 June 2025

Mortality

Endpoint	Sotatercept + PAH background therapy		Placebo + PAH background therapy		Intervention vs control
	N	Median time to event[a] [95% CI] Patients with event n (%)	N	Median time to event[a] [95% CI] Patients with event n (%)	HR [95% CI]; p value[b]
Overall survival					
Primary analysis[c]	20	n.r. [25.4; n.c.] 3 (15.0)	24	n.r. 3 (12.5)	0.68 [0.11; 4.19] 0.679
Sensitivity analysis[c]	20	n.r. [25.4; n.c.] 4 (20.0)	24	n.r. 5 (20.8)	0.78 [0.20; 3.00] 0.717

[5] Data from the dossier assessment of the IQWiG (A26-12) and from the addendum (A26-12), unless otherwise indicated.

Morbidity

Endpoint	Sotatercept + PAH background therapy		Placebo + PAH background therapy		Intervention vs control
	N	Median time to event[a] [95% CI] Patients with event n (%)	N	Median time to event[a] [95% CI] Patients with event n (%)	HR [95% CI]; p value[b]
Symptomatology (disease progression[d])					
Disease progression[d]	20	n.r. [25.4; n.c.] 5 (25.0)	24	9.5 [5.3; n.c.] 14 (58.3)	0.25 [0.08; 0.78] 0.017
Death from any cause	20	3 (15.0)	24	0 (0.0)	
Lung transplant	20	1 (5.0)	24	0 (0.0)	
Hospitalisation ≥ 24 hours due to PAH deterioration	20	1 (5.0)	24	14 (58.3)	
Dyspnoea					
Borg-CR10 scale – Time to 1st improvement[e]	20[f]	24.1 [12.1; n.c.] 12 (60.0)	24[f]	n.r. [24.1; n.c.] 9 (37.5)	2.04 [0.86; 4.85] 0.107

Endpoint	Sotatercept + PAH background therapy			Placebo + PAH background therapy			Intervention vs control
	N[i]	Values at the start of the study [m] Median (Q1; Q3)	Median change at week 24 [m] MV (min; max)[j]	N[i]	Values at the start of the study [m] Median (Q1; Q3)	Median change at week 24 [m] MV (min; max)[j]	Hodges–Lehmann location shift [95% CI]; p value
Walking ability							
6-minute walk test (6MWT) at week 24	20	197.5 [122.9; 306.1]	91.5 [78.8; 95.5]	24	237.5 [173.5; 327.0]	-5.0 [-5.0; -5.0]	86.24 [-7.84; 180.31]; 0.059

Health-related quality of life

No data on health-related quality of life were assessed.

Side effects

Endpoint	Sotatercept + PAH background therapy		Placebo + PAH background therapy		Intervention vs control
	N	Median time to event[a] [95% CI] Patients with event n (%)	N	Median time to event[a] [95% CI] Patients with event n (%)	HR [95% CI]; p value[b]
AEs (presented additionally)	20	0.9 [0.1; 3.1] 19 (95.0)	24	5.2 [2.3; 9.1] 23 (95.8)	-
SAEs[h]	20	46.4 [10.3; n.c.] 12 (60.0)	24	23.1 [11.9; 55.0] 17 (70.8)	0.71 [0.34; 1.49] 0.365
Discontinuation due to AEs	20	n.r. 0 (0)	24	n.r. 1 (4.2)	n.c.; 0.374

a. The median time to event is given in months for the endpoints of overall survival and disease progression, and in weeks for the endpoints of dyspnoea (Borg-CR10 scale) and health status (EQ-5D VAS), as well as for the endpoints in the category of side effects.
b. HR and CI: Cox proportional hazards model; p value: Wald test; score test in case of zero events in one of the study arms.
c. Primary analysis: excluding events that occurred after lung transplant or entry into the SOTERIA extension study; sensitivity analysis: including events that occurred after lung transplant or entry into the SOTERIA extension study.
d. A composite endpoint comprising the components of death from any cause, lung transplant and hospitalisation ≥ 24 hours due to PAH deterioration; following review by an independent, blinded adjudication committee.
e. A decrease by ≥ 1.5 points compared to the start of the study is considered as clinically relevant improvement (scale range: 0 to 10).
f. Number of patients with a value at the start of the study and at a minimum of 1 subsequent time point.
g. An increase by ≥ 15 points compared to the start of the study is considered as clinically relevant improvement (scale range: 0 to 100).
h. It is assumed that the endpoint will also include disease-related events.
i. Number of patients who were taken into account in the effect estimate; the values at the start of the study and at week 24 can be based on other patient numbers. For patients with a missing value at week 24 due to death, the worst rank value compared with the start of the study was imputed. For patients with a missing value at week 24 due to a non-fatal event at the primary endpoint, the next-worst rank value compared with the start of the study was imputed. For patients with missing values at week 24 for other reasons, multiple imputation was used. Imputed values were used for a total of 4 (20%) vs 5 (21%) of patients (calculation by the IQWiG).
j. Mean value, minimum and maximum of the median changes at week 24 resulting from the imputation data records generated by multiple imputation.

Abbreviations used:
6MWT: 6-minute walk test; CR10: 10-point category ratio; FC: Functional Class; HR: hazard ratio; CI: confidence interval; n: number of patients with (at least 1) event; N: number of patients evaluated; n.c.: not calculable; n.r. = not reached; Q1: 1st quartile; Q3: 3rd quartile; PAH: pulmonary arterial hypertension; RCT: randomised controlled trial; SD: standard deviation; SAE: serious adverse event; AE: adverse event; VAS: visual analogue scale

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

Adults with pulmonary arterial hypertension (PAH) of WHO Functional Class (WHO FC) IV

Approx. 35–130 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 Winrevair (active ingredient: sotatercept) at the following publicly accessible link (last access: 22 June 2026):

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

Treatment with sotatercept should only be initiated and monitored by specialists experienced in the therapy of pulmonary arterial hypertension.

4. Treatment costs

Annual treatment costs:

Adults with pulmonary arterial hypertension (PAH) of WHO Functional Class (WHO FC) IV

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Sotatercept	€ 98,428.67
Individual components of PAH background therapy:	
ERA	€ 16,818.84 - € 19,118.34
PDE5I	€ 2,066.51 - € 2,395.86
Parenteral PCA	Different from patient to patient
sGC stimulator	€ 18,987.00 - € -19,507.29
Appropriate comparator therapy: Individualised therapy with selection of the following triple therapies: parenteral PCA (epoprostenol, treprostinil) + ERA (ambrisentan, bosentan, macitentan) + PDE5 inhibitor (sildenafil, tadalafil) or parenteral PCA (epoprostenol, treprostinil) + ERA (ambrisentan, bosentan, macitentan) + sGC stimulator (riociguat)	
Individualised therapy components	
ERA	€ 16,818.84 - € 19,118.34

Designation of the therapy	Annual treatment costs/ patient
PDE5I	€ 2,066.51 - € 2,395.86
Parenteral PCA	Different from patient to patient
sGC stimulator	€ 18,987.00 - € -19,507.29

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

Costs for additionally required SHI services: not applicable

II. The resolution will enter into force on the day of its publication on the G-BA website on 6 August 2026.

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

Berlin, 6 August 2026

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

Dr Optendrenk