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)
Riociguat (new therapeutic indication: pulmonary arterial hypertension, < 18 years)

of 21 December 2023

At its session on 21 December 2023, 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. 4 to the information on the benefit assessment of Riociguat in accordance with the resolution of 3 September 2020:

Riociguat

Resolution of: 21 December 2023
Entry into force on: 21 December 2023
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 31 May 2023):

Adempas is indicated for the treatment of pulmonary arterial hypertension (PAH) in paediatric patients aged less than 18 years of age and body weight ≥ 50 kg with WHO Functional Class (FC) II to III in combination with endothelin receptor antagonists (see section 5.1b).

Therapeutic indication of the resolution (resolution of 21 December 2023):

See therapeutic indication according to marketing authorisation.

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

Paediatric patients less than 18 years of age and body weight ≥ 50 kg with pulmonary arterial hypertension (PAH)

Appropriate comparator therapy:

Patient-individual therapy taking into account in particular previous therapies, severity grade and underlying diseases with selection of

- Endothelin receptor antagonists: Bosentan, ambrisentan
- phosphodiesterase-type-5 (PDE5) inhibitors: Sildenafil, tadalafil

Extent and probability of the additional benefit of riociguat in combination with endothelin receptor antagonists compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:[1]

Paediatric patients less than 18 years of age and body weight ≥ 50 kg with pulmonary arterial hypertension (PAH)

No suitable data versus the appropriate comparator therapy were presented.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	n.a.	There are no assessable data.
Morbidity	n.a.	There are no assessable data.
Health-related quality of life	n.a.	There are no assessable data.
Side effects	n.a.	There are no assessable data.
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 less than 18 years of age and body weight ≥ 50 kg with pulmonary arterial hypertension (PAH)

approx. 5 – 35 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 Adempas (active ingredient: riociguat) at the following publicly accessible link (last access: 20 September 2023):

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) unless otherwise indicated.

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

Treatment with riociguat should only be initiated and monitored by doctors experienced in treating patients with PAH.

Reference is made to the information in the EPAR on safety aspects in children.

4. Treatment costs

Annual treatment costs:

Paediatric patients less than 18 years of age and body weight ≥ 50 kg with pulmonary arterial hypertension (PAH)

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Riociguat	€ 18,237.26 - € 18,743.66
in combination with (endothelin receptor antagonists)	
Bosentan	€ 21,567.42 - € 136,473.76
Total: Riociguat + bosentan	€ 39,804.69 - € 155,217.42
Ambrisentan	€ 21,296.05 - € 21,567.42
Total: Riociguat + ambrisentan[2]	€ 39,533.31 - € 40,311.09
Appropriate comparator therapy:	
Patient-individual therapy taking into account in particular previous therapies, severity grade and underlying diseases with selection of:	
Monotherapy:	
Endothelin receptor antagonists:	
Bosentan	€ 21,567.42 - € 136,473.76
Ambrisentan	€ 21,296.05 - € 21,567.42
phosphodiesterase-type-5 (PDE5) inhibitors:	
Sildenafil	€ 3,151.05
Tadalafil	€ 3,115.01
Combination therapy:	
Bosentan + sildenafil	€ 24,718.47 - € 139,624.81
Bosentan + tadalafil	€ 24,682.44 - € 139,588.78

[2] The lower limit is made up of the lowest riociguat dose and the highest ambrisentan dose, the upper limit is made up of the highest riociguat dose and the lowest ambrisentan dose.

Designation of the therapy	Annual treatment costs/ patient
Ambrisentan + sildenafil	€ 24,447.09 - € 24,718.47
Ambrisentan + tadalafil	€ 24,411.06 - € 24,682.44

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 December 2023

Costs for additionally required SHI services: not applicable

5. 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 riociguat

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 less than 18 years of age and body weight ≥ 50 kg with pulmonary arterial hypertension (PAH)

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

II. **The resolution will enter into force on the day of its publication on the website of the G-BA on 21 December 2023.**

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

Berlin, 21 December 2023

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

Prof. Hecken