Resolution

Gemeinsamer Bundesausschuss

of the Federal Joint Committee (G-BA) on an Amendment of the Pharmaceuticals Directive (AM-RL): Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients According to Section 35a SGB V Riociguat (Reassessment of an Orphan Drug after Exceeding the € 50 Million Limit: PAH)

of 3 September 2020

At its session on 3 September 2020, the Federal Joint Committee (G-BA) resolved to amend the Directive on the Prescription of Medicinal Products in SHI-accredited Medical Care (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 on DD Month YYYY (Federal Gazette, BAnz AT DD MM YYYY BX), as follows:

I. Annex XII will be amended as follows:

1. The information relating to riociguat as amended by the resolution of 16 October 2014 (Federal Gazette, BAnz AT 26 November 2014 B3) is hereby repealed.
2. Annex XII shall be amended in alphabetical order to include the active ingredient riociguat as follows:

Riociguat

Resolution of: 3 September 2020
Entry into force on: 3 September 2020
Federal Gazette, BAnz AT DD MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 27 March 2014):

Adempas, as monotherapy or in combination with endothelin receptor antagonists, is indicated for the treatment of adult patients with pulmonary arterial hypertension (PAH) with WHO Functional Class (FC) II to III to improve exercise capacity.

1. Medicinal product in relation to the appropriate comparator therapy

Adult patients with pulmonary arterial hypertension (PAH) with WHO Functional Class (FC) II to III

Appropriate comparator therapy:

Patient-individual optimised medicinal therapy, taking into account previous therapies and the patient's state of health, taking into account the following therapies:

- Endothelin receptor antagonists (ambrisentan, bosentan, macitentan)
- Phosphodiesterase type 5 inhibitors (sildenafil, tadalafil)
- Prostacyclin analogues (iloprost)
- Selective prostacyclin receptor agonists (selexipag)

Extent and probability of the additional benefit of riociguat compared with the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:

Adult patients with pulmonary arterial hypertension (PAH) with WHO Functional Class (FC) II to III

No suitable data were submitted for the benefit assessment.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ Risk of bias	Summary
Mortality	n.a.	No data suitable for the benefit assessment
Morbidity	n.a.	No data suitable for the benefit assessment
Health-related quality of life	n.a.	No data suitable for the benefit assessment
Side effects	n.a.	No data suitable 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 ∅: There are no usable data for the benefit assessment. n.a.: not assessable		

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

Adult patients with pulmonary arterial hypertension (PAH) with WHO Functional Class (FC) II to III

approx. 580–7,850 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: 18 June 2020):

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

Treatment with riociguat should only be initiated and monitored by specialists who are experienced in the treatment of patients with PAH.

4. Treatment costs

Annual treatment costs:

Adult patients with pulmonary arterial hypertension (PAH) with WHO Functional Class (FC) II to III

Designation of the therapy	Annual treatment costs/patient
Medicinal product to be assessed:	
Riociguat	€ 32,673.87 – 33,178.11
Appropriate comparator therapy:	
Endothelin receptor antagonists	
Ambrisentan	€ 24,455.24 – 24,912.95
Bosentan	€ 22,323.10
Macitentan	€ 24,791.65
Phosphodiesterase type 5 inhibitors	
Sildenafil	€ 8,309.70
Tadalafil	€ 7,228.03
Prostacyclin analogues	
Iloprost Additionally required SHI services (first year)	€ 50,585.09 – 75,877.63 € 3,500
Selective prostacyclin receptor agonists	
Selexipag	€ 31,525.47 – 37,138.14

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 August 2020

II. The resolution will enter into force with effect from the day of its publication on the internet on the website of the G-BA on 3 September 2020.

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

Berlin, 3 September 2020

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

Prof. Hecken