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
Isavuconazole (new therapeutic indication: mucormycosis, ≥ 1 to ≤ 17 years)

of 20 March 2025

At its session on 20 March 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. **In Annex XII, the following information shall be added after No. 5 to the information on the benefit assessment of the active ingredient in the version of the resolution of 20 March 2025 on the therapeutic indication "CRESEMBA is indicated in children and adolescents from 1 year of age and older for the treatment of invasive aspergillosis":**

Isavuconazole

Resolution of: 20 March 2025
Entry into force on: 20 March 2025
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 22 August 2024):

CRESEMBA is indicated in patients from 1 year of age and older for the treatment of

- invasive aspergillosis
- mucormycosis in patients for whom amphotericin B is inappropriate

Therapeutic indication of the resolution (resolution of 20 March 2025):

Cresemba is indicated in children and adolescents from 1 year of age and older for the treatment of mucormycosis in patients for whom amphotericin B is inappropriate.

1. Extent of the additional benefit and significance of the evidence

Isavuconazole is approved as a medicinal product for the treatment of rare diseases in accordance with Regulation (EC) No. 141/2000 of the European Parliament and the Council of 16 December 1999 on orphan drugs. In accordance with Section 35a, paragraph 1, sentence 11, 1st half of the sentence SGB V, the additional medical benefit is considered to be proven through the grant of the marketing authorisation.

The G-BA determines the extent of the additional benefit for the number of patients and patient groups for which there is a therapeutically significant additional benefit in accordance with Chapter 5 Section 12, paragraph 1, number 1, sentence 2 of its Rules of Procedure (VerfO) in conjunction with Section 5, paragraph 8 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV), indicating the significance of the evidence. This quantification of the additional benefit is based on the criteria laid out in Chapter 5 Section 5, paragraph 7, numbers 1 to 4 of the Rules of Procedure (VerfO).

Children and adolescents aged 1 to ≤ 17 years with mucormycosis for whom treatment with amphotericin B is inappropriate

Extent of the additional benefit and significance of the evidence of isavuconazole:

Hint for a non-quantifiable additional benefit since the scientific data does not allow quantification.

Study results according to endpoints:[1]

Children and adolescents aged 1 to ≤ 17 years with mucormycosis for whom treatment with amphotericin B is inappropriate

There are no assessable data.

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	∅	No data available
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

Children and adolescents aged 1 to ≤ 17 years with mucormycosis for whom treatment with amphotericin B is inappropriate

Approx. 8 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 Cresemba (active ingredient: isavuconazole) at the following publicly accessible link (last access: 10 February 2025):

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

[1] Data from the dossier assessment of the G-BA (published on 2. January 2025), unless otherwise indicated.

4. Treatment costs

Annual treatment costs:

Children and adolescents aged 1 to ≤ 17 years with mucormycosis for whom treatment with amphotericin B is inappropriate

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Isavuconazole	€ 45,656.81 - € 165,053.00

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 March 2025)

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:

Children and adolescents aged 1 to ≤ 17 years with mucormycosis for whom treatment with amphotericin B is inappropriate

- 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.

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 20 March 2025.

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

Berlin, 20 March 2025

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

Prof. Hecken