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 Artesunate (severe malaria, from birth)

of 17 April 2025

At their session on 17 April 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 Artesunate as follows:

Artesunate

Resolution of: 17 April 2025
Entry into force on: 17 April 2025
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 22 January 2024):

Artesunate Amivas is indicated for the initial treatment of severe malaria in adults and children. Consideration should be given to official guidelines on the appropriate use of antimalarial agents.

Therapeutic indication of the resolution (resolution of 17 April 2025):

See therapeutic indication according to marketing authorisation.

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

Artesunate 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).

<u>Children (from birth) and adults with severe malaria (for initial treatment)</u>

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

Non-quantifiable additional benefit since the required provision of evidence is incomplete.

Study results according to endpoints:[1]

Children (from birth) and adults with severe malaria (for initial treatment)

No data available.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	∅	No data available.
Morbidity	∅	No data available.
Health-related quality of life	∅	No data available.
Side effects	∅	No data available.
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 (from birth) and adults with severe malaria (for initial treatment)

Approx. 87 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 Artesunate Amivas (active ingredient: artesunate) at the following publicly accessible link (last access: 7 November 2024):

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

Treatment with artesunate should only be initiated and monitored by doctors experienced in severe malaria therapy.

[1] Data from the dossier assessment of the G-BA (published on 3. February 2025), unless otherwise indicated.

4. Treatment costs

Annual treatment costs:

Children (from birth) and adults with severe malaria (for initial treatment)

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Artesunate	€ 7,616.00 – € 11,424.00

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 April 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 (from birth) and adults with severe malaria (for initial treatment)

- 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.

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 17 April 2025.

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

Berlin, 17 April 2025

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

Prof. Hecken