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
Vutrisiran (new therapeutic indication: wild-type or hereditary transthyretin amyloidosis with cardiomyopathy)

of 22 January 2026

At their session on 22 January 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 No. 5 to the information on the benefit assessment of Vutrisiran in accordance with the resolution of 6 April 2023:

Vutrisiran

Resolution of: 22 January 2026
Entry into force on: 22 January 2026
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 5 June 2025):

Amvuttra is indicated for the treatment of wild-type or hereditary transthyretin amyloidosis in adult patients with cardiomyopathy (ATTR-CM).

Therapeutic indication of the resolution (resolution of 22 January 2026):

See new therapeutic indication according to marketing authorisation.

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

Adults with wild-type or hereditary transthyretin amyloidosis with cardiomyopathy (ATTR-CM)

Appropriate comparator therapy:

- Tafamidis

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

An additional benefit is not proven.

Study results according to endpoints:[1]

Adults with wild-type or hereditary transthyretin amyloidosis with cardiomyopathy (ATTR-CM)

There are no assessable data.

[1] Data from the dossier assessment of the IQWiG (A25-93) and from the addendum (A25-149), unless otherwise indicated.

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

Adults with wild-type or hereditary transthyretin amyloidosis with cardiomyopathy (ATTR-CM)

Approx. 1,760 to 2,120 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 Amvuttra (active ingredient: vutrisiran) at the following publicly accessible link (last access: 2 October 2025):

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

Treatment with vutrisiran should only be initiated and monitored by specialists and general practitioners experienced in the treatment of patients with transthyretin amyloidosis with cardiomyopathy (ATTR-CM).

4. Treatment costs

Annual treatment costs:

Adults with wild-type or hereditary transthyretin amyloidosis with cardiomyopathy (ATTR-CM)

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Vutrisiran	€ 300,962.00
Appropriate comparator therapy:	
Tafamidis	€ 135,138.33

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 01 November 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:

Adults with wild-type or hereditary transthyretin amyloidosis with cardiomyopathy (ATTR-CM)

– 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 22 January 2026.

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

Berlin, 22 January 2026

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

Prof. Hecken