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
Diflunisal (hereditary transthyretin-mediated amyloidosis with stage 1 or stage 2 polyneuropathy)

dated 7 May 2026

At their session on 7 May 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, information on the active ingredient Diflunisal shall be added in alphabetical order as follows:

Diflunisal

Resolution of: 7 May 2026
Entry into force on: 7 May 2026
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 17 July 2025):

Attrogy is indicated for the treatment of hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) in adult patients with stage 1 or stage 2 polyneuropathy.

Therapeutic indication of the resolution (resolution of 7 May 2026):

See therapeutic indication according to marketing authorisation.

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

Adults with hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) with stage 1 or stage 2 polyneuropathy

Appropriate comparator therapy:

- vutrisiran

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

An additional benefit is not proven.

Study results according to endpoints:[1]

Adults with hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) with stage 1 or stage 2 polyneuropathy

No suitable data available.

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A25-144), 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 hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) with stage 1 or stage 2 polyneuropathy

Approx. 360 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 Attrogy (active ingredient: diflunisal) at the following publicly accessible link (last access: 12 February 2026):

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

4. Treatment costs

Annual treatment costs:

Adults with hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) with stage 1 or stage 2 polyneuropathy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Diflunisal	€ 92,864.76
Appropriate comparator therapy:	
Vutrisiran	€ 149,203.12

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 March 2026)

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 hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) with stage 1 or stage 2 polyneuropathy

- No medicinal product with new active ingredients for use in combination therapy in compliance with 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 G-BA website on 7 May 2026.

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

Berlin, 7 May 2026

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

Prof. Hecken