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)
Dimethyl fumarate (new therapeutic indication: relapsing remitting multiple sclerosis, ≥ 13 years)

of 18 January 2024

At its session on 18 January 2024, 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. 4 to the information on the benefit assessment of Dimethyl fumarate in accordance with the resolution of 16 March 2018:**

Dimethyl fumarate

Resolution of: 18 January 2024
Entry into force on: 18 January 2024
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 13 May 2022):

Tecfidera is indicated for the treatment of adult and paediatric patients aged 13 years and older with relapsing remitting multiple sclerosis (RRMS).

Therapeutic indication of the resolution (resolution of 18 January 2024):

Tecfidera is indicated for the treatment of paediatric patients aged 13 years and older with relapsing remitting multiple sclerosis (RRMS).

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

Children and adolescents aged ≥ 13 to < 18 years with relapsing remitting multiple sclerosis (RRMS) who have not yet received disease-modifying therapy or children and adolescents pre-treated with disease-modifying therapy whose disease is not highly active

Appropriate comparator therapy for dimethyl fumarate:

– Interferon-beta 1b or glatiramer acetate or teriflunomide, taking into account the authorisation status

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

An additional benefit is not proven.

Study results according to endpoints:

Children and adolescents aged ≥ 13 to < 18 years with relapsing remitting multiple sclerosis (RRMS) who have not yet received disease-modifying therapy or children and adolescents pre-treated with disease-modifying therapy whose disease is not highly active

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

Children and adolescents aged ≥ 13 to < 18 years with relapsing remitting multiple sclerosis (RRMS) who have not yet received disease-modifying therapy or children and adolescents pre-treated with disease-modifying therapy whose disease is not highly active

Approx. 350 to 1,200 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 Tecfidera (active ingredient: dimethyl fumarate) at the following publicly accessible link (last access: 15 December 2023):

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

Treatment with dimethyl fumarate should only be initiated and monitored by specialists in neurology or neurology and psychiatry or paediatrics with specialisation in neuropaediatrics who are experienced in the treatment of patients with multiple sclerosis.

A Direct Healthcare Professional Communication ("Rote-Hand-Brief") is available for dimethyl fumarate for risk minimisation of progressive multifocal leukoencephalopathy (PML).

4. Treatment costs

Annual treatment costs:

Children and adolescents aged ≥ 13 to < 18 years with relapsing remitting multiple sclerosis (RRMS) who have not yet received disease-modifying therapy or children and adolescents pre-treated with disease-modifying therapy whose disease is not highly active

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Dimethyl fumarate	€ 11,266.77
Appropriate comparator therapy:	
Glatiramer acetate	€ 13,121.18
Interferon-ß 1b	€ 18,484.34
Teriflunomide	€ 6,944.91

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 January 2024

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 ≥ 13 to < 18 years with relapsing remitting multiple sclerosis (RRMS) who have not yet received disease-modifying therapy or children and adolescents pre-treated with disease-modifying therapy whose disease is not highly active

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. Entry into force

1. **The resolution will enter into force on the day of its publication on the website of the G-BA on 18 January 2024.**

2. **The period of validity of the resolution is limited to 1 July 2024.**

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

Berlin, 18 January 2024

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

Prof. Hecken