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: Teriflunomide (new therapeutic indication: relapsing remitting multiple sclerosis, 10 - 17 years)

of 20 January 2022

At its session on 20 January 2022, 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 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 Teriflunomide in accordance with the resolution of 20 March 2014:

Teriflunomide

Resolution of: 20 January 2022
Entry into force on: 20 January 2022
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 18 June 2021):

AUBAGIO is indicated for the treatment of adult patients and paediatric patients aged 10 years and older with relapsing remitting multiple sclerosis (MS). See section 5.1 for more information on the patients in whom efficacy has been demonstrated.

Therapeutic indication of the resolution (resolution of 20 January 2022):

Children and adolescents aged ≥ 10 to < 18 years with relapsing remitting multiple sclerosis.

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

Children and adolescents aged ≥ 10 to < 18 years with relapsing remitting multiple sclerosis 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:

- interferon beta-1a or interferon beta-1b or glatiramer acetate, taking into account the authorisation status

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

An additional benefit is not proven.

Study results according to endpoints:

Children and adolescents aged ≥ 10 to < 18 years with relapsing remitting multiple sclerosis 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	∅	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
∅: There are no usable data for the benefit assessment.
n.a.: not assessable

No data submitted.

2. Number of patients or demarcation of patient groups eligible for treatment

Children and adolescents aged ≥ 10 to < 18 years with relapsing remitting multiple sclerosis 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 – 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 Aubagio (active ingredient: teriflunomide) at the following publicly accessible link (last access: 30 September 2021):

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

Treatment with teriflunomide should be initiated and monitored by a specialist in neurology or by a specialist in neurology and psychiatry or by a specialist in paediatrics and adolescent medicine with specialisation in neuropaediatrics and experience in the treatment of multiple sclerosis.

In accordance with the European Medicines Agency (EMA) requirements regarding additional risk minimisation measures, the pharmaceutical company must provide a discussion guide for doctors and health professionals as well as a patient information card. Both materials point, among others, to the teratogenic potential of teriflunomide.

4. Treatment costs

Annual treatment costs:

Children and adolescents aged ≥ 10 to < 18 years with relapsing remitting multiple sclerosis 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:	
Teriflunomide	€ 13,405.15 - € 13,118.23
Appropriate comparator therapy:	
Interferon beta-1a	€ 20,326.95
Interferon beta-1b[1]	€ 16,875.25
Glatiramer acetate[1]	€ 13,121.95

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 1 January 2022)

Costs for additionally required SHI services: not applicable

1 From the age of 12

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 20 January 2022.

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

Berlin, 20 January 2022

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

Prof. Hecken