Gemeinsamer Bundesausschuss

Resolution

of the Federal Joint Committee (G-BA) on an Amendment of the Pharmaceuticals Directive (AM-RL): Annex XII - Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a SGB V:

Ponesimod (relapsing multiple sclerosis)

of 2 December 2021

At its session on 2 December 2021, 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 on DD. 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 ponesimod as follows:

Ponesimod

Resolution of: 2 December 2021
Entry into force on: 2 December 2021
BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 21 June 2021):

Ponvory is indicated for the treatment of adult patients with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features.

Therapeutic indication of the resolution (resolution of 2 December 2021):

see therapeutic indication according to marketing authorisation.

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

b) Adult patients with relapsing forms of multiple sclerosis (RMS) with highly active disease despite disease-modifying therapy[1].

Appropriate comparator therapy:

- alemtuzumab or fingolimod or natalizumab

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

An additional benefit is not proven.

1 An appropriate (pre)treatment usually lasts at least 6 months. Depending on relapse frequency and severity as well as disability progression, the treatment duration with disease-modifying therapy may be less than 6 months and must be justified.

Study results according to endpoints:

b) Adult patients with relapsing forms of multiple sclerosis (RMS) with highly active disease despite disease-modifying therapy.

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

b) Adult patients with relapsing forms of multiple sclerosis (RMS) with highly active disease despite disease-modifying therapy.

approx. 21,000 – 23,000 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 Ponvory (active ingredient: ponesimod) at the following publicly accessible link (last access: 10 August 2021):

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

Treatment with ponesimod should only be initiated and monitored by specialists in neurology or specialists in neurology and psychiatry with experience in the treatment of multiple sclerosis.

According to the requirements of the European Medicines Agency (EMA) with regard to additional measures for risk minimisation, the pharmaceutical company must provide healthcare professionals with a checklist for the reduction of medicinal product and application risks as well as a patient guideline and a patient card for safe use.

4. Treatment costs

Annual treatment costs:

b) Adult patients with relapsing forms of multiple sclerosis (RMS) with highly active disease despite disease-modifying therapy.

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Ponesimod	€ 22,995.39
Appropriate comparator therapy:	
Alemtuzumab Additionally required SHI services: Total:	€ 52,889.80 (year 1) € 31,733.88 (year 2) € 58.00 € 52,947.80 (year 1) € 31,791.88 (year 2)
Fingolimod	€ 22,102.84
Natalizumab	€ 29,782.48

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 15 November 2021)

Other SHI services:

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Alemtuzumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 71	5 (year 1) 3 (year 2)	5 (year 1) 3 (year 2)	€ 355.00 € 213.00
Natalizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 71	1	13	€ 923.00

II. The resolution will enter into force on the day of its publication on the internet on the website of the G-BA on 2 December 2021.

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

Berlin, 2 December 2021

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

Prof. Hecken