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
Faricimab (new therapeutic indication: macular oedema secondary to retinal vein occlusion)

of 20 February 2025

At its session on 20 February 2025, 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 Faricimab in accordance with the resolution of 6 April 2023 (neovascular age-related macular degeneration) last modified on 27 June 2023:

Faricimab

Resolution of: 20 February 2025
Entry into force on: 20 February 2025
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 26 July 2024):

Vabysmo is indicated for the treatment of adult patients with visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO).

Therapeutic indication of the resolution (resolution of 20 February 2025):

See new therapeutic indication according to marketing authorisation.

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

a) Adults with visual impairment due to macular oedema secondary to branch retinal vein occlusion (BRVO)

Appropriate comparator therapy:

– Aflibercept or ranibizumab

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

An additional benefit is not proven.

b) Adults with visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO)

Appropriate comparator therapy:

– Aflibercept or ranibizumab

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

An additional benefit is not proven.

Study results according to endpoints:[1]

a) Adults with visual impairment due to macular oedema secondary to branch retinal vein occlusion (BRVO)

There are no assessable data.

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		

b) Adults with visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO)

There are no assessable data.

Summary of results for relevant clinical endpoints

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[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A24-85) unless otherwise indicated.

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

a) Adults with visual impairment due to macular oedema secondary to branch retinal vein occlusion (BRVO)

and

b) Adults with visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO)

Approx. 59,200 – 96,400 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 Vabysmo (active ingredient: faricimab) at the following publicly accessible link (last access: 11 November 2024):

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

Treatment with faricimab should only be initiated and monitored by doctors experienced in the therapy of macular oedema secondary to retinal vein occlusion.

In accordance with the European Medicines Agency (EMA) requirements regarding additional risk minimisation measures, the pharmaceutical company must provide training material that contains information for patients. In particular, the training material contains information and warnings about infective endophthalmitis and intraocular inflammation.

4. Treatment costs

Annual treatment costs:

a) Adults with visual impairment due to macular oedema macular oedema secondary to branch retinal vein occlusion (BRVO)

and

b) Adults with visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO)

Designation of the therapy	Annual treatment costs/ patient	
Medicinal product to be assessed:		
Faricimab	1st year:	€ 2,728.38 – € 12,732.44
	Subsequent years:	€ 0 – € 11,822.98
Intravitreal injection	1st year:	€ 289.26 – € 2,888.90
	Subsequent years:	€ 0 – € 2,682.55
Postoperative treatment	1st year:	€ 62.10 – € 404.32
	Subsequent years:	€ 0 – € 375.44
Additionally required SHI services	non-quantifiable[2]	
Total	1st year:	€ 3,079.74 – € 16,025.66
	Subsequent years:	€ 0 – € 14,880.97
Appropriate comparator therapy:		
Aflibercept	1st year:	€ 3,112.23 – € 12,448.92
	Subsequent years:	€ 0 – € 12,448.92
Intravitreal injection	1st year:	€ 289.26 – € 2,476.20
	Subsequent years:	€ 0 – € 2,476.20
Postoperative treatment	1st year:	€ 62.10 – € 346.56
	Subsequent years:	€ 0 – € 346.56
Additionally required SHI services	non-quantifiable[2]	
Total	1st year:	€ 3,463.59 – € 15,271.68
	Subsequent years:	€ 0 – € 15,271.68
Ranibizumab	1st year:	3,397.50 – 13,590.00
	Subsequent years:	€ 0 – € 13,590.00
Intravitreal injection	1st year:	€ 289.26 – € 2,476.20
	Subsequent years:	€ 0 – € 2,476.20
Postoperative treatment	1st year:	€ 62.10 – € 346.56

[2] Due to the individual determination of the type and frequency of check-ups by the attending physician, the costs incurred for all therapy options cannot be quantified.

Designation of the therapy	Annual treatment costs/ patient	
	Subsequent years:	€ 0 – € 346.56
Additionally required SHI services	non-quantifiable[2]	
Total	1st year:	€ 3,748.86 – € 16,412.76
	Subsequent years:	€ 0 – € 16,412.76

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 February 2025)

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:

a) Adults with visual impairment due to macular oedema secondary to branch retinal vein occlusion (BRVO)

- No medicinal product with new active ingredients that can be used in a combination therapy and fulfils the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

b) Adults with visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO)

- 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 20 February 2025.

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

Berlin, 20 February 2025

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

Prof. Hecken