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
Bevacizumab (neovascular (wet) age-related macular degeneration (nAMD))

of 16 October 2025

At their session on 16 October 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. Annex XII shall be amended in alphabetical order to include the active ingredient Bevacizumab as follows:

Bevacizumab

Resolution of: 16 October 2025
Entry into force on: 16 October 2025
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 27 May 2024):

Lytenava is indicated in adults for treatment of neovascular (wet) age-related macular degeneration (nAMD).

Therapeutic indication of the resolution (resolution of 16 October 2025):

See therapeutic indication according to marketing authorisation.

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

Adults with neovascular (wet) age-related macular degeneration (nAMD)

Appropriate comparator therapy for bevacizumab:

- Aflibercept or faricimab or ranibizumab

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

An additional benefit is not proven.

Study results according to endpoints:[1]

Adults with neovascular (wet) age-related macular degeneration (nAMD)

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	∅	No data available.
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		

[1] Data from IQWiG's dossier assessment (A25-57)

∅: No data available. n.a.: not assessable

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

Adults with neovascular (wet) age-related macular degeneration (nAMD)

Approx. 85,500 – 504,400 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 Lytenava (active ingredient: bevacizumab) at the following publicly accessible link (last access: 20 June 2025):

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

Treatment with bevacizumab should only be initiated and monitored by specialists experienced in the administration of intravitreal injections.

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. The training material contains, in particular, information and warnings about infective endophthalmitis.

The medicinal product should be discontinued if visual and anatomical findings indicate that the patient will not benefit from continued treatment.

4. Treatment costs

Annual treatment costs:

Adults with neovascular (wet) age-related macular degeneration (nAMD)

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Bevacizumab	1st year: up to € 10,886.52[2]
	Subsequent years: € 0 – € 10,886.52
Intravitreal injection	1st year: up to € 2,476.20[2]
	Subsequent years: € 0 - € 2,476.20

[2] The interval duration is individualised based on the disease activity. The product information does not state how long the treatment interval should be extended in increments. For this reason, no range can be given for the annual treatment costs in the first year of treatment.

Designation of the therapy	Annual treatment costs/ patient
Postoperative treatment	1st year: up to € 346.56[2]
	Subsequent years: € 0 – € 346.56
Additionally required SHI services	non-quantifiable[3]
Appropriate comparator therapy:	
Aflibercept	1st year: € 6,224.46 – € 7,261.87
	Subsequent years: € 0 – € 6,224.46
Intravitreal injection	1st year: € 578.52 – € 1,444.45
	Subsequent years: € 0 – € 1,238.10
Postoperative treatment	1st year: € 124.20 – € 202.16
	Subsequent years: € 0 – € 173.28
Additionally required SHI services	non-quantifiable[3]
Faricimab	1st year: € 4,547.30 – € 7,275.68
	Subsequent years: € 3,001.22 – € 5,911.49
Intravitreal injection	1st year: € 482.10 – € 1,650.80
	Subsequent years: € 318.19 – € 1,341.28
Postoperative treatment	1st year: € 103.50 – € 231.04
	Subsequent years: € 68.31 – € 187.72
Additionally required SHI services	non-quantifiable[3]
Ranibizumab	1st year: € 7,927.50 – € 13,590.00
	Subsequent years: € 0 – € 13,590.00
Intravitreal injection	1st year: € 674.94 – € 2,476.20
	Subsequent years: € 0 – € 2,476.20
Postoperative treatment	1st year: € 144.90 – € 346.56
	Subsequent years: € 0 – € 346.56
Additionally required SHI services	non-quantifiable[3]

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

[3] Due to the patient-individual determination of the type and frequency of check-ups by the attending physician, the costs incurred for additionally required SHI services, e.g. optical coherence tomography and further check-ups are non-quantifiable.

Adults with neovascular (wet) age-related macular degeneration (nAMD)

- 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.

6. Percentage of study participants at study sites within the scope of SGB V in accordance with Section 35a, paragraph 3, sentence 5 SGB V

The medicinal product Lytenava is a medicinal product placed on the market from 1 January 2025.

The percentage of study participants in the clinical studies of the medicinal product conducted or commissioned by the pharmaceutical company in the therapeutic indication to be assessed who participated at study sites within the scope of SGB V (German Social Security Code) is < 5% of the total number of study participants.

The clinical studies of the medicinal product in the therapeutic indication to be assessed were therefore not conducted to a relevant extent within the scope of SGB V.

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 16 October 2025.

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

Berlin, 16 October 2025

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

Prof. Hecken