Resolution

Gemeinsamer Bundesausschuss

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 Brolucizumab (Neovascular Age-related Macular Degeneration)

of 3 September 2020

At its session on 3 September 2020, the Federal Joint Committee (G-BA) resolved to amend the Directive on the Prescription of Medicinal Products in SHI-accredited Medical Care (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 brolucizumab as follows:

Brolucizumab

Resolution of: 3 September 2020
Entry into force on: 3 September 2020
Federal Gazette, BAnz AT DD MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 13 February 2020):

Beovu® is indicated in adults for the treatment of neovascular (wet) age-related macular degeneration (AMD).

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

Adults with neovascular (wet) age-related macular degeneration

Appropriate comparator therapy:
- Ranibizumab or aflibercept

Extent and probability of the additional benefit of brolucizumab compared with ranibizumab or aflibercept

An additional benefit is not proven.

Study results according to endpoints:

Adults with neovascular (wet) age-related macular degeneration

No data were submitted.

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

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

Adults with neovascular (wet) age-related macular degeneration

approx. 85,200–681,400 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 Beovu® (active ingredient: brolucizumab) at the following publicly accessible link (last access: 10 June 2020):

https://www.ema.europa.eu/documents/product-information/beovu-epar-product-information_de.pdf

Brolucizumab may be administered only by a qualified ophthalmologist experienced in the performance and after-care of intravitreal injections.

Officially approved informational materials on risk minimisation are available for the medicinal product.

4. Treatment costs

The annual treatment costs shown refer to the first year of treatment.

Annual treatment costs:

Adults with neovascular (wet) age-related macular degeneration

Designation of the therapy	Annual treatment costs/patient (for one eye)
Medicinal product to be assessed:	
Brolucizumab	€ 5,948.35 – 7,826.78
Intravitreal injection	€ 505.42 – 1,386.83
Postoperative treatment	€ 104.60 – 192.00
Additionally required SHI services	Non-quantifiable[1]
Total:	€ 6,558.36 – 9,405.60
Appropriate comparator therapy:	
Aflibercept	€ 6,359.35 – 7,065.94
Intravitreal injection	€ 558.62 – 1,294.37
Postoperative treatment	€ 115.61 – 179.20
Additionally required SHI services	Non-quantifiable
Total:	€ 7,033.57 – 8,539.51
Ranibizumab	€ 8,236.64 – 13,921.08
Intravitreal injection	€ 629.56 – 2,218.92
Postoperative treatment	€ 130.29 – 307.20
Additionally required SHI services	Non-quantifiable[1]
Total:	€ 8,996.48 – 16,447.20

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 August 2020

[1]Because of the individual determination of the type and frequency of control examinations by the attending doctor, the costs incurred for all therapy options cannot be quantified.

II. Entry into force

1. The resolution will enter into force with effect from the day of its publication on the internet on the website of the G-BA on 3 September 2020.

2. The period of validity of the resolution is limited to 1 November 2023.

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

Berlin, 3 September 2020

Federal Joint Committee
in accordance with Section 91 SGB V
The Chair

Prof. Hecken