

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

Inebilizumab (new therapeutic indication: myasthenia gravis,
anti-AChR antibody positive, anti-MuSK antibody positive)

From 3 September 2026

At their session on 3 September 2026, 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 number 4 to the information on the benefit assessment of Inebilizumab in accordance with the resolution of 3 September 2026 (immunoglobulin G4-related disease):**

Inebilizumab

Resolution of: 3 September 2026

Entry into force on: 3 September 2026

Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 10 February 2026):

Uplizna is indicated as an add-on to standard therapy for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive.

Therapeutic indication of the resolution (resolution of 3 September 2026):

See therapeutic indication according to marketing authorisation.

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

- a) Adults with anti-acetylcholine receptor antibody positive generalized myasthenia gravis who are eligible for an add-on to standard therapy

Appropriate comparator therapy for inebilizumab as an add-on therapy:

- eculizumab (only suitable for refractory patients) or
- efgartigimod alfa or
- ravulizumab or
- rozanolixizumab or
- zilucoplan

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

An additional benefit is not proven.

- b) Adults with anti-muscle-specific tyrosine kinase antibody positive generalized myasthenia gravis who are eligible for an add-on to standard therapy

Appropriate comparator therapy for inebilizumab as an add-on therapy:

- rozanolixizumab

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

An additional benefit is not proven.

Study results according to endpoints:¹

- a) Adults with anti-acetylcholine receptor antibody positive generalized myasthenia gravis who are eligible for an add-on to standard therapy

There are no suitable 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 anti-muscle-specific tyrosine kinase antibody positive generalized myasthenia gravis who are eligible for an add-on to standard therapy

There are no suitable 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.
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¹ Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A26-27), unless otherwise indicated.

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

- a) Adults with anti-acetylcholine receptor antibody positive generalized myasthenia gravis who are eligible for an add-on to standard therapy

Approximately 6,300 – 19,000 patients

- b) Adults with anti-muscle-specific tyrosine kinase antibody positive generalized myasthenia gravis who are eligible for an add-on to standard therapy

Approximately 170 – 730 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 Uplizna (active ingredient: inebilizumab) at the following publicly accessible link (last access: 18 June 2026):

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

Treatment with inebilizumab should only be initiated and monitored by specialists experienced in treating patients with gMG.

4. Treatment costs

Annual treatment costs:

- a) Adults with anti-acetylcholine receptor antibody positive generalized myasthenia gravis who are eligible for an add-on to standard therapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Inebilizumab	€ 102,811.30
Additionally required SHI services:	€ 141.20 – € 153.15
Appropriate comparator therapy:	
Eculizumab (for refractory patients) or efgartigimod alfa or ravulizumab or rozanolixizumab or zilucoplan	
Eculizumab	€ 505,408.51 – € 673,878.02
Efgartigimod alfa	€ 55,891.04 – € 413,593.70
Ravulizumab	€ 301,874.04
Rozanolixizumab	€ 262,793.65 – € 506,121.10
Zilucoplan	€ 281,976.19

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 1 July 2026)

Other SHI services:

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Inebilizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	2.0	1	€ 200
Eculizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	22.8 – 30.4	1	€ 2,280 - € 3,040
Ravulizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	6.5	1	650

b) Adults with anti-muscle-specific tyrosine kinase antibody positive generalized myasthenia gravis who are eligible for an add-on to standard therapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Inebilizumab	€ 102,811.30
Additionally required SHI services:	€ 141.20 – € 153.15
Appropriate comparator therapy:	
Rozanolixizumab	
Rozanolixizumab	€ 262,793.65 – € 506,121.10

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 1 July 2026)

Other SHI services:

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Inebilizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	2.0	1	€ 200

II. The resolution will enter into force on the day of its publication on the G-BA website on 3 September 2026.

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

Berlin, 3 September 2026

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

Dr Optendrenk