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
Nipocalimab (myasthenia gravis, anti-AChR antibody positive, anti-MuSK antibody positive, ≥ 12 years)

From 18 June 2026

At their session on 18 June 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, information on the active ingredient Nipocalimab shall be added in alphabetical order as follows:

Nipocalimab

Resolution of: 18 June 2026
Entry into force on: 18 June 2026
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 28 November 2025):

Imaavy is indicated as an add-on to standard therapy for the treatment of generalised myasthenia gravis (gMG) in adult and adolescent patients aged 12 years of age and older who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive.

Therapeutic indication of the resolution (resolution of 18 June 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 generalised myasthenia gravis who are eligible for an add-on to standard therapy

Appropriate comparator therapy for nipocalimab as an add-on to standard therapy:

- Eculizumab (only refractory patients are eligible) or efgartigimod alfa or ravulizumab or rozanolixizumab or zilucoplan

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

An additional benefit is not proven.

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

Appropriate comparator therapy for nipocalimab as an add-on to standard therapy:

- Rozanolixizumab

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

An additional benefit is not proven.

c) Adolescents with anti-acetylcholine receptor antibody positive refractory generalised myasthenia gravis who are eligible for an add-on to standard therapy

Appropriate comparator therapy for nipocalimab as an add-on to standard therapy:

– Eculizumab

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

An additional benefit is not proven.

d) Adolescents with anti-acetylcholine receptor antibody positive non-refractory generalised myasthenia gravis, or with anti-muscle-specific tyrosine kinase antibody positive generalised myasthenia gravis, who are eligible for an add-on to standard therapy

Appropriate comparator therapy for nipocalimab as an add-on to standard therapy:

– Best supportive care

Extent and probability of the additional benefit of nipocalimab 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 generalised myasthenia gravis who are eligible for an add-on to standard therapy

No data available.

[1] Data from the dossier assessment of the IQWiG (A25-160) and from the addendum (A26-51), unless otherwise indicated.

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

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

No data available.

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

c) <u>Adolescents with anti-acetylcholine receptor antibody positive refractory generalised myasthenia gravis who are eligible for an add-on to standard therapy</u>

No data available.

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

d) Adolescents with anti-acetylcholine receptor antibody positive non-refractory generalised myasthenia gravis, or with anti-muscle-specific tyrosine kinase antibody positive generalised myasthenia gravis, who are eligible for an add-on to standard therapy

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		

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

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

   Approx. 6,300 – 19,000 patients

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

   Approx. 170 – 730 patients

c) Adolescents with anti-acetylcholine receptor antibody positive refractory generalised myasthenia gravis who are eligible for an add-on to standard therapy

   Approx. 40 – 110 patients

d) Adolescents with anti-acetylcholine receptor antibody positive non-refractory generalised myasthenia gravis, or with anti-muscle-specific tyrosine kinase antibody positive generalised myasthenia gravis, who are eligible for an add-on to standard therapy

   Approx. 60 – 150 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 Imaavy (active ingredient: nipocalimab) at the following publicly accessible link (last access: 4 March 2026):

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

Treatment with nipocalimab should only be initiated and monitored by specialists who are experienced in the treatment of patients with neuromuscular diseases.

4. Treatment costs

Annual treatment costs:

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

Name of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Nipocalimab	€ 523,093.85
Appropriate comparator therapy:	
Eculizumab	€ 480,305.71 – € 640,407.62
Efgartigimod alfa	€ 55,887.92 – € 413,570.61
Ravulizumab	€ 301,859.03
Rozanolixizumab	€ 262,781.17 – € 506,097.07
Zilucoplan	€ 281,966.02

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 15 April 2026)

Costs for additionally required SHI services: not applicable

Other SHI services:

Name of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Medicinal product to be assessed:					
Nipocalimab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	26.1	€ 2,610
Appropriate comparator therapy					
Eculizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	22.8 - 30.4	€ 2,280 – € 3,040
Ravulizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	6.5	€ 650.00

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

Name of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Nipocalimab	€ 523,093.85
Appropriate comparator therapy:	
Rozanolixizumab	€ 262,781.17 – € 506,097.07

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 15 April 2026)

Costs for additionally required SHI services: not applicable

Other SHI services:

Name of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Medicinal product to be assessed:					
Nipocalimab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	26.1	€ 2,610

c) Adolescents with anti-acetylcholine receptor antibody positive refractory generalised myasthenia gravis who are eligible for an add-on to standard therapy

Name of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Nipocalimab	€ 395,602.14 – € 523,093.85
Appropriate comparator therapy:	
Eculizumab	€ 480,305.71 – € 640,407.62

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 15 April 2026)

Costs for additionally required SHI services: not applicable

Other SHI services:

Name of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Medicinal product to be assessed:					
Nipocalimab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	26.1	€ 2,610
Appropriate comparator therapy					
Eculizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	22.8 - 30.4	€ 2,280 – € 3,040

d) Adolescents with anti-acetylcholine receptor antibody positive non-refractory generalised myasthenia gravis, or with anti-muscle-specific tyrosine kinase antibody positive generalised myasthenia gravis, who are eligible for an add-on to standard therapy

Name of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Nipocalimab	€ 395,602.14 – € 523,093.85
Best supportive care	Different from patient to patient
Appropriate comparator therapy:	
Best supportive care	Different from patient to patient

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 15 April 2026)

Costs for additionally required SHI services: not applicable

Other SHI services:

Name of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Medicinal product to be assessed:					
Nipocalimab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	26.1	€ 2,610

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 anti-acetylcholine receptor antibody positive generalised myasthenia gravis who are eligible for an add-on to standard therapy

– No medicinal product with new active ingredients for use in combination therapy in compliance with the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

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

– No medicinal product with new active ingredients for use in combination therapy in compliance with the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

c) Adolescents with anti-acetylcholine receptor antibody positive refractory generalised myasthenia gravis who are eligible for an add-on to standard therapy

– No medicinal product with new active ingredients for use in combination therapy in compliance with the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

d) Adolescents with anti-acetylcholine receptor antibody positive non-refractory generalised myasthenia gravis, or with anti-muscle-specific tyrosine kinase antibody positive generalised myasthenia gravis, who are eligible for an add-on to standard therapy

– No medicinal product with new active ingredients for use in combination therapy in compliance with 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 Imaavy 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% (8.0%) of the total number of study participants.

The clinical studies of the medicinal product in the therapeutic indication to be assessed were therefore conducted to a relevant extent within the scope of SGB V.

II. The resolution entered into force on the day of its publication on the G-BA website on 18 June 2026.

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

Berlin, 18 June 2026

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

Prof. Hecken