

Justification

for the Resolution of the Federal Joint Committee (G-BA) 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

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1. Legal basis

According to Section 35a paragraph 1 German Social Code, Book Five (SGB V), the Federal Joint Committee (G-BA) assess the benefit of all reimbursable medicinal products with new active ingredients. This includes in particular the assessment of the additional benefit and its therapeutic significance. The benefit assessment is carried out on the basis of evidence provided by the pharmaceutical company, which must be submitted to the G-BA electronically, including all clinical studies the pharmaceutical company have conducted or commissioned, at the latest at the time of the first placing on the market as well as the marketing authorisation of new therapeutic indications of the medicinal product, and which must contain the following information in particular:

1. approved therapeutic indications,
2. medical benefit,
3. additional medical benefit in relation to the appropriate comparator therapy,
4. number of patients and patient groups for whom there is a therapeutically significant additional benefit,
5. treatment costs for the statutory health insurance funds,
6. requirements for a quality-assured application.

The G-BA may commission the Institute for Quality and Efficiency in Health Care (IQWiG) to carry out the benefit assessment. According to Section 35a, paragraph 2 SGB V, the assessment must be completed within three months of the relevant date for submission of the evidence and published on the internet.

According to Section 35a, paragraph 3 SGB V, the G-BA decide on the benefit assessment within three months of its publication. The resolution is to be published on the internet and is part of the Pharmaceuticals Directive.

2. Key points of the resolution

The active ingredient inebilizumab (Uplizna) was listed for the first time on 1 August 2022 in the "LAUER-TAXE®", the extensive German registry of available drugs and their prices.

On 10 February 2026, inebilizumab received marketing authorisation for a new therapeutic indication to be classified as a major type 2 variation as defined according to Annex 2, number 2, letter a to Regulation (EC) No. 1234/2008 of the Commission of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (OJ L 334 from 12.12.2008, sentence 7).

On 6 March 2026, i.e. at the latest within four weeks of informing the pharmaceutical company about the approval for a new therapeutic indication, the pharmaceutical company submitted a dossier in accordance with Section 4, paragraph 3, number 2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with Chapter 5, Section

8, paragraph 1, number 2 of the Rules of Procedure (VerfO) of the G-BA on the active ingredient inebilizumab with the new therapeutic indication "as an add-on to standard therapy for the treatment of gMG in adult patients who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive".

The G-BA commissioned the IQWiG to carry out the assessment of the dossier. The benefit assessment was published on 15 June 2026 on the G-BA website at (www.g-ba.de), thus initiating the written statement procedure. In addition, an oral hearing was held.

The G-BA came to a resolution on whether an additional benefit of inebilizumab compared with the appropriate comparator therapy could be determined on the basis of the dossier of the pharmaceutical company, the dossier assessment prepared by the IQWiG, the statements submitted in the written statement and oral hearing procedure, and the addenda to the benefit assessment prepared by the IQWiG. In order to determine the extent of the additional benefit, the G-BA have evaluated the data justifying the finding of an additional benefit on the basis of their therapeutic relevance (qualitative), in accordance with the criteria laid down in Chapter 5, Section 5, paragraph 7 VerfO. The methodology proposed by the IQWiG in accordance with the General Methods ¹ was not used in the benefit assessment of inebilizumab.

In the light of the above, and taking into account the statements received and the oral hearing, the G-BA have made the following assessment:

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

2.1.1 Approved therapeutic indication of Inebilizumab (Uplizna) in accordance with the product information

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 03.09.2026):

See the approved therapeutic indication

¹ General Methods, version 8.0 from 19.12.2025. Institute for Quality and Efficiency in Health Care (IQWiG), Cologne.

2.1.2 Appropriate comparator therapy

The appropriate comparator therapy was determined as follows:

- 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

- 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

Criteria according to Chapter 5, Section 6 of the Rules of Procedure of the G-BA and Section 6, paragraph 2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV):

The appropriate comparator therapy must be an appropriate therapy in the therapeutic indication according to the generally recognised state of medical knowledge (Section 12 SGB V), preferably a therapy for which endpoint studies are available and which has proven its worth in practical application unless contradicted by the guidelines under Section 92, paragraph 1 SGB V or the principle of economic efficiency.

In determining the appropriate comparator therapy, the following criteria, in particular, must be taken into account as specified in Chapter 5, Section 6, paragraph 3 VerfO:

1. To be considered as a comparator therapy, the medicinal product must, principally, have a marketing authorisation for the therapeutic indication.
2. If a non-medicinal treatment is considered as a comparator therapy, this must be available within the framework of the SHI system.
3. As comparator therapy, medicinal products or non-medicinal treatments for which the patient-relevant benefit has already been determined by the G-BA shall be preferred.
4. According to the generally recognised state of medical knowledge, the comparator therapy should be part of the appropriate therapy in the therapeutic indication.

According to Section 6, paragraph 2, sentence 2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV), the determination of the appropriate comparator therapy must be based on the actual medical treatment situation as it would be without the medicinal product to be assessed. According to Section 6, paragraph 2, sentence 3 Ordinance on the

Benefit Assessment of Pharmaceuticals (AM-NutzenV), the G-BA may exceptionally determine the off-label use of medicinal products as an appropriate comparator therapy or as part of the appropriate comparator therapy if they determine by resolution on the benefit assessment according to Section 7, paragraph 4 that, according to the generally recognised state of medical knowledge, this is considered a therapy standard in the therapeutic indication to be assessed or as part of the therapy standard in the medical treatment situation to be taken into account according to sentence 2, and

1. for the first time, a medicinal product approved in the therapeutic indication is available with the medicinal product to be assessed,
2. according to the generally recognised state of medical knowledge, the off-label use is generally preferable to the medicinal products previously approved for the therapeutic indication, or
3. according to the generally recognised state of medical knowledge, the off-label use for relevant patient groups or indication areas is generally preferable to the medicinal products previously approved for the therapeutic indication.

An appropriate comparator therapy may also be non-medicinal therapy, the best possible add-on therapy including symptomatic or palliative treatment, or monitoring wait-and-see approach.

Justification based on the criteria set out in Chapter 5, Section 6, paragraph 3 VerfO and Section 6, paragraph 2 AM-NutzenV:

On 1. The active ingredients azathioprine, distigmine bromide, neostigmine methylsulphate and pyridostigmine bromide as well as the glucocorticoids prednisolone and prednisone are generally approved for the treatment of generalized myasthenia gravis (gMG).

The active ingredients efgartigimod alfa, nipocalimab, ravulizumab, rozanolixizumab and zilucoplan are approved as an add-on to standard therapy in adults with anti-acetylcholine receptor (AChR) antibody positive gMG. Furthermore, eculizumab is approved for the treatment of anti-AChR antibody positive, refractory gMG. The active ingredients nipocalimab and rozanolixizumab have been granted the marketing authorisation for the add-on therapy of anti-muscle-specific tyrosine kinase (MuSK) antibody positive gMG. Furthermore, human normal immunoglobulin (IVIg) has been granted the marketing authorisation for the treatment of severe acute exacerbations of myasthenia gravis.

On 2. In the therapeutic indication of gMG, thymectomy and plasmapheresis/ immunoadsorption are considered as non-medicinal treatments.

On 3. For the use as an add-on to standard therapy in adults with gMG, benefit assessments in accordance with Section 35a SGB V are available for efgartigimod alfa (resolutions of 17 February 2023 and 19 September 2024), ravulizumab (resolution of 20 April 2023), rozanolixizumab (resolution of 15 August 2024), zilucoplan (resolution of 15 August 2024) and nipocalimab (resolution of 18 June 2026).

In addition, for the therapeutic indication of "generalized myasthenia gravis", there are resolutions on the off-label use (Annex VI to Section K of the Pharmaceuticals Directive,

Part A) of mycophenolate mofetil for the "long-term therapy of generalized myasthenia gravis in the case of therapy resistance under treatment with the approved substances or in the case of azathioprine intolerance" and of intravenous immunoglobulins in "myasthenic crises/ severe exacerbations".

- On 4. The generally recognised state of medical knowledge was illustrated by a systematic search for guidelines as well as systematic reviews of clinical studies in the present indication and is presented in the "Research and synopsis of the evidence to determine the appropriate comparator therapy according to Section 35a SGB V".

The scientific-medical societies and the Drugs Commission of the German Medical Association (AkdÄ) were also involved in writing on questions relating to the comparator therapy in the present indication according to Section 35a, paragraph 7 SGB V (see "Information on Appropriate Comparator Therapy").

Overall, the identified evidence in the therapeutic indication is very limited. The present body of evidence comprises a systematic review and two additionally presented guidelines: the "International Consensus Guidance for the Management of Myasthenia Gravis: 2020 Update" and the German S2k guideline "Diagnosis and Treatment of Myasthenic Syndromes".

According to the German S2k guideline, treatment decisions are made, in particular, depending on disease activity and disease severity. The corresponding classification into mild/ moderate versus (highly) active generalized myasthenia gravis should be based on the severity of clinical symptomatology, their duration and tendency to regress, as well as clinical residuals and the presence or number of crisis-like deteriorations/ crises. Generalized myasthenia gravis refractory to therapy is subsumed under the (highly) active disease. Furthermore, the treatment of generalized myasthenia gravis is based on the antibody status, with subclassification into, amongst others, AChR, MuSK and low-density lipoprotein receptor-related protein 4(LRP4) antibody positive as well as seronegative myasthenia gravis.

Recommendations of the mentioned guidelines for patients with generalized myasthenia gravis include acetylcholinesterase inhibitors, immunosuppressants (glucocorticoids, azathioprine, mycophenolate mofetil, ciclosporin A, methotrexate and tacrolimus), thymectomy, complement inhibitors (eculizumab, ravulizumab and zilucoplan), a neonatal Fc receptor inhibitor (efgartigimod alfa and rozanolixizumab) and a CD-20 antibody (rituximab).

Mycophenolate mofetil, ciclosporin A, methotrexate, tacrolimus and rituximab are not approved for the present therapeutic indication. However, according to Annex VI of the Pharmaceuticals Directive, mycophenolate mofetil is reimbursable in cases of treatment resistance.

Furthermore, according to the guideline, intravenous immunoglobulins, as well as plasmapheresis or immunoadsorption may be used if the aforementioned options fail, or are recommended as a treatment for a myasthenic crisis. However, these options therefore represent a treatment setting that is different from the therapeutic

indication of inebilizumab and are not considered as the appropriate comparator therapy in the present context.

The G-BA consider "standard therapy" – as mentioned in the therapeutic indication for inebilizumab – as a treatment comprising acetylcholinesterase inhibitors and a basic immunosuppressive therapy (glucocorticoids and/or non-steroidal immunosuppressants). According to the guideline, this standard therapy is an option for patients with mild or moderate disease activity/ severity, and does not significantly differ depending on the antibody status or between adults and adolescents.

An add-on to standard therapy is recommended for active or highly active generalized myasthenia gravis. This add-on therapy is used in particular as escalation therapy after failure to respond to standard therapy, but can also be an early treatment option in highly active courses of the disease.

Given that the guideline recommendations on add-on to standard therapy are based on antibody status, it is considered appropriate to categorise patient populations according to their antibody status as follows:

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

All patient groups are subject to the prerequisite that patients receive guideline-based treatment with acetylcholinesterase inhibitors, as well as basic immunosuppressive therapy alongside the add-on therapy.

Patient group a)

Eculizumab, efgartigimod alfa, ravulizumab, rozanolixizumab and zilucoplan (as an add-on to basic therapy) are equally recommended as approved first-line therapy options for adults with anti-AChR antibody positive generalized myasthenia gravis. The marketing authorisation of eculizumab is however limited to the treatment of refractory patients and therefore only applies as the appropriate comparator therapy to a sub-population of the therapeutic indication.

Furthermore, thymectomy also plays a significant role in the treatment of anti-AChR antibody positive generalized myasthenia gravis. However, it is assumed that patients for whom treatment with inebilizumab is indicated are either ineligible for thymectomy or have already undergone this.

In the overall assessment, for adults with anti-AChR antibody positive generalized myasthenia gravis who are eligible for an add-on to standard therapy, the appropriate comparator therapy for inebilizumab as an add-on to standard therapy is eculizumab (for refractory patients) or efgartigimod alfa or ravulizumab or rozanolixizumab or zilucoplan.

The appropriate comparator therapy determined here includes several alternative therapy options. These therapeutic alternatives are equally appropriate for the comparator therapy.

The additional benefit can be demonstrated compared to one of the several therapeutic alternatives mentioned.

Patient group b)

The current S2k guideline on myasthenia gravis also recommends rozanolixizumab as an approved active ingredient for the treatment of adults with generalized myasthenia gravis, who are anti-MuSK antibody positive and are eligible for an add-on to standard therapy.

Consequently, the approved active ingredient rozanolixizumab is determined as the appropriate comparator therapy for this patient population.

The active ingredient nipocalimab is a new treatment option in the present therapeutic indication and its therapeutic significance cannot be conclusively assessed (marketing authorisation on 28 November 2025). By the G-BA resolution of 18 June 2026, no additional benefit of the active ingredient nipocalimab compared with the appropriate comparator therapy could be identified due to a lack of comparator data. For the present resolution, nipocalimab is not determined as an appropriate comparator therapy.

The findings in Annex XII do not restrict the scope of treatment required to fulfil the medical treatment mandate.

Any change to the appropriate comparator therapy requires a decision by the G-BA based on a prior review of the criteria set out in Chapter 5, Section 6, paragraph 3 VerfO.

2.1.3 Extent and probability of the additional benefit

In summary, the additional benefit of inebilizumab is assessed as follows:

- a) An additional benefit of inebilizumab compared with the appropriate comparator therapy is not proven for adults with anti-acetylcholine receptor antibody positive generalized myasthenia gravis who are eligible for an add-on to standard therapy.
- b) An additional benefit of inebilizumab compared with the appropriate comparator therapy is not proven for adults with anti-muscle-specific tyrosine kinase antibody positive generalized myasthenia gravis who are eligible for an add-on to standard therapy.

Justification:

Patient groups a) and b)

No data in comparison with the appropriate comparator therapy are available for adults with generalized myasthenia gravis who have antibodies against AChR (patient group a) or MuSK (patient group b) and who are eligible for an add-on to standard therapy.

The double-blind, multicentre, randomised MINT study compared inebilizumab with a placebo in terms of efficacy and safety. The study therefore does not allow for a comparison with the appropriate comparator therapy determined in each case. Consequently, an additional benefit of inebilizumab over the appropriate comparator therapy is not proven for both patient groups.

2.1.4 Summary of the assessment

The present assessment is the benefit assessment of a new therapeutic indication for the active ingredient inebilizumab. Inebilizumab is approved as an add-on to standard therapy for the treatment of adult patients with gMG who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive.

In the therapeutic indication to be considered, 2 patient groups were distinguished as follows:

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

Patient group a)

The G-BA determined the appropriate comparator therapy to be eculizumab (only suitable for refractory patients) or efgartigimod alfa or ravulizumab or rozanolixizumab or zilucoplan.

No comparator data versus the appropriate comparator therapy are available for adults with generalized myasthenia gravis who have antibodies against AChR and who are eligible for an add-on to standard therapy.

The double-blind, multicentre, randomised MINT study compared inebilizumab with a placebo in terms of efficacy and safety. The study therefore does not allow for a comparison with the determined appropriate comparator therapy. Consequently, an additional benefit of inebilizumab over the appropriate comparator therapy is not proven for this patient group.

Patient group b)

The G-BA determined rozanolixizumab as the appropriate comparator therapy. No data in comparison with the appropriate comparator therapy are available for adults with generalized myasthenia gravis who have antibodies against MuSK and who are eligible for an add-on to standard therapy.

The double-blind, multicentre, randomised MINT study compared inebilizumab with a placebo in terms of efficacy and safety. The study therefore does not allow for a comparison with the determined appropriate comparator therapy. Consequently, an additional benefit of inebilizumab over the appropriate comparator therapy is not proven for this patient group.

2.2 Number of patients or demarcation of patient groups eligible for treatment

The information on the number of patients is based on the target population in statutory health insurance (SHI).

The pharmaceutical company provided a range of patient numbers in the dossier; however, there are methodological limitations and uncertainties at several steps.

Overall, there is uncertainty regarding the pharmaceutical company's lower limit estimate for the number of adults with anti-AChR antibody positive and anti-MuSK antibody positive generalized myasthenia gravis within the SHI target population. The upper limit, by contrast, is overestimated, particularly due to the operationalisation of high disease activity/ severity only by taking MGFA classes II to IV into account.

Notwithstanding a slight deviation at the upper limit, the number of adult patients with anti-AChR antibody positive generalized myasthenia gravis (patient group a) stated in this dossier falls within the ranges specified in the previous resolutions within the scope of this therapeutic indication (resolution of 18 June 2026 on nipocalimab, resolution of 19 September 2024 on efgartigimod alfa, and resolutions of 15 August 2024 on rozanolixizumab and zilucoplan). In the benefit assessment for efgartigimod alfa, which forms the basis of information from all previous resolutions, the upper limit of approximately 19,000 patients was rated as an overestimate, and the lower limit of approximately 6,300 was deemed uncertain. In order to take greater account of the uncertainty in the information on inebilizumab provided by the pharmaceutical company, the lower limit specified in the previous resolutions within the scope of this therapeutic indication is used for this resolution. As both upper limits have been overestimated, the lower of the two upper limits set out in the previous resolutions is taken into account.

The figures for adults with anti-MuSK antibody positive generalized myasthenia gravis (patient group b) stated in this dossier exceed those set out in the previous resolutions of 18 June 2026 on nipocalimab and of 15 August 2024 on rozanolixizumab within the scope of this therapeutic indication. Although the method used in this dossier to determine patient numbers is considered more appropriate than the procedure used for rozanolixizumab, the fact that high disease activity/ severity is operationalised solely via MGFA classes leads to an overestimation of the patient numbers. In line with the assessment for the patient group with anti-AChR antibody positive disease, the lower figures for the number of patients with anti-MuSK antibody positive disease from the earlier procedures for nipocalimab and rozanolixizumab should currently be regarded as a more appropriate estimate in order to better account for the uncertainty.

2.3 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.

2.4 Treatment costs

The treatment costs are based on the contents of the product information and the information listed in the LAUER-TAXE® (last revised: 1 July 2026). The calculation of treatment costs is generally based on the last revised LAUER-TAXE® version following the publication of the benefit assessment.

For the cost representation, only the dosages of the general case are considered. Patient-individual dose adjustments (e.g. because of side effects or comorbidities) are not taken into account when calculating the annual treatment costs.

In general, initial induction regimens are not taken into account for the cost representation, since the present indication is a chronic disease with a continuous need for therapy and, as a rule, no new titration or dose adjustment is required after initial titration.

If no maximum treatment duration is specified in the product information, the treatment duration is assumed to be one year (365 days), even if the actual treatment duration is different from patient to patient and/or is shorter on average. The time unit "days" is used to calculate the "number of treatments/ patient/ year", time intervals between individual treatments and for the maximum treatment duration, if specified in the product information.

For dosages depending on body weight (BW), the average body measurements from the official representative statistics "2025 Microcensus – body measurements of the population²" were applied (≥ 18 years: 78.3 kg).

The dosage recommended in the product information for efgartigimod alfa was used as the calculation basis. One treatment cycle of efgartigimod alfa lasts 4 weeks. Further treatment cycles are administered on a patient-individual basis according to clinical assessment and at the earliest 7 weeks after the first infusion.

According to the product information, a treatment cycle of rozanolixizumab lasts 6 weeks. A new treatment cycle is initiated patient-individually according to the clinical assessment. In the clinical development programme, most study participants had treatment-free intervals of 4 – 13 weeks. This range is used for the cost calculation.

² Federal Health Reporting. Average body measurements of the population (2025, both sexes), www.gbe-bund.de

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

Treatment period:

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Medicinal product to be assessed:				
Inebilizumab	1 x every 6 months	2.0	1	2.0
Appropriate comparator therapy				
Eculizumab (for refractory patients) or efgartigimod alfa or ravulizumab or rozanolixizumab or zilucoplan				
Eculizumab	Continuously, 1 x every 12-16 days	22.8 – 30.4	1	22.8 – 30.4
Efgartigimod alfa	1 x every 7 days per 4-week cycle	1 – 7.4	4	4 – 29.6
Ravulizumab	Continuously, 1 x every 56 days	6.5	1	6.5
Rozanolixizumab	1 x every 7 days per 6-week cycle	2.7 – 5.2	6	16.2 – 31.2
Zilucoplan	Continuously, 1 x daily	365.0	1	365.0

Consumption:

Designation of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
Medicinal product to be assessed:					
Inebilizumab	300 mg	300 mg	3 x 100 mg	2.0	6 x 100 mg
Appropriate comparator therapy					
Eculizumab (for refractory patients) or efgartigimod alfa or ravulizumab or rozanolixizumab or zilucoplan					
Eculizumab	1,200 mg	1,200 mg	4 x 300 mg	22.8 – 30.4	91.2 x 300 mg - 121.6 x 300 mg
Efgartigimod alfa	1,000 mg	1,000 mg	1 x 1,000 mg	4.0 - 29.6	4.0 x 1,000 mg - 29.6 x 1,000 mg
Ravulizumab	3,300 mg	3,300 mg	3 x 1,100 mg	6.5	19.5 x 1,100 mg
Rozanolixizumab	≥ 70 to < 100 kg BW 560 mg	560 mg	1 x 560 mg	16.2 – 31.2	16.2 x 560 mg - 31.2 x 560 mg
Zilucoplan	32.4 mg	32.4 mg	1 x 32.4 mg	365.0	365 x 32.4 mg

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

Treatment period:

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Medicinal product to be assessed:				
Inebilizumab	1 x every 6 months	2.0	1	2.0
Appropriate comparator therapy				
Rozanolixizumab				
Rozanolixizumab	1 x every 7 days per 6-week cycle	2.7 – 5.2	6	16.2 – 31.2

Consumption:

Designation of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
Medicinal product to be assessed:					
Inebilizumab	300 mg	300 mg	3 x 100 mg	2.0	6 x 100 mg
Appropriate comparator therapy					
Rozanolixizumab					
Rozanolixizumab	≥ 70 to < 100 kg	560 mg	1 x 560 mg	16.2 – 31.2	16.2 x 560 mg
	<u>BW</u> 560 mg				- 31.2 x 560 mg

Patient groups a) and b)

Costs:

In order to improve comparability, the costs of the medicinal products were approximated both on the basis of the pharmacy sales price level and also deducting the statutory rebates in accordance with Section 130 and Section 130a SGB V. To calculate the annual treatment costs, the required number of packs of a particular potency was first determined on the basis of consumption. Having determined the number of packs of a particular potency, the costs of the medicinal products were then calculated on the basis of the costs per pack after deduction of the statutory rebates. Any reference prices shown in the cost representation may not represent the cheapest available alternative.

Costs of the medicinal products:

Designation of the therapy	Packaging size	Costs (pharmacy sales price)	Rebate Section 130 SGB V	Rebate Section 130a SGB V	Costs after deduction of statutory rebates
Medicinal product to be assessed:					
Inebilizumab 100 mg	3 CIS	€ 54,517.59	€ 1.77	€ 3,110.17	€ 51,405.65
Appropriate comparator therapy					
Eculizumab 300 mg	1 CIS	€ 5,878.62	€ 1.77	€ 335.09	€ 5,541.76
Efgartigimod alfa 1,000 mg	IPF 1 S	€ 14,817.42	€ 1.77	€ 842.89	€ 13,972.76
Ravulizumab 1,100 mg	1 CIS	€ 16,419.58	€ 1.77	€ 937.09	€ 15,480.72
Rozanolixizumab 560 mg	1 SFI	€ 17,202.71	€ 1.77	€ 979.11	€ 16,221.83
Zilucoplan 32.4 mg	28 SFI	€ 22,942.43	€ 1.77	€ 1,309.61	€ 21,631.05
Abbreviations: IPFS = solution for injection in a pre-filled syringe; CIS = concentrate for the preparation of an infusion solution; SFI = solution for injection					

LAUER-TAXE® last revised: 1 July 2026

Costs for additionally required SHI services:

Only costs directly related to the use of the medicinal product are taken into account. If there are regular differences in the necessary use of medical treatment or in the prescription of other services in the use of the medicinal product to be evaluated and the appropriate comparator therapy in accordance with the product information, the costs incurred for this must be taken into account as costs for additionally required SHI services.

Medical treatment costs, medical fee services, and costs incurred for routine examinations (e.g. regular laboratory services such as blood count tests) that do not exceed the standard expenditure in the course of the treatment are not shown.

Premedication

According to the product information, premedication with a corticosteroid e.g. methylprednisolone 80-125 mg IV or equivalent is necessary approx. 30 min before the application of inebilizumab. Therefore, the costs for methylprednisolone with the dosage for premedication given in the product information are presented as an example. The costs may vary depending on the corticosteroid used and the dosage form.

Designation of the therapy	Packaging size	Costs (pharmacy sales price)	Rebate Section 130 SGB V	Rebate Section 130a SGB V	Costs after deduction of statutory rebates	Treatment days/year	Costs/patient/year
Inebilizumab							
<i>Premedication</i>							
Methylprednisolone 80 mg - 125 mg, IV	3 PII x 32 mg	€ 26.48	€ 1.77	€ 6.88	€ 17.83	2.0	€ 35.66
	3 PII x 32 mg	€ 26.48	€ 1.77	€ 6.88	€ 17.83	2.0	€ 47.55
Dimetindene IV 1 mg/ 10 kg	5 x 4 mg SFI	€ 26.24	€ 1.77	€ 6.92	€ 17.55	2.0	€ 14.04
Paracetamol ^{3,4} 500 mg - 1,000 mg, oral	10 TAB x 500 mg	€ 2.96	€ 0.15	€ 0.13	€ 2.68	2.0	€ 0.54
	10 TAB x 1,000 mg	€ 3.32	€ 0.17	€ 0.14	€ 3.01		€ 0.60
Abbreviations: TAB = tablets; SFI = solution for injection; PII = powder and solvent for solution for injection or infusion							

Diagnosis of tuberculosis

For the medicinal product under assessment, inebilizumab, costs are regularly incurred for examining for both active and inactive ("latent") tuberculosis infections. The costs presented are a blood test (quantitative determination of an in vitro interferon-gamma release after ex vivo stimulation with antigens specific for Mycobacterium tuberculosis-complex (except BCG)). In addition, a chest radiograph is usually required to detect pulmonary tuberculosis. The tuberculin skin test is not presented due to lack of sensitivity and specificity as well as the possibility of "sensitisation". These examinations are not required when using the appropriate comparator therapy.

³ The dosage of 650 mg paracetamol in premedication stated in the product information cannot be achieved by tablets. Because of this, a dosage of 500 – 1,000 mg is used.

⁴ Fixed reimbursement rate Non-prescription medicinal products that are reimbursable at the expense of the statutory health insurance according to Section 12, paragraph 7, of the AM-RL (information as concomitant medication in the product information of the prescription medicinal product) are not subject to the current medicinal products price regulation. Instead, in accordance with Section 129, paragraph 5a SGB V, when a non-prescription medicinal product is dispensed invoiced according Section 300, a medicinal product sale price applies to the insured person in the amount of the sale price of the pharmaceutical company plus the surcharges according to Sections 2 and 3 of the Pharmaceutical Price Ordinance in the valid version of 31 December 2003.

Hepatitis B and hepatitis C diagnostics

Diagnostics to rule out chronic hepatitis B requires sensibly coordinated steps. A step-by-step serological diagnosis initially consists of the examination of HBs antigen and anti-HBc antibodies. If both are negative, a past HBV infection can be excluded. In certain case constellations, further steps may be necessary in accordance with current guideline recommendations.⁵

Diagnostics to rule out hepatitis C requires sensibly coordinated steps. HCV screening is based on the determination of anti-HCV antibodies. In certain case constellations, it may be necessary to verify the positive anti-HCV antibody findings in parallel or subsequently by HCV-RNA detection to confirm the diagnosis of an HCV infection.⁶

Designation of the therapy	Packaging size	Costs (pharmacy sales price)	Rebate Section n 130 SGB V	Rebate Section 130a SGB V	Costs after deduction of statutory rebates	Treatment days/year	Costs/patient/year
Inebilizumab							
<i>Tuberculosis diagnostics</i>							
Quantitative determination of in vitro interferon-gamma release following ex vivo stimulation with antigens (except BCG) (FSI 32670)	-	-	-	-	€ 53.36	1.0	€ 53.36
Chest radiograph (FSI 34241)	-	-	-	-	€ 18.09	1.0	€ 18.09
<i>HBV screening</i>							
HBV test Hepatitis B surface antigen status (FSI 32781)	-	-	-	-	€ 5.06	1.0	€ 5.06
Anti-HBc antibody (FSI 32614)	-	-	-	-	€ 5.43	1.0	€ 5.43
<i>HCV screening</i>							
Hepatitis C HCV antibody status (FSI 32618)	-	-	-	-	€ 9.02	1.0	€ 9.02

The calculation of the additionally required SHI services is based on packs in distribution with the LAUER-TAXE® last revised on 15 September 2025 and fee structure items (FSI) - last revised

⁵ S3 guideline on prevention, diagnosis and therapy of hepatitis B virus infection; AWMF registry no.: 021/011 https://register.awmf.org/assets/guidelines/021-011l_S3_Prophylaxe-Diagnostik-Therapie-der-Hepatitis-B-Virusinfektion_2021-07.pdf

⁶ S3 guideline on prevention, diagnosis and therapy of hepatitis C virus (HCV) infection; AWMF registry no.: 021/012 https://register.awmf.org/assets/guidelines/021-012l_S3_Hepatitis-C-Virus_HCV-Infektion_2018-07.pdf.

in the 3rd quarter of 2025 of the uniform value scale (UVS 2025/Q3).

Other SHI services:

The special agreement on contractual unit costs of retail pharmacist services (Hilfstaxe) (Sections 4 and 5 of the Pharmaceutical Price Ordinance) from 01.10.2009 is not fully used to calculate costs. Alternatively, the pharmacy sales price publicly accessible in the directory services according to Section 131, paragraph 4 SGB V is a suitable basis for a standardised calculation.

According to the special agreement on contractual unit costs of retail pharmacist services (Hilfstaxe) in its currently valid version, surcharges for the production of parenteral solutions with monoclonal antibodies amount to a maximum of € 100 per ready-to-apply unit. These additional other costs are not added to the pharmacy sales price but rather follow the rules for calculating in the Hilfstaxe. The cost representation is based on the pharmacy retail price and the maximum surcharge for the preparation and is only an approximation of the treatment costs. This presentation does not take into account, for example, the rebates on the pharmacy purchase price of the active ingredient, the invoicing of discards, the calculation of application containers, and carrier solutions in accordance with the regulations in Annex 3 of the Hilfstaxe.

3. Bureaucratic costs calculation

The proposed resolution does not create any new or amended information obligations for care providers within the meaning of Annex II to Chapter 1 VerfO and, accordingly, no bureaucratic costs.

4. Process sequence

The Subcommittee on Medicinal Products determined the appropriate comparator therapy at their session on 23 July 2023.

A review of the appropriate comparator therapy took place once the positive opinion was granted. At their session on 10 February 2026, the Subcommittee on Medicinal Products newly determined the appropriate comparator therapy.

On 6 March 2026, the pharmaceutical company submitted a dossier for the benefit assessment of inebilizumab to the G-BA in due time in accordance with Chapter 5, Section 8, paragraph 1, number 2 VerfO.

By letter dated 12 March 2026 in conjunction with the resolution of the G-BA of 1 August 2011 concerning the commissioning of the IQWiG to assess the benefit of medicinal products with new active ingredients in accordance with Section 35a SGB V, the G-BA commissioned the IQWiG to assess the dossier concerning the active ingredient inebilizumab.

The dossier assessment by the IQWiG was submitted to the G-BA on 11 June 2026, and the written statement procedure was initiated with publication on the G-BA website on 15 June 2026. The deadline for submitting written statements was 6 July 2026.

The oral hearing was held on 27 July 2026.

In order to prepare a recommendation for a resolution, the Subcommittee on Medicinal Products commissioned a working group (Section 35a) consisting of the members nominated

by the leading organisations of the care providers, the members nominated by the SHI umbrella organisation, and representatives of the patient organisations. Representatives of the IQWiG also participate in the sessions.

The evaluation of the written statements received and the oral hearing were discussed at the Subcommittee's session on 25 August 2026, and deliberation of the draft resolution was concluded.

At their session on 3 September 2026, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee on Medicinal Products	23 July 2023	Determination of the appropriate comparator therapy
Subcommittee on Medicinal Products	10 February 2026	New determination of the appropriate comparator therapy
Working group Section 35a	15 July 2026	Information on written statements received; preparation of the oral hearing
Subcommittee on Medicinal Products	27 July 2026	Conduct of the oral hearing
Working group Section 35a	5 August 2026 19 August 2026	Consultation on the dossier assessment by the IQWiG and evaluation of the written statement procedure
Subcommittee on Medicinal Products	25 August 2026	Concluding discussion of the draft resolution
Plenum	3 September 2026	Adoption of the resolution on the amendment of the Pharmaceuticals Directive

Berlin, 3 September 2026

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

Dr Optendrenk