Gemeinsamer Bundesausschuss

Justification

to 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
Efgartigimod alfa (new therapeutic indication: chronic inflammatory demyelinating polyneuropathy, pretreated patients)

of 22 January 2026

Contents

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,
7. number of study participants who participated in the clinical studies at study sites within the scope of SGB V, and total number of study participants.

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 pass a resolution 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 efgartigimod alfa (Vyvgart) was listed for the first time on 1 September 2022 in the "LAUER-TAXE®", the extensive German registry of available drugs and their prices.

Vyvgart is approved as a medicinal product for the treatment of rare diseases under Regulation (EC) No. 141/2000 of the European Parliament and of the Council of 16 December 1999.

Within the previously approved therapeutic indication of myasthenia gravis, the sales volume of efgartigimod alfa with the statutory health insurance at pharmacy sales prices, including value-added tax exceeded € 30 million. Evidence must therefore be provided for efgartigimod

alfa in accordance with Section 5, paragraph 1 through 6 VerfO, and the additional benefit compared with the appropriate comparator therapy must be demonstrated.

On 19 June 2025, efgartigimod alfa 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, 12.12.2008, sentence 7).

On 17 July 2025, the pharmaceutical company has 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 efgartigimod alfa with the new therapeutic indication "monotherapy for the treatment of adult patients with progressive or relapsing active chronic inflammatory demyelinating polyneuropathy (CIDP) after prior treatment with corticosteroids or immunoglobulins" in due time (i.e. at the latest within four weeks after informing the pharmaceutical company about the approval for a new therapeutic indication).

The G-BA commissioned the IQWiG to carry out the assessment of the dossier. The benefit assessment was published on 3 November 2025 on the G-BA website (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 efgartigimod alfa compared to the appropriate comparator therapy could be determined on the basis of the dossier of the pharmaceutical company, the dossier assessment prepared by the IQWiG, and the statements submitted in the written statement and oral hearing procedure. 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 efgartigimod alfa.

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 Efgartigimod alfa (Vyvgart) according to the product information

Vyvgart is indicated as monotherapy for the treatment of adult patients with progressive or relapsing active chronic inflammatory demyelinating polyneuropathy (CIDP) after prior treatment with corticosteroids or immunoglobulins.

Therapeutic indication of the resolution (resolution of 22.01.2026):

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:

Adults with progressive or relapsing active chronic inflammatory demyelinating polyneuropathy (CIDP) after prior treatment with corticosteroids or immunoglobulins

Appropriate comparator therapy for efgartigimod alfa:

– Immunoglobulins *or* corticosteroids

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 in accordance with 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 in 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 in 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. In addition to efgartigimod alfa, intravenous and subcutaneous immunoglobulins are approved for the treatment of adults with CIDP in the present therapeutic indication. Glucocorticoids, in particular prednisolone and prednisone, are also considered approved for this indication.

On 2. A plasmapheresis therapy is generally considered as a non-medicinal treatment in the present therapeutic indication. In addition, measures in accordance with the Remedies Directive (physiotherapy, occupational therapy) may be considered.

On 3. For the treatment of CIDP, there are no resolutions from the G-BA on the benefit assessment of medicinal products with new active ingredients according to Section 35a SGB V.

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 therapeutic indication according to Section 35a, paragraph 7 SGB V.

This body of evidence comprises a systematic review and the "European Academy of Neurology/ Peripheral Nerve Society guideline on diagnosis and treatment of chronic inflammatory demyelinating polyradiculoneuropathy": report of a joint task force - second revision". Based on the evidence, immunoglobulins and corticosteroids are the recommended therapy options for CIDP.

The present therapeutic indication includes patients with CIDP who have active disease following treatment with immunoglobulins or corticosteroids. If there is an inadequate response to one of the two treatment options mentioned, the available evidence recommends switching to the other available therapy option.

The unchanged continuation of an inadequate therapy, if the option of therapy optimisation still exists, does not correspond to the appropriate comparator therapy.

Plasmapheresis is not regarded as a regular appropriate comparator therapy, but in individual cases it may be an acute therapy and a therapy option for patients with CIDP if immunoglobulins and corticosteroids fail.

Based on the available evidence, the G-BA determined immunoglobulins and corticosteroids as the appropriate comparator therapy for efgartigimod alfa for the treatment of adults with progressive or relapsing active chronic inflammatory demyelinating polyneuropathy (CIDP) after prior treatment with corticosteroids or immunoglobulins. Patients with active disease progression after treatment with immunoglobulins or corticosteroids should be switched to the other available therapy option if indicated. The respective marketing authorisation must be taken into account.

The appropriate comparator therapy determined here includes several therapeutic alternatives. These therapeutic alternatives are equally appropriate for the comparator therapy. The additional benefit can be demonstrated compared to one of the therapeutic alternatives mentioned.

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

A change in the appropriate comparator therapy requires a resolution by the G-BA linked to the prior review of the criteria according to Chapter 5 Section 6, paragraph 3 Rules of Procedure.

2.1.3 Extent and probability of the additional benefit

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

The additional benefit thereof is not proven for adults with progressive or relapsing active chronic inflammatory demyelinating polyneuropathy (CIDP) after prior treatment with corticosteroids or immunoglobulins.

Justification:

The pharmaceutical company submitted data from a sub-population of the ADHERE (ARGX-113-1802) study to demonstrate the additional benefit of efgartigimod alfa in adults with progressive or relapsing active CIDP after prior treatment with corticosteroids or immunoglobulins.

ADHERE study

The ADHERE study is a multi-phase phase II study to investigate the safety and efficacy of efgartigimod alfa for the treatment of CIDP. In the first, open-label, single-arm phase (stage A), all patients were treated with efgartigimod alfa. In the subsequent, double-blind, randomised and controlled phase (stage B), the patients received efgartigimod alfa or placebo. The primary endpoint of the controlled phase (stage B) was the time to the first clinical deterioration measured using the adjusted Inflammatory Neuropathy Cause and Treatment (INCAT) score. Other endpoints in the morbidity and side effects category were also collected.

Adult patients with probable or definite progressive or relapsing CIDP according to the criteria of the European Federation of Neurological Societies/ Peripheral Nerve Society (EFNS/ PNS) were enrolled. In addition, the CIDP diagnosis had to be confirmed by an independent expert committee and the adults had to have a CIDP disease activity status value ≥ 2. Patients who received prior treatment with corticosteroids or immunoglobulins as well as patients who were therapy-naïve were enrolled.

During a run-in phase, all pretreated patients had to discontinue their prior therapy. Patients who showed a clinical deterioration within 12 weeks were able to move on to the single-arm phase (stage A). Therapy-naïve patients could proceed directly to the single-arm phase (stage A) if they experienced a clinical deterioration within 3 months prior to enrolment in the study – compared to a comparative value collected within 6 months prior to enrolment in the study.

In the single-arm phase (stage A), patients received efgartigimod alfa. Patients who showed a confirmed clinical improvement were included in the controlled phase (stage B).

In the controlled phase (stage B), adults were randomised in a 1:1 ratio and received weekly treatment with efgartigimod alfa or placebo. No therapy directed against CIDP, such as corticosteroids, immunoglobulins or plasmapheresis, was allowed to be used in the

intervention and control arm. Patients who showed a clinical deterioration or completed week 48 were able to switch to an open-label extension study.

For the benefit assessment, the pharmaceutical company used a sub-population of the controlled phase (stage B). Therapy-naive patients and patients who had not received treatment with corticosteroids or immunoglobulins within the last 6 months prior to enrolment in the study were excluded from this sub-population. Patients who were treated with corticosteroids or immunoglobulins more than 6 months prior to enrolment in the study are considered by the G-BA to be covered by the therapeutic indication and should therefore have been included in the sub-population. Patients who were considered cured after treatment, were in remission or were in a stable health status after treatment were also excluded.

Limitations of the ADHERE study

Corticosteroids or immunoglobulins were determined as appropriate comparator therapy for the present indication. However, the patients in the control arm received only placebo in the controlled phase (stage B) of the ADHERE study. As a consequence, the appropriate comparator therapy was not implemented in the ADHERE study.

According to the product information for efgartigimod alfa, patients who are being switched from their current CIDP therapy should preferably be started on efgartigimod alfa before the clinical effect of these prior therapies begins to diminish. A run-in phase, as was carried out in the ADHERE study, in which the prior CIDP therapy is discontinued before start of treatment with efgartigimod alfa and a clinical deterioration of CIDP must occur, is understandable for determining the activity status, but is not provided for in the product information.

Furthermore, all patients who switched from the single-arm phase (stage A) to the controlled phase (stage B) were already treated with efgartigimod alfa in the single-arm phase. As a result, the patients from the controlled, randomised phase (stage B) do not correspond to the patient population of the approved therapeutic indication for efgartigimod alfa, which comprises adults with progressive or relapsing active CIDP after prior treatment with corticosteroids or immunoglobulins.

In addition, only those patients who showed a clinical improvement during treatment with efgartigimod in the single-arm phase (stage A) were able to move on to the controlled phase (stage B), so that a selection was made.

Conclusion

Overall, the data presented are unsuitable to demonstrate an additional benefit compared with the appropriate comparator therapy. An additional benefit of efgartigimod alfa for the treatment of adults with progressive or relapsing active chronic inflammatory demyelinating polyneuropathy (CIDP) after prior treatment with corticosteroids or immunoglobulins is therefore not proven.

2.1.4 Summary of the assessment

The present assessment is the benefit assessment of a new therapeutic indication for the active ingredient efgartigimod alfa. The medicinal product Vyvgart was approved as an orphan drug. The therapeutic indication assessed here is "Vyvgart is indicated as monotherapy for the treatment of adult patients with progressive or relapsing active chronic inflammatory demyelinating polyneuropathy (CIDP) after prior treatment with corticosteroids or immunoglobulins.".

The G-BA determined immunoglobulins or corticosteroids as the appropriate comparator therapy.

For the benefit assessment of efgartigimod alfa, the pharmaceutical company presented data from a sub-population of the phase II ADHERE study.

All patients were treated with efgartigimod alfa in the first, open-label, single-arm phase (stage A) of the multi-phase study. Due to the single-arm study design, the single-arm phase does not allow a comparison with the appropriate comparator therapy and is therefore unsuitable for the assessment of an additional benefit of efgartigimod alfa.

In the subsequent, double-blind, randomised and controlled phase (stage B), the patients received efgartigimod alfa or placebo. A comparison with placebo does not correspond to the determined appropriate comparator therapy. As a consequence, the appropriate comparator therapy was not implemented in the ADHERE study.

Furthermore, the study population of the controlled phase of the ADHERE study does not correspond to the approved patient population. All subjects who switched from the single-arm phase (stage A) to the controlled phase (stage B) had already been treated with efgartigimod alfa in the single-arm phase. As a result, the patients from the controlled phase (stage B) do not correspond to the patient population of the approved therapeutic indication for efgartigimod alfa, which comprises adults with progressive or relapsing active CIDP after prior treatment with corticosteroids or immunoglobulins.

An additional benefit of efgartigimod alfa over the appropriate comparator therapy in adults with progressive or relapsing active CIDP after prior treatment with corticosteroids or immunoglobulins is therefore not proven.

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 resolution is based on the information provided by the pharmaceutical company in the benefit assessment dossier. Overall, the specified number of patients in the SHI target population is subject to uncertainty. The main reasons for this are outdated diagnostic criteria used to derive the prevalence, potential over or under-reporting of CIDP cases and a lack of information on the methodological approach used to calculate the prevalence rates. In addition, there are uncertainties due to the operationalisation of progressive or relapsing patients via CDAS 4 and 5 (CIDP Disease Activity Status). The pharmaceutical company do not apply any limitation with regard to prior therapy with corticosteroids or immunoglobulins, so it is unclear whether the calculation includes patients who were pretreated with both corticosteroids and immunoglobulins.

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 Vyvgart (active ingredient: efgartigimod alfa) at the following publicly accessible link (last access: 3 December 2025):

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

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

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: 15 November 2025). The calculation of treatment costs is generally based on the last revised LAUER-TAXE® version following the publication of the benefit assessment.

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.

The dosages recommended in the product information were used as the calculation basis.

With regard to the dosage regimens for treatment with corticosteroids, long-term oral therapy with the active ingredient prednisolone was presented in accordance with the product information. According to the guideline[2], high-dose pulse therapy can also be used. No treatment mode is prioritised. The standard dosage of 80 – 100 mg/day according to the product information is shown for the cost representation.

For dosages depending on body weight (BW), the average body measurements from the official representative statistics "Microcensus 2021 – body measurements of the population"[3] were used as a basis (average body weight: 77.7 kg).

The total dose of subcutaneous (SCIg) and intravenous (IVIg) immunoglobulins can be spread over 1 to 2 days. The subcutaneous dosage form is approved for administration in the maintenance phase.

<u>Adults with progressive or relapsing active chronic inflammatory demyelinating polyneuropathy (CIDP) after prior treatment with corticosteroids or immunoglobulins</u>

<u>Treatment period:</u>

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Medicinal product to be assessed				
Efgartigimod alfa	Continuously, 1 x every 7 days	52.1	1	52.1

[2] Van den Bergh PYK, van Doorn PA, Hadden RDM et al. European Academy of Neurology/Peripheral Nerve Society guideline on diagnosis and treatment of chronic inflammatory demyelinating polyradiculoneuropathy: Report of a joint task force – Second revision. J Peripher Nerv Syst 2021;26(3):242-268. doi:10.1111/jns.12455.

[3] Federal Health Reporting. Average body measurements of the population (2021, both sexes, 15 years and older), www.gbe-bund.de

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
	Continuously, 1 x every 14 days	26.1	1	26.1
Appropriate comparator therapy				
Immunoglobulins or corticosteroids				
Immunoglobulin IVIg	Continuously, 1 x every 21 days	17.4	1 – 2	17.4 – 34.8
Immunoglobulin SCIg[4]	Continuously, 1 x every 7 days	52.1	1 – 2	52.1 – 104.2
	or			
Immunoglobulin SCIg/ vorhyaluronidase[5]	Continuously, 1 x every 30.4 days	13.0	1 – 2	13.0 – 26.0
Prednisolone	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					
Efgartigimod alfa	1000 mg	1000 mg	1 x 1000 mg	26.1 – 52.1	26.1 x 1000 mg – 52.1 x 1000 mg
Appropriate comparator therapy					
Immunoglobulins or corticosteroids					
Immunoglobulin IVIg	1 g/kg BW 77.7 g	77.7 g	4 x 20 g	17.4	69.6 x 20 g
Immunoglobulin SCIg[4]	0.2 g/kg BW 15.5 g – 0.4 g/kg BW 31.1 g	15.5 g – 31.1 g	1 x 10 g + 1 x 4 g + 1 x 2 g – 3 x 10 g + 1 x 2 g	52.1	52.1 x 10 g + 52.1 x 4 g + 52.1 x 2 g – 156.3 x 10 g + 52.1 x 2 g

[4] The medicinal product Hizentra is the most economical formulation in high doses in subcutaneous dosage form.
[5] The subcutaneously administered medicinal product Hyqvia contains immunoglobulin G in co-formulation with the enzyme hyaluronidase. It is the most economical formulation in the low dose range.

Designation of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
Immunoglobulin SCIg/ vorhyaluronidase[5]	0.3 g/kg BW 23.3 g – 2.4 g/kg BW 186.5 g	23.3 g – 186.5 g	1 x 20 g + 1 x 5 g – 6 x 30 g + 1 x 5 g + 1 x 2.5 g	13.0	13 x 20 g + 13 x 5 g – 78 x 30 g + 13 x 5 g + 13 x 2.5 g
Prednisolone	80 mg – 100 mg	80 mg – 100 mg	1 x 50 mg + 1 x 20 mg + 1 x 10 mg – 2 x 50 mg	365.0	365 x 50 mg + 365 x 20 mg + 365 x 10 mg – 730 x 50 mg

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					
Efgartigimod alfa 1,000 mg	1 SFI	€ 14,816.64	€ 1.77	€ 842.89	€ 13,971.98
Appropriate comparator therapy					
Immunoglobulin IVIg 20 mg	1 INF	€ 1,687.03	€ 1.77	€ 93.05	€ 1,592.21
Immunoglobulin SCIg 10 g	10 IIS	€ 10,840.40	€ 1.77	€ 1,788.58	€ 9,050.05
Immunoglobulin SCIg 4 g	20 PS	€ 8,683.85	€ 1.77	€ 1,430.82	€ 7,251.26
Immunoglobulin SCIg 2 g	20 PS	€ 4,370.75	€ 1.77	€ 715.42	€ 3,653.56
Immunoglobulin SCIg 30 g / vorhyaluronidase alfa 2,400 U.	1 INF	€ 3,521.59	€ 1.77	€ 197.83	€ 3,321.99
Immunoglobulin SCIg 20 g vorhyaluronidase alfa 1,600 U.	1 INF	€ 2,366.95	€ 1.77	€ 131.88	€ 2,233.30

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
Immunoglobulin SCIg 5 g / vorhyaluronidase alfa 400 U.	1 INF	€ 606.83	€ 1.77	€ 32.97	€ 572.09
Immunoglobulin SCIg 2.5 g / vorhyaluronidase alfa 200 U.	1 INF	€ 309.07	€ 1.77	€ 16.49	€ 290.81
Prednisolone 50 mg[6]	50 TAB	€ 31.44	€ 1.77	€ 1.59	€ 28.08
Prednisolone 20 mg[6]	100 TAB	€ 21.62	€ 1.77	€ 0.81	€ 19.04
Prednisolone 10 mg[6]	100 TAB	€ 17.81	€ 1.77	€ 0.51	€ 15.53
Abbreviations: PS = prefilled syringes; IIS = solution for injection/ infusion; SFI = solution for injection; INF = infusion solution; PSI = powder for solution for injection; TAB = tablet					

LAUER-TAXE® last revised: 15 November 2025

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.

Because there are no 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, no costs for additionally required SHI services had to be taken into account.

2.5 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

According to Section 35a, paragraph 3, sentence 4, the G-BA designate all medicinal products with new active ingredients that can be used in a combination therapy with the assessed medicinal product for the therapeutic indication to be assessed on the basis of the marketing authorisation under Medicinal Products Act.

Basic principles of the assessed medicinal product

A designation in accordance with Section 35a, paragraph 3, sentence 4 SGB V requires that it is examined based on the product information for the assessed medicinal product whether it can be used in a combination therapy with other medicinal products in the assessed therapeutic indication. In the first step, the examination is carried out on the basis of all sections of the currently valid product information for the assessed medicinal product.

If the assessed medicinal product contains an active ingredient or a fixed combination of active

[6] Fixed reimbursement rate

ingredients in the therapeutic indication of the resolution (assessed therapeutic indication) and is approved exclusively for use in monotherapy, a combination therapy is not considered due to the marketing authorisation under Medicinal Products Act, which is why no designation is made.

A designation is also not considered if the G-BA have decided on an exemption as a reserve antibiotic for the assessed medicinal product in accordance with Section 35a, paragraph 1c, sentence 1 SGB V. The additional benefit is deemed to be proven if the G-BA have decided on an exemption for a reserve antibiotic in accordance with Section 35a, paragraph 1c, sentence 1 SGB V; the extent of the additional benefit and its therapeutic significance are not to be assessed by the G-BA. Due to the lack of an assessment mandate by the G-BA following the resolution on an exemption according to Section 35a, paragraph 1c, sentence 1 SGB V with regard to the extent of the additional benefit and the therapeutic significance of the reserve antibiotic to be assessed, there is a limitation due to the procedural privileging of the pharmaceutical companies to the effect that neither the proof of an existing nor an expected at least considerable additional benefit is possible for exempted reserve antibiotics in the procedures according to Section 35a paragraph 1 or 6 SGB V and Section 35a paragraph 1d SGB V. The procedural privileging of the reserve antibiotics exempted according to Section 35a, paragraph 1c, sentence 1 SGB V must therefore also be taken into account at the level of designation according to Section 35a, paragraph 3, sentence 4 SGB V in order to avoid valuation contradictions.

With regard to the further examination steps, a differentiation is made between a "determined" or "undetermined" combination, which may also be the basis for a designation.

A "determined combination" exists if one or more individual active ingredients which can be used in combination with the assessed medicinal product in the assessed therapeutic indication are specifically named.

An "undetermined combination" exists if there is information on a combination therapy, but no specific active ingredients are named. An undetermined combination may be present if the information on a combination therapy:

- names a product class or group from which some active ingredients not specified in detail can be used in combination therapy with the assessed medicinal product, or
- does not name any active ingredients, product classes or groups, but the assessed medicinal product is used in addition to a therapeutic indication described in more detail in the relevant product information, which, however, does not include information on active ingredients within the scope of this therapeutic indication.

Concomitant active ingredient

The concomitant active ingredient is a medicinal product with new active ingredients that can be used in combination therapy with the assessed medicinal product for the therapeutic indication to be assessed.

For a medicinal product to be considered as a concomitant active ingredient, it must be classified as a medicinal product with new active ingredients according to Section 2 paragraph 1 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with the corresponding regulations in Chapter 5 of the Rules of Procedure of the G-BA as of the date of the present resolution. In addition, the medicinal product must be approved in the assessed therapeutic indication, whereby a marketing authorisation is sufficient only for a sub-area of the assessed therapeutic indication.

Based on an "undetermined combination", the concomitant active ingredient must be

attributable to the information on the product class or group or the therapeutic indication according to the product information of the assessed medicinal product in the assessed therapeutic indication, whereby the definition of a product class or group is based on the corresponding requirements in the product information of the assessed medicinal product.

In addition, there must be no reasons for exclusion of the concomitant active ingredient from a combination therapy with the assessed medicinal product, in particular no exclusive marketing authorisation as monotherapy.

In addition, all sections of the currently valid product information of the eligible concomitant active ingredient are checked to see whether there is any information that excludes its use in combination therapy with the assessed medicinal product in the assessed therapeutic indication under marketing authorisation regulations. Corresponding information can be, for example, dosage information or warnings. In the event that the medicinal product is used as part of a determined or undetermined combination which does not include the assessed medicinal product, a combination with the assessed medicinal product shall be excluded.

Furthermore, the product information of the assessed medicinal product must not contain any specific information that excludes its use in combination therapy with the eligible concomitant active ingredient in the assessed therapeutic indication under marketing authorisation regulations.

Medicinal products with new active ingredients for which the G-BA have decided on an exemption as a reserve antibiotic in accordance with Section 35a, paragraph 1c, sentence 1 SGB V are ineligible as concomitant active ingredients. The procedural privileging of the reserve antibiotics exempted according to Section 35a, paragraph 1c, sentence 1 SGB V also applies accordingly to the medicinal product eligible as a concomitant active ingredient.

Designation

The medicinal products which have been determined as concomitant active ingredients in accordance with the above points of examination are named by indicating the relevant active ingredient and the invented name. The designation may include several active ingredients, provided that several medicinal products with new active ingredients may be used in the same combination therapy with the assessed medicinal product or different combinations with different medicinal products with new active ingredients form the basis of the designation.

If the present resolution on the assessed medicinal product in the assessed therapeutic indication contains several patient groups, the designation of concomitant active ingredients shall be made separately for each of the patient groups.

Exception to the designation

The designation excludes combination therapies for which - patient group-related - a considerable or major additional benefit has been determined by resolution according to Section 35a, paragraph 3, sentence 1 SGB V or it has been determined according to Section 35a, paragraph 1d, sentence 1 SGB V that at least considerable additional benefit of the combination can be expected. In this context, the combination therapy that is excluded from the designation must, as a rule, be identical to the combination therapy on which the preceding findings were based.

In the case of designations based on undetermined combinations, only those concomitant active ingredients - based on a resolution according to Section 35a, paragraph 3, sentence 1 SGB V on the assessed medicinal product in which a considerable or major additional benefit had been determined - which were approved at the time of this resolution are excluded from the designation.

Legal effects of the designation

The designation of combinations is carried out in accordance with the legal requirements according to Section 35a, paragraph 3, sentence 4 and is used exclusively to implement the combination discount according to Section 130e SGB V between health insurance funds and pharmaceutical companies. The designation is not associated with a statement as to the extent to which a therapy with the assessed medicinal products in combination with the designated medicinal products corresponds to the generally recognised state of medical knowledge. The examination was carried out exclusively on the basis of the possibility under Medicinal Products Act to use the medicinal products in combination therapy in the assessed therapeutic indication based on the product information; the generally recognised state of medical knowledge or the use of the medicinal products in the reality of care were not the subject of the examination due to the lack of an assessment mandate of the G-BA within the framework of Section 35a, paragraph 3, sentence 4 SGB V.

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.

Justification for the findings on designation in the present resolution:

Adults with progressive or relapsing active chronic inflammatory demyelinating polyneuropathy (CIDP) after prior treatment with corticosteroids or immunoglobulins

No designation of medicinal products with new active ingredients that can be used in combination therapy pursuant to Section 35a, paragraph 3, sentence 4 SGB V, as the active ingredient to be assessed is an active ingredient authorised in monotherapy.

References:
Product information for efgartigimod alfa (Vyvgart); Vyvgart 1,000 mg solution for injection; last revised: June 2025

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

At their session on 27 February 2024, the Subcommittee on Medicinal Products determined the appropriate comparator therapy.

A review of the appropriate comparator therapy took place. The Subcommittee on Medicinal Products determined the appropriate comparator therapy at their session on 5 August 2025.

On 17 July 2025, the pharmaceutical company submitted a dossier for the benefit assessment of efgartigimod alfa to the G-BA in due time in accordance with Chapter 5 Section 8, paragraph 1, number 2 VerfO.

By letter dated 24 July 2025 in conjunction with the resolution of the G-BA of 1 August 2011 concerning the commissioning of the IQWiG to assess the benefits 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 efgartigimod alfa.

The dossier assessment by the IQWiG was submitted to the G-BA on 30 October 2025, and the written statement procedure was initiated with publication on the G-BA website on 3 November 2025. The deadline for submitting statements was 24 November 2025.

The oral hearing was held on 8 December 2025.

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 was discussed at the session of the Subcommittee on 13 January 2026, and the proposed draft resolution was approved.

At their session on 22 January 2026, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee on Medicinal Products	27 February 2024	Determination of the appropriate comparator therapy
Subcommittee on Medicinal Products	5 August 2025	Examination of the appropriate comparator therapy
Working group Section 35a	3 December 2025	Information on written statements received; preparation of the oral hearing
Subcommittee on Medicinal Products	8 December 2025	Conduct of the oral hearing
Working group Section 35a	16 December 2025 6 January 2026	Consultation on the dossier evaluation by the IQWiG and evaluation of the written statement procedure
Subcommittee on Medicinal Products	13 January 2026	Concluding discussion of the draft resolution
Plenum	22 January 2026	Adoption of the resolution on the amendment of the Pharmaceuticals Directive

Berlin, 22 January 2026

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

Prof. Hecken