

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
Efgartigimod alfa (reassessment of an orphan drug after
exceeding the EUR 30 million turnover limit (myasthenia
gravis, AChR antibody+))

of 19 September 2024

At its session on 19 September 2024, 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. Annex XII is amended as follows:

1. The information on efgartigimod alfa in the version of the resolution of 16 February 2023 (Federal Gazette, BAnz AT 09.05.2023 B4) is repealed.
2. Annex XII shall be amended in alphabetical order to include the active ingredient efgartigimod alfa as follows:

Efgartigimod alfa

Resolution of: 19 September 2024
Entry into force on: 19 September 2024
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 10 August 2022):

Vyvgart is indicated as an add-on to standard therapy for the treatment of adult patients with generalised Myasthenia Gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive.

Therapeutic indication of the resolution (resolution of 19 September 2024):

See therapeutic indication according to marketing authorisation.

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

Adults with anti-AChR antibody-positive generalised myasthenia gravis who are eligible for an add-on to standard therapy

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

Eculizumab (for refractory patients) or ravulizumab

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

An additional benefit is not proven.

Study results according to endpoints:¹

Adults with anti-AChR antibody-positive generalised myasthenia gravis who are eligible for an add-on to standard therapy

There are no assessable data.

¹ Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A24-36) unless otherwise indicated.

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

Adults with anti-AChR antibody-positive generalised myasthenia gravis who are eligible for an add-on to standard therapy

Approx. 6,300 - 19,000 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 Vyvgart (active ingredient: efgartigimod alfa) at the following publicly accessible link (last access: 11 June 2024):

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 doctors experienced in the therapy of neuromuscular diseases.

4. Treatment costs

Annual treatment costs:

Adults with anti-AChR antibody-positive generalised myasthenia gravis who are eligible for an add-on to standard therapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Efgartigimod alfa	€ 66,801.76 - € 494,333.02
Appropriate comparator therapy:	
Eculizumab	€ 505,317.31 - € 673,756.42
Ravulizumab	€ 331,003.14

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 September 2024)

Costs for additionally required SHI services: not applicable

Other SHI services:

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
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

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:

Adults with anti-AChR antibody-positive generalised myasthenia gravis who are eligible for an add-on to standard therapy

- No medicinal product with new active ingredients that can be used in a combination therapy and fulfils 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.

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 19 September 2024.

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

Berlin, 19 September 2024

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

Prof. Hecken