Gemeinsamer Bundesausschuss

Resolution

of the Federal Joint Committee on an Amendment of the Pharmaceuticals Directive:
Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a SGB V
Avacopan (reassessment of an orphan drug after exceeding the EUR 30 million limit: granulomatosis with polyangiitis or microscopic polyangiitis, combination with rituximab or cyclophosphamide)

From 5 March 2026

At their session on 5 March 2026, the Federal Joint Committee (G-BA) resolved to amend the Pharmaceuticals Directive (AM-RL) in the version dated 18 December 2008 / 22 January 2009 (Federal Gazette, BAnz. No. 49a of 31 March 2009), as last amended by the publication of the resolution of D Month YYYY (Federal Gazette, BAnz AT DD.MM.YYYY BX), as follows:

I. Annex XII is amended as follows:

1. **The information on Avacopan in the version of the resolution of 16 February 2023 (BAnz AT 06.09.2022 B2) last modified on 27 September 2022 (BAnz AT 18.10.2022 B4) is repealed.**
2. **Annex XII shall be amended in alphabetical order to include the active ingredient Avacopan as follows:**

Avacopan

Resolution of: 5 March 2026
Entry into force on: 5 March 2026
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 19 January 2022):

Tavneos, in combination with a rituximab or cyclophosphamide regimen, is indicated for the treatment of adult patients with severe, active granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA).

Therapeutic indication of the resolution (resolution of 5 March 2026):

See therapeutic indication according to marketing authorisation.

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

Adults with severe, active granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA)

Appropriate comparator therapy for avacopan in combination with a rituximab or cyclophosphamide treatment regimen:

– Cyclophosphamide (induction phase) followed by rituximab (maintenance phase), each in combination with glucocorticoids (only for patients with GPA)

or

– Rituximab (induction and maintenance phase) in combination with glucocorticoids

Extent and probability of the additional benefit of avacopan in combination with a rituximab or cyclophosphamide treatment regimen compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:[1]

Adults with severe, active granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA)

No suitable data available.

[1] Data from the dossier assessment of the IQWiG (A25-114) and from the addendum (A26-07), 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 severe, active granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA)

Approximately 2,330 – 2,850 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 Tavneos (active ingredient: avacopan) at the following publicly accessible link (last access: 4 December 2025):

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

Treatment with avacopan should only be initiated and monitored by specialists experienced in treating patients with GPA or MPA.

Avacopan has not been investigated in patients with severe disease, manifesting as alveolar haemorrhage requiring invasive ventilation and in patients with an estimated glomerular filtration rate (eGFR) below 15 ml/min/1.73m^2 who are dialysis-dependent or are in need of dialysis or plasma exchange treatment.

In order to further characterise the safety profile of avacopan with respect to e.g. liver injury, severe infections, malignancies and cardiovascular events, a PASS study was requested by the EMA upon marketing authorisation.

4. Treatment costs

Annual treatment costs:

Adults with severe, active granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA)

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Avacopan in combination with rituximab (RTX) and, if applicable, glucocorticoids	
Avacopan	€ 73,902.52
Rituximab 1st year: Subsequent year:	 € 10,767.60 € 0.00
Prednisolone	Different from patient to patient
Avacopan + RTX Total for the 1st year: Total for the subsequent year:	 € 84,670.12 € 73,902.52
Additionally required SHI costs:	€ 48.60
Avacopan in combination with intravenous (IV) cyclophosphamide (CYC) administration followed by azathioprine (AZA) or mycophenolate mofetil (MMF) and, if applicable, glucocorticoids	
Avacopan	€ 73,902.52
Cyclophosphamide 1st year: Subsequent year:	 € 202.12 – € 232.80 € 0.00
Azathioprine 1st year: Subsequent year:	 € 120.18 € 164.29
Mycophenolate mofetil 1st year: Subsequent year:	 € 1,609.01 € 2,199.58
Prednisolone	Different from patient to patient
Avacopan + CYC IV + AZA Total for the 1st year: Total for the subsequent year:	 € 74,224.82 – € 74,255.50 € 74,066.81
Avacopan + CYC IV + MMF Total for the 1st year: Total for the subsequent year:	 € 75,713.65 – € 75,744.33 € 76,102.10
Avacopan in combination with peroral (PO) cyclophosphamide administration followed by azathioprine or mycophenolate mofetil and, if applicable, glucocorticoids	
Avacopan	€ 73,902.52
Cyclophosphamide PO 1st year: Subsequent year:	 € 280.35 € 0.00
Azathioprine	

Designation of the therapy	Annual treatment costs/ patient
1st year: Subsequent year:	€ 120.18 € 164.29
Mycophenolate mofetil 1st year: Subsequent year:	 € 1,609.01 € 2,199.58
Prednisolone	Different from patient to patient
Avacopan + CYC PO + AZA Total for the 1st year: Total for the subsequent year:	 € 74,303.05 € 74,066.81
Avacopan + CYC PO + MMF Total for the 1st year: Total for the subsequent year:	 € 75,791.88 € 76,102.10
Designation of the therapy	Annual treatment costs/ patient
Appropriate comparator therapy:	
(Intravenous) cyclophosphamide administration followed by rituximab, each in combination with glucocorticoids	
Cyclophosphamide 1st year: Subsequent year:	 € 202.12 € 0.00
Rituximab 1st year: Subsequent year:	 € 4,528.87 € 3,354.72
Prednisolone	Different from patient to patient
CYC IV + RTX Total for the 1st year: Total for the subsequent year:	 € 4,730.99 € 3,354.72
Additionally required SHI costs[2]:	€ 50.00
(Peroral) cyclophosphamide administration followed by rituximab, each in combination with glucocorticoids	
Cyclophosphamide	€ 280.35
Rituximab 1st year: Subsequent year:	 € 4,528.87 € 3,354.72
Prednisolone	Different from patient to patient
CYC PO + RTX Total for the 1st year: Total for the subsequent year:	 € 4,809.22 € 3,354.72
Additionally required SHI costs[2]:	€ 50.00
Rituximab in combination with glucocorticoids	
Rituximab 1st year:	 € 15,631.94

[2] total costs for the 1st year and the subsequent year

Designation of the therapy	Annual treatment costs/ patient
Subsequent year:	€ 3,354.72
Prednisolone	Different from patient to patient
Additionally required SHI costs[2]:	€ 79.49

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

Other SHI services:

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Medicinal product to be assessed:					
Cyclophosphamide and rituximab each in combination therapy with avacopan					
Cyclophosphamide	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	5 – 7	€ 500 – € 700
Rituximab	Surcharge for the production of a parenteral solution with monoclonal antibodies	€ 100	1	4	€ 400
Appropriate comparator therapy:					
Cyclophosphamide in combination therapy with rituximab					
Cyclophosphamide	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	6	€ 600
Rituximab	Surcharge for the production of a parenteral solution with monoclonal antibodies	€ 100	1	1st year: 2.7 Subsequent year: 2	€ 470
Rituximab					
Rituximab	Surcharge for the production of a parenteral solution with	€ 100	1	1st year: 6.9 Subsequent year:	€ 890

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

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 severe, active granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA)

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

The designation of combinations exclusively serves the implementation of the combination discount according to Section 130e SGB V between statutory 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 G-BA website on 5 March 2026.

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

Berlin, 5 March 2026

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

Prof. Hecken