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
Pegcetacoplan (new therapeutic indication: primary immune-complex membranoproliferative glomerulonephritis, ≥ 12 years)

From 6 August 2026

At their session on 6 August 2026, the Federal Joint Committee (G-BA) resolved to amend the Pharmaceuticals Directive (AM-RL) in the version dated 18 December 2008 / 22 January 2009 (Federal Gazette, BAnz. No. 49a of 31 March 2009), as last amended by the publication of the resolution of D Month YYYY (Federal Gazette, BAnz AT DD.MM.YYYY BX), as follows:

I. In Annex XII, the following information shall be added after number 5 to the information on the benefit assessment of pegcetacoplan in accordance with the resolution of 6 August 2026 (complement-3 glomerulopathy, ≥ 12 years):

Pegcetacoplan

Resolution of: 6 August 2026
Entry into force on: 6 August 2026
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 15 January 2026):

Aspaveli is indicated for the treatment of adult and adolescent patients aged 12 to 17 years with C3 glomerulopathy (C3G) or primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN) in combination with a renin-angiotensin system (RAS) inhibitor, unless RAS inhibitor treatment is not tolerated or contraindicated.

Therapeutic indication of the resolution (resolution of 6 August 2026):

Aspaveli is indicated for the treatment of adult and adolescent patients aged 12 to 17 years with primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN) in combination with a renin-angiotensin system (RAS) inhibitor, unless RAS inhibitor treatment is not tolerated or contraindicated.

1. Extent of the additional benefit and significance of the evidence

Pegcetacoplan is approved as a medicinal product for the treatment of rare diseases under Regulation (EC) No. 141/2000 of the European Parliament and the Council of 16 December 1999 on orphan drugs. In accordance with Section 35a, paragraph 1, sentence 11, 1st half of the sentence SGB V, the additional medical benefit is considered to be proven through the grant of the marketing authorisation.

The G-BA determine the extent of the additional benefit for the number of patients and patient groups for which there is a therapeutically significant additional benefit in accordance with Chapter 5, Section 12, paragraph 1, number 1, sentence 2 of their Rules of Procedure (VerfO) in conjunction with Section 5, paragraph 8 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV), indicating the significance of the evidence. This quantification of the additional benefit is based on the criteria laid out in Chapter 5, Section 5, paragraph 7, numbers 1 to 4 of the Rules of Procedure (VerfO).

Adults and adolescents aged 12 to 17 years with primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN)

Extent of the additional benefit and significance of the evidence of pegcetacoplan:

Hint of non-quantifiable additional benefit since the scientific data does not allow quantification.

Study results according to endpoints:[1]

Adults and adolescents aged 12 to 17 years with primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN)

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	↔	No relevant difference for the benefit assessment.
Morbidity	n.c.	The data are not assessable.
Health-related quality of life	n.c.	The data are not assessable.
Side effects	↔	No relevant difference for the benefit assessment.
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		

VALIANT study:

- a randomised, double-blind, placebo-controlled phase III study
- a 26-week, blinded, placebo-controlled study phase

Relevant sub-population: Patients with IC-MPGN

Mortality

Endpoint	Pegcetacoplan		Placebo		Pegcetacoplan vs placebo
	N[a]	Patients with event n (%)	N[a]	Patients with event n (%)	RR [95% CI] p value
Overall mortality[b]					
	12	0 (0.0)	16	0 (0)	-

[1]Data from the dossier assessment of the G-BA (published on 15 May 2026), unless otherwise indicated.

Morbidity

Endpoint	Pegcetacoplan			Placebo			Pegcetacoplan vs placebo
	N	MV (SD)	LS mean (SE)	N	MV (SD)	LS mean (SE)	LS mean[c] [95% CI] p value
Proteinuria: Change in log-transformed FMU-uPCR relative to baseline (presented additionally)							
Baseline							
	12	8.15 (0.60)		16	7.85 (0.73)		
Week 26							
	11	6.77 (1.60)		15	7.76 (0.93)		
Change from baseline to week 26[e]							
	12[f]		-1.30 (-)	16[f]		0.03 (-)	
Group difference of changes[e]							
							-1.33 [-2.18; -0.48]; 0.0021
Change in eGFR from baseline (presented additionally)							
Baseline							
	12	81.6 (36.3)		16	77.5 (30.5)		
Week *26*							
	11	79.4 (29.1)		16	69.6 (29.3)		
Change from baseline to week 26[e]							
	12[f]		1.9 (5.5)	16[f]		-7.4 (4.5)	
Group difference of changes[e]							
							9.3 [-4.7; 23.3]; 0.19
Fatigue (FACIT-Fatigue, Peds FACIT-F), WPAI:SHP (Question 6), EQ-5D-VAS, PGI-C							

Endpoint	Pegcetacoplan			Placebo			Pegcetacoplan vs placebo
	N	MV (SD)	LS mean (SE)	N	MV (SD)	LS mean (SE)	LS mean[c] [95% CI] p value
No assessable data available							

Health-related quality of life

Endpoint	Pegcetacoplan		Placebo		Pegcetacoplan vs placebo
	N	Subjects with deterioration n (%)	N	Subjects with deterioration n (%)	RR [95% CI] p value
KDQOL-36					
The data are not assessable.					

Side effects

Endpoint MedDRA system organ classes/ preferred terms/ AEs of special interest	Pegcetacoplan		Placebo		Pegcetacoplan vs placebo
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI] p value
Total adverse events (presented additionally)	12	12 (100)	16	15 (93.8)	-
Serious adverse events (SAEs)	12	1 (8.3)	16	2 (12.5)	0.67 [0.07; 6.52]; 0.73
Severe adverse events[g]	12	1 (8.3)	16	1 (6.2)	1.33 [0.09; 19.2]; 0.83
Therapy discontinuation due to adverse events	12	0 (0)	16	0 (0)	-
Severe adverse events according to MedDRA (with an incidence ≥ 5% in one study arm and statistically significant difference between the treatment arms; SOC and PT)					
No significant differences					
SAEs according to MedDRA (with an incidence ≥ 5% in one study arm and statistically significant difference between the treatment arms; SOC and PT)					
No significant differences					

a. The number includes subjects accounted for in the calculation of the respective statistics.
b. Deaths were recorded on an ongoing basis as part of the safety assessment.

c. The MMRM uses fixed categorical effects for treatment group, visit, disease type, intake of immunosuppressants at the start of the study, stratification factors and the interaction between visit and treatment group, as well as the continuous, fixed covariates of the logarithmically transformed uPCR value at the start of the study.
d. Primary endpoint of the VALIANT study.
e. In this instance, the data on changes are drawn from the values for weeks 24–26, as pre-specified for the primary analysis.
f. Imputed values. There is no information on how the missing values are distributed across the C3G and IC-MPGN populations.
g. The study criteria were used for severity grading.

Abbreviations used:
C3G = C3 glomerulopathy; IC-MPGN = immune-complex membranoproliferative glomerulonephritis; FMU = first morning urine; ITT = intention to treat; KDQOL-36 = Kidney Disease Quality of Life instrument – 36 items; CI = confidence interval; KSS = kidney summary score; N = number of patients analysed; n = number of patients with (at least one) event; n.c. = not calculable; n.r. = not reached; pU = pharmaceutical company; RR = relative risk; (S)AE = (serious) adverse event; uPCR = urine protein-to-creatinine ratio; vs = versus

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

Adults and adolescents aged 12 to 17 years with primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN)

Approx. 75 – 180 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 Aspaveli (active ingredient: pegcetacoplan) at the following publicly accessible link (last access: 12 March 2026):

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

Treatment with pegcetacoplan must be initiated and monitored by specialists who are experienced in the treatment of patients with renal diseases.

In accordance with the European Medicines Agency (EMA) requirements regarding additional risk minimisation measures, the pharmaceutical company must provide training material that contains information for medical professionals and patients (incl. patient identification card). The training material contains, in particular, informations and warnings of the increased risk of infection with encapsulated bacteria associated with the use of pegcetacoplan.

4. Treatment costs

Annual treatment costs:

Adults and adolescents aged 12 to 17 years with primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN)

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Pegcetacoplan	€ 362,401.56

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

Costs for additionally required SHI services: not applicable

II. The resolution will enter into force on the day of its publication on the G-BA website on 6 August 2026.

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

Berlin, 6 August 2026

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

Dr Optendrenk