

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

Retifanlimab (new therapeutic indication: squamous cell
carcinoma of the anal canal; first-line)

of 1 October 2026

At their session on 1 October 2026, the Federal Joint Committee (GBA) 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 4 to the
information on the benefit assessment of Retifanlimab in accordance with the
resolution of 1 October 2026 (Merkel cell carcinoma, metastatic or relapsed,
monotherapy, first-line):**

Retifanlimab

Resolution of: 1 October 2026

Entry into force on: 1 October 2026

Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 5 March 2026):

Zynyz is indicated in combination with carboplatin and paclitaxel for the first-line treatment of adult patients with metastatic or with inoperable locally recurrent squamous cell carcinoma of the anal canal (SCAC).

Therapeutic indication of the resolution (resolution of 1 October 2026):

See new therapeutic indication according to marketing authorisation.

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

Retifanlimab 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 German Social Code, Book Five (SGB V), the additional medical benefit is considered to be proven through the grant of the marketing authorisation.

The GBA 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 with metastatic or with inoperable locally recurrent squamous cell carcinoma of the anal canal (SCAC); first-line treatment

Extent of the additional benefit and significance of the evidence of retifanlimab in combination with carboplatin and paclitaxel:

Hint of a minor additional benefit

Study results according to endpoints:¹

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	↑	Advantage in overall survival
Morbidity	n.a.	The data are not assessable
Health-related quality of life	n.a.	The data are not assessable
Side effects	↓	Disadvantage in the endpoint of therapy discontinuation due to AEs
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		

POD1UM-303 study

- Randomised, double-blind phase III study
- Retifanlimab + carboplatin + paclitaxel vs placebo + carboplatin + paclitaxel
- Significance level $\alpha = 0.025$
- Data cut-off from 26 September 2025

Mortality

Endpoint	Retifanlimab + carboplatin + paclitaxel		Carboplatin + paclitaxel		Intervention vs control
	N	Median survival time in months [95% CI] <i>Patients with event n (%)</i>	N	Median survival time in months [95% CI] <i>Patients with event n (%)</i>	Hazard ratio [95% CI] p value Absolute difference (AD) ^a
Overall survival					
	154	32.8 [25.7; 44.5] 79 (51.3)	154	22.2 [15.7; 27.2] 97 (63.0)	0.73 [0.54; 0.99] 0.0204 AD = 10.6 months

¹ Data from the dossier assessment by the GBA (published on 1 July 2026) and the amendment to the dossier assessment of 11 September 2026, unless otherwise indicated.

Morbidity

Endpoint	Retifanlimab + carboplatin + paclitaxel		Carboplatin + paclitaxel		Intervention vs control
	N	Median time to event in months [95% CI] <i>Patients with event n (%)</i>	N	Median time to event in months [95% CI] <i>Patients with event n (%)</i>	Hazard ratio [95% CI] p value Absolute difference (AD) ^a
Progression-free survival (PFS)²					
	154	9.3 [7.6; 12.7] 99 (64.3)	154	7.4 [6.9; 7.6] 119 (77.3)	0.62 [0.47; 0.81] 0.0002 AD = 1.9 months
Symptomatology (EORTC QLQ-C30 symptom scales)					
No suitable data.					
Health status (EQ-5D VAS)					
No suitable data.					

Health-related quality of life

Endpoint	Retifanlimab + carboplatin + paclitaxel		Carboplatin + paclitaxel		Intervention vs control
	N	Median time to event in months [95% CI] <i>Patients with event n (%)</i>	N	Median time to event in months [95% CI] <i>Patients with event n (%)</i>	Hazard ratio [95% CI] p value Absolute difference (AD) ^a
EORTC QLQ-C30 functional scales and global health status, EORTC QLQ-ANL27					
No suitable data.					

² Data cut-off from 1 August 2025

Side effects

Endpoint MedDRA system organ classes/ preferred terms/ AEs of special interest	Retifanlimab + carboplatin + paclitaxel		Carboplatin + paclitaxel		Intervention vs control
	N	Patients with event n (%)	N	Patients with event n (%)	Relative risk [95% CI] p value
Total adverse events (presented additionally)					
	154	154 (100)	152	152 (100)	-
Serious adverse events (SAEs)					
	154	73 (47.4)	152	67 (44.1)	1.08 [0.84; 1.37] 0.56
Severe adverse events (CTCAE grade ≥ 3)					
	154	129 (83.8)	152	125 (82.2)	1.08 [0.92; 1.13] 0.72
Therapy discontinuation due to adverse events					
	154	18 (11.7)	154	5 (3.3)	3.55 [1.35; 9.33] 0.01 AD = 8.4%
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. Indication of absolute difference (AD) only in case of statistically significant difference; own calculation. Abbreviations used: AD = absolute difference; CTCAE = Common Terminology Criteria for Adverse Events; CI = confidence interval; N = number of patients evaluated; n = number of patients with (at least one) event; vs = versus					

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

Adults with metastatic or with inoperable locally recurrent squamous cell carcinoma of the anal canal (SCAC); first-line treatment

Approximately 430 – 700 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 Zynyz (active ingredient: retifanlimab) at the following publicly accessible link (last access: 12 August 2026):

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

Therapy with retifanlimab should only be initiated and monitored by specialists in internal medicine, haematology and oncology who are experienced in the treatment of patients with anal carcinoma, as well as specialists in internal medicine and gastroenterology and other specialists from other specialist groups participating in the Oncology Agreement.

4. Treatment costs

Annual treatment costs:

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Retifanlimab in combination with carboplatin and paclitaxel	
Retifanlimab	€ 166,001.68
Carboplatin	€ 2,188.50
Paclitaxel	€ 8,165.34
Total	€ 176,355.52

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 15 July 2026)

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
Retifanlimab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	13	€ 1,300
Carboplatin	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	6	€ 600
Paclitaxel	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	3	18	€ 1,800

II. The resolution will enter into force on the day of its publication on the GBA website on 1 October 2026.

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

Berlin, 1 October 2026

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

Dr Optendrenk