GBA
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
Retifanlimab (Merkel cell carcinoma, metastatic or relapsed, monotherapy, 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, information on the active ingredient Retifanlimab shall be added in alphabetical order as follows:

Courtesy translation – only the German version is legally binding.

Retifanlimab

Resolution of: 1 October 2026
Entry into force on: 1 October 2026
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 19 April 2024):

Zynyz is indicated as monotherapy for the first-line treatment of adult patients with metastatic or recurrent locally advanced Merkel cell carcinoma (MCC) not amenable to curative surgery or radiation therapy.

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

See 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).

<u>Adult patients with metastatic or recurrent locally advanced Merkel cell carcinoma (MCC) not amenable to curative surgery or radiation therapy; first-line</u>

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

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

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Study results according to endpoints:[1]

Adult patients with metastatic or recurrent locally advanced Merkel cell carcinoma (MCC) not amenable to curative surgery or radiation therapy; first-line

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	n.a.	The data are not assessable.
Morbidity	n.a.	The data are not assessable.
Health-related quality of life	n.a.	The data are not assessable.
Side effects	n.a.	The data are not assessable.
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-201 study:

- Open-label, single-arm phase II study
- Relevant sub-population: 101 chemotherapy-naïve patients
- Final data cut-off from 1 July 2024

Mortality

Endpoint	Retifanlimab	
	N	Median time to event in months [95% CI] Patients with event n (%)
Overall survival		
	101	n/a [45.24; n/a] 39 (38.6)
		Kaplan-Meier estimator [95% CI]
At month 12		0.79 [0.69; 0.86]
At month 24		0.67 [0.57; 0.75]
At month 36		0.63 [0.52; 0.72]

[1] Data from the dossier assessment by the GBA (published on 1 July 2026), unless otherwise indicated.

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Morbidity

Endpoint	Retifanlimab	
	N	Median in months [95% CI] Patients with event n (%)
Progression-free survival (PFS) as defined by the IRC according to the RECIST criteria[2]		
	101	16.03 [9.03; 32.23] 55 (54.5)
		[95% CI] **Patients with event n (%)**
Objective response rate[3] (presented additionally)		
	101	[44.2; 64.4] 55 (54.5)
EQ-5D-VAS		
	No suitable data.[a]	

Quality of life

Endpoint	Retifanlimab	
	N	Patients with event n (%)
FACT-M		
	No suitable data.[a]	

[2] Data from the dossier of the pharmaceutical company (Module 4); final data cut-off from 1 July 2024.
[3] Primary endpoint of the POD1UM-201 study; final data cut-off from 1 July 2024.

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Side effects

Endpoint MedDRA system organ classes/ AEs of special interest	**Retifanlimab**	
	N	**Patients with event n (%)**
Total adverse events (presented additionally)	101	92 (91.1)
Serious adverse events (SAEs)	101	26 (25.7)
Severe adverse events (CTCAE grade 3 or 4)	101	32 (31.7)
Therapy discontinuation due to adverse events	101	21 (20.8)

a. Due to the low return rates (< 70% from the first post-baseline survey), the results are not used for the benefit assessment.

Abbreviations used:
AD = absolute difference; CTCAE = Common Terminology Criteria for Adverse Events; HR = hazard ratio; CI = confidence interval; N = number of patients evaluated; MedDRA = Medical Dictionary for Regulatory Activities; n = number of patients with (at least one) event; n/a = not applicable; n.c. = not calculable; n.r. = not reached; AE = adverse event; vs = versus

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

Adult patients with metastatic or recurrent locally advanced Merkel cell carcinoma (MCC) not amenable to curative surgery or radiation therapy; first-line

Approximately 90 to 220 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: 30 June 2026):

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

Treatment 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 Merkel cell carcinoma, as well as specialists in skin and sexually transmitted diseases and other doctors from other specialist groups participating in the Oncology Agreement.

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4. Treatment costs

Adult patients with metastatic or recurrent locally advanced Merkel cell carcinoma (MCC) not amenable to curative surgery or radiation therapy; first-line

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Retifanlimab	€ 166,001.68

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 parenteral solutions containing monoclonal antibodies	€ 100	1	13	€ 1,300

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

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