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
Belumosudil (chronic graft-versus-host disease (cGvHD), ≥ 12 years, ≥ 40 kg)

of 15 October 2026

At their session on 15 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 Belumosudil shall be added in alphabetical order as follows:

Courtesy translation – only the German version is legally binding.

Belumosudil

Resolution of: 15 October 2026
Entry into force on: 15 October 2026
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 24 March 2026):

REZUROCK is indicated for the treatment of adults and paediatric patients (12 years and older with a body weight of at least 40 kg) with chronic graft-versus-host disease (cGvHD) when other treatment options provide limited clinical benefit, are not suitable or have been exhausted.

Therapeutic indication of the resolution (resolution of 15 October 2026):

See therapeutic indication according to marketing authorisation.

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

Belumosudil 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>Adults and paediatric patients (12 years and older with a body weight of at least 40 kg) with chronic graft-versus-host disease (cGvHD) when other treatment options provide limited clinical benefit, are not suitable or have been exhausted</u>

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

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

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Study results according to endpoints:[1]

Adults and paediatric patients (12 years and older with a body weight of at least 40 kg) with chronic graft-versus-host disease (cGvHD) when other treatment options provide limited clinical benefit, are not suitable or have been exhausted

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	∅	No data available.
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

ROCKstar study (KD025-213):

- Open-label, uncontrolled, multicentre phase II study
- Belumosudil 200 mg once daily versus belumosudil 200 mg twice daily
- Relevant sub-population: belumosudil 200 mg once daily
- Data cut-off: 1 September 2022

Mortality

Endpoint	Belumosudil	
	N	Patients with event n (%)
Overall survival		
Deaths	77	14 (18.2)
		Kaplan-Meier estimator (%) [95% CI]
at month 6	77	0.95 [0.87; 0.98]
at month 12	77	0.91 [0.81; 0.95]
at month 18	77	0.89 [0.79; 0.94]
at month 24	77	0.86 [0.75; 0.92]

[1] Data from the dossier assessment by the GBA (published on 3 August 2026), unless otherwise indicated.

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		Months [min; max]
Median survival time	77	n/a [n/a; n/a]

Morbidity

Endpoint	**Belumosudil**	
	N	**Patients with event n (%) [95% CI]**
cGvHD response		
Overall response rate (ORR)[a] according to NIH criteria (presented additionally)		
	77	57 (74.0) [62.8; 83.4]
		Patients with event n (%)
Complete response		
	77	4 (5.2)
		Patients with event n (%)
Corticosteroid discontinuation[b]		
Events[b]	77	21 (27.3)
Median duration of the last documented steroid-free period[c]	77	8.54 months
Corticosteroid-free for at least 6 months[c,d]	77	14 (18.2)
Corticosteroid-free for at least 12 months[c,d]	77	7 (9.1)
		Patients with event n (%) **MV (SD)** **Median (min; max)**
Lee symptom scale[e] – Total score (30 items)		
Baseline	77	74 (96.1) 28.8 (13.7) 26.6 (0; 56)
Change at cycle 5 compared to baseline	77	52 (67.5) -5.8 (10.3) -4.4 (-32; 18)

Quality of life

No data on health-related quality of life were collected in the ROCKstar study.

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Side effects

Endpoint	Belumosudil	
	N	Patients with event n (%)
Total adverse events (presented additionally)		
	77	76 (98.7)
Serious adverse events (SAEs)		
	77	36 (46.8)
Severe adverse events (CTCAE grade ≥ 3)		
	77	52 (67.5)
Therapy discontinuation due to adverse events		
	77	15 (19.5)
Severe adverse events (CTCAE grade ≥ 3) according to MedDRA system organ class (SOC) (with an incidence ≥ 10%)		
Infections and infestations	77	16 (20.8)
Gastrointestinal disorders	77	14 (18.2)
Respiratory, thoracic and mediastinal disorders	77	12 (15.6)
Metabolism and nutrition disorders	77	11 (14.3)
Vascular disorders	77	11 (14.3)
General disorders and administration site conditions	77	8 (10.4)
SAEs according to MedDRA system organ class (SOC) (with an incidence ≥ 10%)		
Infections and infestations	77	15 (19.5)

a. Primary endpoint of the ROCKstar study; data cut-off from 01.09.2023
b. At least one-time complete discontinuation of systemic corticosteroids for more than 28 days during the belumosudil treatment period; 56 patients were censored due to therapy discontinuation or the commencement of a new systemic therapy
c. Subsequently submitted by the pharmaceutical company in the written statement procedure
d. Of the 21 patients who had discontinued corticosteroids, only 18 patients were fully assessable after 6 months and only 10 patients after 12 months
e. Scale range: 0 to 100. Higher values indicate a greater symptom burden.

Abbreviations used:
CTCAE = Common Terminology Criteria for Adverse Events; CI = confidence interval; MV = mean value; N = number of patients evaluated; n = number of patients with (at least one) event; SD = standard deviation

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

Adults and paediatric patients (12 years and older with a body weight of at least 40 kg) with chronic graft-versus-host disease (cGvHD) when other treatment options provide limited clinical benefit, are not suitable or have been exhausted

Approximately 280 – 600 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 Rezurock (active ingredient: belumosudil) at the following publicly accessible link (last access: 5 August 2026):

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

Treatment with belumosudil should only be initiated and monitored by specialists in internal medicine, haematology and oncology experienced in the treatment of patients with chronic graft-versus-host disease, as well as specialists in paediatrics and adolescent medicine specialising in paediatric haematology and oncology.

This medicinal product received a conditional marketing authorisation. This means that further evidence of the benefit of the medicinal product is anticipated. The European Medicines Agency (EMA) will assess new information on this medicinal product at least annually and update the product information where necessary.

4. Treatment costs

Annual treatment costs:

Adults and paediatric patients (12 years and older with a body weight of at least 40 kg) with chronic graft-versus-host disease (cGvHD) when other treatment options provide limited clinical benefit, are not suitable or have been exhausted

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Belumosudil	€ 166,007.11

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

Costs for additionally required SHI services: not applicable

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II. Entry into force

1. **The resolution will enter into force on the day of its publication on the GBA website on 15 October 2026.**
2. **The period of validity of the resolution is limited to 1 January 2031.**

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

Berlin, 15 October 2026

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

Dr Optendrenk

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