GBA
Gemeinsamer
Bundesausschuss

Justification

for the Resolution of the Federal Joint Committee (GBA) 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

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1. Legal basis

According to Section 35a, paragraph 1 German Social Code, Book Five (SGB V), the Federal Joint Committee (GBA) assess the benefit of all reimbursable medicinal products with new active ingredients.

For medicinal products for the treatment of rare diseases (orphan drugs) that are approved according to Regulation (EC) No. 141/2000 of the European Parliament and the Council of 16 December 1999, the additional medical benefit is considered to be proven through the grant of the marketing authorisation according to Section 35a, paragraph 1, sentence 11, 1st half of the sentence SGB V. Evidence of the medical benefit and the additional medical benefit in relation to the appropriate comparator therapy do not have to be submitted (Section 35a, paragraph 1, sentence 11, 2nd half of the sentence SGB V). Section 35a, paragraph 1, sentence 11, 1st half of the sentence SGB V thus guarantees an additional benefit of an approved orphan drug, although an assessment of the orphan drug in accordance with the principles laid down in Section 35a, paragraph 1, sentence 3, numbers 2 and 3 SGB V in conjunction with Chapter 5, Sections 5 et seqq. of the Rules of Procedure (VerfO) of the GBA has not been carried out. In accordance with Section 5, paragraph 8 AM-NutzenV, only the extent of the additional benefit is to be quantified indicating the significance of the evidence.

However, the restrictions on the benefit assessment of orphan drugs resulting from the statutory obligation to the marketing authorisation do not apply if the turnover of the medicinal product with the SHI at pharmacy sales prices and outside the scope of SHI-accredited medical care, including VAT exceeds € 30 million in the last 12 calendar months. In accordance with Section 35a, paragraph 1, sentence 12 SGB V, the pharmaceutical company shall provide evidence - within three months of being requested to do so by the GBA - in accordance with Chapter 5, Section 5, paragraphs 1 to 6 VerfO, in particular regarding the additional medical benefit in relation to the appropriate comparator therapy specified by the GBA in accordance with Chapter 5, Section 6 VerfO, and in this evidence, demonstrate the additional benefit over the appropriate comparator therapy.

In accordance with Section 35a, paragraph 2 SGB V, the GBA decide whether to carry out the benefit assessment themselves or to commission the Institute for Quality and Efficiency in Health Care (IQWiG). Based on the legal requirement in Section 35a, paragraph 1, sentence 11 SGB V that the additional benefit of an orphan drug is considered to be proven through the grant of the marketing authorisation, the GBA modified the procedure for the benefit assessment of orphan drugs at their session on 15 March 2012 to the effect that, for orphan drugs, the GBA initially no longer independently determine an appropriate comparator therapy as the basis for the solely legally permissible assessment of the extent of an additional benefit to be assumed by law. Rather, the extent of the additional benefit is assessed exclusively on the basis of the approval studies by the GBA indicating the significance of the evidence.

Accordingly, at their session on 15 March 2012, the GBA amended the mandate issued to the IQWiG by the resolution of 1 August 2011 for the benefit assessment of medicinal products with new active ingredients in accordance with Section 35a, paragraph 2 SGB V such that, in the case of orphan drugs, the IQWiG is only commissioned to carry out a benefit assessment in the case of a previously defined comparator therapy when the sales volume of the medicinal product concerned has exceeded the turnover limit according to Section 35a, paragraph 1, sentence 12 SGB V and is therefore subject to an unrestricted benefit assessment. According to Section 35a, paragraph 2 SGB V, the assessment by the GBA must be completed within three months of the relevant date for submission of the evidence and published on the internet.

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According to Section 35a, paragraph 3 SGB V, the GBA decide on the benefit assessment within three months of its publication. The resolution is to be published on the internet and is part of the Pharmaceuticals Directive.

2. Key points of the resolution

The relevant date for the start of the benefit assessment procedure was the first placing on the (German) market of the active ingredient belumosudil on 1 May 2026 in accordance with Chapter 5, Section 8, paragraph 1, number 1, sentence 2 of the Rules of Procedure of the GBA (VerfO). Pursuant to Section 4, paragraph 3, number 1 of the Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with Chapter 5, Section 8, paragraph 1, number 1 of the Rules of Procedure (VerfO), the pharmaceutical company submitted the final dossier to the GBA on 30 April 2026.

Belumosudil for the treatment of chronic graft-versus-host disease (cGvHD) 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.

In accordance with Section 35a, paragraph 1, sentence 11, 1st half of the sentence SGB V, the additional benefit is considered to be proven through the grant of the marketing authorisation. The extent of the additional benefit and the significance of the evidence are assessed on the basis of the approval studies by the GBA.

The GBA carried out the benefit assessment and commissioned the IQWiG to evaluate the information provided by the pharmaceutical company in Module 3 of the dossier on treatment costs and patient numbers. The benefit assessment was published along with the IQWiG assessment on 3 August 2026 on the GBA website (www.g-ba.de), thus initiating the written statement procedure. In addition, an oral hearing was held.

The GBA have adopted their resolution on the basis of the dossier of the pharmaceutical company, the dossier assessment carried out by the GBA, the assessment of treatment costs and patient numbers (IQWiG G26-10) prepared by the IQWiG, and the statements submitted in the written statement and oral hearing procedure.

In order to determine the extent of the additional benefit, the GBA have assessed the studies relevant to the marketing authorisation on the basis of their therapeutic relevance (qualitative), in accordance with the criteria laid down in Chapter 5, Section 5, paragraph 7, sentence 1, numbers 1 to 4 VerfO. The methodology proposed by the IQWiG in accordance with the General Methods [1] was not used in the benefit assessment of belumosudil.

2.1 Additional benefit of the medicinal product

2.1.1 Approved therapeutic indication of Belumosudil (Rezurock) in accordance with the product information

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

[1]General Methods, version 8.0 from 19.12.2025. Institute for Quality and Efficiency in Health Care (IQWiG), Cologne.

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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 the approved therapeutic indication

2.1.2 Extent of the additional benefit and significance of the evidence

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

In summary, the additional benefit of belumosudil is assessed as follows:

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

Justification:

The pharmaceutical company presented the results of the completed ROCKstar approval study (KD025-213) for the assessment of the extent of the additional benefit of belumosudil.

The ROCKstar study is an open-label, randomised, uncontrolled, multicentre phase II study for the assessment of the efficacy and safety of belumosudil in subjects with chronic graft-versus-host disease who have received at least 2 and no more than 5 prior lines of systemic therapy. Among other criteria, stable glucocorticoid treatment for at least 2 weeks prior to screening, a Karnofsky or Lansky performance status ≥ 60, and adequate organ and bone marrow function were prerequisites.

Randomisation was carried out in a 1:1 ratio to arm A (1 x 200 mg belumosudil daily) and arm B (2 x 200 mg belumosudil daily). Arm A of the ROCKstar study (N = 77) was used as the relevant patient population for the benefit assessment. Patients in this assessment-relevant population predominantly had moderate (25%) to severe (73%) cGvHD (according to the National Institutes of Health (NIH) criteria). Patients had a median of 4 affected organs, particularly the skin (81.8%), joints and fascia (76.6%), eyes (72.7%) and mouth (53.2%). Around 65% of patients had previously suffered from acute GvHD.

Treatment with belumosudil was continued until clinically significant cGvHD progression requiring a new systemic cGvHD therapy, histological recurrence of the underlying disease, unacceptable toxicity, or other reasons leading to discontinuation, including an administrative discontinuation rule, according to which patients were transferred to the rollover KD025-217 study after 6 months of treatment with belumosudil.

During treatment with belumosudil, stable systemic standard-of-care therapies (calcineurin inhibitors such as tacrolimus or ciclosporin, as well as sirolimus, mycophenolate mofetil, methotrexate, rituximab or extracorporeal photopheresis), as well as glucocorticoids and topical or organ-specific cGvHD therapies were permitted.

The ROCKstar study was conducted at 34 study sites in the USA between 2018 and 2023.

Results are available for the endpoints of mortality, morbidity and side effects. A total of 3 data cut-offs were carried out: first data cut-off (primary analysis) dated 19 February 2020, 2nd data cut-off (final adult data cut-off) dated 1 September 2022 and 3rd data cut-off (separate final adolescent data cut-off) dated 11 December 2023. A total of 3 adolescents were enrolled in the

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study, of whom 1 subject was assigned to the assessment-relevant arm A. Relevant analyses can be found in the adolescent data cut-off from 11.12.2023. Given the unavailability of the results of this data cut-off, only the final adult data cut-off from 1 September 2022 is used for the benefit assessment. No data are therefore available for children and adolescents.

Mortality

In the Rockstar study, there were 14 deaths (18.2%).

No conclusions on the extent of the additional benefit could be derived due to the absence of comparator data.

Morbidity

cGvHD response

In the ROCKstar study, cGvHD response and the overall response rate (ORR), respectively were assessed as the primary endpoint; this is defined as the percentage of patients achieving a complete response (CR) or partial response (PR) at any post-baseline assessment time point, in each case compared with baseline (cycle 1, day 1). A CR means that all manifestations of cGvHD have regressed in every affected organ or site. A PR means that at least one organ or site has improved, without any progression being documented in another organ or at another site. As another response component, the pharmaceutical company also provided the duration of the response, defined as the time from the first documented response to the first documented deterioration compared with the best response.

In the present therapeutic indication, a complete response is patient-relevant based on the underlying operationalisation. In line with the comments made by clinical experts during the written statement procedure, a partial response may also be of particular significance to patients in the present treatment setting. On the one hand, this is due to the highly heterogeneous manifestation of cGvHD, which is sometimes characterised by multi-organ involvement and an associated, fundamentally highly heterogeneous response rate; on the other, it is also due to partially irreversible damage that may have occurred in individual organs due to cGvHD during the prior course of therapy. In line with the comments made by clinical experts, the parameters of quality of life and symptom improvement are therefore better suited to assessing morbidity in patients with cGvHD.

In the ROCKstar study, a response rate of 74% was achieved; a total of 4 patients also achieved a CR.

In the ROCKstar study, cGvHD response was assessed on the basis of the NIH consensus criteria for cGvHD (2014). Based on this operationalisation, the response assessment is based on a survey conducted by the principal investigator using the cGvHD Activity Assessment for Clinician. Subsequently, it was checked - separately for each organ and functional area - whether there had been any change from baseline, and a CR or PR was determined accordingly. Limitations associated with partial response primarily stem from the fact that the response assessment is based on data collected and classified by the principal investigator and may exclusively be based on laboratory parameters; it is therefore not patient-relevant per se.

The ORR is presented additionally as a primary endpoint of the study.

Notwithstanding the comments on operationalisation, the results for the endpoint of complete response in the ROCKstar study do not allow any conclusions to be drawn regarding the extent of the additional benefit, as no suitable comparator data are available.

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Lee Symptom Scale (LSS)

The LSS is a tool for the assessment of the symptom burden in adults with cGvHD. The impairment of patients is assessed on the basis of cGvHD symptoms using 30 items across 7 domains, including skin (5 items), eyes and mouth (6 items), respiratory function (5 items), nutrition and digestion (4 items), muscles and joints (4 items), energy (3 items) and psychological and emotional symptoms (3 items). The patient-reported items are assessed on a Likert scale ranging from 0 to 4, where 0 corresponds to "not at all" and 4 to "extreme". This is then converted to a scale of 0 to 100. Higher values indicate a greater symptom burden. According to the study protocol, data collection was scheduled for day 1 of cycles 2 to 5, followed by day 1 of every second subsequent cycle, and at the end of treatment.

The LSS is generally suitable for depicting conditions that may be relevant to those affected in their everyday lives and can therefore be used to illustrate patient-relevant changes in morbidity as part of the benefit assessment.

The pharmaceutical company provided both continuous analyses of changes in the total score and the scores for individual domains for cycle 5, as well as responder analyses. With regard to the responder analyses, the pharmaceutical company pre-specified and presented a reduction in the total score by at least 7 points (corresponding to 7% of the scale range) as a clinically significant change. This threshold value does not correspond to the responder threshold of 15% of the scale range as set out in the current IQWiG methods paper and is not used for the present benefit assessment. Therefore, the continuous analyses of the total score are taken into account in the present benefit assessment, as more reliable validation evidence is available for this total score than for the domain scores.

For the total score, a median change of -4.4 points was observed at cycle 5, representing a slight improvement compared to baseline.

Notwithstanding that, the results of the ROCKstar study for the Lee Symptom Scale endpoint do not allow a statement to be made on the extent of the additional benefit due to the absence of suitable comparator data.

Corticosteroid discontinuation

For the endpoint of corticosteroid discontinuation, the pharmaceutical company presented the percentage of patients in the ROCKstar study who achieved complete discontinuation of systemic corticosteroids for more than 28 days during belumosudil treatment (in accordance with the statistical analysis plan (SAP)). As part of the written statement procedure, the pharmaceutical company also subsequently submitted information on the median duration of corticosteroid-free periods (the last documented corticosteroid-free interval for all patients who achieved this event), analyses of corticosteroid-free periods of 6 and 12 months, as well as reasons for censoring.

Systemic corticosteroids form the basis of first-line therapy for moderate and severe cGvHD. In the subsequent lines of therapy, too, corticosteroids generally remain part of the therapy due to their broad anti-inflammatory effect; the primary therapeutic goal is to keep the dose of corticosteroids as low as possible and to discontinue them completely once remission is achieved. During the written statement procedure, clinical experts also confirmed that, given the significant morbidity associated with long-term corticosteroid therapy, a sustained reduction in steroid use is a relevant therapeutic goal in cGvHD. The discontinuation of corticosteroids over a period of 6 or 12 months may be patient-relevant; however, it remains unclear here whether this discontinuation was linked to the overarching aim of achieving or maintaining remission.

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In the ROCKstar study, the mean prednisone-equivalent dose of corticosteroids at baseline was 0.21 mg/kg/day. During the course of the study, 27.3% of patients achieved corticosteroid discontinuation as defined by the pharmaceutical company. Of these, 14 patients had discontinued corticosteroids for at least 6 months, and 7 patients for at least 12 months. It should be noted that, after 6 months, only 18 patients and, after 12 months, only 10 patients remained at risk and could be fully assessed. A median corticosteroid-free period of 8.54 months was reported across all patients who had discontinued corticosteroids. At the same time, the majority of patients (72.7%) were censored due to therapy discontinuation or the initiation of a new therapy, among other factors.

Notwithstanding that, the results of the ROCKstar study for the endpoint of corticosteroid discontinuation do not allow a statement to be made on the extent of the additional benefit due to the absence of suitable comparator data.

In the overall analysis of the results on morbidity, no statements on the extent of additional benefit can be derived due to the absence of suitable comparator data.

Quality of life

Quality of life was not assessed in the ROCKstar study.

Side effects

Total adverse events (AEs)

One adverse event occurred in almost all patients enrolled in the study (98.7%). The results are presented additionally.

Serious adverse events (SAEs)

At least one serious adverse event (SAE) occurred in 36 patients (46.8%). The most frequent SAEs are "Infections and infestations".

Severe adverse events (CTCAE grade ≥ 3)

At least one severe adverse event with CTCAE ≥ 3 occurred in 52 patients (67.5%). "Infections and infestations", "gastrointestinal disorders" and "respiratory, thoracic and mediastinal disorders" represent the most common AEs with a severity grade ≥ 3.

Discontinuation due to AEs

In 15 patients (19.5%), an adverse event occurred that led to the discontinuation of treatment with belumosudil.

In the overall analysis of the results on side effects, no statements can be made on the extent of additional benefit due to the absence of suitable comparator data.

Overall assessment / conclusion

Basis for the benefit assessment of belumosudil for the treatment of adults and children (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, are the results on mortality, morbidity and side effects from the uncontrolled, open-label ROCKstar study.

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The endpoints of overall survival, complete remission, Lee Symptom Scale, corticosteroid discontinuation and side effects were used for the benefit assessment.

As this is an uncontrolled study, a comparative assessment and thus a quantification of the extent of the additional benefit is not possible on the basis of these data.

Significance of the evidence

As the ROCKstar study is an uncontrolled study, no direct comparator data are available for a control group. The available data therefore do not allow for a comparative assessment. Furthermore, no data are available for children and adolescents.

The result is a hint of an additional benefit with regard to significance of the evidence.

2.1.3 Limitation of the period of validity of the resolution

The limitation of the period of validity of the resolution on the benefit assessment of belumosudil finds its legal basis in Section 35a, paragraph 3, sentence 4 SGB V. Thereafter, the GBA may limit the validity of the resolution on the benefit assessment of a medicinal product. In the present case, the limitation is justified by objective reasons consistent with the purpose of the benefit assessment pursuant to Section 35a, paragraph 1 SGB V.

As a requirement for the conditional marketing authorisation for belumosudil, the European Medicines Agency (EMA) has required the pharmaceutical company to conduct a randomised, controlled phase III study (EFC22965) investigating belumosudil versus the best available therapy (BAT), and to confirm the efficacy and safety of belumosudil in the treatment of adults and paediatric patients (12 years and older with a body weight of at least 40 kg) with cGvHD when other treatment options provide limited clinical benefit, are not suitable or have been exhausted. The results of the EFC22965 study must be submitted to the EMA by 31 December 2029. Time limitation of the resolution is justified as these data may be relevant for the assessment of the additional benefit of belumosudil. The time limit enables the inclusion of the expected results from the RCT study in the benefit assessment of the medicinal product according to Section 35a SGB V. For this purpose, a time limit of the validity of the resolution until 1 January 2031 is considered appropriate.

Conditions of the limitation

For the new benefit assessment following the expiry of the deadline, the dossier must include the study results expected by the end of 2029 from the randomised, controlled phase III EFC22965 study - required by the EMA - on belumosudil for the treatment of adults and paediatric patients (12 years and older with a body weight of at least 40 kg) with cGvHD when other treatment options provide limited clinical benefit, are not suitable or have been exhausted. A change in the time limit can generally be granted if it is justified and clearly demonstrated that the period leading to the set time limit is insufficient or too long.

In accordance with Section 3, paragraph 1, number 5 of the Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with Chapter 5, Section 1, paragraph 2, number 7 VerfO, the benefit assessment procedure of the medicinal product with the active ingredient belumosudil recommences when the deadline has expired. For this purpose, the pharmaceutical company must submit a dossier to the GBA at the latest on the date of expiry of the deadline to prove the extent of the additional benefit of belumosudil (Section 4, paragraph 3, number 5 AM-NutzenV in conjunction with Chapter 5, Section 8, paragraph 1, number 5 VerfO). If the dossier is not submitted or is incomplete, the GBA may

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determine that there is a non-quantifiable additional benefit because the required evidence is not complete.

This does not affect the possibility that a benefit assessment of the medicinal product with the active ingredient belumosudil may be carried out at an earlier date for other reasons (see Chapter 5, Section 1, paragraph 2, numbers 2 to 6 or 8 VerfO).

2.1.4 Summary of the assessment

The present assessment concerns the benefit assessment of the new medicinal product Rezurock with the active ingredient belumosudil. Belumosudil received a conditional marketing authorisation as an orphan drug.

The therapeutic indication assessed here is as follows: 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.

For the benefit assessment, the pharmaceutical company presented the results on mortality, morbidity and side effects from the pivotal, open-label, uncontrolled ROCKstar study.

The endpoints of overall survival, complete remission, Lee Symptom Scale, corticosteroid discontinuation and side effects are used for the benefit assessment. No statements on the extent of the additional benefit could be derived due to the absence of comparator data.

As a result, a hint for a non-quantifiable additional benefit of belumosudil is identified since the scientific data does not allow quantification.

The resolution is limited to 1 January 2031.

2.2 Number of patients or demarcation of patient groups eligible for treatment

<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>

The information on the number of patients is based on the target population in statutory health insurance (SHI).

The resolution is based on the information provided by the pharmaceutical company in the benefit assessment dossier. The calculation of the patient numbers made by the pharmaceutical company in the dossier is not entirely plausible from a mathematical and methodological point of view, as, among other reasons, relevant information is missing. The information provided by the pharmaceutical company is unreliable overall.

With regard to the percentage of patients ≥ 12 years of age with cGvHD, it is likely that this figure is an underestimate, as uncertainties may arise regarding the distinction between cGvHD and acute GvHD (aGvHD) based on the operationalisation of cGvHD chosen by the pharmaceutical company. This is essentially due to a partial overlap in clinical symptomatology, as well as the fact that cGvHD can develop from aGvHD. Distinction is generally difficult.

Uncertainties also arise from the determination of the percentage of patients with cGvHD for whom other treatment options provide limited clinical benefit, are not suitable or have been

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exhausted. The pharmaceutical company operationalises this as an approximation of the percentage of patients who have already undergone extracorporeal photopheresis (ECP). In this therapeutic indication, ECP represents an unapproved therapy option that can be used both for the prevention of GvHD and following first- or second-line treatment of cGvHD. Consequently, on the basis of this operationalisation, it is not possible to identify patients with cGvHD for whom other treatment options provide limited clinical benefit, are not suitable or have been exhausted.

Ultimately, it remains unclear what methodology the pharmaceutical company has used for extrapolation to the total German population and the SHI target population, as the information provided in this regard is insufficient and, in particular, no specific calculations and sources have been provided. Nor is the additionally presented information by the pharmaceutical company during the written statement procedure sufficient in this regard.

2.3 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.

2.4 Treatment costs

The treatment costs are based on the contents of the product information and the information listed in the LAUER-TAXE® (last revised: 15 August 2026).

The calculation of treatment costs is generally based on the last revised LAUER-TAXE® version following the publication of the benefit assessment.

If no maximum treatment duration is specified in the product information, the treatment duration is assumed to be one year (365 days), even if the actual treatment duration is different from patient to patient and/or is shorter on average. The time unit "days" is used to calculate the "number of treatments/ patient/ year", time intervals between individual treatments and for the maximum treatment duration, if specified in the product information.

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Treatment period:

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	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Medicinal product to be assessed				
Belumosudil	Continuously, 1 x daily	365.0	1	365.0

Consumption:

For the cost representation, only the dosages of the general case are considered. Patient-individual dose adjustments (e.g. because of side effects or comorbidities) are not taken into account when calculating the 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	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
Medicinal product to be assessed					
Belumosudil	200 mg	200 mg	1 x 200 mg	365.0	365.0 x 200 mg

Costs:

In order to improve comparability, the costs of the medicinal products were approximated both on the basis of the pharmacy sales price level and also deducting the statutory rebates in accordance with Section 130 and Section 130a SGB V. To calculate the annual treatment costs, the required number of packs of a particular potency was first determined on the basis of consumption. Having determined the number of packs of a particular potency, the costs of the medicinal products were then calculated on the basis of the costs per pack after deduction of the statutory rebates. Any reference prices shown in the cost representation may not represent the cheapest available alternative.

Costs of the medicinal products:

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

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Designation of the therapy	Packaging size	Costs (pharmacy sales price)	Rebate Section 130 SGB V	Rebate Section 130a SGB V	Costs after deduction of statutory rebates
Medicinal product to be assessed					
Belumosudil	30 FCT	€ 14,469.19	€ 1.77	€ 823.00	€ 13,644.42
Abbreviations: FCT = film-coated tablets					

LAUER-TAXE® last revised: 15 August 2026

Costs for additionally required SHI services:

Only costs directly related to the use of the medicinal product are taken into account. If the use of the medicinal product to be evaluated regularly incurs costs for necessary medical treatment or the prescription of other services in accordance with the product information, these costs must be taken into account as costs for additionally required SHI services.

Medical treatment costs, medical fee services, and costs incurred for routine examinations (e.g. regular laboratory services such as blood count tests) that do not exceed the standard expenditure in the course of the treatment are not shown.

According to the product information, liver function tests must be carried out prior to start of treatment and at least once a month throughout the course of treatment. The product information provides no further specific details on this, which is why the necessary costs for liver function tests cannot be quantified.

3. Bureaucratic costs calculation

The proposed resolution does not create any new or amended information obligations for care providers within the meaning of Annex II to Chapter 1 VerfO and, accordingly, no bureaucratic costs.

4. Process sequence

On 30 April 2026, the pharmaceutical company submitted a dossier for the benefit assessment of belumosudil to the GBA in due time in accordance with Chapter 5, Section 8, paragraph 1, number 1, sentence 2 VerfO.

The benefit assessment of the GBA was published on 3 August 2026 together with IQWiG's assessment of treatment costs and patient numbers on the GBA website (www.g-ba.de), thus initiating the written statement procedure. The deadline for submitting written statements was 24 August 2026.

The oral hearing was held on 7 September 2026.

In order to prepare a recommendation for a resolution, the Subcommittee on Medicinal Products commissioned a working group (Section 35a) consisting of the members nominated by the leading organisations of the care providers, the members nominated by the SHI umbrella organisation, and representatives of the patient organisations. Representatives of the IQWiG also participate in the sessions.

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The evaluation of the written statements received and the oral hearing was discussed at the Subcommittee's session on 6 October 2026, and deliberation of the draft resolution was concluded.

At their session on 15 October 2026, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee on Medicinal Products	28 July 2026	Information of the benefit assessment of the GBA
Working group Section 35a	1 September 2026	Information on written statements received; preparation of the oral hearing
Subcommittee on Medicinal Products	7 September 2026	Conduct of the oral hearing
Working group Section 35a	15 September 2026 29 September 2026	Consultation on the dossier assessment by the GBA, the assessment of treatment costs and patient numbers by the IQWiG, and the evaluation of the written statement procedure
Subcommittee on Medicinal Products	6 October 2026	Concluding discussion of the draft resolution
Plenum	15 October 2026	Adoption of the resolution on the amendment of the Pharmaceuticals Directive

Berlin, 15 October 2026

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

Dr Optendrenk

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