Gemeinsamer Bundesausschuss

Justification

to the Resolution of the Federal Joint Committee (G-BA) on an Amendment of the Pharmaceuticals Directive: Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a SGB V and Annex XIIa – Combinations of medicinal products with new active ingredients according to Section 35a SGB V Givinostat (Duchenne muscular dystrophy, ≥ 6 years, combination with a corticosteroid)

of 22 January 2026

Contents

1. Legal basis ... 2

2. Key points of the resolution ... 3

2.1 Additional benefit of the medicinal product ... 4

2.1.1 Approved therapeutic indication of Givinostat (Duvyzat) in accordance with the product information ... 4

2.1.2 Extent of the additional benefit and significance of the evidence ... 4

2.1.3 Time limit and period of validity of the resolution ... 11

2.1.4 Summary of the assessment ... 12

2.2 Number of patients or demarcation of patient groups eligible for treatment ... 12

2.3 Requirements for a quality-assured application ... 13

2.4 Treatment costs ... 13

2.5 Designation of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V that can be used in a combination therapy with the assessed medicinal product ... 16

2.6 Percentage of study participants at study sites within the scope of SGB V in accordance with Section 35a, paragraph 3, sentence 5 SGB V ... 19

3. Bureaucratic costs calculation ... 20

4. Process sequence ... 20

1. Legal basis

According to Section 35a paragraph 1 German Social Code, Book Five (SGB V), the Federal Joint Committee (G-BA) 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, the additional medical benefit is considered to be proven through the grant of the marketing authorisation. 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 for 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, No. 2 and 3 SGB V in conjunction with Chapter 5 Sections 5 et seq. of the Rules of Procedure (VerfO) of the G-BA 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. According to Section 35a, paragraph 1, sentence 12 SGB V, the pharmaceutical company must then, within three months of being requested to do so by the G-BA, submit evidence according to Chapter 5 Section 5, paragraphs 1–6 VerfO, in particular regarding the additional medical benefit in relation to the appropriate comparator therapy as defined by the G-BA according to Chapter 5 Section 6 VerfO and prove the additional benefit in comparison with the appropriate comparator therapy.

In accordance with Section 35a, paragraph 2 SGB V, the G-BA decide whether to carry out the benefit assessment itself 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 G-BA 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 G-BA 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 G-BA indicating the significance of the evidence.

Accordingly, at their session on 15 March 2012, the G-BA 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 to that effect 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 threshold 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 G-BA must be completed within three months of the relevant date for submission of the evidence and published on the internet.

According to Section 35a paragraph 3 SGB V, the G-BA pass a resolution 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 givinostat on 15 July 2025 in accordance with Chapter 5 Section 8, paragraph 1, number 1, sentence 2 of the Rules of Procedure (VerfO) of the G-BA. The pharmaceutical company submitted the final dossier to the G-BA in accordance with 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 VerfO on 14 July 2025.

Givinostat in combination with a corticosteroid for the treatment of Duchenne muscular dystrophy, aged 6 years and older, is approved as a medicinal product for the treatment of a rare disease 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 G-BA.

The G-BA carried out the benefit assessment and commissioned the IQWiG to assess the information provided by the pharmaceutical company in Module 3 of the dossier on treatment costs and patient numbers. The benefit assessment was published on 15 October 2025 together with the IQWiG assessment on the website of the G-BA (www.g-ba.de), thus initiating the written statement procedure. In addition, an oral hearing was held.

The G-BA have adopted their resolution on the basis of the pharmaceutical company's dossier, the dossier assessment carried out by the G-BA, the IQWiG assessment of treatment costs and patient numbers (IQWiG G25-22) and the statements made in the written statement and oral hearing procedure, as well as the amendment to the benefit assessment drawn up by the G-BA.

In order to determine the extent of the additional benefit, the G-BA have evaluated the studies relevant for the marketing authorisation with regard to their therapeutic relevance (qualitative) in accordance with the criteria laid down in Chapter 5 Section 5, paragraph 7, sentence 1, numbers 1 – 4 VerfO. The methodology proposed by the IQWiG in accordance with the General Methods [1] was not used in the benefit assessment of givinostat.

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

2.1 Additional benefit of the medicinal product

2.1.1 Approved therapeutic indication of Givinostat (Duvyzat) in accordance with the product information

Duvyzat is indicated for the treatment of Duchenne muscular dystrophy (DMD) in ambulant patients, aged 6 years and older, and with concomitant corticosteroid treatment.

Therapeutic indication of the resolution (resolution of 22 January 2026):

See the approved therapeutic indication

2.1.2 Extent of the additional benefit and significance of the evidence

In summary, the additional benefit of givinostat with concomitant corticosteroid treatment is assessed as follows:

For ambulant patients aged 6 years and older with Duchenne muscular dystrophy (DMD), there is a hint for a non-quantifiable additional benefit, since the scientific data does not allow a quantification.

Justification:

For the benefit assessment, the pharmaceutical company submitted data from the pivotal phase III EPIDYS study.

The EPIDYS study is a randomised, double-blind, placebo-controlled phase III study for assessment of the efficacy and safety of givinostat. The study was open to ambulant male patients with DMD, aged ≥ 6 years, who had been receiving systemic corticosteroid therapy for ≥ 6 months. Only patients up to the age of 16 years were enrolled. Randomisation was carried out in a 2:1 ratio into the givinostat and placebo treatment arms, stratified by the glucocorticoids used. Givinostat was used in combination with the glucocorticoids deflazacort and prednisone, which are not approved for the therapeutic indication. The dosage of Givinostat was dependent on body weight. In the EPIDYS study, the dosage (both the starting dose and dose modifications) was adjusted during the course of the study due to AEs. In contrast to the product information with 4 dose levels, the givinostat dose in the study was divided into 9 dose levels depending on body weight.

The study lasted 19 months and comprised a 4-week screening phase and an 18-month treatment phase. The primary endpoint of the EPIDYS study is the 4-stair climb (4SC).

The study was conducted at study sites in several countries (Europe, North America and Israel) between June 2017 and February 2022.

The results of the single-arm extension study 51, which was supportively considered in the marketing authorisation procedure and for which an indirect comparison with historical study data on the natural course of the disease was pre-specified, were not used by the pharmaceutical company to derive the additional benefit. The indirect comparison is not considered for the benefit assessment as the available information on the indirect comparison is considered inadequate overall for an assessment of validity.

The overall population (givinostat (N = 118) and placebo (N = 61)) is used as the relevant patient population of the EPIDYS study for the present benefit assessment. This is made up of

two sub-populations: the on-target population (muscle fat content in the vastus lateralis muscle > 5% to ≤ 30%; givinostat: N = 81, placebo: N = 39), which represented the primary analysis population for the efficacy endpoints according to information provided by the pharmaceutical company, and the off-target population (muscle fat percentage in the vastus lateralis muscle ≤ 5% and > 30%; givinostat: N = 37, placebo: N = 22).

In the dossier, the pharmaceutical company conducted ANCOVA analyses based on imputed data (primary analysis) and MMRM analyses based on observed values (without replacement of missing values) for the results of the overall population. In line with the EMA's assessment, the procedure described for dealing with missing values in the ANCOVA analysis is viewed critically. The MMRM analyses are therefore used for the benefit assessment.

Based on the information in the dossier, there were also uncertainties regarding the operationalisation of the visit at the end of the study (week 72 (month 18)/ (end of study (EOS)). At week 72, the visit time window was extended from the original ±7 days to an additional ±2 months due to the COVID-19 pandemic. It remained unclear whether and how many patients, who were assessed outside the predefined time window ±7 days or outside the extended time window, were included in the analysis and to what extent premature study dropouts were taken into account. According to the information subsequently submitted by the pharmaceutical company during the written statement procedure, subjects who discontinued the study prematurely were not included in the analyses at week 72. Most patients in both arms (approx. 85%) came to the study centre within the time window week 72 ± 7 days + 14.5/15 days, similar to the visit at week 60 (extension of the visit time window from ±7 days to an additional 14 days). The percentage of subjects who made the study visit at week 72 after the extended visit window of 2 months was low and comparable in both treatment groups (givinostat: n = 6 (5.1%); placebo: n = 4 (6.6%). For the present benefit assessment, the MMRM analyses of the overall population for all assessment-relevant endpoints at the study visit week 72/ EOS are therefore considered suitable.

Mortality

There were no deaths in the course of the EPIDYS study.

Morbidity

4-stair climb (4SC)

The endpoint "4-stair climb" (4SC) measures the time the patient needs to climb four stairs. The endpoint is considered patient-relevant in this therapeutic indication.

Based on the information provided by the pharmaceutical company in the dossier, there were limitations in the statistical analysis of the endpoint, among other things, due to missing information on missing values differentiated by reason. Missing values were differentiated within the study into class 1 (reasons other than physical limitations or walking disability; COVID-19) and class 2 (walking disability, physical limitations). However, the underlying assumption that missing values are missing at random (MAR) does not appear to apply to missing values of class 2. In addition, there were uncertainties regarding the operationalisation of the visit time windows for the last study visit at week 72.

In the written statement procedure, the pharmaceutical company subsequently submitted information on missing values differentiated by class 1 and 2, as well as sensitivity analyses using

MMRM, in which only patients who had appeared within the narrower predefined visit time window ±7 days at week 72 were considered.

For the 4SC, 10-MWT and 6-MWT endpoints, missing values of class 1 (other reasons, COVID-19: Givinostat: 11 – 14%; placebo: 7 - 8%)) were reported in the majority of cases. The percentage of missing values in class 2 (walking disability, physical limitations) was low at ≤ 5%. There is no differentiation of the reasons for missing values in the "Other" class 1 category so it remains unclear to what extent these are missing at random.

For the 4SC endpoint, there was a statistically significant difference between the treatment arms in favour of givinostat at week 72.

The difference between the treatment arms is small and the upper limit of the 95% confidence interval of -0.15 seconds appears too small to classify the observed effect as clinically relevant. This assessment is supported by the uncertain reliability of the results: In the sensitivity analysis using MMRM, taking into account the patients who made the visit within the visit time window ±7 days, no statistically significant difference was observed at the study visit week 72 (LS means difference: -0.17 (95% CI [-0.82; 0.47]), p value: 0.60), a low return rate at week 72 (< 70%) must be taken into account.

Rise from the floor (RFTF)

The endpoint "Rise from the floor" measures the time (in seconds) that a patient with Duchenne muscular dystrophy needs to get from the supine position on the floor to an upright standing position. The test was carried out as part of the "North Star Ambulatory Assessment" (NSAA) (item 12). The endpoint is considered patient-relevant in this therapeutic indication.

Based on the information provided by the pharmaceutical company in the dossier, there were limitations in the statistical analysis of the endpoint, among other things, due to missing information on missing values differentiated by reason (*see explanation for the 4SC endpoint*). In the written statement procedure, the pharmaceutical company subsequently submitted information on missing values differentiated by class 1 and 2, as well as sensitivity analyses using MMRM with the predefined analysis time window (±7 days). The total percentage of missing values in both treatment groups for the RFTF endpoint is approx. 28%, with the majority consisting of missing values in class 2 (walking disability, physical limitations) (givinostat: 16%; placebo: 23%).

For the RFTF endpoint, there was a statistically significant difference between the treatment arms in favour of givinostat at week 72.

The difference between the treatment arms is small and the upper limit of the 95% confidence interval of -0.16 seconds appears too small to classify the observed effect as clinically relevant. This assessment is supported by the uncertain reliability of the results: In the sensitivity analysis using MMRM (without imputation), taking into account the patients who made the visit within the visit time window ±7 days, no statistically significant difference was observed at the study visit week 72 (LS means: -0.77 (95% CI: [-1.95; 0.42], p value: 0.20), a low return rate at week 72 (< 70%) must be taken into account.

10 metre walk/run test (10-MWT)

The "10-metre walk/run test" (10-MWT) endpoint measures the time it takes a patient to walk or run 10 metres. The test was carried out as part of the NSAA (item 17). The endpoint is considered patient-relevant in this therapeutic indication.

Based on the information provided by the pharmaceutical company in the dossier, there were limitations in the statistical analysis of the endpoint, among other things, due to missing information on missing values differentiated by reason. In the written statement procedure, the pharmaceutical company subsequently submitted information on missing values differentiated by class 1 and 2, as well as sensitivity analyses using MMRM with the predefined analysis time window (±7 days) (*see explanation for the 4SC endpoint*).

For the 10-MWT endpoint, there was a statistically significant difference between the treatment arms in favour of givinostat at week 72.

The difference between the treatment arms is small and the upper limit of the 95% confidence interval of -0.1 seconds appears too small to classify the observed effect as clinically relevant. This assessment is supported by the uncertain reliability of the results: In the sensitivity analysis using MMRM without imputation, taking into account the patients who made the visit within the visit time window ±7 days, no statistically significant difference was observed at the study visit week 72 (LS means: -0.26 (95% CI [-0.77; 0.25]), p value: 0.32), a low return rate at week 72 (< 70%) must be taken into account.

6-minute walk test (6-MWT)

The 6-minute walk test (6-MWT) is used to examine physical functioning and measures the distance a patient can walk within 6 minutes. The endpoint is considered patient-relevant in this therapeutic indication.

Based on the information provided by the pharmaceutical company in the dossier, there were limitations in the statistical analysis of the endpoint, among other things, due to missing information on missing values differentiated by reason. In the written statement procedure, the pharmaceutical company subsequently submitted information on missing values differentiated by class 1 and 2, as well as sensitivity analyses using MMRM with the predefined analysis time window (±7 days) (*see explanation for the 4SC endpoint*).

For the 6-MWT endpoint, there was no statistically significant difference between the treatment arms at week 72.

Confirmed loss of the ability to rise from the floor

The start of the endpoint was defined in the study as the time of the first visit at which a loss of the ability to rise from the floor was observed. A confirmed loss of the ability to rise from the floor was present if the patient was unable to rise from the floor on at least 2 consecutive visits (after 6 months at the earliest). The following scores had to be available at the visits for the loss of the ability to rise from the floor: RFTF grade 1 and NSAA score (item 12) "0" (or "0b" = unable to perform the test due to physical limitations).

Survival time analyses were presented for the endpoint "loss of ability to rise from the floor" using imputed data from the overall population. If an event did not apply, it was censored at the last survey time point, i.e. week 72/ EOS. Due to the limitations of the selected imputation strategy, the endpoint "confirmed loss of ability to rise from the floor" is only presented additionally in the resolution and not considered for the assessment of the extent of the additional benefit.

Loss of walking ability without aids

The endpoint "loss of walking ability without aids" was considered to be present in the study if the following criteria were met at a visit at any time before or at the end of the study (last study visit at month 18/ week 72 or end of study (EOS) visit): The patient was unable to perform the

6-MWT and the patient was unable to complete the 10-MWT in ≤ 30 seconds without support or aids (10-MWT ≤ grade 2) due to physical limitations.

The criteria had to be met at all subsequent visits until the end of the study at month 18 or EOS. The endpoint is considered patient-relevant in this therapeutic indication.

Post hoc analyses were conducted using imputed data from the overall population. Due to the limitations of the selected imputation strategy, the endpoint "loss of walking ability without aids" is only presented additionally in the resolution and not considered for the assessment of the extent of the additional benefit.

Functional performance (NSAA)

Functional performance was assessed using the North Star Ambulatory Assessment (NSAA) clinical rating scale by an subject trained in the assessment of the endpoint and assesses the walking ability of male patients with Duchenne muscular dystrophy. Limitations in functional performance, especially walking ability, are considered patient-relevant.

Based on the information provided by the pharmaceutical company in the dossier, there were limitations in the information on reliability, validity and sensitivity to change (ordinal scale) for the NSAA endpoint. In the written statement procedure, the pharmaceutical company submitted further publications on the reliability, validity and change sensitivity of the NSAA, among other things. Following a retest, the endpoint is considered to be largely valid overall. A limiting factor is the existing heterogeneity in the test-retest reliability for individual items.

The RFTF (item 12) and 10-MWT (item 17) were assessed as part of the NSAA. However, double assessment is not assumed, as the type of implementation is assessed as part of the NSAA, while the time required was collected and analysed for the separately presented RFTF and 10-MWT endpoints. The NSAA thus provides information on the patient's basic ability and degree of independence. The evaluation of the ordinal scale of the NSAA is presented here as it was pre-specified.

For the ordinal scale of the NSAA, the pharmaceutical company has submitted post hoc MMRM analyses of the total score for all visits, as well as responder analyses at week 72 for an improvement or deterioration by at least 15% (response threshold: 5.1 points). The responder analyses were adjusted for age at the start of the study and the stratification factors; for the total score, missing values were imputed as non-responders.

Due to the present progressive disease, responder analyses for deterioration are preferred. However, the responder analyses presented for a deterioration by ≥ 15% at week 72 are considered unsuitable, as missing values were evaluated as non-responders (and thus as "no deterioration"). Therefore, the MMRM analyses on the total score of the ordinal scale are preferred for the benefit assessment.

However, due to limitations in dealing with missing values to form the total score, the MMRM analyses are only presented additionally in the resolution and are not considered for the assessment of the extent of the additional benefit. Furthermore, it remains unclear how values went missing after the total score was calculated and whether these are due to premature study discontinuation, for example.

Physical functioning (PODCI)

The "Paediatric Outcomes Data Collection Instrument (PODCI)" is an instrument for assessing general health, pain and the ability to lead activities of daily living and an active lifestyle. The endpoint is considered a patient-relevant endpoint in this case.

However, the present operationalisation can only be understood to a limited extent: The collection of the two versions of the questionnaire used (self-reported version for patients and externally reported version for legal guardians) was not uniform over the course of the study. In addition, the subsequent post hoc adjustments to the evaluation of the questionnaire (non-consideration and imputation of the data collected for patients ≤ 10 years with a completed questionnaire version > 10 years) are viewed critically. Furthermore, only limited data are available on the psychometric properties of both questionnaire versions and their comparability. The endpoint "physical functioning (PODCI)" is therefore not considered in the benefit assessment due to inadequate operationalisation and unclear validity.

Quality of life

No data on quality of life were assessed.

Side effects

In the EPIDYS study, adverse events (AEs) occurred in approx. 95% of the subjects. For each of the endpoints of severe AEs, serious adverse events (SAEs) and AEs leading to discontinuation of the study medication, there were no statistically significant differences between the treatment groups.

Body height, body weight, body mass index (BMI)

Anthropometric parameters were surveyed as safety endpoints in the study. The recommended long-term use of glucocorticoids restricts the development of patients. The administration of glucocorticoids can also lead to severe weight gain and growth retardation or growth arrest[2]. The endpoints of body height and body weight are considered patient-relevant in this indication. Data adjusted for age and sex (z-scores) are preferred over absolute values.

The endpoint of BMI is a composite endpoint consisting of the endpoints of body height and body weight, both of which are presented in the benefit assessment. The endpoint of BMI is therefore not additionally considered in the benefit assessment.

In the course of the written statement procedure, the pharmaceutical company subsequently submitted post hoc analyses for the endpoints of body height and body weight (z scores), as well as information on the body weight assessment. The z scores reflect the number of standard deviations (SD) of a value from the normal mean scores, standardised by age and sex. The reference tables of the "Centers for Disease Control and Prevention" (CDC) were used for calculating the z scores.

For the endpoints of body height (z scores) and body weight (z scores), no information on missing values differentiated by class 1 and 2 was submitted, as documentation of the reasons for missing values was not planned for the study. However, as the percentage of missing values was low (both treatment groups: body weight: approx. 5% and body height: 5 – 8%), the endpoints are taken into account in the benefit assessment.

For the endpoint of body height, there was no statistically significant difference between the treatment arms at week 72.

[2] Biggar WD, Skalsky A, McDonald CM.: Comparing Deflazacort and Prednisone in Duchenne Muscular Dystrophy. J Neuromuscul Dis. 2022;9(4

For the endpoint of body weight, there was a statistically significant difference between the treatment arms in favour of givinostat at week 72. However, the observed statistically significant effect on body weight (z scores) is not considered to be clinically relevant: At baseline, the body height is significantly lower compared to the reference population (givinostat: -1.84 vs placebo: -1.78), catch-up effects can be observed in both arms at the end of the study (givinostat: 0.63 vs placebo: 0.71). Compared to body height, the change in body weight (z score) in the placebo arm with a numerical increase of 0.73 is very close to the numerical increase in body height (z score), unlike the change in the givinostat arm, where the increase of 0.49 is somewhat lower. In summary, the weight gain compared to the reference population in both arms appears to be largely due to the catch-up effects in growth.

Overall assessment

The results of the pivotal, randomised, double-blind, placebo-controlled phase III EPIDYS study are used for assessment of the additional benefit. The results of the indirect comparison of the single-arm extension study 51 with historical study data on the natural course of the disease are not considered for the benefit assessment due to inadequate information for an assessment of validity. Data on overall survival, morbidity and side effects are available for the EPIDYS study.

There were no deaths in the course of the EPIDYS study.

For each of the 4SC, RFTF and 10-MWT endpoints in the morbidity category, there was a statistically significant difference between the treatment arms in favour of givinostat at week 72. However, the observed effects are not classified as clinically relevant due to the small difference between the treatment arms, a low upper limit of the 95% confidence interval in each case and an uncertain reliability of the results. Therefore, no statements on the extent of the additional benefit can be derived from these results.
For the 6-MWT endpoint, there was no statistically significant difference between the treatment arms at week 72.
Due to limitations in the selected imputation strategy or due to limitations in dealing with missing values, the endpoints of confirmed loss of ability to rise from the floor, loss of walking ability without aids and functional performance (NSAA) are only presented additionally in the resolution and not considered for the assessment of the extent of the additional benefit. The endpoint of physical functioning (PODCI) is not considered in the benefit assessment due to inadequate operationalisation and unclear validity.

No data were collected for the endpoint category of quality of life.

For severe adverse events (AEs), serious AEs and AEs that led to discontinuation of the study medication in the side effects category, there was no statistically significant difference between the treatment groups.
The anthropometric parameters of body height and body weight (z scores in each case) collected as safety endpoints are considered patient-relevant in the present indication and are taken into account for the benefit assessment. There was no statistically significant difference for the endpoint of body height at week 72, while there was a statistically significant difference in favour of givinostat for the endpoint of body weight. However, the observed statistically significant effect is not considered to be clinically relevant. Therefore, no statement on the extent of the additional benefit can be derived from this result.

In summary, there is a non-quantifiable additional benefit of givinostat with concomitant corticosteroid treatment in ambulant patients aged 6 years and older with Duchenne muscular dystrophy (DMD) since the scientific data does not allow quantification.

Significance of the evidence

The risk of bias at the study level is estimated to be unclear.

A high risk of bias is assumed for the endpoints of 4-stair climb (4SC), rise from the floor (RFTF), 10-metre walk/run test (10-MWT), 6-minute walk test (6-MWT) and NSAA. For some of these endpoints, there are uncertainties with regard to the missing values (missing at random in the "other" class 1 category unclear, predominant percentage of missing values in class 2 or uncertainties due to a different approach in dealing with missing values), the sensitivity analyses show no statistically significant difference in some cases.

For the endpoints of body height (z scores) and body weight (z scores), the risk of bias is considered low due to the small number of missing values.

Overall, a hint for an additional benefit is assumed.

2.1.3 Time limit and period of validity of the resolution

The limitation of the period of validity of the resolution on the benefit assessment of givinostat finds its legal basis in Section 35a paragraph 3 sentence 5 SGB V. Thereafter, the G-BA 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 according to Section 35a, paragraph 1 SGB V.

As a prerequisite for the conditional marketing authorisation of givinostat, the European Medicines Agency (EMA) has required the pharmaceutical company to conduct a further randomised, double-blind, placebo-controlled study in ambulant patients with Duchenne muscular dystrophy to confirm the efficacy and safety of givinostat in the treatment of Duchenne muscular dystrophy in ambulant patients aged 6 years and older with concomitant corticosteroid treatment. The results of this study must be submitted to the EMA by 31 July 2033. Time limitation of the resolution is justified as these data may be relevant for the assessment of the additional benefit of givinostat. 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 February 2034 is considered appropriate.

Conditions of the limitation:

For the new benefit assessment after expiry of the deadline, the study results of the randomised, double-blind, placebo-controlled study with givinostat in ambulant patients with Duchenne muscular dystrophy required by the EMA and expected for July 2033 should be presented in the dossier. A change in the limitation can generally be granted if it is justified and clearly demonstrated that the limitation is insufficient or too long.

In accordance with Section 3 paragraph 1, number 5 AM-NutzenV in conjunction with Chapter 5 Section 1, paragraph 2, number 7 VerfO, the procedure for the benefit assessment of the medicinal product with the active ingredient givinostat recommences when the deadline has expired. For this purpose, the pharmaceutical company must submit a dossier to the G-BA at the latest on the date of expiry to prove the extent of the additional benefit of givinostat (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 G-BA may determine that there is a non-quantifiable additional benefit because the required evidence is not complete.

The possibility that a benefit assessment for the medicinal product with the active ingredient givinostat can be carried out at an earlier point in time due to other reasons (cf. Chapter 5, Section 1 paragraph 2, Nos. 2 to 6 or No. 8 VerfO) remains unaffected hereof.

2.1.4 Summary of the assessment

The present assessment concerns the benefit assessment of the new medicinal product Duvyzat with the active ingredient givinostat. Duvyzat received a conditional marketing authorisation as an orphan drug. Givinostat (Duvyzat) is indicated for the treatment of Duchenne muscular dystrophy in ambulant patients, aged 6 years and older, and with concomitant corticosteroid treatment. The results of the pivotal, randomised, placebo-controlled phase III EPIDYS study are used for assessment of the additional benefit. The results of the indirect comparison of the single-arm extension study 51 with study data on the natural course of the disease are not considered for the benefit assessment due to inadequate information for an assessment of validity. There were no deaths in the course of the EPIDYS study. For each of the 4SC, RFTF and 10-MWT endpoints in the morbidity category, there was a statistically significant difference between the treatment arms in favour of givinostat. However, the effects are not classified as clinically relevant due to the small difference between the treatment arms, a low upper limit of the 95% confidence interval in each case and an uncertain reliability of the results. For the 6-MWT endpoint, there was no statistically significant difference between the treatment arms. Due to limitations in the selected imputation strategy or due to limitations in dealing with missing values, the endpoints of confirmed loss of ability to rise from the floor, loss of walking ability without aids and functional performance (NSAA) are only presented additionally in the resolution. The endpoint of physical functioning (PODCI) is not considered in the benefit assessment due to inadequate operationalisation and unclear validity. No data were collected for the endpoint category of quality of life. For severe AEs, SAEs and AEs that led to discontinuation of the study medication in the side effects category, there was no statistically significant difference between the treatment groups. There was no statistically significant difference for the endpoint of body height, while there was a statistically significant, but not clinically relevant difference in favour of givinostat for the endpoint of body weight. The risk of bias at the study level is estimated to be unclear. For the endpoints of body height and body weight, the risk of bias is considered to be low; for the other endpoints, a high risk of bias is assumed.

In summary, there is a hint for a non-quantifiable additional benefit of givinostat with concomitant corticosteroid treatment in ambulant patients aged 6 years and older with Duchenne muscular dystrophy (DMD) since the scientific data does not allow quantification.

The validity of the resolution is limited to 1 February 2034.

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

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.

Uncertainties exist in particular due to the fact that mortality is not taken into account in the determination of the prevalence of Duchenne muscular dystrophy. Overall, overestimation can therefore be assumed.

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 Duvyzat (active ingredient: givinostat) at the following publicly accessible link (last access: 22 September 2025):

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

Treatment with givinostat should only be initiated and monitored by specialists experienced in treating patients with Duchenne muscular dystrophy.

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 will evaluate new information on this medicinal product at a minimum once per year 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 November 2025).

For the cost representation, only the dosages of the general case are considered. Patient-individual dose adjustments (e.g. because of side effects or co-morbidities) are not taken into account when calculating the annual treatment costs.

In general, initial induction regimens are not taken into account for the cost representation, since the present indication is a chronic disease with a continuous need for therapy and, as a rule, no new titration or dose adjustment is required after initial titration.

According to the product information, the active ingredient givinostat is approved for the treatment of Duchenne muscular dystrophy (DMD) in ambulant patients, aged 6 years and older, and with concomitant corticosteroid treatment. The recommended dose for givinostat is based on body weight and is taken twice daily. The minimum body weight (2.5 ml twice daily for a weight of 15 kg to < 20 kg) indicated in the product information was used as the lower limit, and the maximum body weight (6 ml twice daily for a weight of 60 kg or more) indicated was used as the upper limit. The product information for givinostat does not contain any information on the dosage and route of administration of the corticosteroid treatment.

The active ingredient vamorolone, which is approved for the treatment of Duchenne muscular dystrophy (DMD) in patients aged 4 years and older, is a corticosteroid treatment option. The recommended dose is 6 mg vamorolone per kilogram of body weight once daily for patients with a body weight of up to 40 kg. For patients weighing over 40 kg, the recommended dose is 240 mg vamorolone (equivalent to 6 ml) once daily. For dosages depending on body weight (BW), the average body measurements from the official representative statistics of the

Microcensus[3] 2017 and 2021 were used as a basis (average body weight of a six-year-old boy: 24.0 kg; average body weight of an adult male: 85.8 kg). The lower consumption limit was based on a dosage of 6 mg/kg/day for a six-year-old boy, and the upper limit was based on a dosage of 240 mg once daily for an adult male.

As an alternative to vamorolone, patients with Duchenne muscular dystrophy can be treated with other corticosteroids such as prednisolone/ prednisone or deflazacort if applicable. These are not approved in the therapeutic indication and are therefore not included in the costs.

Treatment period:

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.

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Medicinal product to be assessed				
Givinostat	Continuously, 2 x daily	365.0	1	365.0
Corticosteroid treatment				
Vamorolone	Continuously, 1 x daily	365.0	1	365.0

Consumption:

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					
Givinostat	2.5 ml	2 x 2.5 ml	2 x 2.5 ml	365	365 x 5 ml
	6 ml	2 x 6 ml	2 x 6 ml	365	365 x 12 ml
Corticosteroid treatment					
Vamorolone	144 mg = 3.6 ml	1 x 3.6 ml	1 x 3.6 ml	365.0	365 x 3.6 ml

[3] Federal Health Reporting. Average body measurements of the population (2017 and 2021: aged 1 year and older and 15 years and older), www.gbe-bund.de

Designation of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
	240 mg = 6 ml	1 x 6 ml	1 x 6 ml	365.0	365 x 6 ml

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:

Ambulant patients aged 6 years and older with Duchenne muscular dystrophy (DMD)

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					
Givinostat	140 ml OS	€ 19,738.05	€ 1.77	€ 1,126.65	€ 18,609.63
Corticosteroid treatment					
Vamorolone	100 ml OS	€ 4,485.49	€ 1.77	€ 252.88	€ 4,230.84
Abbreviations: OS = oral suspension					

LAUER-TAXE® last revised: 15 November 2025

Costs for additionally required SHI services:

Only costs directly related to the use of the medicinal product are taken into account. If there are regular differences in the necessary use of medical treatment or in the prescription of other services in the use of the medicinal product to be evaluated and the appropriate comparator therapy in accordance with the product information, the costs incurred for this 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, the baseline values of platelets and triglycerides must be collected and assessed prior to treatment with givinostat. In addition, platelet counts (every 2 weeks in the first two months of treatment, after three months and then every 3

months) and triglycerides (at least in month 3, month 6 and then every 6 months) should be checked.

Designation of the therapy	Designation of the service	Number	Costs per unit	Costs per patient per year
Givinostat	Platelet count (UVS 32037)	1st year: 9	€ 0.25	1st year: € 2.25
		Subsequent years: 4		Subsequent years: € 1.00
	Triglycerides (UVS 32063)	1st year: 4	€ 0.25	1st year: € 1.00
		Subsequent years: 2		Subsequent years: € 0.50

2.5 Designation of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V that can be used in a combination therapy with the assessed medicinal product

According to Section 35a, paragraph 3, sentence 4, the G-BA designate all medicinal products with new active ingredients that can be used in a combination therapy with the assessed medicinal product for the therapeutic indication to be assessed on the basis of the marketing authorisation under Medicinal Products Act.

Basic principles of the assessed medicinal product

A designation in accordance with Section 35a, paragraph 3, sentence 4 SGB V requires that it is examined based on the product information for the assessed medicinal product whether it can be used in a combination therapy with other medicinal products in the assessed therapeutic indication. In the first step, the examination is carried out on the basis of all sections of the currently valid product information for the assessed medicinal product.

If the assessed medicinal product contains an active ingredient or a fixed combination of active ingredients in the therapeutic indication of the resolution (assessed therapeutic indication) and is approved exclusively for use in monotherapy, a combination therapy is not considered due to the marketing authorisation under Medicinal Products Act, which is why no designation is made.

A designation is also not considered if the G-BA have decided on an exemption as a reserve antibiotic for the assessed medicinal product in accordance with Section 35a, paragraph 1c, sentence 1 SGB V. The additional benefit is deemed to be proven if the G-BA have decided on an exemption for a reserve antibiotic in accordance with Section 35a, paragraph 1c, sentence 1 SGB V; the extent of the additional benefit and its therapeutic significance are not to be assessed by the G-BA. Due to the lack of an assessment mandate by the G-BA following the resolution on an exemption according to Section 35a, paragraph 1c, sentence 1 SGB V with regard to the extent of the additional benefit and the therapeutic significance of the reserve antibiotic to be assessed, there is a limitation due to the procedural privileging of the pharmaceutical companies to the effect that neither the proof of an existing nor an expected

at least considerable additional benefit is possible for exempted reserve antibiotics in the procedures according to Section 35a paragraph 1 or 6 SGB V and Section 35a paragraph 1d SGB V. The procedural privileging of the reserve antibiotics exempted according to Section 35a, paragraph 1c, sentence 1 SGB V must therefore also be taken into account at the level of designation according to Section 35a, paragraph 3, sentence 4 SGB V in order to avoid valuation contradictions.

With regard to the further examination steps, a differentiation is made between a "determined" or "undetermined" combination, which may also be the basis for a designation.

A "determined combination" exists if one or more individual active ingredients which can be used in combination with the assessed medicinal product in the assessed therapeutic indication are specifically named.

An "undetermined combination" exists if there is information on a combination therapy, but no specific active ingredients are named. An undetermined combination may be present if the information on a combination therapy:

- names a product class or group from which some active ingredients not specified in detail can be used in combination therapy with the assessed medicinal product, or
- does not name any active ingredients, product classes or groups, but the assessed medicinal product is used in addition to a therapeutic indication described in more detail in the relevant product information, which, however, does not include information on active ingredients within the scope of this therapeutic indication.

Concomitant active ingredient

The concomitant active ingredient is a medicinal product with new active ingredients that can be used in combination therapy with the assessed medicinal product for the therapeutic indication to be assessed.
For a medicinal product to be considered as a concomitant active ingredient, it must be classified as a medicinal product with new active ingredients according to Section 2 paragraph 1 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with the corresponding regulations in Chapter 5 of the Rules of Procedure of the G-BA as of the date of the present resolution. In addition, the medicinal product must be approved in the assessed therapeutic indication, whereby a marketing authorisation is sufficient only for a sub-area of the assessed therapeutic indication.

Based on an "undetermined combination", the concomitant active ingredient must be attributable to the information on the product class or group or the therapeutic indication according to the product information of the assessed medicinal product in the assessed therapeutic indication, whereby the definition of a product class or group is based on the corresponding requirements in the product information of the assessed medicinal product.

In addition, there must be no reasons for exclusion of the concomitant active ingredient from a combination therapy with the assessed medicinal product, in particular no exclusive marketing authorisation as monotherapy.

In addition, all sections of the currently valid product information of the eligible concomitant active ingredient are checked to see whether there is any information that excludes its use in combination therapy with the assessed medicinal product in the assessed therapeutic indication under marketing authorisation regulations. Corresponding information can be, for example, dosage information or warnings. In the event that the medicinal product is used as

part of a determined or undetermined combination which does not include the assessed medicinal product, a combination with the assessed medicinal product shall be excluded.

Furthermore, the product information of the assessed medicinal product must not contain any specific information that excludes its use in combination therapy with the eligible concomitant active ingredient in the assessed therapeutic indication under marketing authorisation regulations.

Medicinal products with new active ingredients for which the G-BA have decided on an exemption as a reserve antibiotic in accordance with Section 35a, paragraph 1c, sentence 1 SGB V are ineligible as concomitant active ingredients. The procedural privileging of the reserve antibiotics exempted according to Section 35a, paragraph 1c, sentence 1 SGB V also applies accordingly to the medicinal product eligible as a concomitant active ingredient.

Designation

The medicinal products which have been determined as concomitant active ingredients in accordance with the above points of examination are named by indicating the relevant active ingredient and the invented name. The designation may include several active ingredients, provided that several medicinal products with new active ingredients may be used in the same combination therapy with the assessed medicinal product or different combinations with different medicinal products with new active ingredients form the basis of the designation.
If the present resolution on the assessed medicinal product in the assessed therapeutic indication contains several patient groups, the designation of concomitant active ingredients shall be made separately for each of the patient groups.

Exception to the designation

The designation excludes combination therapies for which - patient group-related - a considerable or major additional benefit has been determined by resolution according to Section 35a, paragraph 3, sentence 1 SGB V or it has been determined according to Section 35a, paragraph 1d, sentence 1 SGB V that at least considerable additional benefit of the combination can be expected. In this context, the combination therapy that is excluded from the designation must, as a rule, be identical to the combination therapy on which the preceding findings were based.
In the case of designations based on undetermined combinations, only those concomitant active ingredients - based on a resolution according to Section 35a, paragraph 3, sentence 1 SGB V on the assessed medicinal product in which a considerable or major additional benefit had been determined - which were approved at the time of this resolution are excluded from the designation.

Legal effects of the designation

The designation of combinations is carried out in accordance with the legal requirements according to Section 35a, paragraph 3, sentence 4 and is used exclusively to implement the combination discount according to Section 130e SGB V between health insurance funds and pharmaceutical companies. The designation is not associated with a statement as to the extent to which a therapy with the assessed medicinal products in combination with the designated medicinal products corresponds to the generally recognised state of medical knowledge. The examination was carried out exclusively on the basis of the possibility under Medicinal Products Act to use the medicinal products in combination therapy in the assessed therapeutic indication based on the product information; the generally recognised state of medical knowledge or the use of the medicinal products in the reality of care were not the

subject of the examination due to the lack of an assessment mandate of the G-BA within the framework of Section 35a, paragraph 3, sentence 4 SGB V.
The findings made neither restrict the scope of treatment required to fulfil the medical treatment mandate, nor do they make statements about expediency or economic feasibility.

Justification for the findings on designation in the present resolution:

Ambulant patients aged 6 years and older with Duchenne muscular dystrophy (DMD)

The designated medicinal products concern in each case an active ingredient which may be used in combination therapy with the assessed medicinal product in the context of a therapeutic indication specified in the product information for the assessed medicinal product. This therapeutic indication concerns the administration with concomitant corticosteroid treatment according to the requirements in the product information.

For the designated medicinal products, the prerequisites of Section 35a, paragraph 3, sentence 4 SGB V are fulfilled and, according to the requirements in the product information, there are no reasons for exclusion that prevent a combination therapy with the assessed medicinal product.

References:
Product information for givinostat (Duvyzat); Duvyzat 8.86 mg/ml oral suspension; last revised: July 2025

Product information for vamorolone (Agamree); AGAMREE® 40 mg/ml oral suspension; last revised: January 2025

Supplement to Annex XIIa of the Pharmaceuticals Directive

Since the resolution under I.5 mentions medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V, which can be used in a combination therapy with the assessed active ingredient in the therapeutic indication of the resolution, the information on this designation is to be added to Annex XIIa of the Pharmaceuticals Directive and provided with patient-group-related information on the period of validity of the designation.

2.6 Percentage of study participants at study sites within the scope of SGB V in accordance with Section 35a, paragraph 3, sentence 5 SGB V

The medicinal product Duvyzat is a medicinal product placed on the market from 1 January 2025. In accordance with Section 35a, paragraph 3, sentence 5 SGB V, the G-BA must determine whether a relevant percentage of the clinical studies on the medicinal product were conducted within the scope of SGB V. This is the case if the percentage of study participants who have participated in the clinical studies on the medicinal product to be assessed in the therapeutic indication to be assessed at study sites within the scope of SGB V is at least five per cent of the total number of study participants.

The calculation is based on all studies that were submitted as part of the benefit assessment dossier in the therapeutic indication to be assessed in accordance with Section 35a, paragraph 1, sentence 3 SGB V in conjunction with Section 4, paragraph 6 AM-NutzenV.

Approval studies include all studies submitted to the regulatory authority in section 2.7.3 (Summary of Clinical Efficacy) and 2.7.4 (Summary of Clinical Safety) of the authorisation dossier in the therapeutic indication for which marketing authorisation has been applied for. In addition, studies, which were conducted in whole or in part within the therapeutic indication described in this document, and in which the company was a sponsor or is otherwise financially involved, must also be indicated.

The percentage of study participants in the clinical studies of the medicinal product conducted or commissioned by the pharmaceutical company in the therapeutic indication to be assessed who participated at study sites within the scope of SGB V (German Social Security Code) is < 5% (3.9%)of the total number of study participants according to the information provided by the pharmaceutical company.

The clinical studies of the medicinal product in the therapeutic indication to be assessed were therefore not conducted to a relevant extent within the scope of SGB V.

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 14 July 2025, the pharmaceutical company submitted a dossier for the benefit assessment of givinostat to the G-BA in due time in accordance with Chapter 5 Section 8, paragraph 1, number 1, sentence 2 VerfO.

The benefit assessment of the G-BA was published on 15 October 2025 together with the IQWiG assessment of treatment costs and patient numbers on the website of the G-BA (www.g-ba.de), thus initiating the written statement procedure. The deadline for submitting statements was 05 November 2025.

The oral hearing was held on 24 November 2025.

An amendment to the benefit assessment with a supplementary assessment of data submitted in the written statement procedure was submitted on 12 December 2025.

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.

The evaluation of the written statements received and the oral hearing was discussed at the session of the subcommittee on 13 January 2026, and the draft resolution was approved.

At their session on 22 January 2026, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee on Medicinal Products	7 October 2025	Information of the benefit assessment of the G-BA
Working group Section 35a	18 November 2025	Information on written statements received; preparation of the oral hearing
Subcommittee on Medicinal Products	24 November 2025	Conduct of the oral hearing
Working group Section 35a	2 December 2025 16 December 2025	Consultation on the dossier evaluation by the G-BA, the assessment of treatment costs and patient numbers by the IQWiG, and the evaluation of the written statement procedure
Subcommittee on Medicinal Products	13 January 2026	Concluding discussion of the draft resolution
Plenum	22 January 2026	Adoption of the resolution on the amendment of the Pharmaceuticals Directive

Berlin, 22 January 2026

Federal Joint Committee (G-BA)
in accordance with Section 91 SGB V
The Chair

Prof. Hecken