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
Tovorafenib (malignant low-grade glioma (LGG) harbouring a BRAF fusion or rearrangement or a BRAF V600 mutation, after at least 1 prior therapy, ≥ 6 months)

of 5 November 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. If a joint clinical assessment has been carried out in accordance with Regulation (EU) 2021/2282 of the European Parliament and the Council of 15 December 2021 on health technology assessment and amendment of the Directive 2011/24/EU and has not been discontinued in accordance with Article 10, paragraph 6, sentence 1 of that Regulation, the resolution shall likewise be based on Section 7 in conjunction with Section 4 paragraph 2a of the Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV).

For medicinal products for the treatment of rare diseases (orphan drug) 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,

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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.

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 tovorafenib on 15 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 13 May 2026.

A joint clinical assessment of the active ingredient tovorafenib was carried out in accordance with Regulation (EU) 2021/2282 of the European Parliament and the Council of 15 December 2021 on health technology assessment and amendment of Directive 2011/24/EU. On 9 June 2026, the Joint Clinical Assessment Report (hereinafter referred to as the JCA report) on tovorafenib was published on the European Commission's website. The publication date was after the relevant date for the commencement of the benefit assessment procedure on 15 May 2026; consequently, the JCA report did not form the basis for the benefit assessment in accordance with Section 7, paragraph 1, sentence 3, number 2 AM-NutzenV.

Tovorafenib for the treatment of malignant glioma 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 17 August 2026 on the GBA website (www.g-ba.de), thus initiating the written statement procedure. In addition, an oral hearing was held. Similarly, in accordance with Section 7, paragraph 4, sentence 1 AM-NutzenV, the JCA report was submitted for written statement and hearing on 17 August 2026.

The GBA have adopted their resolution on the basis of the dossier of the pharmaceutical company, including references to the European dossier, the JCA report, the benefit assessment carried out by the GBA, the assessment of treatment costs and patient numbers (IQWiG G26-11) 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,

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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 tovorafenib.

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

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2.1 Additional benefit of the medicinal product

2.1.1 Approved therapeutic indication of tovorafenib (Ojemda) in accordance with the product information

Ojemda is indicated as monotherapy for the treatment of patients 6 months of age and older with paediatric low-grade glioma (LGG) harbouring a BRAF fusion or rearrangement, or BRAF V600 mutation, who have progressed after one or more prior systemic therapies (for biomarkers-based patient selection, see section 4.2).

Therapeutic indication of the resolution (resolution of 5 November 2026):

See the approved therapeutic indication

2.1.2 Extent of the additional benefit and significance of the evidence

Patients 6 months of age and older with paediatric low-grade glioma (LGG) harbouring a BRAF fusion or rearrangement, or BRAF V600 mutation, who have progressed after one or more prior systemic therapies

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

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

Justification:

The pharmaceutical company submitted, in particular, data from the pivotal, non-randomised, non-comparator, multicentre FIREFLY-1 study for the assessment of the extent of the additional benefit of tovorafenib in the therapeutic indication of paediatric low-grade glioma (pLGG) harbouring a BRAF fusion or rearrangement, or BRAF V600 mutation after one or more prior systemic therapies.

The FIREFLY-1 study is a phase II study that has been ongoing since 2021, comprising three cohorts designed to investigate the efficacy and safety of tovorafenib in children, adolescents and young adults (aged 6 months to 25 years) with relapsed or progressive paediatric low-grade glioma or advanced solid tumours.

The study comprises the pivotal study cohort 1, which is relevant for the marketing authorisation and the benefit assessment, and the expansion cohort 2, as well as cohort 3, which is not relevant for the benefit assessment (solid tumours with an activating or putatively activating RAF fusion). Cohort 1 comprises patients with pLGG and an activating BRAF alteration (including BRAF V600 mutations or KIAA1549:BRAF fusions), whilst cohort 2 comprises patients with pLGG and an activating or putatively activating RAF alteration (e.g. BRAF or CRAF/RAF1 fusions). Cohorts 1 and 2 were investigated at 32 study sites in Asia, Australia, Europe and North America.

A total of 137 patients were enrolled in these cohorts 1 and 2 (cohort 1 N=77, cohort 2 N=60), which were relevant for the benefit assessment, and patient-relevant endpoints were assessed in the categories of mortality, morbidity, health-related quality of life and side effects.

In the dossier, the pharmaceutical company submitted data from both the 2-year (10.05.2024) and the 3-year data cut-offs (06.06.2025), with the latter being used and forming the basis of the benefit assessment due to the longer follow-up period.

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On the JCA report:

The JCA report on tovorafenib is based on the 2-year data cut-off (10.05.2024) from the FIREFLY-1 study. In the benefit assessment dossier, the pharmaceutical company also submitted data from the 3-year data cut-off (06.06.2025), with the latter being used and forming the basis of the benefit assessment due to the longer follow-up period.

The JCA report does not specifically discuss the data from the FIREFLY-1 study, as it is a non-comparator study, which, on its own, does not allow statements to be made about the relative effects of the medicinal product under assessment compared with the comparator therapies defined within the scope of the assessment.

In the European dossier, the pharmaceutical company submitted two indirect comparisons without a bridge comparator ("unanchored indirect comparison") of tovorafenib (FIREFLY-1 study) versus a) the combination therapy dabrafenib + trametinib (study by Bouffet et al.) and b) the monotherapy with trametinib (TRAM-01 study), which are discussed in detail in the JCA report.

In the dossier for the benefit assessment, the pharmaceutical company refers to these indirect comparisons in the European dossier for information purposes only and does not use them as evidence for quantification of the extent of the additional benefit.

Mortality

In the FIRELFY-1 study, overall survival was defined as the period from the date of the first dose to the date of death.

Across the two relevant study cohorts, there were 9 (6.57%) deaths. Due to the absence of comparator data, no statement on the extent of the additional benefit can be made on the basis of these results.

Morbidity

Overall response rate

In the FIREFLY-1 study, the overall response rate was defined as the percentage of patients with the best confirmed overall response (complete response (CR); partial response (PR); minor response (MR)), which was achieved after the start of treatment with tovorafenib but before the start of any subsequent anti-tumour therapy. The overall response rate was assessed according to the *"Response Assessment in Neuro-Oncology"* (RANO) criteria for high-grade gliomas (HGG) and low-grade gliomas (LGG) in adults, as well as *"Response Assessment in Paediatric Neuro-Oncology"* for LGG (RAPNO-LGG) criteria in paediatric patients. The overall response rate, assessed using the RANO-HGG criteria, was the primary endpoint.

The RANO and RAPNO criteria include imaging procedures, an assessment of the clinical condition and the use of corticosteroids (only in the case of RANO). In the FIREFLY-1 study, the clinical condition was assessed by a principal investigator using the Karnofsky/Lansky Performance Status (K/L-PS); the L-PS was collected for children under 16 years of age, and the K-PS for children aged ≥ 16 years.

No data were provided on the individual components of the endpoint. The available information does not indicate the criteria used to incorporate the assessment of the patients' clinical condition into the assessment of overall response.

The overall response rate is a relevant clinical parameter for therapy management in the present therapeutic indication, and is presented additionally.

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Progression-free survival

In the FIREFLY-1 study, progression-free survival (PFS) was defined as the period between the administration of the first dose of tovorafenib and the first documented disease progression, as assessed using the RANO-HGG and RANO-LGG criteria as well as the RAPNO-LGG criteria, or death from any cause, whichever occurs first.

The present PFS endpoint is a composite endpoint consisting of endpoints from the "mortality" and "morbidity" categories. The endpoint component "mortality" is already assessed via the endpoint "overall survival" as an independent endpoint. The collection of the morbidity component was on the basis of the RANO/ RAPNO criteria, whereby at least one criterion had to be fulfilled for progression.

The RANO and RAPNO criteria include imaging procedures, an assessment of the clinical condition and the use of corticosteroids (only in the case of RANO).

Given that the present therapeutic indication concerns patients with LGG, only data collected using the RANO-LGG and RAPNO-LGG criteria can be considered relevant to the present treatment setting.

No data were provided on the individual components.

The same uncertainties as described under the overall response rate apply to the assessment of the clinical condition. In addition, for PFS, the presence of a fulfilled criterion was sufficient to be counted as disease progression. No data are available on the number of patients who experienced a deterioration in the clinical condition, and on the number of patients for whom a change in the imaging procedures was the decisive factor.

Notwithstanding this, no statement can be made on the extent of additional benefit based on these results due to the absence of comparator data.

Visual acuity

In the FIREFLY-1 study, visual acuity was assessed using age-specific eye tests (in particular Snellen eye charts, Teller acuity eye charts, HOTV eye charts or other "Early Treatment Diabetic Retinopathy Study" (EDTRS) eye charts). The Snellen eye test uses eye charts with optotypes that become progressively smaller; in the Teller Acuity cards, a striped pattern must be distinguished from a grey background; in the HOTV test, the letters H, O, T and V in descending order of size must be recognised, whilst the EDTRS eye chart consists of 14 lines of optotypes, each containing 5 letters in a line, with the size decreasing in each line. The written statement procedure showed that the Snellen eye charts eye test and HOTV/EDTRS eye charts were predominantly used.

Patients with a glioma of the visual pathway or visual impairment caused by the primary tumour underwent an ophthalmological examination, which also included a measurement of best corrected visual acuity (BCVA), at baseline, at each radiological tumour examination and at the end of treatment. Patients without a glioma of the visual pathway or without visual impairment caused by a primary tumour underwent the eye examination only at baseline and, where clinically indicated, during the study.

The endpoint of visual acuity is rated as patient-relevant.

However, the following uncertainties in particular remain. On the one hand, in 35% of cases, methods "other" than those mentioned above were used for determining visual acuity, but the methods that fall under the "other" category remain unclear. On the other, in the FIREFLY-1 study, there were patients who underwent different eye tests over the course of the study. It remains unclear to what extent the eye tests used can produce comparable results.

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Furthermore, it remains unclear whether all 68 patients with visual pathway glioma were included in the overall analysis of the 105 patients at the start of the study, or for what reason the additional 37 patients without a primary tumour of the visual pathway were included in the analysis at the start of the study.

Notwithstanding this, no statement can be made on the extent of additional benefit based on these results due to the absence of comparator data.

Cognitive functioning (PROMIS CSF7a), fatigue (PROMIS Paediatric Profile-49 and PROMIS Parent-Proxy-49), disease symptomatology (PedsQL Cancer)

In the FIREFLY-1 study, cognitive functioning was assessed using PROMIS SCF7a, fatigue using PROMIS Paediatric Profile-49 and PROMIS Parent-Proxy-49, and disease symptomatology using PedsQL Cancer. However, the respective return rates were already below 70% at baseline. The data are thus classified as being unusable.

Notwithstanding this, no statement can be made on the extent of additional benefit based on these results due to the absence of comparator data.

Quality of life

PedsQL Core

Health-related quality of life was assessed in the FIREFLY-1 study using the PedsQL Core. However, the return rates were already below 70% at baseline. The data are thus classified as being unusable.

Notwithstanding this, no statement can be made on the extent of additional benefit based on these results due to the absence of comparator data.

Side effects

In the FIREFLY-1 study, all adverse events (AEs) were collected from the first dose of tovorafenib up to 30 days after the last dose.

Serious AEs and AEs of special interest were collected beyond 30 days after the last dose of study medication until the start of a new anti-tumour therapy.

AEs occurred in all patients. Across both cohorts, severe AEs occurred in 113 patients (82.5%) and SAEs in 77 patients (56.2%). A total of 19 patients (13.9%) discontinued treatment with tovorafenib due to AEs.

Due to the absence of comparator data, no statement on the extent of the additional benefit can be made on the basis of these results.

Overall assessment

Non-comparator data on overall survival, morbidity, health-related quality of life and side effects from the label-enabling, single-arm, phase II FIREFLY study are available for the assessment of the extent of the benefit.

However, these data do not allow for a comparative assessment due to the single-arm study design. In the overall assessment, the extent of the additional benefit is classified as non-quantifiable since the scientific data does not allow quantification.

Significance of the evidence

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The benefit assessment is based on data from the single-arm FIREFLY-1 study. Due to the single-arm design of this study, a comparative assessment is not possible. The reliability of data is therefore assessed as a hint.

2.1.3 Summary of the assessment

The present benefit assessment concerns the benefit assessment of the new medicinal product Ojemda with the active ingredient tovorafenib.

Tovorafenib was approved as an orphan drug for the treatment of patients 6 months of age and older with paediatric low-grade glioma (LGG) harbouring a BRAF fusion or rearrangement, or BRAF V600 mutation, who have progressed after one or more prior systemic therapies. Data from the non-comparator, pivotal phase II FIREFLY-1 study are available for the benefit assessment.

Due to the absence of comparator data, no statement on the extent of the additional benefit can be made on the basis of these results.

In the overall assessment, a hint of a non-quantifiable additional benefit of tovorafenib is identified since the scientific data does not allow quantification.

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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 GBA base their resolution on the information from the dossier of the pharmaceutical company; however, this information is subject to the following significant uncertainties.

The source cited by the pharmaceutical company to calculate the incidence rates of paediatric LGG, on the one hand, relates solely to the period from 2009 to 2018 and, on the other, does not include percentages for BRAF fusions or rearrangements, or BRAF V600 mutations. In addition, with regard to the lower limit, the pharmaceutical company takes into account only patients who have received only one prior systemic therapy in their calculation based on their source; and with regard to the upper limit, the percentage calculated by the pharmaceutical company, contrary to this therapeutic indication, also includes patients who may have received only radiotherapy.

Overall, the lower limit is thus underestimated and the upper limit is subject to uncertainties.

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 Ojemda (active ingredient: tovorafenib) at the following publicly accessible link (last access: 21 October 2026):

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

Treatment with tovorafenib must only be initiated and monitored by specialists in internal medicine, haematology, and oncology experienced in the treatment of patients with gliomas, specialists in neurology, as well as specialists in neurosurgery or specialists in paediatrics and adolescent medicine with a specialisation in neuropaediatrics or paediatric haematology and oncology, and other specialists from other specialist groups participating in the Oncology Agreement.

Before taking tovorafenib, the presence of the BRAF fusion or rearrangement, or BRAF V600 mutation, must have been detected in patients by a validated test.

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: 1 September 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.

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According to the product information, the dosage of 380 mg/m² once a week is based on the body surface area. For film-coated tablets, dosage recommendations are provided for patients with a body surface area of 0.9 to ≥ 1.40 m² (400–600 mg); for the powder for the preparation of a suspension, dosage recommendations are available for patients with a body surface area of 0.30 to ≥ 1.40 m² (125–600 mg). The maximum recommended dose is 600 mg once a week.

Treatment period:

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Medicinal product to be assessed:				
Tovorafenib	1 x every 7 days	52.1	1	52.1

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.

The requirements in the product information specify the consumption as a weekly minimum dose of 125 mg (suspension) for a body surface area of 0.30 m² to 0.35 m² and a weekly maximum dose of 600 mg (film-coated tablet) for a body surface area ≥ 1.40 m².

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:					
Tovorafenib					
BSA 0.30 m² POS	125 mg	125 mg	1 x 300 mg	52.1	52.1 x 300 mg
BSA ≥ 1.40 m² FCT	600 mg	600 mg	6 x 100 mg	52.1	312.6 x 100 mg
Abbreviations: FCT = film-coated tablets; BSA = body surface area; POS = powder for oral suspension					

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:

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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:					
Tovorafenib 300 mg (25 mg/ml)	1 POS	€ 4,874.63	€ 1.77	€ 277.75	€ 4,595.11
Tovorafenib 100 mg	24 FCT	€ 38,918.63	€ 1.77	€ 2,222.01	€ 36,694.85
Abbreviations: FCT = film-coated tablets; POS = powder for oral suspension					

LAUER-TAXE® last revised: 1 September 2026

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.

Because there are no 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 assessed in accordance with the product information, no costs for additionally required SHI services had to be taken into account.

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

The JCA report was published on the European Commission's website on 9 June 2026.

The benefit assessment by the GBA was published on 17 August 2026 together with the IQWiG 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 7 September 2026. The JCA report was scheduled for hearing on 17 August 2026.

The oral hearing was held on 21 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.

The evaluation of the written statements received and the oral hearing was discussed at the Subcommittee's session on 27 October 2026, and deliberation of the draft resolution was concluded.

At their session on 5 November 2026, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee on Medicinal Products	11 August 2026	Information of the benefit assessment of the GBA
Working group Section 35a	15 September 2026	Information on written statements received, the JCA report, preparation of the oral hearing
Subcommittee on Medicinal Products	21 September 2026	Conduct of the oral hearing
Working group Section 35a	29 September 2026 13 October 2026	Consultation on the benefit assessment by the GBA, the JCA report, the IQWiG assessment of treatment costs and patient numbers, as well as the evaluation of the written statement procedure

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Subcommittee on Medicinal Products	27 October 2026	Concluding discussion of the draft resolution
Plenum	5 November 2026	Adoption of the resolution on the amendment of the Pharmaceuticals Directive

Berlin, 5 November 2026

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

Dr Optendrenk

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