Gemeinsamer Bundesausschuss

Resolution

of the Federal Joint Committee on an Amendment of the Pharmaceuticals Directive:
Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a SGB V and Annex XIIa – Combinations of Medicinal Products with New Active Ingredients according to Section 35a SGB V
Trametinib (malignant glioma, BRAF V600E mutation, ≥ 1 year, low-grade (LGG)/ high-grade (HGG) after at least 1 prior therapy; combination with dabrafenib)

of 17 October 2024

At its session on 17 October 2024, the Federal Joint Committee (G-BA) resolved to amend the Pharmaceuticals Directive (AM-RL) in the version dated 18 December 2008 / 22 January 2009 (Federal Gazette, BAnz. No. 49a of 31 March 2009), as last amended by the publication of the resolution of D Month YYYY (Federal Gazette, BAnz AT DD.MM.YYYY BX), as follows:

I. Annex XII shall be amended in alphabetical order to include the active ingredient Trametinib as follows:

Trametinib

Resolution of: 17 October 2024
Entry into force on: 17 October 2024
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 05 January 2024):

Low-grade glioma

Spexotras in combination with dabrafenib is indicated for the treatment of paediatric patients aged 1 year and older with low-grade glioma (LGG) with a BRAF V600E mutation who require systemic therapy.

High-grade glioma

Spexotras in combination with dabrafenib is indicated for the treatment of paediatric patients aged 1 year and older with high-grade glioma (HGG) with a BRAF V600E mutation who have received at least one prior radiation and/or chemotherapy treatment.

Therapeutic indication of the resolution (resolution of 17 October 2024):

Therapeutic indication according to marketing authorisation.

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

Trametinib is approved as a medicinal product for the treatment of rare diseases in accordance with Regulation (EC) No. 141/2000 of the European Parliament and the Council of 16 December 1999 on orphan drugs. In accordance with Section 35a, paragraph 1, sentence 11, 1st half of the sentence SGB V, the additional medical benefit is considered to be proven through the grant of the marketing authorisation.

The Federal Joint Committee (G-BA) determines the extent of the additional benefit for the number of patients and patient groups for which there is a therapeutically significant additional benefit in accordance with Chapter 5 Section 12, paragraph 1, number 1, sentence 2 of its Rules of Procedure (VerfO) in conjunction with Section 5, paragraph 8 AM-NutzenV, indicating the significance of the evidence. This quantification of the additional benefit is based on the criteria laid out in Chapter 5 Section 5, paragraph 7, numbers 1 to 4 of the Rules of Procedure (VerfO).

a) Paediatric patients aged 1 year and older with low-grade glioma (LGG) with a BRAF V600E mutation who require systemic therapy

Extent of the additional benefit and significance of the evidence of trametinib in combination with dabrafenib:

a1) Patients without prior treatment of LGG

Hint for a considerable additional benefit.

a2) Patients with previous treatment of LGG

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

b) Paediatric patients aged 1 year and older with high-grade glioma (HGG) with a BRAF V600E mutation who have received at least one prior radiation and/or chemotherapy treatment

Extent of the additional benefit and significance of the evidence of trametinib in combination with dabrafenib:

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

Study results according to endpoints:[1]

a) Paediatric patients aged 1 year and older with low-grade glioma (LGG) with a BRAF V600E mutation who require systemic therapy

a1) Patients without prior treatment of LGG

[1] Data from the dossier assessment of the G-BA (published on 1. August 2024), and from the amendment to the dossier assessment from 26 September 2024, unless otherwise indicated.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	↔	No relevant difference for the benefit assessment.
Morbidity	↔	No relevant differences for the benefit assessment.
Health-related quality of life	n.a.	There are no assessable data.
Side effects	↑↑	Advantages in severe AEs and therapy discontinuation due to AEs. In detail, mainly advantages in specific AEs.

Explanations:
↑: statistically significant and relevant positive effect with low/unclear reliability of data
↓: statistically significant and relevant negative effect with low/unclear reliability of data
↑↑: statistically significant and relevant positive effect with high reliability of data
↓↓: statistically significant and relevant negative effect with high reliability of data
↔: no statistically significant or relevant difference
∅: No data available.
n.a.: not assessable

G2201 study: multicentre phase II study with 2 cohorts

Relevant cohort: non-pretreated patients with LGG; randomised, controlled

Trametinib + dabrafenib vs carboplatin + vincristine

Results of the final data cut-off from 28.04.2023

Mortality

Endpoint	Trametinib + dabrafenib		Carboplatin + vincristine		Intervention vs control
	N	Median survival time in months [95% CI] *Patients with event n (%)*	N	Median survival time in months [95% CI] *Patients with event n (%)*	HR [95% CI] p value Absolute difference (AD)[a]
Overall survival					
	73	n.r. [n.c.; n.c.] 0	37	n.r. [n.c.; n.c.] 1 (2.7)	- 0.13

Morbidity

Endpoint	Trametinib + dabrafenib		Carboplatin + vincristine		Intervention vs control
	N	Median time to event in months [95% CI] *Patients with event n (%)*	N	Median time to event in months [95% CI] *Patients with event n (%)*	HR [95% CI] p value Absolute difference (AD)[a]
Progression-free survival[2] (according to RANO[b] – radiological assessment by independent central review)					
	73	24.9 [12.9; 31.6] 44 (60.3)	37	7.2 [2.8; 11.2] 26 (70.3)	0.36 [0.22; 0.59] < 0.001 AD = + 17.7 months

Endpoint	Trametinib + dabrafenib		Carboplatin + vincristine		Intervention vs control
	N	*Patients with event n (%)*	N	*Patients with event n (%)*	RR [95% CI] p value Absolute difference (AD)[a]
Overall response rate[c] (according to RANO[b] – radiological assessment by independent central review)					
Overall response rate (ORR)	73	40 (54.8)	37	6 (16.2)	3.38 [1.58; 7.24] < 0.001
CR PR	73	2 (2.7) 38 (52.1)	37	1 (2.7) 5 (13.5)	-

Endpoint	Trametinib + dabrafenib		Carboplatin + vincristine		Intervention vs control
	N	Median time to event in months [95% CI] *Patients with event n (%)*	N	Median time to event in months [95% CI] *Patients with event n (%)*	Effect estimator [95% CI] p value Absolute difference (AD)[a]
PROMIS PGH 7+2	No assessable data available[d]				

[2] Data on trametinib from module 4 of the pharmaceutical company from 25.04.2024 at the final data cut-off

Health-related quality of life

Endpoint	Trametinib + dabrafenib		Carboplatin + vincristine		Intervention vs control
	N	Median time to event in months [95% CI] *Patients with event n (%)*	N	Median time to event in months [95% CI] *Patients with event n (%)*	Effect estimator [95% CI] p value Absolute difference (AD)[a]
PROMIS PGH 7+2	No assessable data available[d]				

Side effects

Endpoint **MedDRA system organ classes/ preferred terms/ AEs of special interest**	**Trametinib + dabrafenib**		**Carboplatin + vincristine**		Intervention vs control
	N	Median time to event in months [95% CI] *Patients with event n (%)*	N	Median time to event in months [95% CI] *Patients with event n (%)*	HR [95% CI] p value
Total adverse events (AEs) (presented additionally)	73	0.3 [0.2; 0.4] 73 (100)	33	0.1 [0.1; 0.1] 33 (100)	
Serious adverse events (SAE)	73	43.5 [13.9; n.a.] 34 (46.6)	33	9.7 [3.1; n.a.] 14 (42.4)	0.68 [0.35; 1.30] 0.24
Severe adverse events (CTCAE grade 3 or 4)	73	28.6 [10.1; n.a.] 39 (53.4)	33	1.0 [0.7; 1.7] 31 (93.9)	0.16 [0.09; 0.29] < 0.001
Therapy discontinuation due to adverse events	73	n.a. [n.a.; n.a.] 4 (5.5)	33	n.a. [11.3; n.a.] 8 (24.2)	0.13 [0.03; 0.50] < 0.001
Severe adverse events according to MedDRA (with an incidence ≥ 5% in one study arm and statistically significant difference between the treatment arms; SOC and PT)					
Blood and lymphatic system disorders	73	n.a. [n.a.; n.a.]; 7 (9.6)	33	n.a. [1.9; n.a.]; 15 (45.5)	0.13 [0.05; 0.33] < 0.001
Anaemia	73	n.a. [n.a.; n.a.]; 0 (0.0)	33	n.a. [n.a.; n.a.]; 8 (24.2)	n.a. < 0.001
Neutropenia	73	n.a. [n.a.; n.a.]; 7 (9.6)	33	n.a. [3.3; n.a.]; 10 (30.3)	0.21 [0.08; 0.58] 0.001
Thrombocytopenia	73	n.a. [n.a.; n.a.]; 0 (0)	33	n.a. [n.a.; n.a.]; 4 (12.1)	n.a. < 0.001

Endpoint **MedDRA system organ classes/ preferred terms/ AEs of special interest**	**Trametinib + dabrafenib**		**Carboplatin + vincristine**		Intervention vs control
	N	Median time to event in months [95% CI] *Patients with event n (%)*	N	Median time to event in months [95% CI] *Patients with event n (%)*	HR [95% CI] p value
Gastrointestinal disorders	73	n.a. [n.a.; n.a.]; 3 (4.1)	33	n.a. [n.a.; n.a.]; 4 (12.1)	0.16 [0.03; 0.80] 0.01
Infections and infestations	73	n.a. [n.a.; n.a.]; 10 (13.7)	33	n.a. [n.a.; n.a.]; 3 (9.1)	0.81 [0.21; 3.15] 0.76
Investigations	73	n.a. [n.a.; n.a.]; 17 (23.3)	33	3.3 [1.6; n.a.] 18 (54.5)	0.21 [0.10; 0.42] < 0.001
Neutropenia	73	n.a. [n.a.; n.a.]; 4 (5.5)	33	n.a. [1.7; n.a.]; 16 (48.5)	0.08 [0.03; 0.24] < 0.001
Leukopenia	73	n.a. [n.a.; n.a.]; 0 (0)	33	n.a. [n.a.; n.a.]; 5 (15.2)	n.a. < 0.001
SAEs according to MedDRA (with an incidence ≥ 5% in one study arm and statistically significant difference between the treatment arms; SOC and PT)					
No significant differences					
Adverse events of special interest (with statistically significant difference between the treatment arms)					
Toxicity with reference to the skin (AE regardless of severity grade)	73	1.9 [1.0; 4.3]; 58 (79.5)	33	12.6 [9.7; n.a.] 12 (36.4)	2.66 [1.42; 4.99] 0.002
Fever (AE regardless of severity grade)	73	3.3 [1.5; 9.7]; 56 (76.7)	33	n.a. [n.a.; n.a.]; 7 (21.2)	3.72 [1.68; 8.23] < 0.001
Neutropenia (AE regardless of severity grade)	73	n.a. [40.5; n.a.]; 20 (27.4)	33	1.5 [0.9; 1.6]; 27 (81.8)	0.13 [0.07; 0.25] < 0.001
Neutropenia (severe AE)	73	n.a. [n.a.; n.a.]; 10 (13.7)	33	1.9 [1.4; 2.1]; 25 (75.8)	0.09 [0.04; 0.19] < 0.001

a. Indication of absolute difference (AD) only in case of statistically significant difference; own calculation
b. The radiological findings were assessed by an independent central review committee; the assessment of the clinical condition and the corticosteroid consumption sub-component was carried out only by the principal investigator.
c. Primary endpoint of the G2201 study

Endpoint **MedDRA system organ classes/ preferred terms/ AEs of special interest**	**Trametinib + dabrafenib**		**Carboplatin + vincristine**		Intervention vs control
	N	Median time to event in months [95% CI] *Patients with event n (%)*	N	Median time to event in months [95% CI] *Patients with event n (%)*	HR [95% CI] p value

d. Not assessable due to low return rates in one arm (< 70%)

Abbreviations used:
AD = absolute difference; CR = complete response; CTCAE = Common Terminology Criteria for Adverse Events; HR = hazard ratio; n.d. = no data available; CI = confidence interval; MedDRA = Medical Dictionary for Regulatory Activities; N = number of patients evaluated; n = number of patients with (at least one) event; n.a. = not applicable; n.c. = not calculable; n.r. = not reached; PD = progressive disease; PR = partial response; RR = relative risk; SD = stable disease; vs = versus

a2) Patients with previous treatment of LGG

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	n.a.	There are no assessable data.
Morbidity	n.a.	There are no assessable data.
Health-related quality of life	∅	No data available.
Side effects	n.a.	There are no assessable data.
Explanations: ↑: statistically significant and relevant positive effect with low/unclear reliability of data ↓: statistically significant and relevant negative effect with low/unclear reliability of data ↑↑: statistically significant and relevant positive effect with high reliability of data ↓↓: statistically significant and relevant negative effect with high reliability of data ↔: no statistically significant or relevant difference ∅: No data available. n.a.: not assessable		

X2101 study: 4-part, open-label, single-arm phase I/II study

Relevant parts C and D of the X2101 study; patients with relapsed or refractory LGG

Final data cut-off from 29.12.2020.

Mortality

Endpoint	Trametinib + dabrafenib	
	N	Patients with event n (%)
Overall mortality		
	31[a]	No deaths occurred.

Morbidity

Endpoint	Trametinib + dabrafenib	
	N	Patients with event n (%)
Progression-free survival[2] (according to RANO[b] – radiological assessment by independent central review)		
Patients with event	31[a]	7 (22.6)

Endpoint	Trametinib + dabrafenib	
	N	Patients with event n (%)
Overall response rate[2] (according to RANO[b] – radiological assessment by independent central review) – presented additionally		
Overall response rate (ORR), n (%) [95% CI] CR PR	31[a]	8 (25.8) [11.9; 44.6] 0 (0) 8 (25.8)

Quality of life

No health-related quality of life data were collected in the X2101 study.

Side effects

Endpoint MedDRA system organ classes/ AEs of special interest	Trametinib + dabrafenib	
	N	**Patients with event n (%)**
Total adverse events (AEs) (presented additionally)	36[d]	36 (100)
Serious adverse events (SAE)	36[d]	15 (41.7)
Severe adverse events (CTCAE grade 3 or 4)	36[d]	22 (61.1)
Therapy discontinuation due to adverse events	36[d]	8 (22.2)
Severe adverse events according to MedDRA system organ class (with an incidence ≥ 10%)		
Blood and lymphatic system disorders	36[d]	n.d.
Neutropenia	36[d]	4 (11.1)
General disorders and administration site conditions	36[d]	n.d.
Fever	36[d]	4 (11.1)
SAEs according to MedDRA system organ class (with an incidence ≥ 10%)		
General disorders and administration site conditions	36[d]	n.d.
Fever	36[d]	7 (19.4)
AEs of special interest (with an incidence ≥ 10%)		
Fever (severe AE)	36[d]	4 (11.1)
Neutropenia (severe AE)	36[d]	7 (19.4)
Cardiac events (AE regardless of severity grade)	36[d]	4 (11.1)

a. N = 31 is composed of 34 subjects with LGG and 2 subjects with HGG, of whom only 31 patients received a dosage largely in accordance with the product information.

Endpoint MedDRA system organ classes/ AEs of special interest	Trametinib + dabrafenib	
	N	Patients with event n (%)
b. The radiological findings were assessed by an independent central review committee; the assessment of the clinical condition and the corticosteroid consumption sub-component was carried out only by the principal investigator. c. Only patients with CR or PR were included in the analysis. d. No data is available for N = 31, so the results are shown for N = 36. Abbreviations used: AD = absolute difference; CR = complete response; CTCAE = Common Terminology Criteria for Adverse Events; HR = hazard ratio; n.d. = no data available; CI = confidence interval; MedDRA = Medical Dictionary for Regulatory Activities; N = number of patients evaluated; n = number of patients with (at least one) event; n.a. = not applicable; n.c. = not calculable; n.r. = not reached; PD = progressive disease; PR = partial response; RR = relative risk; SD = stable disease; vs = versus		

b) Paediatric patients aged 1 year and older with high-grade glioma (HGG) with a BRAF V600E mutation who have received at least one prior radiation and/or chemotherapy treatment

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	n.a.	There are no assessable data.
Morbidity	n.a.	There are no assessable data.
Health-related quality of life	∅	No data available.
Side effects	n.a.	There are no assessable data.
Explanations: ↑: statistically significant and relevant positive effect with low/unclear reliability of data ↓: statistically significant and relevant negative effect with low/unclear reliability of data ↑↑: statistically significant and relevant positive effect with high reliability of data ↓↓: statistically significant and relevant negative effect with high reliability of data ↔: no statistically significant or relevant difference ∅: No data available. n.a.: not assessable		

G2201 study: multicentre phase II study with 2 cohorts

Relevant cohort: pretreated patients with HGG; single-arm

Results of the final data cut-off from 28.04.2023

Mortality

Endpoint	Trametinib + dabrafenib	
	N	**Patients with event n (%)**
Overall mortality		
Deaths	41	17 (41.5)
Survival rate (%) [95% CI] 6-month survival rate 12-month survival rate 24-month survival rate 30-month survival rate		 87.4 [72.4; 94.6] 77.0 [60.4; 87.3] 61.0 [43.8; 74.4] 58.4 [41.3; 72.1]

Morbidity

Endpoint	Trametinib + dabrafenib	
	N	**Patients with event n (%)**
Progression-free survival[2] (according to RANO[a] – radiological assessment by independent central review)		
Patients with event	41	26 (65.9)

Endpoint	Trametinib + dabrafenib	
	N	**Patients with event n (%)**
Overall response[b] (according to RANO[a] – radiological assessment by independent central review)		
Overall response rate (ORR), n (%) [95% CI] CR PR	41	23 (56.1) [39.7; 71.5] 14 (34.1) 9 (22.0)

Quality of life

No health-related quality of life data were collected in the HGG cohort of the G2201 study.

Side effects

Endpoint MedDRA system organ classes/ AEs of special interest	**Trametinib + dabrafenib**	
	N	**Patients with event n (%)**
Total adverse events (presented additionally)	41	41 (100)
Serious adverse events (SAE)	41	30 (73.2)
Severe adverse events (CTCAE grade 3 or 4)	41	28 (68.3)
Therapy discontinuation due to adverse events	41	2 (4.9)
Severe adverse events according to MedDRA system organ class (with an incidence ≥ 10%)		
Nervous system disorders	41	13 (31.7)
Investigations	41	7 (17.1)
Gastrointestinal disorders	41	6 (14.6)
Infections and infestations	41	5 (12.2)
SAEs according to MedDRA system organ class (with an incidence ≥ 10%)		
Nervous system disorders	41	17 (41.5)
General disorders and administration site conditions	41	6 (14.6)
Infections and infestations	41	6 (14.6)
AEs of special interest (with an incidence ≥ 10%)		
Toxicity related to the skin (AE regardless of severity grade)	41	35 (85.4)
Fever (AE regardless of severity grade)	41	22 (53.7)
Bleeding events (AE regardless of severity grade)	41	15 (36.6)
Neutropenia (AE regardless of severity grade)	41	13 (31.7)
Hypersensitivity response (AE regardless of severity grade)	41	8 (19.5)
Ocular events (AE regardless of severity grade)	41	7 (17.1)

a. The radiological findings were assessed by an independent central review committee; the assessment of the clinical condition and the corticosteroid consumption sub-component was carried out only by the principal investigator.
b. Primary endpoint of the G2201 study
c. Only patients with CR or PR were included in the analysis.

Abbreviations used:
AD = absolute difference; CR = complete response; CTCAE = Common Terminology Criteria for Adverse Events; HR = hazard ratio; n.d. = no data available; CI = confidence interval; MedDRA = Medical Dictionary for Regulatory Activities; N = number of patients evaluated; n = number of patients with (at least one) event; n.a. = not applicable; n.c. = not calculable; n.r. = not reached; PR = partial response; RR = relative risk; SD = stable disease; PD = progressive disease; vs = versus

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

a) Paediatric patients aged 1 year and older with low-grade glioma (LGG) with a BRAF V600E mutation who require systemic therapy

approx. 6-91 patients

b) Paediatric patients aged 1 year and older with high-grade glioma (HGG) with a BRAF V600E mutation who have received at least one prior radiation and/or chemotherapy treatment

Approx. 1–24 patients

3. Requirements for a quality-assured application

The requirements in the product information are to be taken into account. The European Medicines Agency (EMA) provides the contents of the product information (summary of product characteristics, SmPC) for Spexotras (active ingredient: trametinib) agreed upon in the context of the marketing authorisation at the following publicly accessible link (last access: 2 October 2024):

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

Treatment with trametinib should only be initiated and monitored by specialists in paediatrics and adolescent medicine with a focus on neuropaediatrics or paediatric haematology and oncology who are experienced in the treatment of patients with gliomas.

Before taking trametinib combination with dabrafenib, the BRAF V600E mutation must have been detected in patients by a validated test.

4. Treatment costs

Annual treatment costs:

a) Paediatric patients aged 1 year and older with low-grade glioma (LGG) with a BRAF V600E mutation who require systemic therapy

and

b) Paediatric patients aged 1 year and older with high-grade glioma (HGG) with a BRAF V600E mutation who have received at least one prior radiation and/or chemotherapy treatment

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Trametinib	€ 13,198.48 - € 87,989.85
Dabrafenib	€ 14,437.80 - € 108,283.51
Total	€ 27,636.28 - € 196,273.36

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 September 2024)

Costs for additionally required SHI services: not applicable

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

In the context of the designation of medicinal products with new active ingredients pursuant to Section 35a, paragraph 3, sentence 4 SGB V, the following findings are made:

a) Paediatric patients aged 1 year and older with low-grade glioma (LGG) with a BRAF V600E mutation who require systemic therapy

a1) Patients without prior treatment of LGG

The following medicinal products with new active ingredients that can be used in a combination therapy with the assessed medicinal product in the therapeutic indication of the present resolution on the basis of the marketing authorisation under Medicinal Products Act are excluded from the designation, as the G-BA has identified at least considerable additional benefit for the combination with the assessed medicinal product in the present resolution:

Dabrafenib (Finlee)

a2) Patients with previous treatment of LGG

The following medicinal products with new active ingredients that can be used in a combination therapy with dabrafenib in the therapeutic indication of the resolution on the basis of the marketing authorisation under Medicinal Products Act are named (active ingredients and invented names) in accordance with Section 35a, paragraph 3, sentence 4 SGB V:

Dabrafenib (Finlee)

b) Paediatric patients aged 1 year and older with high-grade glioma (HGG) with a BRAF V600E mutation who have received at least one prior radiation and/or chemotherapy treatment

The following medicinal products with new active ingredients that can be used in a combination therapy with trametinib in the therapeutic indication of the resolution on the basis of the marketing authorisation under Medicinal Products Act are named (active ingredients and invented names) in accordance with Section 35a, paragraph 3, sentence 4 SGB V:

Dabrafenib (Finlee)

The designation of combinations exclusively serves the implementation of the combination discount according to Section 130e SGB V between health insurance funds and pharmaceutical companies. 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.

II. **In Annex XIIa of the Pharmaceuticals Directive, the following information shall be added in alphabetical order:**

"Active ingredient of the assessed medicinal product

Trametinib

Resolution according to Section 35a paragraph 3 SGB V from

17 October 2024

Therapeutic indications of the resolution

Low-grade glioma: Trametinib (Spexotras) in combination with dabrafenib is indicated for the treatment of paediatric patients aged 1 year and older with low-grade glioma (LGG) with a BRAF V600E mutation who require systemic therapy.

High-grade glioma: Trametinib (Spexotras) in combination with dabrafenib is indicated for the treatment of paediatric patients aged 1 year and older with high-grade glioma (HGG) with a BRAF V600E mutation who have received at least one prior radiation and/or chemotherapy treatment.

Patient group a2

Paediatric patients aged 1 year and older with low-grade glioma (LGG) with a BRAF V600E mutation who require systemic therapy; patients with previous treatment of LGG

Naming of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V (active ingredients and invented names[2])

Dabrafenib (Finlee)

Period of validity of the designation

Since 17 October 2024

Patient group b

Paediatric patients aged 1 year and older with high-grade glioma (HGG) with a BRAF V600E mutation who have received at least one prior radiation and/or chemotherapy treatment

Naming of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V (active ingredients and invented names[2])

Dabrafenib (Finlee)

Period of validity of the designation

Since 17 October 2024

The designation of combinations exclusively serves the implementation of the combination discount according to Section 130e SGB V between health insurance funds and pharmaceutical companies. 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.

III. The resolution will enter into force on the day of its publication on the website of the G-BA on 17 October 2024.

The justification to this resolution will be published on the website of the G-BA at www.g-ba.de.

Berlin, 17 October 2024

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

Prof. Hecken