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)
Sotorasib (reassessment after the deadline: lung cancer, non-small cell, KRAS G12C mutation, ≥ 1 prior therapy)

of 3 August 2023

At its session on 3 August 2023, 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 is amended as follows:

The information on sotorasib in the version of the resolution of 4 August 2022 (BAnz AT 07.09.2022 B1) last revised on 5 January 2023 remains part of the Pharmaceuticals Directive with the repeal of the limitation for the patient groups b) and c) in accordance with the following changes:

1. **The information for Sotorasib on the date and entry into force of the resolutions is adopted as follows:**

   "Resolution of: 4 August 2022
   Entry into force on: 4 August 2022
   BAnz AT 07.09.2022 B1

   Resolution of: 5 January 2023
   Entry into force on: 5 January 2023
   BAnz AT 10.02.2023 B2

   Resolution of: 3 August 2023
   Entry into force on: 3 August 2023
   BAnz AT DD. MM YYYY Bx“

Therapeutic indication (according to the marketing authorisation of 6 January 2022):

Lumykras as monotherapy is indicated for the treatment of adults with advanced non-small cell lung cancer (NSCLC) with KRAS G12C mutation and who have progressed after at least one prior line of systemic therapy.

Therapeutic indication of the resolution (resolution of 3 August 2023):

See therapeutic indication according to marketing authorisation.

2. The findings under "1. Additional benefit of the medicinal product in relation to the appropriate comparator therapy for the patient populations "b)" and "c)" is adopted as follows:

b) Adults with advanced non-small cell lung cancer (NSCLC) with KRAS p.G12C mutation after first-line therapy with cytotoxic chemotherapy

Appropriate comparator therapy:

- Docetaxel (only for patients with PD-L1 negative tumours)

or

- Pemetrexed (only for patients with PD-L1 negative tumours and except in cases of predominantly squamous histology)

or

- Nivolumab

or

- Pembrolizumab (only for patients with PD-L1 expressing tumours (PD-L1 expression ≥ 1% of tumour cells))

or

- Atezolizumab

or

- Docetaxel in combination with nintedanib (only for patients with PD-L1 negative tumours and adenocarcinoma histology)

Extent and probability of the additional benefit of sotorasib compared to the appropriate comparator therapy:

An additional benefit is not proven.

c) Adults with advanced non-small cell lung cancer (NSCLC) with KRAS p.G12C mutation after first-line therapy with an anti-PD-1/PD-L1 in combination with platinum-containing chemotherapy or after sequential therapy with an anti-PD-1/PD-L1 and platinum-containing chemotherapy

Appropriate comparator therapy:

Patient-individual therapy, taking into account previous therapy and histology with selection of afatinib, pemetrexed, erlotinib, docetaxel, docetaxel in combination with ramucirumab, docetaxel in combination with nintedanib and vinorelbine.

Extent and probability of the additional benefit of sotorasib compared to the appropriate comparator therapy:

c1) Adults for whom docetaxel is the appropriate patient-individual therapy

Hint of a non-quantifiable additional benefit

c2) Adults for whom a therapy other than docetaxel is the appropriate patient-individual therapy

An additional benefit is not proven.

Study results according to endpoints:[1]

b) <u>Adults with advanced non-small cell lung cancer (NSCLC) with KRAS p.G12C mutation after first-line therapy with cytotoxic chemotherapy</u>

No adequate data are available to allow an assessment of the additional benefit.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	∅	No data available.
Morbidity	∅	No data available.
Health-related quality of life	∅	No data available.
Side effects	∅	No data available.

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

1 Data from the dossier assessment of the IQWiG (A23-06) and from the addendum (A23-53), unless otherwise indicated.

c) Adults with advanced non-small cell lung cancer (NSCLC) with KRAS p.G12C mutation after first-line therapy with an anti-PD-1/PD-L1 in combination with platinum-containing chemotherapy or after sequential therapy with an anti-PD-1/PD-L1 and platinum-containing chemotherapy

c1) Adults for whom docetaxel is the appropriate patient-individual therapy

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	↑	Advantages in symptomatology and health status.
Health-related quality of life	n.a.	There are no assessable data.
Side effects	↔	No relevant difference for the benefit assessment.
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		

CodeBreak 200 study: Sotorasib **vs** docetaxel

Study design: randomised, open-label, parallel

Data cut-off: 2 August 2022

Mortality

Endpoint	Sotorasib		Docetaxel		Sotorasib vs docetaxel
	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]
Overall survival					
	171	10.64 [8.94; 13.96] *109 (63.7)*	174	11.30 [9.00; 14.85] *94 (54.0)*	1.010 [0.77; 1.33] 0.94

Morbidity

Endpoint	Sotorasib		docetaxel		Sotorasib vs docetaxel
	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]
Progression-free survival (PFS)[b]					
	171	5.62 [4.27; 7.75] *122 (71.3)*	174	4.47 [3.02; 5.68] *101 (58.0)*	0.663 [0.509; 0.864] 0.003 AD = 1.15
Symptomatology (EORTC QLQ-C30) [b]					
Fatigue	160	3.0 [2.1; 4.3] *104 (65.0)*	130	1.4 [0.8; 1.4] *105 (80.8)*	0.47 [0.35; 0.63] <0.0001
Nausea / vomiting	160	9.1 [5.5; 16.6] *69 (43.1)*	130	5.6 [3.9; 9.9] *56 (43.1)*	0.76 [0.53; 1.11] 0.1583
Pain	160	2.8 [2.1; 4.2] *106 (66.2)*	130	2.1 [1.4; 2.3] *91 (70.0)*	0.77 [0.57; 1.03] 0.0809
Dyspnoea	160	8.3 [5.6; 13.7] *72 (45.0)*	130	3.5 [2.3; 5.0] *68 (52.3)*	0.64 [0.45; 0.91] 0.0113
Insomnia	160	5.9 [4.2; 10.4] *78 (48.8)*	130	3.7 [3.0; 5.6] *66 (50.8)*	0.79 [0.56; 1.11]

Endpoint	Sotorasib		docetaxel		Sotorasib vs docetaxel
	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]
					0.1739
Loss of appetite	160	5.9 [3.5; 9.2] *84 (52.5)*	130	3.5 [2.1; 4.2] *67 (51.5)*	0.68 [0.49; 0.96] 0.0279
Constipation	160	12.8 [6.2; n.r.] *63 (39.4)*	130	2.8 [1.5; 4.9] *73 (56.2)*	0.52 [0.36; 0.74] 0.0002
Diarrhoea	160	2.7 [2.1; 3.5] *94 (58.8)*	130	4.4 [2.1; 9.9] *64 (49.2)*	1.13 [0.81; 1.56] 0.4681
Symptomatology (EORTC QLQ-LC13) [b]					
Dyspnoea	158	3.6 [2.8; 6.2] *93 (58.9)*	124	1.5 [1.4; 2.1] *92 (74.2)*	0.55 [0.40; 0.75] 0.0001
Cough	158	16.6 [11.9; n.r.] *52 (32.9)*	124	4.6 [2.8; n.r.] *52 (41.9)*	0.50 [0.33; 0.76] 0.0010
Haemoptysis	158	n.r. [n.r.; n.r.] *18 (11.4)*	124	n.r. [9.9; n.r.] *21 (16.9)*	0.39 [0.20; 0.78] 0.0058
Chest pain	158	13.1 [6.4; n.c.] *59 (37.3)*	124	7.3 [5.6; n.r.] *48 (38.7)*	0.80 [0.54; 1.18] 0.2592
Pain in arm / shoulder	158	5.2 [4.0; 9.0] *85 (53.8)*	124	14.1 [3.7; 14.1] *49 (39.5)*	1.11 [0.77; 1.61] 0.5632
Other pain	158	4.2 [2.8; 7.8] *90 (57.0)*	124	3.0 [2.3; 4.0] *68 (54.8)*	0.82 [0.59; 1.15] 0.2514
Painkiller use	137	11.0 [7.6; n.r.] *48 (35.0)*	101	n.r. [3.5; n.r.] *32 (31.7)*	0.86 [0.53; 1.39] 0.5322
Alopecia	158	n.r. [19.4; n.r.] *32 (20.3)*	124	0.7 [0.7; 0.8] *110 (88.7)*	0.07 [0.05; 0.12] < 0.0001

Endpoint	Sotorasib		docetaxel		Sotorasib vs docetaxel
	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]
Peripheral neuropathy	158	10.3 [5.5; n.r.] *65 (41.1)*	124	3.5 [2.8; 5.6] *66 (53.2)*	0.61 [0.42; 0.87] 0.0063
Wounded mouth	158	n.r. [14.5; n.r.] *42 (26.6)*	124	4.4 [2.8; n.r.] *57 (46.0)*	0.39 [0.26; 0.60] < 0.0001
Dysphagia	158	n.r. [18.7; n.r.] *45 (28.5)*	124	6.9 [4.7; n.r.] *46 (37.1)*	0.61 [0.40; 0.93] 0.0210
BPI-SF [b]					
Worst pain	163	2.2 [1.4; 3.4] *113 (69.3)*	128	1.5 [1.4; 2.2] *94 (73.4)*	0.76 [0.57; 1.01] 0.0605
Medium pain intensity	163	5.4 [4.2; 8.3] *87 (53.4)*	128	3.5 [2.7; 7.6] *65 (50.8)*	0.88 [0.63; 1.23] 0.4651
Impairment due to pain	163	7.5 [4.2; 9.8] *83 (50.9)*	128	4.3 [2.8; 7.6] *60 (46.9)*	0.80 [0.57; 1.13] 0.2119
Burden due to therapy (FACT-G GP5)					
	163	2.8 [2.2; 3.6] *92 (56.4)*	128	1.4 [0.8; 1.4] *96 (75.0)*	0.52 [0.38; 0.70] < 0.0001
Health status (PGI-C)					
Cough	143	n.r. [3.5; n.r.] *5 (3.5)*	110	4.4 [3.3; n.r.] *19 (17.3)*	0.24 [0.09; 0.66] 0.0028
Shortness of breath	143	n.r. [n.r.; n.r.] *9 (6.3)*	110	4.4 [3.0; n.r.] *28 (25.5)*	0.26 [0.12; 0.56] 0.0002
Chest pain	143	n.r. [n.r.; n.r.] *4 (2.8)*	110	n.r. [n.r.; n.r.] *7 (6.4)*	0.52 [0.14; 1.84] 0.2999
Health status (EQ-5D VAS)[d]					

Endpoint	Sotorasib		docetaxel		Sotorasib vs docetaxel
	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]
	160	5.2 [3.6; 10.4] *83 (51.9)*	138	1.6 [1.0; 3.3] *83 (60.1)*	0.55 [0.40; 0.76] <0.001 AD = 3.6

Health-related quality of life

Endpoint	Sotorasib		docetaxel		Sotorasib vs docetaxel
	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]
Functional scales (EORTC QLQ-C30)					
No suitable data[c]					

Side effects

Endpoint	Sotorasib		docetaxel		Sotorasib vs docetaxel
	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]
Total adverse events (presented additionally)[e]					
	169	0.72 [0.49; 0.82] *165 (97.6)*	151	0.16 [0.13; 0.20] *148 (98.0)*	-
Serious adverse events (SAE)[e]					
	169	9.86 [7.29; 15.34] *82 (48.5)*	151	7.10 [3.68; n.r.] *66 (43.7)*	0.73 [0.52; 1.01] 0.061
Severe adverse events (CTCAE grade ≥ 3)[e]					
	169	3.35 [2.53; 4.73] *114 (67.5)*	151	2.96 [1.38; 4.14] *90 (59.6)*	0.80 [0.61; 1.06] 0.13
Discontinuation due to AEs					
	169	n.r. *28 (16.6)*	151	n.r. [13.40; n.c.] *24 (15.9)*	0.79 [0.45; 1.39] 0.40
Specific adverse events					
Diseases of the liver (SMQ[g], severe AEs[f])	169	n.r. *33 (19.5)*	151	n.r. *2 (1.3)*	13.92 [3.3; 58.76] < 0.001

Endpoint	Sotorasib		docetaxel		Sotorasib vs docetaxel
	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]
Interstitial lung disease (SMQ[g], severe AEs[f])	169	n.r. *2 (1.2)*	151	n.r. *4 (2.6)*	0.31 [0.06; 1.55] 0.17
Stomatitis (PT, AE)	169	n.r. *3 (1.8)*	151	n.r. *19 (12.6)*	0.13 [0.04; 0.41] < 0.001
Chest pain (PT, AE)	169	n.r. *15 (8.9)*	151	n.r. *2 (1.3)*	4.3 [0.91; 20.30] 0.038
Peripheral oedema (PT, AE)	169	n.r. *5 (3.0)*	151	n.r. [16.53: n.r.] *19 (12.6)*	0.14 [0.05; 0.40] < 0.001
Fever (PT, AE)	169	n.r. *11 (6.5)*	151	n.r. *20 (13.2)*	0.32 [0.15; 0.67] 0.002
Peripheral neuropathy (PT, AE)	169	n.r. *1 (0.6)*	151	n.r. *16 (10.6)*	0.03 [0; 0.29] < 0.001
Alopecia (PT, AE)	169	n.r. *3 (1.8)*	151	n.r. *35 (23.2)*	0.06 [0.02; 0.21] < 0.001
Blood and lymphatic system disorders (SOC, severe AEs[e])	169	n.r. *10 (5.9)*	151	n.r. *27 (17.9)*	0.25 [0.13; 0.50] < 0.001
Infections and infestations (SOC, severe AEs[f])	169	n.r. *10 (5.9)*	151	18.37 [18.37; n.r.] *27 (17.9)*	0.20 [0.10; 0.40] < 0.001
Diarrhoea (PT, severe AEs:[f])	169	n.r. *23 (13.6)*	151	n.r. *4 (2.6)*	4.75 [1.65; 13.69] 0.002
Fatigue (PT, severe AEs:[f])	169	n.r. *4 (2.4)*	151	n.r. *9 (6.0)*	0.31 [0.10; 1.05] 0.043

Endpoint	Sotorasib		docetaxel		Sotorasib vs docetaxel
	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]

[a] Indication of absolute difference (AD) only in case of statistically significant difference; own calculation
[b] Information from the dossier of the pharmaceutical company
[c] Weighing the extent of the difference between the treatment arms in terms of the percentage of patients included in the analysis and the magnitude of the effects on the quality of life endpoints.
[d] Time to deterioration by ≥ 15 points (without death)
[e] excluding events deemed by the pharmaceutical company to be progression of the underlying disease (any PTs containing the terms metastasis / metastases, tumour pain, NSCLC / non-small cell lung cancer or adenocarcinoma of the lung)
[f] Operationalised as CTCAE grade ≥ 3
[g] SMQ broad scope

Abbreviations used:
AD = absolute difference; BPI-SF = Brief Pain Inventory - Short Form; CTCAE = Common Terminology Criteria for Adverse Events; EORTC = European Organisation for Research and Treatment of Cancer; QLQ C30 = Quality-of-life Questionnaire Core 30; QLQ-LC13 = Quality-of-life Questionnaire Core 13; FACT-G GP5 = Functional Assessment of Cancer Therapy Tool General form General Population 5; HR = hazard ratio; CI = confidence interval; MedDRA = Medical Dictionary of Drug Regulatory Activities; N = number of patients evaluated; n = number of patients with (at least one) event; n.c. = not calculable; n.r. = not reached; PGIC = Patient Global Impression of Change; PT = preferred term; RCT = randomised controlled trial; SMQ = standardised MedDRA query; SOC = system organ class; SAE = serious adverse event; AE = adverse event; VAS = visual analogue scale; vs = versus

c2) Adults for whom a therapy other than docetaxel is the appropriate patient-individual therapy

No adequate data are available to allow an assessment of the additional benefit.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	∅	No data available.
Morbidity	∅	No data available.
Health-related quality of life	∅	No data available.
Side effects	∅	No data available.

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

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

b) Adults with advanced non-small cell lung cancer (NSCLC) with KRAS p.G12C mutation after first-line therapy with cytotoxic chemotherapy

approx. 60 - 130 patients

c) Adults with advanced non-small cell lung cancer (NSCLC) with KRAS p.G12C mutation after first-line therapy with an anti-PD-1/PD-L1 in combination with platinum-containing chemotherapy or after sequential therapy with an anti-PD-1/PD-L1 and platinum-containing chemotherapy

approx. 420 - 910 patients

4. 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 Lumykras (active ingredient: sotorasib) at the following publicly accessible link (last access: 15 May 2023):

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

Treatment with sotorasib should only be initiated and monitored by specialists in internal medicine, haematology and oncology who are experienced in the treatment of patients with non-small cell lung cancer, as well as specialists in internal medicine and pulmonology or specialists in pulmonary medicine and other doctors from specialist groups participating in the Oncology Agreement.

This medicinal product was approved under "special conditions". This means that further evidence of the benefit of the medicinal product is anticipated. The European Medicines Agency EMA will evaluate new information on this medicinal product at a minimum once per year and update the product information where necessary.

Testing KRAS G12C mutation

The presence of a KRAS G12C mutation must be confirmed by a validated test prior to start of therapy.

5. Treatment costs

Annual treatment costs:

b) Adults with advanced non-small cell lung cancer (NSCLC) with KRAS p.G12C mutation after first-line therapy with cytotoxic chemotherapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Sotorasib	€ 52,955.42
Appropriate comparator therapy:	
Docetaxel (only for patients with PD-L1 negative tumours)	
docetaxel	€ 8,522.69
Pemetrexed[2]	
Pemetrexed	€ 18,931.20
Additionally required SHI costs	€ 129.97 - € 180.78
Nivolumab	
Nivolumab	€ 73,034.06
Pembrolizumab	
Pembrolizumab	€ 93,514.21
Atezolizumab	

[2] only for patients with PD-L1 negative tumours and except in the case of predominantly squamous cell histology

Designation of the therapy	Annual treatment costs/ patient
Atezolizumab	€ 67,863.65 - € 71,692.26
Docetaxel in combination with nintedanib[3]	
docetaxel	€ 8,522.69
Nintedanib	€ 30,728.05
Total	€ 39,250.75

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 July 2023)

c) Adults with advanced non-small cell lung cancer (NSCLC) with KRAS p.G12C mutation after first-line therapy with an anti-PD-1/PD-L1 in combination with platinum-containing chemotherapy or after sequential therapy with an anti-PD-1/PD-L1 and platinum-containing chemotherapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Sotorasib	€ 52,955.42
Appropriate comparator therapy:	
Patient-individual therapy, taking into account previous therapy and histology with selection of afatinib, pemetrexed, erlotinib, docetaxel, docetaxel in combination with ramucirumab, docetaxel in combination with nintedanib and vinorelbine	
Afatinib	
Afatinib	€ 29,625.23
Pemetrexed	
Pemetrexed	€ 18,931.20
Additionally required SHI costs	€ 129.97 - € 180.78
Erlotinib	
Erlotinib	€ 9,849.04
Docetaxel in combination with ramucirumab	
docetaxel	€ 8,522.69
Ramucirumab	€ 54,467.74
Total	€ 62,990.44
Docetaxel in combination with nintedanib	
docetaxel	€ 8,522.69
Nintedanib	€ 30,728.05
Total	€ 39,250.75

[3] only for patients with PD-L1 negative tumours and adenocarcinoma histology

Designation of the therapy	Annual treatment costs/ patient
Vinorelbine	
Vinorelbine	€ 7,061.95 - € 8,513.24

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 July 2023)

Other SHI services:

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Appropriate comparator therapy:					
Atezolizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	13.0 - 26.1	€ 1,300 - € 2,610
Docetaxel (monotherapy or combination therapy)	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
Nivolumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	26.1	€ 2,610
Pembrolizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	8.7 - 17.4	€ 870 - € 1,740
Pemetrexed	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
Ramucirumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	17.4	€ 1,740
Vinorelbine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	52.1	€ 5,210

6. 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 Sotorasib

Medicinal products with new active ingredients pursuant to Section 35a, paragraph 3, sentence 4 SGB V are medicinal products with the following new active ingredients which, on

the basis of the marketing authorisation under Medicinal Products Act, can be used in a combination therapy with sotorasib for the treatment of adults with advanced non-small cell lung cancer (NSCLC) with KRAS G12C mutation in whom disease progression has been identified after at least one prior systemic therapy:

b) Adults with advanced non-small cell lung cancer (NSCLC) with KRAS p.G12C mutation after first-line therapy with cytotoxic chemotherapy

- No designation of medicinal products with new active ingredients that can be used in combination therapy pursuant to Section 35a, paragraph 3, sentence 4 SGB V, as the active ingredient to be assessed is an active ingredient authorised in monotherapy.

c) Adults with advanced non-small cell lung cancer (NSCLC) with KRAS p.G12C mutation after first-line therapy with an anti-PD-1/PD-L1 in combination with platinum-containing chemotherapy or after sequential therapy with an anti-PD-1/PD-L1 and platinum-containing chemotherapy

- No designation of medicinal products with new active ingredients that can be used in combination therapy pursuant to Section 35a, paragraph 3, sentence 4 SGB V, as the active ingredient to be assessed is an active ingredient authorised in monotherapy.

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. The resolution will enter into force on the day of its publication on the website of the G-BA on 3 August 2023.

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

Berlin, 3 August 2023

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

Prof. Hecken