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)
Axicabtagene ciloleucel (reassessment after the deadline: diffuse large B-cell lymphoma, high-grade B-cell lymphoma, after 1 prior therapy, relapsed within 12 months or refractory)

of 19 December 2024

At its session on 19 December 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 is amended as follows:

The information on Axicabtagene ciloleucel in the version of the resolution of 21 December 2023 (BAnz AT 07.03.2024 B4) remains part of the Pharmaceuticals Directive with the repeal of the limitation for patient group "a)" in accordance with the following changes:

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

"Resolution of: 21 December 2023
Entry into force on: 21 December 2023
BAnz AT 07.03.2024 B4

Resolution of: 19 December 2024
Entry into force on: 21 December 2024
Federal Gazette, BAnz AT DD. MM YYYY Bx“

New therapeutic indication (according to the marketing authorisation of 14 October 2022):

Yescarta is indicated for the treatment of adult patients with diffuse large B-cell lymphoma (DLBCL) and high-grade B-cell lymphoma (HGBL) that relapses within 12 months from completion of, or is refractory to, first-line chemoimmunotherapy.

Therapeutic indication of the resolution (resolution of 19 December 2024):

Yescarta is indicated for the treatment of adult patients with diffuse large B-cell lymphoma (DLBCL) and high-grade B-cell lymphoma (HGBL) who are eligible for high-dose therapy and who relapse within 12 months from completion of, or are refractory to, first-line therapy.

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

a) Adults with diffuse large B-cell lymphoma (DLBCL) and high-grade B-cell lymphoma (HGBL) who are eligible for high-dose therapy and who relapse within 12 months from completion of, or are refractory to, first-line therapy

Appropriate comparator therapy:

Induction therapy with

- R-GDP (rituximab, gemcitabine, cisplatin, dexamethasone)

or

- R-ICE (rituximab, ifosfamide, carboplatin, etoposide)

or

- R-DHAP (rituximab, dexamethasone, cytarabine, cisplatin)[1]

followed by high-dose therapy with autologous or allogeneic stem cell transplantation if there is a response to induction therapy

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

Hint for a minor additional benefit.

[1] Taking into account the requirements of the Directive on Inpatient Treatment Methods (last revised 20 November 2024): Section 4, paragraph 2, number 4

Study results according to endpoints:[2]

a) Adults with diffuse large B-cell lymphoma (DLBCL) and high-grade B-cell lymphoma (HGBL) who are eligible for high-dose therapy and who relapse within 12 months from completion of, or are refractory to, first-line therapy

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	↑	Advantage in overall survival.
Morbidity	↑	Advantage in the endpoint failure of the curative therapeutic approach (event-free survival).
Health-related quality of life	n.a.	There are no assessable data.
Side effects	↔	No relevant differences for the benefit assessment. Advantages and disadvantages in the specific AEs, in detail.

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

ZUMA-7 study:

- open-label, randomised phase III study
- Axicabtagene ciloleucel versus induction chemotherapy with R-ICE, R-DHAP, R-ESHAP or R-GDP followed by high-dose therapy (HDT) with autologous stem cell transplantation (autoSCT)
- 1st data cut-off: 18 March 2021
- 2nd data cut-off: 25 January 2023

[2] Data from the dossier assessment of the IQWiG (A24-71) and from the addendum (A24-109), unless otherwise indicated.

Mortality

Endpoint	Axicabtagene ciloleucel		Induction therapy + HDT + autoSCT		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					
	180	n.r. [28.6; n.c.] *82 (46)*	179	31.1 [17.1; n.c.] *95 (53)*	0.726 [0.540; 0.98] 0.017

Morbidity

Endpoint	Axicabtagene ciloleucel		Induction therapy + HDT + autoSCT		Intervention vs control
	N	Median time in months [95% CI] *Patients with event n (%)*	N	Median time in months [95% CI] *Patients with event n (%)*	RR[c] [95% CI] p value Absolute difference (AD)[b]
Failure of the curative therapeutic approach (mEFS1[3] – data cut-off 18.03.2021)					
Event rate[b]	180	– 108 (60)	179	– 133 (74)	0.81 [0.70; 0.94] < 0.004
Death from any cause	180	– 12 (7)	179	– 7 (4)	
Progression according to blinded centralised assessment	180	– 82 (46)		– 72 (40)	
Failure to achieve a CR or PR according to blinded centralised assessment by day 50 in the	180	–	179	– 33 (18)	

[3] Post-hoc modified EFS

Endpoint	Axicabtagene ciloleucel		Induction therapy + HDT + autoSCT		Intervention vs control
	N	Median time in months [95% CI] *Patients with event n (%)*	N	Median time in months [95% CI] *Patients with event n (%)*	RR[c] [95% CI] p value Absolute difference (AD)[b]
comparator arm					
Failure to achieve a CR by day 150 according to blinded centralised assessment (or, if applicable, by month 9)	180	– 8 (4)	179	– 1 (1)	
Start of new lymphoma therapy due to SD/PD according to principal investigator	180	– 6 (3)	179	– 20 (11)	
Failure of the curative therapeutic approach (mEFS2[3] – data cut-off 18.03.2021)					
Event rate[b]	180	– 106 (59)	179	– 125 (70)	0.84 [0.72; 0.99]; 0.033
Death from any cause	180	– 15 (8)	179	– 18 (10)	
Disease progression according to blinded centralised assessment	180	– 82 (46)	179	– 72 (40)	
Failure to achieve a CR or PR according to blinded centralised assessment by	180	–	179	– 33 (18)	

Endpoint	Axicabtagene ciloleucel		Induction therapy + HDT + autoSCT		Intervention vs control
	N	Median time in months [95% CI] *Patients with event n (%)*	N	Median time in months [95% CI] *Patients with event n (%)*	RR[c] [95% CI] p value Absolute difference (AD)[b]
day 50 in the comparator arm					
Failure to achieve a CR on day 150 according to blinded centralised assessment (or, if applicable, by month 9)	180	– 8 (4)	179	– 1 (1)	
Start of a new lymphoma therapy with previous SD after blinded centralised assessment	180	– 1 (1)	179	– 1 (1)	
EORTC QLQ-C30 (symptomatology)					
No suitable data[d]					
Health status (EQ-5D VAS)					
No suitable data[d]					

Health-related quality of life

Endpoint	Axicabtagene ciloleucel		Induction therapy + HDT + autoSCT		Intervention vs control
	N	Median time in months [95% CI] *Patients with event n (%)*	N	Median time in months [95% CI] *Patients with event n (%)*	Effect estimator [95% CI] p value Absolute difference (AD)
EORTC QLQ-C30	No suitable data[d]				

Side effects

Endpoint	Axicabtagene ciloleucel		Induction therapy + HDT + autoSCT		Intervention vs control
	N	Median in months [95% CI] *Patients with event n (%)*	N	Median in months [95% CI] *Patients with event n (%)*	HR [95% CI] p value Absolute difference (AD)[a]
Adverse events in total					
	178	0.5 [0.3; 0.6] 178 (100)	168	0.1 [0.1; 0.1] 168 (100)	-
Serious adverse events (SAE)					
	178	3.6 [1.4; 9.3] 106 (60)	168	4.9 [3.3; 8.6] 75 (45)	1.07 [0.79; 1.45]; 0.677
Severe adverse events (CTCAE grade 3 or 4)					
	178	0.9 [0.8; 1.0] 164 (92)	168	0.5 [0.4; 0.5] 139 (83)	0.93 [0.74; 1.17]; 0.508
Therapy discontinuation due to adverse events					
	178	n.d. 4 (2.2)	168	n.d. 2 (1.2)	n.d.
Specific adverse events					
Cytokine release syndrome	No suitable data				
Severe neurological toxicity	178	n.r. 41 (23)	168	32.2 [n.c.; n.c.] 15 (9)	2.70 [1.47; 4.97]; < 0.001

Severe infections	178	10.9 [5.7; 27.1] 37 (21)	168	19.9 [n.c.; n.c.] 20 (12)	1.08 [0.61; 1.93]; 0.790
Secondary malignancies	No suitable data				
Ear and labyrinth disorders (SOC, AEs)	178	n.r. 5 (3)	168	n.r. 18 (11)	0.23 [0.09; 0.63]; 0.002
Mucosa inflammation (PT, AEs)	178	n.r. 1 (1)	168	7.0 [4.9; n.c.] 16 (10)	0.04 [0.01; 0.32]; < 0.001
Cough (PT, AEs)	178	n.r. 47 (26)	168	n.r. 18 (11)	2.46 [1.43; 4.24]; < 0.001
Hiccup (PT, AEs)	178	n.r. 9 (5)	168	n.r. 21 (13)	0.36 [0.16; 0.78]; 0.007
Hypoxia (PT, AEs)	178	n.r. 38 (21)	168	n.r. 13 (8)	2.80 [1.49; 5.26]; < 0.001
Febrile neutropenia (PT, SAEs)	178	28.3 [12.1; n.c.] 6 (3)	168	n.r. 22 (13)	0.09 [0.03; 0.32]; < 0.001
Neutropenia (PT, severe AEs)	178	n.r. [3.1; n.c.] 74 (42)	168	n.r. 28 (17)	2.71 [1.75; 4.19]; < 0.001
Thrombocytopenia (PT, severe AEs)	178	n.r. 14 (8)	168	n.r. 37 (22)	0.29 [0.16; 0.55]; < 0.001
Gastrointestinal disorders (SOC, severe AEs)	178	12.0 [n.c.; n.c.] 21 (12)	168	5.0 [5.0; n.c.] 30 (18)	0.53 [0.30; 0.94]; 0.026
General disorders and administration site conditions (SOC, severe AEs)	178	6.0 [n.c.; n.c.] 30 (17)	168	7.1 [4.9; n.c.] 13 (8)	2.20 [1.12; 4.31]; 0.018
Psychiatric disorders (SOC, severe AEs)	178	27.6 [n.c.; n.c.] 18 (10)	168	n.r. 2 (1)	7.87 [1.82; 34.10]; 0.001
Hypotension (PT, severe AEs)	178	n.r. 21 (12)	168	n.r. 5 (3)	3.88 [1.46; 10.31]; 0.003

[a] Indication of absolute difference (AD) only in case of statistically significant difference; own calculation
[b] Individual components are shown in the rows below; since only the qualifying events are included in the event rate (total), effect estimators of the individual components are not shown.
[c] IQWiG calculation
[d] Missing data and high differential percentage of patients missing from the evaluation

Abbreviations used:
AD = absolute difference; CR: complete response; CTCAE: Common Terminology Criteria for Adverse Events; EFS: event-free survival; EORTC: European Organisation for Research and Treatment of Cancer; HDCT: high-dose chemotherapy; HR: hazard ratio; n.d.: no data available; CI: confidence interval; mEFS: modified EFS; n: number of patients with (at least 1) event; N: number of patients evaluated; n.c.: not calculable; n.r. = not reached; PD: progressive disease; PR: partial response; PT: preferred term; QLQ-C30: Quality of Life Questionnaire-Core 30; RCT: randomised controlled trial; SD: stable disease; SOC: system organ class; SAE: serious adverse event; SCT: stem cell transplantation; AE: adverse event; VAS: visual analogue scale; vs = versus

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

a) Adults with diffuse large B-cell lymphoma (DLBCL) and high-grade B-cell lymphoma (HGBL) who are eligible for high-dose therapy and who relapse within 12 months from completion of, or are refractory to, first-line therapy

Approx. 800 – 1,130 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 Yescarta (active ingredient: axicabtagene ciloleucel) at the following publicly accessible link (last access: 4 December 2024):

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

In accordance with the EMA requirements regarding additional risk minimisation measures, the pharmaceutical company must provide training material and a patient pass. Training material for all healthcare professionals who will prescribe, dispense, and administer axicabtagene ciloleucel includes instructions for identifying, treating, and monitoring cytokine release syndrome and neurological side effects. It also includes instructions on the cell thawing process, availability of 1 dose of tocilizumab at the point of treatment, provision of relevant information to patients, and full and appropriate reporting of side effects.

The patient training programme should explain the risks of cytokine release syndrome and serious neurologic side effects, the need to report symptoms immediately to the treating

physician, to remain close to the treatment facility for at least 4 weeks after infusion of axicabtagene ciloleucel, and to carry the patient emergency card at all times.

Axicabtagene ciloleucel must be used in a qualified treatment facility. For the infusion of axicabtagene ciloleucel in the present therapeutic indication, the quality assurance measures for the use of CAR-T cells in B-cell neoplasms apply (ATMP Quality Assurance Guideline, Annex 1).

A Direct Healthcare Professional Communication ("Rote-Hand-Brief") which reports on the occurrence of secondary malignancies of T-cell origin, including chimeric antigen receptor (CAR)-positive malignancies, is available for the currently approved CD19- or BCMA-targeted CAR T-cell therapies. Patients who have been treated with CAR-T cell products should therefore be monitored throughout their lives for the occurrence of secondary malignancies.

5. Treatment costs

Annual treatment costs:

The costs for the first year of treatment are shown for the cost representation in the resolution.

a) Adults with diffuse large B-cell lymphoma (DLBCL) and high-grade B-cell lymphoma (HGBL) who are eligible for high-dose therapy and who relapse within 12 months from completion of, or are refractory to, first-line therapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Axicabtagene ciloleucel	€ 272,000.00
Additionally required SHI costs	*€ 767.54*
Appropriate comparator therapy:	
Induction chemotherapy followed by high-dose chemotherapy with autologous stem cell transplantation if there is a response to induction chemotherapy	
Induction chemotherapies	
R-GDP (rituximab + gemcitabine + dexamethasone + cisplatin); 2-3 cycles	
Rituximab	€ 5,427.45 - € 8,482.03
Gemcitabine	€ 734.20 - € 1,101.30
Dexamethasone	€ 44.29 - € 79.59
Cisplatin	€ 230.94 - € 346.41
R-GDP	€ 6,436.88 - € 8,999.88
Additionally required SHI costs	*€ 127.33 - € 164.41*
R-ICE (rituximab + ifosfamide + carboplatin + etoposide); 2-3 cycles including a single dose of rituximab before the start of treatment	
Rituximab	€ 8,482.03 - € 10,854.90
Ifosfamide	€ 671.48 - € 1,007.22
Carboplatin	€ 633.30 - € 822.60 (2 cycles)

Designation of the therapy	Annual treatment costs/ patient
	– € 949.95 - € 1,233.90 (3 cycles)
Etoposide	€ 459.30 - € 688.95
R-ICE	€ 9,236.74 - € 9,426.28 (2 cycles) – € 13,501.14 - € 13,785.45 (3 cycles)
Additionally required SHI costs	*€ 162.06 - € 420.11*
R-DHAP (rituximab + dexamethasone + cytarabine + cisplatin); 2-3 cycles including optional single dose of rituximab before the start of treatment	
Rituximab	€ 5,427.45 - € 10,854.90
Dexamethasone	€ 44.29 - € 79.59
Cytarabine	€ 575.52 - € 863.28
Cisplatin	€ 285.96 - € 428.94
R-DHAP	€ 6,333.22 - € 12,226.71
Additionally required SHI costs	*€ 127.33 - € 164.41*
High-dose chemotherapy with autologous stem cell transplantation	
High-dose chemotherapy with autologous stem cell transplantation	€ 41,096.51
Total	
R-GDP induction chemotherapy + High-dose chemotherapy with autologous stem cell transplantation	€ 47,533.39 - € 50,096.39
Additionally required SHI costs	*€ 127.33 - € 164.41*
R-ICE induction chemotherapy + High-dose chemotherapy with autologous stem cell transplantation	€ 50,333.25 - € 50,522.79 (2 cycles R-ICE) – € 54,597.65 - € 54,881.96 (3 cycles R-ICE)
Additionally required SHI costs	*€ 162.06 - € 420.11*
R-DHAP induction chemotherapy + High-dose chemotherapy with autologous stem cell transplantation	€ 47,429.73 - € 53,323.22
Additionally required SHI costs	*€ 127.33 - € 164.41*
Induction chemotherapy followed by *high-dose chemotherapy with allogeneic stem cell transplantation if there is a response to induction chemotherapy*	
Induction chemotherapies	
R-GDP (rituximab + gemcitabine + dexamethasone + cisplatin); 2-3 cycles	
Rituximab	€ 5,427.45 - € 7,472.58
Gemcitabine	€ 734.20 - € 1,101.30
Dexamethasone	€ 44.29 - € 79.59

Designation of the therapy	Annual treatment costs/ patient
Cisplatin	€ 230.94 - € 346.41
R-GDP	€ 6,436.88 - € 8,999.88
Additionally required SHI costs	*€ 127.33 - € 164.41*
R-ICE (rituximab + ifosfamide + carboplatin + etoposide); 2-3 cycles including a single dose of rituximab before the start of treatment	
Rituximab	€ 7,472.58 - € 10,854.90
Ifosfamide	€ 671.48 - € 1,007.22
Carboplatin	€ 633.38 - € 822.92 (2 cycles) – € 950.07 - € 1,234.38 (3 cycles)
Etoposide	€ 459.30 - € 688.95
R-ICE	€ 9,236.74 - € 9,426.28 (2 cycles) – € 13,501.14 - € 13,785.45 (3 cycles)
Additionally required SHI costs	*€ 162.06 - € 420.11*
R-DHAP (rituximab + dexamethasone + cytarabine + cisplatin); 2-3 cycles including optional single dose of rituximab before the start of treatment	
Rituximab	€ 5,427.45 - € 10,854.90
Dexamethasone	€ 44.29 - € 79.59
Cytarabine	€ 575.52 - € 863.28
Cisplatin	€ 285.96 - € 428.94
R-DHAP	€ 6,333.22 - € 12,226.71
Additionally required SHI costs	*€ 127.33 - € 164.41*
High-dose chemotherapy with allogeneic stem cell transplantation	
High-dose chemotherapy with allogeneic stem cell transplantation	€ 60,148.72
Total	
R-GDP induction chemotherapy + High-dose chemotherapy with allogeneic stem cell transplantation	€ 66,585.60 - € 69,148.60
Additionally required SHI costs	*€ 127.33 - € 164.41*
R-ICE induction chemotherapy + High-dose chemotherapy with allogeneic stem cell transplantation	€ 69,385.46 - € 69,575.00 (cycles R-ICE) – € 73,649.86 - € 73,934.17 (3 cycles R-ICE)
Additionally required SHI costs	*€ 162.06 - € 420.11*
R-DHAP induction chemotherapy + High-dose chemotherapy with allogeneic stem cell transplantation	€ 66,481.94 - € 72,375.43

Designation of the therapy	Annual treatment costs/ patient
Additionally required SHI costs	*€ 127.33 - € 164.41*

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 December 2024)

Other SHI services:

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Medicinal product to be assessed					
Axicabtagene ciloleucel - Lymphocyte depletion					
Cyclophosphamide	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	3	3.0	€ 300
Fludarabine	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	3	3.0	€ 300
Appropriate comparator therapy					
Induction chemotherapy followed by high-dose chemotherapy with autologous stem cell transplantation if there is a response to induction chemotherapy					
Induction chemotherapies					
R-GDP (rituximab + gemcitabine + dexamethasone + cisplatin); 2-3 cycles					
Rituximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	2.0 – 3.0	€ 200 – € 300
Gemcitabine	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	2	4.0 – 6.0	€ 400 – € 600

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Cisplatin	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	1	2.0 – 3.0	€ 200 – € 300
R-ICE (rituximab + ifosfamide + carboplatin + etoposide); 2-3 cycles including a single dose of rituximab before the start of treatment					
Rituximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	3.0 – 4.0	€ 300 – € 400
Ifosfamide	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	1	2.0 – 3.0	€ 200 – € 300
Carboplatin	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	1	2.0 – 3.0	€ 200 – € 300
Etoposide	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	3	6.0 – 9.0	€ 600 – € 900
Mesna	Surcharge for production of other parenteral solutions	€ 54	2	4.0 – 6.0	€ 216 - € 324
R-DHAP (rituximab + dexamethasone + cytarabine + cisplatin); 2-3 cycles including optional single dose of rituximab before the start of treatment					
Rituximab	Surcharge for the preparation of a parenteral solution	€ 100	1	2.0 – 4.0	€ 200 – € 400

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
	containing monoclonal antibodies				
Cytarabine	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	2	4.0 – 6.0	€ 400 – € 600
Cisplatin	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	1	2.0 – 3.0	€ 200 – € 300
Induction chemotherapy followed by high-dose chemotherapy with allogeneic stem cell transplantation if there is a response to induction chemotherapy					
Induction chemotherapies					
R-GDP (rituximab + gemcitabine + dexamethasone + cisplatin); 2-3 cycles					
Rituximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	2.0 – 3.0	€ 200 – € 300
Gemcitabine	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	2	4.0 – 6.0	€ 400 – € 600
Cisplatin	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	1	2.0 – 3.0	€ 200 – € 300
R-ICE (rituximab + ifosfamide + carboplatin + etoposide); 2-3 cycles including a single dose of rituximab before the start of treatment					
Rituximab	Surcharge for the preparation of a	€ 100	1	3.0 – 4.0	€ 300 – € 400

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
	parenteral solution containing monoclonal antibodies				
Ifosfamide	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	1	2.0 – 3.0	€ 200 – € 300
Carboplatin	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	1	2.0 – 3.0	€ 200 – € 300
Etoposide	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	3	6.0 – 9.0	€ 600 – € 900
Mesna	Surcharge for production of other parenteral solutions	€ 54	2	4.0 – 6.0	€ 216 - € 324
R-DHAP (rituximab + dexamethasone + cytarabine + cisplatin); 2-3 cycles including optional single dose of rituximab before the start of treatment					
Rituximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	2.0 – 4.0	€ 200 – € 400
Cytarabine	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	2	4.0 – 6.0	€ 400 – € 600

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Cisplatin	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	1	2.0 – 3.0	€ 200 – € 300

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 December 2024)

6. 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) Adults with diffuse large B-cell lymphoma (DLBCL) and high-grade B-cell lymphoma (HGBL) who are eligible for high-dose therapy and who relapse within 12 months from completion of, or are refractory to, first-line therapy

– No medicinal product with new active ingredients that can be used in a combination therapy and fulfils the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

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 19 December 2024.

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

Berlin, 19 December 2024

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

Prof. Hecken