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
Odronextamab (diffuse large B-cell lymphoma (DLBCL), after ≥ 2 previous therapies)

of 22 January 2026

At their session on 22 January 2026, 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 Odronextamab as follows:

Odronextamab

Resolution of: 22 January 2026
Entry into force on: 22 January 2026
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 22 August 2024):

Ordspono as monotherapy is indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (r/r DLBCL) after two or more lines of systemic therapy.

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

See therapeutic indication according to marketing authorisation.

1. Additional benefit of the medicinal product in relation to the appropriate comparator therapy

a) Adults with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy who are eligible for CAR-T cell therapy or stem cell transplantation

Appropriate comparator therapy:

Individualised therapy with selection of

- tisagenlecleucel,
- axicabtagene ciloleucel,
- lisocabtagene maraleucel,
- an induction therapy with
  - R-GDP (rituximab, gemcitabine, dexamethasone, cisplatin) *or*
  - R-DHAP (rituximab, dexamethasone, cisplatin, cytarabine) *or*
  - R-ICE (rituximab, ifosfamide, carboplatin, etoposide)

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

- an induction therapy with
  - R-GDP (rituximab, gemcitabine, dexamethasone, cisplatin) *or*
  - R-DHAP (rituximab, dexamethasone, cisplatin, cytarabine) *or*
  - R-ICE (rituximab, ifosfamide, carboplatin, etoposide)

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

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

An additional benefit is not proven.

b) Adults with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy who are not eligible for CAR-T cell therapy and stem cell transplantation

Appropriate comparator therapy:

- polatuzumab vedotin in combination with bendamustine and rituximab
  or
- tafasitamab in combination with lenalidomide

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

An additional benefit is not proven.

Study results according to endpoints:[1]

a) Adults with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy who are eligible for CAR-T cell therapy or stem cell transplantation

There are no assessable data.

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	n.a.	There are no assessable data.
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		

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A25-100) unless otherwise indicated.

b) Adults with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy who are not eligible for CAR-T cell therapy and stem cell transplantation

There are no assessable data.

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	n.a.	There are no assessable data.
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		

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

a) Adults with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy who are eligible for CAR-T cell therapy or stem cell transplantation

Approx. 600 to 1,240 patients

b) Adults with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy who are not eligible for CAR-T cell therapy and stem cell transplantation

Approx. 360 to 890 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 Ordspono (active ingredient: odronextamab) at the following publicly accessible link (last access: 19 September 2025):

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

Treatment with odronextamab should only be initiated and monitored by specialists in internal medicine, haematology and oncology, experienced in the treatment of patients with diffuse large B-cell lymphoma.

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 evaluate new information on this medicinal product at a minimum once per year and update the product information where necessary.

In accordance with the European Medicines Agency (EMA) requirements regarding additional risk minimisation measures, the pharmaceutical company must provide training material that contains information for medical professionals and patients (incl. patient identification card).

In particular, the training material contains information and warnings on cytokine release syndrome (CRS) and neurological toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS).

4. 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 relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy who are eligible for CAR-T cell therapy or stem cell transplantation

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Odronextamab	€ 358,941.59 – € 363,437.85
Additionally required SHI costs	*€ 177.60 – € 177.93*
Appropriate comparator therapy:	
Individualised therapy with selection of	
tisagenlecleucel, axicabtagene ciloleucel and lisocabtagene maraleucel	
Axicabtagene ciloleucel	€ 230,621.00
Additionally required SHI costs	*€ 768.44*
Lisocabtagene maraleucel	€ 227,500.00
Additionally required SHI costs	*€ 759.45*
Tisagenlecleucel	€ 239,000.00
Additionally required SHI costs	*€ 419.90*
Induction therapy with R-GDP, R-DHAP or R-ICE followed by high-dose therapy with autologous or allogeneic stem cell transplantation if there is a response to induction therapy	
Induction chemotherapies	
R-GDP (rituximab + gemcitabine + dexamethasone + cisplatin); 2 – 3 cycles	
Rituximab	€ 5,383.80 – € 8,413.88
Gemcitabine	€ 719.68 – € 1,079.52
Dexamethasone	€ 44.52 – € 79.82

Designation of the therapy	Annual treatment costs/ patient
Cisplatin	€ 231.86 – € 347.79
R-GDP	€ 6,379.86 – € 9,921.01
R-DHAP (rituximab + dexamethasone + cytarabine + cisplatin); 2 – 3 cycles including optional single dose of rituximab before the start of treatment	
Rituximab	€ 5,383.80 – € 10,767.60
Dexamethasone	€ 44.52 – € 79.82
Cytarabine	€ 577.36 - € 866.04
Cisplatin	€ 286.88 - € 430.32
R-DHAP	€ 6,292.56 – € 12,143.78
R-ICE (rituximab + ifosfamide + carboplatin + etoposide); 2 – 3 cycles including a single dose of rituximab before the start of treatment	
Rituximab	€ 8,413.88 – € 10,767.60
Ifosfamide	€ 672.40 – € 1,008.60
Carboplatin	€ 726.40 – € 1,185.00
Etoposide	€ 460.68 - € 691.02
R-ICE	€ 10,273.36 – € 13,652.22
High-dose chemotherapy with autologous stem cell transplantation	
Stem cell collection	€ 3,701.58 - € 4,440.07
High-dose chemotherapy with autologous stem cell transplantation	€ 28,304.67
Total	€ 32,006.25 – € 32,744.74
Total	
R-GDP induction chemotherapy + Stem cell collection + High-dose chemotherapy with autologous stem cell transplantation	€ 6,379.86 – € 9,921.01 € 3,701.58 - € 4,440.07 € 28,304.67
Total	€ 38,386.11 - € 42,665.75
R-ICE induction chemotherapy + Stem cell collection + High-dose chemotherapy with autologous stem cell transplantation	€ 10,273.36 – € 13,652.22 € 3,701.58 - € 4,440.07 € 28,304.67
Total	€ 42,279.61 – € 46,396.96
R-DHAP induction chemotherapy + Stem cell collection + High-dose chemotherapy with autologous stem cell transplantation	€ 6,292.56 – € 12,143.78 € 3,701.58 - € 4,440.07 € 28,304.67

Designation of the therapy	Annual treatment costs/ patient
Total	€ 38,298.81 – € 44,888.52
High-dose chemotherapy with allogeneic stem cell transplantation	
Stem cell collection/ acquisition	Not calculable
High-dose chemotherapy with allogeneic stem cell transplantation	€ 54,438.60 – € 62,018.26
Total	Not calculable
Total	
R-GDP induction chemotherapy + Stem cell collection/ acquisition + High-dose chemotherapy with allogeneic stem cell transplantation	€ 6,379.86 – € 9,921.01 Not calculable € 54,438.60 – € 62,018.26
Total	Not calculable
R-ICE induction chemotherapy + Stem cell collection/ acquisition + High-dose chemotherapy with allogeneic stem cell transplantation	€ 10,273.36 – € 13,652.22 Not calculable € 54,438.60 – € 62,018.26
Total	Not calculable
R-DHAP induction chemotherapy + Stem cell collection/ acquisition + High-dose chemotherapy with allogeneic stem cell transplantation	€ 6,292.56 – € 12,143.78 Not calculable € 54,438.60 – € 62,018.26
Total	Not calculable

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 15 November 2025)

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					
Odronextamab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	Cycle 1: 6 Cycle 2 – 4: 3 Maintenance treatment: 1	34.3 – 34.6	€ 3,430 - € 3,460
Appropriate comparator therapy					

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
CAR-T cell therapies: Lymphocyte depletion					
Axicabtagene ciloleucel, tisagenlecleucel, lisocabtagene maraleucel					
Cyclophosphamide	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	3	3.0	€ 300
Fludarabine	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	3	3.0	€ 300
Induction therapy with R-GDP, R-DHAP or R-ICE followed by high-dose therapy with autologous or allogeneic stem cell transplantation if there is a response to induction therapy					
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 the preparation of a parenteral solution containing cytostatic agents	€ 100	2	4.0 – 6.0	€ 400 – € 600
Cisplatin	Surcharge for the preparation 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 the preparation of a parenteral solution containing cytostatic agents	€ 100	1	2.0 – 3.0	€ 200 – € 300
Carboplatin	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	2.0 – 3.0	€ 200 – € 300
Etoposide	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	3	6.0 – 9.0	€ 600 – € 900
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 the preparation of a parenteral solution containing cytostatic agents	€ 100	2	4.0 – 6.0	€ 400 – € 600
Cisplatin	Surcharge for the preparation of a parenteral solution	€ 100	1	2.0 – 3.0	€ 200 – € 300

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
	containing cytostatic agents				

b) Adults with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy who are not eligible for CAR-T cell therapy and stem cell transplantation

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Odronextamab	€ 358,941.59 – € 363,437.85
Additionally required SHI costs	*€ 177.60 – € 177.93*
Appropriate comparator therapy:	
polatuzumab vedotin + bendamustine + rituximab	
Polatuzumab vedotin	€ 44,950.80
Bendamustine	€ 6,148.05
Rituximab	€ 16,151.40
Total	€ 67,250.25
Additionally required SHI costs	*€ 65.82 - € 66.15*
Tafasitamab + lenalidomide	
Tafasitamab	€ 101,821.50
Lenalidomide	€ 428.68
Total	€ 102,250.18
Additionally required SHI costs	*€ 10.49*

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 15 November 2025)

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					
Odronextamab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	Cycle 1: 6 Cycle 2 – 4: 3 Maintenance treatment: 1	34.3 – 34.6	€ 3,430 - € 3,460

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Appropriate comparator therapy					
polatuzumab vedotin + bendamustine + rituximab					
Polatuzumab vedotin	Surcharge for the preparation of a parenteral solution containing polatuzumab vedotin	€ 100	1	6.0	€ 600
Bendamustine	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	2	12.0	€ 1,200
Rituximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	6.0	€ 600
Tafasitamab + lenalidomide					
Tafasitamab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	Cycle 1: 5 Cycle 2 and 3: 4 From cycle 4 onwards: 2	33.0	€ 3,300

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) Adults with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy who are eligible for CAR-T cell therapy or stem cell transplantation

- 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.

b) Adults with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy who are not eligible for CAR-T cell therapy and stem cell transplantation

- 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.

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

The medicinal product Odronextamab is a medicinal product placed on the market from 1 January 2025.

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

The clinical studies of the medicinal product in the therapeutic indication to be assessed were therefore conducted to a relevant extent within the scope of SGB V.

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 22 January 2026.

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

Berlin, 22 January 2026

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

Prof. Hecken