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 (follicular lymphoma, after ≥ 2 prior 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. In Annex XII, the following information shall be added after No. 6 to the information on the benefit assessment of Odronextamab in accordance with the resolution of 22 January 2026 for the therapeutic indication: "Diffuse large B-cell lymphoma":

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 follicular lymphoma (r/r FL) 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

Adults with relapsed or refractory follicular lymphoma (r/r FL) after two or more lines of systemic therapy

Appropriate comparator therapy:

Individualised therapy with selection of

- bendamustine + obinutuzumab followed by obinutuzumab maintenance treatment in accordance with the marketing authorisation,
- lenalidomide + rituximab,
- rituximab monotherapy,
- mosunetuzumab,
- tisagenlecleucel and
- zanubrutinib in combination with obinutuzumab

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]

Adults with relapsed or refractory follicular lymphoma (r/r FL) after two or more lines of systemic therapy

There are no assessable data.

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A25-101) unless otherwise indicated.

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

Adults with relapsed or refractory follicular lymphoma (r/r FL) after two or more lines of systemic therapy

Approx. 370 to 840 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: 16 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 follicular 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 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 annual treatment costs shown refer to the first year of treatment.

Adults with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Odronextamab monotherapy	
Odronextamab	€ 181,830.74 - € 184,104.02
Additionally required SHI costs	*€ 177.60 - € 177.93*
Appropriate comparator therapy:	
Individualised therapy with selection of	
Bendamustine + obinutuzumab	
Bendamustine	€ 6,148.05
Obinutuzumab	€ 27,994.06
Total	€ 34,142.11
Additionally required SHI costs	*€ 10.49*
Lenalidomide + rituximab	
Lenalidomide	€ 428.68
Rituximab	€ 21,535.20
Total	€ 21,963.88
Additionally required SHI costs	*€ 83.37 - € 83.70*
Rituximab monotherapy	
Rituximab	€ 10,767.60
Additionally required SHI costs	*€ 48.27 - € 48.60*
Tisagenlecleucel	
Tisagenlecleucel	€ 239,000.00
Additionally required SHI costs	*€ 419.90*
Mosunetuzumab monotherapy	
Mosunetuzumab	€ 73,882.75 - € 139,676.71
Additionally required SHI costs	*€ 67.20 - € 67.53*
Zanubrutinib + obinutuzumab	
Zanubrutinib	€ 66,643.53
Obinutuzumab	€ 27,994.06
Total	€ 94,637.59
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 monotherapy					
Odronextamab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	Cycle 1 to 4: 4 Maintenance treatment: 1	Cycle 1 to 4: 15 Maintenance treatment: 19.3 – 19.6	€ 3,430 - € 3,460
Appropriate comparator therapy					
Bendamustine + obinutuzumab					
Bendamustine	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	2	6	€ 1,200
Obinutuzumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	Cycle 1: 3 Cycle 2 - 9: 1	11.2	€ 1,120
Lenalidomide + rituximab					
Rituximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	Induction therapy: 4 Maintenance treatment: 1	Induction therapy: 1 Maintenance treatment: 4	€ 800
Rituximab monotherapy					
Rituximab	Surcharge for the preparation of a parenteral solution containing	€ 100	1	4	€ 400

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
	monoclonal antibodies				
Tisagenlecleucel - Lymphocyte depletion					
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
Mosunetuzumab monotherapy					
Mosunetuzumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	Cycle 1: 3 From cycle 2 onwards: 1	10 - 19	€ 1,000 - € 1,900
Zanubrutinib + obinutuzumab					
Obinutuzumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	Cycle 1: 3 Cycle 2 - 9: 1	11.2	€ 1,120

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:

Adults with relapsed or refractory follicular lymphoma (r/r FL) after two or more lines of systemic therapy

- 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