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
Acalabrutinib (new therapeutic indication: mantle cell lymphoma, no prior BTKI therapy, relapsed or refractory, monotherapy)

of 18 December 2025

At their session on 18 December 2025, 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. 5 to the information on the benefit assessment of Acalabrutinib in accordance with the resolution of 18 December 2025 (mantle cell lymphoma, not eligible for autologous stem cell transplant, first-line, combination with bendamustine and rituximab):**

Acalabrutinib

Resolution of: 18 December 2025
Entry into force on: 18 December 2025
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 2 May 2025):

Calquence as monotherapy is indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) not previously treated with a BTK inhibitor.

Therapeutic indication of the resolution (resolution of 18 December 2025):

See new 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 mantle cell lymphoma who have not received pretreatment with a BTK inhibitor

Appropriate comparator therapy:

Individualised therapy with selection of

- Bendamustine + rituximab,
- lenalidomide ± rituximab,
- R-CHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone),
- VRCAP (bortezomib, rituximab, cyclophosphamide, doxorubicin, prednisone),
- R-BAC (rituximab + bendamustine + cytarabine),
- R-FCM (fludarabine + cyclophosphamide + mitoxantrone + rituximab) and
- ibrutinib

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

An additional benefit is not proven.

Study results according to endpoints:[1]

Adults with relapsed or refractory mantle cell lymphoma who have not received pretreatment with a BTK inhibitor

There are no assessable data.

[1] Data from the dossier assessment of the IQWiG (A25-90) and from the addendum (G25-33), 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 mantle cell lymphoma who have not received pretreatment with a BTK inhibitor

Approx. 220 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 Calquence (active ingredient: acalabrutinib) at the following publicly accessible link (last access: 12 November 2025):

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

Treatment with acalabrutinib should only be initiated and monitored by specialists in internal medicine, haematology and oncology experienced in the treatment of patients with mantle cell lymphoma.

4. Treatment costs

Annual treatment costs:

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

Adults with relapsed or refractory mantle cell lymphoma who have not received pretreatment with a BTK inhibitor

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Acalabrutinib	€ 75,182.09
Appropriate comparator therapy:	
Bendamustine + rituximab	
Bendamustine	€ 6,148.05
Rituximab	€ 16,151.40 - € 24,227.10
Total	*€ 22,299.45 - € 30,375.15*
Lenalidomide	
Lenalidomide	*€ 464.40*
Lenalidomide + rituximab	
Lenalidomide	€ 428.68
Rituximab	€ 10,767.60 - € 21,535.20
Total	*€ 11,196.28 - € 21,963.88*
R-CHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone)	
Rituximab	€ 21,714.40 - € 31,214.46
Cyclophosphamide	€ 526.48
Doxorubicin	€ 2,098.48
Vincristine	€ 280.32
Prednisone	€ 123.24
Total	*€ 24,742.92 - € 34,242.98*
VR-CAP (bortezomib, rituximab, cyclophosphamide, doxorubicin, prednisone)	
Rituximab	€ 16,151.40 - € 21,535.20
Bortezomib	€ 4,208.16 - € 5,610.88
Cyclophosphamide	€ 394.86 - € 526.48
Doxorubicin	€ 1,573.86 - € 2,098.48
Prednisone	€ 149.70 - € 190.66
Total	€ 22,477.98 - € 29,961.70
R-BAC (rituximab + bendamustine + cytarabine)	
Rituximab	€ 10,767.60 - € 16,151.40
Bendamustine	€ 3522.84 - € 5305.14
Cytarabine	€ 490.56 - € 1,299.06
Total	*€ 14,781.00 - € 22,755.60*
R-FCM (fludarabine + cyclophosphamide + mitoxantrone + rituximab)	
Rituximab	€ 10,857.20

Designation of the therapy	Annual treatment costs/ patient
Fludarabine	€ 1,270.32
Cyclophosphamide	€ 149.52
Mitoxantrone	€ 892.64
Total	*€ 13,169.68*
Ibrutinib	
Ibrutinib	*€ 99,964.64*

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

Other SHI services:

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Appropriate comparator therapy					
Bendamustine + rituximab					
Bendamustine	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	6	12.0	€ 1,200
Rituximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	6 - 9	6.0 – 9.0	€ 600 - € 900
Lenalidomide + rituximab					
Rituximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1 – 4	4.0 – 8.0	€ 400 - € 800
R-CHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone)					
Rituximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	8.0 – 11.5	€ 800 - € 1,150
Cyclophosphamide	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	8.0	€ 800

Doxorubicin	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	8.0	€ 800
Vincristine	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	8.0	€ 800
VR-CAP (bortezomib, rituximab, cyclophosphamide, doxorubicin, prednisone)					
Bortezomib	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	4	6.0 – 8.0	€ 2,400 - € 3,200
Rituximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	6.0 – 8.0	€ 600 - € 800
Cyclophosphamide	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	6.0 – 8.0	€ 600 - € 800
Doxorubicin	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	6.0 – 8.0	€ 600 - € 800
R-BAC (rituximab + bendamustine + cytarabine)					
Rituximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	4.0 – 6.0	€ 400 - € 600
Bendamustine	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	2	4.0 – 6.0	€ 800 - € 1,200
Cytarabine	Surcharge for the preparation of a parenteral solution	€ 100	3	4.0 – 6.0	€ 1,200 - € 1,800

	containing cytostatic agents				
R-FCM (fludarabine + cyclophosphamide + mitoxantrone + rituximab)					
Fludarabine	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	3	4.0	€ 1,200
Cyclophosphamide	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	3	4.0	€ 1,200
Mitoxantrone	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	4.0	€ 400
Rituximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	4.0	€ 400

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:

<u>Adults with relapsed or refractory mantle cell lymphoma who have not received pretreatment with a BTK inhibitor</u>

- 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 18 December 2025.**

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

Berlin, 18 December 2025

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

Prof. Hecken