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 and Annex XIIa – Combinations of Medicinal Products with New Active Ingredients according to Section 35a SGB V

Acalabrutinib

(new therapeutic indication: chronic lymphocytic leukaemia, first-line, combination with venetoclax and obinutuzumab)

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:

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 June 2025):

Calquence in combination with venetoclax with or without obinutuzumab is indicated for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL).

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

Calquence in combination with venetoclax and obinutuzumab is indicated for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL).

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

Adults with previously untreated chronic lymphocytic leukaemia (CLL)

Appropriate comparator therapy:

– Ibrutinib ± obinutuzumab

or

– venetoclax in combination with obinutuzumab

or

– venetoclax in combination with ibrutinib

or

– acalabrutinib ± obinutuzumab

or

– zanubrutinib

Extent and probability of the additional benefit of acalabrutinib in combination with venetoclax and obinutuzumab compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:[1]

Adults with previously untreated chronic lymphocytic leukaemia (CLL)

There are no assessable data.

[1] Data from the dossier assessment of the IQWiG (A25-85) and from the addendum (G25-36), 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 previously untreated chronic lymphocytic leukaemia (CLL)

Approx. 3,200 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 December 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 chronic lymphocytic leukaemia.

4. Treatment costs

Annual treatment costs:

Adults with previously untreated chronic lymphocytic leukaemia (CLL)

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Acalabrutinib in combination with venetoclax and obinutuzumab	
1st year	
Acalabrutinib	€ 75,182.09
Venetoclax	€ 60,728.03
Obinutuzumab	€ 19,995.76
Total:	€ 155,905.88
Additionally required SHI services	€ 144.40
2nd year	
Acalabrutinib	€ 11,328.81
Venetoclax	€ 5,871.64
Total:	€ 17,200.45
Appropriate comparator therapy:	
Ibrutinib monotherapy	
1st year and subsequent years	
Ibrutinib	€ 75,155.59
Ibrutinib in combination with obinutuzumab	
1st year	
Ibrutinib	€ 75,155.59
Obinutuzumab	€ 19,995.76
Total:	€ 95,151.35
Additionally required SHI services	€ 144.40
Subsequent years	
Ibrutinib	€ 75,155.59
Venetoclax in combination with obinutuzumab	
1st year[2]	
Venetoclax	€ 62,084.87
Obinutuzumab	€ 19,995.76

[2] As treatment with venetoclax is limited to a total of 12 cycles, the costs are only incurred in the 1st year of treatment.

Designation of the therapy	Annual treatment costs/ patient
Total:	€ 82,080.63
Additionally required SHI services	€ 144.40
Venetoclax in combination with ibrutinib	
1st year	
Venetoclax	€ 54,803.49
Ibrutinib	€ 75,155.59
Total:	€ 129,959.08
2nd year	
Venetoclax	€ 11,796.18
Ibrutinib	€ 11,324.81
Total:	€ 23,120.99
Acalabrutinib monotherapy	
1st year and subsequent years	
Acalabrutinib	€ 75,182.09
Acalabrutinib in combination with obinutuzumab	
1st year	
Acalabrutinib	€ 75,182.09
Obinutuzumab	€ 19,995.76
Total:	€ 95,177.85
Additionally required SHI services	€ 144.40
Subsequent years	
Acalabrutinib	€ 75,182.09
Zanubrutinib monotherapy	
1st year and subsequent years	
Zanubrutinib	€ 66,643.53

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
Medicinal product to be assessed:					
Acalabrutinib in combination with venetoclax and obinutuzumab					
Obinutuzumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	Cycle 2: 3 Cycle-3-7: 1	8.0	€ 800
Appropriate comparator therapy:					
Ibrutinib in combination with obinutuzumab					
Obinutuzumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	Cycle 1: 3 Cycle 2–6: 1	8.0	€ 800
Venetoclax in combination with obinutuzumab					
Obinutuzumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	Cycle 1: 3 Cycle 2–6: 1	8.0	€ 800
Acalabrutinib in combination with obinutuzumab					
Obinutuzumab	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	Cycle 2: 3 Cycle-3-7: 1	8.0	€ 800

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 previously untreated chronic lymphocytic leukaemia (CLL)

The following medicinal products with new active ingredients that can be used in a combination therapy with acalabrutinib in the therapeutic indication of the resolution on the basis of the marketing authorisation under Medicinal Products Act are named (active ingredients and invented names) in accordance with Section 35a, paragraph 3, sentence 4 SGB V:

Venetoclax (Venclyxto)

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. **In Annex XIIa of the Pharmaceuticals Directive, the following information shall be added in alphabetical order:**

"Active ingredient of the assessed medicinal product

Acalabrutinib

Resolution according to Section 35a paragraph 3 SGB V from

18 December 2025

Therapeutic indication of the resolution

Calquence in combination with venetoclax and obinutuzumab is indicated for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL).

Patient group

Adults with previously untreated chronic lymphocytic leukaemia (CLL)

Naming of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V (active ingredients and invented names[2])

Venetoclax (Venclyxto)

Period of validity of the designation (since... or from... to)

Since 18 December 2025

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.

III. 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