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)
Pirtobrutinib (mantle cell lymphoma, pretreated patients)

of 7 August 2025

At their session on 7 August 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. Annex XII shall be amended in alphabetical order to include the active ingredient Pirtobrutinib as follows:

Pirtobrutinib

Resolution of: 7 August 2025
Entry into force on: 7 August 2025
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 30 October 2023):

Jaypirca as monotherapy is indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) who have been previously treated with a Bruton's tyrosine kinase (BTK) inhibitor.

Therapeutic indication of the resolution (resolution of 7 August 2025):

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 mantle cell lymphoma who have received at least one prior therapy with a Bruton's tyrosine kinase (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),
- ibrutinib,
- temsirolimus,
- brexucabtagene autoleucel (only for patients with at least two prior therapies),
- venetoclax,
- high-dose therapy with allogeneic stem cell transplantation and
- high-dose therapy with autologous stem cell transplantation

Extent and probability of the additional benefit of pirtobrutinib 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 received at least one prior therapy with a Bruton's tyrosine kinase (BTK) inhibitor

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	∅	No data available.
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 who have been previously treated with a Bruton's tyrosine kinase (BTK) inhibitor

Approx. 105 to 150 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 Jaypirca (active ingredient: pirtobrutinib) at the following publicly accessible link (last access: 16 April 2025):

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

Treatment with pirtobrutinib should only be initiated and monitored by specialists in internal medicine, haematology and oncology experienced in the treatment of patients with mantle 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 will evaluate new information on this medicinal product at a minimum once per year and update the product information where necessary.

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A25-27) unless otherwise indicated.

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 who have been previously treated with a Bruton's tyrosine kinase (BTK) inhibitor

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Pirtobrutinib	€ 143,363.92
Appropriate comparator therapy:	
CAR-T cell therapy	
Brexucabtagene autoleucel	€ 271,000.00
Additionally required SHI costs	*€ 2,240.52*
High-dose chemotherapy with autologous stem cell transplantation	
High-dose chemotherapy with autologous stem cell transplantation	€ 46,549.91
High-dose chemotherapy with allogeneic stem cell transplantation	
High-dose chemotherapy with allogeneic stem cell transplantation	€ 60,654.01
Bendamustine + rituximab	
Bendamustine	€ 6,520.76
Rituximab	€ 16,151.40
Total	*€ 22,672.16*
Additionally required SHI costs	*€ 10.49*
Lenalidomide	
Lenalidomide	€ 464.40
Additionally required SHI costs	*€ 10.49*
Lenalidomide + rituximab	
Lenalidomide	€ 428.68
Rituximab	€ 10,767.60 - € 21,535.20
Total	*€ 11,196.28 - € 21,963.88*
Additionally required SHI costs	*€ 10.49*
R-CHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone)	
Rituximab	€ 31,214.46
Cyclophosphamide	€ 526.48
Doxorubicin	€ 2,214.72
Vincristine	€ 554.24

Designation of the therapy	Annual treatment costs/ patient
Prednisone	€ 123.24
Total	*€ 34,633.14*
Additionally required SHI costs	*€ 10.49*
VRCAP (bortezomib, rituximab, cyclophosphamide, doxorubicin, prednisone)	
Rituximab	€ 51,830.42 - € 57,868.92
Bortezomib	€ 4,208.16 - € 5,610.88
Cyclophosphamide	€ 394.86 - € 526.48
Doxorubicin	€ 8,305.20 - € 11,073.60
Prednisone	€ 82.28 – € 123.24
Total	*€ 64,820.92 - € 75,203.12*
Additionally required SHI costs	*€ 10.49*
R-BAC (rituximab + bendamustine + cytarabine)	
Rituximab	€ 24,227.10 - € 27,726.57
Bendamustine	€ 3,665.04 - € 5,483.12
Cytarabine	€ 866.04 - € 1,299.06
Total	*€ 28,758.18 - € 34,508.75*
Additionally required SHI costs	*€ 10.49*
R-FCM (fludarabine + cyclophosphamide + mitoxantrone + rituximab)	
Rituximab	€ 10,767.60
Fludarabine	€ 1,270.32
Cyclophosphamide	€ 284.52
Mitoxantrone	€ 892.64
Total	*€ 13,215.08*
Additionally required SHI costs	*€ 10.49*
Ibrutinib	
Ibrutinib	*€ 99,964.64*
Temsirolimus	
Temsirolimus	*€ 224,002.99*
Venetoclax	
Venetoclax	*€ 209,501.08*

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 July 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 production 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	6.0	€ 600
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	11.5	€ 1,150
Cyclophosphamide	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	1	8.0	€ 800
Doxorubicin	Surcharge for production of a parenteral solution	€ 100	1	8.0	€ 800

	containing cytostatic agents				
Vincristine	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	1	8.0	€ 800
VRCAP (bortezomib, rituximab, cyclophosphamide, doxorubicin, prednisone)					
Bortezomib	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	4	6.0 – 8.0	€ 2,400 - € 3,200
Rituximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	10.3 – 11.5	€ 1,030 - € 1,150
Cyclophosphamide	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	1	6.0 – 8.0	€ 600 - € 800
Doxorubicin	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	5	6.0 – 8.0	€ 3,000 - € 4,000
R-BAC (rituximab + bendamustine + cytarabine)					
Rituximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	9.0 – 10.3	€ 900 - € 1,030
Bendamustine	Surcharge for production of a parenteral	€ 100	2	4.0 – 6.0	€ 800 - € 1,200

	solution containing cytostatic agents				
Cytarabine	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	3	4.0 – 6.0	€ 1,200 - € 1,800
R-FCM (fludarabine + cyclophosphamide + mitoxantrone + rituximab)					
Fludarabine	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	3	4.0	€ 1,200
Cyclophosphamide	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	3	4.0	€ 1,200
Mitoxantrone	Surcharge for production 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
Temsirolimus					
Temsirolimus	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	1	52.1	€ 5,210

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 mantle cell lymphoma who have who have been previously treated with a Bruton's tyrosine kinase (BTK) inhibitor

- 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 7 August 2025.

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

Berlin, 7 August 2025

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

Prof. Hecken