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: Obinutuzumab (exceeding € 50 million turnover limit: Chronic lymphocytic leukaemia, combination with chlorambucil, first-line)

of 4 November 2021

At its session on 4 November 2021, 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 DD Month YYYY (Federal Gazette, BAnz AT DD.MM.YYYY BX), as follows:

I. Annex XII is amended as follows:

1. The information for obinutuzumab in the section concerning the therapeutic indication "Chronic lymphocytic leukaemia" in the version of the resolution of 5 February 2015 (BAnz AT 26.02.2015 B1) is adopted as follows:

Obinutuzumab

Resolution of: 4 November 2021
Entry into force on: 4 November 2021
BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 23 July 2014):

Gazyvaro in combination with chlorambucil is indicated for the treatment of adult patients with previously untreated CLL and with comorbidities making them unsuitable for full-dose fludarabine based therapy.

Therapeutic indication of the resolution (resolution of 4 November 2021):

see therapeutic indication according to marketing authorisation

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

Adult patients with previously untreated CLL and with comorbidities making them unsuitable for full-dose fludarabine based therapy

Appropriate comparator therapy:

- Ibrutinib

or

- Ibrutinib in combination with rituximab or obinutuzumab

or

- Bendamustine in combination with rituximab (only for patients without genetic risk factors)

or

- Chlorambucil in combination with rituximab (only for patients without genetic risk factors)

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

An additional benefit is not proven.

Study results according to endpoints[1]:

Adult patients with previously untreated CLL and with comorbidities making them unsuitable for full-dose fludarabine based therapy

No complete data available.

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 ∅: There are no usable data for the benefit assessment. n.a.: not assessable		

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

Adult patients with previously untreated CLL and with comorbidities making them unsuitable for full-dose fludarabine based therapy

approx. 820 – 1480 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 Gazyvaro (active ingredient: obinutuzumab) at the following publicly accessible link (last access: 3 September 2021):

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

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A21-64) unless otherwise indicated.

Treatment with obinutuzumab should only be initiated and monitored by specialists in internal medicine, haematology and, oncology experienced in the treatment of patients with chronic lymphocytic leukaemia.

Obinutuzumab (Gazyvaro®) should be used under conditions where full resuscitation equipment is immediately available.

4. Treatment costs

Annual treatment costs:

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Obinutuzumab	€ 27,900.56
Chlorambucil	€ 165.70
Total:	€ 28,066.26
additionally required SHI services	€ 144.76
Appropriate comparator therapy:	
Ibrutinib	
Ibrutinib	€ 75,227.15
additionally required SHI services	€ 11.40
Ibrutinib + rituximab	
Ibrutinib	€ 75,227.15
Rituximab	€ 19,965.55
Total:	€ 95,192.70
additionally required SHI services	€ 69.01
Ibrutinib + obinutuzumab	
Ibrutinib	€ 75,227.15
Obinutuzumab	€ 27,900.56
Total:	€ 103,127.71
additionally required SHI services	€ 156.16
Bendamustine + rituximab (BR)	
Bendamustine	€ 5,046.84
Rituximab	€ 19,965.55
Total:	€ 25,012.39

Designation of the therapy	Annual treatment costs/ patient
additionally required SHI services	€ 57.61
Chlorambucil + rituximab (ClbR)	
Chlorambucil	€ 165.70
Rituximab	€ 19,965.55
Total:	€ 20,131.25
additionally required SHI services	€ 57.61

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 October 2021)

Other SHI services:

Designation of therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient /year	Costs/ patient /year
Obinutuzumab + chlorambucil					
Obinutuzumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 71	Cycle 1: 4 Cycle 2-6: 1	9	€ 639
Ibrutinib + rituximab					
Rituximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 71	1	7	€ 497
Ibrutinib + obinutuzumab					
Obinutuzumab	Surcharge for the preparation of a parenteral solution containing	€ 71	Cycle 1: 4 Cycle 2-6: 1	9	€ 639

	monoclonal antibodies				
Bendamustine + rituximab					
Rituximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 71	1	6	€ 426
Bendamustine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	2	12	€ 972
Chlorambucil + rituximab					
Rituximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 71	1	6	€ 426

I. The resolution will enter into force on the day of its publication on the internet on the website of the G-BA on 4 November 2021.

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

Berlin, 4 November 2021

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

Prof. Hecken