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: Follicular lymphoma, combination with bendamustine, rituximab-refractory)

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 "Follicular lymphoma" in the version of the resolution of 15 December 2016 (BAnz AT 13.01.2017 B2) 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 13 June 2016):

Gazyvaro in combination with bendamustine followed by Gazyvaro maintenance is indicated for the treatment of patients with FL who did not respond or who progressed during or up to 6 months after treatment with rituximab or a rituximab-containing regimen.

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

Adults with follicular lymphoma who did not respond or who progressed during or up to 6 months after treatment with rituximab or a rituximab-containing regimen

Appropriate comparator therapy:

- Patient-individual therapy with selection of bendamustine, CHOP (cyclophosphamide, doxorubicin, vincristine and prednisolone) and CVP (cyclophosphamide, vincristine and prednisolone); taking into account prior therapy and type and duration of response

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

An additional benefit is not proven.

Study results according to endpoints[1]:

Adults with follicular lymphoma who did not respond or who progressed during or up to 6 months after treatment with rituximab or a rituximab-containing regimen

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

Adults with follicular lymphoma who did not respond or who progressed during or up to 6 months after treatment with rituximab or a rituximab-containing regimen

approx. 790 – 940 patients

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

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

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

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

3. Treatment costs

Annual treatment costs:

The annual treatment costs shown refer to the first year of treatment.

Adults with follicular lymphoma who did not respond or who progressed during or up to 6 months after treatment with rituximab or a rituximab-containing regimen

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Obinutuzumab	€ 38,363.27
Bendamustine	€ 5,847.48
Total:	€ 44,210.75
Additionally required SHI services	€ 11.40
Appropriate comparator therapy:	
Bendamustine	€ 24,008.38
CHOP	
Cyclophosphamide	€ 186.92
Doxorubicin	€ 1,702.50
Vincristine	€ 206.22
Prednisolone	€ 40.68
Total:	€ 2,136.32
CVP	

Designation of the therapy	Annual treatment costs/ patient
Cyclophosphamide	€ 280.12
Vincristine	€ 274.96
Prednisolone	€ 55.66
Total:	€ 610.74

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
Medicinal product to be assessed:					
Obinutuzumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 71	Cycle 1: 3 Cycle 2-6: 1 + maintenance treatment 1	11	€ 781
Bendamustine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	2	12	€ 972
Appropriate comparator therapy:					
Bendamustine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	2	34.8	€ 2,818.80
CHOP					
Cyclophosphamide	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	6	€ 486

Doxorubicin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	6	€ 486
Vincristine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	6	€ 486
CVP					
Cyclophosphamide	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	8	€ 648
Vincristine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	8	€ 648

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