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 chemotherapy, 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 on 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, first-line" in the version of the resolution of 15 April 2018 (BAnz AT 18.05.2013 B3) is adopted as follows:

Obinutuzumab

Resolution of: 4. November 2021
Entry into force on: 4. November 2021
BAnz AT TT. MM JJJJ Bx

Therapeutic indication (according to the marketing authorisation of 18 September 2017):

Gazyvaro in combination with chemotherapy, followed by Gazyvaro maintenance therapy in patients achieving a response, is indicated for the treatment of patients with previously untreated advanced FL.

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

Patients with previously untreated follicular lymphoma (FL)

Appropriate comparator therapy:

- Rituximab in combination with cyclophosphamide, doxorubicin, vincristine and prednisolone (CHOP)

  or

- Rituximab in combination with cyclophosphamide, vincristine and prednisolone (CVP)

  or

- Rituximab in combination with bendamustine

  followed by rituximab maintenance treatment for patients who have responded to induction therapy.

Extent and probability of the additional benefit of **Obinutuzumab** in combination with chemotherapy compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints[1]:

Patients with previously untreated follicular lymphoma (FL)

No complete data available.

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A21-64) 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 ∅: 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

Patients with previously untreated follicular lymphoma (FL)

approx. 1300 – 1500 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: 19 August 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.

4. Treatment costs

Annual treatment costs:

Patients with previously untreated follicular lymphoma (FL)

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Obinutuzumab in combination with cyclophosphamide, doxorubicin, vincristine and prednisolone (CHOP)	
Obinutuzumab	€ 45,338.41
Cyclophosphamide	€ 186.92
Doxorubicin	€ 1,702.50
Vincristine	€ 206.22
Prednisolone	€ 40.68
total	€ 47,474.73
Additionally required SHI services	€ 11.40
Obinutuzumab in combination with cyclophosphamide, vincristine and prednisolone (CVP)	
Obinutuzumab	€ 45,338.41
Cyclophosphamide	€ 280.12
Vincristine	€ 274.96
Prednisolone	€ 55.66
total	€ 45,949.15
Additionally required SHI services	€ 11.40
Obinutuzumab in combination with bendamustine	
Obinutuzumab	€ 38,363.27
Bendamustine	€ 5,847.48
total	€ 44,210.75
Additionally required SHI services	€ 11.40
Appropriate comparator therapy:	
Rituximab in combination with cyclophosphamide, doxorubicin, vincristine and prednisolone (CHOP)	
Rituximab	€ 27,136.15
Cyclophosphamide	€ 186.92
Doxorubicin	€ 1,702.50
Vincristine	€ 206.22
Prednisolone	€ 40.68
total	€ 29,272.47

Designation of the therapy	Annual treatment costs/ patient
Additionally required SHI services	€ 11.40
Rituximab in combination with cyclophosphamide, vincristine and prednisolone (CVP)	
Rituximab	€ 27,136.15
Cyclophosphamide	€ 186.92
Vincristine	€ 206.22
Prednisolone	€ 40.68
total	€ 27,569.97
Additionally required SHI services	€ 11.40
Rituximab in combination with bendamustine	
Rituximab	€ 24,763.37
Bendamustine	€ 5,847.48
total	€ 30,610.85
Additionally required SHI services	€ 11.40

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 in combination with cyclophosphamide, doxorubicin, vincristine and prednisolone (CHOP)					
Obinutuzumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 71	Cycle 1: 3 Cycle 2-8: 1 + maintenance treatment 1	10 + 3	€ 923
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
Obinutuzumab in combination with cyclophosphamide, vincristine and prednisolone (CVP)					
Obinutuzumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 71	Cycle 1: 3 Cycle 2-8: 1 + maintenance treatment 1	10 + 3	€ 923
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
Obinutuzumab in combination with bendamustine					
Obinutuzumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 71	Cycle 1: 3 Cycle 2-6: 1 + maintenance treatment 1	8 + 3	€ 781
Bendamustine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	2	12	€ 972
Rituximab in combination with cyclophosphamide, doxorubicin, vincristine and prednisolone (CHOP)					
Rituximab	Surcharge for the preparation of a	€ 71	1	6 + 4	€ 710

	parenteral solution containing monoclonal antibodies				
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
Rituximab in combination with cyclophosphamide, vincristine and prednisolone (CVP)					
Rituximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 71	1	6 + 4	€ 710
Cyclophosphamide	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
Rituximab in combination with bendamustine					

Rituximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 71	1	6 + 3	€ 639
Bendamustine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	2	12	€ 972

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