Resolution

Gemeinsamer Bundesausschuss

of the Federal Joint Committee (G-BA) on an amendment to the Pharmaceuticals Directive (AM-RL): Annex XII – Resolutions on the benefit assessment of medicinal products with new active ingredients according to Section 35a SGB V Venetoclax (Reassessment after cancellation of orphan drug status)

From 16. May 2019

At its meeting on 16. May 2019, the Federal Joint Committee (G-BA) decided to amend the Directive on the Prescription of Medicinal Products in SHI-accredited Medical Care (Pharmaceuticals Directive) in the version dated 18 December 2008/22 January 2009 (BAnz. No. 49a of 31 March 2009), as last amended on TT. Monat JJJJ (BAnz AT TT.MM.JJJJ BX), as follows:

I. Annex XII will be amended as follows

1. The information relating to Venetoclax as amended by the resolution of 15 June 2017 (BAnz AT 14 July 2017 B2) is hereby repealed.

2. Annex XII is expanded to include the active ingredient Venetoclax in alphabetical order as follows:

Venetoclax

Resolution from: 16. May 2019
Entry into force on: 16. May 2019
BAnz AT TT. MM JJJJ Bx

Therapeutic indication (according to the product information last revised December 2018):

Venclyxto monotherapy is indicated for the treatment of chronic lymphocytic leukaemia CLL:

- in the presence of 17p deletion or TP53 mutation in adult patients who are unsuitable for or have failed a B-cell receptor pathway inhibitor, or
- in the absence of 17p deletion or TP53 mutation in adult patients who have failed both chemo-immunotherapy and a B-cell receptor pathway inhibitor

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

a) Adult patients with CLL who have a 17p deletion or TP53 mutation and who are unsuitable for or have failed a B-cell receptor inhibitor

Appropriate comparator therapy:

Ibrutinib

or

Idelalisib + rituximab

or

Best supportive care (only for patients for whom prior therapy with ibrutinib or idelalisib + rituximab failed)

Best supportive care is the therapy that ensures the best possible, individually optimised, supportive treatment to alleviate symptoms and improve the quality of life.

Extent and probability of additional benefit of Venetoclax as a monotherapy compared with the appropriate comparator therapy:

An additional benefit is not proven.

b) Adult CLL patients who do not exhibit 17p deletion or TP53 mutation who have failed both chemo-immunotherapy and a B-cell receptor pathway inhibitor

Appropriate comparator therapy:

Ibrutinib

or

Idelalisib + rituximab

or

Best supportive care

Best supportive care is the therapy that ensures the best possible, individually optimised, supportive treatment to alleviate symptoms and improve the quality of life.

Extent and probability of additional benefit of Venetoclax as a monotherapy compared with the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:[1]

a) Adult patients with CLL who have a 17p deletion or TP53 mutation and who are unsuitable for or have failed a B-cell receptor inhibitor

There is no data that would allow for the assessment of the additional benefit.

b) Adult CLL patients who do not exhibit 17p deletion or TP53 mutation who have failed both chemo-immunotherapy and a B-cell receptor pathway inhibitor.

There is no data that would allow for the assessment of the additional benefit.

[1] Data from the dossier evaluation of the IQWiG (A18-82) unless otherwise indicated.

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

a) Adult patients with CLL who have a 17p deletion or TP53 mutation and who are unsuitable for or have failed a B-cell receptor inhibitor

Approx. 200–540 patients

b) Adult CLL patients who do not exhibit 17p deletion or TP53 mutation who have failed both chemo-immunotherapy and a B-cell receptor pathway inhibitor

Approx. 100–160 patients

3. Requirements for quality-assured application

The requirements of the product information must be taken into account. The European Medicines Agency (EMA) makes the contents of the summary of product characteristics on Venclyxto® (active ingredient: Venetoclax) freely available under the following link (last access: 2. April 2019):

https://www.ema.europa.eu/documents/product-information/venclyxto-epar-product-information_de.pdf

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

Patients who are unsuitable for treatment with a B-cell receptor inhibitor because of a pertinent cardiovascular disease were not investigated in the M13-982 study.

4. Treatment costs

Annual treatment costs:

a) Adult patients with CLL who have a 17p deletion or TP53 mutation and who are unsuitable for or have failed a B-cell receptor inhibitor

and

b) Adult CLL patients who do not exhibit 17p deletion or TP53 mutation who have failed both chemo-immunotherapy and a B-cell receptor pathway inhibitor

Designation of the therapy	Annual treatment costs/patient
Medicinal product to be assessed:	
Venetoclax	

Designation of the therapy	Annual treatment costs/patient
Total	€ 80,022.20[2]
Appropriate comparator therapy:	
Ibrutinib	
Total	€ 77,696.09
Idelalisib + rituximab	
Idelalisib	€ 52,040.00
Rituximab	€ 26,507.36
Additional SHI services required	*€ 42.28*
Total	€ 78,589.64
Best supportive care (BSC)[3]	
Total	patient individualized

Costs after deduction of statutory discounts (LAUER-TAXE® as last revised: 15. April 2019)

Other services covered by SHI funds:

Designation of the therapy	Type of service	Cost per unit	Number per cycle	Number per patient per year	Cost per patient per year
Appropriate comparator therapy					
Idelalisib + rituximab					
Rituximab	Supplement for the preparation of a parenteral solution containing monoclonal antibodies	€ 71	1	8	€ 568

[2] Taking into account the initial 5-week dosage, which does not apply to subsequent years if applied for more than one year. Annual treatment costs in subsequent years: € 85,010.59

[3] In a comparison with BSC, this should also be used in addition to the medicinal product to be assessed.

II. The resolution will enter into force on the day of its publication on the Internet on the websites of the Federal Joint Committee on 16. May 2019.

The justification to this resolution will be published on the website of the Federal Joint Committee at www.g-ba.de .

Berlin, 16. May 2019

Federal Joint Committee
in accordance with Section 91 SGB V
Chair

Prof Hecken