# Resolution

Gemeinsamer Bundesausschuss

## of the Federal Joint Committee (G-BA) on an Amendment of the Pharmaceuticals Directive (AM-RL): Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients According to Section 35a SGB V Ibrutinib (New Therapeutic Indication: Waldenström's Macroglobulinaemia, Combination with Rituximab)

of 20 February 2020

At its session on 20 February 2020, the Federal Joint Committee (G-BA) resolved to amend the Directive on the Prescription of Medicinal Products in SHI-accredited Medical Care (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. In Annex XII, the following information shall be added after No. 4 to the information on the benefit assessment of ibrutinib in accordance with the resolution of 16 March 2017:**

**Ibrutinib**

Resolution of: 20 February 2020
Entry into force on: 20 February 2020
Federal Gazette, BAnz AT DD MM YYYY Bx

**New therapeutic indication (according to the marketing authorisation of 2 August 2019):**

IMBRUVICA in combination with rituximab is indicated for the treatment of adult patients with Waldenström's macroglobulinaemia.

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

Adult patients with Waldenström's macroglobulinaemia

**Appropriate comparator therapy:**

A patient-individual therapy taking into account the general condition of patients and, if appropriate, previous therapies.

**Extent and probability of the additional benefit of ibrutinib compared with the appropriate comparator therapy:**

An additional benefit is not proven.

**Study results according to endpoints:**

Adult patients with Waldenström's macroglobulinaemia

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

**Summary of results for relevant clinical endpoints**

| Endpoint category | Direction of effect/ Risk of bias | Summary |
|---|---|---|
| Mortality | n.a. | No data suitable for the benefit assessment. |
| Morbidity | n.a. | No data suitable for the benefit assessment. |
| Health-related quality of life | n.a. | No data suitable for the benefit assessment. |
| Side effects | n.a. | No data suitable for the benefit assessment. |

Explanations:
↑, ↓: statistically significant and relevant positive or negative effect with high or unclear risk of bias
↑↑, ↓↓: statistically significant and relevant positive or negative effect with low risk of bias
↔: no relevant difference
∅: no data available
n.a.: not assessable

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

approx. 590–1180 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 Imbruvica® (active ingredient: ibrutinib) at the following publicly accessible link (last access: 18 December 2019):

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

Treatment with ibrutinib should only be initiated and monitored by specialists in internal medicine, haematology, and oncology who are experienced in the treatment of patients with Waldenström's macroglobulinaemia.

## 4. Treatment costs

**Annual treatment costs:**

| Designation of the therapy | Annual treatment costs/patient |
|---|---|
| Medicinal product to be assessed: | |
| Ibrutinib | € 77,914.20 |
| Rituximab | € 21,529.72 |
| Additionally required SHI services | € 72.28 |
| Total: | € 99,516.20 |
| Appropriate comparator therapy: | |
| Patient-individual therapy taking into account the general condition of patients and, if appropriate, previous therapies | Different for each individual patient |

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 February 2020

Other services covered by SHI funds:

| Designation of the therapy | Type of service | Costs/ unit | Number/ cycle | Number/ patient/ year | Costs/ patient/ year |
|---|---|---|---|---|---|
| Rituximab | Surcharge for the preparation of a parenteral solution containing monoclonal antibodies | € 71 | 2 cycles each with 4 treatments | 8 | € 568 |

**II. The resolution will enter into force on the day of its publication on the internet on the website of the G-BA on 20 February 2020.**

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

Berlin, 20 February 2020

Federal Joint Committee
in accordance with Section 91 SGB V
The Chair

Prof. Hecken