

Ibrutinib (New Therapeutic Indication: Waldenström's Macroglobulinaemia, Combination with Rituximab)

Resolution of: 20 February 2020
 Entry into force on: 20 February 2020
 Federal Gazette, BAnz 23 03 2020 B5

Valid until: unlimited

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