Zanubrutinib (Waldenström's macroglobulinaemia, first-line (unsuitable for chemo-immunotherapy) or after at least 1 prior therapy)

Resolution of: 16 June 2022 valid until: unlimited
Entry into force on: 16 June 2022
Federal Gazette, BAnz AT 08 08 2022 B2

Therapeutic indication (according to the marketing authorisation of 22 November 2021):

BRUKINSA as monotherapy is indicated for the treatment of adult patients with Waldenström's macroglobulinaemia (WM) who have received at least one prior therapy, or in first line treatment for patients unsuitable for chemo-immunotherapy.

Therapeutic indication of the resolution (resolution of 16 June 2022):

See therapeutic indication according to marketing authorisation.

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

Adults with Waldenström's macroglobulinaemia who have received at least one prior therapy or adults without prior therapy who are unsuitable for chemo-immunotherapy

Appropriate comparator therapy:

- A patient-individual therapy taking into account the general condition and, if applicable, prior therapies and the duration of remission after initial therapy

Extent and probability of the additional benefit of Zanubrutinib compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:[1]

Adults with Waldenström's macroglobulinaemia who have received at least one prior therapy or adults without prior therapy who are unsuitable for chemo-immunotherapy

No complete data available.

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A21-169) 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

Adults with Waldenström's macroglobulinaemia who have received at least one prior therapy or adults without prior therapy who are unsuitable for chemo-immunotherapy

approx. 450 – 1,050 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 Brukinsa (active ingredient: zanubrutinib) at the following publicly accessible link (last access: 5 April 2022):
https://www.ema.europa.eu/en/documents/product-information/brukinsa-epar-product-information_en.pdf

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

4. Treatment costs

Annual treatment costs:

Adults with Waldenström's macroglobulinaemia who have received at least one prior therapy or adults without prior therapy who are unsuitable for chemo-immunotherapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Zanubrutinib	€ 75,317.26
Appropriate comparator therapy:	
Patient-individual therapy taking into account the general condition and, if applicable, prior therapies and the duration of remission after initial therapy[a]	
Ibrutinib	
Ibrutinib	€ 76,273.27
Ibrutinib + rituximab	
Ibrutinib	€ 76,273.27
Rituximab	€ 21,713.72
Total	€ 97,986.99
Additionally required SHI services	€ 62.12
a The active ingredients or combinations of active ingredients bendamustine + rituximab, bortezomib + dexamethasone + rituximab, rituximab + cyclophosphamide + dexamethasone, bortezomib + rituximab and rituximab as monotherapy are suitable comparators for the present benefit assessment in the context of patient-individual therapy. However, these active ingredients or combinations of active ingredients are not approved in the present therapeutic indication, and therefore, no costs are presented for these active ingredients or combinations of active ingredients.	

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 June 2022)

Other SHI services:

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 (with 4 applications each)	8	€ 568