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 Inebilizumab (neuromyelitis optica spectrum disorders, anti-aquaporin-4 IgG seropositive)

of 19 January 2023

At its session on 19 January 2023, 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 by the publication of the resolution of D Month YYYY (Federal Gazette, BAnz AT DD.MM.YYYY BX), as follows:

I. Annex XII shall be amended in alphabetical order to include the active ingredient Inebilizumab as follows:

Inebilizumab

Resolution of: 19 January 2023
Entry into force on: 19 January 2023
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 25 April 2022):

Uplizna is indicated as monotherapy for the treatment of adult patients with neuromyelitis optica spectrum disorders (NMOSD) who are anti-aquaporin-4 immunoglobulin G (AQP4-IgG) seropositive.

Therapeutic indication of the resolution (resolution of 19 January 2023):

See therapeutic indication according to marketing authorisation.

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

Adults with neuromyelitis optica spectrum disorders (NMOSD) who are anti-aquaporin-4 immunoglobulin G (AQP4-IgG) seropositive

Appropriate comparator therapy:

Therapy according to doctor's instructions

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

An additional benefit is not proven.

Study results according to endpoints:

Adults with neuromyelitis optica spectrum disorders (NMOSD) who are anti-aquaporin-4 immunoglobulin G (AQP4-IgG) seropositive

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	n.c.	There are no assessable data.
Morbidity	n.c.	There are no assessable data.
Health-related quality of life	n.c.	There are no assessable data.
Side effects	n.c.	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.c.: not calculable		

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

Adults with neuromyelitis optica spectrum disorders (NMOSD) who are anti-aquaporin-4 immunoglobulin G (AQP4-IgG) seropositive

approx. 460 - 980 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 Uplizna (active ingredient: inebilizumab) at the following publicly accessible link (last access: 22 September 2022):

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

Treatment with inebilizumab should only be initiated and monitored by specialists be performed by a specialist in neurology or a specialist in neurology and psychiatry with experience in the treatment of neuromyelitis optica spectrum disorders.

In accordance with the European Medicines Agency (EMA) requirements regarding additional risk minimisation measures, the pharmaceutical company must provide training material that contains information for medical professionals and patients (incl. patient identification card). The patient identification card contains, in particular, information and warnings about the risk of infections.

4. Treatment costs

Annual treatment costs:

Adults with neuromyelitis optica spectrum disorders (NMOSD) who are anti-aquaporin-4 immunoglobulin G (AQP4-IgG) seropositive

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Inebilizumab	€ 116,541.90
Additionally required SHI services	€ 370.76 - € 376.18
Appropriate comparator therapy:	
Therapy according to doctor's instructions[1]	
Eculizumab	€ 483,509.57 - € 644,679.42
Satralizumab	€ 104,799.80

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 January 2023)

Other SHI services:

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Inebilizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	2.0	1	€ 200
Eculizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	22.8 - 30.4	1	€ 2,280 - € 3,400

[1] In a clinical study, the active ingredients azathioprine, eculizumab, mycophenolate mofetil, rituximab and satralizumab should be available for long-term immunosuppressive therapy. However, the active ingredients azathioprine, mycophenolate mofetil and rituximab are not approved for the present indication, which is why these costs are not presented.

5. Medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V that can be used in a combination therapy with Inebilizumab

Medicinal products with new active ingredients pursuant to Section 35a, paragraph 3, sentence 4 SGB V are medicinal products with the following new active ingredients that can be used in a combination therapy with inebilizumab for the treatment of adults with NMOSD on the basis of the marketing authorisation granted under Medicinal Products Act:

Adults with neuromyelitis optica spectrum disorders (NMOSD) who are anti-aquaporin-4 immunoglobulin G (AQP4-IgG) seropositive

No active ingredient that can be used in a combination therapy that fulfils the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 19 January 2023.

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

Berlin, 19 January 2023

Federal Joint Committee (G-BA)
in accordance with Section 91 SGB V
The Chair

Prof. Hecken