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)
Ravulizumab (new therapeutic indication: neuromyelitis optica spectrum disorders, anti-aquaporin-4 IgG seropositive)

of 7 December 2023

At its session on 7 December 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. **In Annex XII, the following information shall be added after No. 5 to the information on the benefit assessment of Ravulizumab in accordance with the resolution of 20 April 2023 last modified on 21 September 2023:**

Ravulizumab

Resolution of: 7 December 2023
Entry into force on: 7 December 2023
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 5 May 2023):

Ultomiris is indicated in the treatment of adult patients with NMOSD who are anti-aquaporin 4 (AQP4) antibody-positive

Therapeutic indication of the resolution (resolution of 7 December 2023):

See new 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 IgG (AQP4-IgG) seropositive

Appropriate comparator therapy:

Eculizumab (from the 2nd relapse) or satralizumab

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

An additional benefit is not proven.

Study results according to endpoints:[1]

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

No suitable data versus the appropriate comparator therapy were presented.

1 Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A23-50) 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
∅: No data available.
n.a.: not assessable

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

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

approx. 460 – 1,170 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 Ultomiris (active ingredient: ravulizumab) at the following publicly accessible link (last access: 25 August 2023):

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

Treatment with ravulizumab should only be initiated and monitored by a specialist in neurology or a specialist in neurology and psychiatry with experience in the treatment of neuromuscular or neuroinflammatory 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 card). The training material 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 IgG (AQP4-IgG) seropositive

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Ravulizumab	€ 316,689.95
Appropriate comparator therapy:	
Eculizumab	€ 459,539.47 - € 612,719.30
Satralizumab	€ 104,798.94

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

Costs for additionally required SHI services: not applicable

Other SHI services:

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Medicinal product to be assessed					
Ravulizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	6.5	€ 650.00
Appropriate comparator therapy					
Eculizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	22.8 - 30.4	€ 2,280 - € 3,040

5. Designation of 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 the assessed medicinal product

In the context of the designation of medicinal products with new active ingredients pursuant to Section 35a, paragraph 3, sentence 4 SGB V, the following findings are made:

Adults with neuromyelitis optica spectrum disorders (NMOSD) who are anti-aquaporin-4 IgG (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.

The designation of combinations exclusively serves the implementation of the combination discount according to Section 130e SGB V between health insurance funds and pharmaceutical companies. The findings made neither restrict the scope of treatment required to fulfil the medical treatment mandate, nor do they make statements about expediency or economic feasibility.

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 7 December 2023.

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

Berlin, 7 December 2023

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

Prof. Hecken