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: myasthenia gravis, anti-AChR antibody-positive)

of 20 April 2023

At its session on 20 April 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. 4 to the information on the benefit assessment of Ravulizumab in accordance with the resolution of 18 March 2022:

Ravulizumab

Resolution of: 20 April 2023
Entry into force on: 20 April 2023
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 21 September 2022):

Ultomiris is indicated as an add-on to standard therapy for the treatment of adult patients with generalised myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody-positive.

Therapeutic indication of the resolution (resolution of 20 April 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 anti-acetylcholine receptor antibody-positive generalised myasthenia gravis who are eligible for an add-on to standard therapy

Appropriate comparator therapy for ravulizumab as an add-on to standard therapy:

- Eculizumab (for refractory patients) or efgartigimod alfa

Extent and probability of the additional benefit of ravulizumab as an add-on to standard therapy compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:[1]

Adults with anti-acetylcholine receptor antibody-positive generalised myasthenia gravis who are eligible for an add-on to standard therapy

There are no assessable data.

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.

1 Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A22-115) unless otherwise indicated.

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 anti-acetylcholine receptor antibody-positive generalised myasthenia gravis who are eligible for an add-on to standard therapy

approx. 800 – 1,200 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 January 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 doctors experienced in the therapy of neuromuscular diseases.

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. In particular, the training material contains instructions regarding the increased risk of meningococcal infection under ravulizumab.

4. Treatment costs

<u>Adults with anti-acetylcholine receptor antibody-positive generalised myasthenia gravis who are eligible for an add-on to standard therapy</u>

Annual treatment costs:

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Ravulizumab	€ 360,614.28
Appropriate comparator therapy:	
Eculizumab	€ 483,488.59 - € 644,651.46
Efgartigimod alfa	€ 68,750.08 -€ 508,750.59

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	6.5	1	€ 650
Appropriate comparator therapy					
Eculizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	22.8 - 30.4	1	€ 2,280 - € 3,040

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 01 April 2023

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 Ravulizumab

Medicinal products with the 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 ravulizumab for the treatment of adults with acetylcholine receptor antibody-positive generalised myasthenia gravis on the basis of the marketing authorisation granted under Medicinal Products Act:

Adults with anti-acetylcholine receptor antibody-positive generalised myasthenia gravis who are eligible for an add-on to standard therapy

- 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. Entry into force

1. The resolution will enter into force on the day of its publication on the website of the G-BA on 20 April 2023.

2. The period of validity of the resolution is limited to 1 November 2023.

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

Berlin, 20 April 2023

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

Prof. Hecken