# Resolution

Gemeinsamer Bundesausschuss

## of the Federal Joint Committee (G-BA) on an Amendment of the Pharmaceuticals Directive (AM-RL): Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients According to Section 35a SGB V Ravulizumab (New Therapeutic Indication: Atypical Haemolytic Uremic Syndrome (aHUS))

of 21 January 2021

At its session on 21 January 2021 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 on DD 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 6 February 2020:**

**Ravulizumab**

Resolution of: 21 January 2021
Entry into force on: 21 January 2021
Federal Gazette, BAnz AT DD MM YYYY Bx

**New therapeutic indication (according to the marketing authorisation of 26 June 2020):**

Ultomiris is indicated in the treatment of patients with a body weight of 10 kg or above with atypical haemolytic uremic syndrome (aHUS) who are complement inhibitor treatment-naïve or have received eculizumab for at least 3 months and have evidence of response to eculizumab.

**Therapeutic indication of the resolution (resolution of 21 January 2021):**

See new therapeutic indication according to marketing authorisation

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

Patients with a body weight of 10 kg or above with atypical haemolytic uremic syndrome (aHUS) who are complement inhibitor treatment-naïve or have received eculizumab for at least 3 months and have evidence of response to eculizumab

**Appropriate comparator therapy:**

- Eculizumab

**Extent and probability of the additional benefit of ravulizumab compared with eculizumab:**

An additional benefit is not proven.

**Summary of results for relevant clinical endpoints**

| Endpoint category | Direction of effect/ Risk of bias | Summary |
|---|---|---|
| Mortality | n.a. | There are no evaluable data |
| Morbidity | n.a. | There are no evaluable data |
| Health-related quality of life | ∅ | no data available |
| Side effects | n.a. | There are no evaluable 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

**Study results according to endpoints:**

There are no suitable data that would allow for the assessment of the additional benefit.

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

approx. 210–700 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: 28 October 2020):

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

Treatment with ravulizumab should only be initiated and monitored by specialists who are experienced in the therapy of patients with haematological or kidney diseases.

In accordance with the specifications of the European Medicines Agency (EMA) regarding additional measures for risk minimisation, the pharmaceutical company must provide training materials to all doctors and patients expected to use ravulizumab.

In addition to the product information, the training material for doctors contains a guide for the prescribing doctor. In addition to the package leaflet, the training material for patients contains a guide for patients as well as a patient card.

## 4. Treatment costs

**Annual treatment costs:**

| Designation of the therapy | Annual treatment costs/patient |
|---|---|
| Medicinal product to be assessed: | |
| Ravulizumab | € 136,866.08 – 410,159.95 |
| Appropriate comparator therapy: | |
| Eculizumab | € 144,613.58 – 578,454.30 |

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 January 2021

Costs for additionally required SHI services: not applicable

Other services covered by SHI funds:

| Designation of the therapy | Type of service | Costs/ unit | Number/ cycle | Number/ patient/ year | Costs/ patient/ year |
|---|---|---|---|---|---|
| Ravulizumab | Surcharge for the preparation of a parenteral solution containing monoclonal antibodies | € 71 | 1 | 6.5 | € 461.50 |
| | | | | 13.0 | € 923.00 |
| Eculizumab | Surcharge for the preparation of a parenteral solution containing monoclonal antibodies | € 71 | 1 | 26.1 | € 1,853.10 |

**II. The resolution will enter into force with effect from the day of its publication on the internet on the website of the G-BA on 21 January 2021.**

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

Berlin, 21 January 2021

Federal Joint Committee
in accordance with Section 91 SGB V
The Chair

Prof. Hecken