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 Vedolizumab (new therapeutic indication: antibiotic-refractory pouchitis, pretreated patients)

of 1 September 2022

At its session on 1 September 2022, 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 Vedolizumab in accordance with the resolution of 8 February 2015:**

Vedolizumab

Resolution of: 1 September 2022
Entry into force on: 1 September 2022
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 31 January 2022):

Entyvio is indicated for the treatment of adult patients with moderately to severely active chronic pouchitis, who have undergone proctocolectomy and ileal pouch anal anastomosis for ulcerative colitis, and have had an inadequate response with or lost response to antibiotic therapy.

Therapeutic indication of the resolution (resolution of 1 September 2022):

see therapeutic indication according to marketing authorisation

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

Adults with moderately to severely active chronic pouchitis, who have undergone proctocolectomy and ileal pouch anal anastomosis for ulcerative colitis, and have had an inadequate response with or lost response to antibiotic therapy

Appropriate comparator therapy for vedolizumab:

Therapy according to doctor's instructions

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

An additional benefit is not proven.

Study results according to endpoints:[1]

Adults with moderately to severely active chronic pouchitis, who have undergone proctocolectomy and ileal pouch anal anastomosis for ulcerative colitis, and have had an inadequate response with or lost response to antibiotic therapy

No suitable data versus the appropriate comparator therapy available.

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A22-33) unless otherwise indicated.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	∅	No data available.
Morbidity	∅	No data available.
Health-related quality of life	∅	No data available.
Side effects	∅	No data available.
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 moderately to severely active chronic pouchitis, who have undergone proctocolectomy and ileal pouch anal anastomosis for ulcerative colitis, and have had an inadequate response with or lost response to antibiotic therapy

approx. 20 – 40 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 Entyvio (active ingredient: vedolizumab) at the following publicly accessible link (last access: 22 July 2022):

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

Treatment with vedolizumab should only be initiated and monitored by doctors experienced in treating severely active chronic pouchitis.

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. The training material includes instructions on how to deal with any side effects caused by vedolizumab, especially neurological symptoms.

4. Treatment costs

Annual treatment costs:

Adults with moderately to severely active chronic pouchitis, who have undergone proctocolectomy and ileal pouch anal anastomosis for ulcerative colitis, and have had an inadequate response with or lost response to antibiotic therapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Vedolizumab	€ 15,529.87
Additionally required SHI services	€ 112.41
Total	€ 15,642.28
Appropriate comparator therapy:	
Therapy according to doctor's instructions	No data available

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 August 2022)

Other SHI services:

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Vedolizumab	Surcharge for production of a parenteral solution with monoclonal antibodies	€ 71	1	6.5	€ 461.50

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 1 September 2022.

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

Berlin, 1 September 2022

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

Prof. Hecken