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
Mepolizumab (new therapeutic indication: eosinophilic granulomatosis with polyangiitis)

of 19 May 2022

At its session on 19 May 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 Mepolizumab in accordance with the resolution of 19 May 2022 (new therapeutic indication: chronic rhinosinusitis with nasal polyps):

Mepolizumab

Resolution of: 19 May 2022
Entry into force on: 19 May 2022
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 12 November 2021):

Nucala is indicated as an add-on treatment for patients aged 6 years and older with relapsing-remitting or refractory eosinophilic granulomatosis with polyangiitis (EGPA).

Therapeutic indication of the resolution (resolution of 19 May 2022):

See therapeutic indication according to marketing authorisation.

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

Patients aged 6 years and older with relapsing-remitting or refractory eosinophilic granulomatosis with polyangiitis (EGPA)

The appropriate comparator therapy as an add-on treatment is:

- A patient-individual therapy, taking into account the severity of the disease (organ or life-threatening manifestation), the symptomatology, the treatment phase and the course of the disease

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

Additional benefit is not proven

Study results according to endpoints:[1]

Patients aged 6 years and older with relapsing-remitting or refractory eosinophilic granulomatosis with polyangiitis (EGPA)

No suitable data available.

[1] Data from the dossier assessment of the IQWiG (A21-151) and from the addendum (A22-43), 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 ∅: 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

Patients aged 6 years and older with relapsing-remitting or refractory eosinophilic granulomatosis with polyangiitis (EGPA)

approx. 80 - 1130 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 Nucala (active ingredient: mepolizumab) at the following publicly accessible link (last access: 13 May 2022):
https://www.ema.europa.eu/en/documents/product-information/nucala-epar-product-information_en.pdf

Treatment with mepolizumab should only be initiated and monitored by doctors experienced in EGPA therapy.

Mepolizumab is intended for long-term treatment. The need for continued therapy should be reviewed at least once a year. Patients who develop life-threatening manifestations of EGPA should also be assessed for the need for continued therapy as mepolizumab has not been studied in this patient group.

4. Treatment costs

Annual treatment costs:

Patients aged 6 years and older with relapsing-remitting or refractory eosinophilic granulomatosis with polyangiitis (EGPA)

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Mepolizumab	€ 16,163.85 - € 48,491.56
Patient-individual basic therapy[2]	
Glucocorticoids	
Methylprednisolone	Different from patient to patient[3]
Prednisolone	Different from patient to patient[3]
Prednisone	Different from patient to patient[3]
Appropriate comparator therapy:	
A patient-individual therapy, taking into account the severity of the disease (organ or life-threatening manifestation), the symptomatology, the treatment phase and the course of the disease[4]	
Glucocorticoids	
Methylprednisolone	Different from patient to patient[3]
Prednisolone	Different from patient to patient[3]
Prednisone	Different from patient to patient[3]

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 1 May 2022

Costs for additionally required SHI services: not applicable

[2] In addition to corticosteroids and mepolizumab, patients may be treated with immunosuppressants if necessary. These are not approved in the therapeutic indication and are therefore not included in the costs.
[3] The annual treatment costs cannot be specifically quantified due to individual treatment regimens.
[4] In the context of patient-individual therapy, corticosteroids, if necessary with immunosuppressants (cyclophosphamide, rituximab, leflunomide, mycophenolate mofetil, methotrexate and azathioprine), are suitable comparators for the present benefit assessment. Immunosuppressants are not approved in the present therapeutic indication, which is why the costs are not presented.

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 19 May 2022.

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

Berlin, 19 May 2022

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

Prof. Hecken