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: chronic rhinosinusitis with nasal polyps (CRSwNP))

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 22 March 2019:

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 therapy with intranasal corticosteroids for the treatment of adult patients with severe CRSwNP for whom therapy with systemic corticosteroids and/or surgery do not provide adequate disease control.

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

See new therapeutic indication according to marketing authorisation

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

Adults with severe chronic rhinosinusitis with nasal polyps (CRSwNP) for whom therapy with systemic corticosteroids and/or surgery do not provide adequate disease control

Appropriate comparator therapy:

- Dupilumab or omalizumab, each in combination with intranasal corticosteroids (budesonide or mometasone furoate)

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

An additional benefit is not proven.

Study results according to endpoints[1]:

Adults with severe chronic rhinosinusitis with nasal polyps (CRSwNP) for whom therapy with systemic corticosteroids and/or surgery do not provide adequate disease control

There are no suitable data for the benefit assessment compared to the appropriate comparator therapy.

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 IQWiG (A21-150) and from the addendum (A22-42), 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
∅: 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 severe chronic rhinosinusitis with nasal polyps (CRSwNP) for whom therapy with systemic corticosteroids and/or surgery do not provide adequate disease control

approx. 10,500 – 12,600 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: 17 February 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 CRSwNP therapy.

Alternative treatments may be considered for patients who do not respond to treatment for CRSwNP after 24 weeks. Some patients with an initial partial response may benefit from continued treatment beyond 24 weeks.

4. Treatment costs

Annual treatment costs:

Adults with severe chronic rhinosinusitis with nasal polyps (CRSwNP) for whom therapy with systemic corticosteroids and/or surgery do not provide adequate disease control

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Mepolizumab	€ 16,163.85
Intranasal corticosteroids	€ 60.85 – € 243.40

Designation of the therapy	Annual treatment costs/ patient
Total	€ 16,224.70 - € 16,407.25
Appropriate comparator therapy:	
Dupilumab	€ 17,796.15
Intranasal corticosteroids	€ 60.85 – € 243.40
Total	€ 17,857.00 – € 18,039.55
Omalizumab	€ 6,154.33 – € 49,424.00
Intranasal corticosteroids	€ 60.85 – € 243.40
Total	€ 6,215.18 – € 49,667.40

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

Costs for additionally required SHI services: not applicable

II. Entry into force

1. The resolution will enter into force on the day of its publication on the internet on the G-BA website on 19 May 2022.
2. The period of validity of the resolution is limited to 1 December 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