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
Tezepelumab (bronchial asthma, ≥ 12 years)

of 12 May 2023

At its session on 12 May 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. Annex XII shall be amended in alphabetical order to include the active ingredient Tezepelumab as follows:

Tezepelumab

Resolution of: 12 May 2023
Entry into force on: 12 May 2023
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 19 September 2022):

Tezspire is indicated as an add-on maintenance treatment in adults and adolescents 12 years and older with severe asthma who are inadequately controlled despite high dose inhaled corticosteroids plus another medicinal product for maintenance treatment.

Therapeutic indication of the resolution (resolution of 12 May 2023):

- See therapeutic indication according to marketing authorisation.

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

a) Adolescents 12 to 17 years with severe asthma who are inadequately controlled despite high dose inhaled corticosteroids (ICS) plus another medicinal product for maintenance treatment.

Appropriate comparator therapy:

a patient-individual therapy escalation, taking into account the previous therapy with selection of:

- high-dose ICS and LABA and LAMA *or*
- high-dose ICS and LABA and, if necessary, LAMA and omalizumab, provided that the criteria necessary for the administration of omalizumab are met *or*
- high-dose ICS and LABA and, if necessary, LAMA and mepolizumab or dupilumab, provided that the criteria necessary for the administration of omalizumab are met

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

An additional benefit is not proven.

b) Adults with severe asthma who are inadequately controlled despite high dose inhaled corticosteroids (ICS) plus another medicinal product for maintenance treatment.

Appropriate comparator therapy:

a patient-individual therapy escalation taking into account the previous therapy and the pathogenesis of the asthma under selection of:

- high-dose ICS and LABA and LAMA *or*
- high-dose ICS and LABA and, if necessary, LAMA and omalizumab, provided that the criteria necessary for the administration of omalizumab are met *or*
- high-dose ICS and LABA and, if applicable, LAMA and mepolizumab or reslizumab or benralizumab or dupilumab, provided the criteria necessary for the use of the respective antibodies are met

Extent and probability of the additional benefit of tezepelumab compared to the active ingredient (or if necessary, the appropriate comparator therapy):

An additional benefit is not proven.

Study results according to endpoints:

a) Adolescents 12 to 17 years with severe asthma who are inadequately controlled despite high dose inhaled corticosteroids (ICS) plus another medicinal product for maintenance treatment.

No adequate data are available to allow an assessment of the additional benefit.

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
∅: No data available.
n.a.: not assessable

b) Adults with severe asthma who are inadequately controlled despite high dose inhaled corticosteroids (ICS) plus another medicinal product for maintenance treatment.

No adequate data are available to allow an assessment of the additional benefit.

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 ∅: No data available. n.a.: not assessable		

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

a) Adolescents 12 to 17 years with severe asthma who are inadequately controlled despite high dose inhaled corticosteroids (ICS) plus another medicinal product for maintenance treatment.

b) Adults with severe asthma who are inadequately controlled despite high dose inhaled corticosteroids (ICS) plus another medicinal product for maintenance treatment.

Approx. 42,300 to 86,700 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 Tezspire (active ingredient: tezepelumab) at the following publicly accessible link (last access: 31 January 2023):

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

Treatment with tezepelumab should only be initiated and monitored by doctors experienced in severe asthma therapy.

4. Treatment costs

Annual treatment costs:

a) Adolescents 12 to 17 years with severe asthma who are inadequately controlled despite high dose inhaled corticosteroids (ICS) plus another medicinal product for maintenance treatment.

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Tezepelumab	€ 19,625.36
Inhaled corticosteroids (ICS, high dose)	
Fluticasone	€ 248.26
Long-acting beta-2-adrenergic receptor agonists (LABA)	
Formoterol	€ 309.11
Long-acting muscarinic receptor antagonists (LAMA)	
Tiotropium	€ 722.42
ICS + LABA fixed combinations (high-dose)	
Fluticasone | Salmeterol	€ 369.99
Appropriate comparator therapy:	
Inhaled corticosteroids (ICS, high dose)	
Fluticasone	€ 248.26
Long-acting beta-2-adrenergic receptor agonists (LABA)	
Formoterol	€ 309.11
Long-acting muscarinic receptor antagonists (LAMA)	
Tiotropium	€ 722.42
ICS + LABA fixed combinations (high-dose)	
Fluticasone | Salmeterol	€ 369.99
Monoclonal antibodies	
Omalizumab	€ 6,071.30 -€ 48,757.20
Mepolizumab	€ 15,513.38
Dupilumab	€ 17,035.73

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 April 2023)

b) Adults with severe asthma who are inadequately controlled despite high dose inhaled corticosteroids (ICS) plus another medicinal product for maintenance treatment.

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Tezepelumab	€ 19,625.36
Inhaled corticosteroids (ICS, high dose)	
Fluticasone	€ 248.26
Long-acting beta-2-adrenergic receptor agonists (LABA)	
Formoterol	€ 618.23
ICS + LABA fixed combinations (high-dose)	
Fluticasone | Salmeterol	€ 545.76
Long-acting muscarinic receptor antagonists (LAMA)	
Tiotropium	€ 722.42
ICS + LABA + LAMA fixed combinations (high-dose)	
Beclometasone | Formoterol | Glycopyrronium	€ 981.77
Appropriate comparator therapy:	
Inhaled corticosteroids (ICS, high dose)	
Fluticasone	€ 248.26
Long-acting beta-2-adrenergic receptor agonists (LABA)	
Formoterol	€ 618.23
ICS + LABA fixed combinations (high-dose)	
Fluticasone | Salmeterol	€ 545.76
Long-acting muscarinic receptor antagonists (LAMA)	
Tiotropium	€ 722.42
ICS + LABA + LAMA fixed combinations (high-dose)	
Beclometasone | Formoterol | Glycopyrronium	€ 981.77
Monoclonal antibodies	
Mepolizumab	€ 15,513.38
Reslizumab	€ 15,664.35
Benralizumab	€ 15,305.55
Omalizumab	€ 6,071.30 -€ 48,757.20
Dupilumab	€ 17,035.73

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 April 2023)

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
Reslizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	13.0	€ 1,300

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 Tezepelumab

Medicinal products with new active ingredients pursuant to Section 35a, paragraph 3, sentence 4 SGB V are medicinal products with the following new active ingredients, which, on the basis of the marketing authorisation under Medicinal Products Act, can be used in a combination therapy with tezepelumab for the treatment of adults and adolescents 12 years and older with severe asthma who are inadequately controlled despite high dose inhaled corticosteroids plus another medicinal product for maintenance treatment:

a) Adolescents 12 to 17 years with severe asthma who are inadequately controlled despite high dose inhaled corticosteroids plus another medicinal product for maintenance treatment.

- A designation of the concomitant active ingredients shall be made in a further resolution. The adoption of the resolution will be preceded by a written and oral written statement procedure pursuant to Chapter 5, Section 19 of the Regulation, in the course of which the pharmaceutical companies concerned will be given the opportunity to comment on the planned designation.

b) Adults with severe asthma who are inadequately controlled despite high dose inhaled corticosteroids (ICS) plus another medicinal product for maintenance treatment.

- A designation of the concomitant active ingredients shall be made in a further resolution. The adoption of the resolution will be preceded by a written and oral written statement procedure pursuant to Chapter 5, Section 19 of the Regulation, in the course of which the pharmaceutical companies concerned will be given the opportunity to comment on the planned designation.

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. The resolution will enter into force on the day of its publication on the website of the G-BA on 12 May 2023.

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

Berlin, 12 May 2023

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

Prof. Hecken