

Tezepelumab (bronchial asthma, ≥ 12 years)

Resolution of: 12 May 2023/ 21 December 2023
Entry into force on: 12 May 2023/ 21 December 2023
Federal Gazette, BAnz AT 28 06 2023 B1/ 14 02 2024 B7

Valid until: unlimited

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.

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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
<i>Inhaled corticosteroids (ICS, high dose)</i>	
Fluticasone	€ 248.26
<i>Long-acting beta-2-adrenergic receptor agonists (LABA)</i>	
Formoterol	€ 309.11
<i>Long-acting muscarinic receptor antagonists (LAMA)</i>	
Tiotropium	€ 722.42
<i>ICS + LABA fixed combinations (high-dose)</i>	
Fluticasone Salmeterol	€ 369.99
Appropriate comparator therapy:	
<i>Inhaled corticosteroids (ICS, high dose)</i>	
Fluticasone	€ 248.26
<i>Long-acting beta-2-adrenergic receptor agonists (LABA)</i>	
Formoterol	€ 309.11
<i>Long-acting muscarinic receptor antagonists (LAMA)</i>	
Tiotropium	€ 722.42
<i>ICS + LABA fixed combinations (high-dose)</i>	
Fluticasone Salmeterol	€ 369.99
<i>Monoclonal antibodies</i>	
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
<i>Inhaled corticosteroids (ICS, high dose)</i>	
Fluticasone	€ 248.26
<i>Long-acting beta-2-adrenergic receptor agonists (LABA)</i>	
Formoterol	€ 618.23
<i>ICS + LABA fixed combinations (high-dose)</i>	
Fluticasone Salmeterol	€ 545.76
<i>Long-acting muscarinic receptor antagonists (LAMA)</i>	
Tiotropium	€ 722.42
<i>ICS + LABA + LAMA fixed combinations (high-dose)</i>	
Beclometasone Formoterol Glycopyrronium	€ 981.77
Appropriate comparator therapy:	
<i>Inhaled corticosteroids (ICS, high dose)</i>	
Fluticasone	€ 248.26
<i>Long-acting beta-2-adrenergic receptor agonists (LABA)</i>	
Formoterol	€ 618.23
<i>ICS + LABA fixed combinations (high-dose)</i>	
Fluticasone Salmeterol	€ 545.76
<i>Long-acting muscarinic receptor antagonists (LAMA)</i>	
Tiotropium	€ 722.42
<i>ICS + LABA + LAMA fixed combinations (high-dose)</i>	
Beclometasone Formoterol Glycopyrronium	€ 981.77
<i>Monoclonal antibodies</i>	
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. Designation of 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 the assessed medicinal product

In the context of the designation of medicinal products with new active ingredients pursuant to Section 35a, paragraph 3, sentence 4 SGB V, the following findings are made:

- 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.

The following medicinal products with new active ingredients that can be used in a combination therapy with Tezepelumab in the therapeutic indication of the resolution on the basis of the marketing authorisation under Medicinal Products Act are named (active ingredients and invented names) in accordance with Section 35a, paragraph 3, sentence 4 SGB V:

Indacaterol/Mometason (Aectura Breezhaler), Mepolizumab (Nucala), Dupilumab (Dupixent)

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

The following medicinal products with new active ingredients that can be used in a combination therapy with Tezepelumab in the therapeutic indication of the resolution on the basis of the marketing authorisation under Medicinal Products Act are named (active ingredients and invented names) in accordance with Section 35a, paragraph 3, sentence 4 SGB V:

Benralizumab (Fasenra), Indacaterol/Mometason (Aectura Breezhaler), Mepolizumab (Nucala), Reslizumab (Cinqaero), Dupilumab (Dupixent), Indacaterol/ Glycopyrronium/ Mometason (Enerzair Breezhaler), Formoterol/Glycopyrronium/Beclometason (Trimbow)

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.