Resolution

Gemeinsamer Bundesausschuss

of the Federal Joint Committee (G-BA) on an Amendment of the Pharmaceuticals Directive (AM-RL): Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients According to Section 35a SGB V Dupilumab (New Therapeutic Indication: Bronchial Asthma)

of 20 February 2020

At its session on 20 February 2020, the Federal Joint Committee (G-BA) resolved to amend the Directive on the Prescription of Medicinal Products in SHI-accredited Medical Care (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 on DD 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 dupilumab in accordance with the resolution of 17 May 2018:

Dupilumab

Resolution of: 20 February 2020
Entry into force on: 20 February 2020
Federal Gazette, BAnz AT DD MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 6 May 2019):

Dupixent is indicated in adults and adolescents 12 years and older as add-on maintenance treatment for severe asthma with type 2 inflammation characterised by raised blood eosinophils and/or raised FeNO (see section 5.1), who are inadequately controlled with high dose ICS plus another medicinal product for maintenance treatment.

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

a) Adolescents of 12–17 years as add-on maintenance treatment for severe asthma with type 2 inflammation characterised by raised blood eosinophils and/or raised FeNO, who are inadequately controlled with high dose ICS plus another medicinal product for maintenance treatment.

Appropriate comparator therapy:

A patient-individual therapy escalation taking into account previous therapy of either:

- high-dose ICS and LABA and LAMA

  or

- high-dose ICS and LABA and, where appropriate, LAMA and omalizumab, provided that the criteria necessary for the use of omalizumab are met

Extent and probability of the additional benefit of dupilumab compared with the appropriate comparator therapy:

An additional benefit is not proven

Summary of results for relevant clinical endpoints

Endpoint category	Effect	Summary
Mortality	∅	No suitable data were submitted for the benefit assessment.
Morbidity	∅	No suitable data were submitted for the benefit assessment.
Health-related quality of life	∅	No suitable data were submitted for the benefit assessment.
Side effects	∅	No suitable data were submitted for the benefit assessment.

Explanations:
↑, ↓: statistically significant and relevant effect with high or unclear risk of bias
↑↑, ↓↓: statistically significant and relevant effect with low risk of bias
↔: no relevant difference
∅: no data available
n.a.: not assessable

b) Adults as add-on maintenance treatment for severe asthma with type 2 inflammation characterised by raised blood eosinophils and/or raised FeNO, who are inadequately controlled with high dose ICS plus another medicinal product for maintenance treatment

Appropriate comparator therapy:

A patient-individual therapy escalation taking into account previous therapy and the pathogenesis of the asthma of either:

- high-dose ICS and LABA and LAMA

  or

- high-dose ICS and LABA and, where appropriate, LAMA and omalizumab, provided that the criteria necessary for the use of omalizumab are met

  or

- high-dose ICS and LABA and, where appropriate, LAMA and mepolizumab or reslizumab or benralizumab, provided that the criteria necessary for the use of the respective antibodies are met

Extent and probability of the additional benefit of dupilumab compared with the appropriate comparator therapy:

An additional benefit is not proven

Summary of results for relevant clinical endpoints

Endpoint category	Effect	Summary
Mortality	∅	No suitable data were submitted for the benefit assessment.
Morbidity	∅	No suitable data were submitted for the benefit assessment.
Health-related quality of life	∅	No suitable data were submitted for the benefit assessment.
Side effects	∅	No suitable data were submitted for the benefit assessment.

Explanations:
↑, ↓: statistically significant and relevant effect with high or unclear risk of bias
↑↑, ↓↓: statistically significant and relevant effect with low risk of bias
↔: no relevant difference
∅: no data available
n.a.: not assessable

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

a) Adolescents of 12–17 years as add-on maintenance treatment for severe asthma with type 2 inflammation characterised by raised blood eosinophils and/or raised FeNO, who are inadequately controlled with high dose ICS plus another medicinal product for maintenance treatment.

approx. 160 to 2,900 patients

b) Adults as add-on maintenance treatment for severe asthma with type 2 inflammation characterised by raised blood eosinophils and/or raised FeNO, who are inadequately controlled with high dose ICS plus another medicinal product for maintenance treatment

approx. 17,400–51,400 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 Dupixent® (active ingredient: dupilumab) at the following publicly accessible link (last access: 18 November 2019):

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

4. Treatment costs

Annual treatment costs:

a) Adolescents of 12–17 years as add-on maintenance treatment for severe asthma with type 2 inflammation characterised by raised blood eosinophils and/or raised FeNO, who are inadequately controlled with high dose ICS plus another medicinal product for maintenance treatment.

Designation of the therapy	Annual treatment costs/patient
Medicinal product to be assessed:	
Dupilumab	€ 19,058.35
Inhaled corticosteroids (ICS, high-dose)	
Fluticasone	€ 284.40
Long-acting beta-2 agonists (LABA)	
Clenbuterol	€ 122.90–245.79
ICS + LABA fixed combinations (high-dose)	
Fluticasone | formoterol	€ 425.43

Designation of the therapy	Annual treatment costs/patient
Long-acting muscarinic antagonists (LAMA)	
Tiotropium	€ 728.05
Appropriate comparator therapy:	
Inhaled corticosteroids (ICS, high-dose)	
Fluticasone	€ 284.40
Long-acting beta-2 agonists (LABA)	
Clenbuterol	€ 122.90 – 245.79
ICS + LABA fixed combinations (high-dose)	
Fluticasone | formoterol	€ 425.43
Long-acting muscarinic antagonists (LAMA)	
Tiotropium	€ 728.05
Monoclonal antibodies	
Omalizumab	€ 6,040.22–48,507.58

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 February 2020

Costs for additionally required SHI services: not applicable

b) Adults as add-on maintenance treatment for severe asthma with type 2 inflammation characterised by raised blood eosinophils and/or raised FeNO, who are inadequately controlled with high dose ICS plus another medicinal product for maintenance treatment

Designation of the therapy	Annual treatment costs/patient
Medicinal product to be assessed:	
Dupilumab	€ 19,058.35
Inhaled corticosteroids (ICS, high-dose)	
Budesonide	€140.31
Long-acting beta-2 agonists (LABA)	
Clenbuterol	€ 122.90–245.79
ICS + LABA fixed combinations (high-dose)	
Fluticasone | salmeterol	€ 495.51
Long-acting muscarinic antagonists (LAMA)	
Tiotropium	€ 728.05
Appropriate comparator therapy:	
Inhaled corticosteroids (ICS, high-dose)	
Budesonide	€140.31

Designation of the therapy	Annual treatment costs/patient
Long-acting beta-2 agonists (LABA)	
Clenbuterol	€ 122.90–245.79
ICS + LABA fixed combinations (high-dose)	
Fluticasone | salmeterol	€ 495.51
Long-acting muscarinic antagonists (LAMA)	
Tiotropium	€ 728.05
Monoclonal antibodies	
Omalizumab	€ 6,040.22–48,507.58
Mepolizumab	€ 16,230.85
Reslizumab	€ 16,340.81
Benralizumab	€ 15,981.29

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 February 2020

Costs for additionally required SHI services: not applicable

Other services covered by SHI funds:

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	€ 71	1	13	€ 923

The resolution will enter into force on the day of its publication on the internet on the website of the G-BA on 20 February 2020.

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

Berlin, 20 February 2020

Federal Joint Committee
in accordance with Section 91 SGB V
The Chair

Prof. Hecken