Resolution

Gemeinsamer Bundesausschuss

of the Federal Joint Committee (G-BA) on an Amendment of the Pharmaceuticals Directive (AM-RL): Annex XII – Resolutions on the Benefit Assessment of Medicinal Products with New Active Ingredients According to Section 35a SGB V Fluticasone furoate/Umeclidinium/Vilanterol (new therapeutic indication: COPD that is not adequately treated by a combination of LAMA and LABA)

of 2 May 2019

At its session on 2 May 2019, 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 fluticasone furoate/umeclidinium/vilanterol in accordance with the resolution of 16 August 2018:

Fluticasone furoate/umeclidinium/vilanterol

Resolution of: 2 May 2019
Entry into force on: 2 May 2019
Federal Gazette, BAnz AT DD MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 31 October 2018):

Trelegy Ellipta/Elebrato Ellipta is indicated as a maintenance treatment in adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) who are not adequately treated by a combination of an inhaled corticosteroid and a long-acting β2-agonist or a combination of a long-acting β2-agonist and a long-acting muscarinic antagonist (for effects on symptom control and prevention of exacerbations see Section 5.1).

The therapeutic indication to be reassessed includes adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) who are not adequately treated by a combination of a long-acting β2-agonist and a long-acting muscarinic antagonist.

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

Adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) who are not adequately treated by a combination of a long-acting β2-agonist (LABA) and a long-acting muscarinic antagonist (LAMA)

Appropriate comparator therapy:

- LABA and LAMA and ICS

Extent and probability of the additional benefit of fluticasone furoate/umeclidinium/vilanterol compared with the appropriate comparator therapy:

An additional benefit is not proven.

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

Adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) who are not adequately treated by a combination of a long-acting β2-agonist (LABA) and a long-acting muscarinic antagonist (LAMA):

approx. 571,000–1,501,000 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 Trelegy Ellipta®/Elebrato Ellipta® (active ingredient: fluticasone furoate/umeclidinium/vilanterol) at the following publicly accessible link (last access: 26 March 2019):

https://www.ema.europa.eu/documents/product-information/trelegy-ellipta-epar-product-information_de.pdf

4. Treatment costs

Adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) who are not adequately treated by a combination of a long-acting β2-agonist (LABA) and a long-acting muscarinic antagonist (LAMA):

Annual treatment costs:

Designation of the therapy	Annual treatment costs per patient
Medicinal product to be assessed:	
Fluticasone furoate/umeclidinium/vilanterol	€ 1,009.47
Appropriate comparator therapy: - LABA and LAMA and ICS	
LABA and LAMA and ICS	€ 697.83[1]

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 April 2019)

Costs for additionally required SHI services: not applicable

II. The resolution will enter into force on the day of its publication on the internet on the website of the G-BA on 2 May 2019.

1 The figure shows the most cost-effective combination of the fixed combination umeclidinium/vilanterol and additional beclomethasone (daily dose 400 µg).

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

Berlin, 2 May 2019

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

Prof Hecken