Justification

Gemeinsamer Bundesausschuss

to the Resolution 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 Fluticasone Furoate/Umeclidinium/Vilanterol (patient numbers)

of 19 September 2019

Contents

1. Legal basis

According to Section 35a, paragraph 1 German Social Code, Book Five (SGB V), the Federal Joint Committee (G-BA) assesses the benefit of reimbursable medicinal products with new active ingredients. According to Section 35a, paragraph 6 SGB V, the G-BA may also arrange for a benefit assessment according to Section 35a, paragraph 1 SGB V for reimbursable medicinal products containing an active ingredient that is not a new active ingredient within the meaning of Section 35a, paragraph 1 SGB V if a new marketing authorisation with new data protection is granted for the medicinal product. This includes in particular the assessment of the additional benefit and its therapeutic significance. The benefit assessment is carried out on the basis of evidence provided by the pharmaceutical company, which must be submitted to the G-BA electronically, including all clinical trials the pharmaceutical company has conducted or commissioned, at the latest at the time of the first placing on the market as well as the marketing authorisation of new therapeutic indications of the medicinal product, and which must contain the following information in particular:

1. Approved therapeutic indications,
2. Medical benefit,
3. Additional medical benefit in relation to the appropriate comparator therapy,
4. Number of patients and patient groups for whom there is a therapeutically significant additional benefit,
5. Treatment costs for statutory health insurance funds,
6. Requirements for a quality-assured application.

The G-BA may commission the Institute for Quality and Efficiency in Health Care (IQWiG) to carry out the benefit assessment. According to Section 35a, paragraph 2 SGB V, the assessment must be completed within three months of the relevant date for submission of the evidence and published on the internet.

According to Section 35a, paragraph 3 SGB V, the G-BA shall pass a resolution on the benefit assessment within three months of its publication. The resolution is to be published on the internet and forms part of the Pharmaceuticals Directive.

According to Chapter 5, Section 20, paragraph 4 of the VerfO, the sub-committee on Medicinal Products may, in the event of a need for change in the sense of a factual and mathematical correction with regard to the information according to Chapter 5, Section 20, paragraph 3, no. 2 (Number of patients or demarcation of patient groups eligible for treatment) or no. 4 (Treatment costs) of the VerfO, make the corresponding changes by mutual consent.

2. Key points of the resolution

At its session on 2 May 2019, the G-BA passed a resolution on the benefit assessment of fluticasone furoate/umeclidinium/vilanterol in accordance with Section 35a SGB V. Following publication of the resolution on the website of the G-BA, the G-BA concluded that there is a need to adapt the information on the number of patients presented in the resolution or the demarcation of patient groups eligible for treatment.

The resolution of 2 May 2019 was based on the estimate of the number of adult patients with symptomatic, moderate to severe COPD treated with a combination of ICS and LABA, LABA and LAMA, or ICS and LABA and LAMA derived from the dossier of the pharmaceutical

company. This is the target population in the entire therapeutic indication of the active ingredient combination fluticasone furoate/umeclidinium/vilanterol ("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").

The previously approved therapeutic indication ("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" was assessed in the benefit assessment procedure by resolution of 16 August 2018. In the resolution of 16 August 2018, the "Number of patients or demarcation of patient groups eligible for treatment" was based on a target population of COPD patients treated with a double combination of LABA and ICS and with a triple combination of LABA and LAMA and ICS according to the information provided by the pharmaceutical company in the dossier.

The new therapeutic indication assessed in the resolution of 2 May 2019 therefore relates to COPD patients treated with a dual combination of LABA and LAMA and a triple combination of LABA and LAMA and ICS.

Therefore, in accordance with the resolution of 16 August 2018 under "Number of patients or demarcation of patient groups eligible for treatment", the resolution of 2 May 2019 should be based on adult patients with moderate to severe COPD treated with a dual combination of LABA and LAMA as well as with a triple combination of LABA and LAMA and ICS.

For the calculation of COPD patients treated with a dual combination of LABA and LAMA as well as with a triple combination of LABA and LAMA and ICS, the percentages used by the pharmaceutical company in the dossier (data from the German COPD register DACCORD and the national COPD cohort COSYCONET) for patients treated with LABA and LAMA and those treated with ICS and LABA and LAMA are added. Based on the information from the DACCORD register, 43.57% of COPD patients received either a combination of LABA and LAMA or a combination of ICS and LABA and LAMA. Based on the information from the COSYCONET cohort, 63.8% of COPD patients received either a combination of LABA and LAMA or a combination of ICS and LABA and LAMA. The range of COPD patients in the target population is calculated on the basis of proportions (43.57% for the lower limit and 63.8% for the upper limit) and taking into account the data of the pharmaceutical company on symptomatic patients and a SHI proportion of 87.9%.

The number of adult patients with moderate to severe COPD who were treated with a double combination of LABA and LAMA as well as with a triple combination of LABA and LAMA and ICS as determined in the resolution of 2 May 2019, replaces the previous figure under the "Number of patients or demarcation of patient groups eligible for treatment".

3. Written statement procedure according to Section 92, paragraph 3a SGB V

The amendment of the Pharmaceuticals Directive does not require the submission a written statement procedure according to Section 92, paragraph 3a SGB V. Pharmaceutical companies are not adversely affected by the correction of the costs of the active ingredient fluticasone furoate/umeclidinium/vilanterol. The change for the reasons mentioned under 2. is legally necessary.

4. Bureaucratic costs

The proposed resolution does not create any new or amended information obligations for care providers within the meaning of Annex II to Chapter 1 VerfO and, accordingly, no bureaucratic costs.

5. Process sequence

Following the adoption of the resolution, the necessity of the adjustment in the resolution with regard to the patient numbers in the resolution of 2 May 2019 on an amendment of the Pharmaceuticals Directive Annex XII – Resolutions on the benefit assessment of medicinal products with new active ingredients according to Section 35a SGB V – fluticasone furoate/umeclidinium/vilanterol has become apparent.

The matter was discussed in the Working Group Section 35a as well as the medicinal products sub-committee.

At its session on 19 September 2019, the plenum unanimously adopted the amendment to the AM-RL with regard to the adjustment to the number of patients stated in the resolution of 2 May 2019.

Chronological course of consultation

Session	Date	Subject of consultation
Working group Section 35a	20 August 2019 3 September 2019	Consultation on the facts of the case
Subcommittee Medicinal product	10 September 2019	Consultation on an amendment to the resolution of 2 May 2019 regarding the indication of patient numbers
Plenum	19 September 2019	Resolution on an amendment to the resolution of 2 May 2019 regarding the indication of patient numbers

Berlin, 19 September 2019

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

Prof Hecken