Annex 2 to agenda item 6.1.7

Gemeinsamer Bundesausschuss

Justification

on the Resolution of the Federal Joint Committee (G-BA) on the Discontinuation of the Benefit Assessment of the Benefit Assessment of Belimumab According to Section 35a SGB V

of 1 July 2021

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. 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:

1st Approved therapeutic indications,

2nd Medical benefit,

3rd Additional medical benefit in relation to the appropriate comparator therapy,

4th Number of patients and patient groups for whom there is a therapeutically significant additional benefit,

5th Treatment costs for statutory health insurance funds,

6th 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 decides on the benefit assessment within three months of its publication. The resolution is to be published online and is part of the Pharmaceuticals Directive.

2. Key points of the resolution

The active ingredient belimumab (Benlysta) was listed for the first time on 15 August 2011 in the "LAUER-TAXE®", the extensive German registry of available drugs and their prices.

On 30 April 2021, belimumab received marketing authorisation for a new therapeutic indication to be classified as a major type 2 variation as defined according to Annex 2 number 2 letter a to Regulation (EC) No. 1234/2008 of the commission of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (OJ L 334, 12 December 2008, p. 7).

On 12 May 2021, the pharmaceutical company has submitted a dossier in accordance with Section 4, paragraph 3, number 2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with Chapter 5, Section 8, paragraph 1, number 2 of the Rules

of Procedure (VerfO) of the G-BA on the active ingredient belimumab with the new therapeutic indication (lupus nephritis, adults).

Since the factual prerequisites for a benefit assessment according to Section 35a of the SGB V are no longer fulfilled at the time of the timely adoption of the resolution on November 4, 2021, the procedure for the benefit assessment of belimumab according to Section 35a of the SGB V will be discontinued.

3. Bureaucratic costs calculation

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.

4. Process sequence

At its session on 10 September 2019, the Subcommittee on Medicinal Products determined the appropriate comparator therapy.

On 12 May 2021, the pharmaceutical company submitted a dossier for the benefit assessment of belimumab to the G-BA in due time in accordance with Chapter 5, Section 8, paragraph 1, number 2 VerfO.

By letter dated 17 May 2021, in conjunction with the resolution of the G-BA of 1 August 2011 concerning the commissioning of the IQWiG to assess the benefits of medicinal products with new active ingredients in accordance with Section 35a SGB V, the G-BA commissioned the IQWiG to assess the dossier concerning the active ingredient belimumab.

The proposed resolution was discussed and consented to at 22 June 2021 during the subcommittee meeting.

At its session on 1 July 2021, the plenum decided to discontinue the benefit assessment of belimumab according to Section 35a SGB V.

Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee Medicinal products	10 December 2019	Implementation of the appropriate comparator therapy
Subcommittee Medicinal products	22 June 2021	Concluding discussion of the draft resolution
Plenum	1 July 2021	Resolution on the discontinuation of the benefit assessment of belimumab

Berlin, 1 July 2021

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

Prof. Hecken

Last revised: 18. Juni 2021