Justification

Gemeinsamer Bundesausschuss

to the Resolution of the Federal Joint Committee (G-BA) on the Initiation of a Renewed Benefit Assessment According to Section 35a, Paragraph 1, SGB V in Conjunction with Section 3, Paragraph 1, No. 4 of the Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) and Chapter 5, Section 13 of the Rules of Procedure of the G-BA (VerfO): Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients According to Section 35a SGB V Semaglutide

of 16 April 2020

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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:

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.

According to Section 35a, paragraph 1, SGB V in conjunction with Section 3, paragraph 1, No. 4 AM-NutzenV and Chapter 5, Section 13 VerfO, the G-BA may, at the request of its members or of the organisations and institutions mentioned in Section 139b, paragraph 1, sentence 2 SGB V, initiate a new benefit assessment according to Section 35a SGB V at the earliest one year after publication of the resolution according to Chapter 5, Section 20 VerfO because of new scientific findings (Section 13, paragraph 1, sentence 1 VerfO).

2. Key points of the decision

Semaglutide as an active ingredient of the medicinal product Ozempic® was first placed on the (German) market on 1 November 2018. At its session on 2 May 2019 (market launch), the G-BA passed a resolution on the benefit assessment of semaglutide in accordance with Section 35a SGB V. Since 15 January 2020, semaglutide has been available in Germany.

The resolution on semaglutide of 2 May 2019 is based on the SUSTAIN 6 study, which included patients with inadequately controlled type 2 diabetes mellitus and with manifest cardiovascular disease or with risk factors for cardiovascular disease.

With the completed PIONEER 6 study (NCT02692716) and the results thereof, which were published[1]only after completion of the early benefit assessment of semaglutide in August 2019, another cardiovascular endpoint study with relevant data on semaglutide in the therapeutic indication type 2 diabetes mellitus is available. The PIONEER 6 study also included patients with inadequately controlled type 2 diabetes mellitus and with manifest cardiovascular disease

[1] N Engl J Med 2019; 381: 841–51. DOI: 10.1056/NEJMoa1901118
https://www.nejm.org/doi/full/10.1056/NEJMoa1901118?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%3dpubmed

or with risk factors for cardiovascular disease who were treated with semaglutide versus placebo.

The justification for a renewed benefit assessment for the active ingredient semaglutide is that the data of the completed PIONEER 6 Phase III study (NCT02692716) are to be considered new scientific findings that constitute the facts of a renewed benefit assessment to be initiated ex officio by the G-BA based on new scientific findings in accordance with Section 35a, paragraph 1 SGB V in conjunction with Section 3, paragraph 1, No. 4 AM-NutzenV and Chapter 5, Section 13, paragraph 1, sentence 2 VerfO. Because of the size of the study (3,183 adult patients with type 2 diabetes mellitus) and the survey of patient-relevant cardiovascular endpoints[2], the PIONEER 6 study is considered relevant for a renewed benefit assessment because of new scientific findings.

In accordance with Chapter 5, Section 13, paragraph 2, sentence 2 in conjunction with Sections 11, 8, paragraph 1, No. 6 VerfO, the dossier for the benefit assessment for semaglutide must be submitted within three months of notification of the resolution by the G-BA. The date of notification shall be 1 August 2020. Based on this date, the dossier shall be submitted by 2 November 2020 at the latest.

The G-BA hereby offers the pharmaceutical company concerned consultation according to Chapter 5, Section 7 VerfO.

3. 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.

4. Process sequence

At its session on 2 May 2019, the plenum decided to amend Annex XII of the Pharmaceutical Directive for the active ingredient semaglutide.

The matter was discussed in the Working Group Section 35a on 17 March 2020, on 31 March 2020, and in the Subcommittee on Medicinal Products on 7 April 2020, and a corresponding resolution recommendation was prepared for the plenum.

At its session on 16 April 2020, the plenum decided to initiate a renewed benefit assessment according to Section 35a SGB V.

Berlin, 16 April 2020

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

Prof. Hecken

[2] Primary endpoint: cardiovascular death, non-fatal myocardial infarction or non-fatal stroke.