Resolution

Gemeinsamer Bundesausschuss

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 Canagliflozine and Canagliflozine/Metformin

of 16 April 2020

At its session on 16 April 2020, the Federal Joint Committee decided to initiate a new benefit assessment of the active ingredient canagliflozine and the active ingredient combination canagliflozine/metformin:

I. **At the request of its members, the Federal Joint Committee (G-BA) initiates a new benefit assessment for the active ingredient canagliflozine and the active ingredient combination canagliflozine/metformin.**

The benefit assessment is carried out with the following criteria:

1. The renewed benefit assessment of the active ingredient canagliflozine and the active ingredient combination canagliflozine/metformin refers to the therapeutic indication[1]:

   "Invokana® is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise:

   – as monotherapy when metformin is considered inappropriate due to intolerance or contraindications.

   – in addition to other medicinal products for the treatment of diabetes.

   For study results with respect to combination of therapies, effects on glycaemic control and cardiovascular events, and the populations studied, see Sections 4.4, 4.5, and 5.1."

[1] EPAR – Product Information 02/2020

"Vokanamet® is indicated in adults with type 2 diabetes mellitus as an adjunct to diet and exercise:

- in patients insufficiently controlled on their maximally tolerated doses of metformin alone
- in combination with other medicinal products for the treatment of diabetes, in patients insufficiently controlled with metformin and these medicinal products
- in patients already being treated with the combination of canagliflozin and metformin as separate tablets.

For study results with respect to combination of therapies, effects on glycaemic control and cardiovascular events, and the populations studied, see Sections 4.4, 4.5, and 5.1."

2. The renewed benefit assessment is carried out on the basis of data corresponding to the current generally accepted state of medical and scientific knowledge, including the CANVAS study programme, CANVAS (NCT01032629), and CANVAS-R (NCT 01989754).

3. The dossier 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. If Invokana® or Vokanamet® is not available on the German market at that time, the dossier shall be submitted no later than the date on which Invokana® or Vokanamet® is placed on the market in Germany.

4. The pharmaceutical company is hereby offered consultation according to Chapter 5, Section 7 VerfO of the G-BA.

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

Berlin, 16 April 2020

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

Prof. Hecken