Gemeinsamer Bundesausschuss

Resolution

of the Federal Joint Committee on an Amendment of the Pharmaceuticals Directive:
Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a SGB V: Onasemnogene abeparvovec (spinal muscular atrophy); requirement of routine practice data collection and evaluations - amendment

of 21 September 2023

At its session on [date], the Federal Joint Committee (G-BA) resolved to amend Annex XII of the 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 by the publication of the resolution of D Month YYYY (Federal Gazette, BAnz AT DD.MM.YYYY BX), as follows:

I. The information on the requirement of routine practice data collection and evaluations according to Section 35a, paragraph 3b, sentence 1 SGB V on the active ingredient Onasemnogene abeparvovec in the version of the resolution of 4 February 2021 (BAnz AT 19.04.2021 B3) is amended as follows:

1. Section 1.1. "Question according to PICO scheme" is amended as follows:

   In the table, in the "Comparator" row, the word "Nusinersen" is replaced by the words "therapy according to doctor's instructions, taking into account nusinersen and risdiplam".

2. Section 1.2.1 "Study design requirement" is amended as follows:

   After the word "nusinersen", the words "and risdiplam" are inserted.

3. Section 1.4.1 "Study protocol and statistical analysis plan" is amended as follows:

   a. In the sentence "Information on the extent to which the data on nusinersen collected in parallel, as well as data on nusinersen not collected in parallel, are suitable for a pooled analysis", the words "and risdiplam" are inserted after the word "nusinersen".

   b. In the sentence "Information on the extent to which data comparing onasemnogene abeparvovec and nusinersen from different data sources, if any, are suitable for pooled analysis", the word "nusinersen" is replaced by the

words "therapy according to doctor's instructions, taking into account nusinersen and risdiplam".

II. The revised study protocol and the revised SAP are to be submitted to the G-BA by 4 February 2024.

III. The resolution will enter into force on the day of its publication on the website of the G-BA on 21 September 2023.

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

Berlin, 21 September 2023

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

Prof. Hecken