

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:
Onasemnogen abeparvovec (spinal muscular atrophy);
requirement of routine practice data collection and
evaluations

of 20 January 2022

At its session on 20 January 2022, 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:

The information concerning the active ingredient Onasemnogene abeparvovec as set out in the resolution of 4 February 2021 (BAnz AT 19.04.2021 B3) is amended as follows:

1. Section 1.4.2 "Evaluations of the data for the purpose of the benefit assessment" is amended as follows:
 - a. The statement "3 interim analyses" is replaced by the statement "2 interim analyses".
 - b. "18 months" is replaced by "36 months".
2. The following sentence is added to Section 2.2 Submission of information on the course of data collection (in particular information on the status of recruitment)":

"In the course of the first submission of information on the course of data collection 18 months after the date of the resolution, the pharmaceutical company shall additionally present to the G-BA the final versions of the study protocol as well as the statistical analysis plan, taking into account the conditions in the resolution on a determination in the procedure for routine practice data collection and evaluations according to Section 35a (3b) SGB V: Onasemnogene abeparvovec (spinal muscular

atrophy) – study protocol and statistical analysis plan submission dated 20 January 2022."

3. Section 2.3 "Submission of interim analyses" is amended as follows:
 - a. The words "18 months from the date of resolution" shall be deleted.
 - b. "60 months" is replaced by "54 months".

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 20 January 2022.

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

Berlin, 20 January 2022

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

Prof. Hecken