Gemeinsamer Bundesausschuss

Resolution

of the Federal Joint Committee on the initiation of a procedure on the requirement of a routine practice data collection and evaluations according to Section 35a, paragraph 3b SGB V: Risdiplam (spinal muscular atrophy)

of 7 October 2021

The Federal Joint Committee (G-BA) passed the following resolution at its session on 7 October 2021:

I. A procedure for the requirement of a routine practice data collection according to Section 35a paragraph 3b SGB V for the active ingredient risdiplam in the treatment of:

"5q spinal muscular atrophy (SMA) in patients 2 months of age and older, with a clinical diagnosis of SMA Type 1, Type 2 or Type 3 or with one to four SMN2 copies"

is initiated.

II. The Subcommittee on Medicinal Products is commissioned to conduct the procedure for the requirement of a routine practice data collection as set out in I. above.

III. The Institute for Quality and Efficiency in Health Care (IQWiG) is commissioned to develop a concept for routine practice data collection according to I.

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

Berlin, 7 October 2021

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

Prof. Hecken