Resolution

Gemeinsamer Bundesausschuss

of the Federal Joint Committee (G-BA) on the Amendment of the Pharmaceuticals Directive (AM-RL): Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients According to Section 35a SGB V Onasemnogene Abeparvovec (Spinal Muscular Atrophy); Restriction of the Authority to Supply Care

of 4 February 2021

At its session on 4 February 2021 the Federal Joint Committee (G-BA) resolved to amend 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 on DD Month YYYY (Federal Gazette, BAnz AT DD MM YYYY BX), as follows:

I. Annex XII will be amended as follows:

„Restriction of the authority to supply care according to Section 35a, paragraph 3b, sentence 2 SGB V for the active ingredient onasemnogene abeparvovec for the treatment of:

“patients with 5q spinal muscular atrophy (SMA) with a bi-allelic mutation in the SMN1 gene and a clinical diagnosis of SMA Type 1 or patients with 5q SMA with a bi-allelic mutation in the SMN1 gene and up to 3 copies of the SMN2 gene”

to those care providers that participate in the required routine data collection.

Care providers within the meaning this resolution are physicians participating in SHI-accredited medical care, medical care centres, and facilities according to Section 95 SGB V as well as hospitals approved to provide care according to Section 108 SGB V.“

II. Entry into force

The resolution will enter into force with effect from the day of its publication on the internet on the website of the G-BA on 4 February 2021.

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

Berlin, 4 February 2021

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

Prof. Hecken

Courtesy translation – only the German version is legally binding.