Resolution

Gemeinsamer Bundesausschuss

of the Federal Joint Committee (G-BA) on an Amendment of the Pharmaceuticals Directive (AM-RL): Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients According to Section 35a SGB V Erenumab (patient numbers)

of 19 September 2019

At its session on 19 September 2019, the Federal Joint Committee (G-BA) resolved to amend the Directive on the Prescription of Medicinal Products in SHI-accredited Medical Care (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 MM YYYY (Federal Gazette, BAnz AT DD MM YYYY Bx) as follows:

I. In Annex XII, the information on the benefit assessment of the active ingredient erenumab under the heading "2. Number of patients or demarcation of patient groups eligible for treatment" is amended as follows:

Under "a) untreated adult patients who have responded inadequately or are unable to tolerate at least one prophylactic medication", the specification of the number of patients

"approx. 2,365,000–2,454,000 patients" will be replaced by the following specification:

"approx. 1,428,000–1,445,000 patients"

Under "b) adult patients who are not responsive to or do not tolerate the medicinal therapies/active ingredient classes metoprolol, propranolol, flunarizine, topiramate, and amitriptyline", the specification of the number of patients

"approx. 10,000–11,000 patients" will be replaced by the following specification:

"approx. 1,400–11,000 patients"

II. 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 19 September 2019.

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

Berlin, 19 September 2019

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

Prof Hecken