Gemeinsamer Bundesausschuss

Justification

on the Resolution of the Federal Joint Committee (G-BA) 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); restrictions regarding supply

of 6 May 2021

Contents

1. Legal basis

According to Section 35a (3b), Sentence 2, SGB V, the Federal Joint Committee may decide for a medicinal product that is or will be the subject of a resolution according Section 35a (3b), Sentence 1, SGB V that the authority to supply insured individuals such a medicinal product at the expense of the statutory health insurance is restricted to those care providers who participate in the required data collection accompanying the application according to Section 35a (3b), SGB V (restriction of the authority of care providers to supply). The resolution is to be published online and is part of the Pharmaceuticals Directive (AM-RL).

2. Key points of the resolution

In its meeting on 4 February 2021, the G-BA decided on the requirement of an application-supporting data collection and evaluations for the active ingredient onasemnogene abeparvovec in the treatment of patients with spinal muscular atrophy (brief indication of therapy) according to Section 35a (3b), Sentence 1 SGB V.

As a result, the G-BA also resolved in its meeting on 4 February 2021 to restrict the authority to supply insured individuals with the active ingredient onasemnogene-abeparvovec in the treatment of spinal muscular atrophy at the expense of the statutory health insurance to those service providers who participate in the required data collection supporting the application (restriction of the authority of care providers to supply). This resolution on the restriction of supply authority came into force on 4 February 2021 with effect from the day of its publication on website of the G-BA.

Subsequent to this resolution, the G-BA has taken note of the fact that there is a lack of clarity regarding when the regulation on the restriction of the authority to supply takes effect. This is based on the fact that the resolution on the restriction of the power to supply has already entered into force, whereas the required data collection supporting the application has not yet started. It follows from the resolution on the requirement of the application supporting data collection that this can begin at the earliest after the planned agreement of the study protocol and the statistical analysis plan.

Therefore, the present resolution adds the provision on the entry into force of the resolution on the limitation of the power to supply: The restriction of the authority to supply regulated in the resolution to such care providers who participate in the required application-supporting data collection only takes effect from the confirmation of the study protocol and the statistical analysis plan submitted by the pharmaceutical company and publication of the confirmation on the websites of the G-BA.

In this context, the confirmation is only used as a temporal approximation commencing the in-use data collection and therefore does not have to correspond to the actual start of the in-use data collection, which results, for example, from a registered start date of a study or the inclusion of patients.

A new written statement procedure does not need to be carried out, as the factual basis or the content of the resolution has not changed significantly compared to the draft resolution on the restriction of care providers' authority to provide that was submitted for the written statement procedure, see Chapter 1 § 14 of the G-BA's Rules of Procedure (VerfO).

3. Bureaucratic cost calculation

The proposed resolution does not create any new or amended information obligations for care providers within the meaning of Annex II to Chapter 1 VerfO and, accordingly, no bureaucratic costs.

4. Process sequence

The working group AG §35a discussed the amendment of the AM-RL in its meeting on 21 April 2021.

At the Pharmaceutical Subcommittee meeting on 27 April 2021, the draft resolution was discussed, and the draft resolution was consented to.

At its meeting on 6 May 2021, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Berlin, 6 May 2021

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

Prof. Hecken