Pressemitteilung

Gemeinsamer Bundesausschuss gemäß § 91 SGB V

Gemeinsamer Bundesausschuss

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Medicinal products

Resolutions on the early benefit assessment of medicinal products will also be available in English on the website of the G-BA

Berlin, 2 September 2019 – For resolutions on the early benefit assessment of medicinal products passed from 1 August 2019, the Federal Joint Committee (G-BA) will provide an English translation of the resolution and the justification on its website. The translation serves to inform the international professional public; however only the German-language resolution is legally binding. The translations are published no later than four weeks after the resolution on the respective benefit assessment procedure for an active ingredient has been passed. The G-BA is thus implementing an order from the Appointment Service and Supply Act (TSVG), which entered into force on 11 May 2019 and provides for a corresponding amendment to Section 35a of the German Social Code, Book Five (SGB V).

Background – early benefit assessment of medicinal products

The G-BA received the commission for the early benefit assessment via the Act on the Reform of the Market for Medicinal Products (AMNOG). The new law, which came into force on 1 January 2011, obliges pharmaceutical companies to submit a dossier on the (additional) benefit of the medicinal product as early as the market launch of a newly approved active ingredient in Germany or if marketing authorisation has been given for a new therapeutic indication.

For medicinal products with a proven additional benefit, the central SHI organisation and the respective pharmaceutical company shall within six months negotiate a reimbursement amount for the SHI as a rebate on the original selling price set by the company itself. If no agreement can be reached in the hearing, an arbitration commission shall determine the amount to be refunded. The benchmark should be the European price level.

If the G-BA comes to the conclusion that the new medicinal product has no additional benefit compared with the appropriate comparator therapy (preferably a therapy for which endpoint studies are available and which has proven itself in practical application), it is transferred to the fixed amount system within six months of its market launch. If a medicinal product with no additional benefit cannot be assigned to a fixed amount group, a reimbursement amount is also agreed. However, the annual treatment costs should not be higher than for the appropriate comparator therapy.

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The **Federal Joint Committee (G-BA)** is the highest decision-making body of the joint self-government of physicians, dentists, psychotherapists, hospitals, and health insurance funds in Germany. It issues directives for the benefit catalogue of the statutory health insurance funds (SHI) for more approx. 70 million insured persons. The G-BA specifies which services in medical care are reimbursed by the SHI. The legal basis for the work of the G-BA is the German Social Code, Book Five (SGB V). In accordance with the Patient Involvement Act, patient representatives take part in the consultations of the G-BA in an advisory capacity and have the right of petition.

The health policy framework for medical care in Germany is set by the parliament in the form of laws. It is the task of the G-BA to adopt uniform guidelines for practical implementation within this framework. The guidelines adopted by it have the character of subordinate standards and are binding for all stakeholders of the SHI.

In making its decisions, the G-BA takes into account the generally accepted state of medical knowledge and examines the diagnostic or therapeutic benefits, medical necessity, and the principle of economic efficiency of a benefit from the compulsory catalogue of health insurance funds. The G-BA also has other important tasks in the area of quality management and quality assurance in outpatient and inpatient care.

For more information, see **www.g-ba.de**