vfa. Die forschenden Pharma-Unternehmen
Research-Based Pharmaceutical Companies

Position paper - AMNOG 2025

More support for performance-based reimbursement models

In special treatment settings, evidence of drug efficacy at the time of approval may be limited. Performance-based reimbursement models can help counter justifiable uncertainty around the effectiveness of higher-priced therapies and give patients rapid access to these treatments. Adjustment of the legal framework is required to enable the implementation of performance-based reimbursement models.

Lack of implementation

Performance-based reimbursement models have not played a major role in Germany to date because they are difficult to implement within central AMNOG price negotiations with the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband). Thus, such models have mostly been agreed upon in individual contracts for the first year after market entry between individual health insurance funds and pharmaceutical manufacturers. Once the centrally agreed reimbursement amount is established, there are few incentives to stick to agreements already concluded on a decentralized basis, never mind create new ones. The GKV-Spitzenverband says there is no legal basis for implementing case-specific arrangements on a central level.

Existing challenges

Currently, the general legal framework of AMNOG applies to the launch of innovative drugs in Germany. However, this pricing and reimbursement system is not designed for therapies with justifiably limited evidence or permanent effects, including one-time therapies. There are no provisions to ensure pricing levels commensurate with their clinical benefit. Especially where patient populations are too small to support randomized controlled trials (RCTs), health insurers may doubt whether the anticipated therapeutic effect actually occurs. Gene and cell therapies, for example, are expected to have lasting effects, often after being administered only once, but clinical data on the actual duration of effect is necessarily lacking at market entry.

Response to treatment can always vary in principle from one patient to another. This applies equally to continuous therapies and one-time treatments. A continuous therapy can be adjusted or discontinued if necessary and would cease to cost anything from that point on, at least as regards the drug in question. This is simply not possible with one-time therapies. This is why performance-based reimbursement models have been mooted, for one-time therapies in particular. However, certain criteria apply such as measurable success parameters and reasonable administrative effort.

Against this backdrop, vfa suggests expanding the legal framework beyond the traditional normative framework currently provided by the Social Security Code (especially section 130b SGB V). Performance-based reimbursement models should explicitly be an option in suitable individual cases for central AMNOG price negotiations between

pharmaceutical manufacturers and the GKV-Spitzenverband.

Evolution of the legal framework

vfa's proposal is aimed at establishing a standard performance-based reimbursement option that can be flexibly designed in the course of negotiations.

- The idea is that the GKV-Spitzenverband and the pharmaceutical manufacturer always jointly decide which special treatment settings should have a performance-based reimbursement option, in derogation of section 130b SGB V.
- The decisive criterion for pricing can be the actual response to treatment.
- Compensation can be provided in the form of a one-time payment, installments, or annually adjusted payments. Other approaches to performance-related compensation are available.
- An annual compensation will be billed directly between the respective health insurance fund and the pharmaceutical company. Other payers may participate in the new compensation option.
- The agreement is open to arbitration.
- The legal implications of exceeding the orphan drug revenue threshold or an in-use data collection requirement do not apply.
- Agreeing a similar compensation arrangement immediately upon market entry is still an option with individual health insurance funds.
- In addition, specific adjustments in the financial equalization system of health insurance funds ("Morbi-RSA") must be made to adequately reflect the various performance-based reimbursement models. The Federal Social Security Office (BAS) has already developed an initial proposal ready for implementation in a special report dated March 2022.

Success: a multifaceted term

Agreeing on suitable success parameters is essential in performance-based reimbursement models. The contracting parties must agree on criteria that are measurable, and contractually establish the corresponding evidentiary bases, data evaluations, data sharing and delivery deadlines. A legal definition of success criteria does not seem expedient as their suitability would need to be scrutinized case by case. Parameters that can be captured digitally may be useful benchmarks of success. Other relevant questions, such as whether treatment actually went as planned, are impossible to answer outright and always need to be considered with care.

Conclusion

Legislative requirements must provide sufficient flexibility for a variety of contractual models and continue to ensure timely patient access. Creative thinking is required from all parties concerned (especially policymakers, payers and the pharmaceutical industry). In view of the dynamics of medical progress, the GKV-Spitzenverband, health insurance funds and pharmaceutical manufacturers must be enabled to jointly explore which drugs might be compatible with a performance-based reimbursement model. vfa believes that a broad and constructive conversation around these issues is necessary.

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