AMNOG BENEFIT ASSESSMENT IN GERMANY AND ITS IMPACT ON PRICE NEGOTIATIONS
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Results

Since the enactment of the AMNOG in 2011, pharmaceutical companies are required to prove the added medical benefit of newly approved drugs including new area of application compared to the standard of care in Germany. This added medical benefit is evaluated by the Joint Federal Committee (G-BA) and the Institute for Quality and Efficiency in Health Care (IQWiG).

The aim of this study was to investigate the effect of the outcome of the benefit assessment on the negotiated reimbursement price with the National Association of Statutory Health Insurance Funds (GKV-SV).

Since 2011 benefit assessments have become a key component in pricing new drugs in Germany. Between January 2011 and April 2019, 391 benefit assessments with 763 subpopulations were submitted and appraised.

Receiving an added medical benefit influences price negotiations positively whereas no added benefit results in higher rebates on the reimbursement price. Major pitfalls and impact on price negotiations.

Conclusions

Since 2011 benefit assessments have become a key component in pricing new drugs in Germany. Between January 2011 and April 2019, 391 benefit assessments with 763 subpopulations were submitted and appraised.

By law, Orphan Drugs are granted an additional medical benefit by AMNOG rules. Most assessments resulted in a non-quantifiable benefit.

Compliance with the rules of procedure of G-BA/IQWiG and submission of comparative evidence towards the appropriate comparator defined by G-BA is crucial to receive an added benefit. Major pitfalls are quality of evidence (e.g. RCT vs. single arm study), patient relevance of endpoints and the deviations from the appropriate comparator therapy.

Receiving an added medical benefit influences price negotiations positively whereas no added benefit results in higher rebates on the reimbursement price. No added benefit leads to a lower price and may result in the decision by the company to withdraw from the market.