



**BENEFIT ASSESSMENT IN
ACCORDANCE WITH SGB V,
SECTION 35A**



GKM
Gesellschaft für
Therapieforschung mbH

KEY FACTS BENEFIT ASSESSMENT

- Expert group at GKM since 2010 on the benefit assessment of medicinal products in accordance with the Act on the Reform of the Market for Medicinal Products (AMNOG)
- Interdisciplinary team that consists of (bio)statisticians, medical doctors, epidemiologists, pharmacists and health economists
- Full service offer, ranging from medical and statistical consultancy to the development and writing of full benefit dossiers in accordance with the German Social Code, Book Five (SGB V), section 35a
- Development of study designs or study programs with regard to early benefit assessment
- Regular trainings on AMNOG

Consulting

- Design of studies regarding early benefit assessments
- Statistical and medical evaluation of study synopses in view of suitability for early benefit assessments
- Patient relevant endpoints
- Validation of endpoints
- Appropriate comparator
- Strategy development for accompanying studies and patient surveys
- Systematic literature and study register search
- Statistical & medical consulting
- Preparation of documents for consultation with the Federal Joint Committee (G-BA)

Early benefit assessment services

- Preparation of the request form for G-BA consultation
- Writing and/or review of all or individual modules of the early benefit dossier
- Identification of data gaps
- Planning and conduction of analyses for benefit assessments according to §35a SGB V (AMNOG)
- Calculation of indirect comparisons
- Meta-analyses
- Systematic literature and study register search
- Content and formal check on completeness
- Support with and development of the submission form for written hearings
- Participation in oral hearings



Projects (62)


- Full Service
- Partial Service dossier writing
- Consulting service
- Statistical analyses
- Development of consultation requests

Team

- HEOR-Specialists
- Medical Advisors
- Biostatisticians

Indications

- Cardiac diseases
- Oncological diseases
- Metabolic and endocrine diseases
- Diseases of the blood and blood-forming organs
- Infectious diseases



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