HTA354

Determinants of Added Benefit Ratings in Germany: An Econometric Analysis of Assessments from the Federal Joint Committee Between 2012 and 2024

Fiona Tolkmitt;[1] Danitza Chávez-Montoya;[2] Mackenzie Mills;[1,2] Panos Kanavos[2]

[1] Hive Health Optimum Ltd. (HTA-Hive), London, United Kingdom

[2] The London School of Economics and Political Science (LSE), London, United Kingdom

Background

- The German Federal Joint Committee (G-BA) plays a pivotal role in evaluating new pharmaceuticals, directly influencing drug pricing and reimbursement within the healthcare system.
- Since the introduction of the Act on the Reform of the Market for Medicinal Products (AMNOG) in 2011, pharmaceutical manufacturers are required to demonstrate the added benefit of new drugs compared to standard therapy.
- These evaluations significantly impact drug accessibility and reimbursement, making it essential for healthcare stakeholders to understand the factors driving higher ratings.
- Manufacturers, policymakers, and patients are particularly affected by these decisions, underscoring the importance of understanding rating determinants.

Objectives

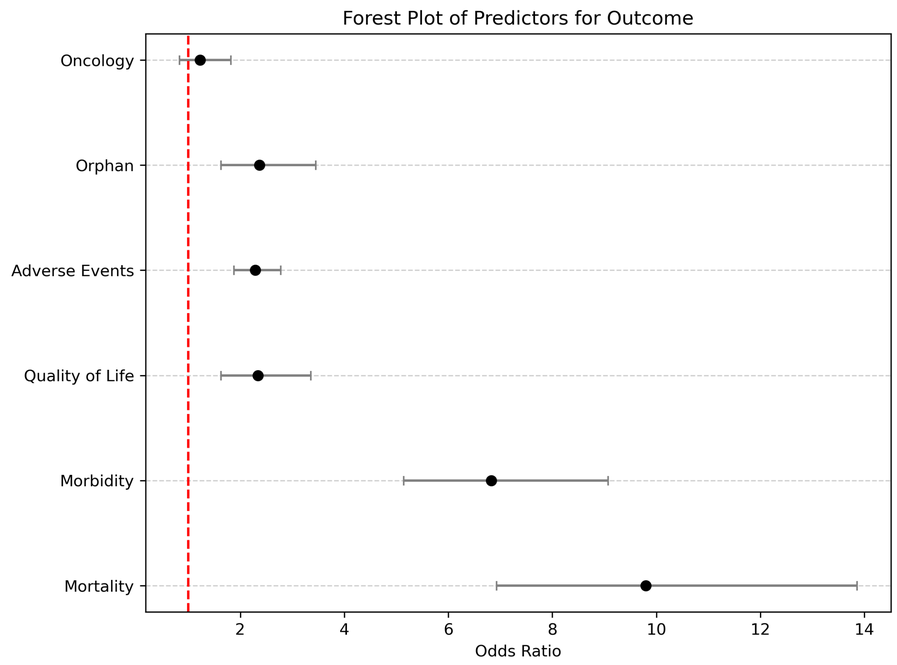
- To investigate the determinants of added benefit ratings by the G-BA, namely the four key endpoints discussed by G-BA: mortality, morbidity, quality-of-life and adverse events.
- Understanding these predictors provides insight into the key factors that influence favourable ratings, aiding pharmaceutical companies in optimizing their submission strategies and informing regulatory policies.

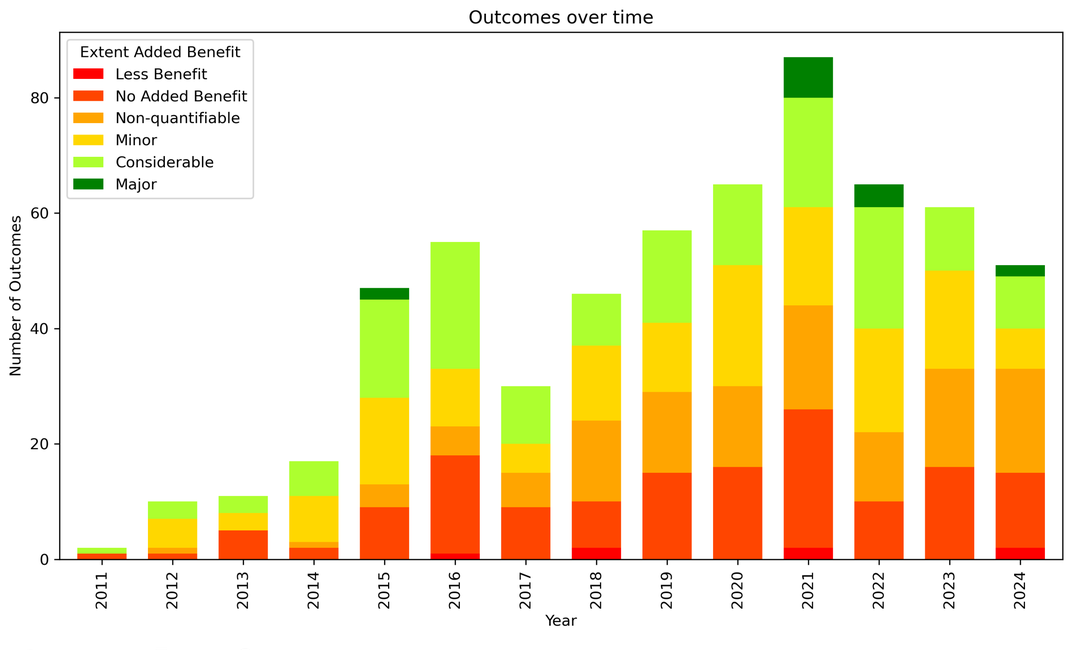
Methods

- Data were collected from G-BA resolutions documented in the HTA-Hive database, from January 1, 2012, to September 1, 2024.
- Information extracted included drug name, therapeutic indication, target population, added benefit rating, orphan status, and judgment on mortality, morbidity, adverse events, and quality-of-life. 1,420 outcomes were identified. All outcomes where no data was available on any endpoints were excluded, 604 outcomes were retained.
- An ordinal multinomial logistic regression model was constructed to evaluate the influence of each variable on the added benefit rating. The model was optimised using the Broyden–Fletcher–Goldfarb–Shanno (BFGS) algorithm.
- To assess the model fit, McFadden's R-squared was calculated by comparing the full model's log-likelihood against a null model without predictors, resulting in a model that explained a substantial proportion of variability in added benefit ratings. Odds ratios were derived to interpret the magnitude of each predictor's influence.

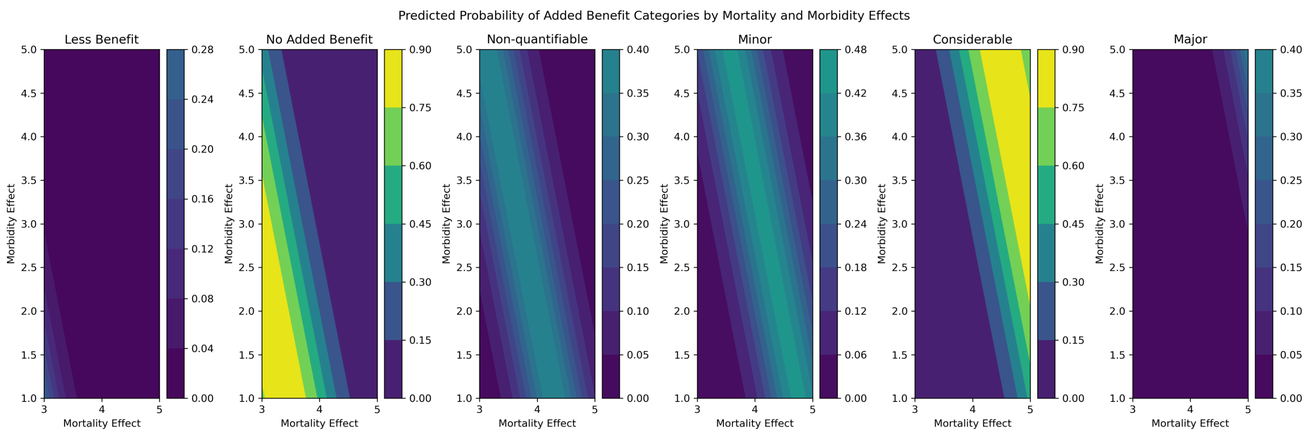
Results

- This ordered logistic regression analysis evaluates the impact of six predictors: mortality effect, morbidity effect, quality of life effect, adverse events effect, orphan designation, and whether the treatment is oncology-related.
- **Mortality** is the strongest predictor, with an odds ratio (OR) of 9.80 ($p < 0.001$), followed by **Morbidity** with an OR of 6.83 ($p < 0.001$).
- **Quality-of-life** and adverse events were moderate predictors with OR of 2.34 ($p < 0.001$) and OR of 2.29 ($p < 0.001$), respectively.
- **Orphan designation** exhibits a significant positive effect, with an OR of 2.37 ($p < 0.001$), showing that treatments with orphan designation are more than twice as likely to achieve higher added benefit ratings, emphasising the priority given to rare conditions.





- **Oncology** related treatments showed a weaker and non-significant effect, with an OR of 1.23 ($p = 0.304$). This suggests that, within this model, disease area does not significantly influence the likelihood of achieving a higher added benefit category.
- **Model Fit**: Pseudo R-squared (McFadden) of 0.3053, suggesting the model explains about 29.4% of the variability in the extent of added benefit, indicating a moderate fit and potential for additional variables to improve explanatory power.
- **Benefit Ratings Over Time:** The distribution of ratings assigned by the G-BA reveals variability over the study period. While "Non-quantifiable" and "Minor" added benefits are consistently present, there is a noticeable increase in "Considerable" and occasionally "Major" benefit ratings starting in 2015.
- **Mortality and Morbidity**: were further analysed as they emerged as the two strongest predictors of higher added benefit ratings. Considerable benefit ratings are particularly associated with a statistically significant and clinically relevant positive effect with high data reliability for both mortality and morbidity. In contrast, No added benefit ratings are specifically linked to a "statistically significant and clinically relevant negative effect with high data reliability" for both endpoints.



Conclusions

- **Mortality and Morbidity as Primary Drivers**: Our analysis highlights mortality and morbidity effects as the strongest predictors of higher added benefit ratings, underscoring their fundamental role in benefit assessment.
- **Significant Contributions from Quality of Life, Safety, and Orphan Designation**: Improvements in quality-of-life, safety (adverse events), and orphan designation also positively impact ratings, reinforcing their value as meaningful contributors alongside mortality and morbidity in evaluating treatment benefits.
- **Model Insights and Future Potential**: The model's moderate fit suggests that while core predictors are established, adding further variables could enhance our understanding of the factors driving added benefit ratings, providing direction for future assessment criteria.

References

- Gemeinsamer Bundesausschuss (G-BA), n.d. Benefit Assessment of Medicinal Products. *G-BA*. [online] Available at: https://www.g-ba.de/english/benefitassessment/
- Ivandic, V., 2014. Requirements for benefit assessment in Germany and England – overview and comparison. *Health Economics Review*, 4(12). [online] Available at: https://healtheconomicsreview.biomedcentral.com/articles/10.1186/s13561-014-0012-8
- Theidel, U. and von der Schulenburg, J.M.G., 2016. Benefit assessment in Germany: implications for price discounts. *Health Economics Review*, 6(33). [online] Available at: https://healtheconomicsreview.biomedcentral.com/articles/10.1186/s13561-016-0109-3
- Lebioda, A., et al., 2014. Relevance of indirect comparisons in the German early benefit assessment and in comparison to HTA processes in England, France and Scotland. *Health Economics Review*, 4(31). [online] Available at: https://healtheconomicsreview.biomedcentral.com/articles/10.1186/s13561-014-0031-5

Acknowledgements

This research was supported by HTA-Hive, whose commitment has been essential to our progress.

Contact Information

For further information, please contact f.tolkmitt@hiveoptimum.com