

An Approach to Value-Based Pricing for Digital Health Applications in Germany – bringing the efficiency frontier (back) to life?

Gensorowsky D¹, Witte J¹, Batram M¹, Greiner W²

¹Vandage GmbH, Bielefeld, Germany, ²Department of Health Economics and Health Care Management, Bielefeld University, Bielefeld, Germany

BACKGROUND AND OBJECTIVE

In December 2019, the Digital Health Care Act (Digitale-Versorgung-Gesetz) introduced a fast-track market access and pricing process for digital health applications (DiGAs) in the German statutory health insurance (SHI) system. Accordingly, after one year of free pricing by manufacturers, DiGA prices must particularly consider the positive health effects (pVE) of the applications in terms of a medical benefit or improvements in care structure and processes. The aim of the negotiations between the DiGA manufacturers and the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband) is to agree on an appropriate DiGA price based on these regulatory requirements. However, the regulations do not indicate how the patient-relevant benefits of a DiGA should be translated into a reasonable price. Therefore, we present and discuss an approach for the practical implementation of value-based pricing of DiGAs.

PREREQUISITES OF THE REGULATORY FRAMEWORK FOR DIGAS

To become eligible for reimbursement, the Federal Institute for Drugs and Medical Devices (BfArM) evaluates the compliance of a DiGA with general requirements (e.g., safety and data protection) and its pVE. In view of a subsequent value-based pricing of DiGAs, the peculiarities of this procedure and its overall regulatory framework must be considered:

- No definition of a specific appropriate comparator therapy
- Required comparator ("non-application of the DiGA") may consist of a usual care mix instead of one single standard therapy
- Unconventional and indication-specific concept of benefit without predefined cost-effectiveness thresholds
- No decision of the BfArM on the extent of benefit and the quality of evidence of a DiGA
- No further specifications on the methods for implementing value-based pricing

IMPLICATIONS FOR VALUE-BASED PRICING

The prerequisites mentioned have several implications for the consideration of patient-relevant benefits in the pricing process of DiGAs:

- Negotiators need to find a way to incorporate benefits into pricing
- Incremental approach is likely to be not feasible due to the comparison with a care mix and a lack of commonly accepted cost-effectiveness thresholds
- Indication-specific outcome measures (e.g., disease-specific symptoms) aggravate willingness to pay (WTP) considerations
- Pricing mechanism may need to account for several dimensions of benefit (i.e., medical and procedural)

Under these conditions, how can objective points of reference be derived for the appropriateness of a DiGA price?

VALUE-BASED PRICING OF DIGAS: REVIVING THE EFFICIENCY FRONTIER

Our approach considers a DiGA price to be (at least still) reasonable if it results in a unit of benefit generated by the DiGA costing no more than a unit of benefit generated by another reimbursable therapy. Thus, in line with the efficiency frontier concept of the Institute for Quality and Efficiency in Health Care (IQWiG), we approximate the SHI's WTP by the average cost-effectiveness of one or more established therapy in a field of indication and furthermore consider the pVE of a DiGA (Fig. 1). Relating both factors to each other, indifference prices can be determined at which a DiGA would have the same cost-effectiveness ratio as its price anchor therapy. Sensitivity analyses can consider both effects, and cost ranges to reflect uncertainties about the costs and benefits of the therapy options to be compared.

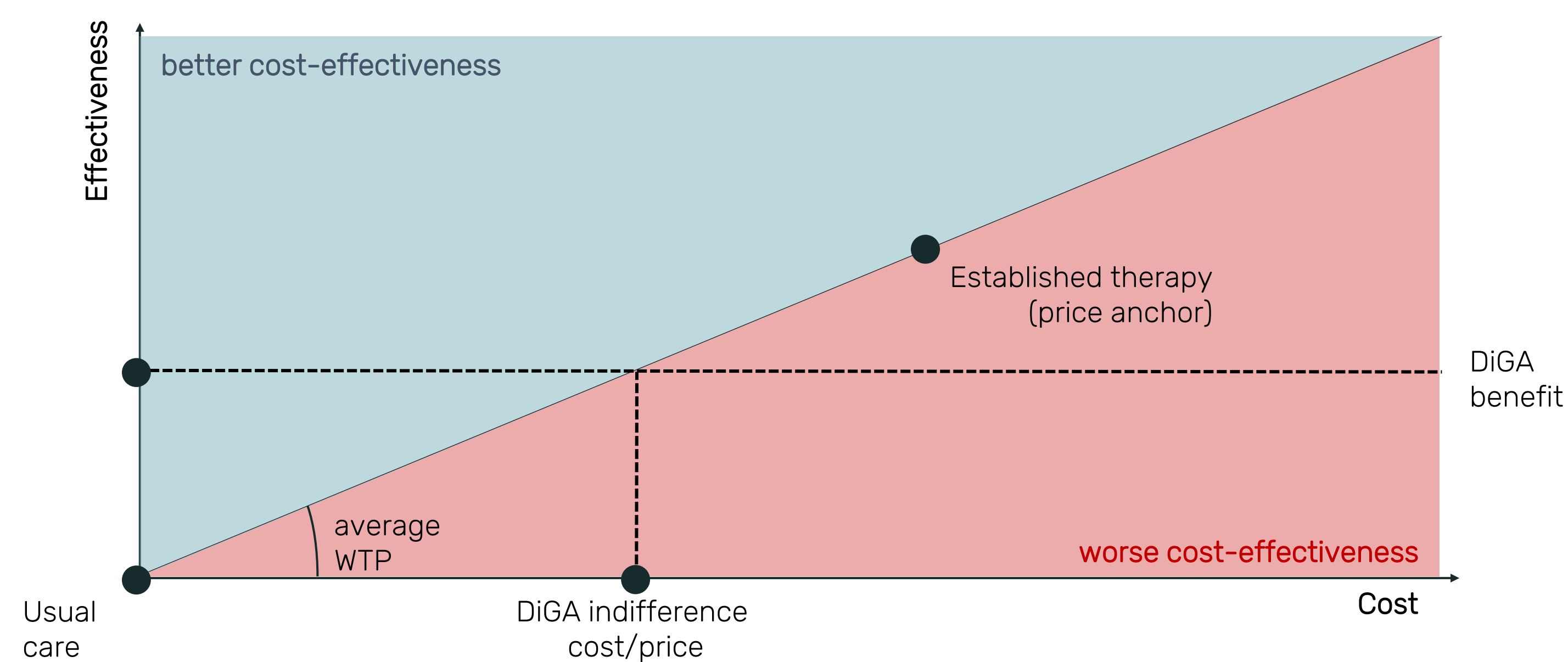


Fig. 1: Graphical derivation of an indifference price.

CONCLUSION

Our pricing approach considers the regulatory peculiarities in the DiGA sector and can provide objective guidance for price negotiations. However, widely-discussed limitations of the efficiency frontier also apply here. As value-based pricing must operate within a given regulatory framework, the appropriateness of the requirements from a health economic perspective and from a system-level efficiency perspective should be further discussed in the future.

USE CASE ELEVIDA

elevida (manufacuter: GAIA AG) is an online therapy program for the treatment of fatigue in multiple sclerosis based on cognitive behavioral therapy (CBT) methods and a DiGA since December 2020. To estimate a value-based price for elevida, we defined personal CBT as a price anchor. For personal CBT, we considered 3 effectiveness estimators (CBT vs. usual care, endpoint: fatigue severity) based on meta-analytic evidence.¹ Furthermore, we considered 9 cost scenarios based on the German uniform value scale (EBM). For elevida, 6 effectiveness estimators (elevida vs. usual care, endpoint: fatigue severity) were considered (3 base case, 3 sensitivity analysis).² Consideration of all scenarios resulted in 54 indifference prices (mean: 1,478€; median: 1,140€), 37 of which above the free manufacturer's price (Fig. 2).

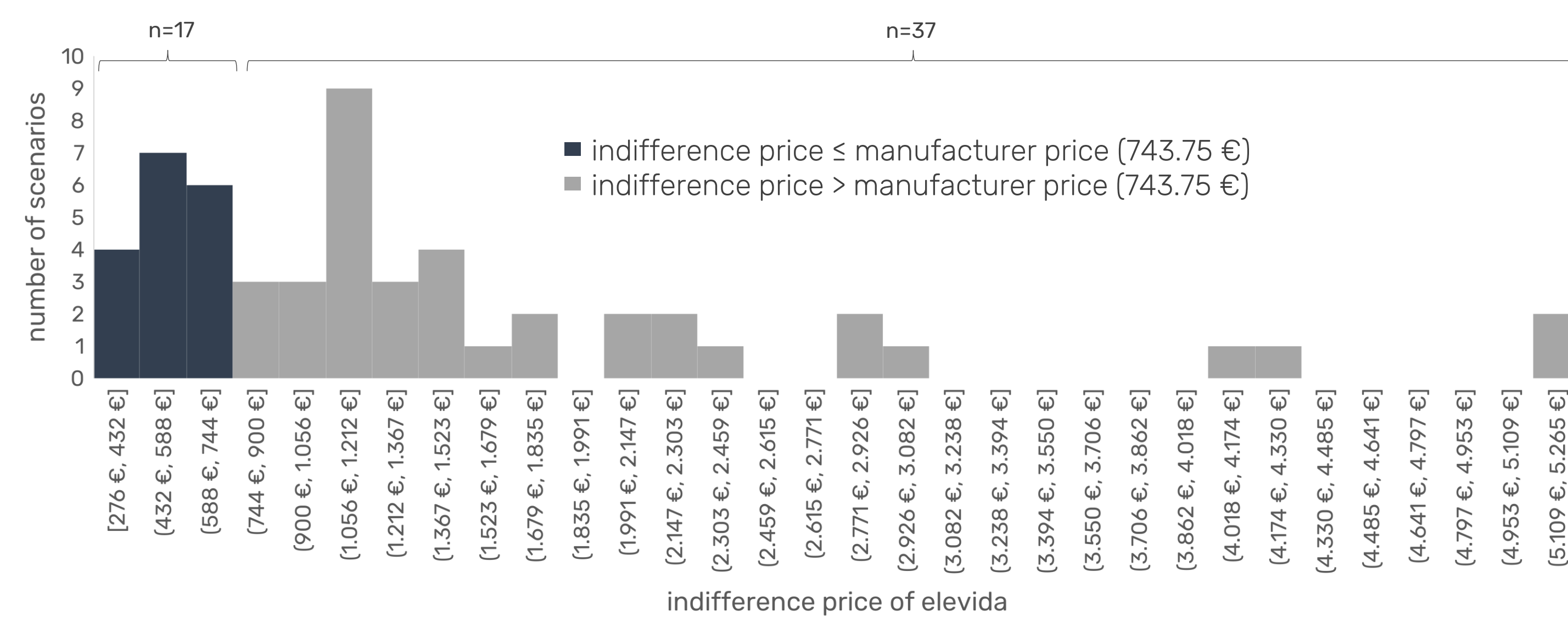


Fig. 2: Estimated indifference prices for elevida (N = 54).