# Cost-Effectiveness in the German AMNOG Process? Analyzing the 2025 SVR Proposal and Its Implementation Challenges

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## INTRODUCTION

The 2025 report by the German Council of Experts on Health (SVR) recommends integrating cost-effectiveness analysis (CEA) into the AMNOG pharmaceutical pricing framework. Specifically, the SVR proposes that a defined subset of medicines—particularly those with high costs or multiple indications—undergo economic evaluation using cost-utility metrics like cost per QALY (quality-adjusted life year).
This marks a paradigm shift in German health technology assessment, which traditionally focuses solely on the added clinical benefit evaluated by the G-BA.

## METHODOLOGY

- Document Analysis: Focused review of Chapters 2 and 5 of the SVR 2025 report.
- Comparative HTA Review: Benchmarking Germany's current CEA approach against established systems in:
  - United Kingdom (NICE),
  - France (HAS), and
  - Netherlands (ZIN)
- Institutional Analysis:
  - Role of IQWiG (performs CEAs) vs. G-BA (does not use them in decision-making).
  - Legal and Political Feasibility:
  - Review of constraints under SGB V (§35a).
  - Identification of implementation barriers using policy diffusion and institutional change frameworks.

## RESULTS

### Key SVR Proposals

CEA should be applied to a targeted selection of drugs, particularly those with high cost, uncertain long-term value, or multiple indications.

A standardized metric such as cost per QALY should be adopted for these evaluations to ensure comparability and pricing consistency.

Insight: Germany is an outlier in Europe, with no formal integration of CEA in price-setting, no cost-effectiveness thresholds, and no legal basis for price negotiation based on economic value.

| Country | HTA Agency | CEA Integration | Threshold Guidance | Use in Pricing Decisions |
|---|---|---|---|---|
| **UK** | NICE | Mandatory for most drugs | £20,000–£30,000/QALY | Directly linked to access decisions; flexible exceptions for end-of-life/ultra-orphan |
| **France** | HAS | Contextual (in ASMR/IQV) | No explicit threshold | CEAs inform pricing; not determinative |
| **Netherlands** | ZIN | Fully integrated | €20,000–€80,000/QALY (severity-based) | Strong influence on pricing and reimbursement |

**Major Implementation Barriers in Germany:**

1. No cost-effectiveness threshold or willingness-to-pay benchmark is officially defined.
2. SGB V lacks legal basis for including economic evaluation in reimbursement decisions.
3. Institutional fragmentation: IQWiG can perform CEAs, but G-BA does not formally consider them.
4. Political and ethical resistance: Concerns about rationing and equity, especially for vulnerable populations (e.g., patients with rare diseases or disabilities).

**Strategic Insights for Implementation**

- Begin with pilot projects: High-budget impact drugs, therapies with multiple indications, gene/cell therapies.
- Introduce CEA initially as non-binding annexes in AMNOG dossiers to test feasibility.
- Develop German-specific methodological guidance aligned with international standards (e.g., NICE's Reference Case, EQ-5D).
- Build an early engagement process with stakeholders - patient groups, physician societies, and payers.
- Define how IQWiG's economic outputs can be operationalized in G-BA assessments and price negotiations.

## CONCLUSIONS

The SVR proposal offers a real opportunity to modernize the AMNOG framework and align it with global HTA best practices. However, successful implementation requires:

- Legal reform of SGB V to incorporate economic value into price negotiations;
- Coordination between IQWiG and G-BA to harmonize CEA integration;
- Public communication strategies to build trust and mitigate fears of cost-based rationing;
- A phased rollout plan during the 2025–2029 legislative period to allow structured learning and adaptation.

Germany has the potential not only to catch up with international standards but to define a uniquely transparent and ethically grounded approach to cost-effectiveness in pharmaceutical access.

## REFERENCES

[1]Sachverständigenrat Gesundheit & Pflege (SVR). Preise innovativer Arzneimittel in einem lernenden Gesundheitssystem. Report 2025 https://www.svr-gesundheit.de/fileadmin/Gutachten/Gutachten_2025/SVR_Gutachten_2025.pdf (last accessed November 1, 2025