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Do the guardrails have any effect at all? An analysis of the impact of the 2022 FinStG guardrails on the German AMNOG process

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Objectives

This study quantifies the impact of the 2022 GKV-Finanzstabilisierungsgesetz (FinStG) "guardrails" (Leitplankenregelung) on price negotiation outcomes within the German AMNOG framework[1]. These guardrails introduced mandatory discount thresholds linking the negotiated reimbursement price to the cost of the appropriate comparator therapy (ACT) **(Figure 1)**, aiming to strengthen fiscal discipline and pricing consistency. However, its actual financial effects remained difficult to quantify. Building on this, our study provides an empirical assessment using Kintiga's AMNOG database, comparing non-orphan first submissions and high-revenue orphan procedures (> €30 million) before and after implementation of the guardrails. We analyze changes in negotiated discounts, launch price differentials, and price-to-ACT ratios with focus on the newly introduced standard for patent and document protected ACT, assessing whether FinStG has reinforced the link between value-based pricing and fiscal sustainability, thus filling a key evidence gap in German HTA.

Figure 1: FinStG "guardrails"

Added benefit category	ACT without patent or document protection[2]	ACT with patent or document protection[2]	ACT or comparable drug with patent protection but without benefit assessment
Added benefit not proven	The negotiated price **must** result in ATC below the ACT to an appropriate extent.	The negotiated price **must** result in ATC at least 10% below the ACT.	The ATC of the ACT **must** be reduced by 15%. The resulting ATC of the ACT are the price anchor.
No added benefit	The negotiated price **shall not** result in higher ATC than the ACT.		
Non-quantifiable or minor added benefit	The negotiated price may result in higher ATC than the ACT.	The negotiated price **must not** result in higher ATC than the ACT.	
Considerable or major added benefit		The negotiated price may result in higher ATC than the ACT.	

Methods

Data as of June 2025 were derived from Kintiga's proprietary AMNOG database, comprising 72 benefit assessments (non-orphan, initial assessment, completed negotiation) and price negotiations conducted after the introduction of the FinStG guardrails and a matched set of 72 procedures before implementation. Analyses focused on non-orphan indications with a clearly defined comparator and without patient-individualized therapies. For each case, the gross cost level of the lowest-cost comparator was compared to that of the evaluated therapy. Descriptive comparisons and regression analyses were performed to assess negotiated discounts and launch price dynamics between procedures affected by the guardrails and those that were not and those conducted prior to FinStG.

Figure 2: Filter used for selected procedures

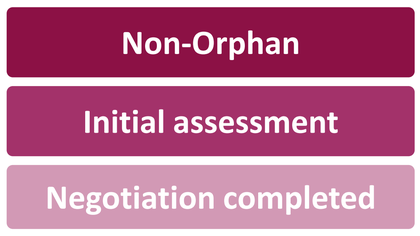
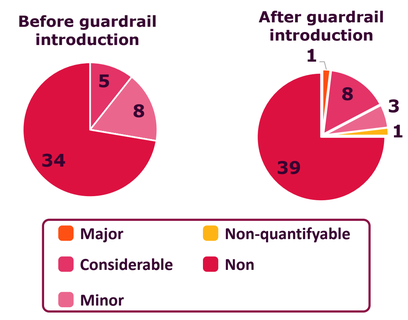


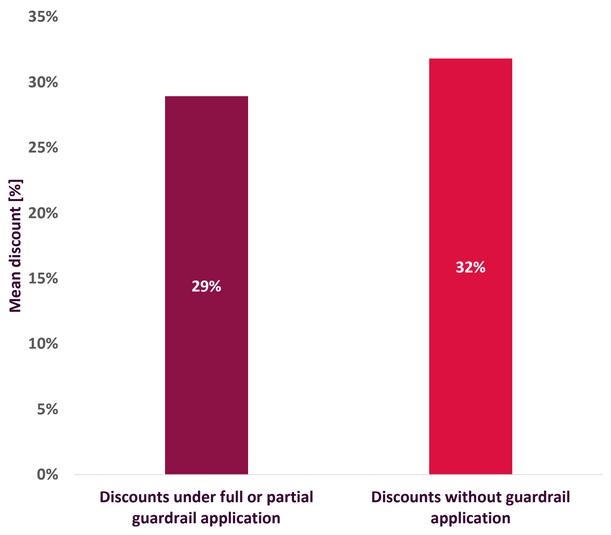
Figure 3: HTA outcomes of non-orphan procedure before and after guardrail introduction



Results

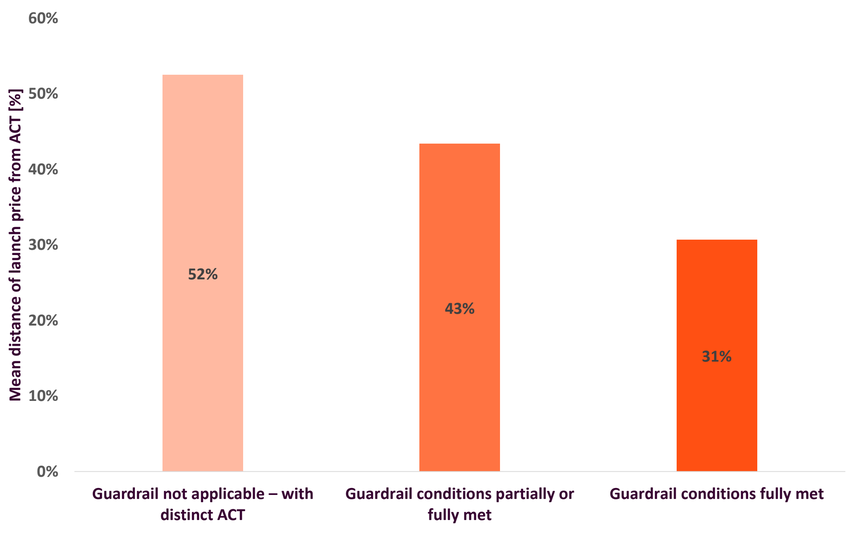
The analysis found that the introduction of the FinStG guardrails had only a limited impact on average negotiated discounts within AMNOG price negotiations. Across all non-orphan procedures without patient-individualized therapies, the mean discount remained relatively stable (pre-guardrails: 28.80% vs. post-guardrails: 28.03%). Similarly, when comparing procedures in which the appropriate comparative therapy (ACT) was subject to the new guardrail conditions with those in which it was not, the results showed comparable discount levels (28.91% vs. 31.81%) **(Figure 4)**. However, a clear difference emerged at the launch price level: therapies falling under the new guardrails showed a smaller markup over the ACT cost (guardrails partially or fully applicable e.g., for a subpopulation: 43.36%, guardrails fully applicable: 30.68%) compared with those outside the guardrail scope (52.48%) **(Figure 5)**. This suggests that the legislation may have influenced initial pricing strategies rather than the negotiated discount outcomes themselves. Moreover, the analysis revealed a strengthened positive correlation between the launch price deviation from the ACT and the final negotiated discount after the introduction of the guardrails. The coefficient of determination (R^2) increased from 0.187 before to 0.207 (for ACT´s where guardrails were not applicable) after FinStG implementation, reaching 0.336 for ACTs under the guardrail regime—indicating tighter alignment between starting price levels and negotiation outcomes **(Figure 6)**.

Figure 4: Average discount depending on guardrail application[2]



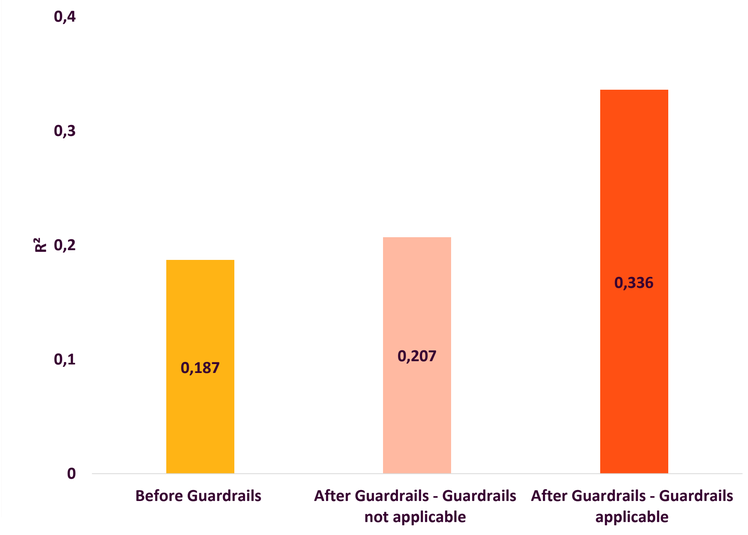
[2]**Discounts under full or partial guardrail application:** Procedures in which at least one subgroup of the appropriate comparator therapy (ACT) met the following criteria: (1) the ACT was clearly defined and not patient-individualized (i.e., a specific, most economical comparator was applicable), and (2) the ACT was subject to documentation and/or patent protection, thus falling within the FinStG guardrail conditions.
Discounts without guardrail application: Include procedures where the comparator therapy was not subject to patent or documentation protection, or where the ACT required patient-specific therapy selection, rendering the FinStG guardrails inapplicable.

Figure 5: Distance from launch price to ACT depending on the applicability of the guardrails after their introduction[3]



[3]**Guardrails not applicable – with distinct ACT:** Procedures conducted after FinStG introduction where a clearly defined comparator existed, but guardrail conditions (patent or documentation protection) did not apply.
Guardrail conditions partially or fully met: Procedures where at least one ACT subgroup met the FinStG guardrail criteria (patent and/or documentation protection).
Guardrail conditions fully met: Procedures in which all relevant ACTs fulfilled the FinStG guardrail requirements.

Figure 6: Correlation distance launch price from ACT vs. negotiated discount[4]



[4]**Before guardrails:** Negotiation completed prior to the implementation of the GKV-Finanzstabilisierungsgesetz (FinStG).
After guardrails – guardrails not applicable: Procedures completed after FinStG introduction but outside the scope of guardrail applicability (e.g., ACT not patent-protected or patient-specific).
After guardrails – guardrails applicable: Procedures conducted after FinStG introduction in which ACTs met the conditions for guardrail application.

Conclusion

This analysis provides **quantitative evidence** of how the **FinStG guardrails** have affected AMNOG price negotiations since their introduction in 2022. While average negotiated discounts remained virtually unchanged before and after implementation, the results indicate a **shift in manufacturers' pricing behavior at launch**. Therapies subject to the guardrails showed a markedly smaller markup over the appropriate comparative therapy (ACT), suggesting that companies are now adjusting initial list prices more cautiously to remain within the newly defined cost thresholds.

The strengthened correlation between the **launch price deviation from the ACT** and the **final negotiated discount** further supports this interpretation: negotiation outcomes appear increasingly anchored in the initial pricing position relative to the comparator. Thus, the FinStG framework may have achieved its policy goal of improving **pricing discipline and cost alignment**, not through larger discounts, but through **pre-emptive price calibration** at market entry.

For manufacturers, these findings underscore the growing importance of **robust ACT knowledge, pricing analytics, and strategic launch planning**. As AMNOG negotiations evolve toward stronger linkage between evidence, comparator costs, and fiscal sustainability, early **HEOR-informed price strategy** becomes critical to optimize outcomes under Germany's new regulatory guardrails.

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References:
Act on the Financial Stabilisation of Statutory Health Insurance (GKV-FinStG) of 6 November 2022, Federal Law Gazette I No. 42, p. 1990.

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