

# The Influence of the Claimed Benefit Versus the Given Benefit on the Negotiated Rebate During the German Health Technology Assessment



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## Objectives

For the German AMNOG assessment, one could assume a positive effect on the rebate of the price of a medicinal product to be negotiated with the GKV-SV if the added benefit claim in the dossier is set as high as possible, irrespective of whether this claim is confirmed in the resolution by the G-BA. During the assessment, the benefit claimed in the dossier was not confirmed by the G-BA in 68% of the procedures. The aim of this analysis was to investigate if a downgrade of the benefit was associated with a higher rebate negotiated with the GKV-SV and if a high benefit claim was linked with a lower rebate.

## Methods

We performed an analysis with our SKC-internal database "Market Access Intelligence System" (short: MAIS) encompassing all G-BA procedures with a claimed added benefit and a negotiated rebate until 05/2022. To enable a comparability of these procedures, we selected for those whose benefit claim is identical for all subpopulations and for all subpopulations in the G-BA decision. We then compared the negotiated rebate on net annual therapy costs (ATC) of products with a downgrade or confirmation of the claimed benefit during the AMNOG process. Opt-Out procedures were excluded from the calculations. The results refer to the effect of achieving the claimed added benefit alone without including other success factors of the price negotiations.

## Results

### A typical picture: Pharmaceutical manufacturers and HTA bodies only agree in 20% of cases.

	Procedures A+B	Average net rebate	Initial submission A	Average net rebate	Further procedures* B	Characteristics AB		
						Orphan	Arbitration	Opt-Out
<b>Claimed benefit (dossier) confirmed by G-BA resolution</b>								
No added benefit	25	9.09%	8	11.83%	17	2		2
Non-quantifiable added benefit	20	17.58%	11	28.82%	9	17	2	
Minor added benefit	2	8.66%	2	8.66%				
Considerable added benefit	22	6.64%	6	21.38%	16	13	2	
Major added benefit	4	0.50%	2	1.00%	2	4		
<b>Σ procedures / Ø net rebate</b>	<b>73</b>	<b>10.19%</b>	<b>29</b>	<b>19.28%</b>	<b>44</b>	<b>36</b>	<b>4</b>	<b>2</b>
<b>Claimed benefit (dossier) downgraded in G-BA resolution</b>								
Major to no added benefit	14	25.47%	8	34.59%	6	1	1	1
Major to non-quantifiable added benefit	28	14.70%	18	19.85%	10	21	5	
Major to minor added benefit	12	10.61%	4	9.97%	8	2		
Major to considerable added benefit	27	9.92%	13	16.01%	14	7		
Considerable to no added benefit	44	26.62%	21	37.25%	23	4	8	4
Considerable to non-quantifiable added benefit	41	17.09%	26	23.39%	15	35	2	1
Considerable to minor added benefit	44	13.35%	19	24.83%	25	19	2	
Minor to no added benefit	21	24.65%	11	33.67%	10	5	2	1
Minor to non-quantifiable added benefit	8	14.42%	6	17.46%	2	8		
Non-quantifiable to no added benefit	57	18.11%	26	29.10%	31	6	4	2
<b>Σ procedures / Ø net rebate</b>	<b>296</b>	<b>17.87%</b>	<b>152</b>	<b>26.56%</b>	<b>144</b>	<b>108</b>	<b>24</b>	<b>9</b>

- Table 1 depicts all 381 AMNOG procedures analyzed with the MAIS database and their classification into subgroups. One of the medicinal products was already withdrawn from the market before the price negotiation.
- In 75 procedures the claimed added benefit was confirmed. Nearly half of the medicinal products had an orphan designation (36).
- A downgrade by the G-BA was identified in 305 procedures. In nearly half of these procedures, the claimed benefit was downgraded to "no added benefit".
- Only two procedures received an upgrade of the added benefit in all subpopulations (data not listed).

Table 1: Classification of analyzed AMNOG procedures utilizing the MAIS database.

\*Further submissions: new indication, reassessment after time limitation, exceeding the 50 million limit, new indication + exceeding the 50 million limit, exceeding the 1 million limit, loss of orphan drug status, reassessment §13 (new scientific evidence), reassessment §14 (5. Kap. § 1 Abs. 2 Nr. 6 VerfO).

### "Claim high": A downgrade of the added benefit by the G-BA resolution leads to an average rebate of 17.87%.

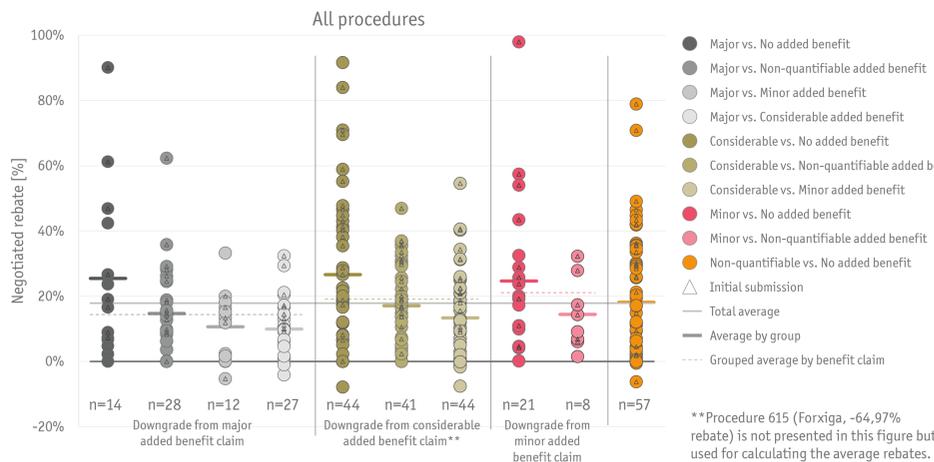


Figure 1: Negotiated rebate in all procedures where the claimed added benefit unequal the G-BA resolution.

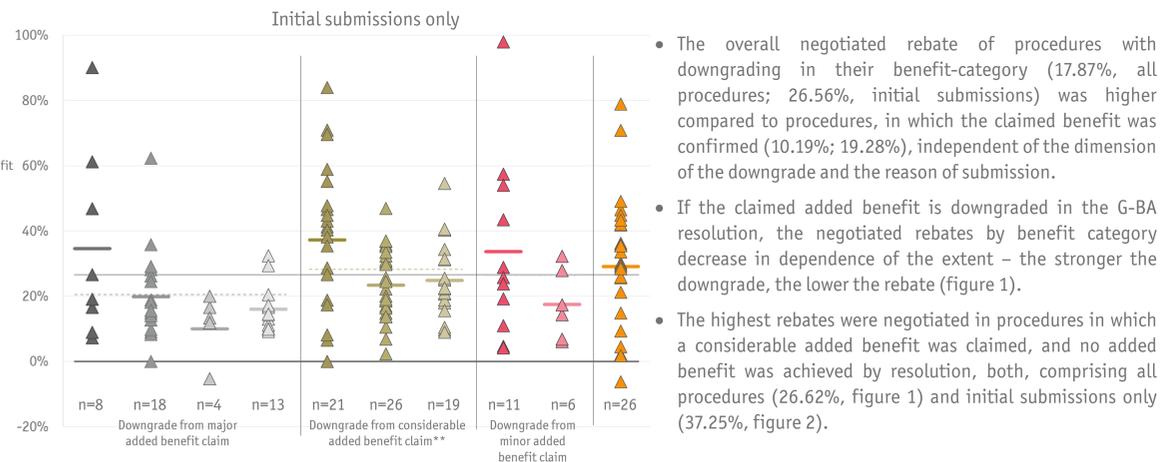


Figure 2: Negotiated rebate in initial submission procedures where the claimed added benefit unequal the G-BA resolution.

- The overall negotiated rebate of procedures with downgrading in their benefit-category (17.87%, all procedures; 26.56%, initial submissions) was higher compared to procedures, in which the claimed benefit was confirmed (10.19%; 19.28%), independent of the dimension of the downgrade and the reason of submission.
- If the claimed added benefit is downgraded in the G-BA resolution, the negotiated rebates by benefit category decrease in dependence of the extent – the stronger the downgrade, the lower the rebate (figure 1).
- The highest rebates were negotiated in procedures in which a considerable added benefit was claimed, and no added benefit was achieved by resolution, both, comprising all procedures (26.62%, figure 1) and initial submissions only (37.25%, figure 2).

### "Stay humble": A confirmation of the added benefit by the G-BA resolution leads to an average rebate of 10.19%.

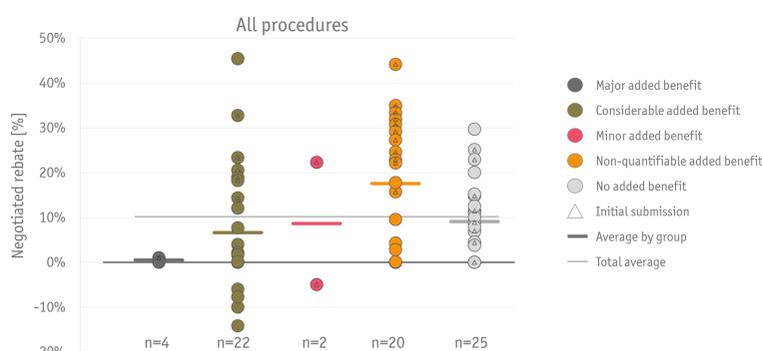


Figure 3: Negotiated rebate in all procedures where the claimed added benefit equals the G-BA resolution.

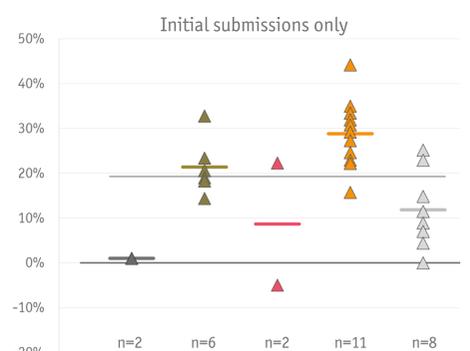


Figure 4: Negotiated rebate in initial submission procedures where the claimed added benefit equals the G-BA resolution.

- Figure 3 shows all 73 negotiated procedures where the claimed benefit category was confirmed in the G-BA resolution. The majority of procedures reached no added benefit, considerable added benefit or a non-quantifiable added benefit, respectively. The highest average rebate on ATC was negotiated for procedures with a non-quantifiable added benefit claim (17.58%). If a claimed major added benefit was confirmed by the G-BA, the average negotiated rebate was minimal (0.5%).
- Considering only the initial submission procedures in figure 4, the average rebate is 19.28%, thus, nearly twice of the average rebate of all procedures in figure 3, independently of the reason of submission.
- The lowest rebate was shown in initial submissions achieving a major added benefit (1.0%), the highest average rebate was negotiated in procedures with a non-quantifiable added benefit (28.82%), which is also the group where the most orphan drugs are included (table 1).
- Initial submissions with a considerable added benefit showed an average rebate of 21.38%, which is greater than in the group of a minor added benefit (8.6%). However, these two procedures come with a wide range of negotiated rebate.

## Conclusion

- The average negotiated rebates on the ATC following initial submissions are higher (worse) than the overall average rebates of benefit assessments comprising all procedures, irrespective of the reason of submission.
- In general, it appears that the higher the added benefit category, the lower the negotiated rebate on the ATC. An exception is the category of a non-quantifiable benefit, which is probably biased due to the number of orphan drugs within this group.
- A downgrade of the claimed benefit was associated with a higher rebate on the ATC, regardless of the category. In addition, the higher the downgrade was, the higher was the rebate. In conclusion, it is not advisable to generally claim as high as somehow arguable, but rather consider receiving a confirmation of the claimed added benefit by the G-BA as a stronger argument for the negotiation table.



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All analyses have been conducted with our own comprehensive MAIS database that contains and links AMNOG information of all completed and ongoing benefit assessment procedures according to §35a SGB V of the German Federal Joint Committee (G-BA).