Analysis of Health Technology Assessments of Lung Cancer Therapies in Germany in the Last Decade: Is there an Association between Added Benefit Ratings and Negotiated Reimbursement Prices?

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Background

Reimbursement for novel therapies in Germany is determined through a two-step process. First, the Federal Joint Committee (G-BA) conducts a clinical benefit assessment. Following this, reimbursement prices, effective from the seventh month onward, are negotiated between the 'GKV-Spitzenverband' (Association of Statutory Health Insurance Funds) and pharmaceutical companies. A crucial part of this assessment is determining the "appropriate comparator therapy" (ACT). The ACT is selected based on the standard treatment considered most relevant and appropriate for the therapeutic area. This comparator serves as the benchmark for assessing the added benefit of the new therapy [1,2]. This study analyzes launch prices and negotiated prices for lung cancer therapies authorized in Germany between 2013 and 2023, exploring whether there is a relationship between G-BA's added benefit ratings and reimbursement prices.

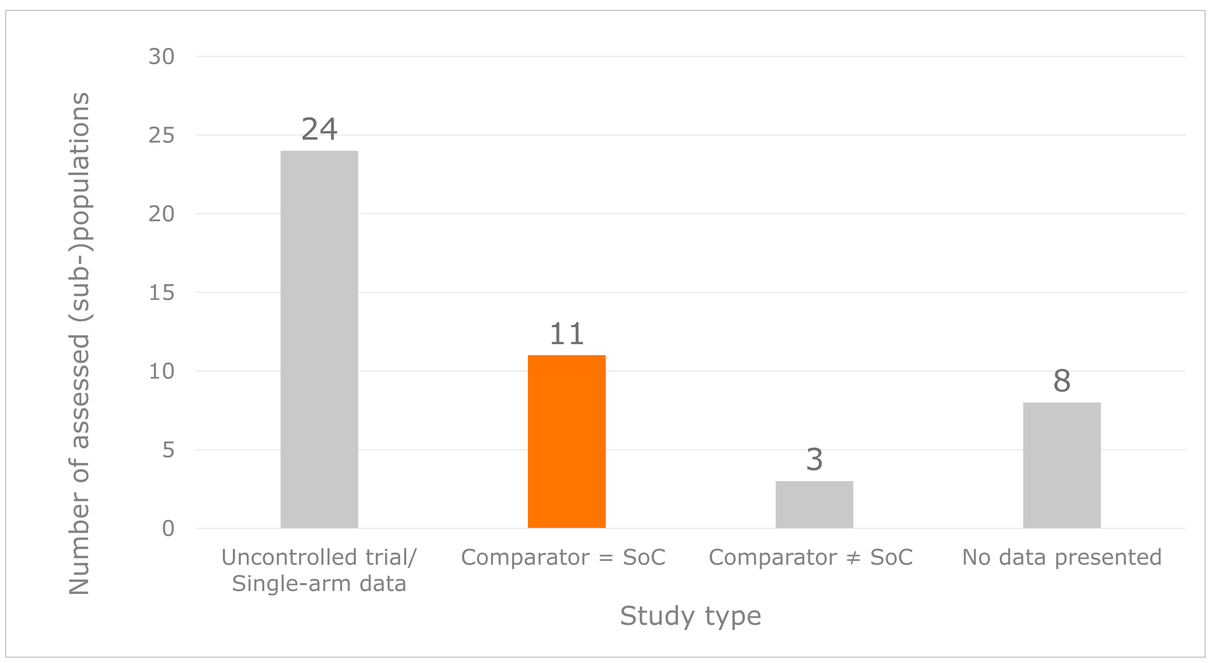
Methods

The data for this analysis were drawn from 22 initial assessments conducted by the G-BA, which encompassed 21 active ingredients, spanning 46 distinct subpopulations. For each G-BA assessment, the added benefit of the therapy was classified into two categories: 'major/considerable benefit' and 'minor/no added benefit'. The reimbursement prices of these therapies were then analyzed at two time points: the price at launch and the negotiated price 15 months after market entry. The prices were expressed as absolute values and compared relative to the least expensive ATC in the respective (sub-)population. The relative price differences were calculated as percentages, representing the price of the new therapy in relation to the cost of the least expensive therapy available in that category. However, a relative cost comparison could not be made if Best Supportive Care (BSC) was the only available ACT, due to the lack of available information on the associated costs of BSC. Accordingly, these observations were excluded from the cost comparison.

Results

Between 2012 and 2023, 52% of initial benefit assessments for oncology therapies for lung cancer were based on a non-controlled study design (see **Figure 1**). In the 14 cases where a randomized controlled trial (RCT) was available, it was found that in three (21%) of these cases, the comparator did not match the appropriate ACT. Thus, only 24% of the assessed patient (sub-)populations had comparative evidence based on RCTs. In the remaining 8 cases, no comparative evidence was presented that could be considered by the G-BA.

Figure 1: Trial Designs for Lung Cancer within the AMNOG Process



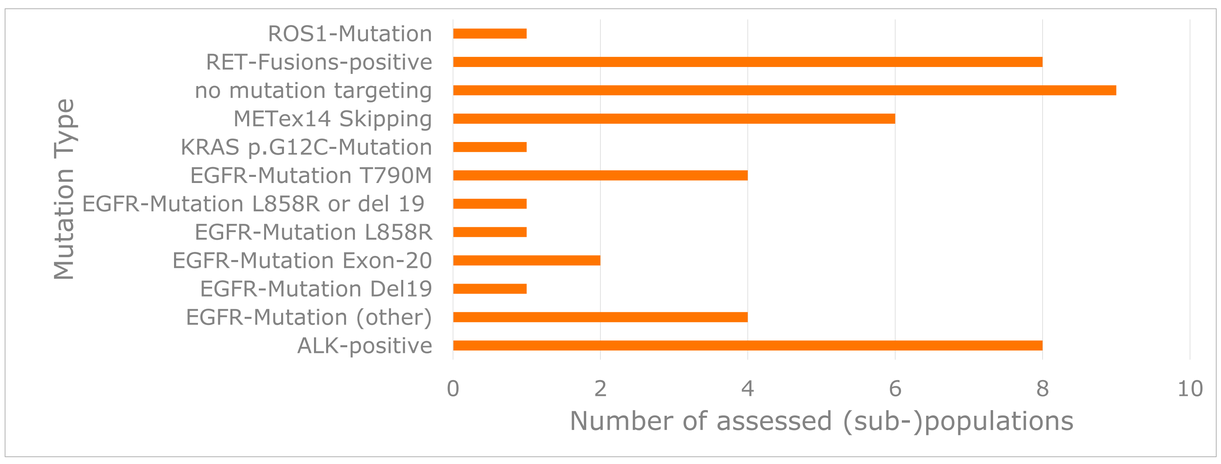
The vast majority of included assessments (44 out of 46) pertained to therapies for non-small cell lung cancer (NSCLC), none of which benefited from orphan drug designation. The distribution of assessed mutation types in lung cancer therapies includes ALK-positive, RET fusion-positive, and MET exon 14 skipping mutations. Most health technology assessments, however, addressed lung cancer patients without a targeted mutation (see **Figure 2**).

Table 1: Initial Added Benefit Ratings For Lung Cancer Therapies

Not Proven	Not Quantifiable	Minor	Considerable	Major
84.8%	0.0%	4.3%	8.7%	2.2%

Most lung cancer therapies were rated as having 'no added benefit' when compared to the ACT, and no therapy was assigned a 'Not Quantifiable' benefit at the initial G-BA assessment (see **Table 1**). These treatments were initially launched at an average cost of €106,525 per patient-year. Within 15 months, their mean price dropped by 38%. During this same period, three therapies were withdrawn from the market, likely due to concerns over economic viability following a significant drop in price, especially given that no additional benefit was recognized in these cases. In the remaining 33 assessments (excluding comparison to BSC), novel therapies averaged a cost difference of €23,367 (244% increase over the least expensive ACT), ranging from -61% to 871%. Those with 'major' or 'considerable' added benefit had a higher median cost difference of €32,992, compared to €12,821 for those without added benefits, highlighting a trend where greater clinical benefit correlates with larger price premiums relative to the ACT price.

Figure 2: Targeted mutations of novel therapies in lung cancer



Conclusion

The rapid drop in mean price, along with the withdrawal of therapies lacking additional benefit, underscores the economic pressures on high-cost treatments without clear clinical advantages. Therapies with 'major' or 'considerable' benefit command higher premiums, highlighting the importance of demonstrable value in sustaining prices and market access. The new German pricing regulations prevent price markups for therapies without added benefit, suggesting G-BA ratings may have even greater impact on future price negotiations.

Disclosure statement

Nils Picker and Sabrina Mueller are employees of GIPAM GmbH and have nothing to declare. Thomas Wilke participated in this study as member of IPAM e.V. and has nothing to declare.

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