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AMNOG benefit assessment in Germany: outcomes from 2011 to 2023

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Abstract

- Since the enactment of the German Medicines Market Reorganization Act (AMNOG) in Germany in 2011, pharmaceutical companies are required to demonstrate an added benefit of newly approved drugs within their specific therapeutic area(s).

Background

- The benefit assessment is conducted by the Federal Joint Committee (G-BA) and Institute for Quality and Efficiency in Healthcare (IQWiG) serving as the basis for price negotiations with the National Association of Statutory Health Insurance Funds (GKV-SV).

Objective

- This study aims to examine the outcomes of the AMNOG benefit assessments from Jan. 2011 to Nov. 2023.

Methods

- A database containing all evaluated AMNOG assessments was analyzed and Information on G-BA assessments and decisions on added benefit were extracted.
- Pricing data from the Lauer Taxe® database, which captures prices at launch and after G-BA decisions, were also obtained.
- Qualitative and quantitative analysis was conducted to identify predictors of assessment outcomes and their impact on price negotiations.

Conclusions

- Since 2011, benefit assessments have become the key component in the pricing of new drugs in Germany.
- A total of 944 AMNOG assessments were published, with oncological, metabolic, infectious, and neurological diseases accounting for the vast majority of all assessed indications.
- Our analysis shows that most subpopulations were not granted an added benefit, indicating that the provided evidence did not meet either sufficient efficacy, safety, or methodological criteria.
- By law, Orphan Drugs are granted an added benefit in accordance with AMNOG rules. Data indicate that the majority of Orphan Drugs received a "non-quantifiable" added benefit.
- Receiving an added benefit is essential for price negotiation. Assessments with no added benefit resulted in higher rebates on the reimbursement price compared to assessments with an added benefit.

References: 1. Lauer-Taxe®. Accessed 2 December 2023. https://portal.cgmlauer.cgm.com/LF/Seiten/Verwaltung/Kundencenter/1.aspx **2.** Gemeinsamer Bundesausschuss. Accessed 2 December 2023. https://www.g-ba.de/bewertungsverfahren/nutzenbewertung/

Results

- **Figure 1A** depicts the difference between the assessment-level and subpopulation-level of German benefit assessments.
- Drug X is approved for indication A and indication B, which are 2 distinct benefit assessments. Indication B is further differentiated in subpopulation 1 and subpopulation 2 (e.g., untreated and previously treated patients, respectively).
- From Jan. 2011 to Nov. 2023, 944 AMNOG assessments were published, covering 1,614 separately evaluated subpopulations (**Figure 1B**).
- **Figure 2A and Figure 2B** depict the distribution of the 6 possible benefit categories among the subgroup benefit assessments for each year (Jan. 2011 to Nov. 2023).
- Over the last decade, a trend increase in the annual total number of subgroup assessments can be observed (**Figure 2A**).
- The annual percentage of the benefit category at "no added benefit" remained stable at a high level (around 50–60%) for the last 10 years (**Figure 2B**).
- Non-Orphan & Orphan Drugs, as well as Orphan Drugs were analysed for the highest added benefit on assessment level, (**Figure 3A**) and highest added benefit on subpopulation level, (**Figure 3B**).
- On assessment level, approx. 52% of the Non-Orphan & Orphan Drugs and 83% of the Orphan Drugs received an added benefit ("major", "considerable", "minor", "non-quantifiable") in at least 1 subpopulation. "No added benefit" was granted for 42% of the Non-Orphan & Orphan Drugs on assessment level, as well as for 15% of the Orphan Drugs.
- Approx. 37% of the Non-Orphan & Orphan Drug subpopulations and 78% of the Orphan Drug subpopulations received an added benefit ("major", "considerable", "minor", "non-quantifiable").
- "No added benefit" was granted for 59% of the Non-Orphan & Orphan Drug subpopulations and for 20% of the Orphan Drug subpopulations.
- After the G-BA benefit assessment, the manufacturer and the GKV-SV negotiate a reimbursement price.
- The difference between the original manufacturer price at market launch and the reimbursement price shows the potential discount.
- An added medical benefit allowed the manufacturer to negotiate a lower discount on the original price (approx. 23% on average for "non-quantifiable", "minor", "considerable", and "major added benefit"). In contrast, in assessments with "no added benefit", the discounts are higher (approx. 33%) **(Figure 4)**.
- The four indications with the most benefit assessments, i.e., oncological **(A),** metabolic **(B)**, infectious **(C),** and neurological diseases **(D)** comprise 77.1% of all assessed subpopulations. These were representatively selected to determine the distribution of benefit categories among individual indications and further categorised into "All Drugs" vs. "Non-Orphan Drugs".
- While for the All Drugs category in the four indications, the highest proportion of subpopulations were granted "no added benefit" (53.5–65.9%), for Orphan Drugs most subpopulations were granted a "non-quantifiable added benefit" (34.4–76.9%). This is comparable for all indications.
- Among all drugs, products for oncological diseases received the highest additional benefit ("considerable" 16.2% and "minor" 13.0% **Figure 5A**), while amongst Orphan Drugs neurological products showed the highest additional benefit ("major" 9.4%, "considerable" 21.9% **Figure 5D**).

Figure 1. AMNOG-assessed subpopulations

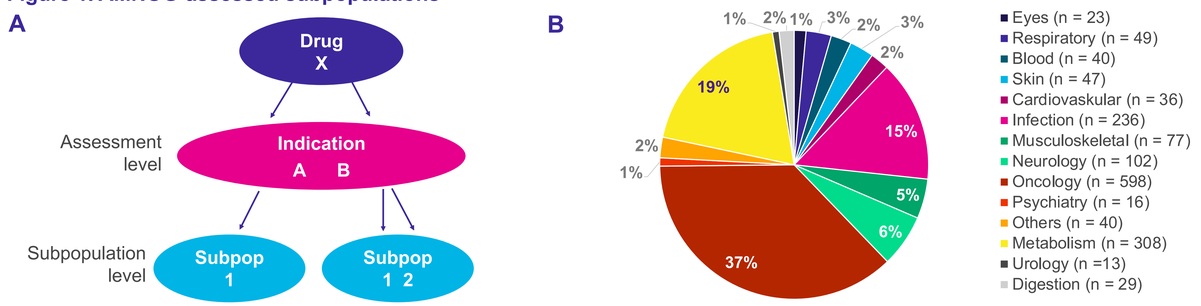
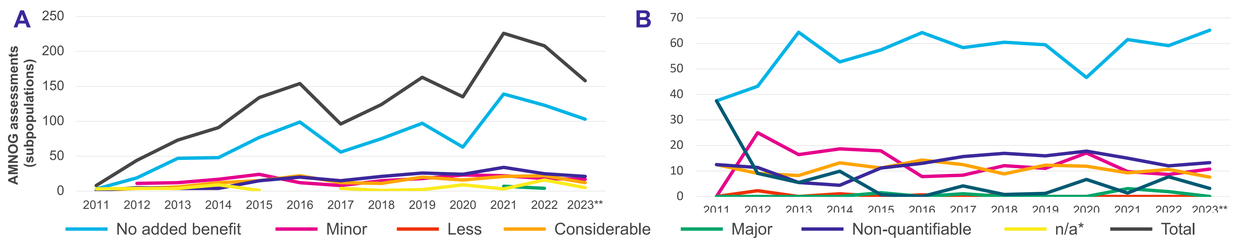
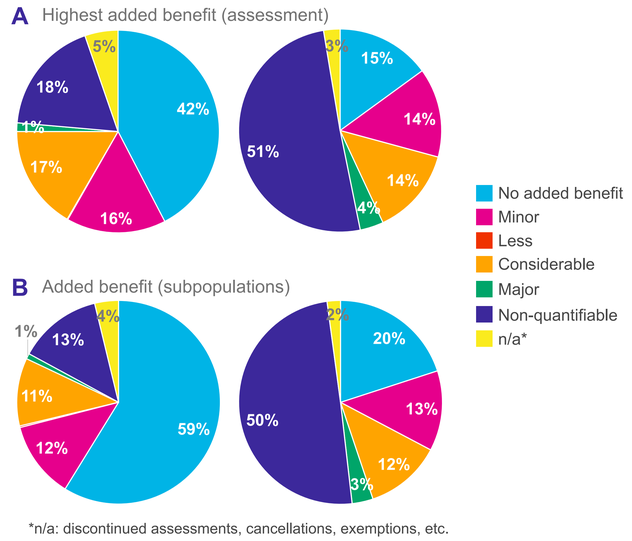


Figure 2. Distribution of assessment outcomes from Jan. 2011 to Nov. 2023



*n/a: Reserve antibiotic assessment, exemptions, discontinuation, fixed-amount grouping, etc. **Subgroup assessments for the year 2023 were evaluated until November.

Figure 3. Added benefit for Non-Orphan & Orphan Drugs



*n/a: discontinued assessments, cancellations, exemptions, etc.

Figure 4. Discount after price negotiation

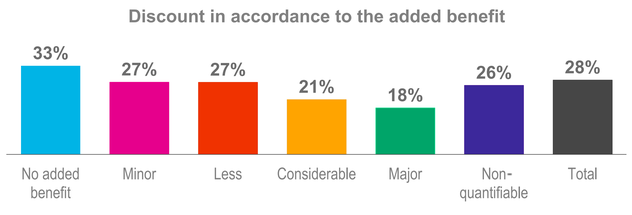
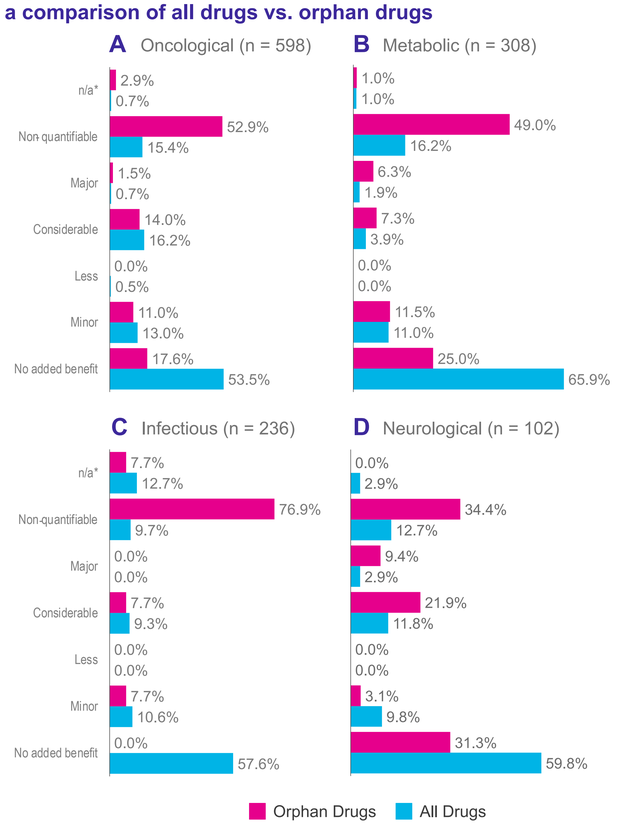


Figure 5. Indications with the most benefit assessments – a comparison of all drugs vs. orphan drugs



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