AMNOG benefit assessment in Germany: Outcomes from 2011 to 2022

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Objectives

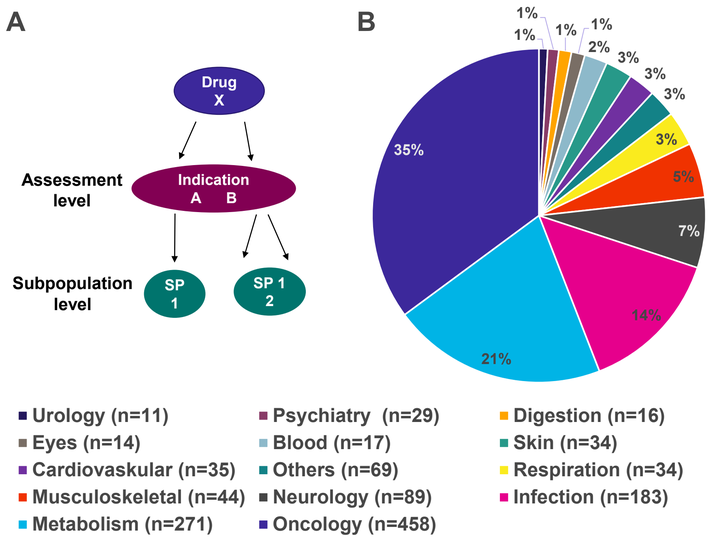
- Since the enactment of the AMNOG in Germany in 2011, pharmaceutical companies are required to prove the benefit of newly approved drugs within the therapeutic area(s) of interest.
- The potential benefit is evaluated by the Federal Joint Committee (G-BA) and Institute for Quality and Efficiency in Healthcare (IQWiG) forming the basis for price negotiations with the statutory health insurance providers.
- Aim of this study was to investigate the distribution and the outcomes of the assessments from 2011 to May 2022.

Methods

- A database containing all evaluated AMNOG assessments was analyzed. Information on G BA assessments and decisions on added benefit were extracted.
- Prices at the time of launch including changes after G-BA decision were obtained from Lauer-Taxe®. At assessment level, multiple assessed subpopulations in one assessment were possible. Discount on manufacturer price at market launch were also considered in new application areas, new assessments etc. Obligatory rebates were not considered. Benefit assessments were qualitatively and quantitatively analyzed for predictors of assessment outcome and impact on price negotiations.

Results

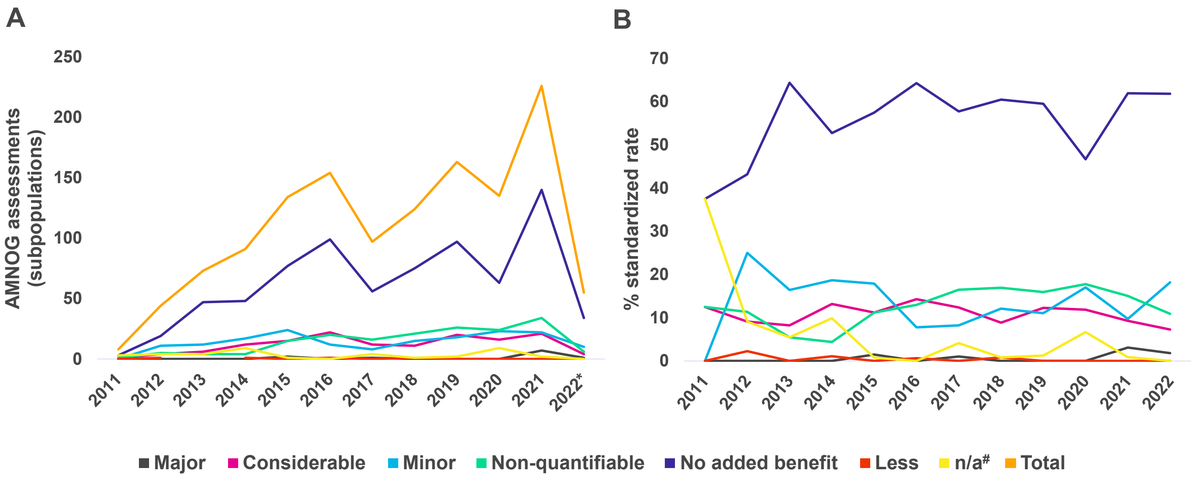
Figure 1. Assessed AMNOG Dossiers



(A) Schematic diagram to depict the difference between the "Assessment" and "Subpopulation" level of German benefit assessments: Drug X is approved for indication A und indication B, which are two distinct benefit assessments. Indication B is further differentiated in subpopulation (SP) 1 und SP 2, eg, untreated and previously treated patients, respectively.

(B) 741 AMNOG assessments were published from 2011 to May 2022 and conclusively assessed by G-BA. These dossiers included 1,304 separately evaluated indications and relevant subpopulations.

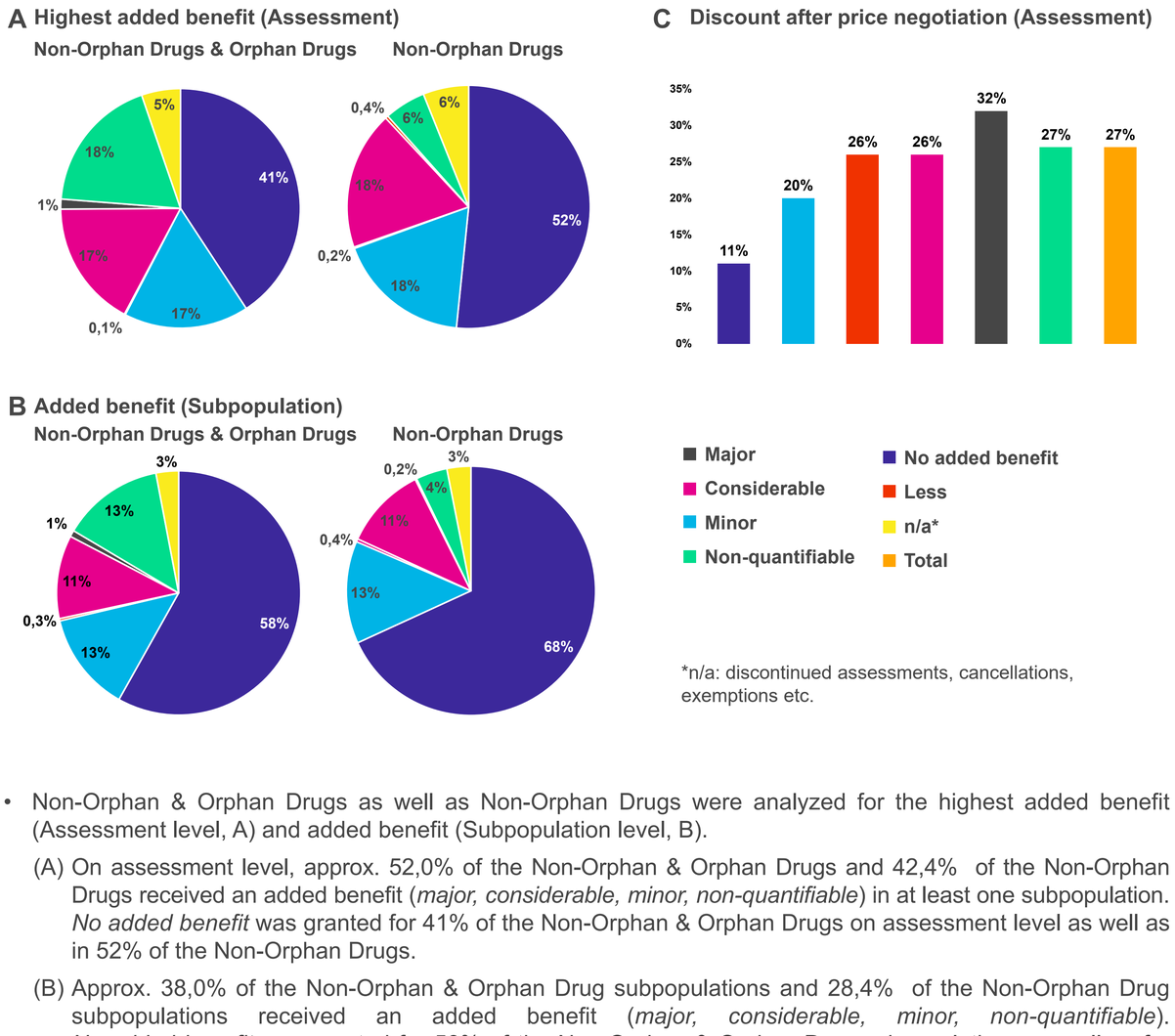
Figure 2. Distribution of assessment outcomes from 2011 to May 2022



- The line chart depicts the distribution of the six possible benefit categories among the subgroup benefit assessments for each year (2011 to May 2022).
- Total annual assessed AMNOG subpopulations (A) and standardized rates (B) were analyzed.
  (A) Over the last decade, a trend increase in annual total number of subgroup assessments can be observed.
  (B) The annual percentage of the benefit category no added benefit increased from 38% (2011) to 62% (2022).

*Subgroup assessments for the year 2022 are evaluated until May. #n/a: discontinued assessments, cancellations, exemptions etc.

Figure 3. Added benefit and discount after price negotiation



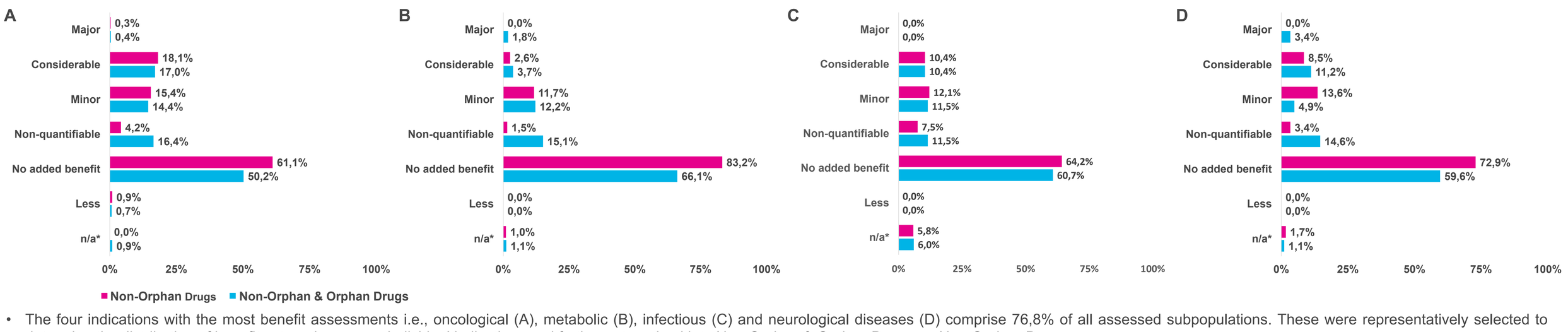
*n/a: discontinued assessments, cancellations, exemptions etc.

- Non-Orphan & Orphan Drugs as well as Non-Orphan Drugs were analyzed for the highest added benefit (Assessment level, A) and added benefit (Subpopulation level, B).
  (A) On assessment level, approx. 52,0% of the Non-Orphan & Orphan Drugs and 42,4% of the Non-Orphan Drugs received an added benefit (*major, considerable, minor, non-quantifiable*) in at least one subpopulation. *No added benefit* was granted for 41% of the Non-Orphan & Orphan Drugs on assessment level as well as in 52% of the Non-Orphan Drugs.
  (B) Approx. 38,0% of the Non-Orphan & Orphan Drug subpopulations and 28,4% of the Non-Orphan Drug subpopulations received an added benefit (*major, considerable, minor, non-quantifiable*). *No added benefit* was granted for 58% of the Non-Orphan & Orphan Drug subpopulations as well as for 68% of the Non-Orphan Drug subpopulations.
  (C) After the G-BA benefit assessment the manufacturer and the National Association of Statutory Health Insurance Funds (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. 24% in sum for *non-quantifiable, minor, considerable* and *major added benefit*). In contrast in assessments with *no added benefit* the discounts are higher (approx. 32%).

Figure 4. Assessment outcomes on subpopulation level of the four most prevalent indications



- The four indications with the most benefit assessments i.e., oncological (A), metabolic (B), infectious (C) and neurological diseases (D) comprise 76,8% of all assessed subpopulations. These were representatively selected to determine the distribution of benefit categories among individual indications and further categorized into Non-Orphan & Orphan Drugs vs. Non-Orphan Drugs.
- For Non-Orphan & Orphan Drugs, *no added benefit* was granted for 50,2-66,1% of the subpopulations, with oncological diseases (50,2%) having the lowest and metabolic diseases having the highest (66,1%) percentage.
- For Non-Orphan Drugs, *no added benefit* was granted for 61,1-83,2% of the subpopulations, with oncological diseases (61,1%) having the lowest and metabolic diseases having the highest (83,2%) percentage as well.
- The percentage distribution of *no added benefit* for infectious and neurological diseases were comparable to the entirety of the analyzed subpopulations. Contrary, oncological indications had lower and metabolic indications higher percentage of *no added benefit* (compare Fig. 3B).

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

Conclusions

- Since 2011, benefit assessments have become the key component in pricing of new drugs in Germany. To receive an added benefit that positively influences price negotiations, evidence must be generated in accordance with G-BA/IQWiG regulations.
- From 2011 to May 2022, 741 AMNOG assessments with 1,304 subpopulations were published and consecutively assessed by the G-BA. With more than 76%, oncologic, metabolic, and infectious diseases account for the vast majority of all assessed therapeutic 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.

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