Repurposed Drugs Launched Under the AMNOG in Germany: Effects on Benefit Assessment and Price Development

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Objective

Drug repurposing, the use of established drugs in new, previously unrelated indications, offers many potential advantages, such as lower development costs and higher success probabilities in clinical trials, which is thought to be attractive especially for orphan indications. This analysis was conducted to assess the success of repurposed drugs in German HTA procedures and subsequent price negotiations based on AMNOG.

Methods

A drug was defined as repurposed if it was launched under the AMNOG in more than one therapeutic area as defined by the G-BA. Utilizing our MAIS database, containing information on dossier content, benefit assessment, G-BA resolution and negotiated rebate of all AMNOG procedures ever performed, we compared procedure outcomes of repurposed drugs to those active substances approved in more than one indication in a single therapeutic area (non-repurposed drugs).

Results

The distribution of therapeutic areas of AMNOG procedures and orphan designations differs between repurposed and non-repurposed drugs.

Figure 2: Share of procedures per therapeutic area

- AMNOG procedures for repurposed drugs were performed in 12 out of the 14 therapeutic areas – procedures for infectious and psychological diseases did not occur.
- The distribution of therapeutic areas differs significantly between procedures of repurposed and non-repurposed drugs:
  - The most common therapeutic areas of repurposed drugs were oncological and the musculoskeletal system followed by skin diseases and diseases of the respiratory system.
  - The most common therapeutic areas of non-repurposed drugs were oncological, metabolic and infectious diseases.

Figure 3: Frequency of therapeutic area combinations of repurposed drugs

Method deep dive
- For all shown analyses only initial submissions and procedures due to indication extension were considered. Other procedure initiators such as limitation expiry or loss of orphan status were not included.

While the additional benefit categories between repurposed and non-repurposed drugs does not differ profoundly, the current negotiated gross box rebate is lower for repurposed drugs.

Figure 4: Benefit ratings as assigned by the G-BA

- The rate of non-quantifiable additional benefit ratings is more than twice as high for non-repurposed (19%) vs. repurposed (8%) drugs.
- With 54% the majority of procedures of repurposed drugs resulted in no additional benefit compared to 43% of procedures of non-repurposed drugs.
- Both repurposed and non-repurposed drugs are only very rarely granted the best or worst benefit categories: major additional (0% vs. 1%) and less (0% vs. 0%) benefit.
- The shares of minor (20% vs. 17%) and considerable (18% vs 20%) additional benefits are similar for procedures of repurposed and non-repurposed drugs.

Conclusion

The lower average negotiated rebate for repurposed drugs cannot solely be explained by the extent of the granted additional benefit. Hence, in addition to the launch sequence for repurposed drugs, the same applies as for other drugs: Besides the granted additional benefit, the result of the price negotiation also depends on a convincing value story, (sub-)population sizes, costs of the appropriate comparator therapy and a harmonized strategy for pricing throughout the complete AMNOG process.