COMPARATIVE ANALYSIS OF THE MARKET PENETRATION OF PERSONALIZED MEDICINE DRUGS UNDER THE CONDITIONS OF AMNOG

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INTRODUCTION

- Personalized medicine has made it possible to identify patients for whom therapy with a particular drug is effective
- Pharmaceutical companies are also facing the so-called "fourth hurdle" with their approved drugs, as the evaluation of new drugs in Germany has been regulated by the AMNOG since 2011
- The goal of AMNOG in Germany is to regulate the balance between innovation and affordability of medicines due to growing drug expenditures
- For this reason, a comparative analysis of the market penetration of personalized medicine drugs is carried out under the conditions of AMNOG in order to derive possible opportunities and risks for personalized medicine drugs

METHODOLOGY

- The list of personalized medicine drugs was identified according to the definition by the Research-Based Pharmaceutical Companies (vfa) (status September 2018) [1]
- Personalized medicine drugs that already underwent the AMNOG procedure were used for the evaluation
- The available procedural documents were used to evaluate the early benefit assessment [2]
- The magnitude of the additional benefit was transferred in a nominal scale with the following items: less (1), no additional benefit (2), non-quantifiable (3), minor (4), considerable (5) and major (6)
- The market penetration of drugs of personalized medicine was analyzed in comparison to other active substances evaluated during AMNOG on the basis of prescription data taken from the IMS PharmaScope® database (observed period 2011 to September 2018)
- The level of market penetration was assessed by the relation of the prescriptions in the first and second year after market entry to the total prescription volume in the target population

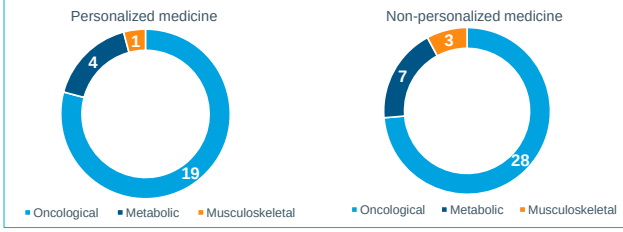
RESULTS

- A total of n=251 (personalized medicine=34, other=217) products were identified in the pool of early benefit assessments
- A total of n=62 (personalized medicine=24, other=38) products were included in the analysis based on the therapeutic area of diseases of the musculoskeletal system, metabolic disorders and oncological diseases (the only identified therapeutic areas for personalized medicine) and for which at least 24 months of data after market entry was available
- 75% (n=18) of the evaluated drugs of personalized medicine were evaluated with an additional benefit, being a higher rate than for other benefit assessments
- 4% (n=1) of the personalized medicine included were prescribed in the therapeutic area of diseases of the musculoskeletal system, 17% (n=4) in the therapeutic area of metabolic disorders and 79% (n=19) in the therapeutic area of oncological diseases (Figure 1)
- Therefore, the focus of the analyses was on the therapeutic area of oncological diseases and of metabolic disorders
- Metabolic drugs for personalized medicine achieved a much higher average market penetration of 50% [Min: 13%; Max: 98%] than the metabolic drugs for non-personalized medicine (12% [Min: 0%; Max: 32%]) within the 2nd year (Figure 2)
- The market penetration of personalized medicine drugs under the conditions of AMNOG was particularly successful in oncological diseases
- Oncological drugs for personalized medicine achieved an average market penetration of 23% [Min: 0%; Max: 23%] and oncological drugs for non-personalized medicine achieved an comparable average market penetration of 25% [Min: 0%; Max: 181%] within the 2nd year (Figure 3 and 4)
- Oncological drugs for personalized medicine achieved an average market penetration of 21% [Min:0%; Max: 49%] for non-orphans and 30% [Min: 7; Max:78] for orphan drugs within the 2nd year (Figure 3 and 4)

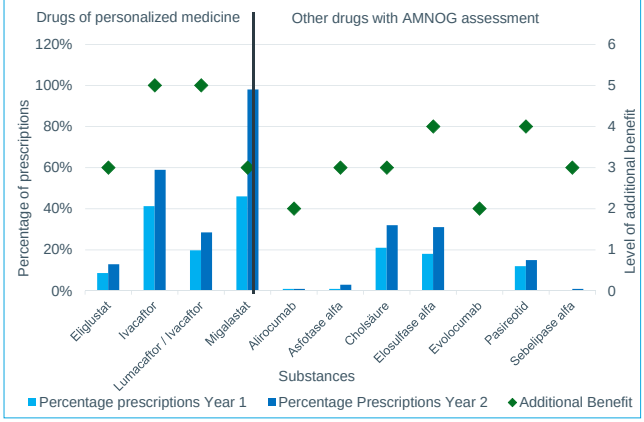
CONCLUSION

- Due to the small number of products no generally valid statements can be made. Additional analyses, for example on price trends, could provide further information

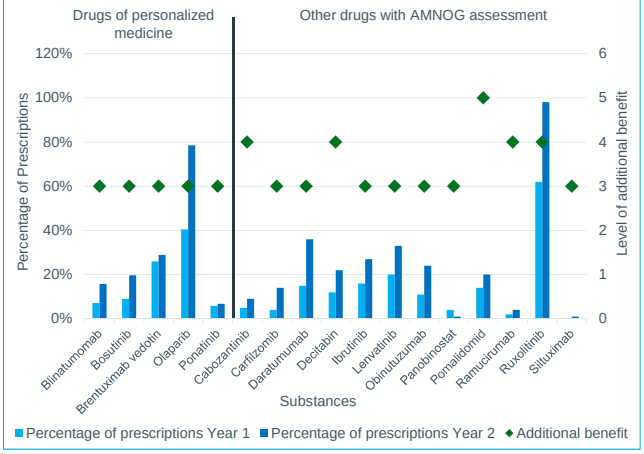
1 Share of the therapeutic areas of oncological diseases, metabolic disorders and diseases of the musculoskeletal system for personalized and non-personalized medicine drugs



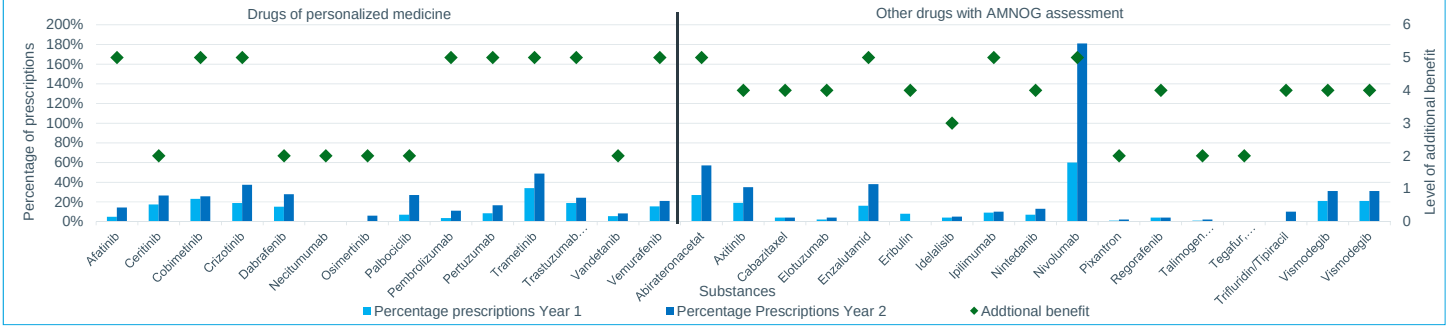
2 Percentage of prescriptions for drugs of metabolic diseases in the calculated total number of prescriptions in the target population in the first and second year after market entry



3 Percentage of prescriptions for orphan drugs of oncological diseases in the calculated total number of prescriptions in the target population in the first and second year after market entry



4 Percentage of prescriptions for non-orphan drugs of oncological diseases in the calculated total number of prescriptions in the target population in the first and second year after market entry



Sources:

1. Research-Based Pharmaceutical Companies (vfa) (2018): In Deutschland zugelassene Arzneimittel für die Personalisierte Medizín https://www.vfa.de/de/arzneimittel-forschung/datenbanken-zu-arzneimitteln/individualisierte-medizin.html, last accessed: 1st November 2018
2. Gemeinsamer Bundesausschuss (G-BA) (2018): Verfahren der Nutzenbewertung nach § 35a SGB V, https://www.g-ba.de/informationen/nutzenbewertung/, last accessed: 1st November 2018.

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