HTA303

# Are Best Supportive Care and Patient-Individual Therapy as Appropriate Comparators Detrimental for AMNOG Benefit Assessment and Price Rebates in Germany?

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## Background

- In Germany, the AMNOG benefit assessment of new pharmaceuticals is based on a comparative analysis with appropriate comparators.
- The choice of an appropriate comparator (ACT) is made by the Federal Joint Committee (G-BA) according to the criteria of (i) being approved, (ii) being effective, and (iii) ideally having G-BA-approved patient relevance for the respective application area.
- Although mostly concrete comparators are assigned, adequate therapeutic options might be lacking completely for certain subpopulations/therapy lines, in particular in the field of oncology.
- Consequently, the G-BA might choose patient-individual therapy or best supportive care (BSC) as ACT.
- The assignment of an inconcrete ACT is both challenging to meet but also underlining a high unmet therapeutical need.

## Objectives

- This study aimed to assess the consequences of inconcrete ACTs on the granted added medical benefit and outcomes of the price negotiation.
- The effects were compared between assessed subpopulations with inconcrete comparators and total G-BA assessed subpopulations within the field of oncology.

## Methods

- All AMNOG assessments were retrieved from the G-BA website[1] and from an internal database[2].
- All assessments that were screened from AMNOG came into effect in the years from January 2011 to February 2023.
- Within the therapeutical field of oncology, data were extracted for all subpopulations that had attributed the ACTs “patient-individual therapy” or “BSC.”
- Information about the therapy line, the patient population, and the inconcrete comparator were categorized.
- The resulting added medical benefit was extracted from the G-BA resolution.
- The results of the subsequent price negotiations were analyzed using the manufacturer’s price at the start of the assessment and, if identifiable, changes in the price after the assessment. Prices were retrieved from the pharmacy software Lauer-Taxe[3].

## Conclusions

- A database of 814 AMNOG benefit assessments with 1,496 subpopulations has been screened for all assessments with an inconcrete ACT in the therapeutic field of oncology.
- A minority of ACTs (12%) is inconcrete and mostly consists of BSC (77%).
- These assessments cover mostly first- and second-line treatment.
- Inconcrete ACT are challenging in the AMNOG benefit assessment and often are granted no added medical benefit. Nevertheless, one third of inconcrete ACT received a positive added medical benefit.
- In our analysis we found that acceptance of the provided evidence for inconcrete ACTs in a dossier led to a granted added medical benefit in most cases.
- Finally, we found that inconcrete ACTs for assessments with a considerable added medical benefit received low price rebates and therefore might be of advantage in this situation compared to concrete ACTs.

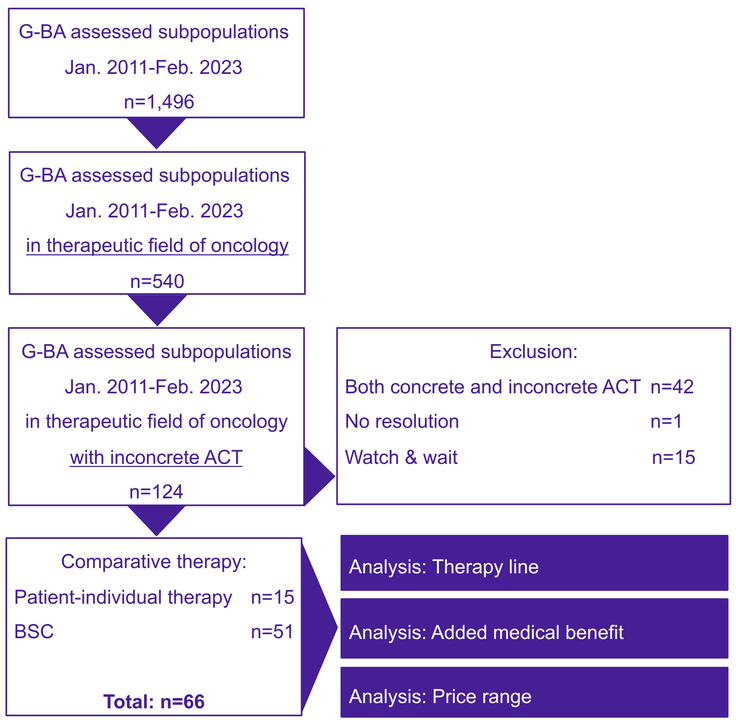
## References

1. Gemeinsamer Bundesausschluss (G-BA) 2023 [Available from: https://www.g-ba.de/; accessed March 2, 2023]
2. Internal AMNOG-database [Accessed March 2, 2023]
3. CGM LAUER. Lauer-Taxe Online 4.0 2023 [Available from: https://lauer-fischer.de/LF/Seiten/Verwaltung/Kundencenter/1.aspx; accessed March 2, 2023]

## Results

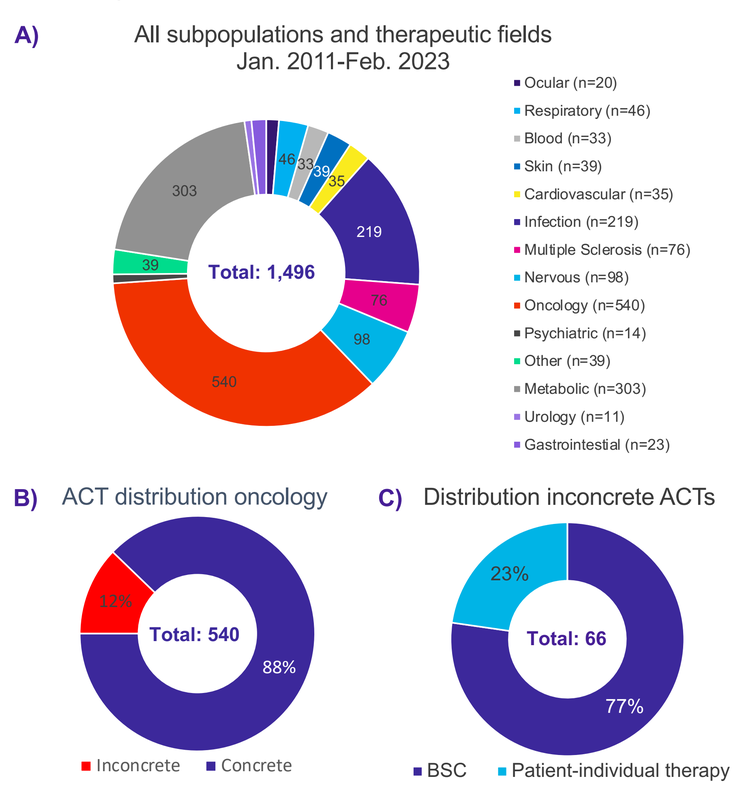
- From January 2011 to February 2023, 814 AMNOG assessments were published containing a total of 1,496 subpopulations (**Figure 1**).
- The therapeutic field of oncology contained 540 subpopulations (**Figure 2A**), of which 124 had attributed an inconcrete ACT.

**Figure 1.** Sequential analysis of assessed subpopulations from G-BA database



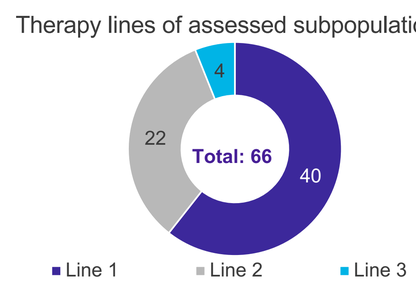

- The 124 assessed subpopulations with inconcrete ACTs were categorized. Cases with multiple comparators, lacking a resolution, or watch and wait were excluded, which resulted in 66 cases for further analysis.
- Inconcrete comparators were assigned to 12% (n=66) of assessed subpopulations in oncology (**Figure 2B**).

**Figure 2.** Distribution of concrete and inconcrete ACTs among all assessed subpopulations within the field of oncology: (A) Distribution of assessed subpopulations among therapeutic fields; (B) ratio of concrete and inconcrete ACTs and (C) ratio of BSC and patient-individual ACTs



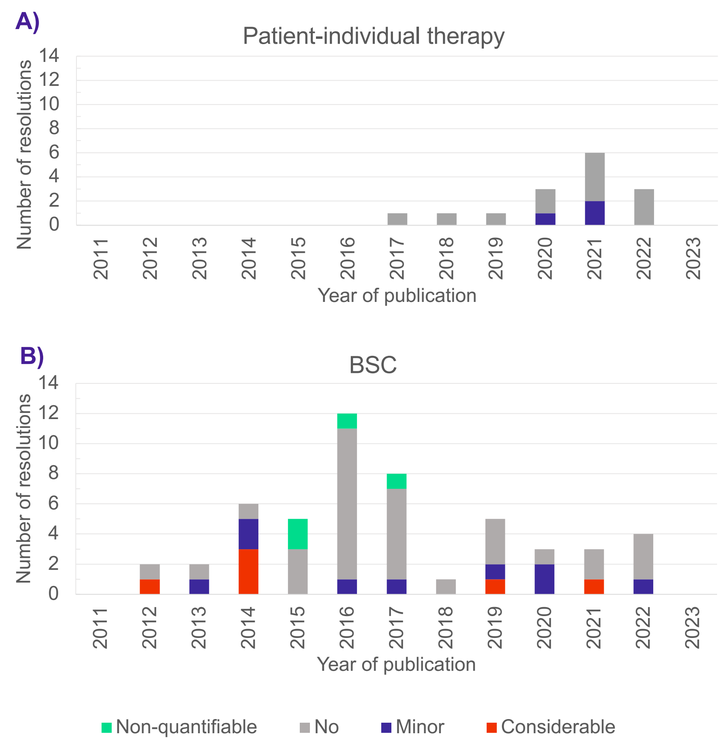

- Within the inconcrete ACTs, BSC comprises the largest amount with 77% (**Figure 2C**). The category patient individual comprises 23% of comparators.
- Assessed subpopulations only comprised a minority of cases with indication for late therapy lines (eg, therapy line 3) (**Figure 3**).

**Figure 3.** Distribution of therapy lines within subpopulations with inconcrete ACTs



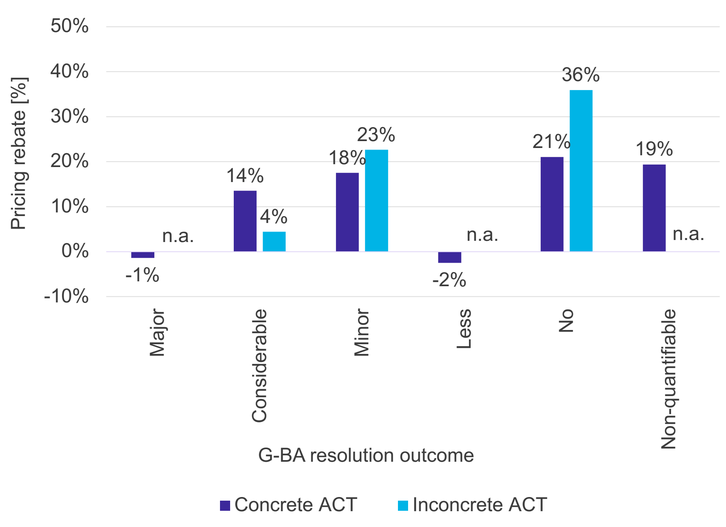

- Furthermore, there was no correlation of therapy line and added benefit resolution (not shown).
- Within the category patient individual (n=15 assessed subpopulations), over the time period of 10 years, 3 assessments led to a minor added benefit and 12 to no added benefit (**Figure 4A**).

**Figure 4.** Added medical benefits attributed to inconcrete comparator categories during the years from January 2011 to February 2023. Within 66 assessed subpopulations, added medical benefit categories according to G-BA resolutions per year are shown for subpopulations with patient-individual therapy (A) or BSC (B) as ACT




- The majority of inconcrete ACT was BSC (n=51 assessed subpopulations). Over the time period of 10 years, 6 (12%) assessments led to a considerable added benefit, 9 (18%) assessments were granted minor added benefit, and 4 (8%) with non-quantifiable benefit. Nevertheless, most assessments were granted no added medical benefit (n=32; 63%) (**Figure 4B**).
- Of 540 subpopulations, 22 (33% of 66) sub-assessments with inconcrete ACT were granted an added benefit vs 233 (49.8% of 468) of the concrete ACTs (data not shown).
- On the overall assessment level, within the subcategory of BSC, the provided evidence for the ACT was accepted by the G-BA in 16 of 51 assessments which led to an added medical benefit in 88% of cases.

**Figure 5.** Pricing rebates for different G-BA resolution outcomes




- We compared pricing rebates in a total of 238 overall resolutions in the field of oncology after price negotiations (**Figure 5**).
- Of those, 220 and 18 assessments had attributed concrete and inconcrete ACTs, respectively.
- Pricing rebates were lower for assessments with considerable added medical benefit in the inconcrete vs the concrete ACT group (4% vs 14%).
- In contrast, rebates were higher for assessments with minor and no added benefit in the inconcrete vs the concrete ACT group (23% vs 18% and 36% vs 21%).



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