

# GERMAN AMNOG BENEFIT ASSESSMENT: THE TYPE OF APPROPRIATE COMPARATOR MAKES THE DIFFERENCE

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## OBJECTIVES

- For the mandatory assessment of the benefit of new drugs in Germany, an appropriate comparator is defined by the Federal Joint Committee (FJC).
- Appropriate comparators can be categorized into 4 classes: (1) one specific drug; (2) a list of drugs; (3) patient individual therapy; (4) best supportive care (BSC).
- The aim of the study was to reveal the impact of the type of appropriate comparator on the added benefit.

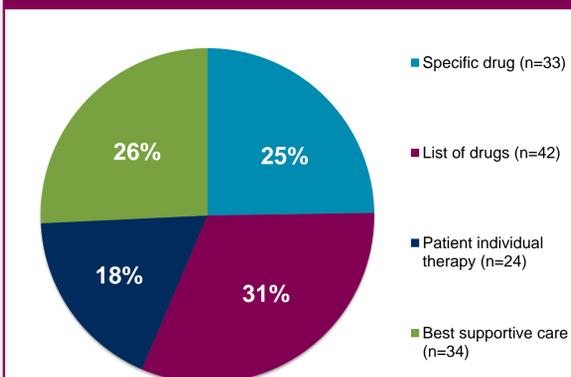
## METHODS

- Information was retrieved from all non-orphan Pharmaceuticals Market Reorganization Act (AMNOG) dossiers in the field of oncology published on the FJC website (<https://www.g-ba.de>) until the end of 2016.
- Information concerning indication, size of target population, line of therapy, and outcomes was obtained. In addition, we examined whether the comparator used in the relevant trials was accepted as appropriate by the FJC.

## RESULTS

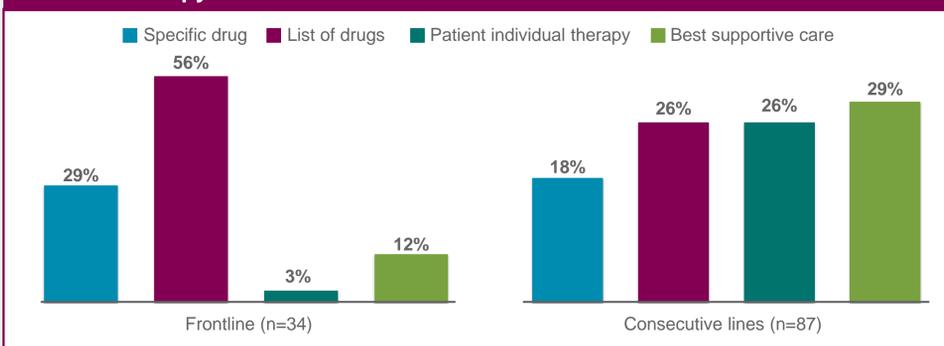
- 67 relevant AMNOG dossiers in the field of oncology were published within the years 2011 to 2016 and conclusively assessed by the FJC. These dossiers included 133 separately evaluated labels and sub-labels.

**Figure 1. The Most Commonly Assigned Category of Appropriate Comparators Is a List of Drugs**



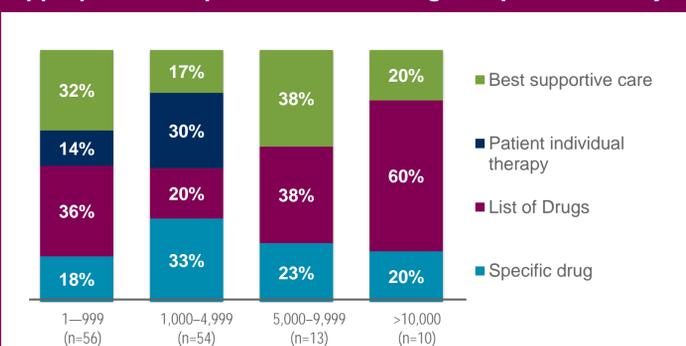
- The assignment of appropriate comparators was distributed as follows: 33 (25%) specific drug; 42 (32%) list of drugs; 24 (18%) patient individual therapy; and 34 (26%) BSC (**Figure 1**).
- The most common appropriate comparator was a list of drugs (31%) (**Figure 1**).
- Patient individual therapy was named as the appropriate comparator in 24 cases (18%) (**Figure 1**).

**Figure 2. The Assignment of Appropriate Comparators Differs Remarkably Between Therapy Lines**



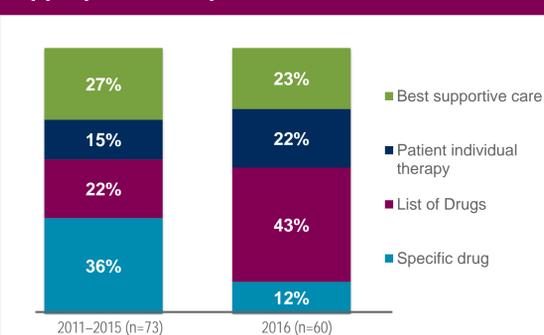
- In more than half of the cases, a list of drugs was the appropriate comparator for frontline therapies (**Figure 2**).
- Patient individual therapy and BSC do not play a major role in this therapy line (**Figure 2**).
- In consecutive therapy lines, the assignment of appropriate comparators was almost evenly distributed (**Figure 2**).

**Figure 3. Patient Individual Therapy Was Assigned as the Appropriate Comparator in Small Target Populations Only**



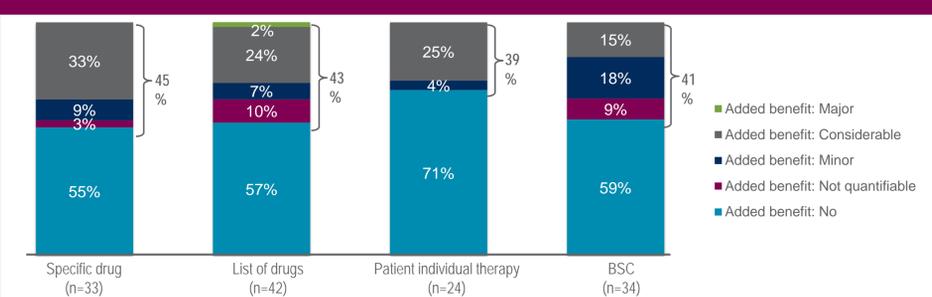
- The size of the target population influences the assignment of the appropriate comparator (**Figure 3**).
- In sub-labels with large target populations, the predominant appropriate comparator is a list of drugs (**Figure 3**).

**Figure 4. A List of Drugs Has Replaced a Specific Drug as the Most Commonly Assigned Appropriate Comparator in 2016**



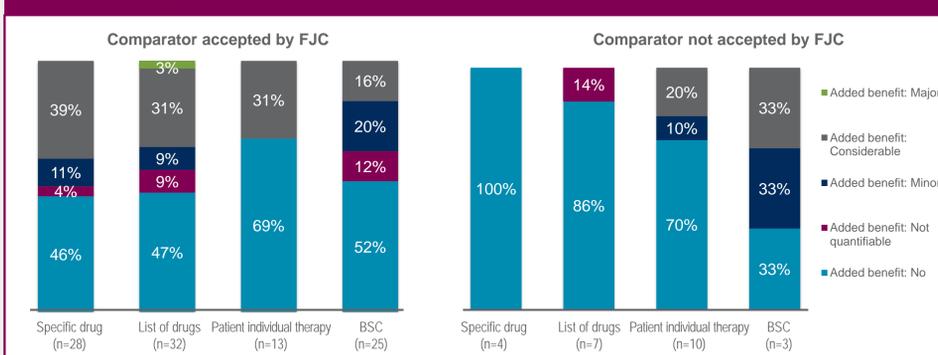
- In the first 5 years of AMNOG (2011 to 2015), the category "specific drug" was the most frequently defined appropriate comparator (36%) (**Figure 4**).
- The pattern of allocation changed in 2016. The assignment of a specific drug was reduced to one-third, whereas the determination of a list of drugs as the appropriate comparator almost doubled (**Figure 4**).

**Figure 5. A Specific Drug Is the Most Promising Appropriate Comparator**



- Dossiers with a specific drug as the appropriate comparator had the highest probability to gain an added benefit (45%) (**Figure 5**).
- A major benefit was only achieved if the appropriate comparator was a list of drugs (**Figure 5**).
- The category of appropriate comparators with the lowest chance to achieve an added benefit was patient individual therapy (**Figure 5**).
- For AMNOG dossiers with patient individual therapy as the FJC-defined appropriate comparator in the majority of cases, no added benefit was granted (71%). However, in 6 cases (25%), a considerable added benefit was proven (**Figure 5**).

**Figure 6. For the Categories "Specific Drug" and "List of Drugs," FJC Acceptance of the Actually Used Comparator Is Vital in Order to Gain an Added Benefit**



- In most dossiers, the comparator used in the relevant trials was accepted as appropriate by the FJC (appropriate: n=98; not appropriate: n=24) (**Figure 6**).
- In the categories of a "specific drug" and a "list of drugs," an added benefit was gained in more than half of the assessments—if the comparator was accepted. If the comparator was not accepted, it was nearly impossible to achieve an added benefit (**Figure 6**).
- In the case of patient individual therapy and BSC, there seems to be more flexibility regarding the comparator used in the AMNOG dossier (**Figure 6**).
- 30% of the assessments in the category of patient individual therapy resulted in an added benefit, independent of the acceptance of the comparator by FJC (**Figure 6**).

## CONCLUSIONS

- A list of drugs is the most common appropriate comparator. This category is predominantly assigned in larger populations and in early therapy lines.
- Until 2015, the category "specific drug" played a major role as the appropriate comparator. In 2016, the pattern of allocation changed. The list of drugs now is the most prominent category of appropriate comparators. This may reflect the increasing number of AMNOG-assessed drugs in the field of oncology.
- AMNOG dossiers with a specific drug as the FJC-defined comparator have the highest probability to achieve a considerable added benefit. The chance of getting an added benefit granted is low if the appropriate comparator is patient individual therapy.
- If the comparator used in the relevant trial was not accepted as appropriate by the FJC, it was nearly impossible to achieve an added benefit in the categories "specific drug" and "list of drugs." In the case of patient individual therapy and BSC, there seems to be more flexibility regarding the acceptance of the comparator used in the AMNOG dossier.

